ZOLL®

ZOLL M2® Operator's Guide

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Table of Contents

Chapter 1 General Information

Chapter 9 Monitoring CO2

Chapter 10 Monitoring SpO2

Chapter 11 Monitoring Temperature

Chapter 12 Automated External Defibrillator (AED) Operation

Chapter 13 12-Lead ECG Monitoring

Chapter 14 Manual Defibrillation

Chapter 15 Real CPR Help

Chapter 16 External Pacing

Chapter 17 Incident Data and Reports

Chapter 18 Maintenance and Troubleshooting

Appendix A Specifications

Chapter 1
General Information

Product Description

The ZOLL M2® unit is an easy-to-use portable monitor/defibrillator that combines defibrillation and external pacing with the following monitoring capabilities:

- ECG
- Heart Rate
- CPR-related Chest Compressions rate and depth
- Oxygen Saturation of Arterial Hemoglobin (SpO_2)
- Non-invasive Blood Pressure (NIBP)
- Respiration Rate
- Respiratory CO_2/$EtCO_2$
- Temperature

Note: The ZOLL M2 can be configured for manual defibrillation or Semiautomatic (AED) operation.

The ZOLL M2 is a rugged, compact and lightweight unit that is designed for all resuscitation situations and is ideal for ground transport. The ZOLL M2 can be powered by AC mains power and/or an easily replaceable battery pack that automatically recharges when the ZOLL M2 is connected to AC mains power. In addition, a ZOLL® SurePower™ Charger Station can be used to recharge and test the ZOLL M2 battery.

The product is designed for use in both the hospital and the rugged EMS environments. The device is a versatile automated external defibrillator with manual capabilities and may be configured to start its Defibrillator mode in Semiautomatic (AED) mode or Manual mode.

When operating in manual defibrillation mode, the device operates as a conventional defibrillator where the device's charging and discharging is fully controlled by the operator. In AED mode, some features of the device are automated and a sophisticated detection algorithm is used to identify ventricular fibrillation and wide-complex ventricular tachycardia, and to determine the appropriateness of defibrillator shock delivery. Units may be configured to automatically analyze the patient's ECG rhythm, charge the defibrillator, and prompt the operator to "*Press Shock*", depending on local protocols. The unit is switched from AED mode to Manual mode for ACLS use by pressing the appropriate key on the front panel.

The ZOLL M2 unit assists caregivers during cardiopulmonary resuscitation (CPR) by evaluating the rate and depth of chest compressions and providing feedback to the rescuer.

The unit has a large colorful LCD display of numerics and waveform data that provides easy visibility from across the room and at any angle. ECG, SpO_2 plethysmographic, and respiration waveform traces can be displayed simultaneously, giving easy access to all patient monitoring data at once. The ZOLL M2 includes a transcutaneous pacemaker consisting of a pulse generator and ECG sensing circuitry. Pacing supports both demand and fixed rate noninvasive pacing for adult, pediatric, and neonatal patients.

The ZOLL M2 has a patient data review and collection system that allows for printing, storing and transferring patient data. The ZOLL M2 unit contains a printer and USB port, which can be used to print data and transfer it to a PC.

The ZOLL M2 unit can send full disclosure logs to a remote server through an optional wireless connection. 12-lead reports can be sent wirelessly in portable document format (PDF) to any designated email address. In addition, ZOLL M2 recorded full disclosure cases can be reviewed and printed using ZOLL RescueNet® CaseReview and RescueNet EventSummary software (sold separately).

Contraindications

Carefully review the Cautions and Warnings contained in this manual before device use.

The AED mode is not indicated for use on patients less than 1 year of age.

The NIBP function is not intended for use on patients who are allergic to blood pressure cuff made of nylon, TPU, or PVC.

How to Use This Manual

The ZOLL M2 Operator's Guide provides information operators need for the safe and effective use and care of the ZOLL M2 product. It is important that all persons using this device read and understand all the information contained within.

Please thoroughly read the safety considerations and warnings section.

Procedures for daily checkout and unit care are located in the Chapter 18, "Maintenance and Troubleshooting".

Operator's Guide Updates

An issue or revision date for this manual is shown on the back of the front cover. If more than three years have elapsed since this date, contact ZOLL Medical Corporation to determine if additional product information updates are available.

All users should carefully review each manual update to understand its significance and then file it in its appropriate section within this manual for subsequent reference.

Product documentation is available through the ZOLL website at www.zoll.com. From the Products menu, choose Product Manuals.

Unpacking

Carefully inspect each container for damage. If the shipping container or cushion material is damaged, keep it until the contents have been checked for completeness and the instrument has been checked for mechanical and electrical integrity. If the contents are incomplete, there exists mechanical damage, or the monitor/defibrillator does not pass its power on self-test, contact the nearest ZOLL authorized representative. If the shipping container is damaged, also notify the carrier.

Starting up the ZOLL M2

After unpacking and inspection, the ZOLL M2 unit can be prepared to monitor and treat the patient.

1. Before starting the ZOLL M2, verify that there is no mechanical damage to the monitor/defibrillator, and that external cables and accessories are properly connected.
2. Insert the power cord into the rear panel AC power socket. If using battery power, make sure the battery is fully charged and that a spare fully charged battery is readily available.
3. Turn the Mode Selector to enter the working mode required. When the screen illuminates, the device starts to self-test and print out a report (if configured): the system beeps, the two visual alarm indicators will light yellow and red respectively (then extinguish), and the All Tests Passed window displays.
4. Press the Trim Knob to select OK to start monitoring and treating the patient.

   Note: Refer to the applicable chapter in this manual for instructions on how to prepare patient before treatment.

Symbols Used on the Equipment

Any or all of the following symbols may be used in this manual or on this equipment, or on the equipment or accessory packaging:

Symbol	Description
	Dangerous voltage.
	General warning: Observe and follow all safety signs.
	Fragile, handle with care.

Symbol	Description
	Keep dry.
	This end up.
	Country of Manufacture
	Temperature limitation.
	Humidity limitation
	Atmospheric Pressure limitation
	**Conformité Européenne** Complies with medical device directive 93/42/EEC.
	Type BF patient connection (applied part).
	Type CF patient connection (applied part).
	Defibrillator-proof type BF patient connection (applied part).
	Defibrillator-proof type CF patient connection (applied part).
	Equipotentiality.

Symbol	Description
	Alternating current (ac).
	Direct current (dc).
	Caution, high voltage.
	Protective earth (ground).
	Contains lithium. Recycle or dispose of properly.
	Keep away from open flame and high heat.
	Do not open, disassemble, or intentionally damage.
	Do not crush.
	Do not discard in trash. Recycle or dispose of properly.
	Return to a collection site intended for waste electrical and electronic equipment (WEEE). Do not dispose of in unsorted trash.
	Date of manufacture.
	Use by.

Symbol	Description
	Latex-free.
	Do not reuse.
	Do not fold.
	Not sterile.
	Manufacturer.
	Authorized representative in the European Community.
	Catalogue number.
	Consult instructions for use.
	Refer to instruction manual/booklet.
IP44	Ingress Protection rating
	WiFi
	Alarm off.
	Alarm audio is currently off.

Symbol	Description
	Alarm audio is currently paused.
	Performs the following alarm functions when pressed and held for various time periods: • Silences patient alarm for preconfigured period of time. • Silences patient alarm audio permanently. • Disables patient alarm processing. • Responds to equipment related alarms. • Clears latched alarms.
	Implanted pacer markers disabled.
	Battery charging status.
	Do not use device, cables, or probes in an MRI environment.
	No physiological signal is being acquired for the displayed monitoring parameter or the acquired signal is inadequate for monitoring patient condition.
	Indicates a carrier that contains Unique Device Identifier information.
	Indicates the item is a medical device.

Conventions

This guide uses the following conventions:

Within text, the names and labels for physical buttons and quick access keys appear in **boldface** type (for example, “Press the **CHARGE** button”).

This guide uses italics for audible prompts and for text messages displayed on the screen (for example, *ECG Lead Off*.

Caution	Caution statements alert you to conditions or actions that can result in damage to the unit.

Warning!	**Warning statements alert you to conditions or actions that can result in personal injury or death.**

ZOLL M2 Indications for Use

The ZOLL M2 is intended for use by trained medical personnel who are familiar with patient monitoring, vital sign assessment, emergency cardiac care, and the use of the ZOLL M2 monitor/defibrillator.

The ZOLL M2 is also intended for use by (or on the order of) physicians at the scene of an emergency or in a hospital emergency room, intensive care unit, cardiac care unit, or other similar areas of a hospital. The ZOLL M2 device may be used in any road ambulance. It is also intended to be used during the transport of patients. The ZOLL M2 will be used primarily on patients experiencing symptoms of cardiac arrest or in post trauma situations. It may also be used to monitor patient physiological parameters whose measurement is supported by the device. The ZOLL M2 unit can be used on neonatal, pediatric and adult patients (as described in the following table):

Neonate	Children 28 days or less of age if born at term (37 weeks gestation or more); otherwise, up to 44 gestational weeks.
Pediatric	Individuals between 29 days and 8 years of age, or weighing less than 55 lbs (25 kg).
Adult	Individuals greater than 8 years of age, or weighing greater than 55 lbs (25kg).

Manual Defibrillation

Use of the ZOLL M2 in the manual mode for external and open chest defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse

This product should be used only by qualified medical personnel for converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heartbeats.

The unit can also be used for synchronized cardioversion of certain atrial or ventricular arrhythmias. Qualified medical personnel must decide when synchronized cardioversion is appropriate.

Manual mode can be used with all patient types with appropriate energy settings.

Semiautomatic Operation (AED)

ZOLL M2 products are designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the device operator controls delivery of shocks to the patient.

ZOLL M2 products are specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically-approved patient care protocol.

Use of the ZOLL M2 in the semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

• Unconsciousness

• Absence of breathing

• Absence of pulse

Specifications for the ECG rhythm analysis function are provided in the section “ECG Analysis Algorithm Accuracy” on page A-33.

When the patient is less than 8 years of age or weighs less than 55 lbs. (25 kg), ZOLL pediatric defibrillation electrodes should be used. Do not delay therapy to determine patient’s exact age or weight.

AED mode is not indicated for use on patients less than 1 year of age.

ECG Monitoring

The ZOLL M2 is intended for use to monitor and record 2-lead (defibrillation pads/paddles), 3-, 5-, or 12-lead ECG waveforms and heart rate, and to alarm when heart rate is above or below limits set by the operator. The patient population ranges from neonate to adult.

CPR Monitoring

The CPR monitoring function provides visual and audio feedback designed to encourage rescuers to perform chest compressions at a rate that falls within AHA/ERC recommended guidelines. Voice and visual prompts encourage a compression depth of at least 2.0 inches (5.0 cm) for adult patients and a compression rate of greater than 100 cpm.

Compression depth and monitoring without audio prompting is provided in pediatric patient mode. Rescuers must determine the appropriate compression depth for their pediatric patient.

External Transcutaneous Pacing

This product can be used for temporary external cardiac pacing in conscious or unconscious patients as an alternative to endocardial stimulation.

The purposes of pacing include:

- Resuscitation from standstill or bradycardia of any etiology
- As a standby when standstill or bradycardia might be expected
- Suppression of tachycardia
- Pediatric pacing

Non-Invasive Blood Pressure Monitoring

The ZOLL M2 unit's NIBP option is intended for making non-invasive measurements of arterial blood pressure, and to alarm if systolic, diastolic, or mean pressure is outside of the limits set by the user. Measurements are made using an inflatable cuff on the patient's arm or leg. The intended patient population ranges from pediaric (greater than 3 years of age) to adult.

Temperature Monitoring

The ZOLL M2 is intended for making continuous measurements of rectal, esophageal, or surface temperatures, and to alarm if the temperature is outside of the limits set by the user. The intended patient population ranges from pediatric to adult.

SpO_2 Monitoring

The ZOLL M2 SpO_2 module is intended for use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), and to alarm if either parameter is outside of the limits set by the user. The pulse oximeter and accessories are intended for use on adult and pediatric patients.

Impedance Respiration Monitoring

The ZOLL M2 is intended for continuously monitoring respiration rate and to alarm if the rate falls outside of the range set by the operator. Because the measurement method actually measures respiratory effort (not airflow), apnea episodes with continued respiratory effort (such as obstructive apnea) may not be detected. It is not intended to be used as an apnea monitor. The intended patient population ranges from pediatric to adult.

CO_2 Monitoring

The ZOLL M2 mainstream and sidestream CO_2 modules are intended for making continuous noninvasive measurement of breathing rate and of carbon dioxide concentration in the expired and inspired gases. The CO_2 concentration in end-tidal gases (gases at the end of exhalation) is also measured and displayed numerically. The intended patient population ranges from pediatric to adult.

12-Lead ECG Monitoring

The 12-Lead ECG monitoring function is intended for simultaneously acquiring ECG data from chest and limb leads and presenting that data in standard format 12-lead reports. Among other things, these reports are useful for identifying patients with STEMI and other significant. arrhythmias.The intended patient population ranges from neonate to adult.

ZOLL M2 Product Functions

Defibrillator Function

The ZOLL M2 contains a direct current (dc) defibrillator capable of delivering 200 joules or more. It may be used in synchronized mode to perform synchronized cardioversion using the patient's R-wave as a timing reference. The unit uses paddles; reusable electrodes with replaceable gel; or disposable, pregelled electrodes for defibrillation.

Defibrillator Output Energy

ZOLL M2 defibrillators can deliver biphasic energy at settings from 1 joule to 200 joules. The energy delivered through the chest wall, however, is determined by the patient's transthoracic impedance. An adequate amount of electrolyte gel must be applied to the paddles and a force of 10 to 12 kilograms (22 to 26.4 pounds) must be applied to each paddle in order to minimize this impedance. If hands-free therapy electrodes are used, make sure that they are within their expiration date and properly applied. (Refer to the instructions on the electrode package.)

External Pacemaker

ZOLL M2 defibrillators include a transcutaneous pacemaker consisting of a pulse generator and ECG-sensing circuitry. Noninvasive transcutaneous pacing (NTP) is an established and proven technique. This therapy is easily and rapidly applied in both emergency and nonemergency situations when temporary cardiac stimulation is indicated.

The output current of the pacemaker is continuously variable from 8 to 140 mA (the pacing is paused when the output current is 0 mA). The rate is continuously variable from 30 to 180 pulses per minute (ppm), by increments of 2 ppm.

The pacing output pulse is delivered to the heart via ZOLL hands-free defibrillation/pacing electrodes placed on the patient's back and the precordium.

Proper operation of the device, together with correct electrode placement, is critical to obtaining optimal results.

ECG Monitoring

The patient's ECG is monitored by connecting the patient to the unit via a 3-, 5-, or 12-lead patient cable, internal/external defibrillator paddles, or hands-free therapy electrodes. The ECG waveform is presented on the display along with the following information:

- Average heart rate, derived by measuring R to R intervals in ECG waveform, shown at the top of the ZOLL M2 display
- Lead selection - I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 (with ECG cable), PADDLES, or PADS.
- ECG gain 0.125, 0.25, 0.5, 1.0, 1.5, 2.0, 3.0 cm/mV, AUTO
- Status messages

The ECG bandwidth is user selectable.

Electrodes

The ZOLL M2 units will defibrillate, cardiovert, and monitor ECG using hands-free therapy electrodes, external paddles, or internal paddles. The ZOLL M2 unit will pace using ZOLL hands-free therapy electrodes.

Energy Select, **Charge** and **Shock** controls are located on the paddles and front panel. When using hands-free therapy electrodes, use the controls on the front panel of the unit. To switch between paddles and hands-free therapy electrodes, remove the multifunction cable (MFC) from the apex paddle and connect the hands-free therapy electrodes to the cable.

Always check the expiration date on the electrode packaging. Do not use expired electrodes, which might result in inaccurate patient impedance readings and affect the level of delivered energy, or cause burns.

This symbol on the electrode package is accompanied by the expiration date.

For Stat-padz® II, this symbol does not appear; the expiration date appears on the lower right corner of the label, below the lot number.

Note: ZOLL electrodes contain no hazardous materials and may be disposed of in general trash unless contaminated with pathogens. Use appropriate precautions when disposing of contaminated electrodes.

When the patient is less than 8 years old or weighs less than 55 lb. (25 kg), use ZOLL Pediatric defibrillation electrodes. Do not delay therapy while attempting to determine the patient's exact age or weight.

Batteries

ZOLL M2 models use an easily replaced rechargeable lithium-ion battery pack (the *SurePower* Battery Pack). A new, fully charged battery pack typically delivers more than 4 hours of ECG monitoring. Use of other functions (such as the defibrillator, printer or pacemaker) reduces the time.

When ZOLL M2 issues a *Low Battery* warning and continuously displays the *Low Battery* message, the battery must be replaced and recharged.

Charge the battery by either of the following methods:

- **Internal charging** — connect the ZOLL M2 unit to AC mains power to automatically begin charging the installed battery pack. The front panel battery indicator operates as follows:

When the indicator is:	It means:
Steady amber	Battery is charging.
Steady green	Battery is charged.
Alternating amber and green	There is no battery installed or a battery charging fault has been detected.
Not lit	The monitor/defibrillator is not connected to AC mains.

Note: Upon power up, it takes approximately 7 seconds for the LEDs on the battery to accurately display run time.

- **External charging** — use the ZOLL SurePower Battery Charger or Single Bay Charger to charge the battery pack and test the battery's capacity. For details, refer to the *SurePower Battery Pack Guide*.

For information about the battery status icons and their indications, see "Battery Status and AC Power Indicators" on page 2-7.

When battery calibration is required, an equipment alert displays and the Recalibration LED icon (?) on the battery package lights for approximately 10 seconds (after pressing and releasing the Home button). If the Recalibration LED lights, the runtime indicator will not display run time for that battery. To restore battery run time indications and avoid unexpected low battery conditions or device shutdown, recalibrate the battery as soon as possible.

To manually recalibrate the SurePower Battery Pack, insert the battery into the SurePower Charger Station or Single Bay Charger and perform a Manual Test (for more information, refer to the ZOLL *SurePower Charger Station Operator's Guide*).

After recalibrating the battery, the Recalibration LED will only flash when the display button is pressed.

Clinical Benefits

The clinical benefits of the ZOLL M2 are:

- Displays an ECG and can deliver a shock
- Can provide successful capture for external transcutaneous pacing
- Provides guidance to healthcare professionals to perform standard of care cardiopulmonary resuscitation.

The Summary of Safety and Clinical Performance (SSCP) is available in the European database on medical devices (Eudamed) - https://ec.europa.eu/tools/eudamed. The Basic UDI-DI is 697324397M2001BG.

Safety Considerations

All operators should review these safety considerations before using the ZOLL M2 unit.

ZOLL M2 units are high-energy defibrillators capable of delivering 200 joules. To deactivate the unit, turn the Mode Selector to **OFF**.

To manually disarm a charged (or charging) defibrillator, do one of the following:

- Press the **Disarm** quick access key.
- Change the selected energy.
- Rotate the Mode Selector to **OFF** or **MONITOR**.
- Change the patient type.

For safety, the ZOLL M2 automatically disarms if left charged for more than 60 seconds (or other user configurable interval), if the **SHOCK** button is not pressed.

Warnings

General

- Only appropriately trained, skilled personnel who are familiar with equipment operation should perform emergency defibrillation. The responsible physician should determine what training certification, such as Advanced Cardiac Life Support (ACLS) or Basic Life Support (BLS), is appropriate.
- Only skilled personnel trained in Advanced Cardiac Life Support (ACLS) and who are familiar with equipment operation should perform synchronized cardioversion. The precise cardiac arrhythmia must be determined before attempting defibrillation.
- The operating instructions describe the functions and proper operation of the ZOLL M2 products. They are not a substitute for a formal patient care training course. Operators should obtain formal training from an appropriate authority before using this monitor/defibrillator for patient care.
- Proper operation of the unit and correct electrode placement is critical to obtaining optimal results. Operators must be thoroughly familiar with proper device operation.
- The use of external pacing/defibrillation electrodes, accessories, or adapter devices from sources other than ZOLL is not recommended. ZOLL makes no representations or warranties regarding the performance or effectiveness of its products when used with pacing/defibrillation electrodes or adapter devices from other sources. Defibrillator failures attributable to the use of pacing/defibrillation electrodes or adapters not manufactured by ZOLL might void ZOLL's warranty.
- At receipt of shipment, check pacing/defibrillation electrodes to ensure compatibility with the ZOLL M2 system.
- Place patient cables so that they do not inadvertently tug on electrodes.
- Carefully route patient cables to avoid tripping over them, entangling the patient, or inadvertently pulling the unit onto the patient.
- The ZOLL M2 unit meets IPX4 when it is powered by battery. It is recommended to only use the battery to power an ZOLL M2 unit in rain or snow. If AC power has to be used in rain or snow, always ensure that the AC power cord is firmly plugged into the ZOLL M2 unit.
- When positioning a ZOLL M2 unit that is connected to AC power, always locate the unit so that its power plug is easily accessible in case an emergency disconnection is needed.
- Do not disassemble the unit. A shock hazard exists. Refer all problems to authorized service personnel.
- Follow all recommended maintenance instructions. If a problem occurs, obtain service immediately. Do not use the monitor/defibrillator until it has been inspected by appropriate personnel.
- The ZOLL M2 unit should not be stored or used outside of the environmental limits shown in Appendix A of this manual.
- The ZOLL M2 device may not perform to specifications when stored at the upper or lower extreme limits of storage temperature and immediately put into use. It takes up to 20 minutes for the ZOLL M2 device to be fully functional after storing at -30°C; it takes up to 160 minutes for the ZOLL M2 device to be fully functional after storing at 70°C. If the ZOLL M2 device is needed immediately after storage, ZOLL recommends not to store the unit at or near the upper or lower limits of storage temperature.
- Avoid using the ZOLL M2 adjacent to, or stacked on, other equipment. If unavoidable, verify that the unit operates normally in this configuration before clinical use.

- The ZOLL M2 unit should be installed and put into service according to the EMC information in Appendix A of this manual.
- The use of accessories, transducers, and cables other than those specified in this manual may result in increased emissions or decreased electromagnetic interference immunity of the ZOLL M2 monitor/defibrillator.
- To ensure protection against the effects of defibrillator discharge, use only ZOLL-approved accessories.
- Always perform a functional test of internal paddles prior to use.
- Always inspect the unit for damage if it has been dropped.
- Only authorized personnel should use the Supervisor menus.
- If uncertain about the accuracy of any measurement, first check the patient's vital signs by alternate means, and then make sure the monitor is functioning correctly.
- Do not use the ZOLL M2 in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents (such as gasoline). Using the unit in such environments might cause an explosion.
- While the device can operate normally in an environment up to 50° C, continued monitoring or treatment should be performed in a more normal temperature environment to reduce the chance of heat-related injury to the patient.
- Before disposing of equipment, in order to avoid contaminating or infecting personnel, the environment, or other equipment, it is important to disinfect and decontaminate the monitor/defibrillator and any accessories and to remove the batteries. Dispose of the device and accessories in accordance with your country's regulations for equipment containing electronic parts.
- When other devices are used with the ZOLL M2 unit, their potential equalization terminals can be connected together to eliminate potential differences between different devices.
- Do not perform preventative maintenance service on the ZOLL M2 unit while it is connected to a patient.
- Do not modify the ZOLL M2 unit.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ZOLL M2 unit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

ECG Monitoring

- Implanted pacemakers can cause the heart rate meter to count the pacemaker rate during incidents of cardiac arrest or other arrhythmias. Dedicated pacemaker detection circuitry may not detect all implanted pacemaker spikes. Check the patient's pulse; do not rely solely on heart rate meters. Patient history and physical examination are important factors in determining the presence of an implanted pacemaker. Pacemaker patients should be carefully observed. See "Pacemaker Pulse Rejection:" on page A-4 of this manual for disclosure of the pacemaker pulse rejection capability of this instrument.
- Use only ECG electrodes that meet the AAMI standard for electrode performance (AAMI EC-12). Use of electrodes not meeting this AAMI standard could cause the ECG trace recovery after defibrillation to be significantly delayed.
- Prior to attempting synchronized cardioversion, ensure the ECG signal quality is good and that sync markers are displayed above each QRS complex.
- Do not place electrodes directly over an implanted pacemaker.

- The ZOLL M2 unit detects ECG electrical signals only. It does not detect a pulse (effective circulatory perfusion). Always verify pulse and heart rate by physical assessment of the patient. Never assume that the display of a nonzero heart rate means that the patient has a pulse.
- Poor or improper skin preparation of the ECG electrode sites can lead to undesirable levels of signal artifact. Follow skin preparation instructions in Chapter 6: “Monitoring ECG.”
- Equipment such as electrocautery or diathermy equipment, RFID readers, electronic article surveillance (EAS) systems, or metal detectors that emit strong radio frequency signals can cause electrical interference, distort the ECG signal displayed by the monitor, and prevent accurate rhythm analysis. Ensure adequate separation between such emitters, the ZOLL M2 unit, and the patient when performing rhythm analysis.
- Use of accessories, other than those specified in the operating instructions, may adversely affect patient leakage currents.
- Certain line-isolation monitors may cause interference on the ECG display and may inhibit heart rate alarms.

Defibrillation

- The ZOLL M2 can deliver more than 200 joules of electrical energy. If this electrical energy is not discharged properly, as described in the this manual, it can cause personal injury or death to the operator or bystander.
- To avoid possible damage to the ZOLL M2 unit, turn off pacing before defibrillating the patient with a second defibrillator.
- Except as needed during emergency patient treatments, do not repeatedly charge and discharge the defibrillator in rapid succession. If defibrillator testing requires repetitive discharges, allow a waiting period of at least one minute after every third discharge.
- When the ZOLL M2 unit is used for cardioversion, the SYNC mode may be cleared after each shock. The user may have to reselect (press) the SYNC button after each synchronized shock performed on a patient. In the Supervisor menus, the ZOLL M2 can be configured to remain in the SYNC mode after each shock.
- Synchronized cardioversion can be performed using external paddles for ECG monitoring. However, paddles movement can cause ECG artifact that might unintentionally cause the defibrillator to discharge. It is recommended that monitoring in leads I, II or III be used during synchronized cardioversion; hands free pads can also be used effectively as the ECG source for cardioversion.
- If conductive gel forms a continuous path between the defibrillator electrodes, delivered energy may be dramatically reduced; reposition the electrodes to eliminate the shunting path before attempting additional shocks.
- Improper defibrillation technique can cause skin burns. To limit possible skin burns, use only ZOLL defibrillation gel on paddles, ensure the gel covers the entire paddle surface and press firmly against patient’s chest.
- Do not use hands free electrodes or gel accessories past their expiration date as such use can lead to reduced energy delivery, skin burns or inability to deliver defibrillation shocks.
- Selecting a new energy level while the defibrillator is charging or charged automatically disarms the defibrillator. Press the **CHARGE** button again to re-initiate defibrillator charging.
- Prior to defibrillation, disconnect the patient from any medical electronic devices that are not labeled “defibrillation protected.”
- Before charging the defibrillator, verify that the desired energy has been selected on the display.

Pacing

- Ventricular fibrillation does not respond to pacing and requires immediate defibrillation. Therefore, the patient's dysrhythmia must be determined immediately, so appropriate therapy can be employed. If the patient is in ventricular fibrillation and defibrillation is successful but cardiac standstill (asystole) ensues, use the pacemaker.
- Ventricular or supraventricular tachycardias can be interrupted with pacing, but in an emergency or during circulatory collapse, synchronized cardioversion is faster and more certain.
- Pulseless electrical activity (PEA) can occur following prolonged cardiac arrest or in other disease states with myocardial depression. Pacing might then produce ECG responses without effective mechanical contractions, making other effective treatment necessary.
- Pacing can evoke undesirable repetitive responses, tachycardia, or fibrillation in the presence of generalized hypoxia, myocardial ischemia, cardiac drug toxicity, electrolyte imbalance, or other cardiac diseases.
- Pacing by any method tends to inhibit intrinsic rhythmicity. Abrupt cessation of pacing, particularly at rapid rates, can cause ventricular standstill and should be avoided.
- Noninvasive temporary pacing can cause discomfort of varying intensity, which occasionally can be severe and preclude its continued use in conscious patients.
- Transcutaneous pacing may cause discomfort ranging from mild to severe, depending on the patient's tolerance level, muscle contractions and electrode placement. In certain cases, discomfort may be decreased by slightly relocating the pacing pads.
- Unavoidable skeletal muscle contraction might be troublesome in very sick patients and might limit continuous use to a few hours. Erythema or hyperemia of the skin under the hands-free therapy electrodes often occurs; this effect is usually enhanced along the perimeter of the electrode. This reddening should lessen substantially within 72 hours.
- There have been reports of burns under the anterior electrode when pacing adult patients with severely restricted blood flow to the skin. Prolonged pacing should be avoided in these cases and periodic inspection of the underlying skin is advised.
- There are reports of transient inhibition of spontaneous respiration in unconscious patients with previously available units when the anterior electrode was placed too low on the abdomen.
- Always verify that the patient is being effectively paced by palpating his/her pulse rate and comparing it to the pacer rate setting.
- Artifact and ECG noise can make R-wave detection unreliable, affecting the HR meter and the demand mode pacing rate. Always observe the patient closely during pacing operations. Consider using asynchronous pacing mode if a reliable ECG trace is unobtainable.
- It is important to monitor the patient closely to verify that both mechanical and electrical capture are occurring. Electrical capture can be verified by observing the presence of a large ectopic beat after the pacing pulse is delivered. The size and morphology of the beat are dependent on the patient. Mechanical capture can be verified by checking for signs of increased blood flow i.e., reddening of the skin, palpable pulses, increased blood pressure, etc. Continuously observe the patient during pacing administration, to insure capture retention. Do not leave the patient unattended when administering external pacing therapy.

WARNING! **This device can only be used for external pacing of patients and cannot be used for internal pacing. Do not connect internal pacing lead wires to the ZOLL M2 monitor/ defibrillator.**

CPR

- Place the patient on a firm surface before performing chest compressions.
- The patient must be motionless during chest compressions to ensure accurate CPR measurements. When performing chest compressions on children, ensure that the ZOLL M2 patient type is set to pediatric. Failure to set the correct patient type can result in audio "Push Harder" prompts that are inappropriate for some pediatric patients.
- Place CPR electrodes on the patient as indicated on the electrode packaging to ensure the accurate measurement of compressions depth.

SpO_2

- Keep the finger probe clean and dry.
- Do not reuse any components that are labeled for single use only.
- SpO_2 measurements may be affected by certain patient conditions: severe right heart failure, tricuspid regurgitation or obstructed venous return.
- SpO_2 measurements may be affected when using intravascular dyes, in extreme vasoconstriction or hypovolemia or under conditions where there is no pulsating arterial vascular bed.
- SpO_2 measurements may be affected in the presence of strong EMI fields, electrosurgical devices, IR lamps, bright lights, improperly applied sensors; the use of non-ZOLL sensors, or damaged sensors; in patients with smoke inhalation, or carbon monoxide poisoning, or with patient movement.
- Tissue damage can result if sensors are applied incorrectly, or left in the same location for an extended period of time. Move sensor every 4 hours to reduce possibility of tissue damage.
- Do not use any oximetry sensors during MRI scanning. MRI procedures can cause conducted current to flow through the sensors, causing patient burns.
- Do not apply SpO_2 sensor to the same limb that has an NIBP cuff. The SpO_2 alarm may sound when the arterial circulation is cut off during NIBP measurements, and may affect SpO_2 measurements.

Noninvasive Blood Pressure

- Blood pressure measurement results may be affected by the position of the patient, his or her physiological condition and other factors.
- Substitution of a component different from that supplied by ZOLL (cuff, hoses, etc.) may result in measurement error. Use only ZOLL-approved cuffs and hoses.
- Do not use a blood pressure cuff on the limb being used for IV infusion or for SpO_2 monitoring.
- Accurate pressure readings may not be achieved on a person experiencing arrhythmias, shaking, convulsions or seizures. Medication may also affect pressure readings. The correct size cuff is essential for accurate blood pressure readings.
- Blood pressure hoses must be free of obstructions and crimps.
- If the patient’s cuff is not at heart level, an error in measurement may result.
- When monitoring blood pressure at frequent intervals, observe the cuffed extremity of the patient for signs of impeded blood flow.
- Blood pressure measurement may be inaccurate if taken while accelerating or decelerating in a moving vehicle.
- If an NIBP measurement result is questionable, repeat the measurement. If the repeated measurement result is still questionable, use another blood pressure measurement method.

- Do not attempt to take NIBP measurements on patients during cardiopulmonary bypass procedures.
- Ensure that the patient is not allergic to blood pressure cuffs made of nylon, TPU or PVC before use.

CO_2

- During MRI scanning, the monitor must be placed outside the MRI suite. When the monitor is used outside the MRI suite, $EtCO_2$ monitoring can be implemented using a long sampling line which permits placement of the monitor outside the MRI site.
- When using the monitor with anesthetics, nitrous oxide or high concentrations of oxygen, connect the gas outlet to a scavenger system.
- Only use CO_2 sampling lines specified by ZOLL.
- CO_2 sampling lines are labeled for single patient use only. Do not reuse sampling lines.
- CO_2 readings and respiratory rate can be affected by sensor application errors, certain ambient environmental conditions, and certain patient conditions.
- To ensure accurate CO_2 measurement results, adjust the O_2 and/or N_2O compensation whenever N_2O or high levels of O_2 are present in the patient's breathing circuit.

Respiration

- When using impedance pneumography, do not use the M2 unit with another impedance-based respiration monitor on the same patient because the respiration measurement signals may interfere with one another.
- Do not rely on impedance-based respiration monitoring for detecting cessation of breathing. Follow hospital guidelines and best clinical practices, including monitoring additional parameters that indicate the patient’s oxygenation status.
- With any monitor that detects respiratory effort through impedance pneumography, artifact due to patient motion, apnea mattress shaking, or electrocautery use may cause apnea episodes to go undetected. Always monitor and set alarms for SpO_2 when using impedance pneumography to monitor respiratory function.
- The device should not be used as an apnea monitor.
- In some instances, such as an obstructed airway, the patient’s breathing attempts may not produce any air exchange but till produce chest size changes, creating impedance changes that can be detected by the respiration detector. It is best to use the pulse oximeter and CO_2 monitoring when monitoring respirations to obtain accurate patient readings.

Temperature

- Only use the temperature sensors specified by ZOLL.
- Temperature sensors are reusable and should be cleaned and maintained according to the guidelines in Chapter 18, “Maintenance and Troubleshooting”.

Ferromagnetic Equipment

- Biomedical equipment and accessories, such as ECG electrodes, cables, and SpO_2 probes contain ferromagnetic materials. Ferromagnetic equipment must not be used in the presence of high magnetic fields created by either magnetic resonance imaging (MRI) equipment or nuclear magnetic resonance (NMR) equipment.

- The large magnetic fields generated by either an MRI device or a NMR device can attract ferromagnetic equipment with an extremely violent force, which could cause serious personal injury or death to persons between the equipment and the MRI device or the NMR device.

Battery

- Although the device can operate with AC mains power alone, ZOLL strongly recommends operating the unit with a battery installed at all times. Operating the unit with a battery provides a backup in case of AC power shortage. The battery can be automatically recharged while it is installed in the unit. Keep a fully charged spare battery pack with the monitor/defibrillator at all times.
- ZOLL M2 meets IPX4 when it is powered by battery; it is recommended to only use battery to power an ZOLL M2 unit in rain or snow. If AC power has to be used in rain or snow, always ensure that the AC power cord is firmly plugged into the ZOLL M2 unit.
- Test battery packs regularly. A battery that does not pass the ZOLL charger's capacity test might cause the ZOLL M2 unit to shut down unexpectedly.
- When the *Low Battery* alarm appears, plug the ZOLL M2 unit into an AC mains or install a fully charged battery pack as soon as possible. When the *Replace Battery* alarm appears, immediately replace the battery pack with a fully charged pack or plug the ZOLL M2 unit into an AC mains, as unit shut down due to a low battery condition is imminent.
- If mistreated, a battery pack might cause a fire hazard. Do not disassemble a battery pack, short circuit its terminals, or dispose of it in fire.

Operator Safety

- The ZOLL M2 can deliver more than 200 joules of electrical energy. If this electrical energy is not discharged properly (as described in this manual), it could cause personal injury or death to the operator or bystanders.
- Do not use the unit near or within standing water. Electrical safety might be compromised when the monitor/defibrillator is wet.
- Do not discharge the defibrillator except as indicated in the instructions. Discharge the defibrillator only when defibrillation electrodes or paddles are properly applied to the patient.
- To avoid risk of electric shock, this equipment must only be connected to AC mains outlets that include protective earth connection.
- To avoid risk of electrical shock, do not touch the gelled area of the hands-free therapy electrodes during pacing or defibrillation.
- To avoid risk of electrical shock, do not allow electrolyte gel to accumulate on hands or between paddle electrodes and paddle handles.
- For defibrillation using paddles, use only high-conductivity electrolyte gel specified for such use by the manufacturer.
- When using paddles for defibrillation, use thumbs to operate the **SHOCK** buttons. Doing so helps to avoid inadvertent shock to the operator.
- The use of accessory equipment that does not comply with the equivalent safety requirements of the ZOLL M2 monitor/defibrillator could reduce the level of safety of the combined system. When choosing accessory equipment, consider the following:
  - Use of the accessory in the patient vicinity.
  - Evidence that the safety certification of the accessory has been performed in accordance with the appropriate IEC (EN) 60601-1.
- Always check that the equipment functions properly and is in proper condition before use.
- Before discharging the defibrillator, warn everyone to STAND CLEAR of the patient.

- Do not touch the bed, patient, or any equipment connected to the patient during defibrillation. A severe shock can result. To avoid hazardous pathways for the defibrillation current, do not allow exposed portions of the patient's body to touch any metal objects, such as a bed frame.
- To avoid risk of electrical shock, do not allow printer to come into contact with other conductive parts, such as equipment connected to the USB port.

Patient Safety

- Inappropriate defibrillation or cardioversion of a patient (for example, with no malignant arrhythmia) may precipitate ventricular fibrillation, asystole, or other dangerous arrhythmias.
- Defibrillation without proper application of electrodes or paddle electrolyte gel might be ineffective and cause burns, particularly when repeated shocks are necessary. Erythema or hyperemia of the skin under the paddles, or electrodes often occurs; this effect is usually enhanced along the perimeter of the paddles or electrodes. This reddening should diminish substantially within 72 hours.
- This equipment should be connected to only one patient at a time.
- Adult and pediatric defibrillation energy level settings should be based on site-specific clinical protocols.
- To ensure patient safety, do not place the ZOLL M2 unit in any position that might cause it to fall on the patient.
- To ensure patient safety, connect the ZOLL M2 only to equipment with circuits that are electrically isolated.
- Use only high-quality ECG electrodes. ECG electrodes are for rhythm acquisition only; ECG electrodes cannot be used for defibrillation or pacing.
- Do not use therapy or ECG electrodes if the gel is dried, separated, torn or split from the foil; patient burns may result from using such electrodes. Poor adherence and/or air pockets under therapy electrodes can cause arcing and skin burns.
- Check the expiration date on the electrode packaging. Do not use electrodes after their expiration date.
- Excessive body hair or wet, diaphoretic skin can inhibit electrode coupling to the skin. Clip excess hair and dry any moisture from the area where an electrode is to be attached.
- Therapy electrodes should be replaced periodically during continuous pacing. Consult electrode directions for proper replacement instructions.
- Prolonged pacing (more than 30 minutes), particularly in patients with severely restricted blood flow, may cause burns. Periodically inspect the skin under the electrodes.
- Carefully route the patient cables away from the patient's neck to reduce the possibility of patient entanglement or strangulation.
- To avoid electrosurgery burns at monitoring sites, ensure proper connection of the electrosurgery return circuit so that a return path cannot be made through monitoring electrodes or probes.
- During electrosurgery, observe the following guidelines to minimize electrosurgery unit (ESU) interference and provide maximum operator and patient safety:
  - Keep all patient monitoring cables away from earth ground, ESU knives, and ESU return wires.
  - Use electrosurgical grounding pads with the largest practical contact area.
- Always ensure proper application of the electrosurgical return electrode to the patient.
- Check electrical leakage levels before use. Leakage current might be excessive if more than one monitor or other piece of equipment is connected to the patient.
- To avoid risk of electric shock to the patient in an ambulance, the ZOLL M2 unit must only be connected to an AC mains outlet that includes a reliable protective earth connection. If no

reliable protective earth connection is available, the ZOLL M2 must be operated using battery power only.

- To avoid risk of electrical shock, do not allow the conductive parts of electrodes (including the neutral electrode) or connectors associated with applied parts to contact any other conductive parts, including earth.

Cautions

- If the unit is to be stored longer than 30 days, remove the battery pack.
- Do not sterilize the monitor/defibrillator, or its accessories unless the accessories are labeled as sterilizable.
- Do not immerse any part of the monitor/defibrillator in water.
- Do not use the monitor/defibrillator if excessive condensation is visible on the device.
- Do not use ketones (such as acetone or MEK) on the monitor/defibrillator.
- Avoid using abrasives (including paper towels) on the display window.
- To achieve the specified level of protection against spilled or splashed liquids, thoroughly dry all exposed surfaces of this device prior to operation or connections to AC mains power.
- If liquids enter the device connectors, remove all liquid from the connectors and allow the device to dry thoroughly prior to use.
- Grounding reliability can be achieved only when the equipment is connected to a receptacle marked “HOSPITAL ONLY,” “HOSPITAL GRADE,” or equivalent. If the grounding integrity of the line cord or ac receptacle is questionable, operate the monitor/defibrillator using battery power only.
- Do not connect to an electrical outlet controlled by a wall switch or dimmer.
- To protect the unit from damage during defibrillation, for accurate ECG information, and to protect against noise and other interference, use only internal current-limiting ECG cables specified or supplied by ZOLL.
- For continued safety and EMI performance, use only the line cord supplied by ZOLL.
- Electrical wiring of the room or the building in which the ZOLL M2 unit is to be used must comply with regulations specified by the country in which the equipment is to be used.
- Dispose of battery packs in accordance with national, regional and local regulations. Battery packs should be shipped to a reclamation facility for recovery of metal and plastic compounds as the proper method of waste management.
- Do not place the device where the controls can be changed by the patient.
- Install the ZOLL M2 in a position that is easy to observe, operate and maintain.
- Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with EN/IEC 60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of a 1/2 meter or greater or a spillage of blood or other liquids on/into the unit occurs, retest before further use to avoid personal injury.

Restarting the Monitor/Defibrillator

Certain events require the ZOLL M2 products to be restarted after they shut off or become inoperative (for example, when the battery runs down and the unit shuts off).

In such a case, always try to restore monitor/defibrillator operation as follows:

1. Turn the Mode Selector to **OFF**.
2. If necessary, replace a depleted battery with a fully charged pack, or connect the monitor/defibrillator to AC mains power.
3. Turn the Mode Selector to the desired operating mode to restart the unit.

This sequence is necessary to restart the monitor/defibrillator and can also be used to clear some fault messages when immediate use of the monitor/defibrillator is required.

If the ZOLL M2 unit is powered off for less than 30 seconds, all patient monitoring parameter settings will be retained. If the unit has been powered off for more than 30 seconds, all of the patient-specific parameters (alarm limits, defibrillator energy, etc.) will be reset to their default values.

Software License

Note: Read this Operator's Guide and License agreement carefully before operating any of the ZOLL M2 products.

Software incorporated into the system is protected by copyright laws and international copyright treaties as well as other intellectual property laws and treaties. This software is licensed, not sold. By taking delivery of and using this system, the Purchaser signifies agreement to and acceptance of the following terms and conditions:

1. **Grant of License:** In consideration of payment of the software license fee which is part of the price paid for this product ZOLL Medical Corporation grants the Purchaser a non-exclusive license, without right to sublicense, to use the system software in object-code form only.
2. **Ownership of Software/Firmware:** Title to, ownership of and all rights and interests in the system software and all copies thereof remain at all times vested in the manufacturer, and Licensors to ZOLL Medical Corporation and they do not pass to purchaser.
3. **Assignment:** Purchaser agrees not to assign, sublicense or otherwise transfer or share its rights under the license without the express written permission of ZOLL Medical Corporation.
4. **Use Restrictions:** As the Purchaser, you may physically transfer the products from one location to another provided that the software/firmware is not copied. You may not disclose, publish, translate, release or distribute copies of the software/firmware to others. You may not modify, adapt, translate, reverse engineer, decompile, crosscompile, disassemble or create derivative works based on the software/firmware.

Service

Appropriately trained and qualified personnel should perform periodic tests of the monitor/defibrillator functionality to verify proper operation.

If a unit requires service, contact the ZOLL Technical Service Department.

For International customers
Call the nearest authorized ZOLL Medical Corporation representative. To locate an authorized service center, contact the International Sales Department at ZOLL Medical Corporation 269 Mill Road Chelmsford, MA 01824-4105 Telephone: 1-978-421-9655

When requesting service, please provide the following information to the service representative:

- Unit serial number
- Description of the problem
- Department using the equipment and name of the person to contact
- Purchase order to allow tracking of loan equipment
- Purchase order for a unit with an expired warranty
- Sample ECG or other stripcharts demonstrating the problem (if available and applicable), less any confidential patient information.

Returning a unit for service

Before sending a unit to the ZOLL Technical Service Department for repair, obtain a service request (SR) number from the service representative.

Remove the battery pack from the unit. Pack the unit with its cables and battery in the original containers (if available) or equivalent packaging. Be sure the assigned service request number appears on each package.

Return the unit to
The nearest authorized ZOLL Medical Corporation representative. To locate an authorized service center, contact the International Sales Department at ZOLL Medical Corporation 269 Mill Road Chelmsford, MA 01824-4105 Telephone: 1-978-421-9655

The ZOLL Serial Number

Each ZOLL product displays a serial number that contains information about that product. From left to right, ZOLL serial numbers are structured as follows:

- A two-character product code
- A three-character date-of-manufacture code
- A product serial number of six or more alphanumeric characters

The first two characters of the date-of-manufacture code give the last two digits of the year (for example, “18” appears for products manufactured in 2018). The last character of the date-of-manufacture code gives the month in which the product was manufactured. The month appears in the form of a single alphanumeric character: “A” for January, “B” for February, “C” for March, and so on through “L” for December.

The product serial number is a unique set of alphanumeric characters that ZOLL assigns to each individual unit.

Chapter 2
Product Overview

Overview

This chapter contains information about the functionality of the ZOLL M2 monitor/ defibrillator, and how to operate the unit and perform everyday tasks. See the following sections of this chapter for more information:

- Controls and Indicators
- Navigating the Display Screen
- Replacing a Battery Pack

Controls and Indicators

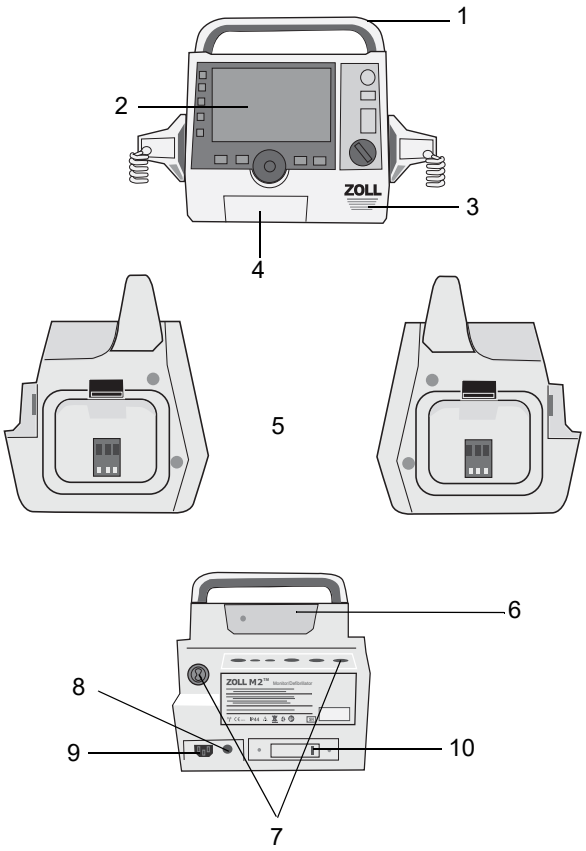


Table 1: ZOLL M2 Unit Features

	Item	Description
1	Handle	Integrated carrying handle.
2	Front panel	Includes the display screen and primary controls.
3	Speaker	Emits voice prompts and alarm tones.
4	Paper Compartment	Holds the paper for the printer.
5	Paddle wells	Holds the external paddles.
6	Battery compartment	Holds a rechargeable lithium ion battery pack.
7	Patient connectors	For details, refer to “Upon powering up the ZOLL M2 unit, the battery capacity will be displayed within a short period under normal conditions. Under some circumstances, such as activating the monitor/defibrillator immediately after the unit is turned on, the battery icon may display less than one hour battery capacity for up to two minutes after exiting the defibrillation mode.” on page 2-8.
8	Potential equalization conductor	Earth-grounded terminal provided for the convenient connection of biomedical test equipment requiring an equipotential ground. This terminal has no clinical function and should not be used for electrical safety purposes.

Table 1: ZOLL M2 Unit Features

	Item	Description
9	AC mains connector	For connecting the device to an AC mains power cord.
10	USB port	For connecting the ZOLL M2 monitor/defibrillator to a USB memory device. For details, refer to “Full Disclosure Recording” on page 17-13.

The Front Panel

The front panel of the ZOLL M2 device includes a display screen and various buttons, keys, and indicators that provide feedback to the user. See Figure 2-1. Refer to Table 2 on page 2-3 for information about the controls and indicators.

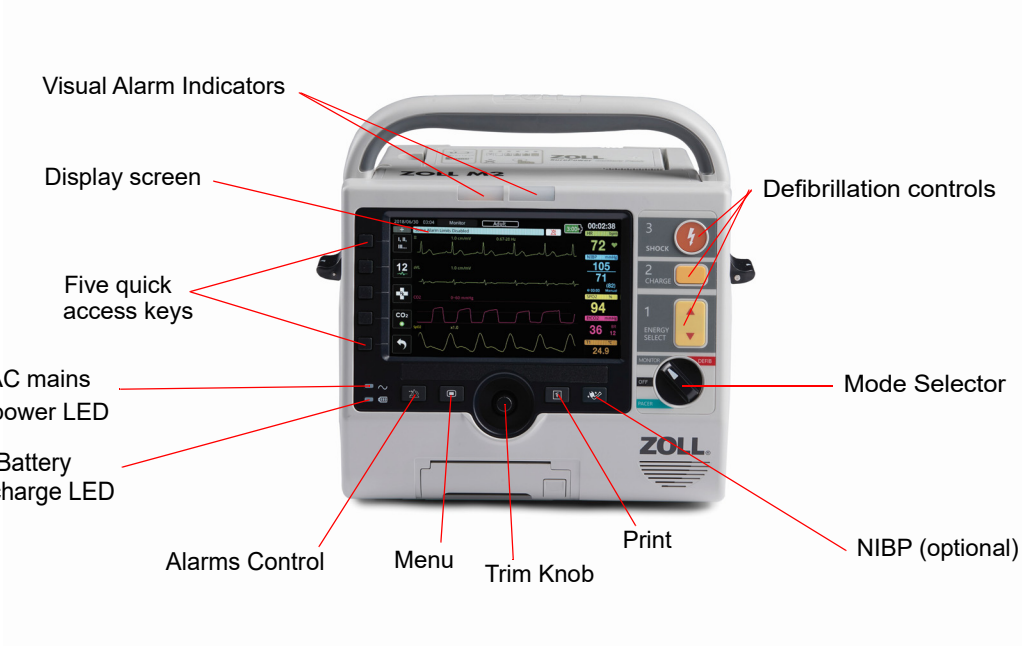


Figure 2-1 Front Panel

Table 2: ZOLL M2 Controls and Indicators

Control or Indicator	Description
Display screen	Shows therapeutic settings, physiological waveforms and other information for each monitored parameter, messages, time, and quick access key labels.
Quick access keys	Five buttons control different functions of the unit. Labels for the quick access keys appear on the display to the right of each key.
AC mains power LED	Illuminated when the unit is plugged into AC mains power.

Table 2: ZOLL M2 Controls and Indicators (Continued)

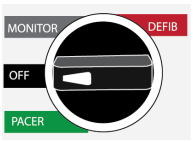
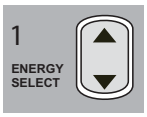
Control or Indicator	Description
Battery charge LED	Indicates battery status. Steady amber: Battery is charging. Steady green: Battery is charged. Alternating green and amber: There is no battery installed or a battery charging fault has been detected. No light The monitor/defibrillator is not connected to AC mains.
Visual alarm indicators	Red and yellow lights located on the top of the unit that flash to indicate patient and equipment alarms. These lights also flash momentarily when the unit is turned on.
Mode Selector 	Selects the mode of operation: • OFF — Unit is powered off • MONITOR — Physiological monitoring • DEFIB — Manual defibrillation or AED • PACER — Noninvasive external pacing
ENERGY SELECT buttons 	Front panel up-down arrow buttons control the selection of defibrillator energy. **Note:** These buttons are also available on certain paddles.
CHARGE button 	Initiates charging of the defibrillator to the selected energy. **Note:** This button is also available on certain paddles.
SHOCK button 	The front panel **SHOCK** button is only active when using hands-free therapy electrodes or defibrillation paddles without a discharge button. The **SHOCK** button illuminates when this control is active, defibrillator is charged and ready. **Note:** This button is also available on certain paddles.
NIBP button (optional) 	Starts/stops an NIBP measurement.
Print button 	Starts/stops printing.

Table 2: ZOLL M2 Controls and Indicators (Continued)

Control or Indicator	Description
Trim Knob 	Rotating the Trim Knob in either direction causes the cursor to travel in a clockwise direction around the display screen, or downward in a list or window, allowing the user to: • Navigate around the display screen • Navigate in a vertical list • Modify parameter settings Pressing the Trim Knob performs a selection related to the cursor highlighted display field.
Menu button 	Displays the Settings menu from the Monitor, Defib, or Pacer display screen. Functions as a Home button when in a menu.
Alarm Control button 	Performs the following alarm functions when pressed and held for various time periods: • Silences patient alarm audio for preconfigured period of time. • Silences patient alarm audio permanently. • Disables patient alarm processing. • Responds to equipment related alarms. • Clears latched alarms.

Display Screen

The front panel includes a color display which shows:

- Date and time
- Operation mode
- Patient type
- WiFi status
- USB status
- Battery status indicator
- Time elapsed (since unit was turned on)
- Quick access keys
- Waveform source
- Color-coded waveforms and ECG lead identifiers
- SpO_2 numeric data
- Heart rate numeric data
- Respiration rate numeric data
- Temperature numeric data
- Non-invasive blood pressure numeric data
- $EtCO_2$ numeric data
- CPR waveform and numeric data
- Selected energy, charging status, and delivered energy for defibrillation and synchronized cardioversion in Defib mode
- Output current, mode, and stimulus rate for pacing in Pacer mode
- Messages and prompts

The image below shows the layout of parameter values, waveforms, system data, and quick access key labels. The unit displays the information in user-configurable colors.

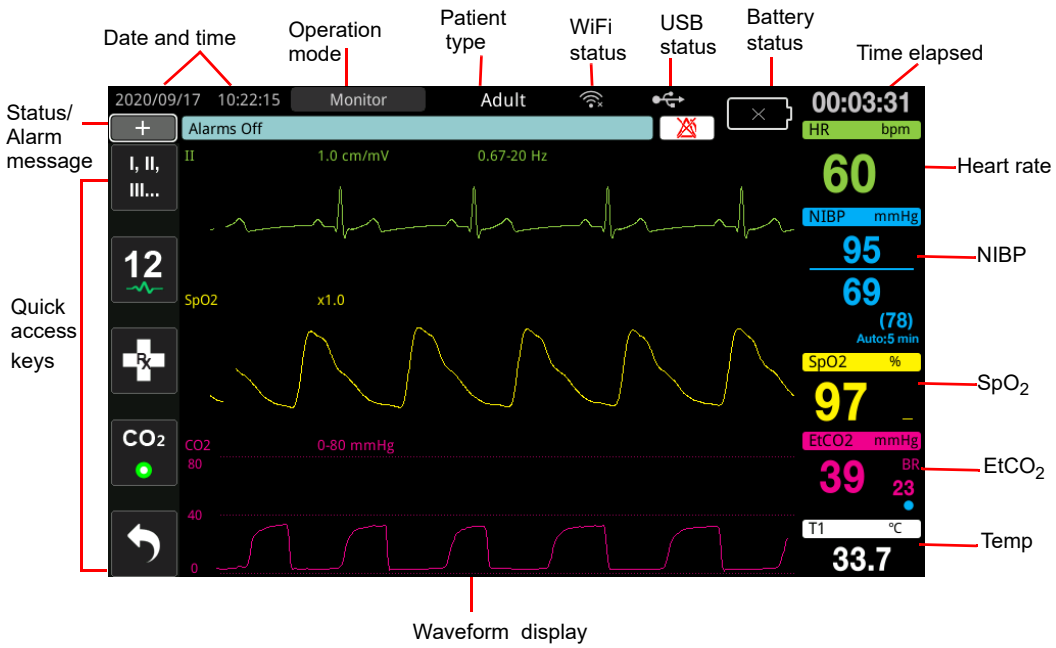
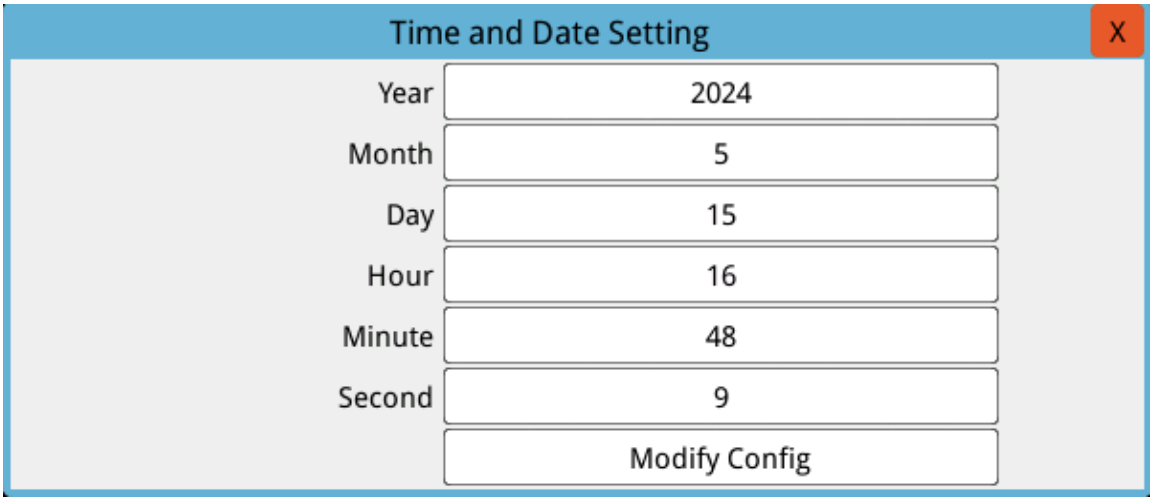


Figure 2-2 ZOLL M2 Display Screen

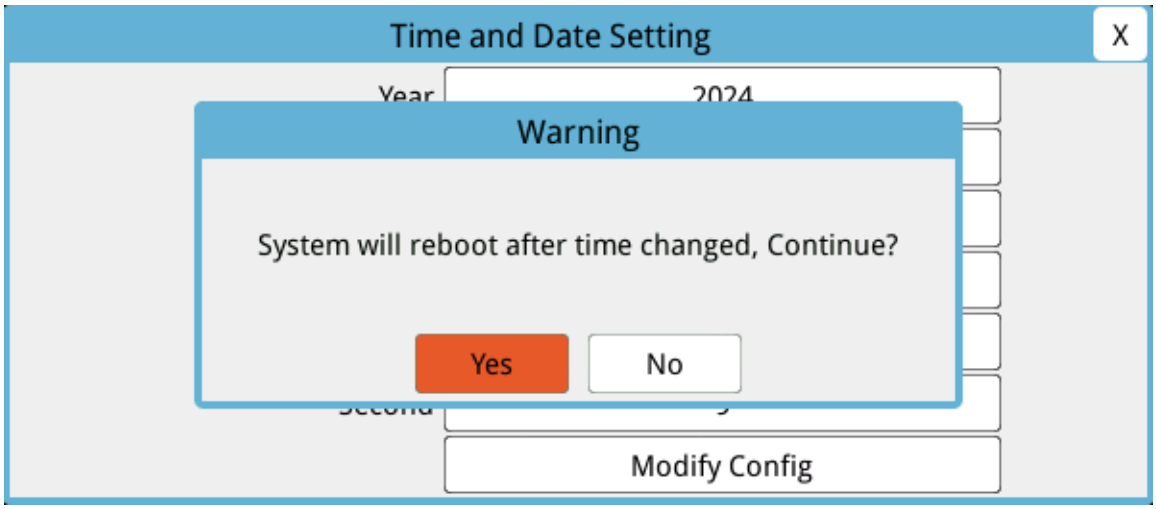
Date and Time

To modify the system time, do the following:

1. Turn the Trim Knob to highlight the Date and Time, and then press the knob. The Time and Date Setting menu displays.



2. You can modify the Year, Month, Day, Hour, Minute, and Second.
3. After setting the system time, turn the Trim Knob to Modify Config and press the knob to select it. The system must reboot to apply any changes.



4. To exit the Time and Date Setting menu:
   - Rotate the Trim Knob to the X in the window's top right corner and press the knob.
   - Press the Menu button ( ) to leave the window.

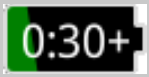
Battery Status and AC Power Indicators

When the unit is plugged in to AC mains, the AC power LED illuminates.

The battery status indicator displays various battery icons to indicate the approximate remaining unit run time based on the charge state of the battery. Additionally, these icons provide status indications of the battery connection and communication with the unit. Not all

battery icons are shown in the table below; there are additional battery icons that display thirty minute increments, such as 1:30+ and 2:30+.

Note: Upon powering up the ZOLL M2 unit, the battery capacity will be displayed within a short period under normal conditions. Under some circumstances, such as activating the monitor/defibrillator immediately after the unit is turned on, the battery icon may display less than one hour battery capacity for up to two minutes after exiting the defibrillation mode.

Icon	Status	Indication/Action
	No battery detected	Either there is no battery in the unit while it is being powered by the AC mains, or the device cannot detect that the battery is connected. Install new battery or replace existing battery.
	Communication fault	The unit is unable to establish communication with the battery. Check the battery contacts.
	Battery Error	A battery fault has been detected. Plug the ZOLL M2 unit into an AC power source or install a new battery.
	Low battery capacity	The battery has reached a low battery state. Replace the battery immediately.
	Battery Level 1	The battery has enough energy to operate the ZOLL M2 unit for more than 30 minutes under current operating conditions.
	Battery Level 2	The battery has enough energy to operate the ZOLL M2 unit for more than one hour under current operating conditions.
	Battery Level 3	The battery has enough energy to operate the ZOLL M2 unit for more than two hours under current operating conditions.
	Battery Level 4	The battery has enough energy to operate the ZOLL M2 unit for more than three hours under current operating conditions.
	Battery Level 5	The battery is fully charged.

Patient Cables and Connectors

The back of the ZOLL M2 unit includes connectors for patient cables.

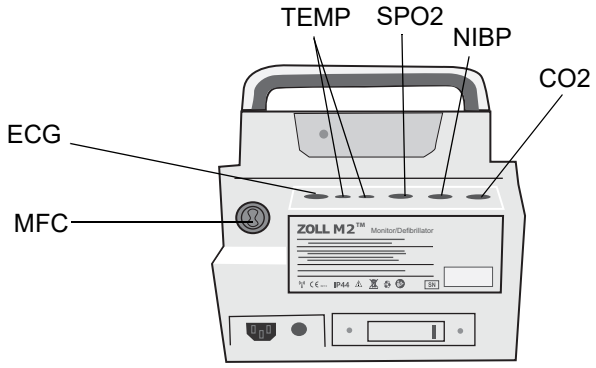


Figure 2-3 Patient Cable Connectors on back of the ZOLL M2 Unit

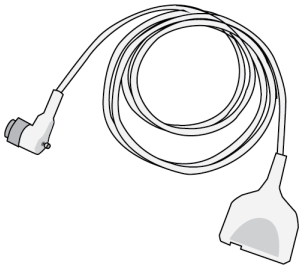
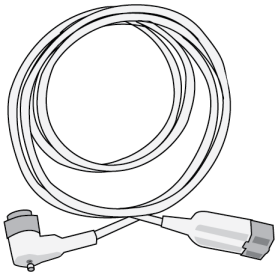
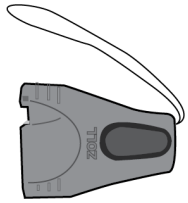
Connector	Description
ECG	For connecting 3-lead, 5-lead, or 12-lead ECG cable.
SpO_2	For connecting SpO_2 cable.
NIBP	For connecting NIBP hose.
CO_2	For connecting mainstream or sidestream CO_2 module.
Temp1/Temp2	For connecting temperature probe(s).
Multifunction cable (MFC) (with or without CPRD connector)	For MFC connection to paddles or hands-free therapy and pacing electrodes.

Cables and Accessories

The ZOLL M2 unit ships with an MFC cable that is used with internal/external paddles.To use internal/external paddles and hands-free CPR monitoring electrodes, you must carry both an MFC and a CPRD adapter; use the CPRD adapter for all hands-free electrode applications. Remove the adapter to connect internal or external paddles to the ZOLL M2 unit.

An MFC with CPRD Connector is also available. This cable can be used with hands-free electrodes for ECG monitoring, defibrillation, external pacing, and CPR monitoring/feedback; this cable cannot be used with internal or external paddles.

Both cables (MFC with CPRD connector and the MFC) ship with a test connector that is used for the 30J self test.

• MFC with CPRD Connector	
• MFC	
• CPRD Adapter	
• Test connector (used for 30 Joule Self-test)	

See the following section for a list of compatible cables and paddles/electrodes and how they function together.

Compatible Accessories

See the list below for the compatible MFC (or MFC and CPRD combination) based on the paddles or hands-free electrodes that you are using.

Internal/External Paddles

- MFC (for ECG and defibrillation)

Hands-Free Electrodes with CPR Sensor

- MFC with CPRD Connector (for defibrillation, ECG, CPR feedback, and pacing)
- MFC with CPRD Adapter (for defibrillation, ECG, CPR feedback, and pacing)

Hands-Free Electrodes without CPR Sensor

- MFC (for ECG, defibrillation and pacing)

Inserting Cables into Unit

Insert the cable connector into the MFC connector on the back of the unit and tighten the screw.

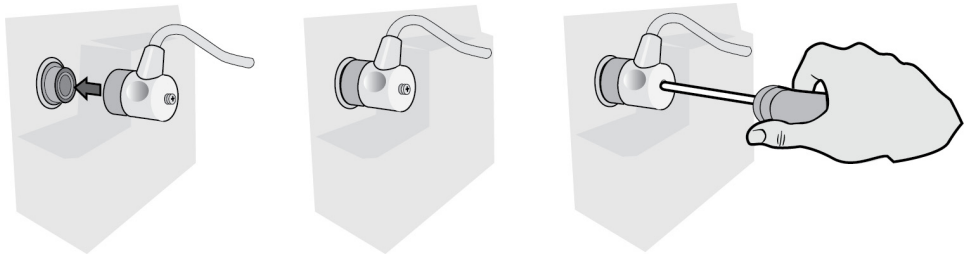


Figure 2-4 MFC Connected to Unit

Inserting Test Connector into MFC (30J Self Test)

To perform a 30J self-test, plug in the test connector as shown.

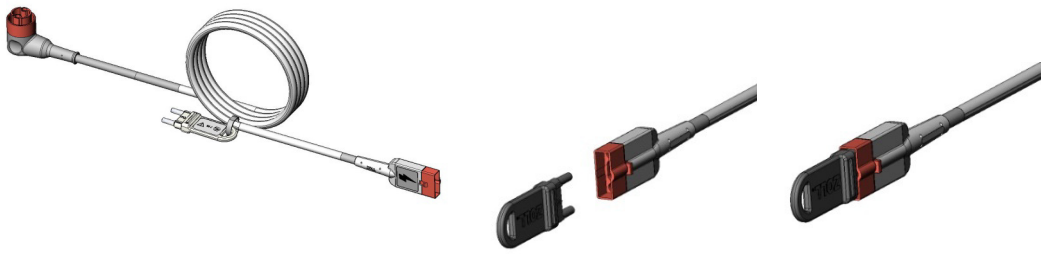


Figure 2-5 30J Self Test with MFC

Inserting Test Connector into MFC with CPRD Connector (30J Self Test)

To perform a 30J self-test, plug in the test connector as shown.

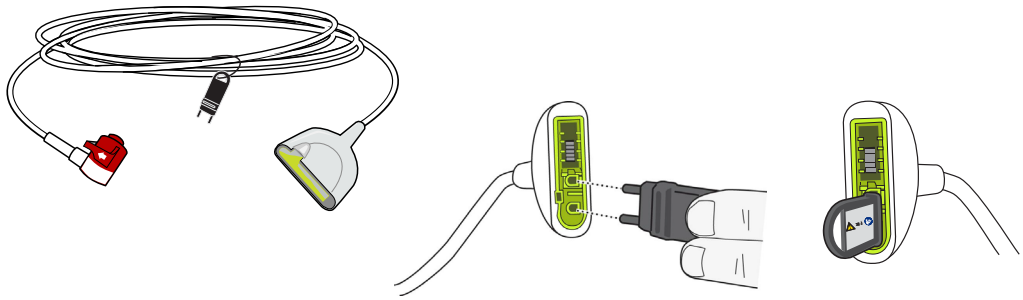


Figure 2-6 30J Self Test with CPRD Connector

External Paddles

External paddles are defibrillation-proof Type CF equipment.

The external paddles on the ZOLL M2 device are used for defibrillation and synchronized cardioversion.

Caution	You cannot use paddles for external transcutaneous pacing.

Releasing the Paddles

The paddles are stowed in wells on either side of the unit. To release the paddles, grasp the handles and then press down on the latch button above each paddle. Rotate the paddle edge away from the latch then remove from the well.

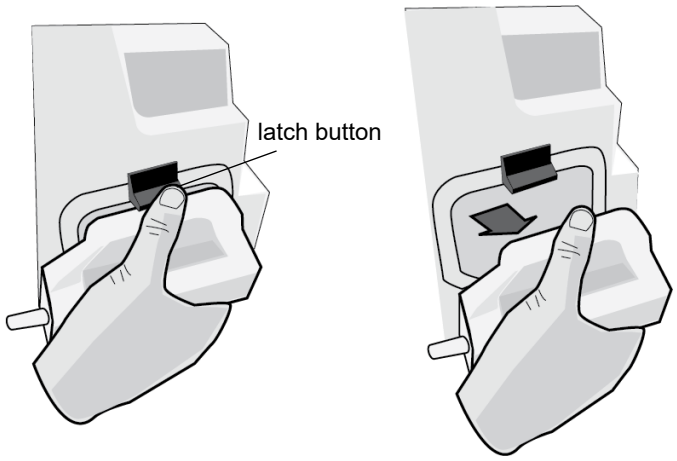


Figure 2-7 Paddle Release

Attaching the MFC Cable

Attach the MFC from the ZOLL M2 unit to the connector at the base of the APEX paddle.

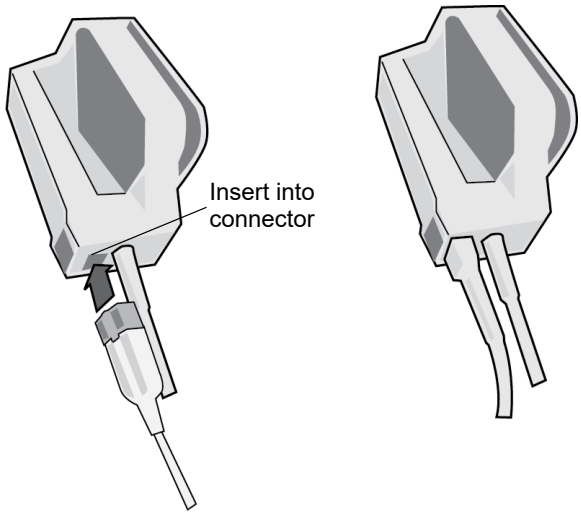
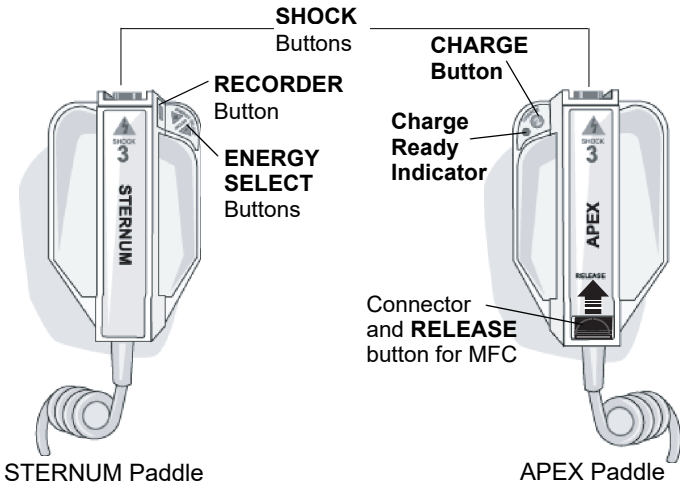


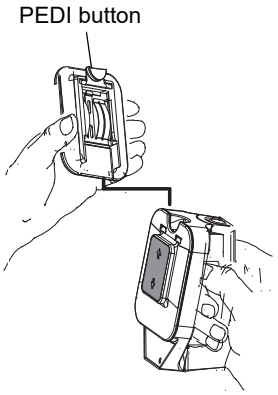
Figure 2-8 MFC Connected to APEX Paddle

If you need to detach the MFC from the APEX paddles, push the RELEASE button in the direction of the arrow and unplug the MFC.

Refer to Chapter 14, "Manual Defibrillation" before using paddles for defibrillation. The paddles include controls for selecting defibrillation energy, charging, delivering a shock, and turning the printer on and off.



Pediatric-size electrodes are built in to the paddle assembly beneath the standard electrode plates. The user must manually adjust energy settings to pediatric levels consistent with their institution’s protocols.



To expose the pediatric plate, press the PEDI button at the top of the paddle, then slide the Adult plate upward.

Before replacing the Adult plate, be sure to clean the pediatric plate and surrounding area thoroughly.

Slide the Adult plate onto the paddle until it locks into place.

Figure 2-9 Pediatric Plate

Note: The ZOLL M2 monitor/defibrillator also supports ZOLL autoclavable internal paddles for use during open chest defibrillation procedures.

Navigating the Display Screen

You can access the ZOLL M2 functions using the quick access keys that are located on the left side of the display screen, and the Trim Knob that is located in the middle of the front panel.

Quick Access Keys

The five quick access keys on the left side of the display screen are an easy way to access the functionality of the ZOLL M2. The functions of some keys change when the ZOLL M2 unit is switched between the Monitor and Defib or Pacer modes. When you press the More/back key (), additional keys are displayed.

Note: When you press the Data quick access key (), an additional level of data-related keys is displayed.

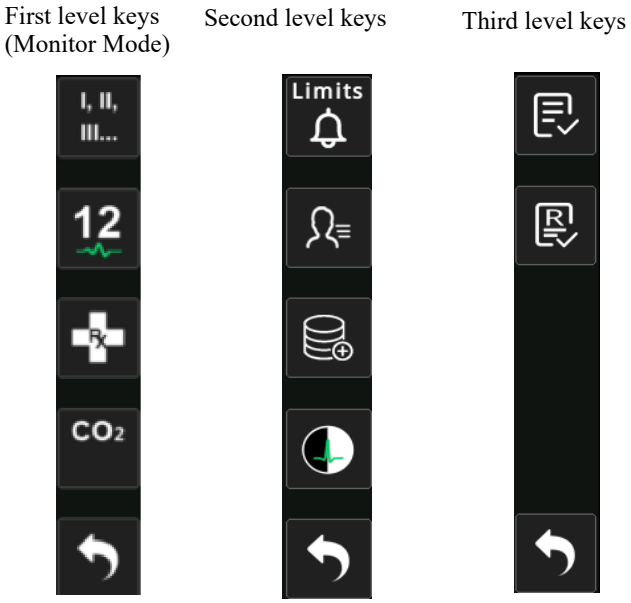


Table 3: ZOLL M2 Quick Access Keys

Quick access key	Description
Lead 	Selects the ECG input source for the top waveform trace. This trace is used for counting heart rate, synchronized defibrillation, and demand pacing.
12-Lead (optional) 	Displays the 12-Lead monitoring screen on units equipped with the 12-lead ECG option.
CO_2 	Enables or disables CO_2 module.

Table 3: ZOLL M2 Quick Access Keys

Quick access key	Description
CO_2 (with green light) 	CO_2 module is connected and CO_2 monitoring is enabled.
CO_2 Zero 	When CO_2 zeroing is required, the CO_2 quick access key changes to this key for 10 seconds. Activates the CO_2 zeroing process.
Diag ECG (3- and 5-lead) 	All ECG leads displayed with a “diagnostic” (0.525-40 Hz) frequency response for 12 seconds.
Code Marker 	Allows you to note clinical treatments in the patient record.
Sync 	Activates the synchronized cardioversion mode.
More/Back 	Goes to the next or previous level of quick access keys.
Alarm Limits 	Allows you to view/set all parameter alarm limits.
Treatment Summary 	Displays treatment summary events for one or more cases that you can print.
Trend 	Displays current patient trends data.
Manual Mode 	Allows you to change from AED Mode to Manual Defib Mode. **Note:** Depending on configuration, it may require a password.
AED Mode 	Allows you to enter AED Mode from Manual Defib Mode.
Analyze 	Analyzes the patient’s ECG to determine whether a shockable rhythm is present. **Note:** Only available in AED mode.

Table 3: ZOLL M2 Quick Access Keys

Quick access key	Description
Export Data 	Exports the data through a USB drive or WiFi.
Clear Selection 	Deletes selected data that is stored in non-volatile memory.
Acquire 	Collects 10 seconds of 12-lead ECG data for print or transmission. **Note:** Only available with 12-lead option.
Patient Information 	Allows you to enter patient information to accompany Summary and full disclosure reports.
Data 	Displays additional data quick access keys: Trend, Treatment summary, Export data, and Clear.
Brightness 	Changes the brightness setting — toggles through high contrast display (white background) and color display (black background).
12-Lead Review 	Provides access to 12-lead captured data for printing reports. **Note:** Only available with 12-lead option.
Exit 12-Lead 	Exits the 12-lead monitoring screen. **Note:** Only available with 12-lead option.
Disarm 	Safely discharges the defibrillator internally. No energy is delivered to the patient.
30 Joule Test 	Performs 30 joule defibrillator test.
4:1 	Enable/Disable 4:1 pacer mode.
Clear 	Displays and flashes yellow in Pacer mode when there is a pads off or shorted condition.

Table 3: ZOLL M2 Quick Access Keys

Quick access key	Description
System Self-test Report 	Displays all Power On and 30J system self-test reports stored on the unit (up to 2,000 reports), with options to print.
Readiness Test Report 	Collects results of all the unit's self-tests in one report.

Trim Knob

Rotate the Trim Knob clockwise to make the cursor travel in a clockwise direction around the display screen, or downward in a list or window. Rotate the Trim Knob counterclockwise to make the cursor to travel in a counterclockwise direction around the display screen, or upward in a list or window.

Rotate the Trim Knob in clockwise and counterclockwise direction to do the following:

- Move clockwise and counterclockwise through the main display windows.
- Move up and down in a window.
- Change parameter settings.

Press the Trim Knob to do the following:

- Display the settings window while a parameter is highlighted in the main window.
- Select options from within a window.

Display Brightness

The monitor can display different brightness modes. They range from very bright to very dim. The display modes with more contrast make the numerics and waveforms easiest to read.

The following procedure shows how to select the different brightness options.

5. Press the Menu Button ().
6. Rotate the Trim Knob to highlight and select the System setting, and press the knob to select it.
7. Rotate the Trim Knob to Display Brightness and press the knob to select the field.
8. Rotate the Trim Knob to select the brightness setting (number) and press the knob to select it.
9. Rotate the Trim Knob to highlight the X in the top right corner of the window, and press the knob to close the window.

Note: Selecting a higher brightness setting (such as Level 5) will deplete the battery pack at a faster rate than when choosing a lower brightness setting (such as Level 3).

You can also toggle between high contrast with white background (for optimal display in bright sunlight), and color with black background (numerics and waveforms are easier to read).

Using Code Markers

Pressing the Code Marker quick access key () causes the unit to display a preconfigured list of clinical actions, such as drugs or treatments administered to the patient. Up to 28 code markers can be displayed on the screen at one time. Using the Trim Knob (rotating then pressing the knob) to select a particular action causes that action to be recorded along with a date and time stamp in the Summary Report and Full Disclosure memory.

Replacing a Battery Pack on the ZOLL M2 Unit

This section describes how to replace a battery pack on the ZOLL M2.

Replacing a Battery Pack on the ZOLL M2

To remove a battery pack, press the tab on the end of the battery pack inward, and rotate and lift the battery pack out of the compartment.

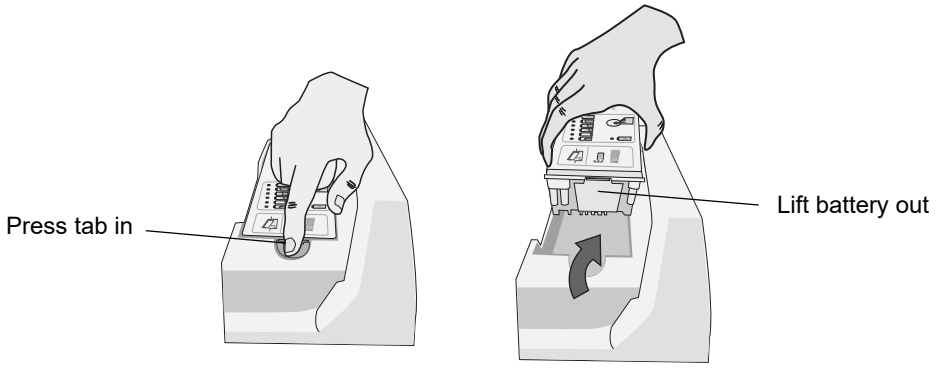


Figure 2-10 Removing a Battery Pack

To install a battery pack:

1. Insert the non-tabbed end of the battery pack into the battery compartment, as shown in the diagram on the SurePower battery label.
2. Lower the tabbed end of the battery pack into the compartment, and press down on the tabbed end of the battery until it locks into place.

Caution When installing the battery, be careful not to pinch your fingers.

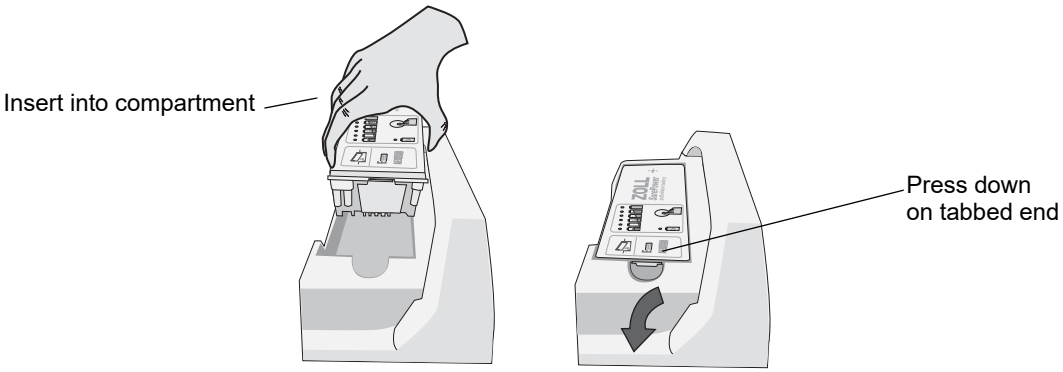


Figure 2-11 Installing a Battery Pack

Chapter 3
Monitoring Overview

This chapter provides an overview of the ZOLL M2 unit's monitoring functions. It describes the types of vital sign monitoring that ZOLL M2 provides, and the flexibility that the ZOLL M2 unit provides in displaying a patient's vital signs information.

ZOLL M2 Monitoring Functions

The ZOLL M2 unit provides standard monitoring functions, and allows you to view the vital signs measurements in a variety of formats. The ZOLL M2 unit also allows you to set alarm limits for the monitoring functions. If a patient's vital signs measurements go outside of these limits when alarm functions are enabled, the ZOLL M2 issues an audible alarm tone and displays visual alarm indications to alert you.

When the ZOLL M2 unit is powered off for less than 30 seconds, all patient monitoring parameter settings are retained. When the ZOLL M2 unit is powered off for 30 seconds or longer, all patient-specific parameters (alarm limits, defibrillator energy, etc.) are reset to their default values.

The ZOLL M2 unit can monitor the following patient vital signs:

- ECG
- Heart Rate
- CPR-related Chest Compressions rate and depth
- Oxygen Saturation of Arterial Hemoglobin (SpO_2)
- Non-invasive Blood Pressure (NIBP)
- Respiration Rate
- Respiratory CO_2/$EtCO_2$
- Temperature

ECG

An ECG waveform appears at the top of the display area. You can specify that the unit displays the waveform of any available ECG source (such as PADS, ECG Leads I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6). You can configure the ZOLL M2 unit to display up to four ECG waveform traces. In addition to being able to specify the ECG source for each waveform trace, you can adjust the display scale of those traces to make them easier to view.

Printing ECG Waveforms

You can print waveforms that are displayed on the screen by pressing the Print button ( ). The ZOLL M2 unit prints the displayed waveforms as configured in the Number of Traces option. The Print Number of Traces option can be set to 1, 2, 3, or 4. Patient vital sign numerics are printed above the waveforms. Real-time chart recordings are annotated every 10 seconds with the current values of physiological parameters.

Note: If there is a dashed line on the display instead of an ECG waveform, the ECG data is not being acquired. Check the pads, paddles or ECG cable connection, and that the pads, paddles, or monitoring electrodes are properly applied.

ECG waveforms are printed on a grid with major divisions every 5mm and minor divisions every 1 mm. The ECG waveform is always printed if ECG is monitored.

The default chart speed for printing physiological waveforms is 25 mm/sec; 50 mm/sec print speed is also available.

Heart Rate

A Heart Rate meter gives the patient's heart rate in Beats Per Minute (**bpm**). The heart rate is derived from the monitor's top ECG trace.

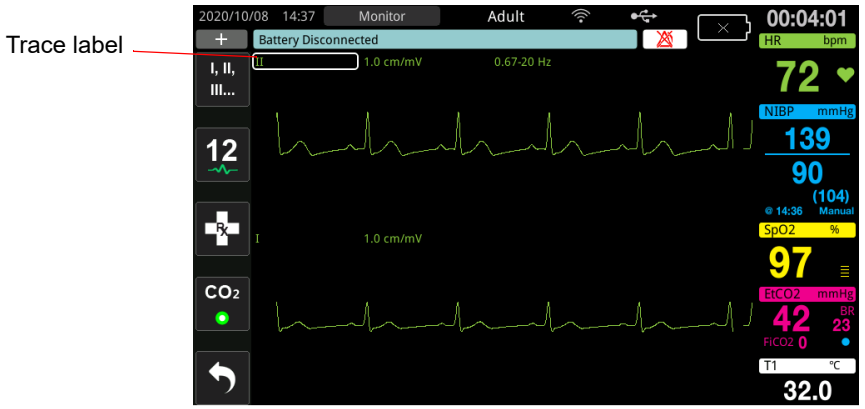
Selecting the Waveform Display

In Monitor mode, you can display up to four waveform traces on the screen. The first waveform trace always uses an ECG lead as its source (such as PADS, ECG Leads I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, or V6). The power up lead in Monitor and Manual Defib mode is configurable. Lead II is the default lead for Monitor mode; PADS is the default lead for Defib mode. Lead II is the default lead for Pacer mode and cannot be changed.

Inserting, Removing, or Replacing a Waveform Trace

To insert, remove, or replace a waveform trace on the display screen, do the following:

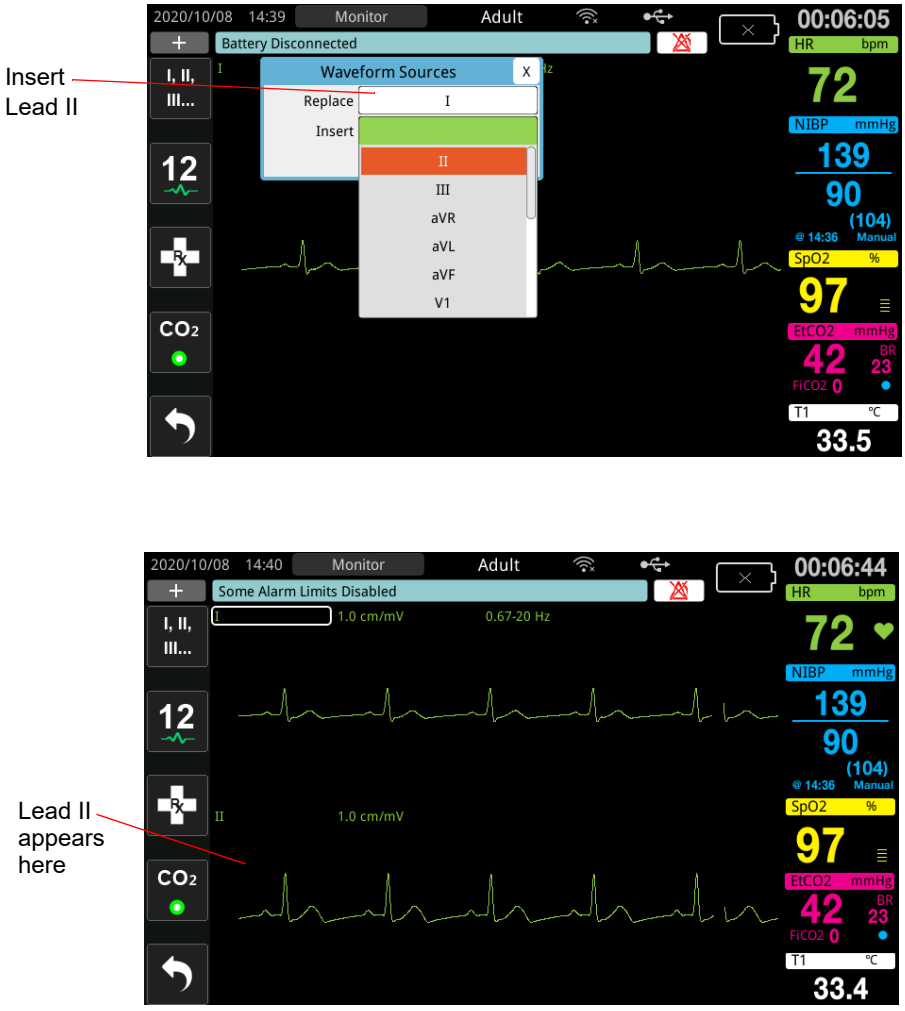
1. Turn the Trim Knob to highlight the trace label above the trace, then press the Trim Knob to select it. The Waveform Sources menu displays.



2. In the Waveform Sources menu you can do the following:
   - **Insert** - To insert a new waveform trace below the current trace you have selected.
   - **Replace** - To replace the current waveform trace you have selected.
   - **Remove** - To remove the current waveform trace you have selected.

   Note: The top waveform trace cannot be removed.
3. If insert or replace is selected, turn the Trim Knob to move around the menu and press the knob to make your selection. A new window appears for you to select the new or additional waveform to display.
4. To leave the menu once you are finished, do one of the following:
   - Rotate the Trim Knob to the X in the top right corner of the window and press the knob to leave the window.
   - Press the Menu button ( ) to leave the window.

In the example below, a ECG Lead II trace is inserted below the current trace (Lead I).



Chapter 4
Trends

The ZOLL M2 unit logs a patient's vital signs trend information to memory at user configurable intervals between 30 seconds and 30 minutes (default is 30 seconds).

It also logs all monitored vital sign measurements when a patient alarm occurs and NIBP measurement is completed.

You can view and print all logged trend information.

Displaying the Patient Trend Data Window

The Trends status window displays the accumulated vital signs trend information and the time that the trend measurements were logged. Patient alarm occurrences and NIBP measurements, with values, are logged and reported at the specific times they occur. In this window, you can specify the interval between displayed trend measurements information in a Trend Data Report.

Viewing the Patient Trend Data window

See the following procedure to view incidents in the Patient Trend Data window.

Note: Turning off the ZOLL M2 unit for more than 30 seconds ends an incident. When the unit is turned back on after more than 30 seconds without power, the unit creates a new incident even if the same patient is being monitored.

1. Press the More quick access key ( ), then press the Data quick access key ( ).
2. Press the Trend quick access key ( ) to display the Patient Trend Data window.

Note: While a patient is connected to the ZOLL M2 unit, only data acquired during the current incident displays in the window. When no patient is connected to the unit, you can view trend data recorded during other rescue incidents.

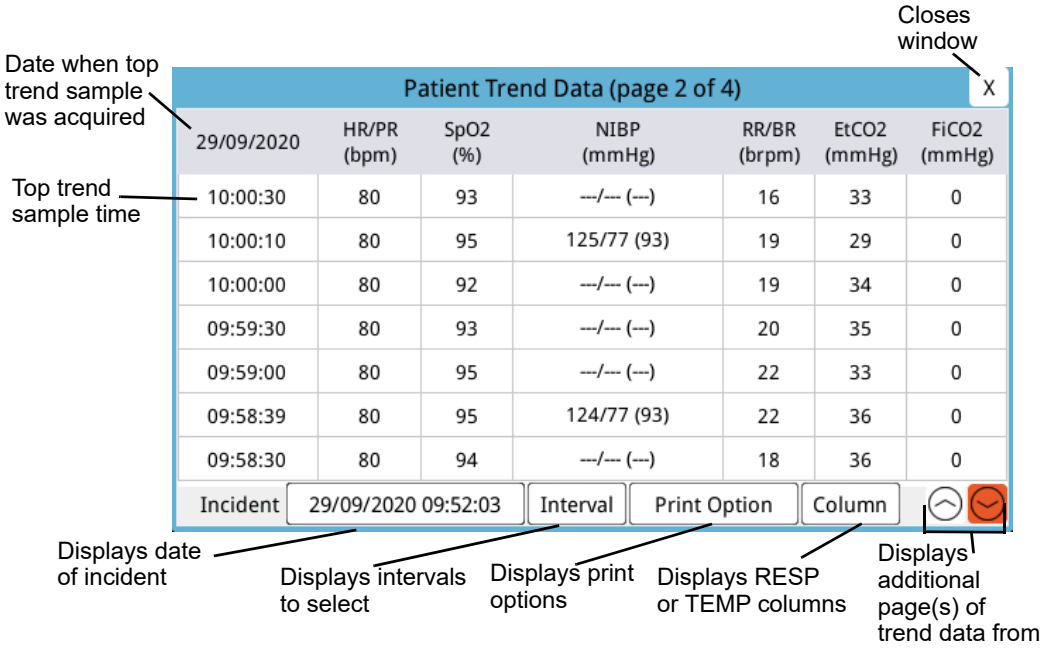


Figure 4-1 Trends Status window

To navigate in the Patient Trend Data window

Rotate the Trim Knob clockwise or counterclockwise to move around the window. To select another incident, use the Trim Knob to highlight the desired incident, and press the knob to select it. You can make the following selections:.

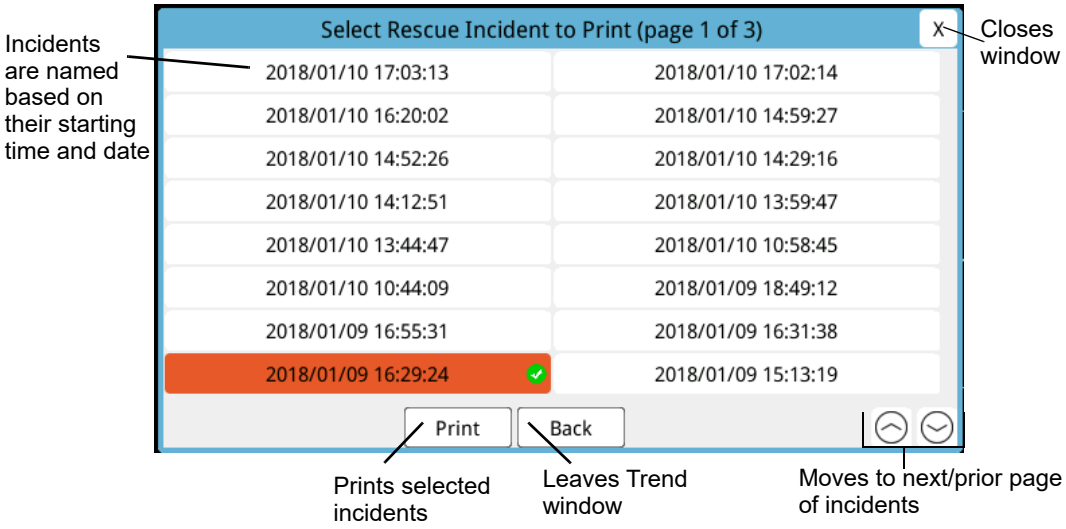
Field/Button	Function
Incident button	Press to display additional incidents for the current or previous patients.
Interval button	Displays trend intervals to view (30 sec, 1 min, 2 min, 5 min, 10 min, 30 min).
Print Option button	Prints the current or selected incident. See the following section, *Printing Trend Information*, for additional information.
Column button	Allows you to toggle the last three columns between RESP (BR, EtCO2, FiCO2) and TEMP (T1, T2, △T) columns.
Up/down carets	Displays more pages for the current incident. Up caret displays page(s) more recently acquired trend data; down caret displays page(s) older trend data.

Printing Trend Information

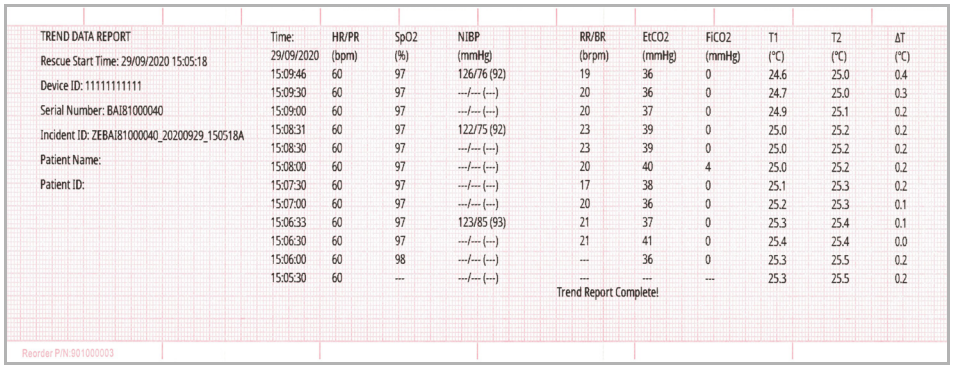
You can print vital signs trend data for a current incident or for a selected series of incidents in a Trend Data Report.

To Print Incidents

1. In the Patient Trend Data window, rotate the Trim Knob to select Print Option, and press the knob to select it.
2. Use the Trim Knob to make one of the following selections:
   - **Current Incident** -- Print the incident that is currently displayed in the window. Press Back to go back to the Patient Trend Data window.
   - **Selected Incident** -- To display the Select Rescue Incident to Print window (see below).



3. Turn the Trim Knob to move around the window and press the knob to select an incident. Once an incident is selected, a green check mark displays next to the incident.
4. When you have selected all of the incidents to print, turn the Trim Knob to highlight **Print** then press the Knob to select it. See the following step for an example of a Trend Data Report.
5. Press the X in the top right hand corner to exit the Trend window, or press **Back** to go back to the Patient Trend Data window.



TREND DATA REPORT
Rescue Start Time: 29/09/2020 15:05:18
Device ID: 11111111111
Serial Number: BAI81000040
Incident ID: ZEBAI81000040_20200929_150518A
Patient Name:
Patient ID:

Time:	HR/PR	SpO2	NIBP	RR/BR	EtCO2	FiCO2	T1	T2	ΔT
29/09/2020	(bpm)	(%)	(mmHg)	(brpm)	(mmHg)	(mmHg)	(°C)	(°C)	(°C)
15:09:46	60	97	126/76 (92)	19	36	0	24.6	25.0	0.4
15:09:30	60	97	---/--- (---)	20	36	0	24.7	25.0	0.3
15:09:00	60	97	---/--- (---)	20	37	0	24.9	25.1	0.2
15:08:31	60	97	122/75 (92)	23	39	0	25.0	25.2	0.2
15:08:30	60	97	---/--- (---)	23	39	0	25.0	25.2	0.2
15:08:00	60	97	---/--- (---)	20	40	4	25.0	25.2	0.2
15:07:30	60	97	---/--- (---)	17	38	0	25.1	25.3	0.2
15:07:00	60	97	---/--- (---)	20	36	0	25.2	25.3	0.1
15:06:33	60	97	123/85 (93)	21	37	0	25.3	25.4	0.1
15:06:30	60	97	---/--- (---)	21	41	0	25.4	25.4	0.0
15:06:00	60	98	---/--- (---)	---	36	0	25.3	25.5	0.2
15:05:30	60	---	---/--- (---)	---	---	---	25.3	25.5	0.2

Trend Report Complete!

Reorder P/N:901000003

Figure 4-2 Trend Data Report

Chapter 5
Alarms

The ZOLL M2 unit supports the detection and indication of patient (physiological) alarms and equipment (technical) alarms.

A patient alarm is issued when a monitored physiological parameter is out of range, such as a measured vital sign that falls outside of a configured alarm limit. A patient alarm condition is indicated in three ways: beeping alarm tone, highlighted text message, and flashing indicator lights on the front panel of the unit. You can configure patient alarm limits for each physiologic monitoring function.

An equipment alarm is issued when an equipment-related condition that adversely affects or limits the ZOLL M2's operation is detected, such as a disconnected ECG or defibrillator lead, malfunctioning temperature or pulse oximetry sensor, or internal diagnostics failure. An equipment alarm condition is also indicated in three ways: beeping alarm tone, text message, and flashing indicator lights on the front panel of the unit. *Equipment alarms are always enabled and are not user-configurable*.

Patient alarms are always classified as high-priority alarms. Equipment alarms can be classified as high, medium, and low priority alarms. Other equipment status messages are classified as information signals.

If more than one alarm is active, the alarm messages are shown in the alarm status area in succession. All patient alarms are indicated by beeping alarm tones and flashing indicator lights, and are driven by the highest priority active alarm.

Information related to the occurrence of patient alarms and equipment alarms is stored in the ZOLL M2 unit's memory and retained until erased or replaced with new data.

Note: When you power up the unit and one or more alarm limits are disabled, the ZOLL M2 unit displays the message *Some Alarm Limits Disabled* as a reminder.

Note: Voice prompts in AED mode and CPR prompts are not affected when the alarm audio is paused or the alarm audio is off.

Alarm Indicator Self-Test

The ZOLL M2 unit performs a self-test of the audible and visual alarm indicators upon start up. To ensure that the alarms are functioning properly, verify that you hear an alarm tone and the indicator lights are illuminated for three seconds upon start up of the unit.

Patient Alarm Display

When a patient's vital signs measurements trigger an alarm, in addition to an alarm tone and the illumination of indicator lights, the ZOLL M2 unit displays an alarm text message in the status/alarm message field, and changes the display characteristics of the monitoring function's numeric display (the alarming parameter appears in red text with white background).

Note: When more than one alarm message occurs, the field to the left of the status/alarm message field changes from "-" into "+". Click the plus sign to see the hidden alarm messages.

In the following example, the heart rate (160 bpm) has risen above the upper alarm limit (HR High Alarm):

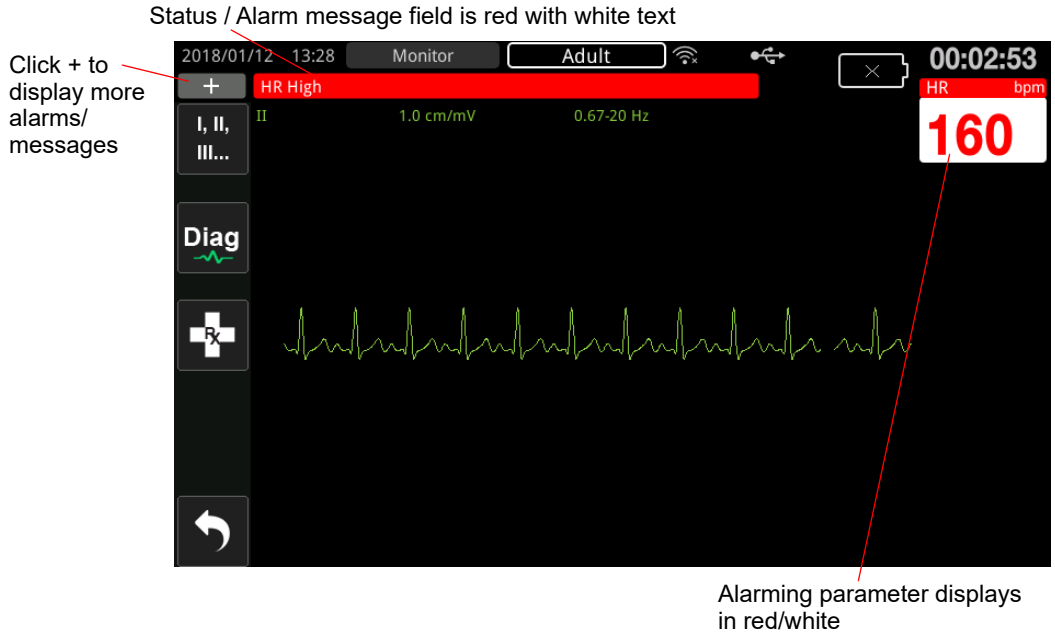


Figure 5-1 Patient Alarm Display

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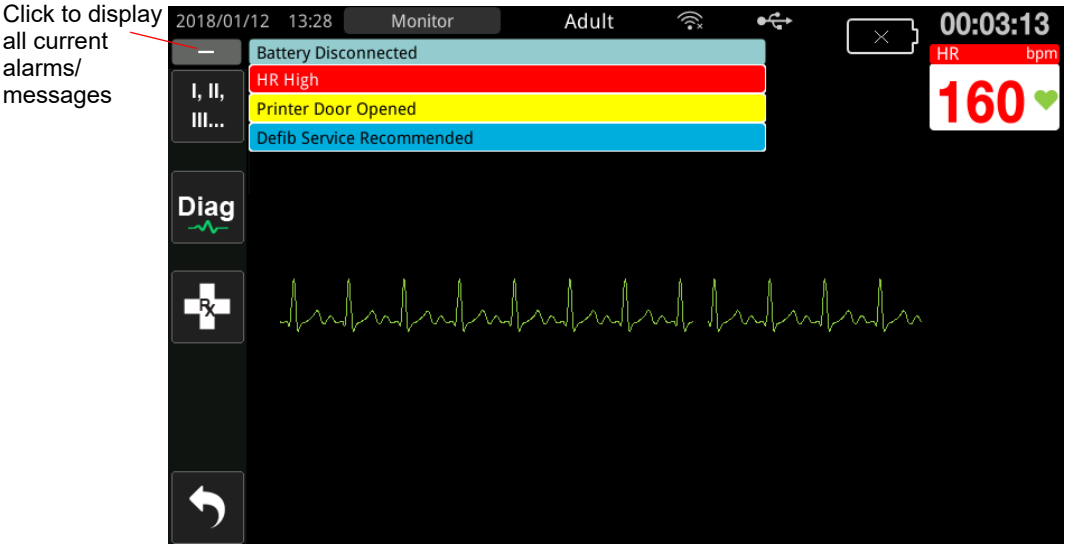


Figure 5-2 Multiple Alarms Display

Equipment Alert Display

When a problem with the ZOLL M2 unit or an attached sensor triggers an alarm, in addition to an alarm tone and the flashing indicator lights of an equipment alarm, the ZOLL M2 unit displays an alert message in the status/alarm message field as follows:

High Priority Alarm	Red background, white text Low Battery
Medium Priority Alarm	Yellow background, black text Printer Door Opened
Low Priority Alarm	Dark blue background, black text Defib Service Recommended
Informational Message	Light blue background, black text Some Alarm Limits Disabled

Warning! Always respond immediately to a equipment alarm since the patient may not be monitored during certain alarm conditions.

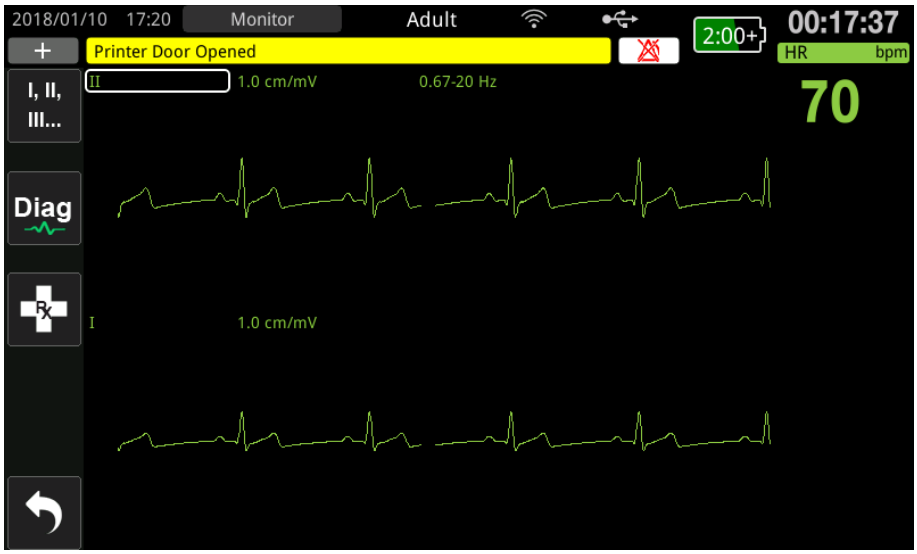


Figure 5-3 Equipment Alarm Display

Visual and Audible Alarm Indicators

In addition to status/alarm messages that appear on the display, the ZOLL M2 unit illuminates the red or yellow indicator lights on the front panel and emits an audible alarm to show the priority level of the highest-priority active alarm.

The ZOLL M2 unit has three levels of alarms.

Active Alarm/Alert Priority	Visual Alarm Indicator	Audible Alarm Indicator
High Priority -- Patient alarms and some equipment alarms that need immediate attention.	Flashing red indicator light.	Two sets of five short beep tones, repeated at 10-second intervals.
Medium Priority -- Some equipment alarms, but not alarms that need immediate attention.	Flashing yellow indicator light.	One set of three longer beep tones, repeated at 15-second intervals.
Low Priority -- Other minor equipment alarms.	Constant yellow indicator light.	A single short beep tone, repeated at 25-second intervals.

Note: The ZOLL M2 unit also displays prompts in the status/alarm message field without flashing indicator lights or beeping alarm tones to help users resolve issues that are not as important as alarms.

Responding to Active Patient Alarms

When a patient alarm occurs, the unit emits a repeating pattern of sounds indicative of alarm priority, highlights the value of the alarming parameter on the display, and flashes the bell icon associated with that parameter. Do the following:

1. Check the patient and provide appropriate care.
2. Press the Alarm Control () button on the ZOLL M2 unit's front panel for *less than one second* to stop the patient alarm audio for 90 seconds (default). The alarm tone stops, and the unit displays the Alarm Audio Paused icon () and the *Alarm Audio Paused* message displays. The alarm message still displays, and the value for the alarming parameter remains highlighted. (This pause period can only be configured in the Supervisor menu.)
3. After caring for the patient, check that the appropriate alarms are set (for more information about setting alarms, see "Setting Alarm Limits" on page 5-7).

During the 90 seconds, if you press the Alarm Control button again, alarm and audio functions resume.

After 90 seconds, if the patient parameter remains at a value that triggers the alarm, the unit sounds the alarm tone again and removes the Alarm Audio Paused icon.

If the patient parameter returns to the normal range within the 90 second Audio Paused Period, the ZOLL M2 unit:

- Does not sound the alarm tone again
- Removes the alarm message display
- Removes the alarming parameter indications on the display
- Removes the Audio Paused icon
- Stops flashing the indicator lights

If a second, different alarm occurs after you pause an alarm tone, you can pause the alarm tone for that second parameter by pressing the Alarm Control button again. The unit behaves the same as described above for the first alarm. Pausing a second alarm does not alter the timing or processing of the previously paused alarm.

Note: Patient alarms are suspended for 10 seconds following each shock. After 10 seconds, the unit resumes the alarm as configured prior to the shock delivery. Equipment alarms are not suspended during this post-shock period.

Silencing Patient Alarms

To silence all audio patient alarms indefinitely, press the Alarm Control button () *for one to three seconds*. The Alarm Audio Off icon () and the *Alarm Audio Off* message display to indicate the status. No audio alarms are issued as long as the ZOLL M2 unit is in this mode.

Note: The visual alarm indicators still flash and alarming parameters are highlighted while the patient alarm audio is off.

If the patient alarm condition clears (the patient parameter returns to a value within range) after the alarm tones are turned off, the unit continues to display the Alarm Audio Off icon indefinitely.

To re-enable the silenced patient alarm audio, press the Alarm Control button for *less than one second*.

Warning!

- **Do not pause or silence the audible alarm if patient safety may be compromised.**
- **Do not adjust the alarm signal volume lower than the ambient noise level; this may impede operator recognition of alarm signals.**

Disabling Patient Alarms

To disable all patient alarms on the ZOLL M2 unit:

1. Press and hold the Alarm Control button () on the front panel *for more than 3 seconds*. The ZOLL M2 switches to the Alarm off condition and displays the Alarm Off icon () and the *Alarms Off* message. Patient alarms are disabled and all patient alarm parameter values display normally (no highlighting).

To re-enable the alarms, press the Alarm Control button for *less than one second*.

Warning! **When audible alarms are disabled, make sure that the patient is closely observed.**

Alarm Reminders

The ZOLL M2 unit may be configured to sound a reminder alarm at specified intervals. When the Alarm Off Prompting feature is enabled, a single beep sounds for the duration of 190 ms every 5, 10, or 15 minutes (depending on configuration) if an Audio Off or Alarm Off condition persists. When the Alarm Off Prompting feature is disabled, no reminders are issued if the Audio Off or Alarm Off condition continues.

Latching Alarms

All ZOLL M2 patient alarms are configured to be latching. Alarm indicators (beeping alarm tone, text message, indicator lights) continue whether or not the alarm condition is present until the user responds. Latched alarms must be responded to even if the alarm condition no longer exists. The latched alarm can only be canceled by pressing the Alarm Control button (). Latching alarms are useful in situations where the patient may not be continuously attended by the clinical operator; these alarms call attention to patient alarm conditions whether or not they are still occurring.

Responding to Equipment Alarms

When a equipment alarm occurs, the unit emits a repeating pattern of sounds indicative of alarm priority, illuminates the red or yellow indicator lights on the front panel, and the status/alarm message appears on the display.

Do the following:

1. Check the patient and provide appropriate care.
2. Attempt to correct the equipment alarm condition if possible. For example, for the *ECG Lead Off* alarm, check the ECG lead connection to the patient or the connection to the ZOLL M2 unit. Also, refer to “ECG System Messages” on page 6-13 or “Troubleshooting” on page 18-18”.
   After the alarm condition is cleared, the alarm tone stops, the indicator lights stop flashing, and the status/alarm message stops displaying on the screen.

3. If needed, (for example, patient cables/sensors were intentionally disconnected by the operator), press the Alarm Control ( ) button on the ZOLL M2 unit's front panel for *less than one second* to clear the alarm. The alarm tone stops and the indicator lights stop flashing. For certain technical alarms, the status/alarm message stops displaying on the screen after clearing the alarm.

Setting Alarm Limits

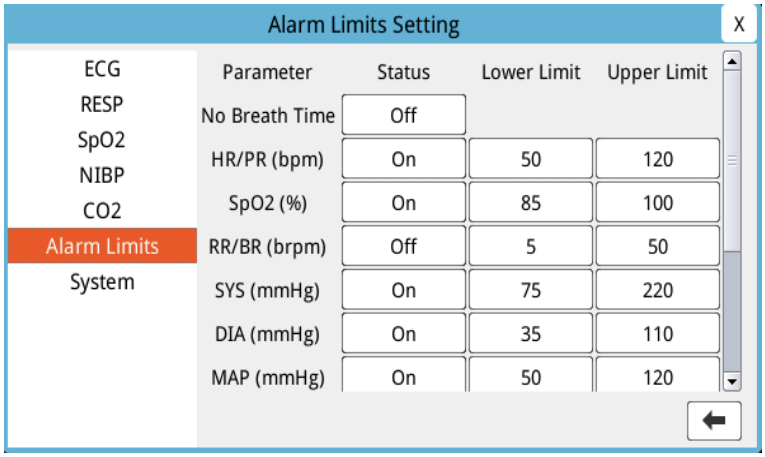
Follow the steps below to view or change the settings in the Alarm Limits Setting window.

Note: Alarm settings are retained when power is turned off for less than 30 seconds. If power is turned off for more than 30 seconds, alarm settings are reset to default alarm settings.

Note: Resolution of alarm limit setting:
HR - 1 bpm
Resp - 1 brpm
NIBP - 1 mmHg or 0.1 kPa
CO_2 - 0.1% or 0.1 kPa or 1 mmHg
SpO_2 - 1%
Temp - 0.1 °C or 0.1 °F

1. To set alarm limits, press the More quick access key ( ) and then the Alarm Limits quick access key ( ). The Alarm Limits Setting window displays.

Note: You can also press the Menu button ( ) one or more times until the Alarm Limits Setting window displays. Rotate the Trim Knob to highlight the Alarm Limits field and press the knob to select it.



2. Rotate the Trim Knob to highlight the vital sign status or limit you want to adjust, then press the knob to select it. The field turns green.
3. Turn the Trim Knob clockwise or counterclockwise to change the value and press the knob to select the new value.
4. When you have completed your changes, do one of the following:
   - Rotate the Trim Knob to the X in the top right corner of the window and press the knob to leave the window.

- Press the Menu button () to leave the window.

Warning!

- **Confirm the alarm limits are appropriate for each patient.**
- **Do not set alarm limits to extreme values that render the alarm system useless.**
- **A potential hazard can exist if different alarm presets are used for the patient monitoring equipment in a single area.**

Chapter 6
Monitoring ECG

This chapter describes how to use the ZOLL M2 device to monitor ECG.

ZOLL M2 units can perform ECG monitoring through 3-, 5-, or 12-lead ECG patient cables, multi-function pads, or defibrillation paddles.

You can use a 3-lead, 5-lead, or 12-lead configuration for ECG monitoring (see “12-Lead ECG Monitoring” on page 13-1 for more information).

Note: The 12-lead monitoring function is optional.

Warning!

- **Excessive body hair or wet, sweaty skin may interfere with electrode adhesion. Remove the hair and/or moisture from the area where the electrode is to be attached.**
- **Use only electrodes that are well within the expiration date indicated on the package.**
- **Remove ECG electrodes from their sealed package immediately prior to use. Using previously opened or out-of- date electrodes may degrade the ECG signal quality.**
- **Monitoring electrodes may become polarized during defibrillator discharge, causing the ECG waveform to briefly go off screen. ZOLL Medical Corporation recommends the use of high quality silver/silver chloride (Ag/AgCl) electrodes to minimize this effect; the circuitry in the instrument returns the trace to the monitor display within a few seconds.**
- **To ensure protection against the effects of defibrillator discharge, use only ZOLL-approved accessories.**
- **To avoid a shock hazard and interference from nearby electrical equipment, keep electrodes and patient cables away from grounded metal and other electrical equipment.**
- **To avoid electrosurgery burns at monitoring sites, ensure proper connection of the electrosurgery return circuit so that the return paths cannot be made through monitoring electrodes or probes.**
- **Check the operation and integrity of the ZOLL M2 unit and ECG cable regularly by performing the Daily Operational Verification Test.**
- **Implanted pacemakers may cause the heart rate meter to count the pacemaker rate during incidents of cardiac arrest or other arrhythmias. Carefully observe pacemaker patients. Check the patient's pulse; do not rely solely on heart rate meters. Dedicated pacemaker detection circuitry may not detect all implanted pacemaker spikes. Patient history and physical exam are important in determining the presence of an implanted pacemaker.**

ECG Monitoring Setup

The proper application and placement of electrodes is essential for high quality ECG monitoring. Good contact between the electrode and skin minimizes motion artifact and signal interference.

Note: ECG monitoring is not suitable for direct cardiac application.

The following procedure describes how to monitor a patient's ECG using 3-, 5-, and 12-lead ECG cables. For information on the application and use of multi-function pads and external paddles, which you can also use to monitor ECG, refer to *Chapter 14, "Manual Defibrillation"*.

To monitor a patient's ECG using 3-, 5-, and 12-lead ECG cables, perform the following steps:

1. Prepare the patient's skin for electrode application:
2. Apply the electrodes to the patient.
3. Connect each lead of the ECG cable to the appropriate electrode.
4. Plug the patient cable into the ECG input connector on the ZOLL M2 unit.
5. Select the ECG waveforms to be displayed on the waveform trace display screen.

Note: To ensure accurate heart rate counting, optimal demand pacing, and cardioversion, select the ECG lead with the largest, most distinct noise-free R waves.

6. Observe the patient's electrocardiogram on the display, and adjust the size of the ECG waveform trace, as necessary.

Preparing the Patient for Electrode Application

The proper application of electrodes is essential for high quality ECG monitoring. Good contact between the electrode and skin minimizes motion artifact and signal interference.

Before applying electrodes, prepare the patient's skin, as follows:

- Shave or clip excess hair at electrode site.
- Clean oily skin with mild soap and water.
- Rub site briskly to dry.
- Lightly abrade the skin at the proposed electrode site.

Applying Electrodes to the Patient

The following sections show where to place electrodes when using 3- and 5-lead cables to perform ECG monitoring. For 3-lead ECG cables, apply electrodes as shown in Figure 6-1, *3-Lead Electrode Placement*. For 5-lead ECG cables, apply electrodes as shown in Figure 6-2, *5-Lead Electrode Placement*.

Note: See Chapter 13, "12-Lead ECG Monitoring" for placement of 12-lead ECG electrodes.

Avoid placing electrodes over tendons and major muscle masses.

Make sure that the ECG electrodes are placed to allow defibrillation, if necessary.

3-Lead Electrode Placement

Depending upon local usage, the ECG leads are marked either RA, LA, and LL (or R, L, and F). The following table shows the markings and color codes for the different lead sets.

AHA/AAMI Color Coding	IEC Color Coding	Placement of Electrodes
RA/White Electrode	R/Red Electrode	Place near patient's right mid-clavicular line, directly below clavicle.
LA/Black Electrode	L/Yellow Electrode	Place near patient's left mid-clavicular line, directly below clavicle.
LL/Red Electrode	F/Green Electrode	Place between 6th and 7th intercostal space on patient's left mid-clavicular line.

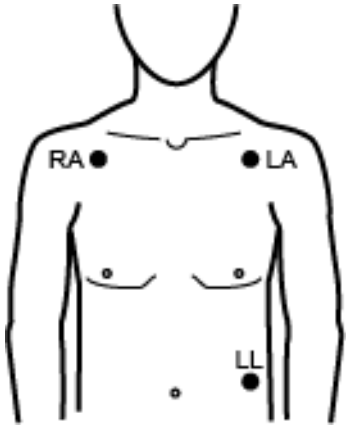


Figure 6-1 3-Lead Electrode Placement

5-Lead Electrode Placement

Depending upon local usage, the ECG leads are marked either RA, LA, LL, RL, and V or R, L, F, N and C. The following table shows the markings and color codes for the different lead sets.

AHA/AAMI Color Coding	IEC Color Coding	Placement of Electrodes
RA/White Electrode	R/Red Electrode	Place near patient's right mid-clavicular line, directly below clavicle.
LA/Black Electrode	L/Yellow Electrode	Place near patient's left mid-clavicular line, directly below clavicle.
LL/Red Electrode	F/Green Electrode	Place between 6th and 7th intercostal space on patient's left mid-clavicular line.
RL/Green Electrode	N/Black Electrode	Place between 6th and 7th intercostal space on patient's right mid-clavicular line.
V/Brown Electrode	C/White Electrode	Single movable chest electrode. Place this electrode in one of the positions, V1 - V6, as shown in the following figure. V1 (C1) -- 4th intercostal space at right sternal margin. V2 (C2) -- 4th intercostal space at left sternal margin. V3 (C3) -- Midway between V2 and V4 leads. V4 (C4) -- 5th intercostal space at mid-clavicular line. V5 (C5) -- Same transverse level as V4 at left anterior-axillary line. V6 (C6) -- Same transverse level as V4 at left mid-axillary line.

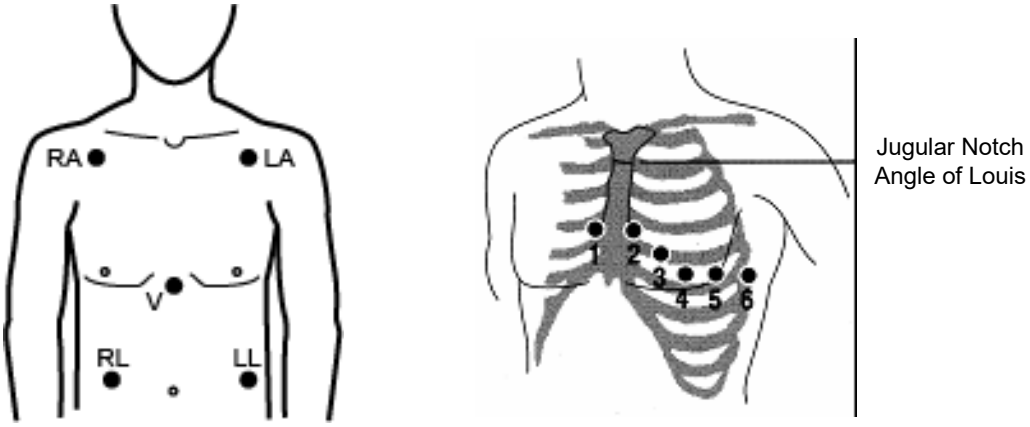


Figure 6-2 5-Lead Electrode Placement

Connecting the ECG Cable To the ZOLL M2 Unit

Connect the ECG cable to the ECG connector on the back of the ZOLL M2 unit as follows:

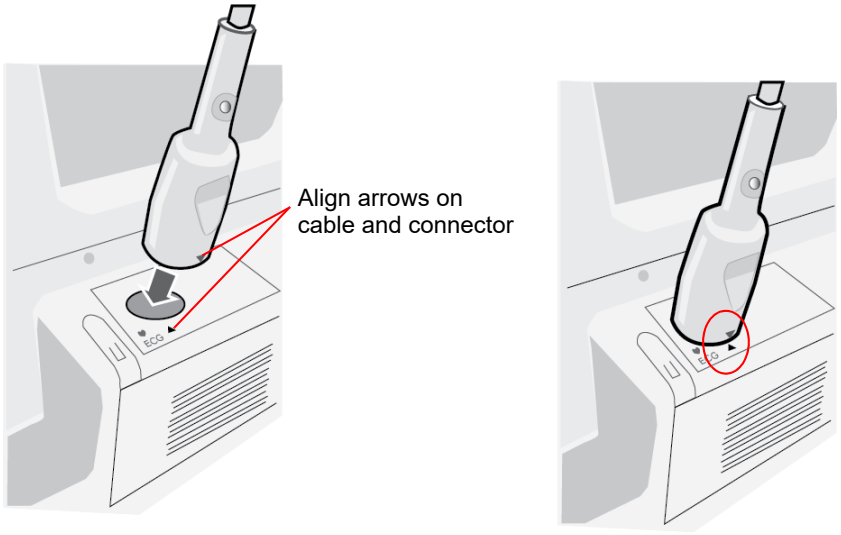


Figure 6-3 Connecting ECG Cable to ZOLL M2 Unit

Note: Orient the ECG cable so that the arrow on the end of the cable connector lines up with the arrow of the label on the ZOLL M2 unit, and plug it in.

Selecting Patient Type

The ZOLL M2 can operate in either the Adult or Pediatric mode; select adult for adult patients, select pediatric for pediatric/neonate patients.

Selecting ECG Waveforms for Display

In Monitor mode, the ZOLL M2 device can fit up to four waveforms on the display. The first waveform at the top of the display is always an ECG waveform. In the following example, Lead II (RA-LL), is the source of the ECG waveform trace:

The ZOLL M2 device displays a different default top waveform trace according to current operating mode. In Pacing and Monitor modes, the default ECG waveform is Lead II. In Manual Defib and AED modes, the default ECG waveform is Pads/Paddles. The default waveform selected for display at the top of the display screen in Monitor and Manual Defib can be changed in the Supervisor menu.

There are two ways to specify which ECG lead is the source of the primary (top) waveform trace:

- Press the ECG lead selection quick access key  to sequence through the display of the available ECG lead waveforms. The available waveform sources are determined by the type of ECG cable connected to the unit.
- Rotate the Trim Knob to navigate to the source label for the primary ECG waveform (Lead I displays in the following screen) and then press the knob to select it. The ZOLL M2 unit then displays the available ECG waveform sources. You can select Lead I (the currently displayed waveform), or rotate the Trim Knob to highlight and press the knob to select another ECG lead as the source for the waveform trace.

When you select a waveform source that is currently being acquired, the unit displays the waveform immediately. If you select a waveform source that is not currently available, the unit displays a dashed line and the message *ECG Lead Off* (for ECG Lead) or *Attach Pads* or *Check Pads - Pads Shorted* (for PADS). If you select Paddles, the ZOLL M2 unit always displays the Paddles ECG signal (solid line) even when paddles are shorted together or not connected to the patient.

For more information on how to configure the display of waveforms on the ZOLL M2 device, see Chapter 3, *Monitoring Overview*.

Selecting the Waveform Trace Size

The ZOLL M2 unit allows you to adjust the size of displayed the ECG waveform.

To select the waveform size, rotate the Trim Knob to highlight the trace size that appears to the right of the electrode label then press the Knob to view the drop down menu:

The default trace size is **1cm/mV**. You can select a larger (**1.5, 2.0, 3.0 cm/mV**) or smaller (**0.125, 0.25, 0.5 cm/mV**) trace size or Auto.

Note: The Auto size option is only available in Monitor mode. It is not available in Defib or Pacer mode.

Diagnostic ECG

ZOLL M2 units without the 12-lead option have a Diagnostic mode that when activated causes the displayed ECG leads to be displayed/printed with a 0.525 – 40 Hz frequency response. This frequency response setting preserves the ST segment characteristics of the ECG waveform, allowing ST segment deviations from normal to be detected/evaluated. Press the Diagnostic quick access key 

to enter diagnostic mode.

Once the unit is in diagnostic mode, the unit switches filtering of the ECG lead to 0.525 – 40 Hz and scrolls a slightly delayed version of the real time signal display for a period of 12 seconds. After displaying the diagnostically filtered ECG for 12 seconds, the primary ECG waveform filtering returns to its previously selected monitoring frequency response.

Note: When you switch frequencies in diagnostic mode, there is a short delay before you can view the waveform in the new ECG frequency.

ECG Monitoring and Implanted Pacemakers

When the ZOLL M2 unit performs ECG monitoring on a patient with an implantable pacemaker, the unit can indicate the occurrence of pacemaker signals. If the patient has a cardiac pacemaker, the Paced Marker should be set to On.

When the Pace Marker setting is on, the ZOLL M2 unit performs the following actions:

- Detects the implantable pacemaker pulses.
- Blanks the pacemaker pulses from the waveform—preventing them from disturbing the ECG waveform and allowing for an accurate QRS detection.
- Displays and prints vertical dashed lines to indicate the detected pacemaker signals.

When the Pace Marker setting is off, the Pacer Off Marker icon () appears at the top of the display screen. In this setting, implanted pacer pulses are not detected by the ZOLL M2 unit or eliminated from the ECG signal.

There are situations where ECG artifact can simulate pacemaker signals and cause false pacemaker detection and blanking. It may cause inaccurate QRS detection and in these cases it may be desirable to turn the Pacer Marker off. Inversely, when the Pacer Marker setting is off, implantable pacemaker signals may cause inaccurate QRS detection and it may be desirable to turn the Pacer Marker on.

See the following section for more information on turning the Pace Marker on/off.

Accessing the ECG Setting Window

Follow the steps below to view or change the settings in the ECG Settings window.

1. Do one of the following:
   - Rotate the Trim Knob to highlight and select the HR numeric display, then press the knob.

     OR
   - Press the Menu button ( ).
2. Press the Trim Knob to select ECG.

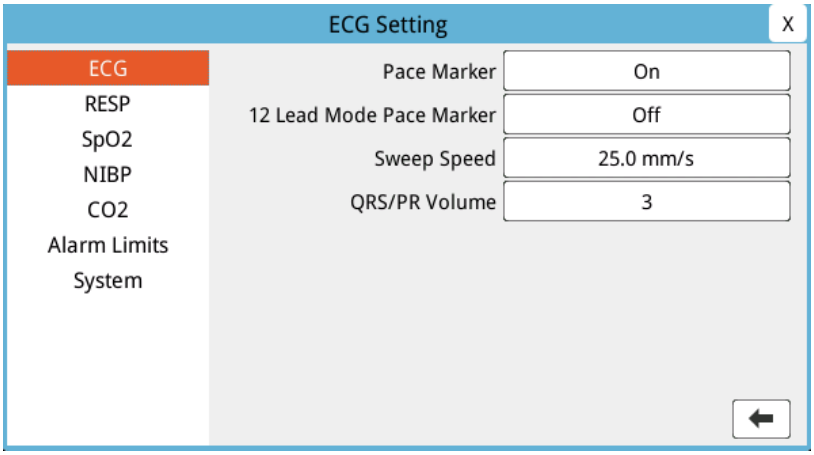


Figure 6-4 ECG Setting window

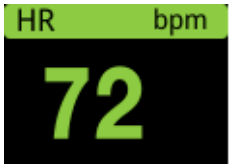
The ECG Settings window displays the following fields:

Setting	Function
Pace Marker	Enables/disables the pace marker function in 3 and 5 lead modes.
12 Lead Mode Pace Marker	Enables/disables the pace marker function in 12 Lead mode.
Sweep Speed	Sets the display sweep speed of ECG in mm/s (12.5, 25, 50).
QRS/PR Volume	Sets the volume of sound when an R wave is detected (Off, 1, 2, 3, 4, 5). **Note:** 5 is the highest volume setting.

3. Rotate the Trim Knob to navigate through the settings, then press the knob to make selections.
4. When you are finished viewing and making changes to the settings, do one of the following:
   - Rotate the Trim Knob to the X in the top right corner of the window and press the knob to leave the window.
   - Press the Menu button ( ) to leave the window.

Heart Rate Meter

The Heart Rate meter displays the QRS complex rate that it derives from the ECG monitoring function. The Heart Rate meter always computes the heart rate from the top waveform. The Heart Rate meter is labeled **HR** (as in the following example).



Configuring Heart Rate (HR) Meter Alarms

The ZOLL M2 unit allows you to enable and disable the Heart Rate (HR) alarm, to set alarm limits, and to select a QRS detection tone volume. The default HR alarm settings (enable/disable, alarm limits) are supervisor configurable.

Heart Rate (HR) Alarm Limits

Initially, the HR Alarm Settings menu specifies that alarms are enabled (**ON)** or disabled (**OFF),** and displays the default Upper and Lower heart rate alarm limits. The following table lists the default HR alarm limits for adult and pediatric patients, and gives the range in which you can set these limits:

Patient Type	HR Default Limit Alarm	HR Alarm Limits Range
Adult	Lower: 50 BPM Upper: 120 BPM	Lower: 20 to 299 BPM Upper: 21 to 300 BPM
Pediatric	Lower: 50 BPM Upper: 150 BPM	Lower: 20 to 299 BPM Upper: 21 to 300 BPM

Enabling/Disabling HR Alarms and Setting Alarm Limits

When enabled, the ZOLL M2 unit sounds and displays alarms whenever the patient's heart rate is above or below the specified heart rate alarm limits.

You can enable (or disable) HR alarms and set Upper and Lower alarm limits using the **Alarm Limits** quick access key (Limits).

To configure HR alarm through the **Alarm Limits** quick access key:

1. Press ( ).
2. Press (Limits) to enter the Alarm Limits menu.
3. Rotate the Trim Knob to select the fields that you want to change for HR:
   - Status - to turn the HR alarm function on or off
   - Lower Limit - set the lower alarm limit
   - Upper Limit - set the upper alarm limit
4. To change a setting, press the Trim Knob and the vital sign field turns green. Turn the Trim Knob clockwise or counterclockwise to change the value and press the knob to select the new value.
5. When you have completed your changes, do one of the following:
   - Rotate the Trim Knob to the X in the top right corner of the window and press the knob to leave the window.
   - Press the Menu button ( ) to leave the window.

Check Patient Alarm

If the Heart Rate alarm is on in Monitor mode or Defib mode (with some AED configurations), the unit runs a continuous analysis on the ECG top waveform trace. If ventricular fibrillation or wide complex ventricular tachycardia is detected, the Check Patient alarm feature triggers an audible alarm and displays the *Check Patient* message.

If the Heart Rate alarm is on in Pacer mode, the unit displays the *VF/VT Alarms Disabled* message, indicating that the Check Patient alarm feature has been disabled.

ECG System Messages

When monitoring ECG, the ZOLL M2 unit may display the following messages:

Message	Cause/Action
Apply Paddles to Patient	Paddles are in an open condition. Apply paddles firmly to the patient's chest.
Attach Pads	Therapy pads are not connected to the patient. Check the MFC/pads/paddles connections.
Check Paddles - Paddles Shorted	The paddles have become shorted. Check the paddles connection. Make sure the defibrillator gel is not forming a conductive connection between the paddles. If this does not resolve the problem, contact the ZOLL Technical Service department.
Check Pads - Pads Shorted	The therapy pads have become shorted together. Check the pads connection. If this does not resolve the problem, contact the ZOLL Technical Service department.
Connect Therapy Cable	The MFC is not connected to the unit. Check the therapy cable connections.
ECG Lead Off	One or more leads or the ECG cable are not connected to the patient or to the ZOLL M2 unit. -- OR -- An unavailable waveform source has been specified for the trace display. (Check specified waveform source and correct, if necessary.)
HR High	The patient heart rate is above the HR upper alarm limit.
HR Low	The patient heart rate is below the HR lower alarm limit.

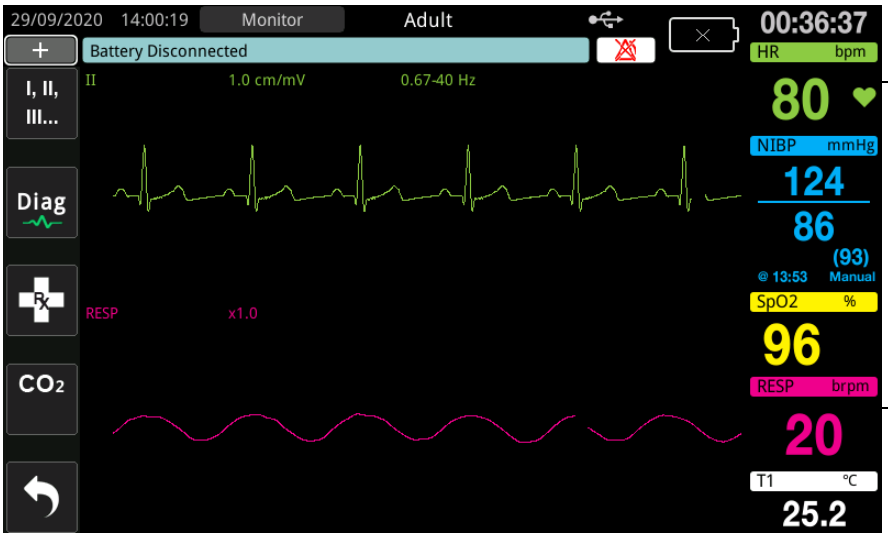
Note: If an ECG Monitoring cable/lead is intentionally disconnected, you can respond to the ECG Lead Off alarm by pressing the Alarm Control button.

Chapter 7

Monitoring Respiration (Resp) and Heart Rate (HR)

This chapter describes how to use the ZOLL M2 unit to monitor Respiration Rate (Resp) and Heart Rate (HR) using ECG leads.

The ZOLL M2 unit displays Respiration Rate (RESP) and Heart Rate (HR) meters. The Respiration and Heart Rate meters display values that the ZOLL M2 unit derives from ECG and chest impedance measurements made via ECG leads. When ECG leads are not connected to a patient, HR and RESP can be derived from other monitoring functions such as pulse oximetry (PR) and CO_2 (BR).



Note: Impedance respiration monitoring is disabled during Manual defibrillation, AED, and Pacer modes. When CO_2 monitoring is active, impedance respiration is disabled.

Respiration/Breath Rate Meter

By default, the respiration meter displays the respiration rate that it measures from the unit's optional CO_2 monitoring function. If CO_2 monitoring is not available (or the CO_2 monitoring function is Off or no CO_2 sensor is connected), the unit derives the respiration rate by measuring changes in chest impedance caused by breathing (impedance pneumography) between the Lead I ECG electrodes (RA - LA). If ECG monitoring is not functioning and is not connected, the RESP/BR meter will not display a respiration rate.

Using Impedance Pneumography to Measure Respiration

Impedance pneumography detects respiration by applying a high-frequency, low-current AC signal to the patient and measuring the changes in impedance through the Lead I ECG electrodes (RA - LA). As the patient inhales and chest volume expands, impedance increases; as the patient exhales, impedance decreases.

Preparing Patients for Impedance Monitoring

Keep patient quiet to avoid motion induced artifact.

1. Apply electrodes to standard RA and LA locations. For better results, apply RA and LA electrodes across the chest on the mid-axillary line, just below the right and left axilla.
2. Enable impedance monitoring.
3. Display respiration signal (waveform).
4. Adjust Respiration Signal Size.

To enable Resp Monitoring at power up whenever CO_2 monitoring is not in use, and to enable the RESP Automatic Activation function, see the *ZOLL M2 Configuration Manual*. Impedance respiration monitoring is disabled by default

During clinical use, to enable the RESP Automatic Activation setting, go to the Resp Setting window and set Automatic Activation to *Enabled*.

Warning!

- **Impedance pneumography detects respiratory effort by measuring changes in impedance caused by chest wall movements. It does not detect airflow to and from the lungs. Therefore, respiratory efforts without airflow can be falsely detected as effective breathing. Always monitor and set alarms for SpO_2 when using impedance pneumography to monitor respiratory function.**
- **With any monitor that detects respiratory effort through impedance pneumography, artifact due to cardiovascular activity, patient motion, apnea mattress shaking, or electrocautery use may cause apnea episodes to go undetected. Always monitor and set alarms for SpO_2 when using impedance pneumography to monitor respiratory function.**

- **When using impedance pneumography, don't use the ZOLL M2 unit with another respiration monitor on the same patient, because the respiration measurement signals may interfere with one another.**
- **Impedance pneumography is not recommended for use with high frequency ventilation.**
- **Since impedance pneumography uses the same leads as the ECG channel, the ZOLL M2 unit determines which signals are caused by cardiovascular artifact and which signals are the result of respiratory effort. If the breath rate is within five percent of the heart rate, the monitor may not be able to distinguish between respiratory and cardiac activity. When this occurs, "- -" appears in the RR field and the "RESP CV Artifact Detected" message is displayed.**

Configuring Respiration (RR/BR) Alarms and Settings

The ZOLL M2 unit allows you to enable and disable the Respiration Rate (RR/BR) alarm, to set alarm limits, to set the respiration waveform's sweep speed, and to enable/disable impedance respiration monitoring.

If respiration is monitored by impedance, then the display shows RR, if CO_2 monitoring is available, the display shows BR.

Respiration Rate Alarm Limits

Initially, the Resp Alarm Settings window specifies that Resp alarms are enabled (On) or disabled (Off), and displays the default Upper and Lower respiration rate alarm limits. The following table lists the default respiration rate alarm limits for adult and pediatric patients, and gives the range over which you can set these limits:

Patient Type	Respiration Rate Default	Respiration Rate Range
Adult/Pediatric	Lower: 5 brpm Upper: 50 brpm	Lower: 2 to 149 brpm Upper: 3 to 150 brpm

Respiration No Breath Alarm

No Breath Alarm Time can be set to Off (default) or a range of time between 10 and 60 seconds. When the No Breath Alarm Time is set to Off, the No Breath check function is disabled. When the alarm is set to a configured time, the ZOLL M2 unit produces a No Breath alarm if the time since the last breath exceeds the configured time.

Setting RR/BR Alarms and Setting Alarm Limits

When enabled, the ZOLL M2 unit sounds alarms whenever the patient's respiration rate is above or below the specified respiration rate alarm limits.

To enable (or disable) Resp alarms and set Upper and Lower alarm limits, press the Alarm Limits quick access key (

).

To configure RR/BR alarm through the Alarm Limits quick access key:

1. Press the More quick access key ( ) until the Alarm Limits quick access key displays.
2. Press Limits to display the Alarm Limits window.
3. Rotate the Trim Knob to select the fields that you want to change for RR/BR:
   - Status - turn alarms on or off
   - Lower Limit - set the lower alarm limit
   - Upper Limit - set the upper alarm limit
4. To change a setting, press the Trim Knob and the field turns green. Rotate the Trim Knob to change the value and press the knob to select the new value.
5. When you have completed your changes, rotate the Trim Knob to highlight **X** in the upper right corner and press the knob to close the Alarm Limits Setting window.

Using the Resp Setting Menu

To display the Resp Setting window, do one of the following:

- Rotate the Trim Knob to highlight the RESP numeric display and press the knob to select it.

or

- Press the Menu button ( ). Rotate the Trim Knob to RESP and press the knob to select it.

The RESP Setting window displays.

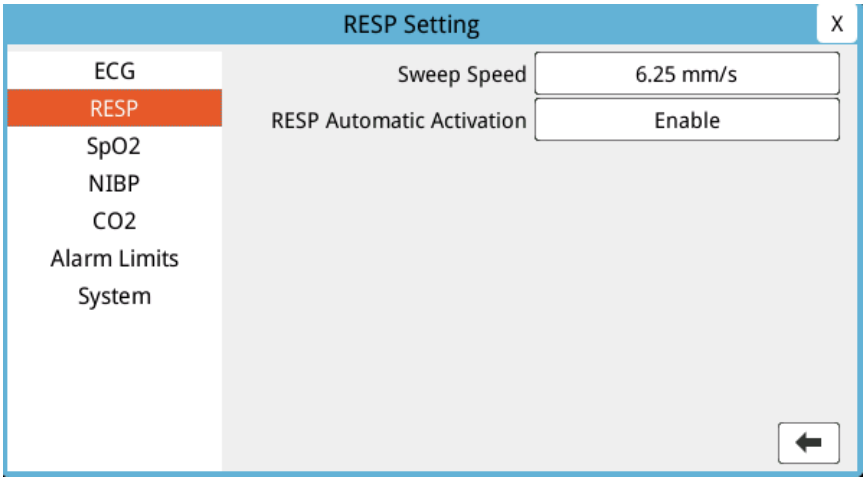


Figure 7-1 Respiration Parameter Control Panel

The Resp Parameter Control Panel allows you to set the following parameters:

- Sweep Speed -- sets the respiratory sweep speed on the display.
- RESP Automatic Activation -- enable/disable respiration monitoring when CO_2 is not in use.

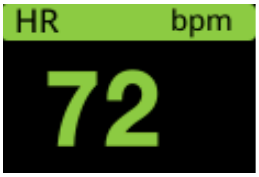
Enabling/Disabling Respiratory Automatic Activation

Select the Resp Automatic Activation prompt to enable or disable Resp monitoring. When set to Disable (default), the ZOLL M2 unit displays the Resp Rate meter as a dashed line when CO_2 monitoring is not in use. When Resp Automatic Activation is set to Enable, the ZOLL M2 unit displays the Respiration Rate Meter and measured rate values when the CO_2 module is not active and ECG leads are connected to a patient.

Warning! **When using impedance pneumography, the ZOLL M2 unit automatically rejects cardiovascular artifact (CVA). This function requires accurate ECG R-wave detection. Therefore, it is recommended that ECG lead with the most prominent QRS complex is selected as the source for the top ECG waveform trace when using impedance pneumography to monitor respiration. Note that impedance respiration monitoring is always performed using the Lead I electrodes (RA - LA), regardless of the lead selected for ECG heart rate monitoring.**

Heart Rate Meter

The Heart Rate meter displays the heart rate that ZOLL M2 unit derives from the ECG monitoring function or from the pulse oximeter when ECG leads (or pads/paddles) are not connected to a patient. The Heart Rate meter derives the heart rate from the top ECG waveform trace. The Heart Rate meter is labeled HR (as in the following example) if the source is ECG, and PR if SpO_2 is measured and ECG lead (or pads/paddles) is disconnected.



Note: In optional 12-Lead mode, HR is derived from the selected primary ECG lead in Monitor mode (e.g., PADS).

Configuring Heart Rate (HR) Meter Alarms

The ZOLL M2 unit allows you to enable and disable the Heart Rate (HR) alarms function, to set alarm limits, and to select a Heart Rate tone volume.

Heart Rate (HR/PR) Alarm Limits

Initially, the HR/PR Alarm Settings menu specifies that alarms are enabled (On) or disabled (Off), and displays the default Upper and Lower heart rate alarm limits. The following table lists the default HR alarm limits for adult and pediatric patients, and gives the range in which you can set these limits:

Patient Type	HR Default	HR Range
Adult	Lower: 50 BPM Upper: 120 BPM	Lower: 20 to 299 BPM Upper: 21 to 300 BPM
Pediatric	Lower: 50 BPM Upper: 150 BPM	Lower: 20 to 299 BPM Upper: 21 to 300 BPM

Enabling/Disabling HR Alarms and Setting Alarm Limits

When enabled, the ZOLL M2 unit sounds alarms whenever the patient's heart rate is above or below the specified heart rate alarm limits.

To enable (or disable) HR alarms and set Upper and Lower alarm limits, you can do so through the Alarm Limits quick access key (Limits).

To configure HR alarm through the Alarm Limits quick access key:

1. Press ( ).
2. Press (Limits) to enter the Alarm Limits menu.
3. Rotate the Trim Knob to highlight and select HR/PR.
4. In the HR/PR Settings menu, you can change the following fields:
   - Status - turn alarms on/off
   - Lower Limit - set the lower alarm limit
   - Upper Limit - set the upper alarm limit
5. To change a setting, press the Trim Knob and the field turns green. Rotate the knob to change the value and press the knob to select the new value.
6. When you have completed your changes, rotate the Trim Knob to highlight **X** in the upper right corner and press the knob to close the Alarm Limits Setting window.

RESP System Message

When monitoring Respiration using impedance pneumography, the ZOLL M2 unit may display the following messages:

System Message	Cause/Action
No Breath	The ZOLL M2 unit detects that the time since the last breath exceeded the configured No Breath time.
RESP Communications Fault	The impedance respiration detection function has failed. Turn off the ZOLL M2 unit and then turn it on again. If the condition persists, call Technical Service.
ECG Lead Off	One or more RA/R, LA/L, RL/N, LL/F leads have been disconnected from the patient. Check the leads.
RESP CV Artifact Detected	The breath rate is within five percent of the heart rate and RR is displayed as --. Verify that the patient is breathing, then reapply or adjust the ECG leads to the patient to reduce the cardiovascular artifact. Reverify that the displayed respiration rate is accurate and not falsely counting the patient's heart rate.
Check RESP Electrodes	The basal impedance measured from the respiration circuit is out of the specified range. Check that the respiration electrodes are properly connected to the patient.

System Message	Cause/Action
RR High	The RR value exceeds the upper alarm limit selected.
RR Low	The RR value exceeds the lower alarm limit selected.

Chapter 8
Monitoring Non-Invasive Blood Pressure (NIBP)

ZOLL M2 NIBP cuffs are a defibrillation-protected Type BF patient connection (applied part).

This chapter describes how to use the ZOLL M2 unit's NIBP option to perform Non-Invasive Blood Pressure (NIBP) measurements using an inflatable cuff to measure arterial pressure.

Note: The NIBP function is intended for adult and pediatric patients only; it is not intended for use on neonates or pregnant women, including pre-eclamptic patients.

Warning!

- **Do not use the NIBP feature without proper training.**
- **Periodically inspect the patient's cuffed limb to ensure that repeated blood pressure measurements have not impaired limb function.**
- **When monitoring mastectomy patients, do not place the cuff on the same side as the mastectomy wound. For patients with bilateral mastectomy, only use the NIBP monitoring function if the associated risks are clinically acceptable.**
- **Do not apply the cuff to a limb that has an intravenous infusion catheter in place. This can cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.**
- **Make sure the air hose connecting the cuff to the blood pressure monitor is not blocked, kinked, or entangling the patient, as it may result in continuous cuff pressure, impaired blood flow, and potential patient injury.**
- **If a non-invasive blood pressure measurement is suspect, repeat the measurement. If you are still uncertain about the measurement, use another method to determine blood pressure such as auscultation.**
- **Check that the correct patient mode has been selected to ensure that the initial inflation pressure is set correctly. If an over-range alarm occurs when monitoring NIBP on a large or older child, change the patient mode selection from pediatric to adult.**
- **Ensure that the patient type setting is correctly set when performing measurements on children. Incorrect patient type setting can cause discomfort or injury to the child because adult cuff inflation pressures are higher than those used for children.**
- **Patient movement, shivering, a weak pulse, cardiac arrhythmia, or vibration from outside sources can degrade the accuracy of blood pressure measurements.**
- **Do not attempt to take NIBP measurements on patients during cardiopulmonary bypass procedures.**
- **Some or all NIBP safety functions are disabled when performing the NIBP test in the Service menu. Do not conduct NIBP tests when the cuff is attached to a patient.**
- **The effectiveness of this sphygmomanometer has not been established in pregnant, including pre-eclamptic, patients.**
- **Ensure that the patient is not allergic to blood pressure cuffs made of nylon, TPU or PVC before use.**

How does NIBP Work?

The ZOLL M2 NlBP option non-invasively measures arterial blood pressure in resting adult and pediatric patients.

The blood pressure cuff and hose connect to the ZOLL M2 unit through the NIBP connector on the back of the unit. The NIBP button on the front panel of the unit allows you to initiate and terminate blood pressure measurements, which are displayed in the NIBP area of the monitor. You can also initiate and terminate Auto or STAT mode measurements from the NIBP menu.

The ZOLL M2 non-invasively measures arterial blood pressure using the oscillometric method. This method works by measuring arterial pulsations induced in the inflatable cuff at different cuff pressures and using the amplitude of these pulsations to estimate systolic, diastolic and mean blood pressure.

The pressure measurement cycle typically takes 30-45 seconds and proceeds as follows:

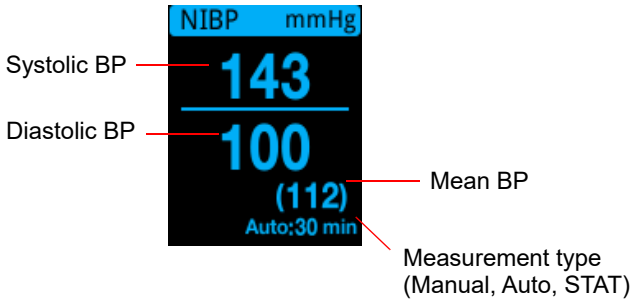
1. The cuff inflates to a preconfigured pressure above the patient's systolic blood pressure, to occlude blood flow through the arteries in the monitored limb.The configured default cuff pressure value for adult patients is 160 mmHg.
2. The cuff deflates in steps, allowing blood to flow through the cuff and into the monitored limb.
3. As blood flows through the partially deflated cuff, it produces oscillations in the cuff pressure that are transmitted to the ZOLL M2 unit through the hose.
4. The ZOLL M2 unit measures the blood flow-induced pulsations and uses them to calculate the corresponding systolic, diastolic, and mean blood pressure.
5. The NIBP option automatically adjusts the blood pressure measurement procedure in response to certain error conditions such as:

Condition	Adjustment/Response
The unit cannot detect systolic pressure.	The unit automatically increases the cuff inflation pressure and completes the blood pressure measurement.
The unit cannot detect systolic, diastolic, or mean pressure after 3 minutes.	The unit aborts the blood pressure measurement and deflates the cuff.
The unit detects a fault.	The unit displays a corresponding error message on the monitor, aborts the measurement, and deflates the cuff.

Note: Refer to "NIBP System Messages" on page 8-13 for additional system messages and their conditions.

The NIBP Numeric Display

When NIBP monitoring has been set up and the ZOLL M2 unit has begun taking NIBP measurements, the systolic, diastolic, and mean blood pressure measurements appear on the NIBP numeric display as follows:



When the Auto measurement type has been selected, the interval (default: 30 minutes) between measurements is shown. If the STAT measurement type has been selected, the time remaining in the current STAT measurement cycle is shown (in MM:SS). If the Manual measurement type has been selected, the time of the last BP measurement is shown at the lower left of the display (in HH:MM). Pressure readings are displayed in either mmHg or kPa, depending upon the configuration settings in the Supervisor menu.

If patient motion artifact is detected during the measurement, a "**?**" will be displayed to the right of the blood pressure reading. If needed, reattempt the NIBP measurement while keeping the patient as still as possible.

The following sections describe how to set up NIBP monitoring.

NIBP Setup and Use

To take safe and accurate NIBP measurements using the ZOLL M2 unit, you must perform the following steps, each of which corresponds to a section in this chapter. Read each section carefully before you perform NIBP measurements.

1. Select the correct size cuff.
2. Connect the inflation hose to the ZOLL M2 unit and to the cuff.
3. Apply the cuff to the patient.
4. Configure NIBP alarms and settings (if the current NIBP alarms and settings are not appropriate).
5. Press the NIBP button () on the ZOLL M2 unit's front panel to take the blood pressure measurement.

Selecting the NIBP Cuff

To take accurate measurements, you must use the proper sized cuff: the cuff's bladder length should be at least 80 percent of the limb circumference, while the cuff width should be equal to approximately 40 percent of the limb circumference.

Caution Use only hoses and cuffs that are approved by ZOLL Medical Corporation. See Appendix B, *Accessories*, for a listing of the approved hoses and cuffs. Use the following guidelines when selecting the appropriate hose and cuff:

	Adult Mode	**Pediatric Mode**
Cuffs (typical cuff labeling)	Adult, Large Adult, Small Adult, Thigh	Child, Small Child
Recommended Limb Circumference	18 cm or greater.	10 to 26 cm

The ZOLL M2 unit uses the same definitions of Pediatrics and Adults as defined in the ISO 81060-2 standard:

Pediatric or Child (other than newborn)	Individuals between 3 years and 12 years of age
Adult	Individuals greater than 12 years of age

Connecting the Hose

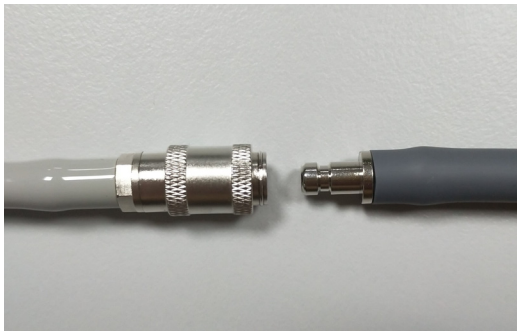
The NIBP option has a hose with a metal connector on each end; you must attach the hose to both the ZOLL M2 rear panel and the cuff's hose using the two metal connectors. The cuff has its own short length of hose with a connector on the end. This connector fits into the end of the hose that is not connected to the ZOLL M2 unit.

To connect the hose:

1. Center the metal connector of the NIBP hose over the NIBP connector on the back of the ZOLL M2 unit, then push the connector until it snaps into place.

Figure 8-1 Attaching NIBP Hose to the ZOLL M2 Unit

2. Insert the cuff hose connector (male) into the metal connector (female) on the NIBP hose and push the connectors until they lock into place.



You can now apply the cuff to the patient.

Applying the Cuff to the Patient

To apply the cuff to the patient:

1. Ensure the patient is lying down or comfortably seated with legs uncrossed, both feet flat on the floor, back and arm supported, and middle of the cuff at the level of the right atrium of the heart. It is recommended that the patient remain in a quiet, resting state and not talk for 5 minutes before the first measurement is taken. The limb to be used for NIBP measurement should be relaxed, extended, and placed on a smooth surface for support.
2. Squeeze as much air from the cuff as possible before placing it on the patient.
3. Place the cuff 2 to 3 cm (0.8 to 1.2 inches) above the elbow crease or 3 to 5 cm (1.2 to 2 inches) above the knee crease.

Warning!

- **Do not place the NIBP cuff on the same arm or leg as an SpO_2 sensor. Inflation of the cuff causes the SpO_2monitor to read incorrectly.**
- **Do not attach the cuff to a limb being used for IV infusion. Cuff inflation might block the infusion, causing harm to the patient.**
- **Do not place the cuff over a wound, as this can cause further injury.**

4. Adjust the cuff so that the artery marker on the cuff is over the artery, pointing towards the hand or foot.
5. While wrapped around the limb, check that the cuff ends between the range lines marked on the cuff.
6. If they do not line up, use a different size cuff.
7. Wrap the deflated cuff snugly around the limb without impeding blood flow.
8. Ensure that the hose is routed to avoid excessive movement, kinking or compression.

Caution

- Using a cuff that is loosely applied or too small results in measurements higher than the patient's actual blood pressure.
- Using a cuff that is too large results in values lower than the patient's actual blood pressure.
- Ideally, the cuff should be at the same level as the heart. Cuff placement substantially above or below heart level will result in blood pressure measurements that are erroneously low or high.

The following illustrates one possible cuff placement for adult/pediatric patients:

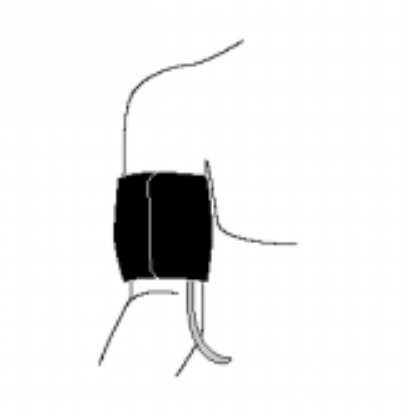


Figure 8-2 Applying Cuff to the Patient

You can now access the NIBP features.

Accessing NIBP Features

Unless you are sure that the NIBP patient type, cuff inflation and alarm settings are appropriate for the patient, display the NIBP Setting window before you take a blood pressure measurement. When you first turn on the ZOLL M2 unit, the NIBP settings are at their default values.

While the factory-installed default settings are appropriate for most adult patients, do not assume the settings are at their default. A previous user may have:

• Changed the settings (if you did not turn on the ZOLL M2 unit).

• Reconfigured the default settings.

Use the default settings unless they are clearly inappropriate for the patient. Any changes to these settings remain in effect until either the settings are again changed, or for 30 seconds after the ZOLL M2 unit is turned off. If you have not received training on setting NIBP features, do not use the NIBP option.

To facilitate quick reaction during emergency situations, you can directly access many NIBP features without displaying the NIBP menu (see the following table).

Task	Action
Taking a single measurement	Press the **NIBP** button ().
Taking STAT measurements	Press and hold the **NIBP** button () for at least two seconds, or see the next section, “Accessing the NIBP Setting Window.” The NIBP display field should show **STAT** and the time remaining in the current STAT measurement cycle (in MM:SS).
Taking automatic measurements	See the next section, “Accessing the NIBP Setting Window.” The NIBP display field should show **AUTO** and the selected interval (default: 30 minutes) between measurements.
Aborting measurement in progress	Press the **NIBP** button ().
Changing NIBP settings	See the next section, Accessing the NIBP Setting Window.

Note: Configuration options are accessed via the Supervisor menus. For more information on these settings, refer to the *ZOLL M2 Configuration Manual*.

Accessing the NIBP Setting Window

Unless it is an emergency situation where quick reaction is essential, you should always check that the cuff inflation and alarm settings are properly set before taking a measurement.

To display the **NIBP Setting** window do one of the following:

- Rotate the Trim Knob to highlight and select the NIBP numeric display and press the knob to select it.

or

- Press the **Menu** button ( ), rotate the Trim Knob to NIBP, then press the knob to select it.

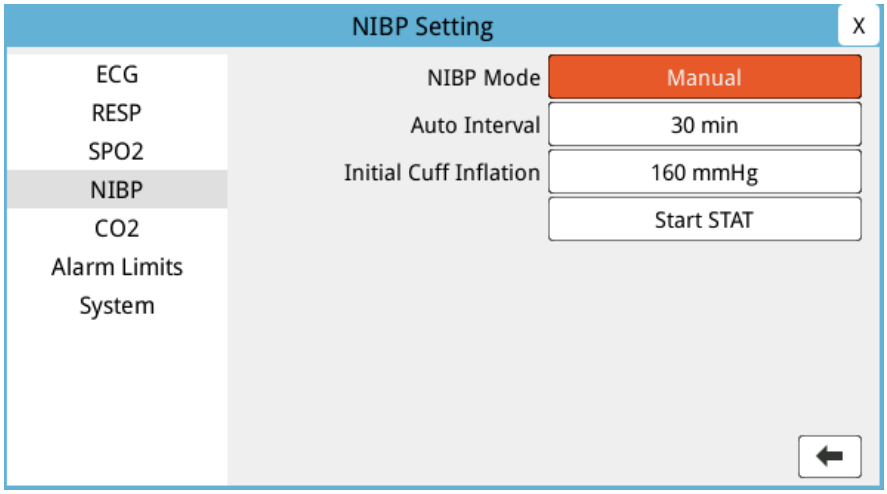


Figure 8-3 NIBP Setting window

See the following table for information on these settings and their function:

Setting	Function
NIBP Mode	You can specify that the ZOLL M2 unit operate in either *Manual* or *Automatic Mode*. In Manual Mode, the ZOLL M2 unit takes a single NIBP measurement when you press the NIBP button on the front panel. To repeat the NIBP measurement, you must press the NIBP key again. In Automatic Mode, the ZOLL M2 unit takes the first of a series of NIBP measurements when the Auto Interval timer expires, and then repeats the NIBP measurement at this specified interval. **Note:** If an Auto measurement is scheduled to occur within 30 seconds after a Manual measurement is finished, the automatic measurement will be skipped.
Auto Interval	You can specify the time interval between NIBP measurements in Automatic Mode. The default interval between measurements is 30 minutes. You can specify intervals of **2.5**, **5**, **10**, **15**, **20**, **30**, **45**, **60**, **90**, and **120** minutes between NIBP measurements.

Initial Cuff Inflation	The Initial Cuff Inflation pressure is dependent on the patient type and the configured inflation pressure preset. The default and configurable inflation pressure presets for each patient type are indicated in the table below on page 8-11 (default values are in bold). The initial cuff inflation pressure should be set 20 to 40 mmHg above the patient's highest expected systolic pressure.
Start/Stop STAT Measurements	Selecting **Start STAT** starts Short-term Automatic (STAT) NIBP measurements. The ZOLL M2 unit begins its first NIBP measurement then continues to perform as many NIBP measurements as possible over a 5-minute period. Select **Stop STAT** to immediately stop STAT measurements. Pressing the **NIBP** button () on the front panel for at least two seconds initiates an STAT measurement. Pressing the **NIBP** button () again stops the STAT measurement cycle.

Selecting the Correct Patient Type

Before taking an NIBP measurement, make sure the correct patient type is specified (at the top of the window display). On ZOLL M2 units, you can select adult or pediatric patient type for NIBP measurements. The patient type setting determines the default cuff inflation pressure, as well as default alarm limits for high/low systolic, diastolic and mean blood pressure values.

To access the patient type, turn the Trim Knob to highlight the patient type at the top of the display window. To change the patient type, press the Trim Knob to display the drop down menu and then turn it to select another patient type. Press the Trim Knob again to confirm the selection.

Selecting Cuff Inflation Settings

Before taking a measurement, ensure that the cuff inflation settings are appropriate for the patient.

Check that the correct patient type is selected. The initial cuff inflation pressure (the pressure that the cuff is inflated to at the beginning of each measurement cycle) is dependent on the patient type and configured cuff inflation preset. The default and configurable cuff inflation pressure presets for each patient are indicated in the following table (default values are in bold).

If the Smart Inflation Function is enabled in the Supervisor menu, after the first measurement is complete, the initial cuff inflation pressure used for the next NIBP measurement is automatically adjusted by the ZOLL M2 unit, based on the previous systolic measurement value.

Use the default setting unless it is clearly inappropriate. Any changes to this setting remain in effect until either the setting is changed or 30 seconds after the ZOLL M2 unit is turned off (returning the setting to its default).

The cuff inflation pressure options are:

Adult	Pediatric
120 mmHg	80 mmHg
140 mmHg	90 mmHg
160 mmHg	100 mmHg
180 mmHg	110 mmHg
200 mmHg	**120 mmHg**
220 mmHg	130 mmHg
240 mmHg	140 mmHg
260 mmHg	150 mmHg

To change the current cuff inflation pressure setting, see “Accessing the NIBP Setting Window” on page 8-8.

In order to accurately measure systolic pressure, the cuff inflation pressure must be high enough to occlude the underlying artery. However, setting the cuff inflation pressure too high may unnecessarily increase the reading determination time and patient discomfort. As a general rule, the initial cuff inflation pressure should be set 20 to 40 mmHg above the patient’s highest expected systolic pressure.

If the Smart Inflation Function is enabled in the Supervisor menu, after each NIBP measurement, the ZOLL M2 unit adjusts the cuff inflation pressure to optimize the next NIBP measurement.

Warning! **Before using the ZOLL M2 unit to monitor a new patient, power down the unit for *at least 30 seconds* to reset all settings to power on default values and eliminate all adjustments made for the previous patient.**

Configuring NIBP Alarms and Settings

The last step in preparing to perform NIBP measurements is to ensure that the necessary alarms are enabled (or disabled), that alarm limits are properly set, and that the NIBP settings are correct.

Enabling/Disabling NIBP Alarms and Setting Alarm Limits

When enabled, the ZOLL M2 unit sounds high priority alarms whenever measurements are outside set limits for the following:

- High and Low Systolic Pressure
- High and Low Diastolic Pressure
- High and Low Mean Arterial Pressure (MAP)

To configure NIBP alarm limits:

1. Press the More ( ) quick access key until the Limits ( ) quick access key is displayed, then press the Limits ( ) quick access key to enter the Alarm Limit setting menu. Or, press the Menu button ( ) and use the Trim Knob to select Alarm Limits.
2. Rotate the **Trim Knob** to highlight and select the appropriate alarm menu selection. The Alarm Limit Settings window displays.
3. Press the Trim Knob to select Alarm Limits. For NIBP, the alarm menu selections are **SYS, DIA,** and **MAP**.
4. On the selected NIBP alarm settings menu, rotate the **Trim Knob** to highlight the fields that you want to change and press the knob to select them. The fields are:
   - **Status**
   - **Lower Limit**
   - **Upper Limit**
5. When you are finished changing values on the Alarm Limit Settings window, rotate the Trim Knob to navigate to the Backarrow key ( ) or the Exit key ( ) and press the knob to confirm your choices and exit the menu.

Setting Upper and Lower Systolic Alarm Limits

Initially, the **NIBP Systolic Alarm Settings** menu specifies that the NIBP systolic pressure alarms are on or off**,** and displays the default upper and lower systolic limits. The following table lists the default NIBP Systolic limits for adult and pediatric patients, and gives the range over which you can set these limits:

Patient Type	NIBP Systolic Limit Default	NIBP Systolic Limit Range
Adult	Lower: 75 mmHg (10.0 kPa) Upper: 220 mmHg (29.3 kPa)	Lower: 20-264 mmHg (2.6-35.3 kPa) Upper: 21-265 mmHg (2.7-35.4 kPa)
Pediatric	Lower: 75 mmHg (10.0 kPa) Upper: 145 mmHg (19.3kPa)	Lower: 20-239 mmHg (2.6-35.3 kPa) Upper: 21-240 mmHg (2.7-35.4 kPa)

Setting Upper and Lower Diastolic Alarm Limits

Initially, the **NIBP Diastolic Alarm Settings** menu specifies that the NIBP diastolic pressure alarms are on or off**,** and displays the default Upper and Lower diastolic limits. The following table lists the default diastolic limits for adult and pediatric patients, and lists the range for which you can set these limits:

Patient Type	Diastolic Limit Default	Diastolic Limit Range
Adult	Lower: 35 mmHg (4.7 kPa) Upper: 110 mmHg (14.7 kPa)	Lower: 10-219 mmHg (1.3-29.3 kPa) Upper: 11-220 mmHg (1.4-29.4 kPa)
Pediatric	Lower: 35 mmHg (4.7 kPa) Upper: 100 mmHg (13.3 kPa)	Lower: 10-179 mmHg (1.3-23.9 kPa) Upper: 11-180 mmHg (1.4-24.0 kPa)

Setting Upper and Lower NIBP MAP Alarm Limits

Initially, the **NIBP MAP Alarm Settings** menu specifies that **NIBP MAP** alarms are on or off**,** and displays the default Upper and Lower MAP limits. The following table lists the default MAP alarm limits for adult and pediatric patients, and gives the range over which you can set these limits:

Patient Type	MAP Default	MAP Range
Adult	Lower: 50 mmHg (6.7 kPa) Upper: 120 mmHg (16.0 kPa)	Lower: 13-234 mmHg (1.7-31.3 kPa) Upper: 14-235 mmHg (1.8-31.4 kPa)
Pediatric	Lower: 50 mmHg (6.7 kPa) Upper: 110 mmHg (14.7 kPa)	Lower: 13-199 mmHg (1.7-26.6 kPa) Upper: 14-200 mmHg (1.8-26.7kPa)

Alarms are set to enabled by factory default.

NIBP System Messages

When monitoring NIBP, the ZOLL M2 unit may display the following messages:

System Message	Cause/Action
NIBP Communications Fault	Communication to the NIBP module failed. Power the unit off and back on. If the error continues, contact the ZOLL Service Department.
NIBP Measurement Aborted - Check Hose/ Cuff	The cuff or hose cuff or hose is faulty or not installed correctly during measurement. Check the hose/cuff connection, correct the issue, and reattempt the NIBP measurement.
NIBP Measurement Aborted - Artifact	Excessive artifact is preventing the NIBP measurement; cease stretcher or patient movement and reattempt the NIBP measurement
NIBP Measurement Aborted – Cuff/Hose Leak	A major air leak is preventing cuff inflation. Check the hose and cuff connections, replace a defective hose or cuff as necessary, and reattempt the NIBP measurement.
NIBP Measurement Aborted - Signal Weak	The patient’s pulse is too weak to obtain an NIBP measurement. Check the cuff placement/connection, then take an additional NIBP measurement.
NIBP Measurement Aborted - Over Range	The blood pressure is out of the measurement range. Check the cuff connection, then take an additional NIBP measurement and ensure there is no patient movement.
NIBP Measurement Aborted - Cuff Over Pressure	The cuff pressure exceeded safety limits. Check the cuff connection. If there is no cuff connection problem, stop using NIBP feature and call the ZOLL Service Department.
NIBP Measurement Aborted - Measurement Timeout	Measurements not completed in the allowed maximum time. Check the cuff connection. Take an additional NIBP measurement and ensure there is no patient movement.

System Message	Cause/Action
NIBP Measurement Aborted – Hose Blocked	Check the hose and cuff connections for kinked hose or air blockage, correct the issue, then reattempt the NIBP measurement.
Measurement Stopped	The operator has pressed the NIBP button and canceled the measurement.
Measurement Failed	Operation error or weak pulse. Check the connection or reattempt a measurement. An additional error message may be displayed, indicating one of the causes listed above.
NIBP Inflation Timeout	The pump running time exceeds the limit. Power cycle the unit. If the message persists, contact the ZOLL Service Department.
NIBP Disabled - Critical Fault	A critical fault has occurred to the NIBP module. Power cycle the unit. If the message persists, contact the ZOLL Service Department.
NIBP Pressure Measurement Error	The pressure measurement subsystem has an error and the NIBP measurement function is disabled. Power cycle the unit. If the message persists, contact the ZOLL Service Department.
NIBP Diastolic High	The NIBP Diastolic value exceeds the upper alarm limit selected.
NIBP Diastolic Low	The NIBP Diastolic value exceeds the lower alarm limit selected.
NIBP Map High	The NIBP Map value exceeds the upper alarm limit selected.
NIBP Map Low	The NIBP Map value exceeds the lower alarm limit selected.
NIBP Systolic High	The NIBP Systolic value exceeds the upper alarm limit selected.
NIBP Systolic Low	The NIBP Systolic value exceeds the lower alarm limit selected.
Waiting	After an NIBP Measurement has completed, the unit waits for a period of time before initiating another measurement in order to avoid patient discomfort and excessive blood flow restriction in the measured limb. After this message disappears, reattempt the NIBP measurement.
Zero Failed	The zeroing of the NIBP module's pressure system failed during the measurement. Check the cuff and hose connection, ensure there is no patient movement, then reattempt the NIBP measurement.

Chapter 9
Monitoring CO_2

The ZOLL M2 CO_2 accessories are a defibrillation-protected Type BF patient connection (applied part).

This chapter describes how to use the ZOLL M2 unit to monitor End Tidal Carbon Dioxide ($EtCO_2$), breath rate, and Fractional Inspired Carbon Dioxide ($FiCO_2$). These physiological parameters can be measured using either a ZOLL M2 mainstream or sidestream sensor. These options use the same connector on the ZOLL M2 unit and may be used interchangeably.

Overview

The ZOLL M2 unit uses external mainstream or sidestream sensors to monitor the CO_2 in inhaled and expired gases.

The mainstream sensor is attached to an airway adapter that connects to an endotracheal (ET) tube and measures gases flowing through these breathing circuit components.

The sidestream sensor contains a gas sampling pump, which draws small samples of gas from the patient's airway via a nasal cannula or airway adapter, and passes these gases through a solid state infrared sensor (located within the sidestream module) that measures CO_2. While the sidestream system is typically used on non-intubated patients, it can also be used for $EtCO_2$ measurement on intubated infant, pediatric and adult patients. The sidestream system should not be used, however, on patients who cannot tolerate the 50ml/min removal of the sample gases from their breathing circuit. The sidestream module uses specially designed cannulas and airway adapters for sampling airway gases, which connect to the module's CO_2 sensor. These cannulas incorporate a water trap that captures fluids in the sampling line, thereby protecting the system from aspiration of these fluids.

In both systems, the CO_2 sensor generates infrared light and beams it through the airway adapter or sample cell to a detector on the opposite side. CO_2 from the patient, flowing through the mainstream airway adapter or sample cell, absorbs some of this infrared energy. The ZOLL M2 unit determines CO_2 concentration in the breathing gases by measuring the amount of light absorbed by gases flowing through the airway adapter or sample cell.

The ZOLL M2 unit displays $EtCO_2$ (the concentration of carbon dioxide detected at the end of each exhalation) as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, the unit can display a capnogram. This capnogram is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal (ET) tube placement. The unit calculates respiration rate by measuring the time interval between detected peaks of the CO_2 waveform.

The ZOLL M2 unit automatically compensates for changes in barometric pressure which would otherwise influence CO_2 readings.

Warning!

- **When using a sampling line for intubated patients with a closed suction system, do not place the airway adapter between the suction catheter and endotracheal tube. This is to ensure that the airway adapter does not interfere with the functioning of the suction catheter.**
- **Do not cut or remove any part of the sampling line. Cutting the sampling line could lead to erroneous readings.**
- **If too much moisture enters the sampling line (i.e., from ambient humidity or breathing of unusually humid air), the message *Check CO2 Sampling Line* will appear in the message area.**
- **Loose or damaged connections may compromise ventilation or cause an inaccurate measurement of respiratory gases. Securely connect all components and check connections for leaks according to standard clinical procedures.**
- **To ensure safe and reliable operation including biocompatibility, use only appropriate mainstream and sidestream CO_2 accessories specified by ZOLL for use with the ZOLL M2 system.**
- **Always ensure the integrity of the patient breathing circuit after insertion of the airway adapter by verifying a proper CO_2 waveform (capnogram) on the monitor display.**
- **The exhaust port of the sidestream CO_2 sensor is an output for expired gases from the patient and any connected breathing apparatus. It is intended only for connection to gas collection equipment, such as gas scavenger devices -- *there should be no other connections to the exhaust port.* Connecting the exhaust port with the patient breathing system can cause patient cross-infection.**
- **When connecting the sidestream CO_2 accessory to patients who are receiving or have recently received anesthetics, connect the CO_2 exhaust port to a scavenging system, or to the patient's anesthetic machine or ventilator to prevent exposing medical staff to anesthetics.**
- **Do not lift the sidestream module by the sampling line, as it could disconnect from the module, causing the module to fall on the patient or be damaged.**

- **The sampling line may ignite in the presence of high O_2 concentrations when directly exposed to laser or ESU devices. Use caution when performing these procedures.**
- **The disposable sidestream nasal sampling line and cannula or airway adapter sets are intended for single patient use. Do NOT reuse or sterilize any part of this product, as the sensor may be damaged by reuse of the sampling line.**
- **The nasal cannula cannot be used to deliver oxygen.**
- **Check the connections between the nasal cannula or airway adapter, water trap and sidestream module to make sure that they are secure prior to and during patient use.**

Caution CO_2 sampling lines are designed for single patient use, and are not to be reprocessed. It is recommended to replace the kit of sampling line and water trap every 15 hours; every 120 hours for the kit with dryer; or immediately if the line becomes blocked, damaged, contaminated, or leaks breathing gases. Do not attempt to clean, disinfect, sterilize or flush any part of the sampling line as this can cause damage to the CO_2 sensor.

Before use, carefully read the CO_2 sampling line's *Directions for Use*.

Dispose of sidestream $EtCO_2$ consumables according to standard operating procedures or local regulations for the disposal of contaminated medical waste.

Airway adapters are designed for single patient use, and are not to be reprocessed.

Replace the airway adapter if excessive secretions are observed.

Do NOT place the mainstream or sidestream airway adapters between the ET tube and the breathing circuit elbow, as this may cause patient secretions to accumulate in the adapter.

Position airway adapters with windows in a vertical, NOT a horizontal, position. This helps keep patient secretions from pooling on the windows.

Mainstream CO_2 Setup

To set up the mainstream CO_2 sensor, follow these steps:

1. Attach the mainstream module CO_2 connector to the ZOLL M2 unit.
2. Select the mainstream airway adapter for the patient type (adult/pediatric or infant).
3. Connect the airway adapter to the CO_2 sensor.
4. Zero the mainstream sensor/airway adapter.
5. Attach the sensor/adapter to the airway circuit.

Attaching the Mainstream CO_2 Module Connector to the ZOLL M2 Unit

To connect the mainstream CO_2 module to the ZOLL M2 unit, gently push and rotate the module's metal connector while inserting into the ZOLL M2's recessed CO_2 connector until it clicks into place.

Selecting the Mainstream Airway Adapter

Determine the correct CO_2 airway adapter, based on the patient's ET tube diameter and monitoring situation.

You can use the following mainstream accessories for CO_2 monitoring with the ZOLL M2 unit. ZOLL M2 mainstream airway adapters are disposable and single patient use.

Table 7-1. Mainstream airway adapters for use with ZOLL M2 units.

Accessory	**Type**
Mainstream airway adapter, single use	Adult/Pediatric
Mainstream airway adapter, single use	Infant

Connecting the Airway Adapter to the Mainstream CO_2 Sensor

Before connecting the airway adapter to the CO_2 sensor, verify that the airway adapter windows are clean and dry. Clean or replace the adapter if necessary.

Connect the airway adapter to the sensor, as follows:

1. Align the airway adapter with the bottom of the CO_2 sensor (there is only one way to assemble it into place).
2. Press the sensor and airway adapter together until they click.
3. Turn the mode selector on the unit to **MONITOR**.
4. Check the CO_2 quick access key. If it is a grey dot, press the CO_2 quick access key to turn on the CO_2 sensor and the green dot appears. 

5. Wait for the airway adapter and sensor to warm up.

   The unit will display the *CO2 Warm Up* message for approximately two minutes while the sensor and adapter warm to operating temperature. The message disappears when the sensor is ready to use.

Note: Warm up time varies with ambient temperature of the sensor.

6. If the unit displays the *Check CO2 Airway Adapter* message, follow steps a through c.

   a. Verify proper connection of the adapter to the sensor.

   b. Verify that the airway adapter windows are clean and dry.

   c. If the adapter is properly connected, and the windows are clean and dry, then zero the adapter as described in the next section, "Zeroing the Mainstream CO_2 Sensor/Airway Adapter."

Zeroing the Mainstream CO_2 Sensor/Airway Adapter

Note: Do not zero the sensor without an airway adapter installed.

Adapter zeroing compensates for the optical differences between airway adapters and should be performed when the message *CO2 Zeroing Required* appears. Zeroing is recommended between each use of the mainstream module, in order to obtain accurate readings. It is required when the *CO2 Zeroing Required* message appears. To zero the adapter:

1. Place the sensor with the adapter installed away from all sources of CO_2 (including the patient's – and your own – exhaled breath and ventilator exhaust valves).
2. Check the CO_2 quick access key. If it is a grey dot, press the CO_2 quick access key to turn on the CO_2 sensor and the green dot appears.
3. Press the Menu button, or, using the Trim Knob, select the CO_2 field then press the Trim Knob.
4. Select the CO_2 menu.
5. Rotate the Trim Knob to **Zero**, then press the Trim Knob.

   The unit zeroes the adapter and displays the *CO2 Zeroing in Progress* message for about 10 seconds.

   The unit displays the message *CO2 Zeroing Completed* upon completion of the zeroing.

Note: Do not attempt zeroing until 20 seconds after removing the adapter from the patient's

airway. This time allows any CO_2 remaining in the adapter to dissipate before zeroing. Do not attempt to zero the adapter while it is connected to the patient's airway. Zeroing with CO_2 in the adapter can lead to inaccurate measurement and/or other error conditions. If you attempt zeroing while CO_2 remains in the adapter, the time required to zero the adapter may be increased. If zeroing cannot be completed, the message *CO2 Zeroing Failed* will be displayed. If this occurs, clear any occlusion in the adapter, remove any source of CO_2, wait 20 seconds, and try zeroing again.

Note: When the CO_2 module needs to be zeroed, the message *CO2 Zeroing Required* appears and the CO_2 quick access key changes to Zero Control. Press this key to initiate zeroing. If the key is not pressed after 10 seconds, it reverts to the CO_2 On/Off control.

Attaching the Airway Adapter to the Airway Circuit

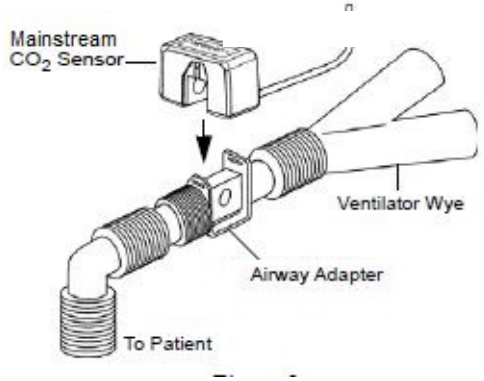
If you have not yet done so, you must attach the airway adapter to the breathing circuit before attaching it to the CO_2 sensor.

Attach the airway adapter to the breathing circuit as follows:

1. Place the CO_2 airway adapter between the elbow and the ventilator circuit wye.

   Note: Do NOT place the airway adapter between the ET tube and the elbow, as this may allow patient secretions to accumulate in the adapter.

   Position the airway adapter with its windows in a vertical, NOT a horizontal, position. This helps keep patient secretions from pooling on the windows. If pooling does occur, the airway adapter may be removed from the circuit, rinsed with water and reinserted into the circuit. To prevent moisture from draining into the airway adapter, do NOT place the airway adapter in a gravity dependent position.



2. Connect the CO_2 sensor to the airway adapter until it "clicks" into place.
3. Check that connections have been made correctly by verifying the presence of a proper CO_2 waveform on the ZOLL M2 display.
4. The sensor cable should face away from the patient.

Sidestream CO_2 Setup

To set up the sidestream CO_2 system, follow these steps:

1. Attach the sidestream module to the ZOLL M2 CO_2 connector.
2. Select one of the following:

- the correct sidestream airway adapter kit for the patient. The sidestream airway adapter kit is composed of a water trap, sampling line, and L or T tube connector.

or

- the correct CO_2 nasal sampling line kit for the patient. The nasal sampling line kit is composed of a water trap, sampling line, and nasal cannula (adult or pediatric).

3. Check the Luer Lock connections between the different parts in the kit to make sure that they are secure. Connect the kit (water trap end) to the sidestream module.
4. Zero the CO_2 module.
5. Connect a sidestream airway adapter kit to the breathing circuit, or apply the nasal sampling lines to the patient.

Attaching the Sidestream Module CO2 Connector to the ZOLL M2 Unit

To connect the sidestream module to the ZOLL M2 unit, gently push and rotate the module's metal connector while inserting into the ZOLL M2's recessed CO_2 connector until it clicks into place.

Selecting a Sidestream Airway Adapter Kit

Select an airway adapter kit based on the patient's size, ET tube diameter, and monitoring situation. Airway adapter kits are disposable and single patient use.

Airway Adapter Kit	**Notes:**
Sidestream Sampling Line Kit (L Tube), Single Use, Intubated Adult/Pediatric/Infant	Replace after 15 hours of use
Sidestream Sampling Line Kit (T Tube), Single Use, Intubated Adult/Pediatric/Infant	Replace after 15 hours of use

Airway Adapter Kit	Notes:
Sidestream Sampling Line Kit with Dryer (L Tube), Single Use, Intubated Adult/Pediatric/Infant	Replace after 120 hours of use
Sidestream Sampling Line Kit with Dryer (T Tube), Single Use, Intubated Adult/Pediatric/Infant	Replace after 120 hours of use

Note: If you use a gas scavenging system, ensure that it is installed and connected to the exhaust port of the sidestream module according to the manufacturers instructions. The gas scavenging system should comply with ISO 8835-3.

Note: In order to avoid moisture buildup and sampling line occlusion during nebulization or suction for intubated patients, disconnect the sampling line Luer connector from the module.

Selecting a Sidestream Nasal Cannula

Select a sidestream nasal cannula based on the patient's size and monitoring situation. Cannulas are disposable and single patient use.

Cannula	Notes:
Sidestream Nasal Sampling Line, Single Use, Adult	Replace after 15 hours of use
Sidestream Nasal Sampling Line, Single Use, Pediatric	Replace after 15 hours of use
Sidestream Nasal Sampling Line Kit with Dryer, Single Use, Adult	Replace after 120 hours of use
Sidestream Nasal Sampling Line Kit with Dryer, Single Use, Pediatric	Replace after 120 hours of use

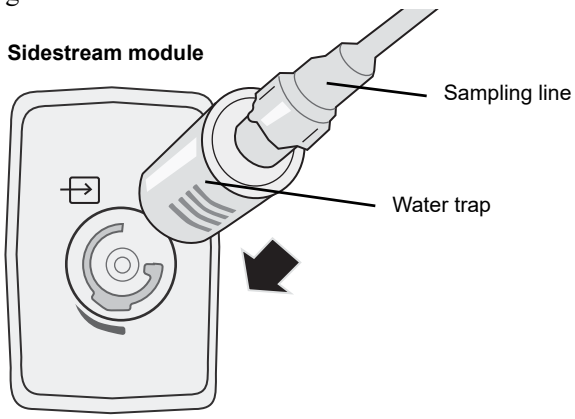
Connecting the sampling line and water trap to the sidestream CO_2 module

Follow these steps:

1. Remove the sampling cannula or airway adapter kit from the package.

2. Check the Luer Lock connections between the different parts in the kit to make sure that they are secure.

3. Connect the water trap to the sidestream module by pushing the end into the CO_2 inlet, then turning it clockwise until tight.



4. Ensure that the module exhaust tube vents gases away from the module environment.
5. Turn the Trim Knob on the ZOLL M2 unit to **MONITOR**. Press the CO_2 quick access key until the green dot appears.
6. Wait for the CO_2 module to warm up.

   The unit will display the *CO2 Warm Up* message for approximately 30 seconds while the module warms up to operating temperature. The message disappears when the module is ready for use.

Note: Warm up time varies with ambient temperature of the module.

Zeroing the CO_2 Module/Sample Cell

Zeroing allows the CO_2 module to adjust the optical characteristics of the module's sample cell for accurate CO_2 measurement. Zeroing is recommended before each use of the CO_2 module in order to obtain accurate readings. It is required when the *CO2 Zeroing Required* message appears.

Caution Always ensure that the water trap is properly connected to the module before zeroing.

1. Ensure that the nasal cannula or on-airway adapter is not connected to the patient or close to any source of CO_2 (including the patient's—and your own—exhaled breath and ventilator exhaust valves).
2. If necessary, press the **CO2** quick access key to activate CO_2 (green dot displays in the quick access field display).
3. Press the Menu button, or, using the Trim Knob, select the CO2 field then press the Trim Knob.
4. Rotate the Trim Knob to **Zero**, then press the Trim Knob to start the zeroing process.

   The unit zeroes the module and displays the *CO2 Zeroing in Progress* message for approximately 10 seconds.

   The units displays the message *CO2 Zero Completed* upon completion of the zeroing.

Note: Do not attempt zeroing until 20 seconds after removing the adapter or cannula from the patient's airway. This time allows any CO_2 remaining in the adapter or cannula to dissipate before zeroing. Do not attempt to zero the module while the adapter or cannula is in the patient's airway. Zeroing with CO_2 in the adapter or cannula can lead to inaccurate measurements and/or other error conditions. If you attempt zeroing while CO_2 remains in the adapter or cannula, the time required to zero the module may be increased. If zeroing cannot be completed, the message *CO2 Zeroing Failed* will be displayed. If this occurs, clear any occlusion in the adapter or cannula, remove the source of CO_2, wait 20 seconds, and try zeroing again.

Applying a Sidestream Airway Adapter Kit

The sidestream airway adapter kit is intended for monitoring the CO_2 of intubated patients. The sidestream airway adapter kit is composed of a water trap, sampling line, and L or T tube connector.

Before attaching the airway adapter to the breathing circuit, verify that the adapter is clean, dry, and undamaged. Replace if necessary.

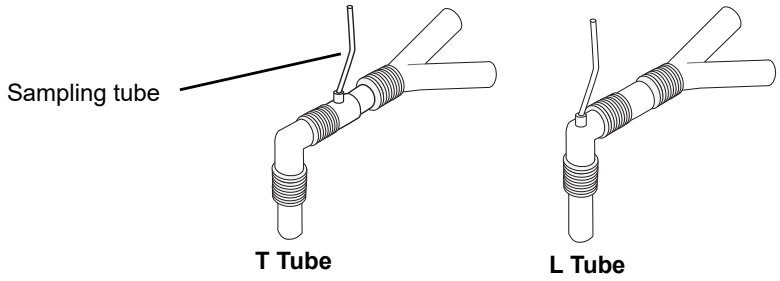
Caution The disposable (SPU) Adult and Pediatric airway adapter kits are intended for single patient use. Do NOT reuse or sterilize these adapters as system performance will be compromised.

1. Check the Luer Lock connections between the different parts in the airway adapter kit to make sure that they are secure. Connect the airway adapter kit (water trap end) to the sidestream module CO_2 inlet. Ensure that all connections are secure and air tight.

2. For the T tube connector kit, place the T tube connector at the proximal end of the airway circuit between the elbow and the ventilator circuit wye. Do NOT place the airway adapter between the ET tube and the elbow, as this may allow patient secretions to accumulate in the adapter. For the L tube connector kit, use the L tube connector as the elbow and place it between the ET tube and the ventilator circuit wye.

   If pooling does occur, the airway adapter may be removed from the circuit, rinsed with water and reinserted into the circuit. To prevent moisture from draining into the sample tubing, ensure that the sampling tube exits from the top of the airway adapter, not its bottom or sides.

Figure 9-1 T Tube and L Tube Connector Kits



3. Check that connections have been made correctly by verifying the presence of a proper capnogram on the ZOLL M2 display.

Applying Sampling lines with Nasal Cannula

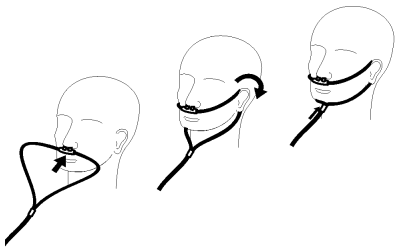
Applying Sampling line Set

The sampling line set is intended for the CO_2 monitoring of non-intubated patients. Check the Luer Lock connections between the water trap and nasal sampling line in the kit to make sure that they are secure. Connect the kit (water trap end) to the sidestream module.

Placing the Cannula onto the Patient

The nasal cannula is intended for the CO_2 monitoring of non-intubated patients.

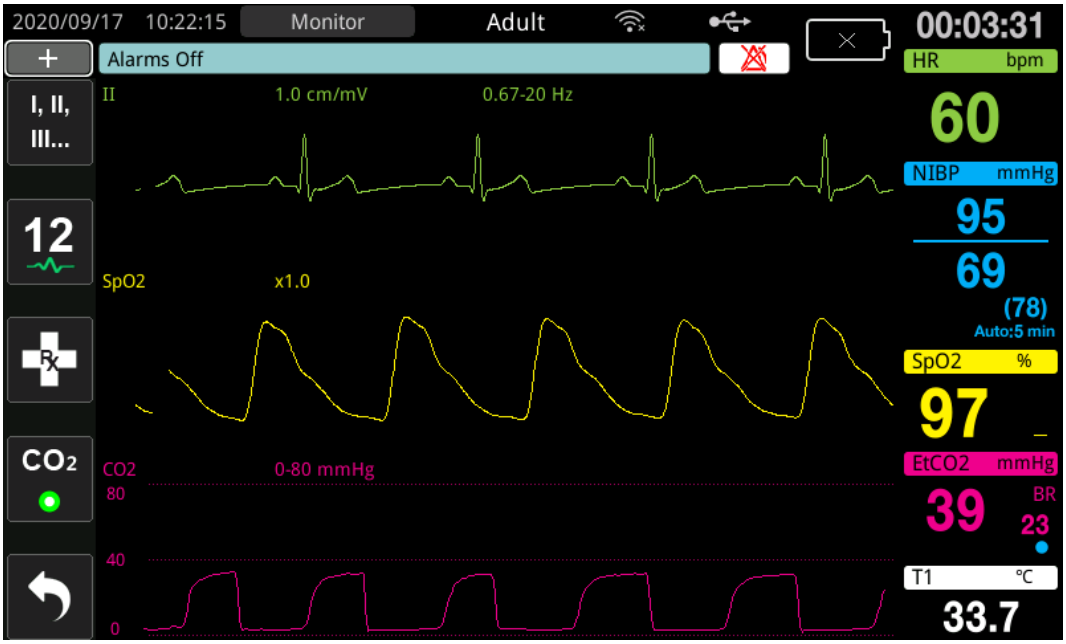
Place the nasal cannula onto the patient as shown below.



Measuring CO_2

Once setup is complete, verify that CO_2 monitoring has begun (green dot displays on CO_2 button) and the numeric CO_2 display appears on the screen. The display of $FiCO_2$ value can be enabled or disabled (the default). The CO_2 display gives the current $EtCO_2$ value and the patient's Respiration Rate (in Breaths/Minute), identified as **BR**:

Check that connections have been made correctly by verifying the display of a proper capnogram (the waveform is inserted automatically on the waveform display window).



The unit display of CO_2 can be set in kPa, mmHg or %. The display range of the CO_2 waveform can be adjusted: rotate the Trim Knob to highlight the display range and press the knob to select it. The available display range options are:

Unit display	Ranges
kPa	0.0 - 3.0 kPa 0.0 - 5.0 kPa 0.0 - 10.0 kPa (default) 0.0 - 15.0 kPa 0.0 - 20.0 kPa
mmHg	0 - 20 mmHg 0 - 40 mmHg 0 - 80 mmHg (default) 0 - 100 mmHg 0 - 150 mmHg
%	0.0 - 3.0% 0.0 - 5.0% 0.0 - 10.0% (default) 0.0 - 15.0% 0.0 - 20.0%

When the O_2 compensation is set to be greater than 0 in the CO_2 setting menu, a blue dot will be displayed under the BR reading. When the N_2O compensation is set to be greater than 0 in the CO_2 setting menu, an orange dot will be displayed under the BR reading. When the O_2 and N_2O compensations are both set to be greater than 0, both blue and orange dots will be displayed under the BR reading.

The CO_2 waveform can be displayed as Filled (color underneath the waveform) for clarity; to change the style of the CO2 display, refer to the *ZOLL M2 Configuration Manual* for instructions.

Setting CO_2 and Respiration Rate Alarms

The ZOLL M2 unit sounds alarms whenever measurements are outside set limits for the following:

- High and Low $EtCO_2$
- High and Low Respiration Rate (in Breaths/Minute, identified as BR)
- High and Low $FiCO_2$
- No Breath Time

Enabling/Disabling Alarms and Setting CO_2 Alarm Limits

To enable (or disable) CO_2 alarms and set upper and lower alarm limits, you can do so through the Alarm Limits quick access key.

To configure CO_2 alarms through the Alarm Limit quick access key:

1. Press the More ( ) quick access key until the Limits ( ) quick access key is displayed, then press the Limits ( ) quick access key to enter the Alarm Limit setting menu. Or, press the Menu button ( ) and use the Trim Knob to select Alarm Limits.
2. Rotate the Trim Knob to highlight and select the appropriate alarm menu selection. For CO_2, the alarm menu selections are: $EtCO_2$ Alarm, $FiCO_2$ Alarm, or RR/BR Alarm.
3. On the alarm settings menu, use the Trim Knob to select the fields that you want to change. Make the change and press the Trim Knob to confirm the change. The fields are
   - **Status**
   - **Lower Limit**
   - **Upper Limit**
   - **No Breath Time**
4. When you are finished changing values on the alarm limit setting menu, navigate to the Backarrow key ( ) or the Exit key ( ) to exit the menu.

Setting Upper and Lower $EtCO_2$ Limits

Initially, the $EtCO_2$ Alarm menu specifies that the $EtCO_2$ alarms are enabled (**ON**) or disabled (**OFF**), and displays the default Upper and Lower $EtCO_2$ Limits. The following table lists the default $EtCO_2$ limits for adult and pediatric patients, and gives the range over which you can set these limits:

Patient Type	$EtCO_2$ Limit Default	$EtCO_2$ Limit Range
Adult	Lower: 1.0%/1.0 kPa (8 mmHg) Upper: 8.0%/8.0 kPa (60 mmHg)	Lower: 0-19.9%/0-19.9 kPa (0-149 mmHg) Upper: 0.1-20.0%/0.1-20.0 kPa (1-150 mmHg)
Pediatric	Lower: 1.0%/1.0 kPa (8 mmHg) Upper: 8.0%/8.0 kPa (60 mmHg)	Lower: 0-19.9%/0-19.9 kPa (0-149 mmHg) Upper: 0.1-20.0%/0.1-20.0 kPa (1-150 mmHg)

Caution In high-altitude environments, $EtCO_2$ values may be lower than values observed at sea level, as described by Dalton's law of partial pressures. When using the ZOLL M2 unit in high-altitude environments, it is advisable to adjust $EtCO_2$ alarm settings accordingly.

Setting Upper and Lower $FiCO_2$ Limits

Initially, the $FiCO_2$ Alarm menu specifies that the $FiCO_2$ alarms are enabled (**ON**) or disabled (**OFF**), and displays the default upper and lower $FiCO_2$ limits. The following table lists the

default $FiCO_2$ upper limits for adult and pediatric patients, and gives the range in which you can set these limits:

Patient Type	$FiCO_2$ Limit Default	$FiCO_2$ Limit Range
Adult	Lower: 0%/0 kPa (0 mmHg) Upper: 1.0%/1.0 kPa (8 mmHg)	Lower: 0-13.1%/0-13.1 kPa (0-98 mmHg) Upper: 0.1-13.2%/0.1-13.2 kPa (1-99 mmHg)
Pediatric	Lower: 0%/0 kPa (0 mmHg) Upper: 1.0%/1.0 kPa (8 mmHg)	Lower: 0-13.1%/0-13.1 kPa (0-98 mmHg) Upper: 0.1-13.2%/0.1-13.2 kPa (1-99 mmHg)

Setting No Breath Time Limit

Initially, the No Breath Time alarm menu is disabled (**OFF**). For both adult and pediatric patients, the amount of time for the alarm between breaths can be selected from the following: 10 seconds, 15 seconds, 20 seconds, 25 seconds, 30 seconds, 40 seconds, 50 seconds, or 60 seconds.

Setting Upper and Lower Respiratory Rate (RR/BR) Limits

Initially, the RR/BR Alarm menu specifies that RR/BR alarms are enabled (**ON**) or disabled (**OFF**), and displays the default Upper and Lower respiratory rate limits. The following table lists the default Respiratory limits for adult and pediatric patients in Breaths/Minute, and gives the range in which you can set these limits:

Patient Type	Respiration Rate Default	Respiration Rate Range
Adult	Lower: 5 brpm Upper: 50 brpm	Lower: 2 to 149 brpm Upper: 3 to 150 brpm
Pediatric	Lower: 5 brpm Upper: 50 brpm	Lower: 2 to 149 brpm Upper: 3 to 150 brpm

Using the CO_2 Setting Menu

To display the CO_2 Setting Menu:

Rotate the Trim Knob to highlight and select the CO_2 numeric display.

or:

1. Press the Menu button ( ).
2. Rotate the Trim Knob to CO_2 and press the Trim Knob.

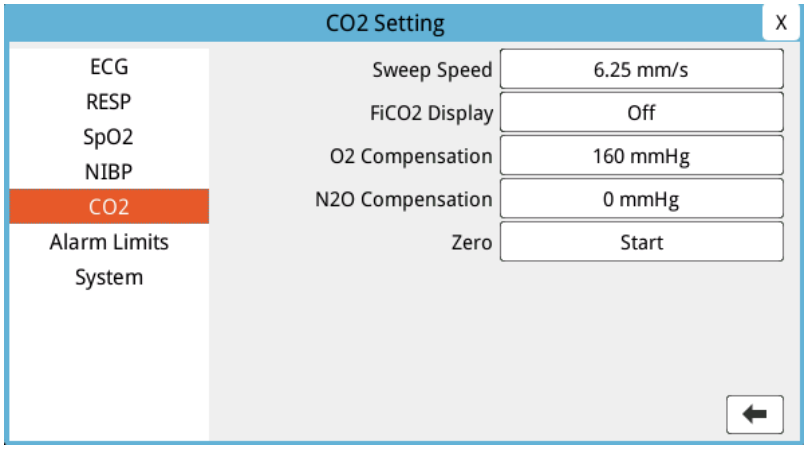


Figure 9-2 CO_2 Setting Menu

On the CO_2 Setting Menu, you can enable and disable the $FiCO_2$ display, zero the CO_2 sensor, adjust the O_2 or N_2O compensation, and select the capnogram display sweep speed.

Setting the CO_2 Sweep Speed

The $EtCO_2$ sweep speed determines the X-axis scale of the capnogram. For patients with slower respiration rates, a slower sweep speed will make the capnogram easier to view. You can specify sweep speeds of 6.25, 12.5, and 25 mm/second. The default sweep speed is 6.25 mm/second.

O_2 and N_2O Compensation

The ZOLL M2 unit can compensate for elevated levels of oxygen and/or the presence of nitrous oxide in the patient's breathing gases. Oxygen compensation should be activated when oxygen levels in excess of 30% are present in the airway circuit. Nitrous oxide compensation should be activated when nitrous oxide is present in the airway circuit.
Use the Trim Knob to set the O_2 and N_2O compensation values to match the percentage of O_2 and N_2O gas in the patient's airway circuit. The default for O_2 Compensation is 21.0%; the default for N_2O Compensation is 0.0%.

When the O_2 compensation is set to be greater than 0 in the CO_2 setting menu, a blue dot will be displayed under the BR reading. When the N_2O compensation is set to be greater than 0 in the CO_2 setting menu, an orange dot will be displayed under the BR reading. When the O_2 and N_2O compensations are both set to be greater than 0, both blue and orange dots will be displayed under the BR reading.

Start Zero

The ZOLL M2 unit allows users to start CO_2 zeroing function manually when the CO_2 sensor is connected to an airway adapter or sampling line. To start CO_2 zeroing:

1. Apply an air adapter or a sampling line to the CO_2 sensor/module.

2. Press CO_2 quick access key to initiate CO_2 measurement function.
3. Place sampling tube inlet or mainstream adapter away from sources of CO_2 such as the nose or mouth of breathing patients or caregivers.
4. Press the Menu button ( ).
5. Rotate the Trim Knob to CO_2 and press the Trim Knob.
6. Rotate the Trim Knob to Zero and press the Trim Knob.

Note: Before initiating CO_2 zeroing, make sure the airway adapter or sampling line is connected to the CO_2 sensor, exposed to the air and far away from any CO_2 source or patient's respiratory system.

CO_2 System Messages

When monitoring CO_2, the ZOLL M2 unit may display the following messages:

System Message	Cause/Action
CO2 Warm Up	The sensor/module needs to warm up. If the message persists for more than 5 minutes, replace the sensor/module.
Check CO2 Airway Adapter	The airway adapter is blocked, contaminated, has too many secretions, or is not connected properly to the mainstream module. Correct the issue in the airway adapter, remove and reinsert the airway adapter to the mainstream module. If the problem persists, replace the airway adapter.
Check CO2 Sampling Line	The sampling line and water trap are not properly connected to sidestream module; the sampling line or the exhaust tube is blocked, kinked, or pinched; or the airway adapter is blocked or otherwise compromised. Correct the blockage/kink in the sampling line kit, remove and reinsert the sampling line kit to the sidestream module. If the problem persists, replace the sampling line kit.
CO2 Out of Range	The CO_2 value is out of accuracy range. Take the device to a place within the normal operating range.
CO2 Ambient Pressure Out of Range	The ambient pressure is out of the specified working range of the CO_2 module; the reading may not be accurate. Take the device to a place within the normal operating range.
CO2 Temperature Out of Range	The ambient temperature of the CO_2 module is lower than 0° C or higher than 50° C. The accuracy of the CO_2 value may be out of the specified range. Take the device to a place within the normal operating range.
CO2 Zeroing Required	The CO_2 module needs to be zeroed. Zero the module as described above.

System Message	Cause/Action
EtCO2 High	The $EtCO_2$ value exceeds the upper alarm limit selected.
EtCO2 Low	The $EtCO_2$ value is less than the lower alarm limit selected.
FiCO2 High	The $FiCO_2$ value exceeds the upper alarm limit selected.
FiCO2 Low	The $FiCO_2$ value is less than the lower alarm limit selected.
BR High	The detected BR value exceeds upper alarm limit selected.
BR Low	The detected BR value is less than the lower alarm limit selected.
No Breath	The unit has detected that the period between breaths is longer than the selected No Breath alarm time.

Chapter 10
Monitoring SpO_2

ZOLL M2 SpO2 sensors are a defibrillation-protected Type BF patient connection (applied part).

This chapter describes how to use the ZOLL M2 unit to monitor SpO_2 and pulse rate.

The ZOLL M2 SpO_2 module continuously and noninvasively measures the following at a peripheral site, such as finger:

- Oxygen saturation of arterial hemoglobin (SpO_2)
- Pulse rate (PR)

This monitoring gives information about the cardiac and respiratory systems, and provides details of oxygen transportation in the body. It is widely used because it is noninvasive, continuous, easily applied, and painless.

SpO_2 monitoring and related accessories are to be used only on adult and pediatric patients.

Warning! **Do not reuse any components that are labeled for single use only.**

The ZOLL M2 SpO_2 module (optional) is intended for use only with ZOLL M2 pulse oximetry sensors. The SpO_2 sensor contains light-emitting diodes (LEDs) that transmit red and infrared light through the body's extremities. The transmitted light is then received by a photodetector within the sensor, which converts it to an electronic signal. The signal is then sent to the ZOLL M2 unit for processing.

In blood, oxygen-saturated hemoglobin absorbs light differently than unsaturated hemoglobin. Thus the amount of red and infrared light absorbed by blood flowing through a suitable peripheral area of the body, typically the finger in adults, can be used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood. The monitor displays this ratio as a percent of fully saturated (normal values typically range from 95% to 100% at sea level).

The quality of measurements depends on the correct size and application of the sensor, adequate blood flow through the sensor site, and the sensor's shielding against exposure to ambient light. For correct placement and location of the sensors, refer to the *Directions for Use* contained with all SpO_2 sensor packages.

Note: The ZOLL M2 displays the pulse rate (PR) value when you do not connect ECG leads or defibrillation electrodes to the patient.

Note: The SpO_2 sensor's LED wavelength information (Appendix A) may be useful to clinicians.

Note: The SpO_2 functional check (e.g., SpO_2, PR, plethysmograph display) can be conducted by applying the SpO_2 sensor to the operator's finger.

Warning!

- **As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.**
- **Do not place the ZOLL M2 monitor/defibrillator in any position that might cause it to fall on the patient.**
- **The cables and sensors listed in *Appendix B: Accessories* are designed for use with this specific monitor and tested for compliance with the ISO 80601-2-61: 2017 standard.**
- **Tissue damage can occur if sensors are applied incorrectly, or left in the same location for an extended period of time. Move the SpO_2 sensor every 4 hours to reduce the possibility of tissue damage.**
- **Do not use the SpO_2 monitoring function if it appears or is suspected to be damaged or malfunctioning.**
- **SpO2 measurements may be affected in the presence of strong electromagnetic fields, electrosurgical devices, IR lamps, bright lights, improperly applied sensors; the use of non-ZOLL M2 sensors, or damaged sensors; in patients with smoke inhalation, or carbon monoxide poisoning, or with patient movement.**
- **To ensure safety, avoid stacking multiple devices or placing anything on the instrument during operation.**
- **To protect against injury, follow the directions below:**
  - **Avoid placing the device on surfaces with visible liquid spills.**
  - **Do not soak or immerse the device in liquids.**
  - **Do not attempt to sterilize the device or its accessories.**
  - **Use cleaning solutions only as instructed in this operator's manual.**
  - **Do not attempt to clean the device while monitoring a patient.**
  - **To protect against electric shock, always remove the sensor before bathing the patient.**
  - **If any measurement is questionable, check the patient's vital signs by alternate means.**

- **Inaccurate SpO_2 readings may be caused by:**
  - **– Improper sensor application.**
  - **– Intravascular dyes, such as indocyanine green or methylene blue.**
  - **– Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.**
  - **– Elevated levels of bilirubin.**
  - **– Severe anemia.**
  - **– Low arterial perfusion.**
  - **– Patient movement of the sensor site.**
  - **– Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.**
- **The responsible organization and/or operator needs to verify the compatibility of the monitor, probe, and cable before use, otherwise patient injury can result.**

Cautions

- Electrical shock and flammability hazard: before cleaning, always turn off the instrument and disconnect from any power source.
- When patients are undergoing photodynamic therapy they may be sensitive to light sources. SpO_2 measurement may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- If SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
- When the SpO_2 probe signal is not sufficient to determine arterial hemoglobin saturation, SpO_2 numerical zone displays "- - -".
- If monitoring SpO_2 during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to radiation, the reading might be inaccurate or the instrument might read zero for the duration of the active irradiation period.
- Variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
- Disposal of product - Comply with local laws governing the disposal of the instrument and its accessories.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be placed in close proximity to the ZOLL M2 monitor/defibrillator or its SpO_2 sensors.
- Functional simulators cannot be used to assess the accuracy of the SpO_2 probe or monitor.

SpO_2 Setup and Use

To take accurate SpO_2 measurements using the ZOLL M2 unit, you must perform the following steps, each of which corresponds to a section in this chapter.

1. Select the correct sensor.
2. Apply the sensor to the patient.
3. Connect the sensor to the ZOLL M2 unit.
4. Configure alarms and settings (if the current alarms and settings are not appropriate).

SpO_2 measurements begin as soon as the sensor is applied to the patient and connected to the ZOLL M2 unit.

Note: The ZOLL M2 unit is calibrated to display functional oxygen saturation.

Note: A functional SpO_2 tester such as the Index 2 can be used to assess the basic operation and pulse rate accuracy of the SpO_2 system, but not its measurement accuracy.

Before applying the sensor to the patient, inspect the sensor and its cable to verify cleanliness and good electrical condition. Replace the sensory cable if it shows any signs of wear, breakage, or fraying.

Selecting the SpO_2 Sensor

When selecting the sensor, consider the patient's weight, the adequacy of perfusion, the available sensor sites, and the anticipated duration of monitoring. For more information, refer to the *Accessories* section of this chapter, which provides a list of ZOLL-approved reusable sensors for adult and pediatric patients. Reusable sensors can be reused on different patients after they have been cleaned and disinfected. Before applying the sensor, always familiarize yourself with the *Directions for Use* provided with the sensor.

Applying the SpO_2 Sensor

Choose a site that is well perfused and restricts a conscious patient's movements the least. The ring finger or middle finger of the nondominant hand is preferred.

To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

Do not select an SpO_2 sensor site on the same arm/leg as an NIBP cuff. Inflation of the cuff will cause the SpO_2 values to read incorrectly.

Check that the patient type displayed on the ZOLL M2 unit is appropriate for the patient.

Connecting the SpO_2 Sensor

To connect the sensor to the ZOLL M2 unit:

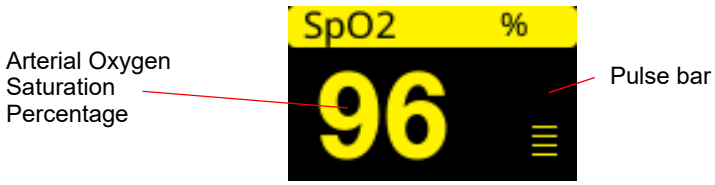
1. Plug the sensor extension cable into the SpO_2 receptacle on the back of the ZOLL M2 unit.

Note: Orient the SpO_2 cable so the arrow on the SpO_2 cable connector aligns with the arrow on the ZOLL M2 rear panel connector, then push the cable connector into the panel connector.

Displaying SpO_2 Measurements

When the connection is made between the sensor and the ZOLL M2 unit, the unit displays the plethysmograph normalized waveform and the messages *Pulse Searching* and *Initializing*.

The SpO_2 numeric display window is shown on the right side of the unit.



A pulse bar appears on the right side of the SpO_2 numeric display window. This tracks the amplitude of the plethysmography normalized waveform.

Note: If "- -" displays and persists for an extended period, no pulse is being detected. Try applying the sensor to another site.

Note: If "?" displays adjacent to the SpO_2 value, arterial pulsations are too weak to allow accurate SpO_2 measurements. Increase the SpO_2 monitoring sensitivity, or move the sensor to a patient site with better perfusion.

See “SpO2 System Messages” on page 10-9 for more information about SpO_2 related messages that may display.

Adjustable SpO_2 Settings

The pulse oximeter includes several settings which you can adjust when the unit is in clinical mode:

- Sensitivity level
- Plethysmogram display
- SpO_2 alarm state and limits (SpO_2 and pulse rate)

Setting the Sensitivity Level

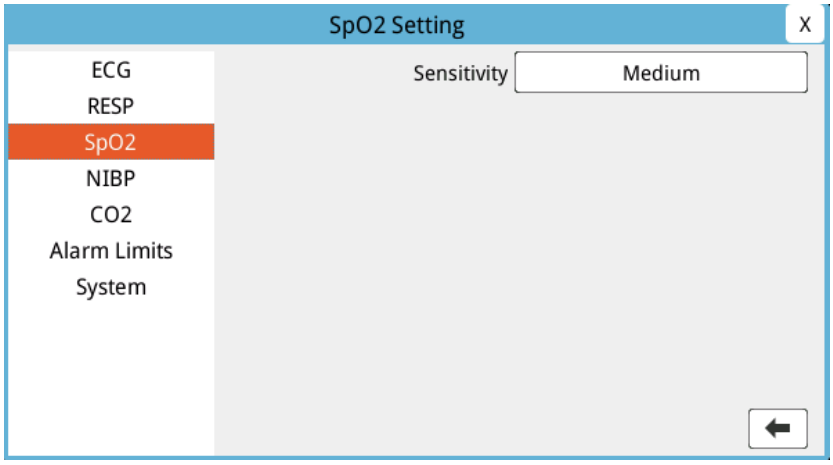
The ZOLL M2 unit allows you to select Low, Medium, or High sensitivity for SpO_2 monitoring. Medium sensitivity is recommended for most patients. Under very low perfusion conditions, such as severe hypotension or shock, high sensitivity might provide more accurate measurements.

Note: With high sensitivity, SpO_2 measurements are more easily contaminated by artifact; carefully and continuously observe the patient.

To set the SpO_2 sensitivity level:

1. With SpO_2 numeric display highlighted, press the Trim Knob.

The SpO_2 Setting window displays:



2. Rotate the Trim Knob to select the desired sensitivity from the drop down menu, and press the knob to select it.
3. When you have completed your changes, rotate the Trim Knob to highlight **X** in the upper right corner, and press the knob to close the window.

Adjusting the Plethysmogram Display

When pulse oximetry is in use, the unit can display a normalized plethysmogram below the ECG in the second, third, or fourth trace position in MONITOR mode.

The amplitude of the normalized plethysmogram remains constant for all patients. The shape of the waveform itself is variable.

Adjusting the Size of the Plethysmogram

The ZOLL M2 unit allows you to adjust the size of the displayed SpO_2 plethysmogram waveform. To select the waveform size:

1. Use the Trim Knob to highlight and select the trace size that displays to the right of the trace label (SpO2):

2. Rotate the Trim Knob to highlight the trace size and press the knob to select it.

The default trace size is 1.0. You can also select a larger trace size (2.0, 4.0 or 8.0), or a smaller trace size (0.5).

Enabling/Disabling SpO_2 Alarms and Setting Alarm Limits

When enabled, the ZOLL M2 unit sounds alarms whenever measurements are outside set limits for the high and low SpO_2 values (and, if ECG electrodes are not connected, PR value).

You can enable (or disable) alarms and set Upper and Lower alarm limits through the Alarm Limits quick access key (

).

To configure alarms through the Alarm Limits quick access key:

1. Press the More () quick access key until the Limits (

) quick access key is displayed, then press the Limits (

) quick access key to enter the Alarm Limit setting menu. Or, press the Menu button () and use the Trim Knob to select Alarm Limits.
2. Rotate the Trim Knob to highlight and select **SpO_2 (%)**.
3. In the SpO_2 (%) Settings menu, you can change the following fields:
   - Status - turn alarms on/off
   - Lower Limit - set the lower alarm limit
   - Upper Limit - set the upper alarm limit
4. To change a setting, press the Trim Knob and the field turns green. Rotate the Trim Knob to change the value and press the knob to select the new value.
5. When you have completed your changes, rotate the Trim Knob to highlight **X** in the upper right corner and press the knob to close the Alarm Limits Setting window.

Setting Upper and Lower SpO_2 Alarm Limits

Initially, the SpO_2 Alarm Settings menu specifies whether the SpO_2 alarms are enabled (On) or disabled (Off), and displays the default upper and lower SpO_2 limits. The following table lists the default SpO_2 limits for adult and pediatric patients, and gives the range in which you can set these limits.

Patient Type	**SpO_2 Limit Default**	**SpO_2 Limit Range**
Adult	Lower: 85% Upper: 100%	Lower: 85 - 99% Upper: 86 - 100%
Pediatric	Lower: 85% Upper: 100%	Lower: 85 - 99% Upper: 86 - 100%

Setting Upper and Lower HR/PR Alarm Limits

Initially, the HR/PR Alarm Settings menu specifies that alarms are enabled (On) or disabled (Off), and displays the default Upper and Lower pulse rate alarm limits. The following table

lists the default HR/PR alarm limits for adult and pediatric patients, and gives the range in which you can set these limits:

Patient Type	HR/PR Default	HR/PR Range
Adult	Lower: 50 BPM Upper: 120 BPM	Lower: 20 to 299 BPM Upper: 21 to 300 BPM
Pediatric	Lower: 50 BPM Upper: 150 BPM	Lower: 20 to 299 BPM Upper: 21 to 300 BPM

SpO_2 System Messages

When monitoring SpO_2, the ZOLL M2 unit may display the following system messages:

System Message	Cause/Action
Initializing	The pulse oximeter function is starting up and preparing to begin searching for arterial pulses.
Low Perfusion	Arterial pulsations are too weak to allow accurate SpO_2 measurements. A “?” is displayed adjacent to the SpO_2 value under this condition.
PR High	The pulse rate value exceeds the selected alarm limit.
PR Low	The pulse rate value is below the selected alarm limit.
Pulse Searching	The unit is searching for a pulse.
Check SpO2 Sensor	The SpO_2 sensor has become disconnected from the unit, or the sensor is no longer on the patient. Check sensor and then reconnect it to the unit or reapply it to the patient.
SpO2 Communications Fault	The unit has not received any data from SpO_2 module for more than 5 seconds. Power cycle the unit. If the condition continues, call Technical Service.
SpO2 Disabled - Critical Fault	The ZOLL M2 pulse oximetry function has malfunctioned and is disabled. Power cycle the unit. If the message reappears, call Technical Service.
SpO2 High	The SpO2 value exceeds the selected alarm limit.

System Message	Cause/Action
SpO2 Low	The SpO2 value is below the selected alarm limit.
SpO2 Sensor Fault	The connected SpO_2 sensor or extension cable is damaged and/or malfunctioning.
Unknown Sensor	The ZOLL M2 does not recognize the attached sensor. The SpO_2 sensor may be damaged or not supported by the unit.

Chapter 11
Monitoring Temperature

ZOLL M2 Temperature inputs are a defibrillation-protected Type BF patient connection (applied part).

This chapter describes how to use the ZOLL M2 unit to monitor temperature.

The ZOLL M2 unit provides two temperature channels. When both channels are in use, the unit displays each channel's temperature successively, followed by the difference between the temperatures (labeled **ΔT**).

Temperature Monitoring Setup

To monitor temperature using the ZOLL M2 unit, perform the following steps:

1. Select the temperature probe and apply it to the patient.
2. Connect the temperature probe to the ZOLL M2 unit.
3. Configure Temperature alarms and settings (if the current Temperature alarms and settings are not appropriate).

Selecting and Applying Temperature Probes

You should use only temperature probes that are approved for use with the ZOLL M2 unit. See Appendix B, *Accessories* for a list of ZOLL-approved temperature probes. The use of other probes that do not match the performance specifications of the ZOLL-approved probes may produce incorrect temperature readings.

To apply the temperature probe to the patient, follow your organization's standard procedures. Always refer to probe manufacturer's *Directions for Use* before using the probe.

Warning!

- **The application and use of metal-jacketed temperature probes that come in contact with conductive objects or clinical personnel during electrocautery may cause burns at the point of contact between the patient and the temperature probe.**
- **To ensure safe and reliable operation, use only ZOLL-approved temperature probes.**

Connecting the Temperature Probes to the ZOLL M2 Unit

Connect the temperature probe cable to one of the two connection jacks (beside the ECG connector) on the back of the ZOLL M2 unit as shown below.

Note: Orient the temperature cable so the arrow located on the temperature probe connector aligns with the arrow on the unit's rear panel connector.

Figure 11-1 Connecting the Temperature Probe to the ZOLL M2 Unit

Displaying Temperature

When you connect the cable, the unit displays the temperature after a brief pause. The ZOLL M2 unit displays temperature as a numeric value in the Temperature window. You can configure the unit to display the temperature in ° C or ° F.

Enabling/Disabling Temperature Alarms and Setting Alarm Limits

When enabled, the ZOLL M2 unit sounds alarms whenever temperature measurements are outside set limits.

You can enable (or disable) temperature alarms and set the upper and lower alarm limits through the Alarm Limits quick access key (Limits).

To configure temperature alarms through the Alarm Limits quick access key:

1. Press the More ( ) quick access key until the Limits (Limits) quick access key is displayed, then press the Limits (Limits) quick access key to enter the Alarm Limit setting menu. Or, press the Menu button ( ) and use the Trim Knob to select Alarm Limits.
2. Rotate the Trim Knob to highlight and select the appropriate alarm menu selection. For the Temperature selection, the alarm menu selections are: T1 Alarm, T2 Alarm, or Δ**T** Alarm.
3. In the Temp menu, you can change the following fields:
   - Status - turn alarms on/off
   - Lower Limit - set the lower alarm limit
   - Upper Limit - set the upper alarm limit
4. To change a setting, press the Trim Knob and the field turns green. Rotate the knob to change the value and press the knob to select the new value.
5. When you have completed your changes, rotate the Trim Knob to highlight **X** in the upper right corner and press the knob to close the Alarm Limits Setting window.

Setting Upper and Lower ΔTemperature Alarm Limits

Initially, the ΔTemperature Alarm Settings menu specifies that the ΔTemperature alarms are On or Off and displays the default upper and lower limits. The following table lists the default ΔTemperature limits for adult and pediatric patients, and gives the range in which you can set these limits:

Patient Type	ΔTemperature Limit Default	Temperature Limit Range
Adult	Lower: 0.0 ° C (0.0 ° F) Upper: 0.5 ° C (0.9 ° F)	Lower: 0.0 - 4.9 ° C (0.0 - 8.8 ° F) Upper: 0.1 - 5.0 ° C (0.1 - 8.9 ° F)
Pediatric	Lower: 0.0 ° C (0.0 ° F) Upper: 0.5 ° C (0.9 ° F)	Lower: 0.0 - 4.9 ° C (0.0 - 8.8 ° F) Upper: 0.1 - 5.0 ° C (0.1 - 8.9 ° F)

Setting Upper and Lower Temperature Alarm Limits

Initially, the Temperature Alarm Settings menu specifies that the Temperature alarms are On or Off and displays the default upper and lower limits. The following table lists the default Temperature limits for adult and pediatric patients, and gives the range in which you can set these limits:

Patient Type	Temperature Limit Default	Temperature Limit Range
Adult	Lower: 35.0 ° C (95.0 ° F) Upper: 37.8 ° C (100.0 ° F)	Lower: 0.0 - 49.9 ° C (32.0 - 121.9 ° F) Upper: 0.1 - 50.0 ° C (32.1 - 122.0 ° F)
Pediatric	Lower: 35.0 ° C (95.0 ° F) Upper: 37.8 ° C (100.0 ° F)	Lower: 0.0 - 49.9 ° C (32.0 - 121.9 ° F) Upper: 0.1 - 50.0 ° C (32.1 - 122.0 ° F)

Temperature System Messages

The ZOLL M2 unit may display the following messages when monitoring Temperature.

Note: The temperature function performs a self test when initially powered on while the function is active.

System Message	Cause/Action
T1 Out of Range T2 Out of Range T1&T2 Out of Range	Temperature is outside of the measurement range.
TEMP Communications Fault	The unit has not received any data from TEMP module during the past 5 seconds.
TEMP Disabled - Critical Fault	The indicated temperature measurement has malfunctioned and is now disabled. Power cycle the unit. If the message persists, contact the ZOLL Technical Service Department.

System Message	Cause/Action
T1 Sensor Fault T2 Sensor Fault T1&T2 Sensor Fault	A temperature probe fault(s) is detected. Replace with a new temperature probe(s).
T1 High	The T1 value exceeds the selected high temperature limit.
T1 Low	The T1 value is below the selected low temperature limit.
T2 High	The T2 value exceeds the selected high temperature limit.
T2 Low	The T2 value is below the selected low temperature limit.
△T High	△T value exceeds the selected high value limit.
△T Low	△T value is below the selected low value limit.

Chapter 12
Automated External Defibrillator (AED) Operation

ZOLL hands-free therapy electrodes are a defibrillation-protected Type CF patient connection (applied part).

WARNING! ZOLL M2 AED mode is not indicated or available for use with neonatal patients. Use the Manual Defib mode for patients under 1 year of age. The ECG analysis algorithm integrated within the ZOLL M2 unit has not been validated for use on neonates.

WARNING! Be sure to use the pediatric patient mode for patients under 8 years of age. Using the adult mode with pediatric patients can result in the delivery of excessive energy doses.

This chapter describes the factory default configuration for the AED function. This configuration is compliant with and supports the BLS treatment protocols recommended by the American Heart Association (AHA) and European Resuscitation Council (ERC) Guidelines for Adult Basic Life Support and Use of Automated External Defibrillators.[1,2]

This chapter also describes how to switch the AED unit to Manual mode (see “Switching to Manual Mode Operation” on page 12-12).

1. **AHA: Circulation. 2015; 132:S414-S435**
2. **ERC: Resuscitation (2015); 95:81-99**

Modes of Operation

The ZOLL M2 monitor/defibrillator can be configured to operate as either an AED or a manual defibrillator when the Mode Selector is initially set to the DEFIB position. The operating mode of the ZOLL M2 monitor/defibrillator is indicated by the words AED or Manual Defib at the top of the display screen.

When configured as an AED, the ZOLL M2 will begin operating as a semi-automatic defibrillator each time you set the Mode Selector to DEFIB Mode (until you enter Manual Defib mode, as described later in this chapter). Once in manual defibrillator mode, the ZOLL M2 unit operates in the manual mode whenever you set the Mode Selector to DEFIB until the device is turned off for more than 30 seconds, or the **AED** quick access key is pressed to enter AED mode.

When configured as a manual defibrillator, the ZOLL M2 will begin operating in the manual mode each time you set the Mode Selector to DEFIB (until you enter the AED mode by pressing the **AED** quick access key). Once in AED mode, the ZOLL M2 unit operates in AED mode whenever you set the Mode Selector to DEFIB until the device is turned off for more than 30 seconds, or you enter Manual Defib mode, as described later in this chapter.

AED Mode

In AED operation, the ZOLL M2 starts up in Analysis/Shock/CPR Protocol mode and guides you through a cardiac resuscitation event (or a cardiac arrest event) by performing ECG analysis to determine whether the patient's ECG indicates the need for defibrillation treatment. If a shockable ECG rhythm is detected during analysis, it then charges the defibrillator, preparing the device to deliver a shock, then prompts you to press the **SHOCK** button.It then leads you through a period of CPR. This cycle is repeated as long as Analysis/Shock/CPR Protocol is active and pads are attached to the patient. If pads become detached from the patient during the analyzing, charging, or ready periods, the unit will issue an *Attach Pads* warning.

The ZOLL M2 defibrillator analysis can be initiated either automatically where it follows the preprogrammed sequence of AED modes/functions, or user initiated by pressing the configurable **ANALYZE** button during CPR periods (depending on configuration). When you press Analyze during a CPR period, the ZOLL M2 unit halts (cuts short) the CPR period and begins an ECG analysis.

The ECG analysis determines if there is a shockable rhythm. If a shockable rhythm is present, the device prompts you to shock the patient at the preconfigured energy level. If the analysis does not detect a shockable rhythm, the device alerts you that no shock is advised. If the **SHOCK** button is pressed and a shock is successfully delivered, the shock count increments by one and is displayed on the screen.

In both cases (shock or no shock), the device then starts a CPR period by prompting you to start CPR. If defibrillator electrodes with a CPR sensor are connected to the ZOLL M2, the device begins monitoring the depth and rate of chest compressions, displays these values, and may issue audible prompts and display messages to help you deliver compressions at the recommended depth and rate.

Patient Type

The ZOLL M2 AED can operate in either the Adult or Pediatric mode based on the adult or pediatric patient type selection. In adult mode, the ECG analysis algorithm and automatic defibrillator energy selections are tailored for use on adult patients. In pediatric mode, the ECG analysis algorithm and defibrillator energy selections are oriented toward use on pediatric patients from 1 - 8 years of age or < 25 Kg.

The ZOLL M2 AED mode is preconfigured to deliver the first three shocks at increasing energy settings (120, 150, 200 joules) for adults and energy settings (50, 70, 85 joules) for pediatric patients. All shocks after the initial three shocks are delivered at the same energy setting as the third shock.

All three energy settings in adult and pediatric modes are preconfigured. You can choose between the adult and pediatric energy selection protocols but cannot change energy settings or their sequence except via the device configuration function.

Once you have set the patient type, the ZOLL M2 selects and displays the default energy for that patient type. After the first shock is delivered, the ZOLL M2 automatically escalates the shock energy setting for the next shock that is appropriate for the patient. After the third shock, all subsequent shocks are delivered at the third shock energy setting. Changing the patient type causes the energy selection to return to the first shock setting.

Determine Patient Condition Following Medical Protocols

Verify:

- Unconsciousness
- Absence of breathing
- Absence of pulse

Begin CPR Following Medical Protocols

Request additional assistance.

Prepare Patient

1. Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, clip or shave it to ensure proper adhesion of the electrodes.
2. Attach hands-free therapy electrodes according to instructions on the electrode or Dura-padz gel packaging. Pads can be placed in the apex/sternum locations or in the anterior/posterior (front/back) position for ECG analysis and defibrillation (see next section for illustration).

Note: The CPR sensor must always be placed in the center of the patient's chest (over the Xiphoid process) for accurate CPR monitoring.

3. Ensure that the electrodes are making good contact with the patient's skin and are not covering any part of the ECG electrodes or other wires/devices attached to the patient.
4. Connect the hands-free therapy electrodes to the multi-function cable (MFC and CPR Series adapter or MFC-CPRD cable) if not already connected.

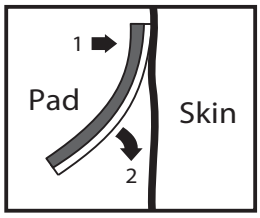
Note: If the therapy electrodes are not making good contact with the patient, the message *Attach Pads* is displayed and energy delivery will not be allowed.

Note: In AED Mode, analysis is only performed when Pads is the selected ECG lead (top trace).

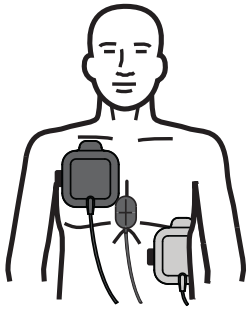
Therapy Electrode Application

WARNING! Poor adherence and/or air under the therapy electrodes can lead to the possibility of arcing and skin burns.

1. Apply one edge of the pad securely to the patient.
2. Roll the pad smoothly from the applied edge to the other, being careful not to trap any air pockets between the gel and skin.



Note: If it is not possible to place the "BACK" pad on the patient's back, the pads should be placed in the standard apex-sternum positions (as shown below). Effective defibrillation will result, but higher current will usually be required for effective pacing.



WARNING! Do not conduct manual chest compressions through the electrodes. Doing so may cause damage to the electrodes that could lead to the possibility of arcing and skin burns. For electrodes with the CPR sensor, place hands directly on the CPR sensor when conducting chest compressions.

Turn on Unit

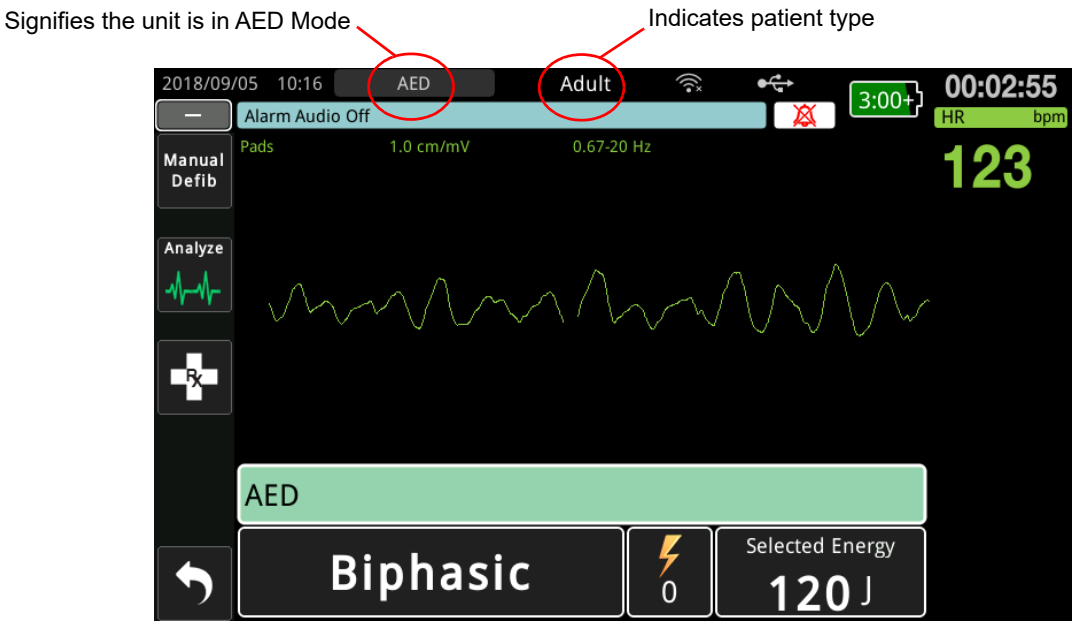
Turn the Mode Selector to DEFIB. If the unit was previously turned off, the red and yellow lights on the top of the unit flash on and off, and then the unit displays the message *All Tests Passed*.

If no hands-free therapy electrodes have been attached to the patient and connected to the ZOLL M2 unit, the *Attach Pads* message and voice prompt will be issued.

Set Patient Type

Before starting therapy, make sure to specify the correct patient type (that appears at the top of the window display). To change the patient type, turn the Trim Knob to highlight the patient type at the top of the window. Press the Trim Knob to select it and then turn it to select another patient type. Press the Trim Knob again to confirm the selection.

After setting the patient type, the ZOLL M2 selects and displays the default energy for the selected patient type. It also automatically selects the energy for subsequent shocks that are appropriate for the patient.



Follow the prompts to begin the rescue. If the ZOLL M2 unit has been configured to begin CPR upon start up, it will automatically begin with the CPR interval (the default setting starts with analysis).

1 Analyze

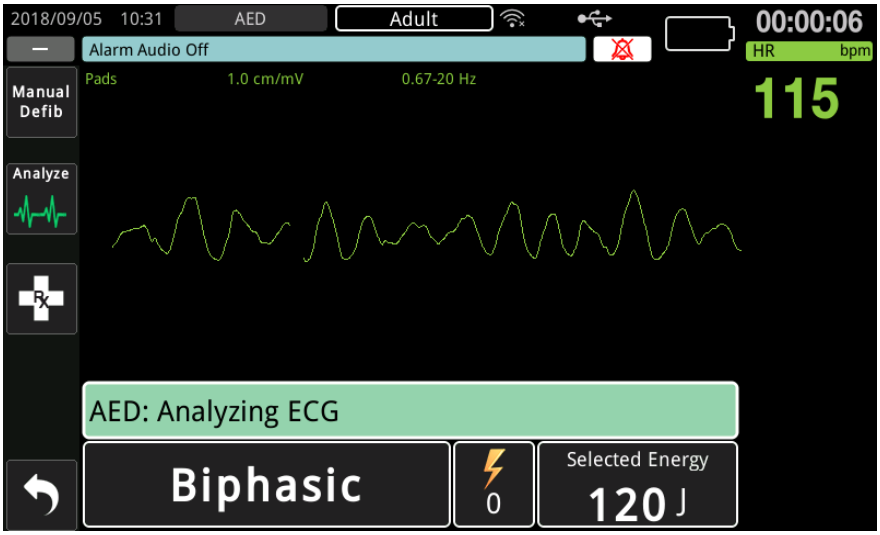
ECG analysis is designed to detect life-threatening ECG rhythms treatable by defibrillation. These rhythms include ventricular fibrillation (VF) and wide complex ventricular tachycardia (VT).

WARNING! ECG rhythm analysis does not warn of patient asystole, which is not a shockable rhythm.

WARNING! Do not analyze the patient ECG during patient movement. A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Cease all movement via stretcher or vehicle before analyzing the ECG.

The ZOLL M2 unit automatically begins the analysis of the patient's ECG rhythm, displays an *Analyzing ECG* message for 5 seconds, and announces and displays a *Stand Clear* message. If therapy electrodes have not been properly connected to the patient, an *Attach Pads* or *Check Pads* message is displayed and analysis will be inhibited.

Note: If the ZOLL M2 unit has been configured to perform CPR at startup, it displays a configurable CPR message along with a voice prompt for the configured duration before analysis begins. To start an ECG analysis during the CPR interval, press the **ANALYZE** button.



An *Analyzing ECG* message is displayed while the patient's ECG is analyzed. Once the analysis is completed, the unit indicates whether or not a shock is advised.

Energy Selections

Energy selections are pre-configured, and can only be changed in the Supervisor menu.

The default energy selections for adult patients:

Shock 1 - 120 joules
Shock 2 - 150 joules
Shock 3 - 200 joules

The default energy selections for pediatric patients:

Shock 1 - 50 joules
Shock 2 - 70 joules
Shock 3 - 85 joules

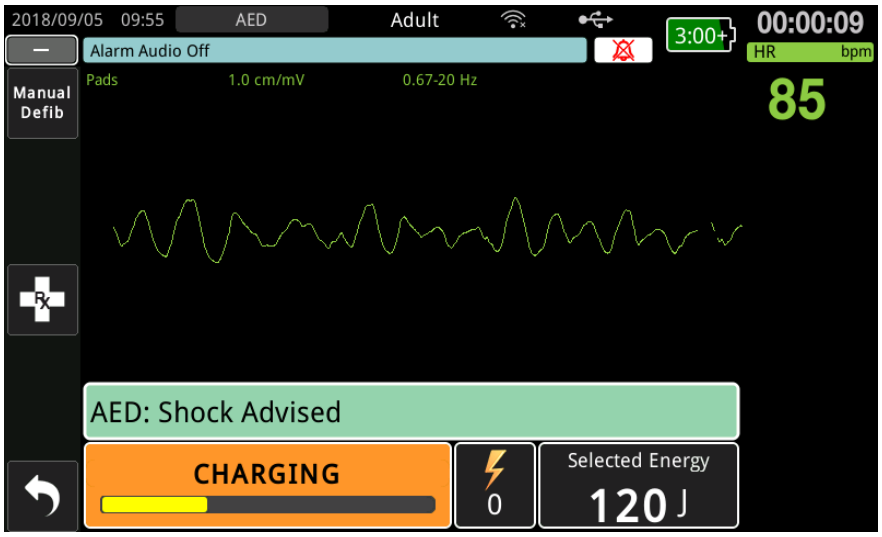
Note: Pediatric defibrillator energy levels should be pre-configured based on site-specific protocols.

Note: Subsequent shocks are delivered at the same energy as the third shock (Shock 3).

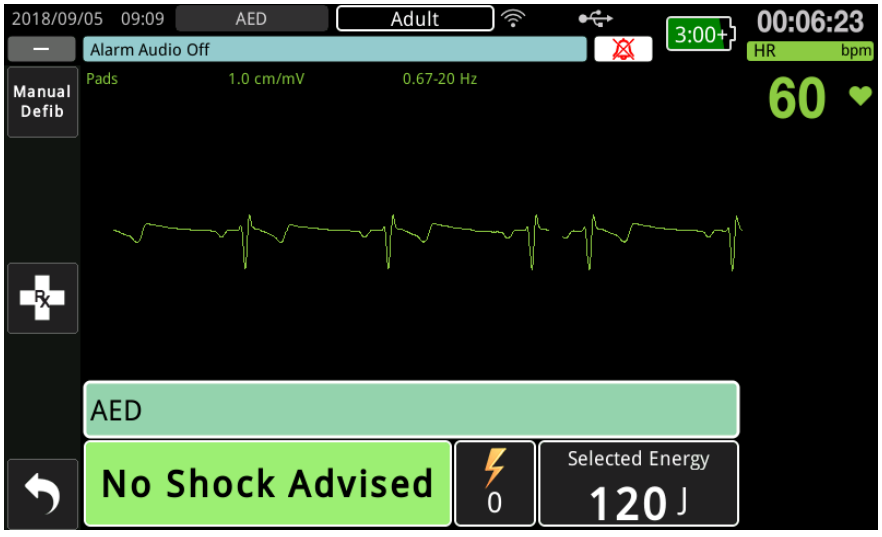
Shock Advised If the patient's rhythm is shockable, the unit displays and announces *Shock Advised* then automatically charges the defibrillator to the preconfigured energy setting. Once the defibrillator is ready to deliver the shock, it announces and displays the *Press Shock* message. The defibrillator automatically prompts the operator to shock the patient at the preconfigured energy level and the **SHOCK** button illuminates.

A continuous tone sounds for 10 to 50 seconds (depending on configuration), followed by a higher pitch tone for 5 to 10 seconds. If the shock is not delivered within this 15 or 60 second interval (depending on configuration), the defibrillator disarms itself and begins a CPR period.

See "2 Press SHOCK" on page 12-8 for the next steps to follow.



No Shock Advised When a nonshockable rhythm is detected, the unit displays a *No Shock Advised* message. After this message, immediately begin chest compressions and continue other treatments per protocol.



2 Press SHOCK

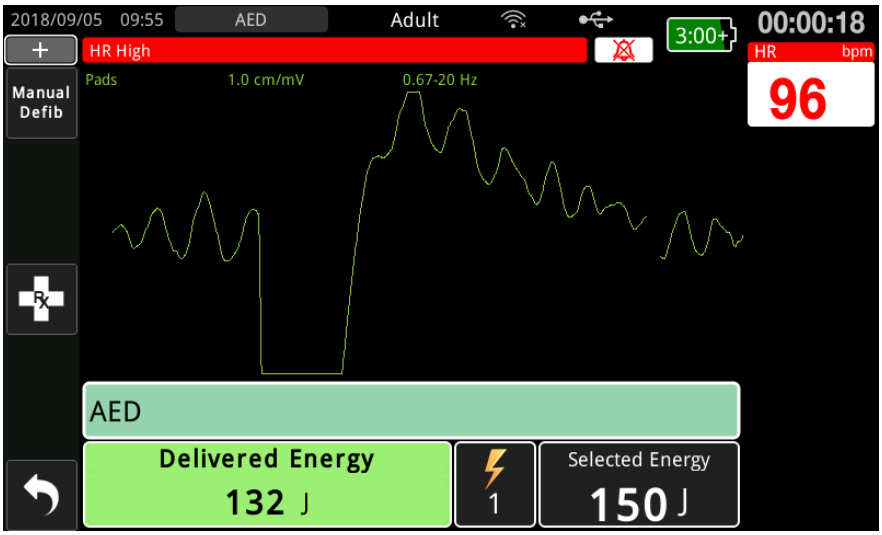
WARNING! **Warn all persons in attendance of the patient to *STAND CLEAR* prior to defibrillator discharge.**

Do not touch the bed, patient, or any equipment connected to the patient during defibrillation. A severe shock can result. Do not allow exposed portions of the patient's body to come in contact with metal objects, such as a bed frame, as unwanted pathways for defibrillation current may result.

Press and hold the illuminated SHOCK button on the front panel until energy is delivered to the patient.

Observe the patient or ECG response to verify that the shock has been delivered.

The delivered energy level and the shock number (1) are displayed in the panel at the bottom of the screen.



Perform CPR

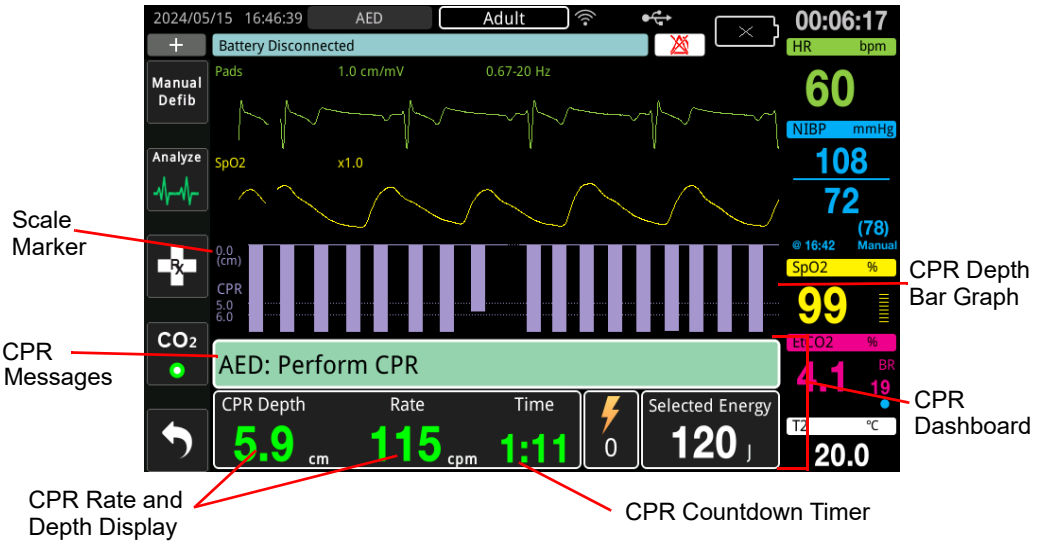
Begin chest compressions and rescue breathing per local protocol. Follow the CPR metronome by compressing the patient's chest in synchronization with the metronome beeps.

WARNING! **Place the patient on a hard surface before starting chest compressions. Compression depth monitoring may not be accurate when compressions are performed with the patient on a flexible surface such as a mattress.**

Note: If ZOLL CPR pads are connected and the patient is an adult, the unit monitors the rate and depth of chest compressions and can display *Push Harder* and *Good Compressions* messages and voice prompts.

CPR Dashboard

The CPR Dashboard displays at the bottom of the screen and shows the CPR rate and depth measurements, CPR messages, and the CPR interval countdown timer. In AED mode, the dashboard is only displayed during CPR periods and is replaced with defibrillation messages during non-CPR periods.



CPR Depth and Rate

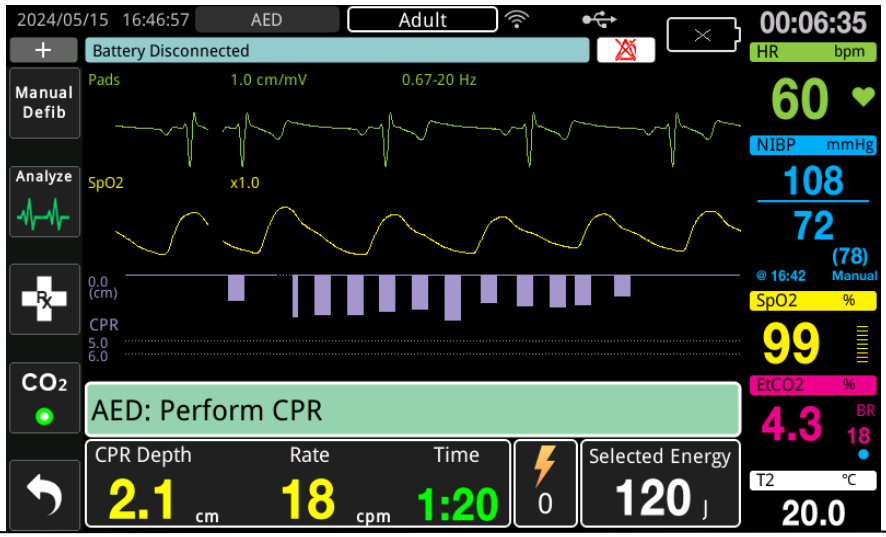
The CPR depth and rate value displays the current chest compression depth and rate (compressions per minute) determined by the ZOLL M2 unit. When no chest compressions have been detected during the past few seconds, the rate display shows "- - -".

CPR Rate and Depth Measurements

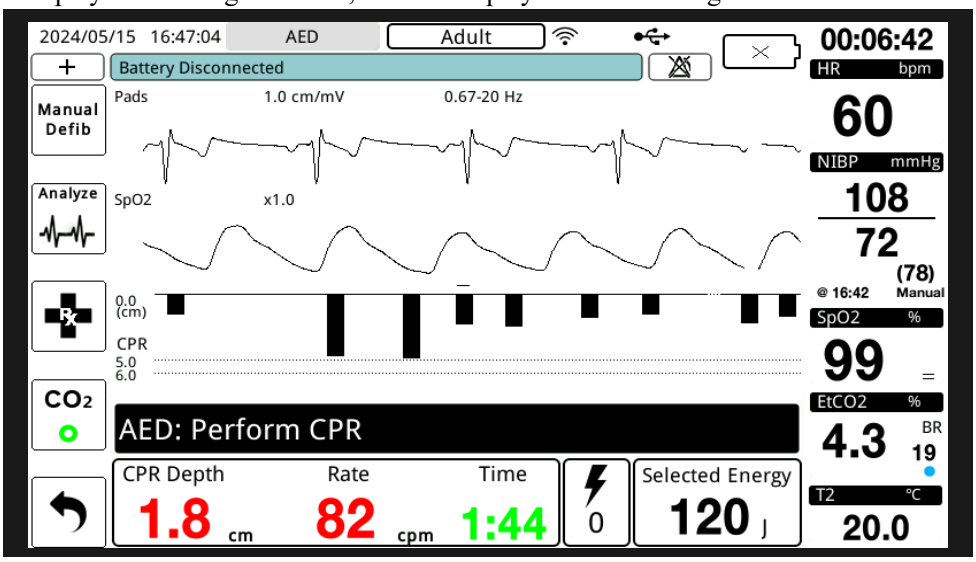
The display of CPR rate and depth measurements differ depending on whether adult or pediatric CPR electrodes are attached.

With Adult CPR Electrodes Attached --

By default, the M2 unit displays CPR rate and depth measurements in green when adult CPR electrodes are attached. If compression depth or rate is consistently out of range of AHA/ERC-recommended numbers (Depth 5-6 cm, Rate 100-120 cpm), the unit displays the measurements in yellow.



If the display is set to high contrast, the unit displays the out-of-range measurements in red.



This color coding is intended to assist the rescuer in determining whether the chest compression rate or depth should be increased or maintained.

With Pediatric CPR Electrodes Attached --

CPR rate and depth measurements *always* display in green when pediatric CPR electrodes are attached.

CPR Countdown Timer

This indicator displays a CPR countdown timer to indicate the time (in minutes and seconds) left in the current CPR interval. It decrements the time until it reaches zero.

During CPR periods, the default value for target compression depth is 5 centimeters. The default value for the CPR interval is 2.0 minutes. These values can be configured using the Supervisor menu when the ZOLL M2 unit is not in use.

Note: Pressing the Analyze button during a CPR period cuts the CPR period short and starts a new ECG analysis.

Compression Voice Prompts (Adults Only)

When chest compressions are detected but their depth is consistently less than the target depth of 5 centimeters (2 inches), the device periodically issues the “Push Harder” voice prompt. If the rescuer responds by increasing compression depth to more than the target depth on a consistent basis, the unit issues a “Good Compressions” prompt.

Note: CPR voice prompts are only available when the patient type is set to adult.

CPR Metronome

The CPR Metronome default configuration is to beep at 105 beeps per minute during all AED CPR periods. The metronome can also be configured to begin beeping at 105 beeps per minute after the first few chest compressions are detected and continue to beep until chest compressions have stopped for more than a few seconds. The metronome can also be configured for other rates using the Supervisor menu.

Operating Messages

The ZOLL M2 device uses both audio and visual prompts to present critical information to operators. The device only issues audio prompts once, but continues to display visual prompts until you take a new action or the device status changes. The following information describes the unit default configuration. If your device has been custom configured, some of the information may be different.

Audio and Display Messages

The display messages and voice prompts that can occur during AED operation are described below.

ATTACH PADS

If the unit powers up without therapy pads connected to the patient or if the pads become detached from the patient during treatment, the *Attach Pads* message is announced and displayed.

ATTACH THERAPY CABLE

If the unit powers up without an MFC attached to the unit or the cable becomes detached during AED mode operation, the *Connect Therapy Cable* message is announced and displayed.

ANALYZING ECG/STAND CLEAR

The *Analyzing ECG* message is displayed and the *Stand Clear* message is displayed and announced when the ECG analysis starts automatically or after pressing the **ANALYZE** button. These messages indicate that an active ECG analysis is in progress.

SHOCK ADVISED

This message is displayed and announced when a shockable rhythm has been detected and defibrillation is advised. The selected energy level is displayed.

PRESS SHOCK

This message is displayed and announced when the ECG analysis has determined that a shock is advised and the selected energy is ready to be delivered.

NO SHOCK ADVISED

When ECG analysis detects a nonshockable rhythm, this message is announced and displays for 5 seconds following completion of the analysis.

CHECK PULSE, IF NO PULSE PERFORM CPR

If configured to do so, this message is displayed and announced in the following situations:

- At the start of the CPR interval
- After a No Shock Advised analysis result
- After a shock is delivered
- If a shock is advised but not delivered

IF NO PULSE, PERFORM CPR

If configured to do so, this message is displayed and announced in the following situations:

- At the start of the CPR interval
- After a No Shock Advised analysis result
- After a shock is delivered
- If a shock is advised but not delivered

PERFORM CPR

If configured to do so, this message is displayed and announced in the following situations:

- At the start of the CPR interval
- After a No Shock Advised analysis result
- After a shock is delivered
- If a shock is advised but not delivered

STOP CPR

After performing CPR for the configured period, the unit will announce and display a *STOP CPR* prompt immediately prior to restarting ECG analysis.

PUSH HARDER (Adult Patients only)

This message is announced when the chest compressions applied during CPR are not deep enough compared to configured target depth settings (5 centimeters or 2 inches) or greater in AHA/ERC recommended protocols).

GOOD COMPRESSIONS (Adult Patients only)

This message is announced when the rescuer responds to a *Push Harder* prompt by consistently increasing chest compression depth to or above the configured target depth.

CHECK PADS - PADS SHORTED

This message is displayed and *Check Pads* is announced when a pads shorted condition is detected. This condition needs to be corrected before ECG analysis or defibrillation treatment can be delivered. This message is displayed when the MFC is connected to the test plug used for the 30 Joule self-test or external paddles are in their storage wells.

CHECK PATIENT

This message is displayed and announced when the unit detects a shockable rhythm after a full Analysis/CPR cycle when the ZOLL M2 is configured to pause after each CPR period. In this configuration, the **ANALYZE** button initiates the ECG analysis/CPR cycle.

Switching to Manual Mode Operation

Follow the steps below to switch the defibrillator from AED mode to Manual Defib mode.

1. Turn the mode selector to DEFIB. The unit enters AED mode.
2. Press the **Manual Defib** quick access key on the left side of the unit to enter the manual mode of operation.
3. Do one of the following based on the password configuration:

- If the unit has not been configured to require a password, the message *Exit AED and Enter Manual Defib Mode?* is displayed. Use the Trim Knob to select **Yes**.

- If the unit has been configured to require a password, when the password screen displays, use the Trim Knob to enter the password, and press the knob to select **OK**. The unit then switches to manual mode.

Note: If you enter the wrong password, the unit remains in AED mode.

To transfer back to AED mode from Manual Defib mode, press the **AED** quick access key, or power off the unit for more than 30 seconds and then power it back on.

Chapter 13
12-Lead ECG Monitoring

This chapter describes how to use the ZOLL M2 unit to acquire, display, print, store, and transmit 12-lead ECG information from adult and pediatric patients.

12-Lead Monitoring Overview

The ZOLL M2 12-lead ECG monitoring has the following functionality:

- Simultaneously acquires and displays 12 Leads of ECG data.
- Acquires and transmits 12-lead ECG data in 4x3 or 2x6, standard, or Cabrera format.
- Prints 12-lead snapshots in 4x3 standard or Cabrera format following acquisition or upon recall from memory.
- Transmits 12-lead snapshots via WiFi in PDF format to e-mail recipients.
- Stores 12-lead snapshot data in full disclosure case files for transfer to a USB memory device.

The 12-lead ECG data displays in the same way that 3- and 5-lead monitor mode waveforms are presented on the screen (newest data on the left of the moving bar and oldest data on the right).

12-lead snapshots are stored in both Summary Report and in full disclosure files. Previously stored 12-lead reports that are still in non-volatile memory can be accessed and printed or sent via e-mail to designated receiving sites. Emailed reports can be sent in the form of PDF files.

When operating in 12-lead ECG mode, all ECG signals are acquired with diagnostic filter bandwidth settings that accurately preserve the S-T segment characteristics. The ZOLL M2 can be configured to acquire 12-lead signals at either 0.525-40 Hz or 0.05 - 150 Hz bandwidth. Both bandwidths accurately preserve S-T segment characteristics, but the 0.525 - 40 Hz filter response attenuates higher frequency components of the ECG signal to reduce noise.

Warning!

- **12-lead ECG monitoring is intended for the recording of signals from adult and pediatric patients in the supine, resting position -- always ensure that the patient is kept motionless during 12-lead ECG signal acquisition.**
- **Excessive body hair or wet, sweaty skin may interfere with electrode adhesion. Remove the hair and/or moisture from the area where the electrode is to be attached.**
- **Remove ECG electrodes from their sealed package immediately prior to use. Using previously opened or out-of-date electrodes may degrade the ECG signal quality.**
- **Monitoring electrodes may become polarized during defibrillator discharge, causing the ECG waveform to briefly go off screen. ZOLL Medical Corporation recommends the use of high-quality silver/silver chloride (Ag/AgCl) electrodes to minimize this effect; the circuitry in the instrument returns the trace to the monitor display within a few seconds.**
- **Wait 15 seconds after defibrillator discharge before attempting a 12-lead acquisition. Electrode polarization subsequent to defibrillator discharge may result in excessive noise on the 12-lead ECG printout.**
- **To ensure protection against the effects of defibrillator discharge and against high-frequency burns, use only 12-lead cables supplied by ZOLL Medical Corporation.**
- **Implanted pacemakers may cause the heart rate meter to count the pacemaker rate during incidents of cardiac arrest or other arrhythmias. Carefully observe pacemaker patients. Check the patient's pulse; do not rely solely on heart rate meters. Dedicated pacemaker detection circuitry may not detect all implanted pacemaker spikes. Patient history and physical exam are important in determining the presence of an implanted pacemaker.**

12-Lead Snapshots

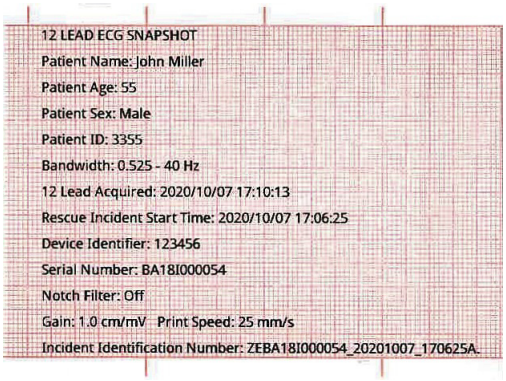
12-lead ECG snapshots that are either printed or sent to other devices include the following:

- 12 ECG snippets, including both limb and chest lead signals, plus 10 seconds of continuous ECG lead II waveform displayed in the configured format
- 12-lead acquisition time and date
- Rescue incident start time
- ZOLL M2 device identifier
- ZOLL M2 serial number
- ECG bandwidth used for signal acquisition
- Patient name (if available), or a blank data entry field for writing in the patient's name
- Patient ID number (if available), or a blank data entry field for writing in the patient's ID
- Patient age (if available), or a blank data entry field writing in the patient's age
- Patient sex (if available), or a blank data entry field writing in the patient's sex
- Incident identification number (name of full disclosure file for the incident)

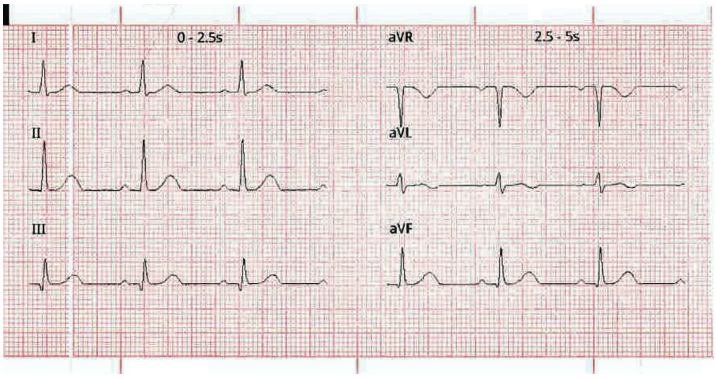
Note: 12-lead ECG snapshots are included in case files and summary reports.

12-Lead Snapshot Example (4 x 3 Standard)

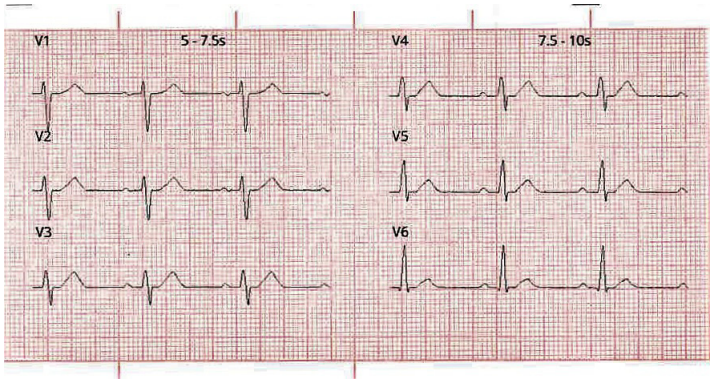
Patient/Case Information



Leads I, II, III (0 to 2.5 seconds) and leads aVR, aVL, aVF (2.5 to 5 seconds)



Leads V1, V2, V3 (5.0 to 7.5 seconds) and leads V4, V5, V6 (7.5 to 10 seconds)



Lead II

12-Lead ECG Monitoring Setup

To set up 12-lead ECG monitoring, perform the following steps. These steps are covered in detail in this section. Once the setup is complete, you can monitor the patient.

1. Prepare the patient's skin for electrode application.
2. Apply the electrodes to the patient; connect each lead of the ECG cable to the appropriate electrode.
3. Connect the 12-lead cable to the ZOLL M2 unit.

Preparing the Patient for Electrode Application

The proper application and location of electrodes is essential for high quality 12-lead ECG monitoring. Good contact between the electrode and skin minimizes motion artifact and signal interference. Electrode application at standardized locations facilitates 12-lead ECG interpretation.

Before applying electrodes, prepare the patient's skin, as necessary:

- Shave or clip excess hair at electrode site.
- Clean oily skin with an alcohol pad or soap and water.
- Rub site briskly to dry.
- Abrade skin at each electrical site to remove dead/flaking skin and to optimize electrode to skin contact.

Applying Electrodes to the Patient

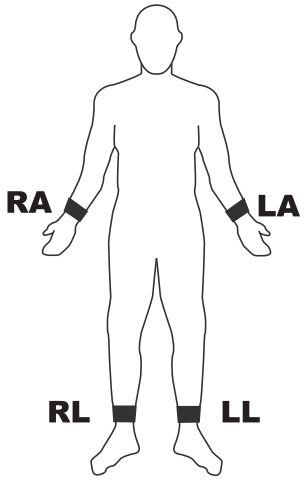
Depending on local usage, ECG lead wires are marked with certain labels. Refer to the following table for labels and color codes for the different lead sets

Location	AHA[1] Labels	IEC[2] Labels
Right Arm	RA (white)	R (red)
Left Arm	LA (black)	L (yellow)
Right Leg	RL (green)	N (black)
Left Leg	LL (red)	F (green)
Chest	V1	C1
Chest	V2	C2
Chest	V3	C3
Chest	V4	C4
Chest	V5	C5
Chest	V6	C6

[1] American Heart Association

[2] International Electrotechnical Commission

Patients should be in a resting, supine position (with limbs supported) when performing 12-lead ECG monitoring. ZOLL Medical Corporation recommends placing the limb electrodes anywhere along the ankles and wrists.



Avoid placing electrodes over tendons and major muscle masses.

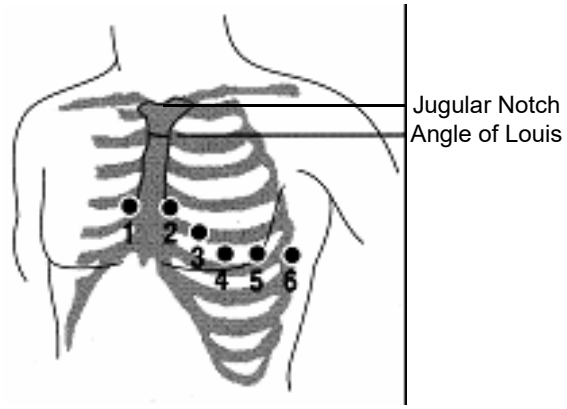
Make sure that the ECG electrodes are placed to allow defibrillation, if necessary.

Place the precordial electrodes across the chest in the following locations:

Electrode	Placement
V1/C1	Fourth intercostal space, at the patient's right sternal margin.
V2/C2	Fourth intercostal space, at the patient's left sternal margin.
V3/C3	Midway between V2/C2 and V4/C4.
V4/C4	Fifth intercostal space, on the patient's midclavicular line.
V5/C5	Patient's left anterior axillary line, at the horizontal level of V4.
V6/C6	Patient's left midaxillary line, at the same horizontal level as V4 and V5.

Locating the V1/C1 position (fourth intercostal space) is critically important because it is the reference point for locating the placement of the remaining V-leads. To locate the V1/C1 position:

1. Place finger on top of the jugular notch (figure below).
2. Move finger slowly downward about 1.5 inches (3.8 centimeters) until a slight horizontal ridge or elevation is felt. This is the "Angle of Louis," where the manubrium joins the body of the sternum.



3. Locate the second intercostal space on the patient's right side, lateral to and just below the "Angle of Louis."
4. Move finger down two more intercostal spaces to the fourth intercostal space which is the V1 position.

Note: When placing electrodes on female patients, always place leads V3-V6 under the breast rather than on the breast.

Connecting the 12-Lead Cable to the ZOLL M2 Unit

Connect the 12-lead ECG cable to the ECG input connector on the back of the unit as shown below:

Monitoring the Patient's 12-Lead ECG

After aquiring a patient's 12-lead ECG data, it can be transferred to a USB flash drive or the corresponding 12-lead ECG snapshot (in the configured format) can be emailed to a selected internet destination(s) via Wi-Fi.

Note that default email addresses must be set up in order to transfer data via email. If you have not already done so, refer to the *ZOLL M2 Configuration Manual* for instructions.

Setting the Controls

Turn the mode selector to MONITOR. The red and yellow lights on the top of the unit flash on and off, and then the unit displays the message *All Tests Passed*.

If the unit displays the *ECG Lead Off* message, inspect the ECG electrodes, lead wires, and cables for proper connections.

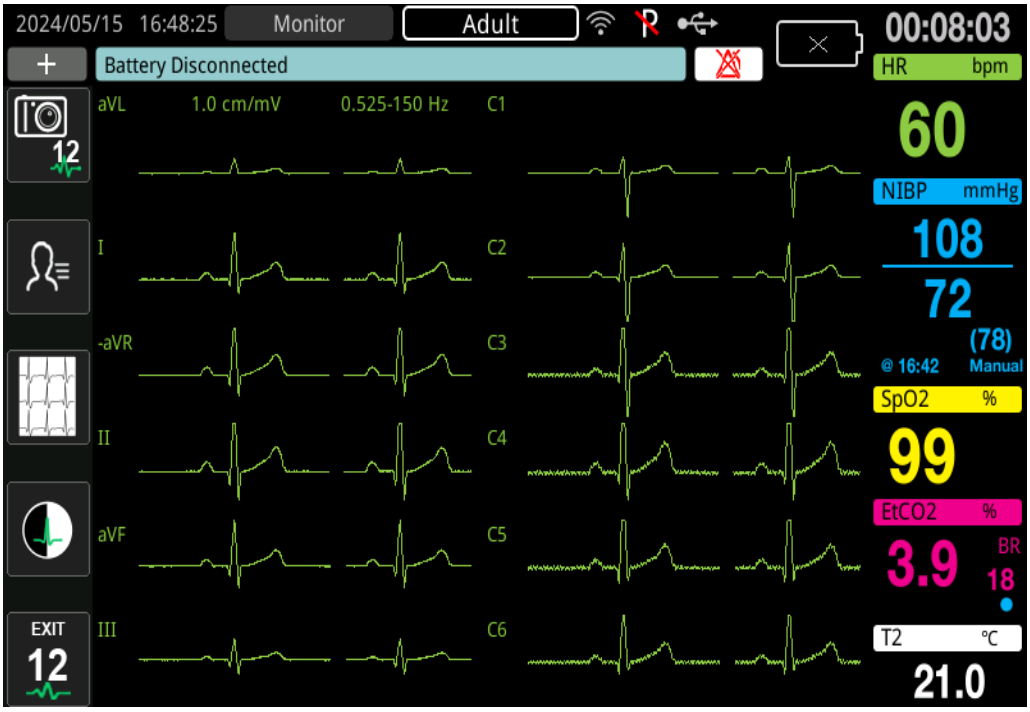
Entering 12-Lead Monitoring Mode

To enter 12-lead monitoring mode, press the 12-lead quick access key (12). The ZOLL M2 unit replaces the waveform field of the monitor mode display with a field scrolling the 12-lead

ECG signals in a 2 column by 6 row “real time” format, with the size setting for all leads displayed above the waveforms area.

The ECG signals that are displayed in the 2-column by 6-row format include (from top to bottom of the screen):

- Leads I,II,III, aVR, aVL and aVF in the left column
- Leads V1 - V6 in the right column
- A dashed line **“- - - ”**for any lead indicates that that electrode/lead wire is not connected to the patient. If all leads are dashed, this indicates that at least one of the limb leads is disconnected.



12-Lead Monitoring Functions

In the 12-lead monitoring mode, ZOLL M2 unit displays quick access keys on the left side of the screen to facilitate performing the following functions:

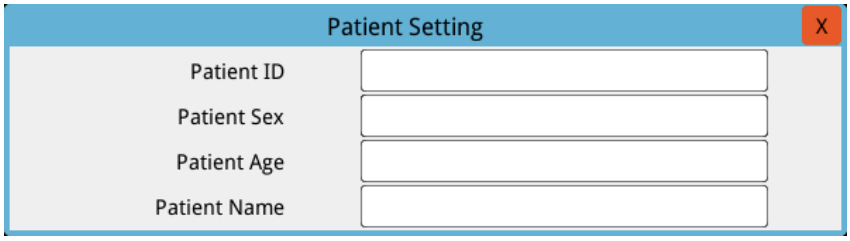
Quick Access Key	Function
	Acquire a 12-lead ECG snapshot. (See *“Acquiring 12 Lead Snapshots” on page 13-11*.)
	Enter patient demographic data (ID, sex, age, name). (See “Entering Patient Demographic Information” on page 13-9).

Quick Access Key	Function
	Select and print previously acquired (stored) 12-lead ECG snapshots. Select and transfer previously acquired (stored) ECG snapshots to a USB flash drive or other device via email. (See “Printing and Transferring Previously Acquired Snapshots” on page 13-14.)
	Changes the brightness setting — toggles through high contrast display (white background) and color display (black background).
	Return to MONITOR mode to view the waveforms and controls that were displayed prior to entering the 12-lead ECG mode.

Entering Patient Demographic Information

Patient demographic information can appear in the 12-lead ECG data snapshots if it is entered in the Patient Setting window. If this information is not entered during the 12-lead monitoring process, it is not included in 12-lead ECG snapshots.

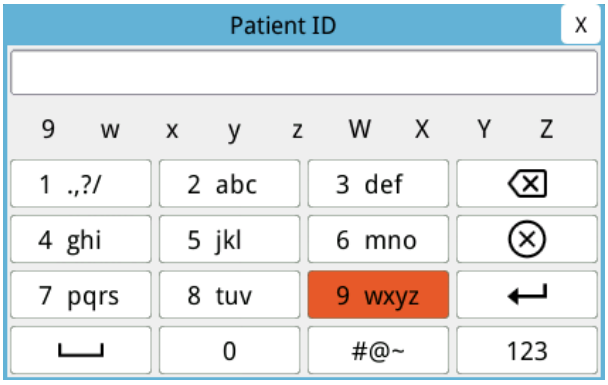
To enter patient information, press the Patient Information quick access key (). The screen displays the Patient Setting window to allow entering the patient’s identification number, sex, age, and name:



To enter patient information, rotate the Trim Knob to highlight a parameter in the window, then press the Trim Knob to select it.

Entering the Patient ID

When selecting the Patient ID from the Patient Setting window, the screen displays the Patient ID window.



To select a character for the patient identification, rotate the Trim Knob to highlight the key containing the desired character, then press the knob to select it. The characters shown on the selected key are now displayed below the ID field. Using the Trim Knob, highlight the desired character then press the Trim Knob to select it. The selected character now appears in the ID field.

Use the Trim Knob to highlight the next or previous character in the ID field then repeat the above procedure to enter a new character.

When the patient ID is complete, rotate the Trim Knob to highlight **Enter** (↵), then press the knob to select it.

Entering Patient Sex and Age

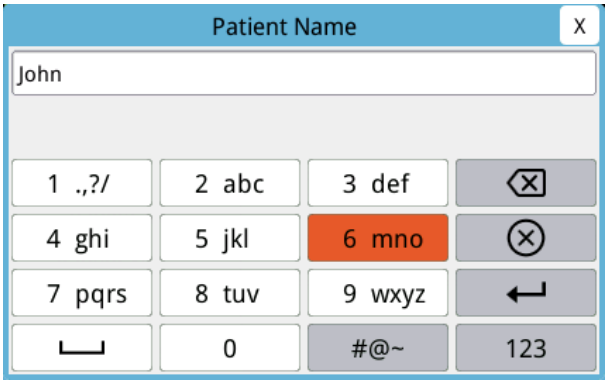
The Patient Setting window provides fields for the Patient Age and Patient Sex parameters. To enter a value, highlight and select the parameter, and then specify a new value as follows:

To enter a value for Patient Age, turn the Trim Knob until the desired value displays in the field, then press the knob to select the age.

To enter a setting for Patient Sex, use the Trim Knob to toggle between M (male), and F (female), then press the knob to select the value.

Entering the Patient Name

When you select the Patient Name from the Patient Setting window, the screen displays the Patient Name window.



To select a character for the patient name, rotate the Trim Knob to highlight the key containing the desired character, then press the knob to select it. The characters shown on the selected key are now displayed in the line below the patient name field. Using the Trim Knob, highlight the desired character then press the Trim Knob to select it. The selected character now appears in the patient name field.

Use the Trim Knob to highlight the next or previous character in the patient name field then repeat the above procedure to enter a new character.

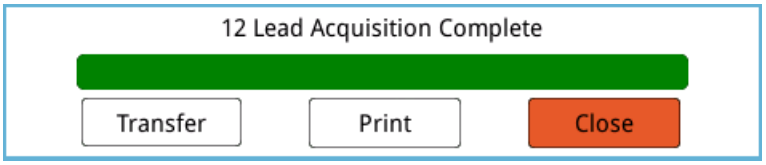
When the patient name is complete, rotate the Trim Knob to highlight **Enter** ( ), then press the knob to select it.

Acquiring 12 Lead Snapshots

Press the Acquire quick access key ( ). The ZOLL M2 displays the *Acquiring 12 Lead* status bar as it collects 10 seconds of 12-lead ECG data.

Note: If you press **Cancel** to stop the acquisition, the unit displays the message *12 Lead Acquisition Halted* and the data is not saved to memory.

After acquiring the ECG data, the unit displays the message *12 Lead Acquisition Complete*. If the Automatic Printing of 12-Lead Report setting is enabled in the Supervisor menu, the ZOLL M2 automatically prints the 12-lead ECG data after it has been acquired.



Choose from the following options:

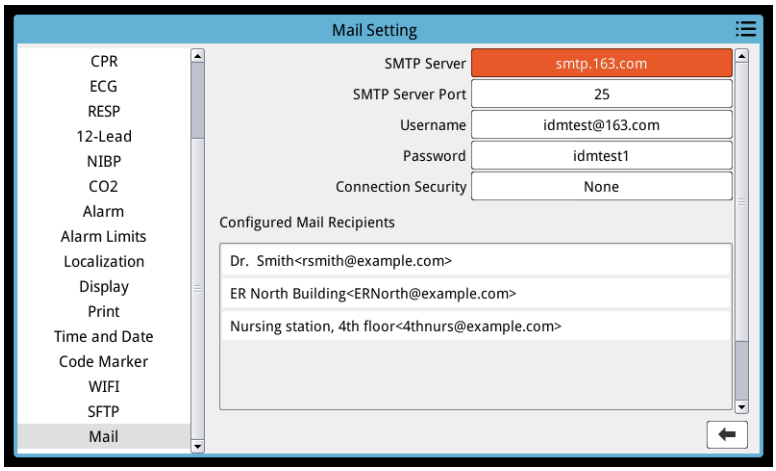
To Select	Do This
Transfer	Turn the Trim Knob to highlight **Transfer** and press the knob to select it. The device displays the following options: **USB** - Insert the USB flash drive into the USB connector on the rear panel of the unit. Turn the Trim Knob to highlight **USB** and press the knob to select it. The 12-lead ECG snapshot is automatically transferred to the USB flash drive. When the data transfer is complete, the ZOLL M2 displays the message, *Transfer Successful, You Can Remove the USB Disk.* **E-mail** - Rotate the Trim Knob to highlight **E-mail** and press the knob to select it. Select one of the previously configured email addresses in the Supervisor menu (See “Adding E-mail recipients,” below.) When the data transfer is complete, the ZOLL M2 unit displays the message,*12 Lead ECG Transfer - Successful.*
Print	(This option is only needed when the ZOLL M2 unit has been configured to not automatically print after acquiring the 12-lead data or when an additional printed copy is desired.) Rotate the Trim Knob to highlight **Print** and press the knob to select it. The ZOLL M2 unit automatically prints the 12-lead ECG snapshot.
Close	Rotate the Trim Knob to highlight **Close** and press the knob to select it. The ZOLL M2 returns to 12-lead ECG monitoring without printing or transferring the 12-lead report.

Adding E-mail recipients

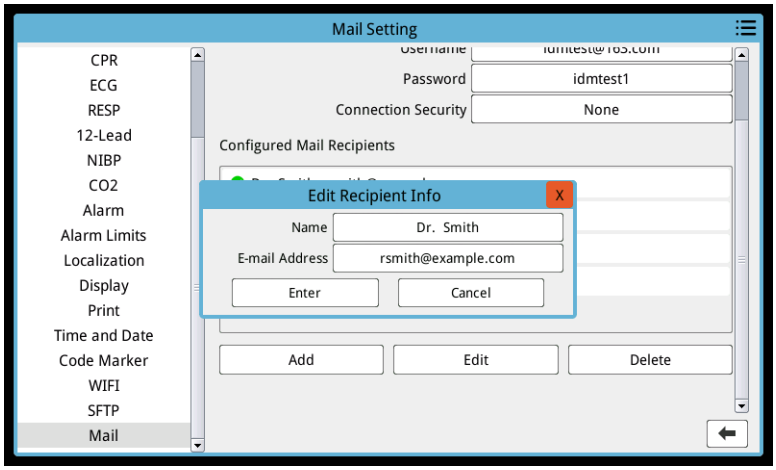
12-lead snapshots can be sent in PDF format to e-mail addresses via a wireless connection. To add e-mail addresses:

1. In the Supervisor menu, press the Trim Knob to select Modify Config.

2. Rotate the Trim Knob to highlight Mail from the menu on the left side of the window and press the knob to select it. The Mail Setting window displays.



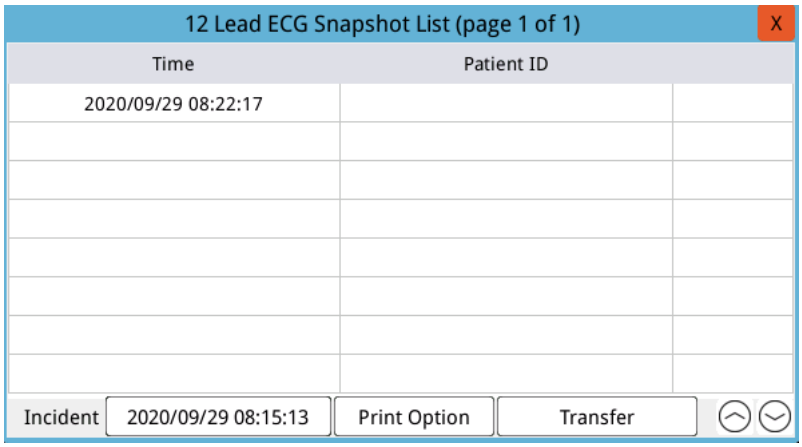
3. Rotate the Trim Knob to move to each field on the top and press the knob to enter the applicable information, including SMTP server, SMTP server port, Username, Password, and Connection Security that are used to log in the sender's email to send email to the recipients.
4. Rotate the Trim Knob to move to the Add field then press the knob to select it. The Edit Recipient Info menu displays.



5. Rotate the Trim Knob to move to each field and press the knob to enter the applicable information.
6. After completing entering the recipient information, rotate the Trim Knob to move to **Enter,**
7. Rotate the Trim Knob to move to the category list icon at the top right corner and press the knob to exit to the Supervisor Menu. Select "Save Config then Exit" to save the configuration and exit the Supervisor menu.

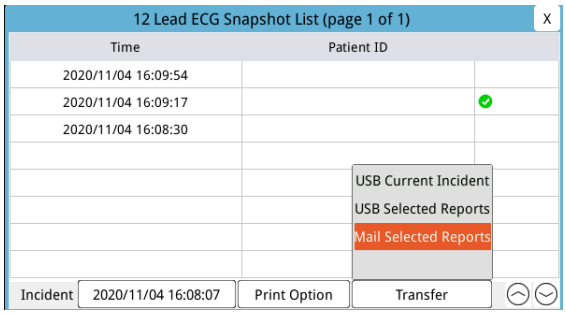
Printing and Transferring Previously Acquired Snapshots

To acquire and send 12-lead snapshots to either a USB flash drive or an email address via a wireless connection, press the Select/Transfer 12-lead snapshots quick access key ( ). The 12-Lead Snapshot window displays:



If you want to print or transfer multiple incidents, rotate the Trim Knob to highlight each incident, then press the knob to select each one. Use the up and down caret keys on the bottom right of the window to select incidents that do not display on the current page. Once you have

selected the incident a green check mark displays next to each one. You can then do one of the following:

To Select	Do This
Print Option	Turn the Trim Knob to select **Print Option** and press in the knob to select it, then use the Trim Knob for the following options: **Current Incident** - Automatically prints the 12-lead snapshots acquired during the incident that is currently highlighted. **Selected** - Automatically prints 12-lead snapshots acquired during the incidents that you have selected (indicated by a green check mark). See “Viewing 12-Lead Snapshot Printouts” on page 13-15 to view an example of a printed snapshot.
Transfer	Use the Trim Knob to select **Transfer**, then the device displays the following options: **Mail Current Rescue** - Automatically emails the incident that is currently highlighted to one of the previously configured email addresses. **Mail Selected Reports** - Automatically emails 12-lead reports acquired during the selected incidents (indicated by a green check mark) to one of the previously configured email addresses. In the dialog box, use the Trim Knob to select **E-Mail** to confirm.  **USB Current Incident** - Automatically sends 12-lead reports acquired during the incident that is currently highlighted to the connected USB flash drive. **USB Selected Reports** - Automatically sends 12-lead reports acquired during the incidents that you have selected (indicated by a green check mark) to the connected USB flash drive. In the dialog box, use the Trim Knob to select **E-mail** to confirm.

Viewing 12-Lead Snapshot Printouts

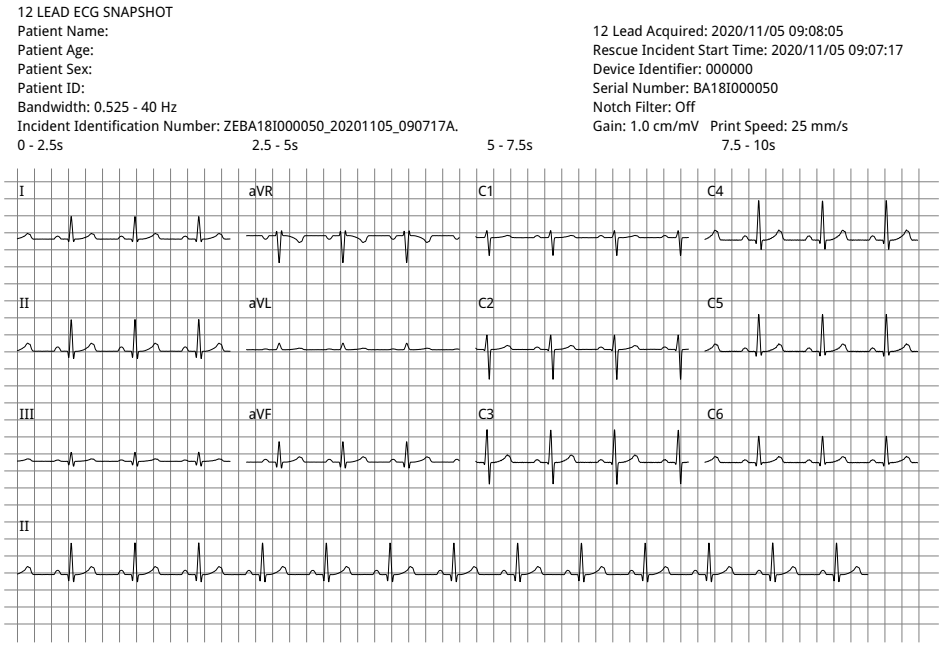
This option allows you to specify the print format for the 12-lead waveform traces. When you are printing to a printer, you can print in the 4 x 3 standard (default) or the 4 x 3 Cabrera format.

12-lead reports that are transferred via PDF can be printed in the following formats: 4 x 3 standard (default), 4 x 3 Cabrera, 2 x 6 standard, or 2 x 6 Cabrera. Each of the 12-lead print formats are described below. Note that each format includes a 10 second Lead II ECG strip after the ECG snippets.

4 x 3 Standard

The 4 x 3 format provides 2.5-second ECG snippets arranged in a staggered time windows format:

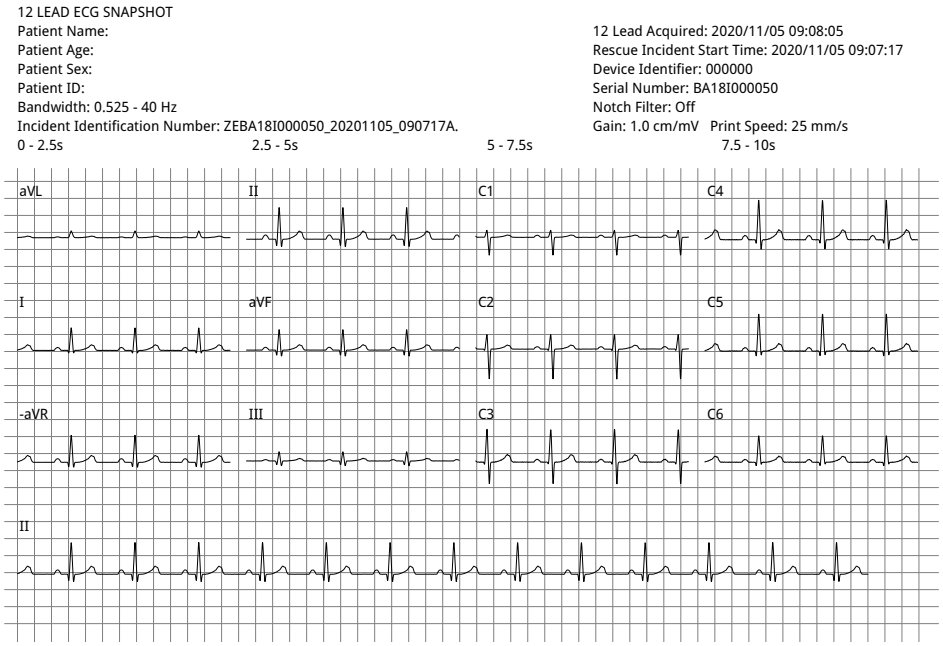
- Leads I, II, III (0 to 2.5 seconds)
- Leads aVR, aVL, aVF (2.5 to 5.0 seconds)
- Leads V1, V2, V3 (5.0 to 7.5 seconds)
- Leads V4, V5, V6 (7.5 to 10.0 seconds)



4 x 3 Cabrera

The 4 x 3 Cabrera format provides 2.5-second ECG snippets arranged in a staggered time windows format:

- First column of 3 leads (aVL, I, -aVR) for 0 - 2.5 seconds of acquisition period
- Second column of 3 leads (II, aVF, III) for 2.5 - 5.0 seconds of the acquisition period
- Third column of 3 leads (V1, V2, V3) for 5.0 - 7.5 seconds of the acquisition period
- Fourth column of 3 leads (V4, V5, V6) for 7.5 - 10 seconds of the acquisition period

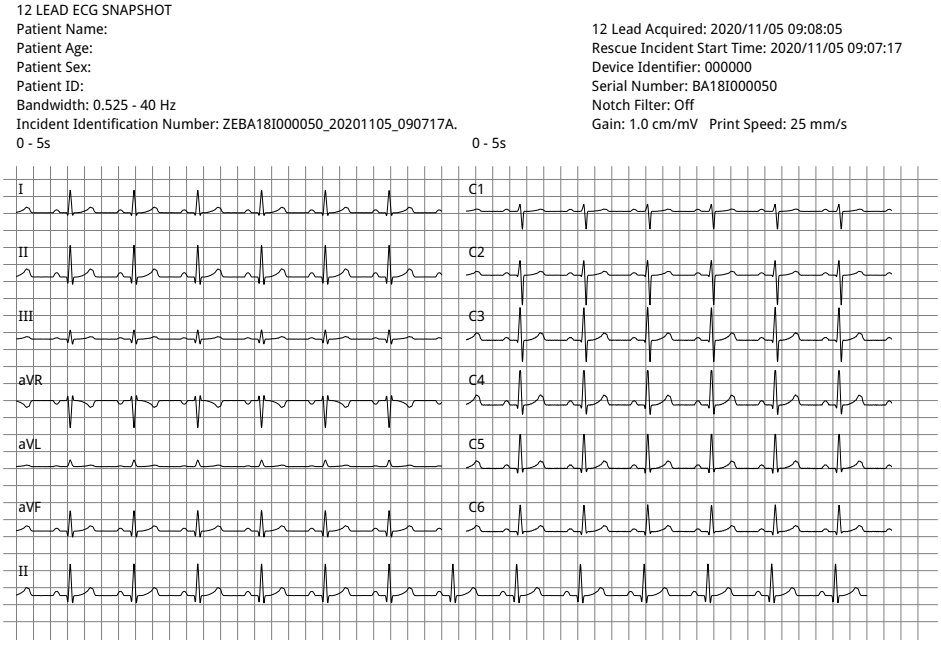


2 x 6 Standard (PDF Only)

The 2 x 6 standard format provides 5-second ECG snippets that are transferred to PDF formatted in a matrix of 2 columns and 6 rows:

- First column of 6 leads (I, II, III, aVR, aVL, aVF)
- Second column of 6 leads (V1, V2, V3, V4, V5, V6)

Each column shows 5 seconds of data; all data shown is simultaneously recorded during the first 5 seconds of the acquisition period.

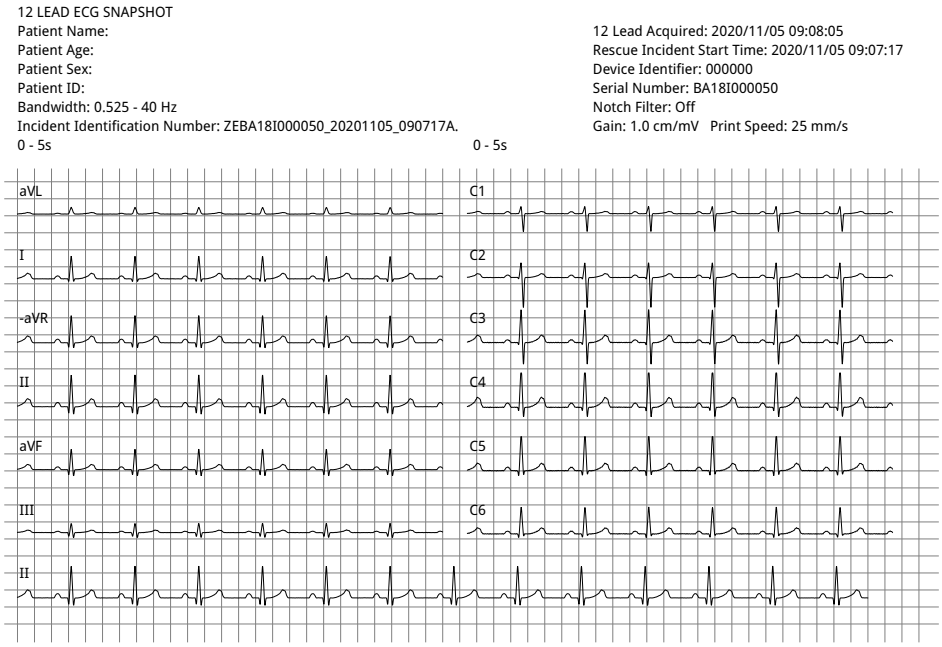


2 x 6 Cabrera (PDF Only)

The 2 x 6 Cabrera format provides 5-second ECG snippets that are transferred to PDF formatted in a matrix of 2 columns and 6 rows:

- First column of 6 leads (aVL, I, -aVR, II, aVF, III)
- Second column of 6 leads (V1, V2, V3, V4, V5, V6)

Each column shows 5 seconds of data; all data shown is simultaneously recorded during the first 5 seconds of the acquisition period.



When you are done viewing and printing the 12-lead waveform traces, press Exit 12-lead quick access key (Exit 12) to restore the display of other monitoring functions.

Chapter 14
Manual Defibrillation

ECG leads and paddles are a defibrillation-protected Type CF patient connection (applied part).

Warning! **To avoid risk of electrical shock, do not allow electrolyte gel to accumulate on hands or paddle handles.**

When defibrillating with paddles, use thumbs to operate the SHOCK buttons in order to avoid inadvertent operator shock. No portion of the hands should be near the paddle plates.

Be sure to use the proper paddles/electrodes based on the size of the patient (adult - large, pediatric/neonatal - small) and patient type (energy settings).

Emergency Defibrillation Procedure with Paddles

The Manual Defibrillation mode (or Manual mode) provides the user with full control over the defibrillator's functions. This mode allows for determining the need for treatment, selecting the defibrillator energy setting, charging the unit, then delivering therapy when needed.

Modes of Operation

When configured as a manual defibrillator, the ZOLL M2 will begin operating in the manual mode each time you set the Mode Selector to DEFIB. You can then enter AED mode by

pressing the **AED** quick access key. The operating mode of the defibrillator is indicated by the words Manual Defib or AED at the top of the display screen. Once in AED mode, the ZOLL M2 unit operates in AED mode whenever you set the Mode Selector to DEFIB until the device is turned off for more than 30 seconds, or you enter the manual mode through the Manual Defib quick access key.

Manual Mode

In Manual Defibrillation mode, you can choose any available energy setting and deliver energy in any desired sequence of selected energies. However, the default configuration provides pre-configured shock energy selections for each patient type. The ZOLL M2 monitor/defibrillator displays the selected energy at all times, but if configured to automatically select energy settings, it increases the energy setting after each shock delivery until the maximum available energy is selected. To stop this automatic sequencing at any time, select a different energy.

The following actions can be performed in manual mode:

- Defibrillate using internal or external paddles, hands free electrodes, or CPR equipped electrodes.
- Charge the unit and defibrillate at any time during the cardiac cycle or perform synchronized cardioversion with shock delivery synchronized to the patient's R-waves.
- Deliver chest compressions while the ZOLL M2 provides feedback regarding rate and depth (when using ZOLL CPR sensor-equipped electrodes).

Patient Type

The ZOLL M2 can operate in either the Adult or Pediatric mode; select adult for adult patients, select pediatric for pediatric/neonate patients. In adult mode, the automatic defibrillator energy selections are tailored for use on adult patients. In the pediatric mode, the defibrillator energy selections are oriented towards use on patients from 1 - 8 years of age or < 25 Kg. See the default energy selections for adult and pediatric patients on page 14-4.

Determine the Patient's Condition Following Local Medical Protocols

Verify the following:

- Unconsciousness
- Absence of breathing
- Absence of pulse

Begin CPR Following Local Medical Protocols

Request additional assistance.

Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary.

Turn on Unit

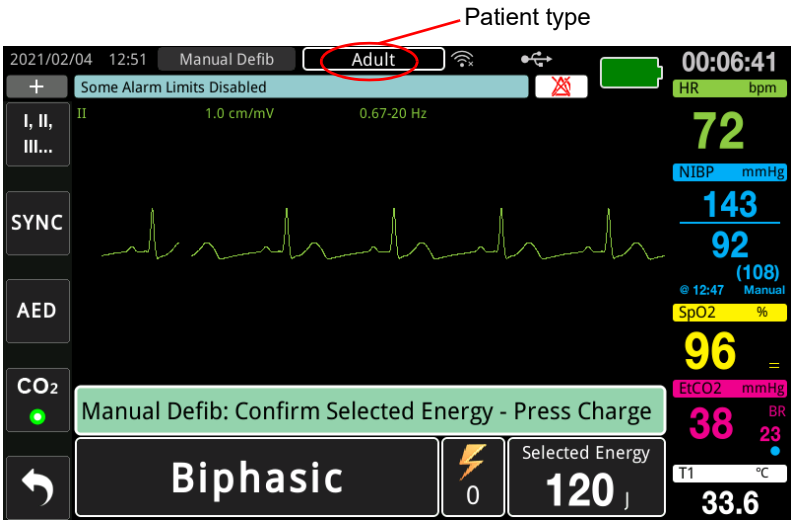
Turn the mode selector to DEFIB. If the unit was previously turned off, the red and yellow lights on the top of the unit flash on and off, and the message *All Tests Passed* displays.

Note: If the ZOLL M2 unit is configured to start up in AED mode, you need to press the **Manual Defib** quick access key on the left side of the unit's front panel to enter the Manual mode of operation.

Set Patient Type

Before starting therapy, make sure to specify the correct patient type (that appears at the top of the window display). To change the patient type, turn the Trim Knob to highlight the patient type at the top of the window. Press the Trim Knob to select it and then turn it to select another patient type. Press the Trim Knob again to confirm the selection.

After setting the patient type, the ZOLL M2 unit selects and displays the default energy for the selected patient type. It also automatically selects the energy for subsequent shocks that are appropriate for the patient.



1 Select Energy Level

You can either manually select the energy level or use the pre-configured energy settings. To select the energy level, press the **Energy Select** arrows up or down to select the desired energy level. These buttons are located either on the front of the unit or on the STERNUM paddle.

If Shocks 1, 2, and 3 have been configured to escalating energy levels using the Auto Energy Escalation feature, the ZOLL M2 automatically sets the energy to the preconfigured Energy Level: Shock 1, 2, 3 setting at power-up and after each of the first two shocks. Manually changing the energy level outside the preprogrammed sequence and delivering a shock disables the automatic escalation function.

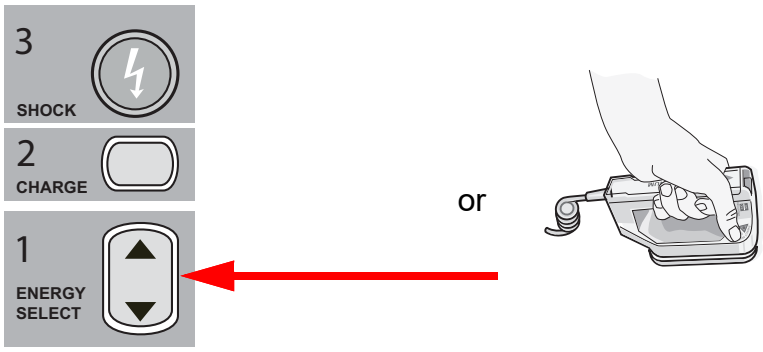
The default energy selections for adult patients:

Shock 1 - 120 joules
Shock 2 - 150 joules
Shock 3 - 200 joules

The default energy selections for pediatric patients:

Shock 1 - 50 joules
Shock 2 - 70 joules
Shock 3 - 85 joules

Note: Pediatric and neonatal defibrillator energy levels should be selected based on site-specific protocols.



The selected energy level is displayed at the bottom of the display screen.

Prepare Paddles

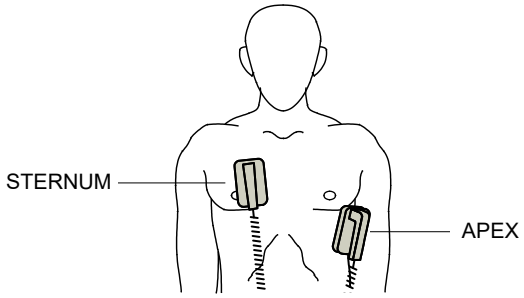
Ensure that the paddles are connected to the multi-function cable (MFC), and that the cable is connected to the ZOLL M2 unit. Apply a liberal amount of electrolyte gel to the electrode surface of each paddle, and rub the electrode surfaces together to evenly distribute the applied gel. (Electrode gel patches can be substituted for the gel.)

Warning! **To avoid risk of electrical shock, do not allow electrolyte gel to accumulate on hands or paddle handles.**

Apply Paddles to Chest

Apply the paddles firmly to the anterior wall of the chest. Place the STERNUM paddle to the right of the patient's STERNUM (patient's right), just below the clavicle.

Place the APEX paddle on the chest wall, just below and to the left of the patient's left nipple, along the anterior-axillary line.



Rub the paddles against the skin to maximize the paddle-to-patient contact.

WARNING! **Do not permit gel to accumulate between the paddle electrodes on the chest wall (gel bridge). This could cause burns and reduce the amount of energy delivered to the heart.**

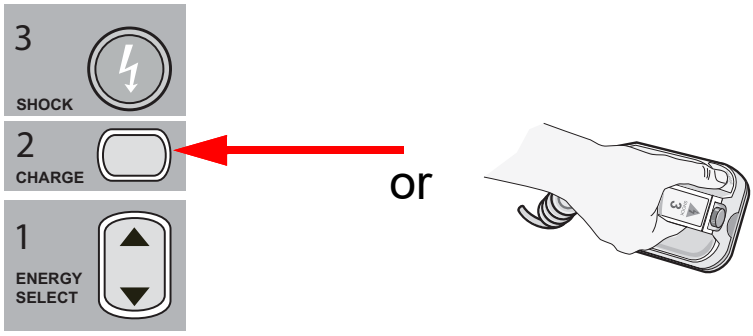
If using defibrillator gel pads, make sure that the size of the pad is large enough to cover the entire paddle electrode area.

The paddles may be used for ECG monitoring in emergency situations when time does not allow connection of standard ECG monitoring electrodes.

If an ECG cable and ECG electrodes are in use, press the LEAD button to select the desired ECG lead.

2 Charge Defibrillator

Press the **CHARGE** button on the APEX paddle handle or on the front panel.



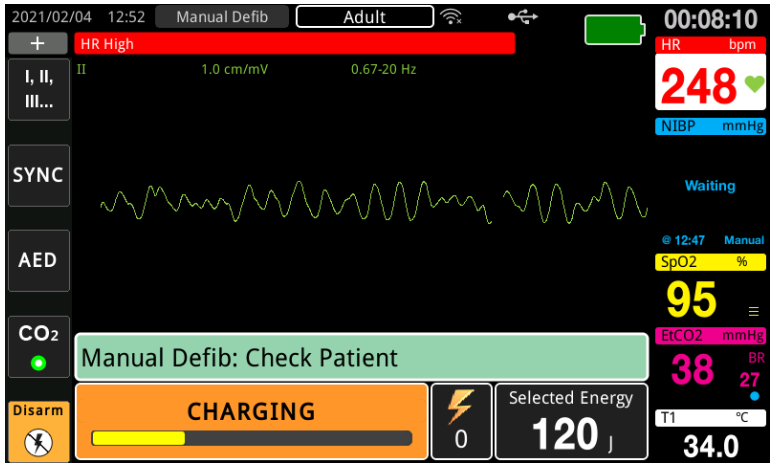
If the SHOCK buttons on the paddles are depressed when the unit is charging, a *Release Shock Button* message appears on the display.

To increase or decrease the selected energy after pressing the **CHARGE** button, use the defibrillator **ENERGY SELECT** buttons on either the STERNUM paddle or the defibrillator front panel, then press the **CHARGE** button again to restart the charging process.

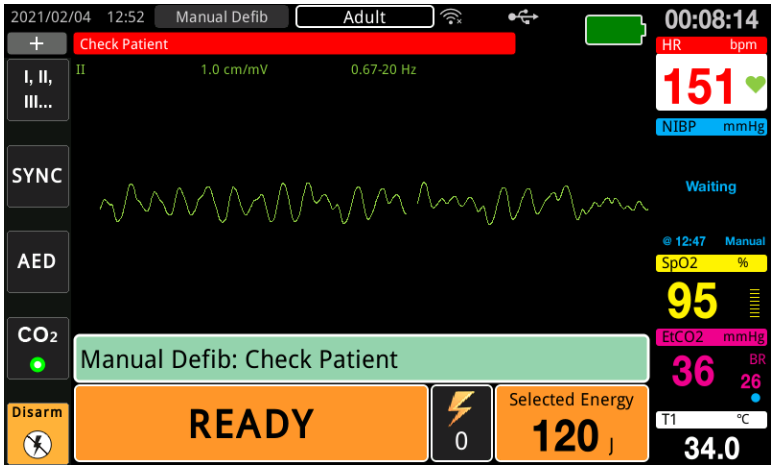
Note: This disables auto energy escalation until the unit is turned off for greater than 30 seconds and then turned back on.

Caution Changing the selected energy while the unit is charging or charged causes the defibrillator to disarm itself. Press the **CHARGE** button again to charge the unit to the newly selected energy level.

A *CHARGING* message displays at the bottom of the screen, and a distinctive tone sounds indicating that the unit is charging.



The energy bar graph on the bottom of the screen highlights the charge level until it reaches the selected energy. When the unit is fully charged, the tone changes to a continuous charge ready tone, and the *READY* message displays at the bottom of the screen. The charge indicator on the apex paddle illuminates when the ZOLL M2 unit is ready to deliver defibrillation energy to the patient.



3 Deliver Shock

WARNING! **Warn all persons in attendance of the patient to STAND CLEAR prior to defibrillator discharge.**

Do not touch the bed, patient, or any equipment connected to the patient during defibrillation. A severe shock can result. Do not allow exposed portions of the patient's body to come into contact with metal objects, such as a bed frame, as unwanted pathways for defibrillation current may result.

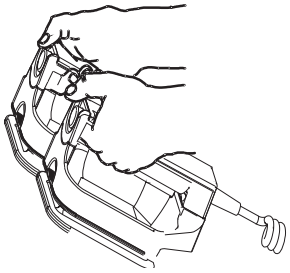
Apply each paddle to the patient's chest with a force of 10 - 12 kilograms (22 - 26.4 pounds) in order to minimize patient impedance and achieve optimal results.

Note: To cancel the defibrillation and disarm the defibrillator at any time, press the **Disarm** quick access key (or press the Energy select up or down key).

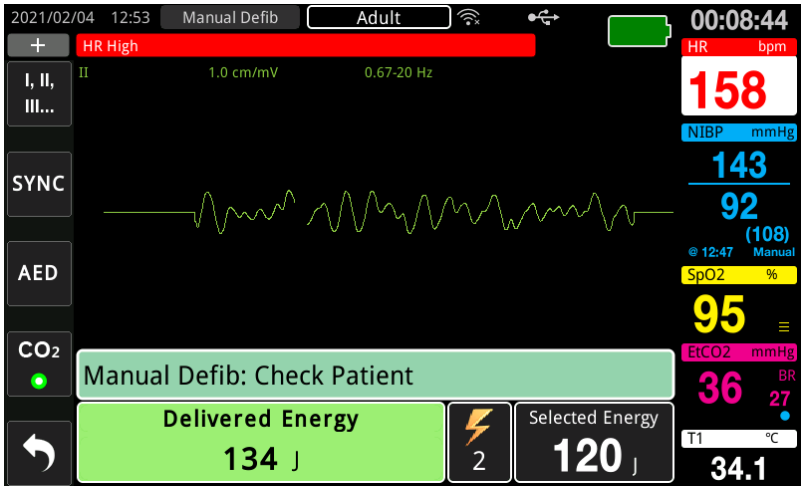
The shock must be delivered within 15 to 60 seconds after the ready state begins (depending on configuration), or the defibrillator will automatically disarm itself.

Use both thumbs to simultaneously press and hold both **SHOCK** buttons (one on each paddle) until energy is delivered to the patient.

Note: The front panel **SHOCK** button ( ) is inactive when using external paddles with Shock button(s). Pressing this button instead of the paddle **SHOCK** buttons produces an audible invalid operation tone.



The delivered energy level and the shock number are displayed at the bottom of the screen.



If additional countershocks are needed, follow steps 1 through 3 of this procedure starting on page 14-3 to readjust the energy settings, charge the unit, and deliver the shock.

Emergency Defibrillation Procedure with Hands-Free Therapy Electrodes

ECG leads and ZOLL hands-free therapy electrodes are a defibrillation-protected Type CF patient connection (applied part).

Determine the Patient's Condition Following Local Medical Protocols

Verify:

- Unconsciousness
- Absence of breathing
- Absence of pulse

Begin CPR Following Medical Protocols

Request additional assistance.

Prepare Patient

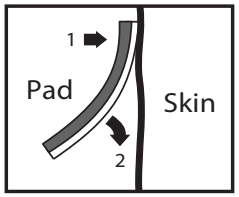
1. Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, clip or shave it to ensure proper adhesion of the electrodes.
2. Attach hands-free therapy electrodes according to instructions on the electrode packaging. Pads can be placed in the apex/sternum locations or in the anterior/posterior (front/back) position for defibrillation.

   Note: The CPR sensor must always be placed in the center of the patient's chest (over the Xiphoid process) for accurate CPR monitoring.
3. Ensure that the therapy electrodes are making good contact with the patient's skin and are not covering any part of the ECG electrodes or patient cables.

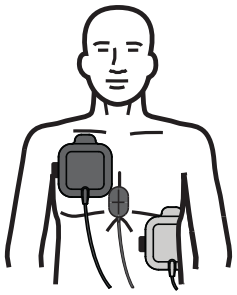
Therapy Electrode Application

WARNING! Poor adherence and/or air under the therapy electrodes can lead to the possibility of arcing and skin burns.

1. Apply one edge of the pad securely to the patient.
2. Roll the pad smoothly from the applied edge to the other, being careful not to trap any air pockets between the gel and skin.



Note: If it is not possible to place the "BACK" electrode on the patient's back, place the electrodes in the standard apex-sternum positions (see below). Effective defibrillation results, but higher current settings will usually be required for effective pacing.



WARNING! Do not conduct manual chest compressions through the electrodes. Doing so may cause damage to the electrodes that could lead to the possibility of arcing and skin burns. For electrodes with the CPR sensor, place hands directly on the CPR sensor when conducting chest compressions.

Turn on Unit

Turn the Mode Selector to DEFIB. If the unit was previously turned off, the red and yellow lights on the top of the unit flash on and off, and the message *All Tests Passed* displays.

Note: If the ZOLL M2 unit is configured to start up in AED mode, you need to press the **Manual Defib** quick access key on the left side of the unit's front panel to enter the Manual mode of operation.

If defibrillation electrodes are not making good contact with the patient's skin and the ECG lead selection is PADS, the unit issues the message *Attach Pads* and does not allow the delivery of energy.

Set Patient Type

Before starting therapy, make sure to specify the correct patient type (that appears at the top of the window display). To change the patient type, turn the Trim Knob to highlight the patient type at the top of the window. Press the Trim Knob to select it and then turn it to select another patient type. Press the Trim Knob again to confirm the selection.

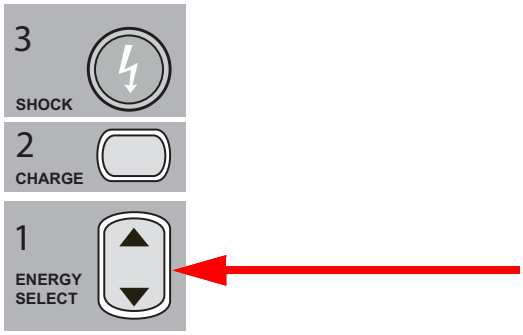
After setting the patient type, the ZOLL M2 selects and displays the default energy for the selected patient type. It also automatically selects the energy for subsequent shocks that are appropriate for the patient.

1 Select Energy Level

The energy level can be manually selected or the pre-configured energy settings can be used. Observe the energy setting on the display before changing it manually since manually changing the energy level outside the preprogrammed sequence and delivering a shock disables the automatic escalation function.

Manual Energy Selection

To select the energy level, press the front panel **Energy Select** arrows up or down to select the desired energy level.



The selected energy level is shown on the display.

Pre-configured Energy Selection

If Shocks 1, 2, and 3 have been configured to escalating energy levels using the Auto Energy Escalation feature, the ZOLL M2 unit automatically sets the energy to the preconfigured Energy Level: Shock 1, 2, 3 setting at power-up and after each of the first two shocks.

Note: After the third shock, all subsequent shocks are delivered at the same energy as the third shock in both Adult and Pediatric modes.

The default energy selections for adult patients:

Shock 1 - 120 joules
Shock 2 - 150 joules
Shock 3 - 200 joules

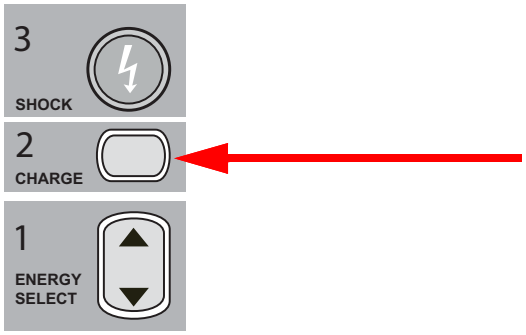
The default energy selections for pediatric patients:

Shock 1 - 50 joules
Shock 2 - 70 joules
Shock 3 - 85 joules

Note: Pre-configured energy settings may not always be appropriate. Verify that the currently selected energy is appropriate for the patient and change the setting if deemed necessary.

2 Charge Defibrillator

Press the **CHARGE** button on the front panel.

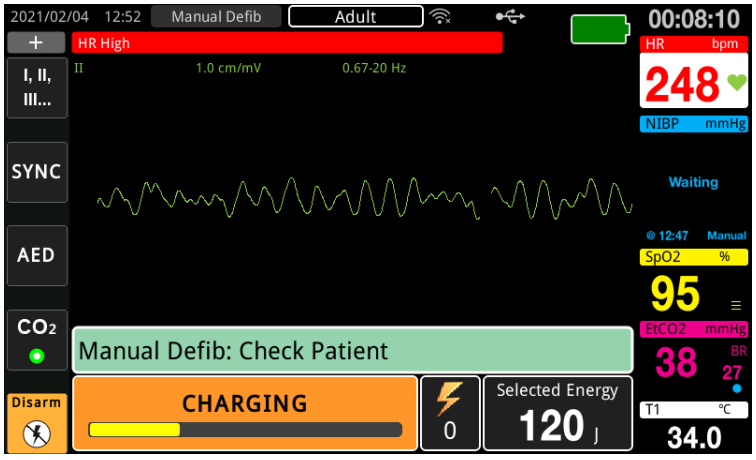


To increase or decrease the selected energy after pressing the **CHARGE** button, use the defibrillator **ENERGY SELECT** arrows on the front panel, then press the **CHARGE** button again to resume charging.

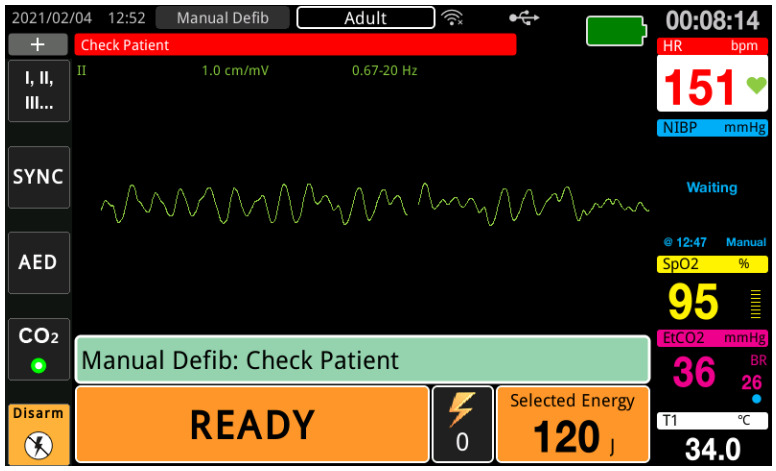
Note: This will disable automatic energy escalation.

Caution Changing the selected energy while the unit is charging or charged causes the defibrillator to disarm itself. Press the **CHARGE** button again to charge the unit to the newly selected energy level.

A *CHARGING* message displays at the bottom of the screen, and a distinctive tone sounds indicating that the unit is charging.



The energy bar graph on the bottom of the screen highlights the charge level until it reaches the selected energy. When the unit is fully charged, the tone changes to a continuous charge ready tone, the *READY* message displays at the bottom of the screen, and the front panel **SHOCK** button illuminates.

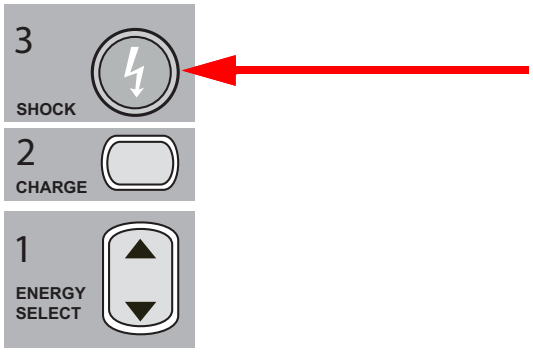


3 Deliver Shock

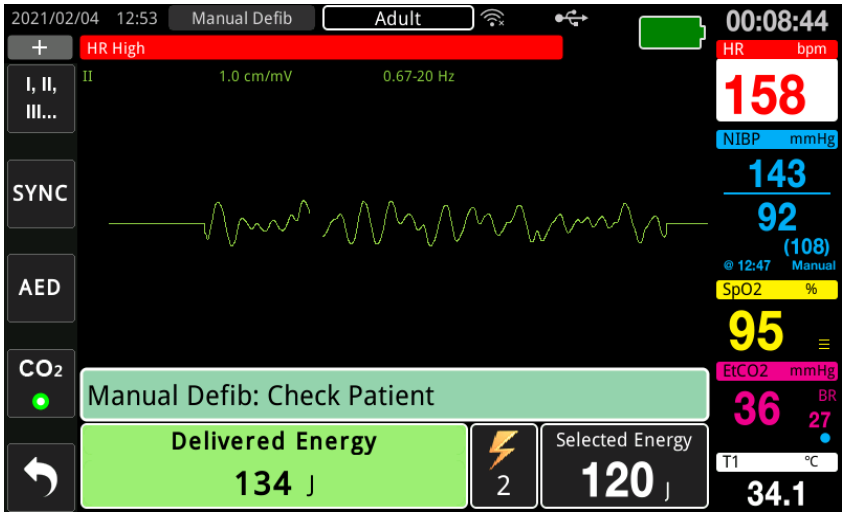
WARNING! **Warn all persons in attendance of the patient to *STAND CLEAR* prior to defibrillator discharge.**

Do not touch the bed, patient, or any equipment connected to the patient during defibrillation. A severe shock can result. Do not allow exposed portions of the patient's body to come into contact with metal objects, such as a bed frame, as unwanted pathways for defibrillation current may result.

Press and hold the **SHOCK** button on the front panel until energy is delivered to the patient.



The delivered energy level and the shock number display at the bottom of the screen.



Note: To cancel the ready state at any time, press the **Disarm** quick access key.

If the defibrillator is not discharged within 15 to 60 seconds (depending on configuration) after reaching the selected energy level, the unit automatically disarms itself.

If additional countershocks are needed, follow steps 1 through 3 of this procedure starting on page 14-10 to readjust the energy settings, charge the unit, and deliver shock.

Synchronized Cardioversion

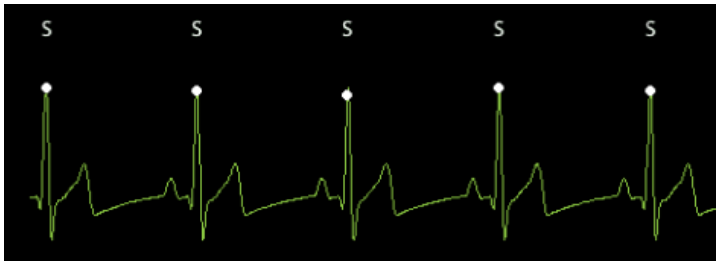
WARNING! **Only skilled personnel trained in Advanced Cardiac Life Support and familiar with equipment operation should perform synchronized cardioversion. The precise cardiac arrhythmia must be determined before attempting defibrillation or cardioversion.**

Before attempting synchronized cardioversion, ensure that ECG signal quality is sufficient to minimize the risk of synchronizing on artifact.

Certain arrhythmias, such as ventricular tachycardia, atrial fibrillation, and atrial flutter, require synchronizing the defibrillator discharge with the ECG R-wave to avoid the induction of ventricular fibrillation. In this case, a synchronizing (SYNC) circuit within the defibrillator detects the patient's R-waves. When the **SHOCK** button (or buttons, if using paddles) is pressed and held, the unit discharges with the next detected R-wave, thus avoiding the vulnerable T-wave segment of the cardiac cycle.

The ECG signal used for synchronized cardioversion can be derived from hands-free electrodes, defibrillator paddles or ECG limb/chest leads. ZOLL recommends that hands-free electrodes or ECG leads be favored over paddles ECG which is susceptible to artifact caused by paddle movement. For best results, select the ECG lead with the clearest, most noise free and most prominent R-wave as the synchronizing source. The ECG trace displayed in the top ECG waveform field is the ECG source used to synchronize the shock.

When in the SYNC mode, the unit displays markers (**S**) above the top ECG trace to indicate the points in the cardiac cycle (R waves) where discharge can occur.



S marker indicates each detected R wave during synchronization.

Verify that markers are clearly visible on the monitor and their location is appropriate (not above the T wave) and consistent from beat to beat.

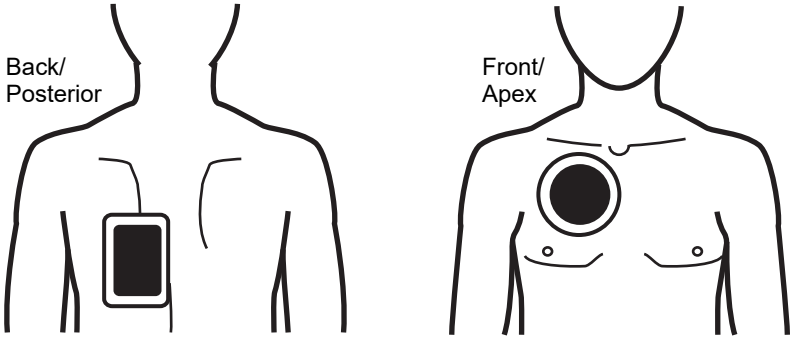
In SYNC mode, the defibrillator does not discharge without a command signal (R-wave detection) from the ECG monitor indicated by a SYNC marker on the trace.

Note: The synchronized cardioversion procedure for ZOLL hands-free therapy electrodes is identical to that for paddles with the exception of the SHOCK button location (paddles for shock buttons for paddles cardioversion; front panel shock button for hands-free cardioversion).

Synchronized Cardioversion of Atrial Fibrillation

Cardioversion of atrial fibrillation (AF) and overall clinical effectiveness is enhanced by proper pad placement. Clinical studies (refer to above) of the ZOLL M2 Biphasic Defibrillator Waveform demonstrated that high conversion rates are achieved when defibrillation pads are placed as shown in the following diagram.

Recommended Anterior/Posterior Placement



Place the front (apex) pad on the third intercostal space, mid clavicular line on the right anterior chest. The back/posterior pad should be placed in the standard posterior position on the patient's left as shown.

Synchronized Cardioversion Procedure

Determine the Patient's Condition and Provide Care Following Local Medical Protocols

Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, clip or shave it to ensure proper adhesion of the electrodes.

Attach ECG electrodes (see Chapter 6, "Monitoring ECG" for instructions on attaching ECG electrodes to the patient).

A standard ECG cable and ECG electrodes are recommended for use during cardioversion. Hands-free therapy electrodes may be used as an ECG source. Signal quality will be equal to that of limb/chest leads except immediately following a discharge when there may be more noise due to muscle tremors, especially if an electrode is not in complete contact with the skin.

Attach hands-free therapy electrodes according to instructions on the electrode packaging and as described in "Therapy Electrode Application" on page 14-8. If cardioverting atrial fibrillation, place the hands free electrodes as shown in the figure above.

Ensure that the therapy electrodes are making good contact with the patient's skin and are not covering any part of any other electrodes.

If therapy electrodes are not making good contact with the patient's skin, the unit issues the message *Attach Pads* and does not allow delivery of energy. If a short circuit exists between the electrodes, the unit issues the message *Check Pads - Pads Shorted*.

An *ECG Lead Off* condition prevents synchronized discharge if leads are selected as the primary ECG trace (ECG source). This condition does not prevent the use of the defibrillator; it simply prevents use in a synchronized manner.

If paddles are being used for synchronized cardioversion, refer to "Emergency Defibrillation Procedure with Paddles" on page 14-1 for preparing paddles, applying paddles, charging the defibrillator, and delivering a shock. Note, however, that synchronized discharge with paddles as an ECG source is discouraged since the artifact induced by moving the paddles may resemble an R-wave and trigger defibrillator discharge at the wrong time.

Turn on Unit

Turn the Mode Selector to DEFIB. If the unit was previously turned off, the red and yellow lights on the top of the unit flash on and off, and then the message *All Tests Passed* displays.

Note: If the ZOLL M2 unit is configured to start up in AED mode, you need to press the **Manual Defib** quick access key on the left side of the unit to enter the Manual mode of operation.

If defibrillation electrodes are not making good contact with the patient's skin and the ECG lead selection is PADS, the unit issues the message *Attach Pads* and does not allow the delivery of energy.

Set Patient Type

Before starting therapy, make sure to specify the correct patient type (that appears at the top of the window display). To change the patient type, turn the Trim Knob to highlight the patient type at the top of the window. Press the Trim Knob to select it and then turn it to select another patient type. Press the Trim Knob again to confirm your selection.

After setting the patient type, the ZOLL M2 selects and displays the default energy for the selected patient type. It also automatically selects the energy for subsequent shocks that are appropriate for the patient.

Press the Sync Key

Press the **Sync** quick access key on the front panel. The sync button turns green to indicate the system is now in R-wave synchronized discharge (Sync) mode. A sync marker (**S**) appears on the ECG source above each detected R-wave to indicate where discharge will occur, and a *Sync Defib* message replaces the *Manual Defib* message at the bottom of the screen.

Note: If the marker does not appear over the R-wave, select a different ECG lead. If the sync marker does not display, the defibrillator will not discharge.

Unless otherwise configured, the unit automatically exits Sync mode after each shock. To reactivate Sync mode, press the **Sync** quick access key on the front panel again. The unit can be configured to stay in Sync mode after defibrillation in the Basic Defib default settings in the Supervisor menu.

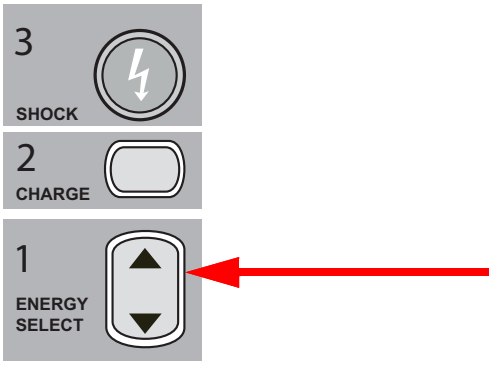
The unit will not leave Sync mode when the following actions occur:

- Allowing the Ready state to time out
- Changing the selected energy levels
- Pressing the Disarm key without pressing Shock

1 Select Energy Level

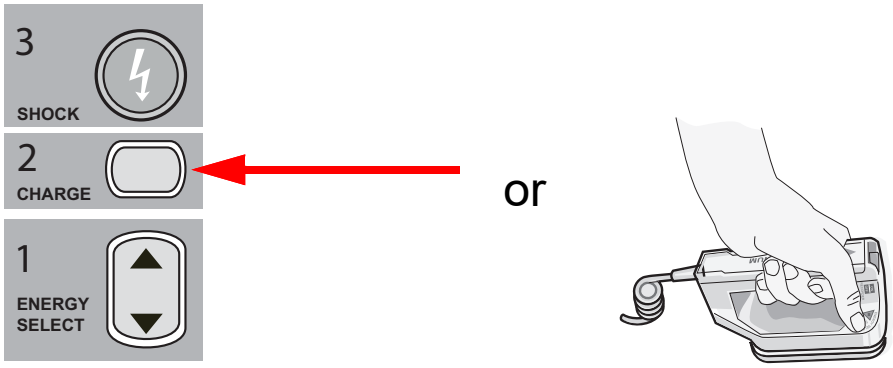
Press the **ENERGY SELECT** arrows up or down to select the desired energy level.These buttons are located either on the front of the unit or on the STERNUM paddle.

WARNING! **When using pediatric defibrillation electrodes, the patient type must be set to Pediatric and the defibrillator energies must be set based on site-specific institutional protocols for pediatric defibrillation.**



2 Charge Defibrillator

Press the **CHARGE** button on the front panel or on the APEX paddle handle.



To increase or decrease the selected energy after you have pressed the **CHARGE** button, use the defibrillator **ENERGY SELECT** arrows on the front panel or sternum panel.

Caution Changing the selected energy while the unit is charging or charged causes the defibrillator to disarm itself. Press the **CHARGE** button again to charge the unit to the newly selected energy level.

A *CHARGING* message displays at the bottom of the screen, and a distinctive tone sounds indicating that the unit is charging.

The energy bar graph on the bottom of the display highlights the charge level until it reaches the selected energy. When the unit is fully charged, the tone changes to a continuous charge ready tone, the unit displays *READY* on the display screen, and the charge indicator on the front panel or the apex paddle light up.

3 Deliver Shock

WARNING! **Warn all persons in attendance of the patient to *STAND CLEAR* prior to defibrillator discharge.**

Verify that no one is in contact with the patient, monitoring cable or leads, bed rails, or any other potential current pathways.

Verify that the primary ECG waveform is stable and that sync markers appear over each R-wave and that they do not appear over the T-wave. If not, switch the top ECG trace to another ECG lead or electrode to ensure that the sync markers are appropriate and consistent from beat to beat.

Press and hold the illuminated **SHOCK** button on the front panel, (or simultaneously press and hold both paddle **SHOCK** buttons) until energy is delivered to the patient. The defibrillator will discharge with the next detected R-wave.

The delivered energy level is displayed at the bottom of the screen and the shock number displays in the dashboard.

Note: To cancel the defibrillation at any time, press the **Disarm** quick access key.

Caution If the defibrillator is not discharged within 15 to 60 seconds (depending on configuration) after reaching the selected energy level, the unit automatically disarms itself but remains in Sync mode.

If additional countershocks are needed, press the **Sync** quick access key again and follow steps 1 through 3 of this procedure starting on page 14-17 to readjust the energy settings, charge the unit, and deliver shock.

Internal Paddles

ZOLL molded autoclavable internal handles with integrated electrodes are designed for use with the ZOLL M2 monitor/defibrillator to defibrillate the heart during open chest procedures.

When an internal handle set is connected to the ZOLL M2 unit, it automatically sets the selected energy to 10 Joules. The maximum allowed energy selection is 50 Joules when internal paddles are in use.

For step-by-step procedures for open chest defibrillation as well as important cleaning and sterilization information regarding the autoclavable electrodes, refer to the *Autoclavable Internal Handle and Electrode Operator's Guide*.

Verification Prior to Use

Before each use with the ZOLL M2 unit, verify the proper operation of the ZOLL internal paddles using the following procedure. This procedure requires a second person if internal handles without a Discharge button are being used.

WARNING! When performing internal paddle verification, keep hands away from the electrode plates while pressing the SHOCK button.

1. Inspect the connector contact sockets for damage or corrosion. If damage or corrosion in the connector contact sockets is observed, remove the handle set from use.
2. Connect the Autoclavable Internal Handles to the ZOLL M2 unit. Use the Lead quick access key  to verify that the ZOLL M2 unit correctly identifies the Internal Handle and Electrode set by displaying **Int. Paddles**.
3. Before charging the defibrillator, press the **Discharge** button on the handle set (if present) and verify that there is an audible click and that the button springs back upon release. Verify that the defibrillator window displays the message *Defib Not Ready - Press Charge*. This message verifies that the **Discharge** button located on the right handle is operating correctly.
4. Press the electrode plate surfaces firmly together and away from any person or object.
5. Press the 30J self test quick access key while holding the paddle plates together. The defibrillator charges to 30 joules, displays *30J Test - CHARGING* and *30J Test - READY*, and then issues a ready tone.
6. Discharge the energy in the following manner.

- For internal handles with a Discharge button:
  Press and hold the **Discharge** button on the apex handle to deliver the test energy to the electrodes.
- For internal handles without a Discharge button:

  Have a second person press and hold the **SHOCK** button  on the defibrillator front panel to deliver the test energy to the electrodes.

The ZOLL M2 device unit discharges and displays the message *30J Test Passed*.

Chapter 15
Real CPR Help

ZOLL hands-free therapy electrodes are a defibrillation-protected Type CF patient connection (applied part).

WARNING! When using the ZOLL M2 CPR monitoring function, make sure to select the correct patient type. Selecting the adult patient type when the patient is a child can result in Push Harder prompts being issued inappropriately for a child.

When used with CPR accessories, the ZOLL M2 unit can provide rescuers with feedback about the quality of CPR they are delivering to their patients. The way that Real CPR Help is provided varies with respect to the operational mode and user configuration, but is derived from chest compression rate and depth measurements.

When applied according to package instructions, CPR electrodes provide a chest compression sensor that is located between the rescuer's hands and the patient's lower sternum. This sensor monitors the rate and depth of chest compressions and sends this information to the ZOLL M2 unit for processing and display.

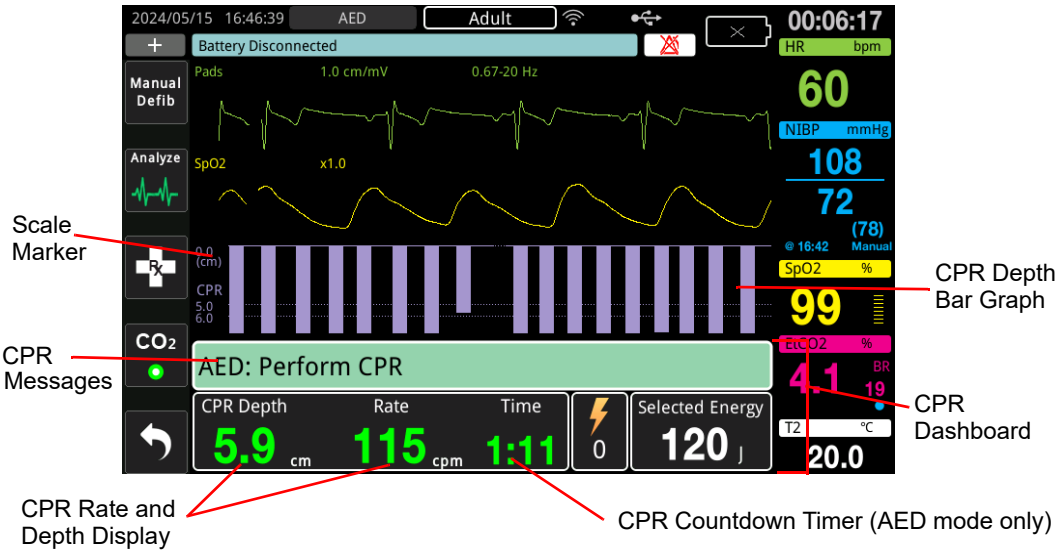
The ZOLL M2 monitor/defibrillator's CPR function uses this information to provide feedback to the rescuer in one or more of the following components of the CPR monitoring subsystem:

- CPR Dashboard
- CPR voice prompts
- CPR rate metronome
- CPR compression bar graph

CPR User Interface

Whenever CPR electrodes are connected to the ZOLL M2 monitor/defibrillator and it senses chest compressions, it activates the CPR functionality which provides sounds and visuals to guide the rescuer in Manual Defib or AED mode.

Note: In AED mode, CPR monitoring functionality only issues sounds and visuals during intervals when chest compressions are recommended. In Manual Defib mode, the CPR monitoring functionality is active during periods when chest compressions are being detected (if configured to enable CPR monitoring in Manual Defib mode in the Supervisor menu).



CPR Dashboard

The CPR Dashboard displays at the bottom of the screen and includes the CPR depth and rate, CPR messages, and the CPR interval countdown timer (AED mode only). In AED mode, the dashboard is only displayed during CPR periods and is replaced with defibrillation messages during non-CPR periods.

When the ZOLL M2 is in the Manual Defib mode, the CPR Dashboard replaces the lowest waveform trace (displayed at the bottom of the screen) when the following conditions are met:

- CPR electrodes are connected
- Chest compressions are detected

CPR Messages

The ZOLL M2 unit displays text messages (along with voice prompts) that provide feedback to rescuers performing CPR. The following CPR messages may display on the CPR dashboard:

- *Perform CPR* (AED mode only)
- *Stop CPR* (AED mode only)
- *Push Harder* (Adult patients only)
- *Good Compressions* (Adult patients only)
- *IF No Pulse, Perform CPR* (AED mode only)

- *Check Pulse* (AED mode only)

CPR Depth and Rate

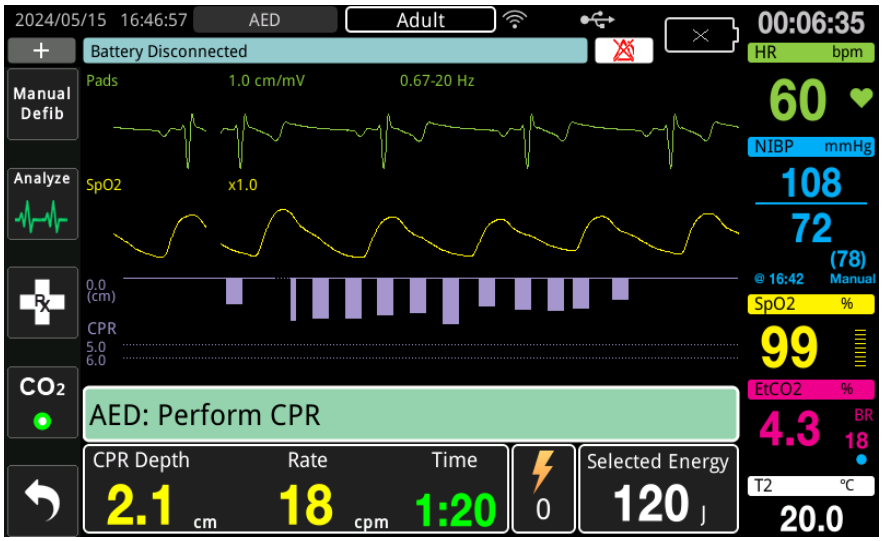
The CPR depth and rate value displays the current chest compression depth and rate (compressions per minute) determined by the ZOLL M2 unit. When no chest compressions have been detected during the past few seconds, the rate display shows "- - -".

CPR Rate and Depth Measurements

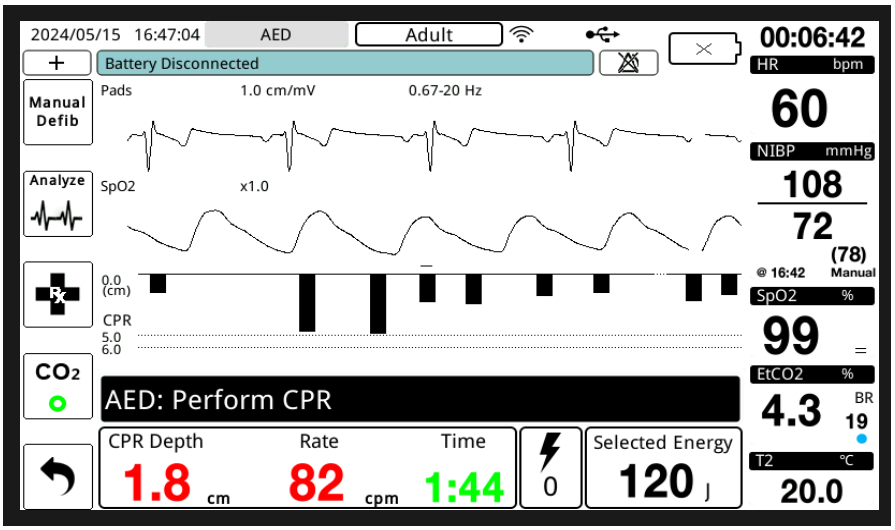
The display of CPR rate and depth measurements differ depending on whether adult or pediatric CPR electrodes are attached.

With Adult CPR Electrodes Attached --

By default, the ZOLL M2 unit displays CPR rate and depth measurements in green when adult CPR electrodes are attached. If compression depth or rate is consistently out of range of AHA/ERC-recommended numbers (Depth 5-6 cm, Rate 100-120 cpm), the unit displays the measurements in yellow.



If the display is set to high contrast, the unit displays the out-of-range measurements in red.



With Pediatric CPR Electrodes Attached --

CPR rate and depth measurements *always* display in green when pediatric CPR electrodes are attached.

CPR Countdown Timer (AED Mode Only)

This indicator displays a CPR countdown timer to indicate the time (in minutes and seconds) left in the current CPR interval. It decrements the time until it reaches zero.

CPR Rate Metronome

The ZOLL M2 includes a CPR metronome feature that can be used to encourage rescuers to perform chest compressions at the recommended rates. The metronome beeps at the AHA/ERC recommended rate to provide a compression rhythm for rescuers to follow.

In AED mode, metronome beeps are issued at the configured rate when CPR electrodes are in use and the ZOLL M2 unit is in a CPR period. The metronome can also be configured to begin beeping after the first few chest compressions are detected and continue to beep until chest compressions have stopped for more than a few seconds.

In Manual Defib mode, the metronome is silent when no chest compressions are being detected by CPR-equipped hands-free therapy electrodes; the ZOLL M2 unit begins issuing metronome beeps when compressions are detected and stops issuing beeps a few seconds after chest compressions have stopped.

CPR Compression Voice Prompts (Adult Patients Only)

The ZOLL M2 unit issues voice prompts related to the depth of chest compressions as feedback to rescuers performing CPR. Two voice prompts are available for this purpose:

• Push Harder

• Good Compressions

When chest compressions are detected but their depth is consistently less than the target depth of 5 centimeters (2 inches), the device periodically issues the “Push Harder” voice prompt. If the rescuer responds by increasing compression depth to more than the target depth on a consistent basis, the unit issues a “Good Compressions” prompt.

CPR compression voice prompts are only available when the patient type is set to adult. In AED mode, CPR voice prompts are always on during the time that clinical protocol instructs the user to perform CPR. In Manual Defib mode, the only voice prompts are “Push Harder” and “Good Compressions”.

CPR Compression Bar Graph

When the ZOLL M2 monitor/defibrillator has CPR electrodes connected to it and detects repeating chest compressions over a short period of time, it displays the compression depth bar graph at a sweep speed of 12.5 mm/sec. The CPR compression bar graph is computed from the CPR sensor signals and displays above the dashboard. This bar graph, representing depth of compression, is presented on a 0 to 7.6 cm (0 to 3 in) displacement scale with reference markers at 0, 5, and 6 cm (0, 2.0, and 2.4 in) for adult patients, and 0, 2.5, and 5 cm (0, 1.0, and 2.0 in) for pediatric patients. The bar graph units (in, cm) can be configured.

The bar graph displays as the lowest waveform trace at the bottom of the window and remains on the display until the rescuer selects a different waveform or exits from Manual Defib or AED mode.

Chapter 16
External Pacing

ECG leads and ZOLL hands-free therapy electrodes are a defibrillation-protected Type CF patient connection (applied part).

WARNING! **To avoid risk of electrical shock, do not touch the gelled area of the hands-free therapy electrodes while pacing.**

Therapy electrodes should be replaced periodically during treatment. Consult electrode directions for specific recommendations.

Prolonged pacing (in excess of 30 minutes), particularly in adolescent, child, and infant patients or adults with severely restricted blood flow, may cause burns. Periodic inspection of the underlying skin is recommended.

When pacing in demand mode, the pacer may be adversely affected by EMI, RFI, or ESU induced artifact in the ECG signal. Move patient away from any potential sources of interference.

If the unit has not been turned off for more than 30 seconds and less than 10 minutes have passed since the pacing mode was last used, re-entering the pacer mode will cause pacing to resume at the previously selected rate and output current after a few seconds. If the previous pacer settings are not desired, immediately press the Trim Knob and set the pacer output to 0 mA. This will stop pacing and provide the time needed to change pacer settings to the desired values.

External Pacing

The ZOLL M2 monitor/defibrillator contains a noninvasive temporary pacemaker for the emergency treatment of hemodynamically compromising bradycardia, bradycardia with escape rhythms that are unresponsive to pharmacological therapy, refractory tachycardia (supraventricular or ventricular), and bradyasystolic cardiac arrest.

The ZOLL M2 monitor/defibrillator's demand pacing function is a VVI demand pacemaker (VVI = Ventricular paced; ventricle sensed; pacing inhibited if beat sensed).

Proper demand pacing requires a reliable, high-quality surface ECG signal. For best results, apply both standard ECG monitoring electrodes and hands-free pacing therapy electrodes to the patient.

Note: The use of an ECG patient cable and electrodes is required to monitor ECG during pacing.

Note: In Pacer mode, a pads off condition triggers an *Attach Pads* message even if the alarm audio or the alarm function is off.

Note: In Pacer mode, the Pads off or shorted condition during active pacing triggers an equipment alarm with a flashing yellow **Clear** quick access key and an alarm tone even if the alarm audio is off or the alarm is off. If this alarm is triggered, properly attach pads to the patient and press the **Clear** quick access key to respond to the alarm.

Caution The ZOLL M2 continues to apply pace pulses across the pacer output cable's patient contacts even when hands free electrodes are disconnected from the patient or pacing cable. Do not touch pacer electrode surfaces when the output current setting is not set to 0 ma.

Pacer Modes

The ZOLL M2 has two pacer mode settings: Demand and Fixed. The defibrillator always defaults to the Demand pacer setting when the Pacer function is initially activated.

In Demand mode, pacing pulses are inhibited when the patient's R-to-R interval is shorter than the interval between pacer pulses at the selected rate. If no QRS complexes are detected during the interval between pace pulses (at the selected rate), a pacing pulse is delivered to the patient. In the demand mode, the pacer supplies the required number of pacing pulses to maintain the patient's heart rate at approximately the rate selected in the pacing rate window. See the procedure below, "Pacing in Demand Mode" for more information.

In Fixed mode, pacing pulses are not dependent on the patient's cardiac activity. Fixed pacing delivers pacer pulses at the selected rate without regard to the presence of intrinsic electrical heart activity and should be performed only in an emergency when no alternative is available. See "Pacing in Fixed Mode" on page 16-6 for more information.

Pacing in Demand Mode

Determine patient condition and provide care following local medical protocols.

Follow the procedure below for pacing in demand mode.

Prepare the Patient

Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, clip it to ensure proper adhesion of the electrodes.

1 Apply ECG Electrodes

Apply ECG electrodes to the patient, attach lead wires, and connect the ECG cable to the ZOLL M2 rear panel (see Chapter 6, "Monitoring ECG" for instructions on attaching ECG electrodes to the patient).

While monitoring the patient, press the Lead quick access key  to select the lead (I, II, or III) with the cleanest signal with large and distinctive QRS complexes.

Note: When the defibrillator is initially placed in Pacer mode, the ECG lead selection defaults to Lead II.

Verify that R-waves are being properly detected by confirming that a QRS tone (and/or flashing heart beat light) occurs with each displayed R-wave or by verifying that the ZOLL M2 unit's heart rate display accurately reflects the patient's pulse rate.

2 Apply Hands-Free Therapy Electrodes

Attach hands-free therapy electrodes according to instructions on the electrode packaging. Pads can be placed in the apex/sternum locations or in the anterior/posterior (front/back) position.

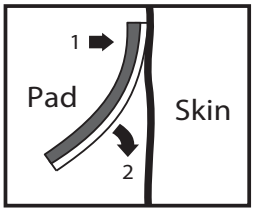
Note: Anterior/posterior positioning is preferred because it typically requires lower current to achieve capture.

Connect these therapy electrodes to the multifunction cable (MFC).

Note: ECG monitoring through therapy electrodes is not available in pacer mode.

WARNING! Poor adherence and/or air under the therapy electrodes can lead to the possibility of arcing and skin burns.

1. Apply one edge of the pad securely to the patient.
2. Roll the pad smoothly from the applied edge to the other, being careful not to trap any air pockets between the gel and skin.

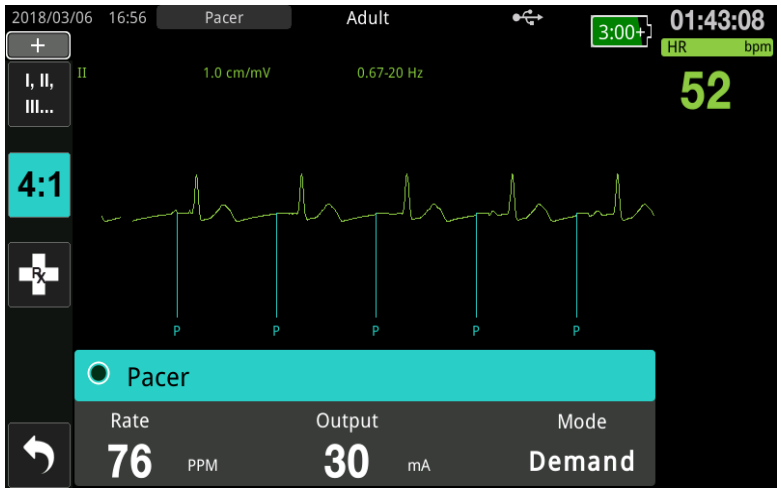


3. Ensure that hands-free therapy electrodes are making good contact with the patient's skin and are not covering any part of any other ECG electrodes, lead wires, or sensor cables.

3 Turn Mode Selector to PACER

Turn the Mode Selector to **PACER**. The Pacer Dashboard displays.

Note: If the unit's default mode is AED mode and has been configured to require a password, when the password screen displays, use the Trim Knob to enter the password, and press the knob to select **OK**.



Navigating the Pacer Dashboard

When the unit is in Pacer mode, the Pacer Dashboard displays and the Output field is highlighted. To navigate around the pacer dashboard, turn the Trim Knob to move to and highlight a field. Press the Trim Knob to select the field, and turn the Trim Knob to change the setting, then press the knob again to enter the selected setting.

If the pacer mode and rate settings are acceptable without making any changes, go to step 7 to set the output current. Otherwise, go to step 4.

4 Set Pacer Mode

Use the Trim Knob to navigate to the Mode field in the Pacer Dashboard. Press the Trim Knob to activate the mode field. Turn the Trim Knob to change the setting to Demand, and press the Trim Knob to select it.

5 Set Pacer Rate

In order to determine the optimal current for demand pacing, the pacer rate must be temporarily set high enough to initiate pacing.

Use the Trim Knob to navigate to the Rate field in the Pacer Dashboard, press the knob, and then turn the knob to set the Pacer Rate to a value 10-20 ppm higher than the patient's intrinsic heart rate. If no intrinsic rate exists, use 100 ppm. You can increase or decrease the pacer rate in increments of 2 ppm.

Note: The default pacing rate is 70 ppm. This default rate is configurable.

6 Start Pacer

Once the desired pacer rate is displayed, press the Trim Knob to enter the selected pacer rate and start the pacer.

Note: If pacing was active during the past 10 minutes and the ZOLL M2 has not been turned off for more than 30 seconds since the pacing episode, the unit begins pacing at the last current setting about 3 seconds after activation of the pacer mode. The Pacer current defaults to the 0 mA setting under all other conditions.

7 Set Pacer Output

Use the Trim Knob to navigate to and select the Output field in the Pacer Dashboard. Turn the Trim Knob to gradually increase pacer output current. The pacer output is adjustable in 2 mA increments/decrements when increasing or decreasing the output. The output range is between 8 to 140 mA. Observe the ECG for evidence of electrical capture. Select the lowest output current that ensures both consistent electrical and consistent mechanical capture. When the desired current is displayed, press the knob again to lock in the selected output current setting.

8 Determine Capture

It is important to recognize when pacing stimulation has produced a ventricular response (capture). Determination of capture must be assessed both electrically and mechanically in order to ensure appropriate circulatory support of the patient.

Electrical capture is determined by the presence of a widened QRS complex, the loss of any underlying intrinsic rhythm, and the appearance of an extended (and sometimes enlarged) T-wave.

Ventricular response is normally characterized by suppression of the intrinsic QRS complex.

WARNING! Determination of electrical capture should only be performed by viewing the ECG trace on the ZOLL M2 display with its ECG connection directly attached to the patient. Use of other ECG monitoring devices might provide misleading information due to the presence of pacer artifacts.

Mechanical capture is assessed by palpation of the peripheral pulse.

To avoid mistaking muscular response to pacing stimuli for arterial pulsations, use ONLY the following locations for palpating pulse during pacing:

- femoral artery
- right brachial or radial artery

Effective pacing

Changing ECG leads and size can sometimes be helpful in determining capture.

Note: The shape and size of the paced ECG waveforms can vary depending on the chosen ECG lead configuration. Variation of waveforms from patient to patient can be expected.

9 Determine Optimum Threshold

The ideal pacer current is the lowest value that maintains capture — it is usually about 10% above threshold. Typical threshold currents range from 40 to 80 mA. Location of the hands-free or therapy electrodes affects the current required to obtain ventricular capture. Typically the lowest threshold is obtained when the position of the electrodes provides the most direct current pathway through the heart while avoiding large chest muscles. Lower stimulation currents produce less skeletal muscle contraction and are better tolerated.

4:1 Mode

Pressing and holding the 4:1 quick access key temporarily withholds pacing stimuli, thereby allowing you to observe the patient's underlying ECG rhythm and morphology. When pressed, this key causes pacing stimuli to be delivered at ¼ of the indicated ppm setting.

10 Set Demand Pacing Rate

Once optimal pacer current has been determined, readjust the pacer rate to the HR value below which demand pacing is desired.

Pacing in Fixed Mode

If ECG electrodes are not available or there is some circumstance that prevents or interferes with the acquisition of a high quality surface ECG signal, fixed rate pacing may be used.

Fixed pacing should be performed only in an emergency when no alternative is available.

Note: When ECG leads are off during pacing, the ZOLL M2 unit always reverts to fixed rate pacing.

Determine Patient Condition and Provide Care Following Local Medical Protocols

Prepare the Patient

Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, clip it to ensure proper adhesion of the electrodes.

1 Apply ECG Electrodes

Apply ECG electrodes to the patient, attach lead wires, and connect the ECG cable to the ZOLL M2 rear panel (see Chapter 6, "Monitoring ECG" for instructions on attaching ECG electrodes to the patient).

While monitoring the patient, press the Lead quick access key 

to select the lead (I, II, or III) with the cleanest signal with large and distinctive QRS complexes.

Note: When the defibrillator initially enters Pacer mode, the lead selection defaults to Lead II.

Verify that R-waves are being properly detected by confirming that a QRS tone (and/or flashing heart beat light) occurs with each displayed R-wave or by verifying that the ZOLL M2 unit's heart rate display accurately reflects the patient's pulse rate.

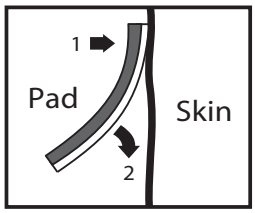
2 Apply Hands-Free Therapy Electrodes

Attach hands-free therapy electrodes according to instructions on the electrode packaging. Connect these therapy electrodes to the multifunction cable (MFC).

Note: ECG monitoring through MFE pads is not available in pacer mode.

WARNING! Poor adherence and/or air under the therapy electrodes can lead to the possibility of arcing and skin burns.

1. Apply one edge of the pad securely to the patient.
2. Roll the pad smoothly from the applied edge to the other, being careful not to trap any air pockets between the gel and skin.

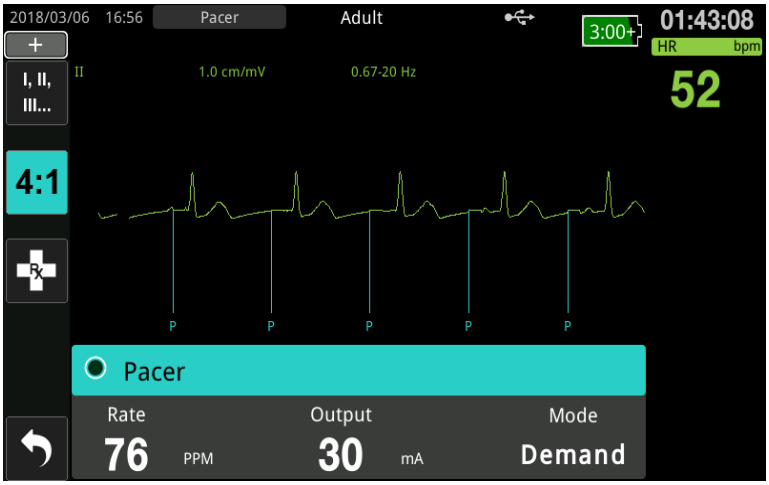


3. Ensure that hands-free therapy electrodes are making good contact with the patient's skin and are not covering any part of any other ECG electrodes.

3 Turn Mode Selector to PACER

Turn the Mode Selector to **PACER**. If the unit was previously turned off, the red and yellow lights on the top of the unit flash on and off, and then the unit displays the message *ALL TESTS PASSED*.

The Pacer Dashboard displays:



Navigating the Pacer Dashboard

When the unit is in Pacer mode, the Pacer Dashboard displays and the Output field is highlighted. To navigate around the pacer dashboard, turn the Trim Knob to move to and highlight a field. Press the Trim Knob to select the field, and turn the Trim Knob to change the setting, then press the knob again to enter the selected setting.

If the pacer mode and rate settings are acceptable without making any changes, go to step 7 to set the output current. Otherwise, go to step 4.

4 Set Pacer Mode

Use the Trim Knob to navigate to the Mode field in the Pacer Dashboard. Press the Trim Knob to activate the mode field. Turn the Trim Knob to change the setting to Fixed, and press the knob to select it.

5 Set Pacer Rate

Use the Trim Knob to navigate to the Rate field in the Pacer Dashboard, press the Trim Knob, and then turn the knob to set the Pacer Rate to a value 10-20 ppm higher than the patient's intrinsic heart rate. If no intrinsic rate exists, use 100 ppm. You can increase or decrease the pacer rate by a value of 2 ppm.

Note: The default pacing rate is 70 ppm. This default rate can be changed in the Supervisor menu.

6 Start Pacer

Once the desired pacer rate is displayed, press the center button of the Trim Knob to enter the selected pacer rate and start the pacer.

Note: If pacing was active during the past 10 minutes and the ZOLL M2 unit has not been turned off for more than 30 seconds since the pacing episode, the unit begins pacing at the last current setting about 3 seconds after activation of the pacer mode. The Pacer current defaults to the 0 mA setting under all other conditions.

7 Set Pacer Output

Use the Trim Knob to navigate to and select the Output field in the Pacer Dashboard. Turn the Trim Knob to gradually increase pacer output current. The pacer output is adjustable in 2 mA increments/decrements when increasing or decreasing the output. The output range is between 8 to 140 mA. Observe the ECG for evidence of electrical capture. Select the lowest output current that ensures both consistent electrical and consistent mechanical capture. When the desired current is displayed, press the knob again to lock in the selected output current.

8 Determine Capture

It is important to recognize when pacing stimulation has produced a ventricular response (capture). Determination of capture must be assessed both electrically and mechanically in order to ensure appropriate circulatory support of the patient.

Electrical capture is determined by the presence of a widened QRS complex, the loss of any underlying intrinsic rhythm, and the appearance of an extended, and sometimes enlarged, T-wave.

Ventricular response is normally characterized by suppression of the intrinsic QRS complex.

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Mechanical capture is assessed by palpation of the peripheral pulse.

To avoid mistaking muscular response to pacing stimuli for arterial pulsations, use ONLY the following locations for palpating pulse during pacing:

- femoral artery
- right brachial or radial artery

Effective pacing

Changing ECG leads and size can sometimes be helpful in determining capture.

Note: The shape and size of the paced ECG waveforms can vary depending on the ECG lead configuration chosen. Variation of waveforms from patient to patient can be expected.

9 Determine Optimum Threshold

The ideal pacer current is the lowest value that maintains capture — it is usually about 10% above threshold. Typical threshold currents range from 40 to 80 mA. Location of the hands-free or therapy electrodes affects the current required to obtain ventricular capture. Typically the lowest threshold is obtained when the position of the electrodes provides the most direct current pathway through the heart while avoiding large chest muscles. Lower stimulation currents produce less skeletal muscle contraction and are better tolerated.

4:1 Mode

Pressing and holding the 4:1 quick access key temporarily withholds pacing stimuli, thereby allowing you to observe the patient's underlying ECG rhythm and morphology. When pressed, this key causes pacing stimuli to be delivered at ¼ of the indicated ppm setting.

Pediatric Pacing

Noninvasive pacing of pediatric patients is performed in an identical manner to adult pacing. Smaller size pediatric therapy electrodes are available for patients weighing less than 33 lbs/15 kg. If it is necessary to pace for more than 30 minutes, periodic inspection of the underlying skin is strongly advised. Carefully follow all instructions on electrode packaging.

Pacing Messages

The ZOLL M2 unit may display the following messages when pacing.

System Message	Description
4:1 Selected	The 4:1 function is activated while the unit is in Pacer mode.
Attach Pads	Therapy pads are not connected or are not making good contact with the patient. Apply therapy pads to the patient.
Check Pads - Pads Shorted	The pacer output is short circuited due a test plug connection or a device/MFC fault. Check the pads connection.
Connect Therapy Cable	The MFC cable is disconnected from the unit while the unit is in Pacer mode.
Demand Pacing Disabled	Demand pacer function disabled due to self-test failure. Fixed rate pacing may be available for use under this condition.
ECG Lead Off	One or more leads is not connected to the patient or to the ZOLL M2 unit. If the ECG lead displayed in the primary waveform is off, the pacer is pacing in Fixed mode.
Pacer Disabled	Pacer function disabled due to self-test failure.
Release 4:1 Button	The 4:1 quick access key was pressed while switching to Pacer mode.
Set Pacer Output MA	The pacer output is 0 mA after switching to Pacer mode.
Use Pads to Pace	The paddles are connected to the unit when in Pacer mode.

Chapter 17
Incident Data and Reports

The ZOLL M2 monitor/defibrillator records important event information during rescue incidents. A rescue incident begins when the device is initially turned on (after being off for at least 30 seconds), and continues until the unit is turned off for 30 seconds or longer. You can retrieve this information in various forms:

- **Trend Data** — A patient's vital signs trend information that is logged to memory at a user configurable interval between 30 seconds and 30 minutes. See Chapter 4, "Trends" to view and print patient trend information.
- **Summary Report** — A collection of snapshot events automatically taken or user initiated during each rescue incident. For more information about the summary report and how to print it, refer to the "Summary Report" on page 17-2.
- **Snapshots** — Up to 18 seconds of time stamped vital signs, waveforms, alarms, and treatment data recorded before and during important clinical events. For more information about snapshots and how to print them, refer to "Snapshots" on page 17-6.
- **Event Log** — An abbreviated list of all events recorded in Summary Report. For more information about the event log and how to print it, refer to "Event Log" on page 17-4.
- **Full Disclosure Recording** — A complete rescue incident that contains Full Disclosure waveforms along with event information. This information can be transferred via USB or WiFi. For information about the Full Disclosure Recording, refer to "Full Disclosure Recording" on page 17-13.

Note: The ZOLL M2 unit retains stored incidents even if you turn off the unit, remove its battery power, and disconnect it from AC mains until its memory is full. When memory is full, new incident data automatically replaces the oldest data in memory.

Data Storage

The ZOLL M2 unit includes a 2 GB memory for continuously recording and storing important rescue event information in unique case files for each patient being monitored. When the ZOLL M2 unit is used primarily for emergency situations, its data storage capacity is usually sufficient for more than 100 rescue incidents (or cases); when it is used for long term patient monitoring, the unit can store at least 4 incident (case) files. Each incident (case) file can contain a maximum of 500 MB of information which includes all snapshots, all displayed waveforms, all monitored parameter trends, and full disclosure data for each rescue incident. When data storage space for the current rescue incident reaches the 500 MB capacity, the ZOLL M2 stops storing incident data and displays a *Case File Full* message. When a *Case File Full* message appears, additional patient data can be stored in a new case file by powering the ZOLL M2 unit off for 30 seconds, and then powering it back on. The ZOLL M2 unit stores completed cases until its memory is full, and then erases old cases (one by one) to make room for the current incident.

The actual information that is stored depends on usage. Also, the specific combination of stored continuous waveform data depends on how the waveform recording settings are configured in the Supervisor menu.

Note: The ZOLL M2 provides user access to the alarm system log while in Supervisor mode. The ZOLL M2 retains stored logs even if the unit is turned off, the battery is removed and/or the unit is disconnected from AC mains. Once the ZOLL M2's memory is full (reaches the maximum storage capacity of 1000 logs), newly created logs automatically replace the oldest logs in memory as needed.

Summary Report

The ZOLL M2 monitor/defibrillator automatically records all snapshot events during a rescue incident such as defibrillation events (ECG analyses, shock delivery), Pacer mode information, heart rate alarms, and presenting ECG rhythm. Associated event information including device control settings, time, and date are also recorded. This information can be printed as a Summary Report. It is helpful to print the Summary Report of the current incident before powering off the unit.

The following is a list of snapshot events included in the Summary Report that are automatically recorded or user initiated during each rescue incident:

- Presenting ECG rhythm (when power is turned on following the first attachment of ECG leads or defibrillator electrodes to the patient).
- ECG Shockable Rhythm Analysis (AED mode only)
- Shock delivery
- *Check Patient* alert is triggered
- Mode Selector is turned to PACER (after entering Manual mode)
- Patient alarm is triggered
- Stripchart recorder is turned on
- Code marker is entered
- Diagnostic ECG quick access key is activated
- 12-lead Acquire button is pressed

The ZOLL M2 unit stores and prints summary information in chronological order. The memory allocated for summary data can hold more than 1000 defibrillation or recorder-activated events.

Each Summary Report begins with an overview of all events currently stored in memory including:

- Date (YYYY/MM/DD) and time (HH:MM:SS) when incident began
- Device ID
- Incident duration (HH:MM:SS)
- Number of snapshots recorded during the incident
- Total number of shocks delivered during the incident
- Total pacing time during the incident
- Date and time of last snapshot
- System serial number

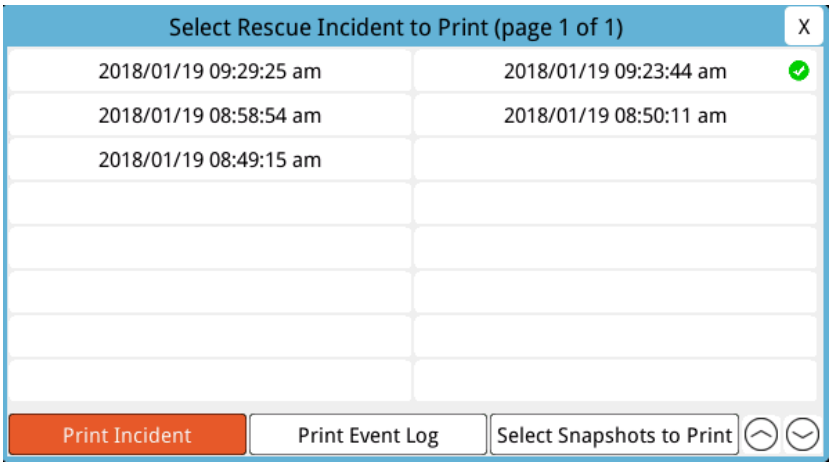
Printing Summary Report

Printing a Summary Report

To print a summary report of the rescue incident, do the following:

1. Press the More quick access key ( ) until the Data quick access key displays.
2. Press the Data quick access key ( ).
3. Press the Treatment Summary quick access key ( ). The Select Rescue Incident to Print window displays.

Note: The incidents are displayed based on the date and time the incident began.



4. Rotate the Trim Knob to highlight the incident you want to print and then press the knob to select it. A green check mark displays next to the selected incident.

Note: You can only select one incident at a time to print.

5. Rotate the Trim Knob to highlight **Print Incident** and press the knob to select it. The ZOLL M2 unit prints the summary report for the incident you have selected.
6. When the Summary Report has finished printing, do one of the following:
   - Rotate the Trim Knob to the X in the top right corner of the window and press the knob to leave the window.
   - Press the Menu button ( ) to leave the window.

Caution You can print Summary Reports of previous incidents while monitoring/treating a new patient during the current incident. Always use the time and date displayed on Summary Report snapshots to verify that the printed data was recorded from the intended patient.

On the last event recorded, the unit prints “Summary Report Complete” on the bottom of the stripchart.

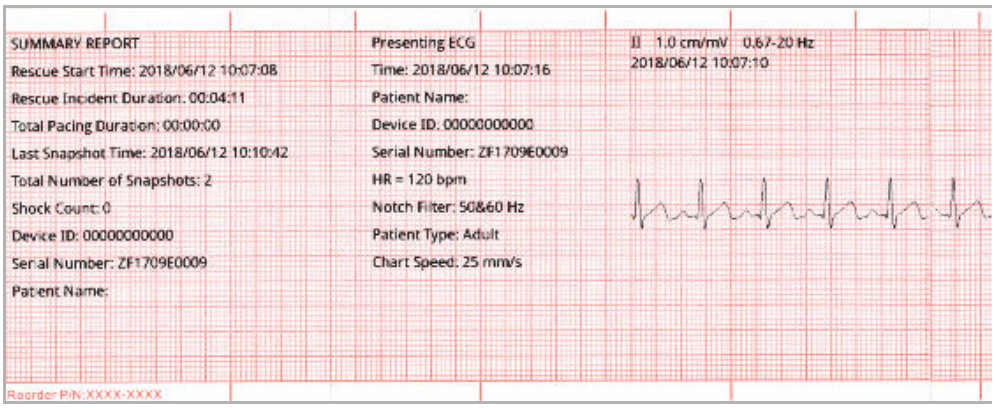


Figure 17-1. Summary Report

Event Log

An Event Log is an abbreviated list of all events recorded in the summary report, beginning with the rescue start time. You can print an event log that includes the following events and their time of occurrence:

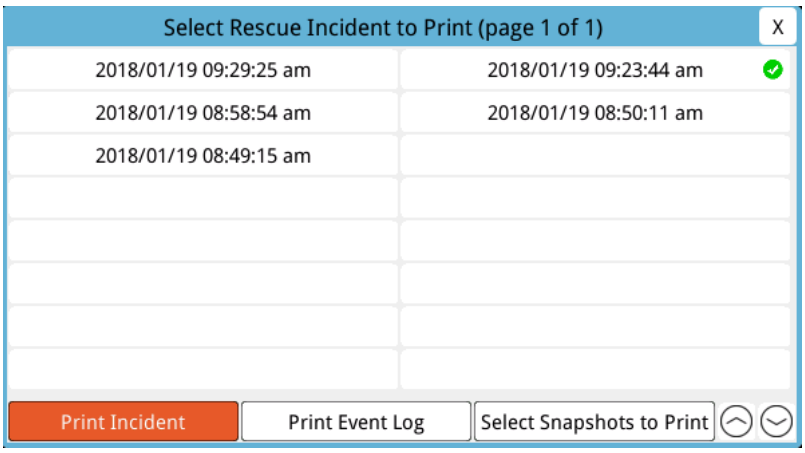
- Presenting ECG (when power is turned on)
- ECG Analysis (AED mode only)
- Shock delivery
- *Check Patient* alert is triggered
- Mode Selector is turned to PACER (after entering Manual mode)
- Patient alarm is triggered
- Stripchart recorder is turned on
- Code marker is entered
- Diagnostic ECG (when quick access key is pressed)
- 12-lead ECG acquisition

Printing Event Log

To print an Event Log, do the following:

1. Press the More quick access key ( ) until the Data quick access key displays.
2. Press the Data quick access key ( ).
3. Press the Treatment Summary quick access key ( ). The Select Rescue Incident to Print window displays.

Note: The incidents are displayed based on the date and time the incident began.



4. Rotate the Trim Knob to highlight the incident you want to print and then press the knob to select it. A green check mark displays next to the selected incident.
5. Rotate the Trim Knob to highlight **Print Event Log** and press the knob to select it. The ZOLL M2 unit prints the event log for the incident you have selected.
6. When the event log has finished printing, do one of the following:
   - Rotate the Trim Knob to the X in the top right corner of the window and press the knob to leave the window.
   - Press the Menu button ( ) to leave the window.

On the last event recorded, the unit prints “Summary Report Complete” on the bottom of the stripchart.

Note: You can only print event logs and snapshots from one rescue incident at a time.

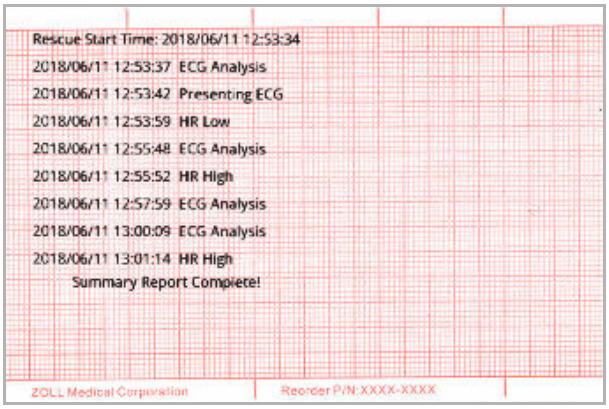


Figure 17-2. Event Log

Snapshots

When one of the events described in “Event Log” on page 17-4 occurs, the ZOLL M2 automatically captures and saves up to 6 seconds of physiological waveform and other data that preceded the event and 12 seconds of data following the event. This data capture is called a snapshot. Snapshot recording can be initiated automatically or by the user. The recorded data is stored in non-volatile memory and can be printed either during or after the initiating event.

The following incident information is included in every snapshot:

- Snapshot type
- Event date and time
- Patient type
- Printed ECG waveform start time and date (six seconds before the event start time)
- Pacer rate, output current, and pacer mode (demand or fixed) setting at the start of snapshot (if pacing is active)
- Heart rate at start of event (if available)
- Time stamped ECG strip from the primary lead (top ECG waveform on display screen)
- Primary lead name
- ECG size (cm/mV) and chart speed as printed
- ECG bandwidth used during acquisition of the ECG printed strip
- Device serial number
- User configured device ID (or bank field if identifier is not defined)
- Blank field for writing in the patient name (unless completed by device)

Note: Snapshots taken when the defibrillator is in Sync mode display the word “Sync” in the snapshot header.

Snapshot Types

The ZOLL M2 unit triggers snapshots in response to nine different types of events. Besides the information in the previous section that is included with every snapshot, the ZOLL M2 unit stores additional information in each of the following types of snapshots.

Presenting ECG

This snapshot is taken one time at the start of each new rescue incident. The snapshot is not retaken if the unit is shut off for less than 30 seconds. Additional information in this snapshot includes 18 seconds of the primary ECG lead waveform recorded after the first ECG leads connection to the patient.

Note: Once started, ECG recording continues during the presenting rhythm period even if there is a *Leads Off* condition.

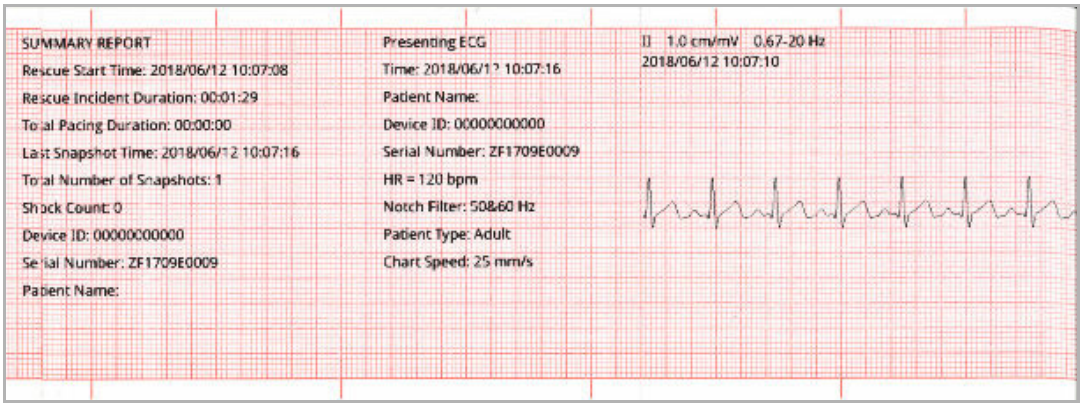


Figure 17-3. Presenting ECG Snapshot

ECG Analysis (AED Mode Only)

This snapshot is taken during ECG analysis (shockable rhythm analysis) and records six seconds of pre-analysis and 12 seconds of ECG data recorded during and after the analysis period. Additional information in this snapshot includes markers at the beginning and end of each 3-second segment of the ECG trace used by the analysis to determine whether ventricular fibrillation or shockable ventricular tachycardia is present. (Each segment is represented at the top of the strip with either an asterisk (*) for shockable, or a dash (-) for non shockable.) Analysis results includes the messages: *Shock Advised*, *No Shock Advised*, *Noisy ECG*, *Analysis Halted*.

Note: The date/time printed on the top of the strip is located directly above the data that was recorded at that time.

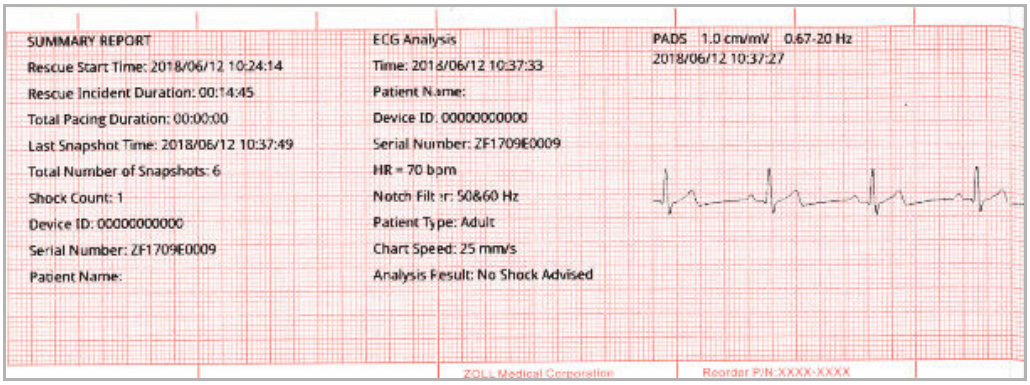


Figure 17-4. ECG Analysis Snapshot

Shock Delivery

This snapshot is taken when a shock is delivered. Additional information in this snapshot includes shock count, selected defibrillator energy, delivered defibrillator energy, patient impedance value, delivered RLB waveform first phase average current, and sync if active (including sync markers).

Note: Snapshots recorded during 30J self-test shocks include a *Test OK* or *Test Failed* annotation.

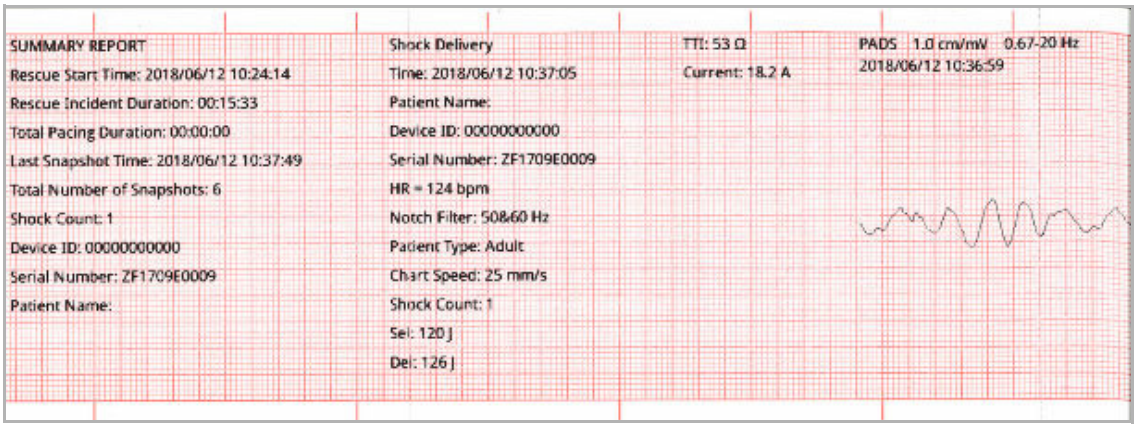


Figure 17-5. Shock Delivery Snapshot

Check Patient

This snapshot is taken when a *Check Patient* alert is issued. *Check Patient* messages and audio tones are issued in the Defib and/or Monitor mode when heart rate alarms are enabled and the ZOLL M2 unit detects ventricular fibrillation or wide complex ventricular tachycardia in the patient's ECG rhythm. Additional information in this snapshot includes the device operating mode (AED, DEFIB, MONITOR), and *Check Patient* annotation with the left edge of the annotation directly above the ECG signals recorded when the alarm occurred.

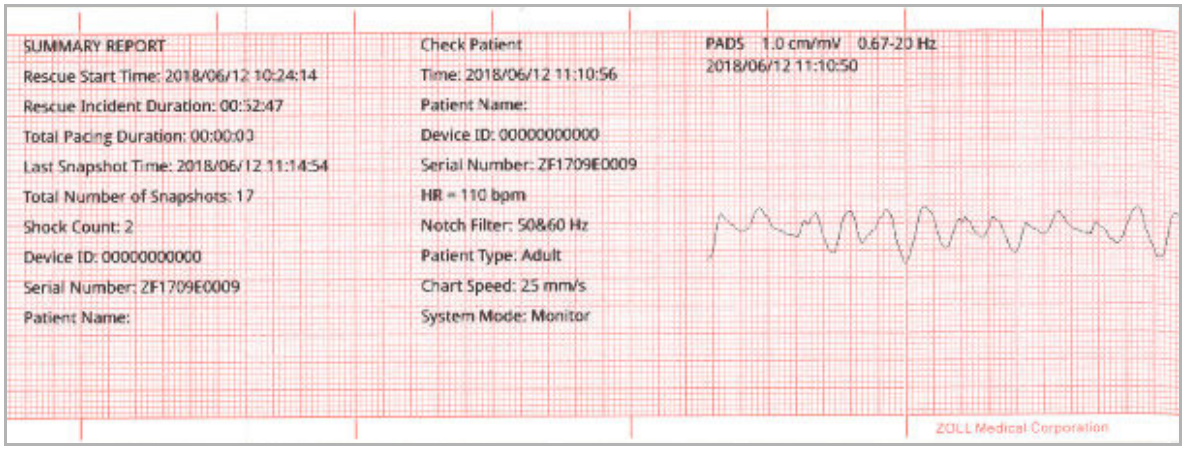


Figure 17-6. Check Patient Snapshot

Pacer Startup

This snapshot is taken when the unit enters the Pacer mode. It shows the patient's ECG waveform during the six seconds prior to the initiation of pacing and the rhythm during the following 12 seconds.

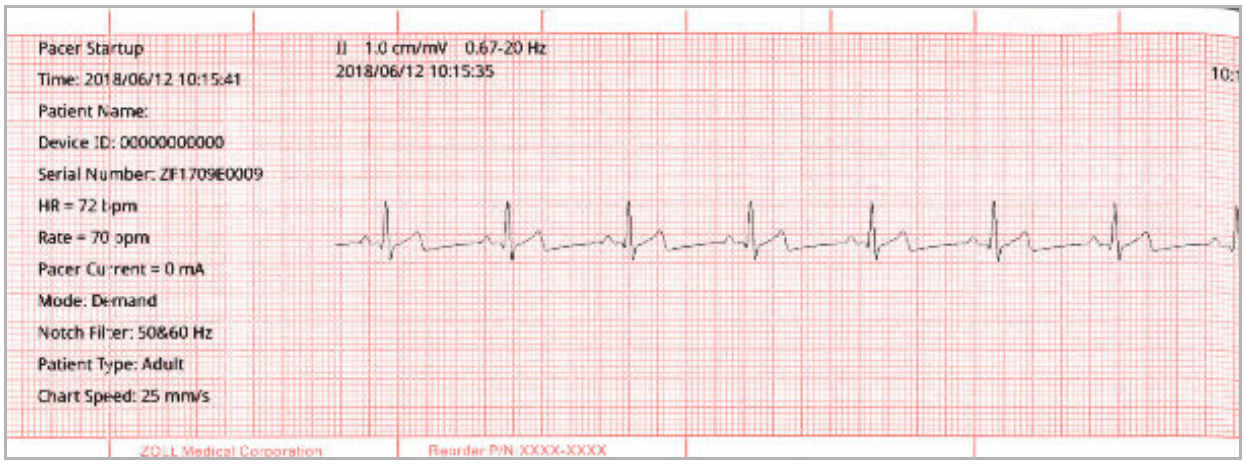


Figure 17-7. Pacer Startup Snapshot

Patient Alarm

This snapshot is taken when a patient alarm occurs. Additional information in this snapshot include the identification of physiological parameter causing alarm, indication of all currently active patient alarms, and the indication for each alarm of the limit violated (high or low).

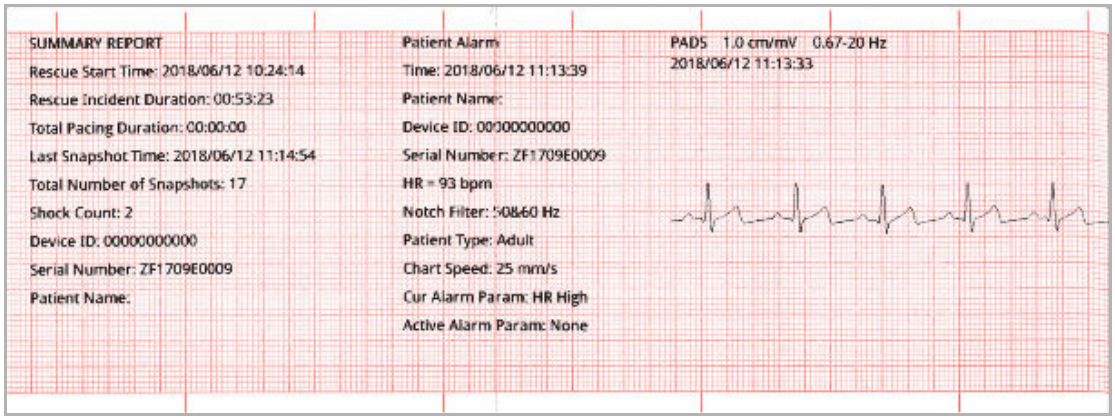


Figure 17-8. Patient Alarm Snapshot

Recorder Activation

This snapshot is taken when the recorder is activated by pressing the front panel recorder button. The 18-second snapshot is stored in memory even if the printer is turned off during the snapshot data acquisition period.

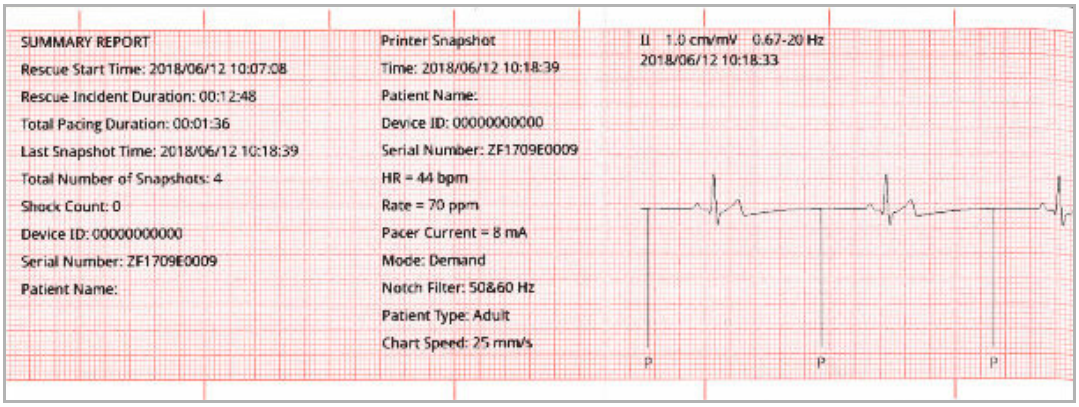


Figure 17-9. Recorder Activation Snapshot

Code Marker

This snapshot is taken when a code marker is entered. No ECG is printed in this case, just the code marker snapshot header and a record of the selected code marker.

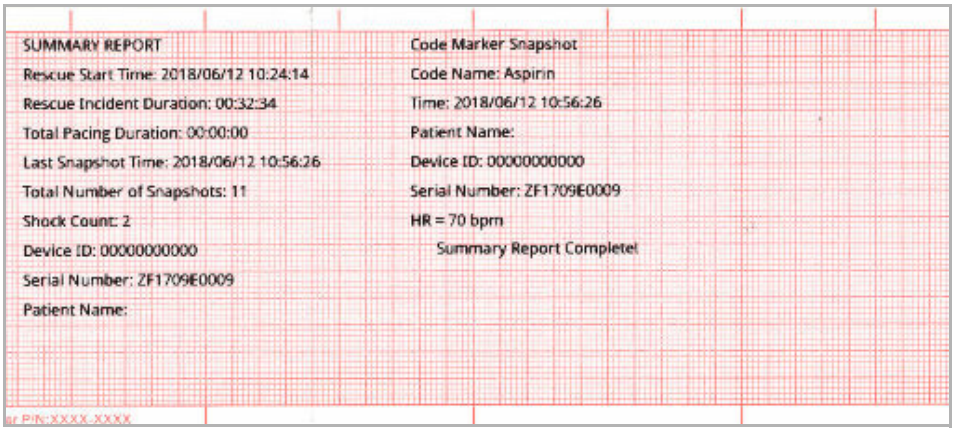


Figure 17-10. Code Marker Snapshot

Diagnostic ECG

This snapshot is taken when the ZOLL M2 unit is in Monitor mode and the **Diag** ECG front panel quick access key is pressed. ECG data captured in this snapshot is filtered with a .525-40 Hz frequency response in order to accurately preserve ST segment elevation or depression characteristics. When the **Diag** ECG key is pressed, the ECG filter characteristics are changed from normal ECG monitoring frequency response to diagnostic frequency response. The first six seconds of the snapshot that is recorded at monitor bandwidth is followed by approximately one second of blank ECG data as the new filtering initializes. The 11 seconds of diagnostic bandwidth ECG data for the top display lead is stored and printed.

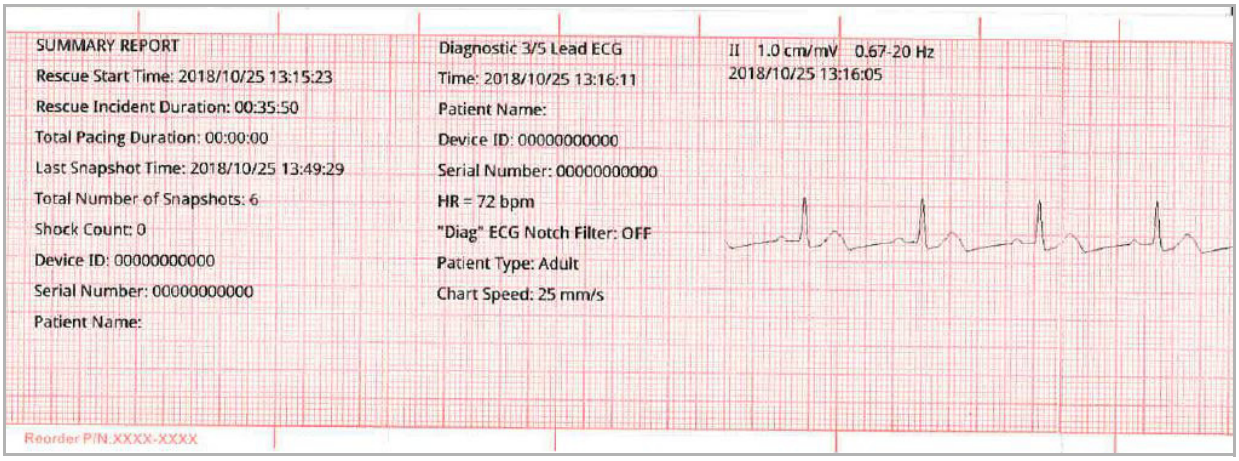


Figure 17-11. Diagnostic ECG Snapshot

12-Lead ECG

See Chapter 13, “12-Lead ECG Monitoring” for information on 12-lead ECG snapshots.

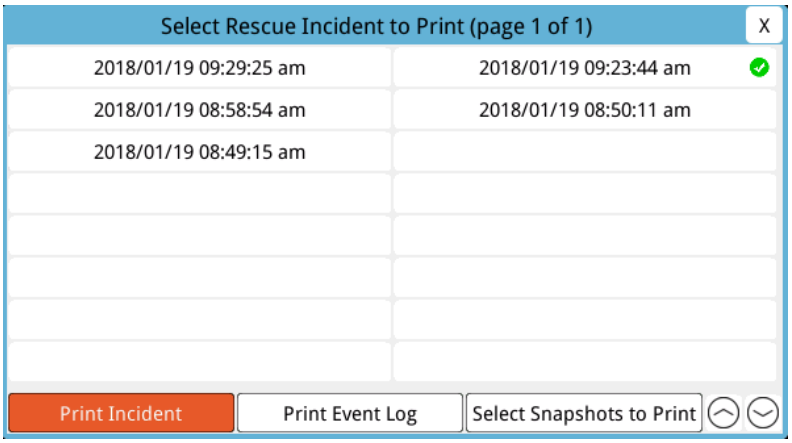
Printing Snapshots

The ZOLL M2 unit can be configured to automatically print some or all types of snapshots as they are acquired, or to store each snapshot without printing. This configuration is in the Supervisor menus. You can print stored snapshots at any time.

To print snapshots for a particular incident, do the following:

1. Press the More quick access key ( ) until the Data quick access key displays.
2. Press the Data quick access key ( ).
3. Press the Treatment Summary quick access key ( ). The Select Rescue Incident to Print window displays.

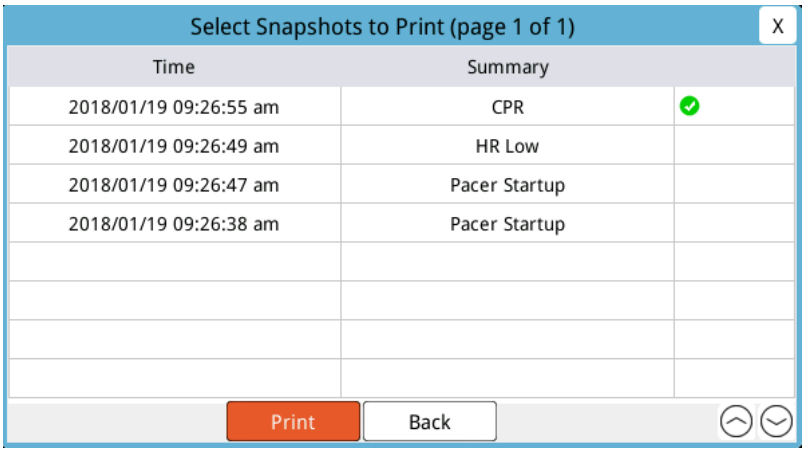
Note: The incidents are displayed on the screen based on the date and time the incident began.



4. Rotate the Trim Knob to highlight the incident your want to print and then press the knob to select it. A green check mark displays next to the selected incident.
5. To print:

- **All snapshots related to a selected incident** -- rotate the Trim Knob to highlight **Print Incident** and press the knob to select it. Go to step 8 in this procedure.

- **Select Snapshots related to a selected incident** -- rotate the Trim Knob to highlight **Select Snapshots to Print** and then press the knob to select it. The Select Snapshots to Print window displays.



6. Rotate the Trim Knob to highlight a snapshot and then press the knob to select it. You can print more than one snapshot. A green check mark displays next to the snapshot(s) that you have selected to print.
7. Rotate the Trim Knob to highlight **Print**, and press the knob to select it. The ZOLL M2 unit prints the snapshot(s) you have selected.
8. When the snapshot(s) has finished printing, do one of the following:
   - Rotate the Trim Knob to the X in the top right corner of the window and press the knob to leave the window.
   - Press the Menu button ( ) to leave the window.

On the last snapshot recorded during each incident, the unit prints “Summary Report Complete” on the bottom of the stripchart.

Note: You can only print snapshots from one rescue incident at a time.

Full Disclosure Recording

Along with event information captured in Summary Report, the ZOLL M2 monitor/defibrillator also records the CPR sensor and physiological parameter waveforms in a full disclosure file, which can accommodate at least 6 hours of data.

You can transfer a full disclosure file containing rescue incident information using USB or WiFi. Data transferred by either method can be viewed in RescueNet CaseReview and RescueNet EventSummary. To transfer the full disclosure recording of the current rescue incident, the unit has to be turned off for 30 seconds or longer to end the incident, then turned on again to transfer the incident data.

Note: Before using WiFi, you must have internet access and a secure access point.

Transferring Full Disclosure Recording Using USB

Note: Data transfers via USB will not be successful if the USB flash storage device is full or does not have sufficient memory available.

Before starting the data transfer, insert a USB memory device into the ZOLL M2 USB port.

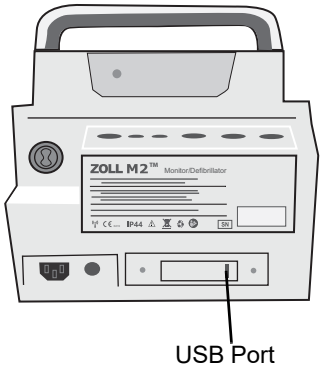
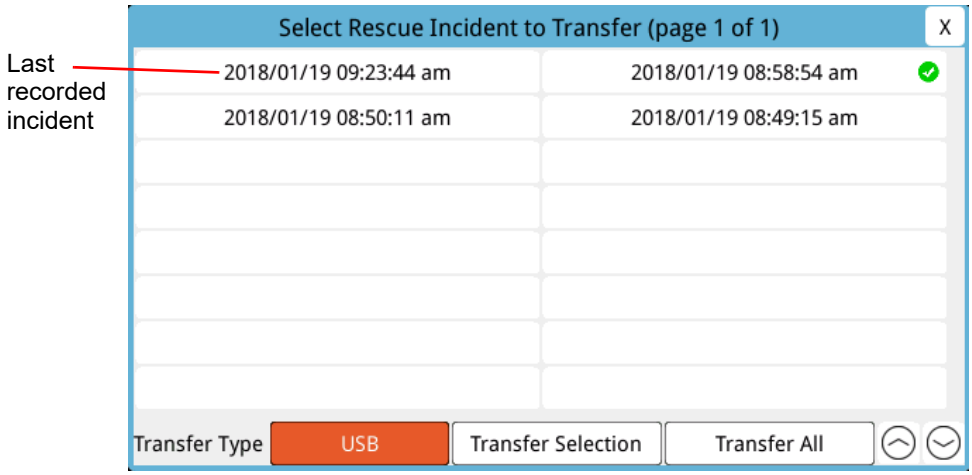


Figure 17-12. USB Port

Note: If the USB device does not establish communication with the ZOLL M2 unit, turn off the unit and then turn it back on again to establish communication.

To transfer data do the following:

1. Press the More quick access key ( ) until the Data quick access key displays.
2. Press the Data quick access key ( ).
3. Press **Transfer** quick access key ( ). The Select Rescue Incident to Transfer menu displays.



4. Rotate the Trim Knob to select USB as the transfer type, then press the knob to select **USB**.
5. To transfer:

   Specific incident(s) - rotate the Trim Knob to highlight a rescue incident, and press the knob to select it (a green check marker displays next to the incident). Rotate the Trim Knob to highlight **Transfer Selection** then press the knob to select it.

   All incidents - rotate the Trim Knob to highlight **Transfer All** and then press the knob to select it.
6. When the transfer is finished, the message *Rescue Data Transfer - Successful* displays.
7. Do one of the following
   - Rotate the Trim Knob to the X in the top right corner of the window and press the knob to leave the window.
   - Press the Menu button ( ) to leave the window.

Note: Do not remove the USB device from the ZOLL M2 unit during transfer.

Warning! **To avoid a possible shock hazard, do not make any electrical connections to the USB port except to connect a USB flash drive while the ZOLL M2 unit is connected to or within touching distance of the patient.**

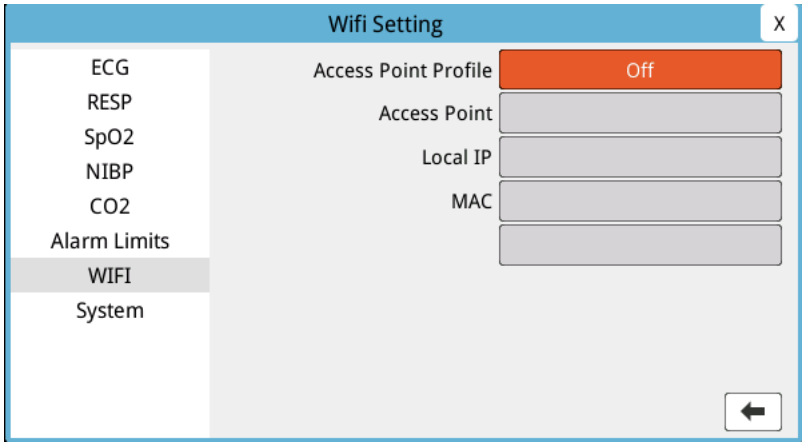
Transferring Full Disclosure Recording Using WiFi

For units with an SFTP server or Case Push configured, the ZOLL M2 unit sends patient disclosure logs to a remote server through a wireless connection. WiFi, SFTP, and Case Push settings can be configured in the Supervisor menu. If the WiFi, SFTP, and Case Push settings have not been configured, see “Setting Up WiFi/SFTP Server/Case Push” on page 17-19 before completing the following procedure.

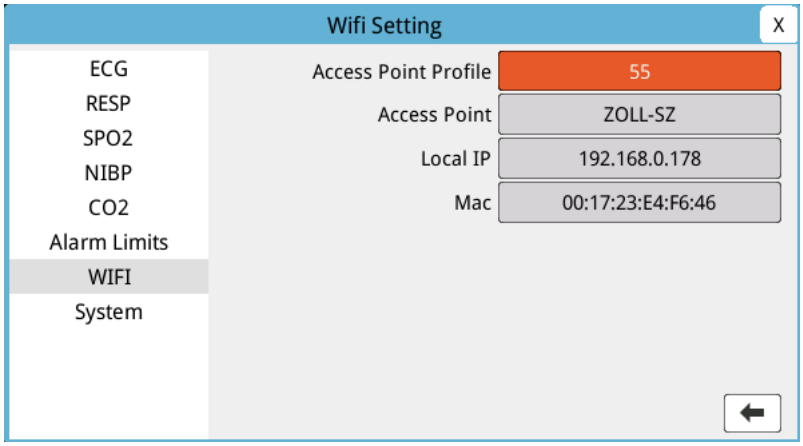
Note: The ZOLL M2 unit automatically cancels any full disclosure log transmissions when defibrillation is activated.

To connect to a WiFi network:

1. Rotate the Trim Knob to the Wifi icon ( ) on the top center of the display, then press the knob to display the Wifi Setting. Or press the Menu button ( ), rotate the Trim Knob to the Wifi Setting, then press the knob to display the Wifi Setting.

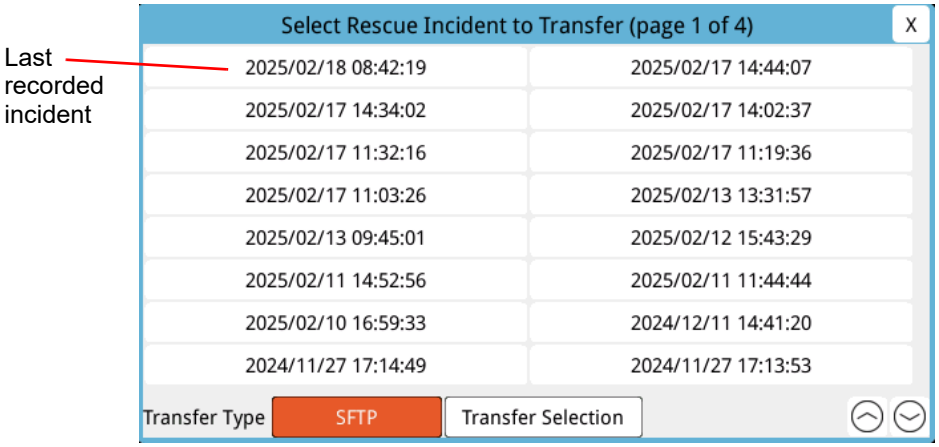


2. Rotate the Trim Knob to Access Point Profile setting, press the knob to select one of the pre-configured Wifi access points.
3. The ZOLL M2 unit attempts to connect to the selected Wifi access point. If successful, The status window displays Connected and the Wifi connected icon ( ) is displayed on the top center of the display. If not successful (due to a Wifi connection timeout or firmware error), turn the Wifi off and turn it back on. If still not successful, power cycle the unit to reconnect the Wifi. You may also need to check the selected Wifi access point profile in supervisor mode to correct any profile error.



Transferring full disclosure recording using SFTP:

1. Press the **More** quick access key ( ) until the Data quick access key displays.
2. Press the **Data** quick access key ( ).
3. Press **Transfer** quick access key ( ). The Select Rescue Incident to Transfer window displays.



4. Rotate the Trim Knob to select **SFTP** as the Transfer Type then press the knob to select it.
5. Rotate the Trim Knob to highlight a rescue incident, then press the knob to select it (a green check marker displays next to the incident). Rotate the Trim Knob to highlight **Transfer Selection** then press the knob to select it.
6. When the transfer is finished, the message *Rescue Data Transfer - Successful* displays.
7. Do one of the following:
   - Rotate the Trim Knob to the X in the top right corner of the window and press the knob to leave the window.
   - Press the Menu button ( ) to leave the window.

Transferring full disclosure recording using Case Push

The ZOLL M2 unit has two Case Push options:

- Automatic
- Manual

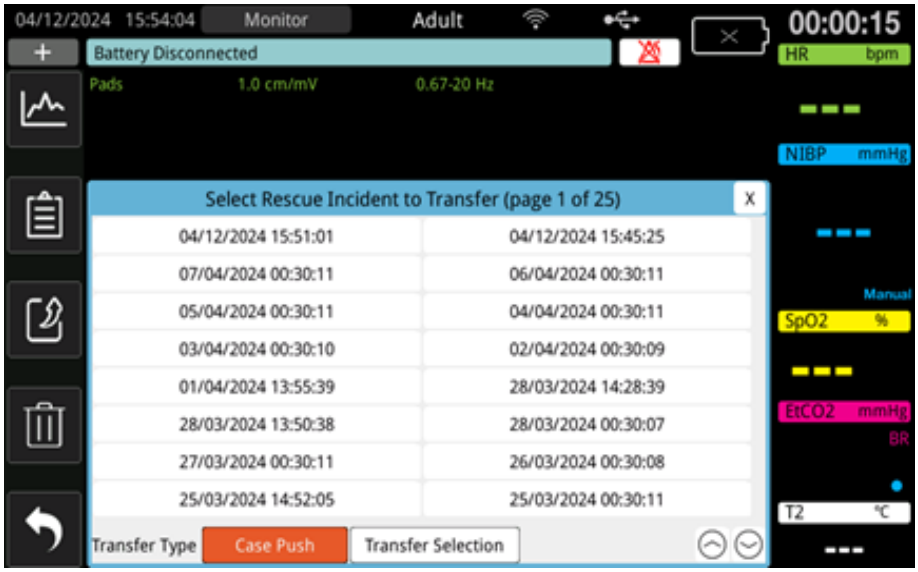
Automatic Case Push

The ZOLL M2 unit allows the transfer of up to three most recent full disclosure files. When enabled and the unit is connected to the WiFi network, Automatic Case Push is activated every time the unit is powered off.

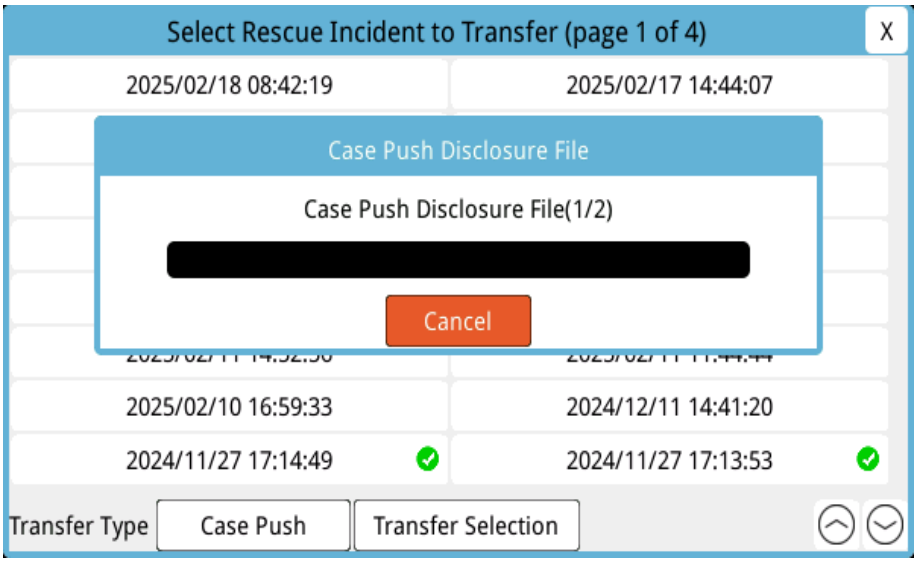
Manual Case Push

1. Press the **More** quick access key ( ) until the Data quick access key displays.
2. Press the **Data** quick access key ( ).

3. Press the **Transfer** quick access key ( ). The Select Rescue Incident to Transfer menu displays.
4. Rotate the Trim Knob to highlight a rescue incident, then press the Trim Knob to select it (a green check marker displays next to the incident). You can select up to 15 cases.
5. To select **Case Push**, rotate the Trim Knob to highlight **USB** and press the Trim Knob to display the Transfer Type drop down menu. Rotate the Trim Knob to highlight **Case Push** and press the Trim Knob to select it.



6. Rotate the Trim Knob to highlight **Transfer Selection** and press the Trim Knob to select it.



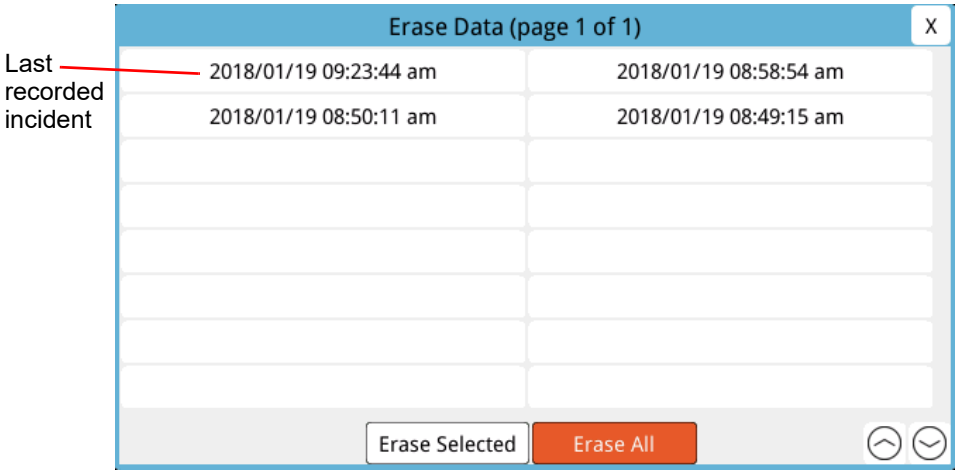
When the transfer is finished, the message *Transfer Complete* is displayed.

Deleting a Rescue Incident

You can delete a rescue incident to erase all the patient data (full disclosure recording, summary report, trend data, 12-lead reports) that is associated with that incident.

To delete a rescue incident:

1. Press the **More** quick access key ( ) until the Data quick access key displays.
2. Press the **Data** quick access key ( ).
3. Press **Clear** quick access key ( ). The Erase Data window displays.



4. To erase:

   Specific incident(s) - rotate the Trim Knob to highlight a rescue incident, then press the knob to select it (a green check marker displays next to the incident). Rotate the Trim Knob to highlight **Erase Selected** and then press the knob to select it.

   All incidents - rotate the Trim Knob to highlight **Erase All** then press the knob to select it.
5. At the *Erase Selected Rescue Data?* or *Clear All Rescue Data?* prompt, press the Trim Knob to select **Yes**.
6. Do one of the following:
   - Rotate the Trim Knob to the X in the top right corner of the window and press the knob to leave the window.
   - Press the Menu button ( ) to leave the window.

Setting Up WiFi/SFTP Server/Case Push

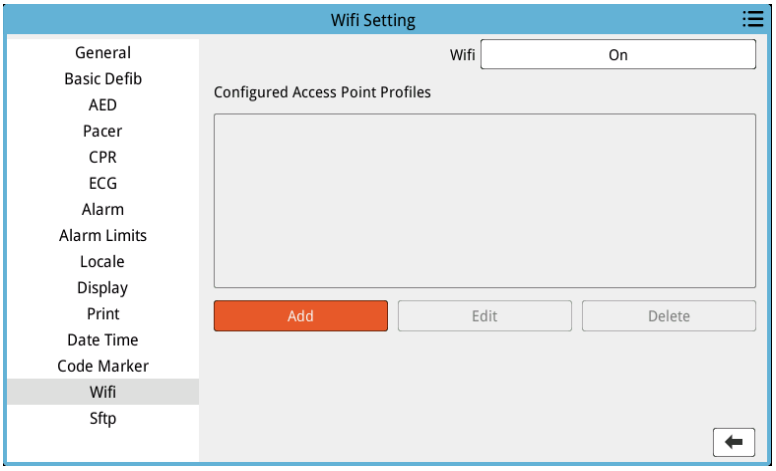
This section describes how to set up a wireless connection, SFTP server, and Case Push feature for your ZOLL M2 unit in order to send full disclosure files through a wireless connection. The disclosure files can be sent over Wi-Fi using one of these two methods:

- Secure File Transfer Protocol (SFTP) which requires an SFTP server on the receiving end.
- Case Push feature to send files to ZOLL RescueNet® CaseReview software

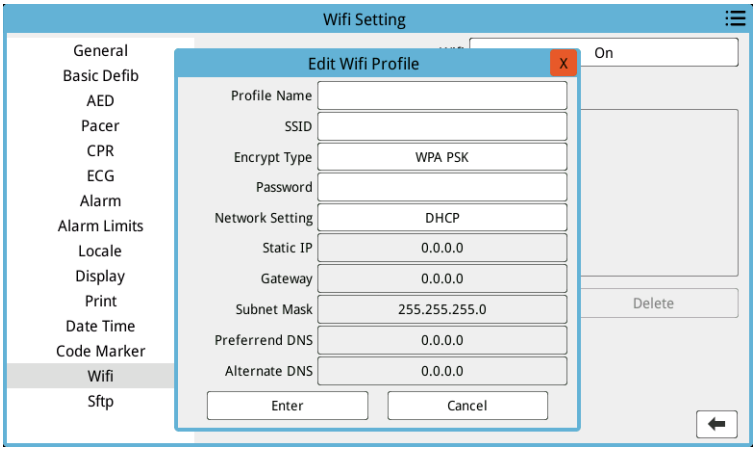
These settings are accessible in the Supervisor menu. You will need a passcode to enter this menu.

To Set Up A Wifi Network

1. In the Supervisor menu, press the Trim Knob to select Modify Config.
2. Rotate the Trim Knob to highlight Wifi from the menu on the left side of the window and press the knob to select it. The Wifi setting window displays.



3. Rotate the Trim Knob to move to the Add field then press the knob to select it. The Edit Wifi Profile menu displays.



4. Rotate the Trim Knob to move to each field and press the knob to enter the applicable information. See the following table for assistance on entering information in each field.

Note: Some of these fields require you to enter information in a alpha-numeric keypad. See “Entering Information Using Alpha-numeric Keypad” on page 17-22 for information on how to navigate this keypad.

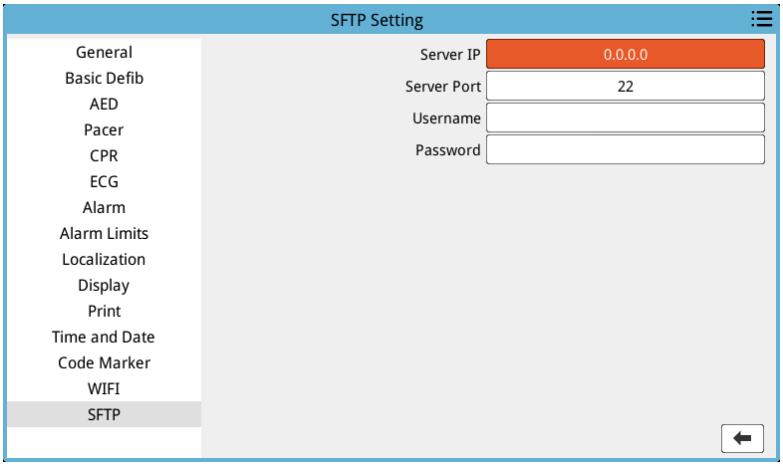
Table 17-1. Edit Wifi Profile Fields

Field	What to Enter
Profile Name	Use the alpha-numeric keypad to enter the name for the access point to which you want to connect.
SSID	Use the alpha-numeric keypad to enter the SSID (Service Set IDentifier) name that identifies your wireless network access point.
Encrypt Type	Rotate the Trim Knob to select the authentication type. The unit supports two types of Wi-Fi authentication: • WPA-PSK (Wi-Fi Protected Access, Pre-shared key) • WPA2-PSK (Wi-Fi Protected Access II, Pre-shared key)
Password	Use the alpha-numeric keypad to enter the access point password.
Network Setting	Rotate the Trim Knob to select either DHCP or Static IP. If you select DHCP, you do not have to complete anymore fields. If you select Static IP, use the alpha-numeric keypad to enter values for the IP Address, Subnet Mask, Default Gateway, Preferred DNS Server, and Alternate DNS Server (see below).
Static IP	Use the numeric keypad to enter your Static IP address (format is 0.0.0.0).
Gateway	Use the numeric keypad to enter your Gateway IP address (format is 0.0.0.0).
Subnet Mask	Use the numeric keypad to enter your Subnet Mask (format is 255.255.255.0).
Preferred DNS	Use the numeric keypad to enter your Preferred DNS IP address (format is 0.0.0.0).
Alternate DNS	Use the numeric keypad to enter your Alternate DNS IP address (format is 0.0.0.0)

5. Rotate the Trim Knob to move to the category list icon at the top right corner and press the knob to exit to the Supervisor Menu. Select “Save Config then Exit” to save the configuration and exit the Supervisor menu.

To Set Up A SFTP Server

1. In the Supervisor menu, press the Trim Knob to select Modify Config.
2. Rotate the Trim Knob to select SFTP from the menu on the left side of the window. The SFTP setting window displays.



3. Rotate the Trim Knob to move to each field and enter the applicable information. See the following table for assistance on entering information in each field.

Note: Most of these fields require you to enter information in a alpha-numeric keypad. See the following section, Entering Information Using Alpha-numeric Keypad, for information on how to navigate this keypad.

Table 17-2. SFTP Setting Fields

Field	What to Enter
Server IP	Use the numeric keypad to enter your Alternate DNS IP address (format is 0.0.0.0)
Server Port	Use the numeric keypad to enter the server port.
Username	Use the alpha-numeric keypad to enter the SFTP server username.
Password	Use the alpha-numeric keypad to enter the SFTP server password.

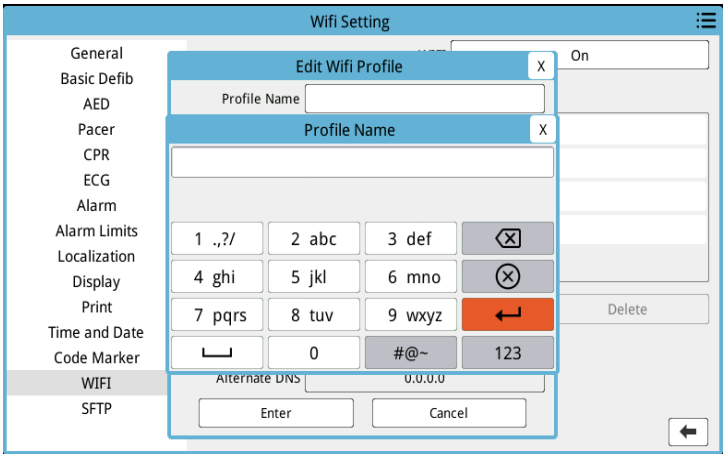
Entering Information Using Alpha-numeric Keypad

Use the following procedure to enter information in the Wifi Setting and SFTP Setting windows.

Note: When a field requires a numeric entry, only numbers are available on the keypad.

Note: If you don't use a format that is required by a field, the message *Invalid Input!* displays.

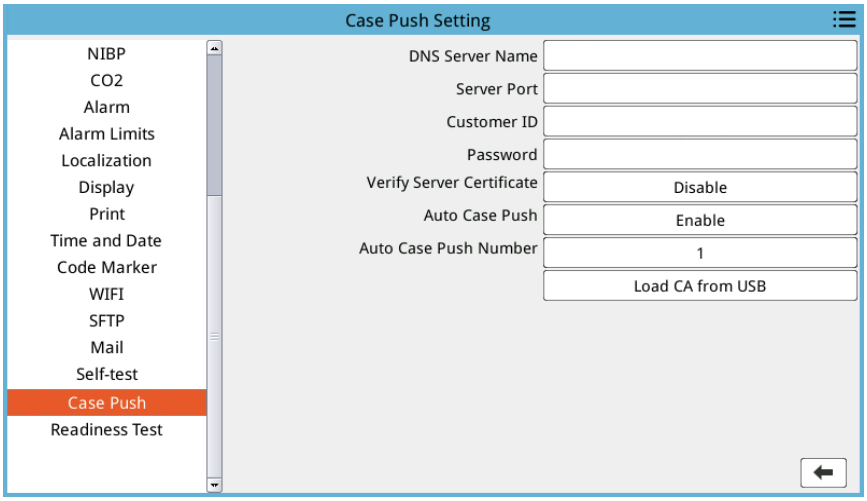
1. Rotate the Trim Knob to place the cursor in the field for which you want to enter information, and press the knob. The keypad displays for that field.



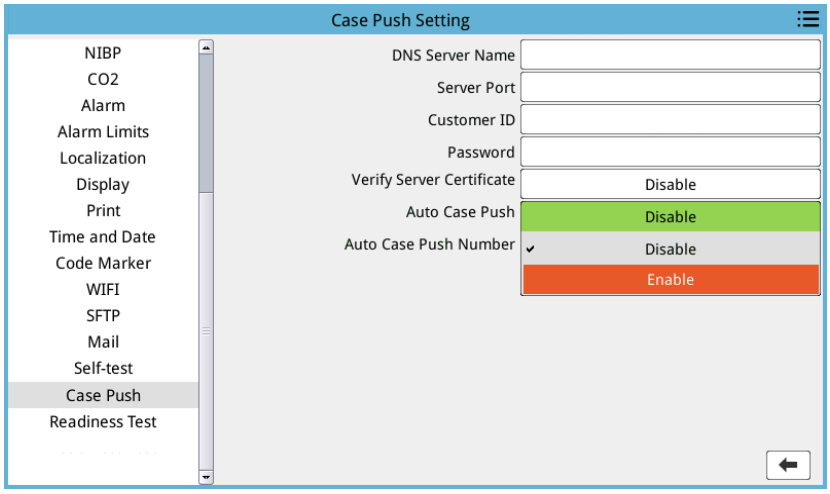
2. Rotate the Trim Knob to highlight the alpha/numeric key and press the knob to display the letters/numbers for that key at the top of the keypad.
3. Rotate the Trim Knob to highlight the number/letter selection, and press the knob to select it. Repeat steps 2 and 3 until you have selected all the numbers/letters for the field.
4. Rotate the Trim Knob to highlight the **Enter** (↵) key and press the knob to select it. The selected characters display in the field in the applicable window.
5. Rotate the Trim Knob to move to the category list icon at the top right corner and press the knob to exit to the Supervisor Menu. Select "Save Config then Exit" to save the configuration and exit the Supervisor menu.

To Set Up A Case Push Server

1. In the Supervisor menu, press the Trim Knob to select Modify Config.
2. Rotate the Trim Knob to select Case Push from the menu on the left side of the window. The Case Push Setting window displays.



3. Rotate the Trim Knob to move to each field and enter the applicable information. See Table 17-3 for assistance on entering information in each field.



Note: Most of these fields require entering information in a alpha-numeric keypad. See "Entering Information Using Alpha-Numeric Keypad" on page 17-22 for information on how to navigate this keypad.

4. Rotate the Trim Knob to move to the category list icon at the top right corner and press the knob to exit to the Supervisor Menu. Select “Save Config then Exit” to save the configuration and exit the Supervisor menu.

Table 17-3. Case Push Setting Fields

Field	What to Enter
DNS Server name	Use the alpha-numeric keypad to enter server DNS name.
Server Port	Use the numeric keypad to enter the server port number.
Customer ID	Use the alpha-numeric keypad to enter the customer ID number.
Password	Use the alpha-numeric keypad to enter the associated password.
Verify Server Certificate	Rotate the Trim Knob to select either Disable or Enable. If Enabled, the unit connects to the server and verifies the server's certificate and identity before transmitting. If the verification fails, the unit displays an error message. Enabling this option improves the security of the connection by confirming the unit is communicating with the actual server.
Auto Case Push	Rotate the Trim Knob to select either Disable or Enable.
Auto Case Push Number	Rotate the Trim Knob to select number of files to send. Possible values: 1, 2, 3. Default value: 1.
Load CA from USB	When Verify Server Certificate is enabled, the unit connects to the server and verifies the default certificate included with the ZOLL M2 unit. The Certificate of Authentication can also be uploaded from a USB stick: • Insert a USB stick with the certificate into the USB port on the device. • Rotate the Trim Knob to select the Load CA Certificate from USB field. A list of available CA certificate files displays. • Select the desired certificate files and select Import. The message *CA Import Successful* displays.

Table 17-4. Communication Messages – Case Push

The ZOLL M2 unit may display one of the following messages during the manual and automatic Case Push transmissions:

Manual Case Push Message	Automatic Case Push Message	Cause/Action
Transfer complete (preceded by a progress bar per case - up to 15 cases)	Case Push Disclosure File (with a full green progress bar – up to 3 cases)	Indicates a successful transmission of the Full Disclosure file.
Transmission failed	Transmission failed - Unit Powering Off.	The data transfer has failed. The communication error is undefined: • Verify that the Wi-Fi settings are correct. • Verify that the server setting is configured correctly. • Make sure that the unit is within range of the wireless network.
Server Connection Failed	Server Connection Failed - Unit Powering Off	The data transfer has failed. • Verify that the server settings are configured correctly.
Authentication Failed	Authentication Failed - Unit Powering Off	The data transfer has failed. • Verify that password/username combination is correct.
Certificate Error	Certificate Error - Unit Powering Off	The data transfer has failed. The CA certificate is expired, or the trust chain cannot be established.
Cancel Transfer	Cancel Transfer - Unit Powering Off	The user canceled the transmission.
Network disconnected	No message displayed. When the network is not available, the unit will skip the transmission	The data transfer has failed. • Verify that the Wi-Fi settings are correct. • Make sure that the unit is within range of the wireless network.

Chapter 18
Maintenance and Troubleshooting

Resuscitation equipment must be maintained to be ready for immediate use. To ensure the readiness and optimum working condition of the ZOLL M2 unit, you should perform the following inspections and tests daily or at each shift change.

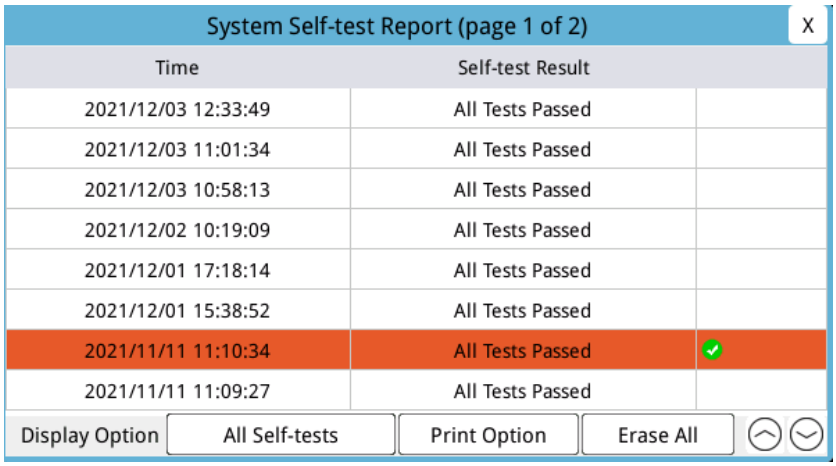
In addition to the daily check, authorized personnel should complete performance and calibration testing at regularly scheduled intervals, which should not exceed one year.

A maintenance log is an important part of a successful maintenance program in which you record information on a regular basis. This allows for verification of necessary maintenance and for scheduling periodic requirements such as calibration and certification. You can also configure the ZOLL M2 to print out both power-on and 30J self-test results.

Based on the recommendations of the Defibrillator Working Group of the U.S. Food and Drug Administration[1], ZOLL suggests using an operator's shift check list, which is included in this chapter (and can be copied for use as needed).

The ZOLL M2 unit can display both power-on and 30J self-test reports stored in the device (up to 2,000 reports) by pressing the  Quick Access key. The user can select the tests to display on the unit: All Self-tests, Power On Self-tests, or 30J Self-tests. You can then select reports to print: select Print Option, then choose Selected, Last 30 Days, or All Self-tests. To select an individual report, turn the Trim Knob to select the desired report, then press the Trim Knob to select it.

1. **JAMA. 1990;264:1019-1025**



The daily power-on self test can be configured to a specific time of day; refer to the *ZOLL M2 Configuration Guide* for instructions on how to configure the self tests.

Note: The ZOLL M2 unit must be plugged in to AC power in order to run the daily self test.

Warning! **Do not perform service on the ZOLL M2 unit while it is connected to a patient.**

Readiness Test Report Review, Printing, and Transfer

When the Readiness Test Report feature is enabled, the ZOLL M2 unit can either Print the report or Transfer the report via WiFi. A Readiness Test Report is created after a 30J test is performed. When enabled, the automated report activates upon start up of the unit. The ZOLL M2 unit can store up to one thousand Readiness Test Reports.

Note: The Readiness Test Report is only available on ZOLL M2 units with integrated WiFi.

The Readiness Test Report includes the following items:

Report Items	Result
Date and time	
Readiness test result	• Pass • Fail
Unit serial number	
Test type	• Auto • Manual
Defibrillation self-test	• Pass • Fail
Pacer self-test	• Pass • Fail • Not available
ECG self-test	• Pass • Fail

Report Items	Result
Battery	• Pass • Fail • Not connected
30J self-test	• Pass • Fail • Not performed
AC Power status	• Connected • Not connected

Readiness Test Report during Automatic Power On Self-Test (APOST)

When the Automatic Power On Self-Test (APOST) is enabled, the Readiness Test Report is generated after completion of the automatic 30J test. If Readiness Test Report Auto Print is enabled, the unit prints the Readiness Test Report after completion of all self-tests. If Readiness Test Report Auto Transfer is enabled and the ZOLL M2 unit is properly configured to the WiFi, the unit transmits the Readiness Test Report to the receiving server.

Note: To configure self-tests, refer to the ZOLL M2 Configuration Guide.

Readiness Test Report in Defib Mode

In defibrillation mode, the Readiness Test Report is generated after completion of the manual 30J test. If Readiness Test Report Auto Print is enabled, the unit prints the Readiness Test Report after completion of the 30J test. If Readiness Test Report Auto Transfer is enabled and the ZOLL M2 unit is properly configured to the WiFi, the unit transmits the Readiness Test Report to the receiving server.

Communication Messages – Readiness Test Report Transfer

The ZOLL M2 unit displays one of the following messages after the Readiness Test Report transmission:

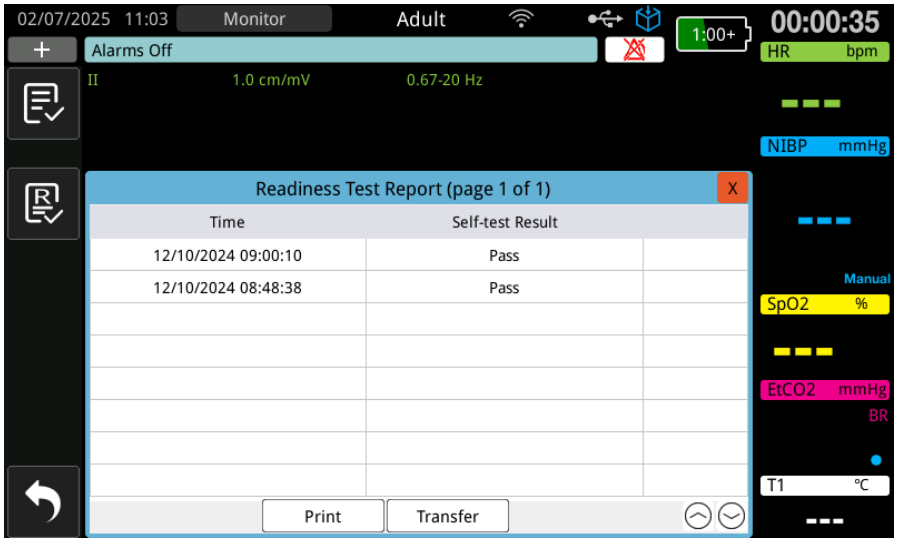
Note: During automatic transmission, the messages below are displayed in blue in the status/alarm message field.

Message	Cause/Action
Readiness Test Report Transfer - Successful	Indicates a successful transmission of the Readiness Test Report.
Readiness Test Report Transfer - Failed	The data transfer failed. The communication error is undefined: • Verify that the Wi-Fi settings are correct. • Verify that the server setting is configured correctly. • Make sure that the unit is within range of the WiFi.
Readiness Test Report Transfer - Server Connection Failed	The data transfer failed. • Verify that the server settings are configured correctly and the unit is connected to Wi-Fi.
Readiness Test Report Transfer - Authentication Failed	The data transfer failed. Verify that the password/username combination is correct.

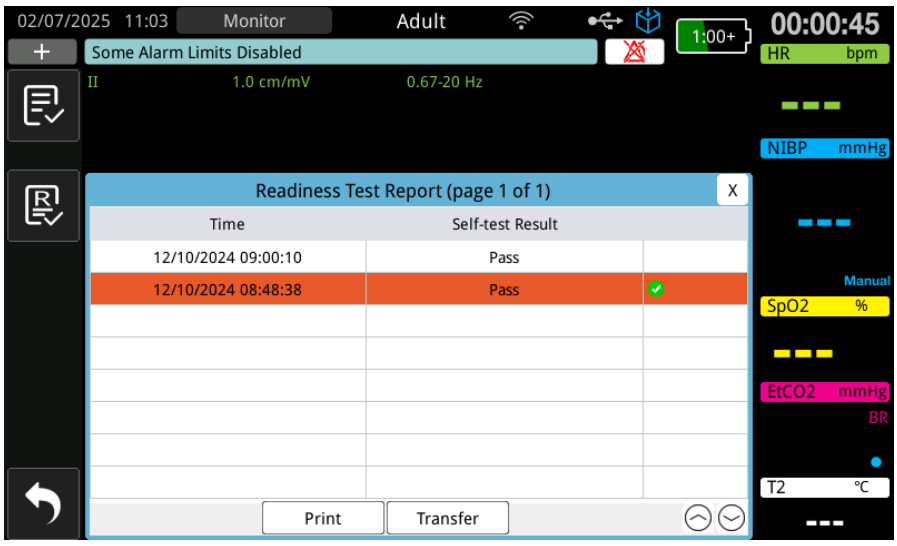
Message	Cause/Action
Readiness Test Report Transfer - Certificate Error	The data transfer failed. The certificate expired, or the trust chain cannot be established.

To print or transfer a Readiness Test

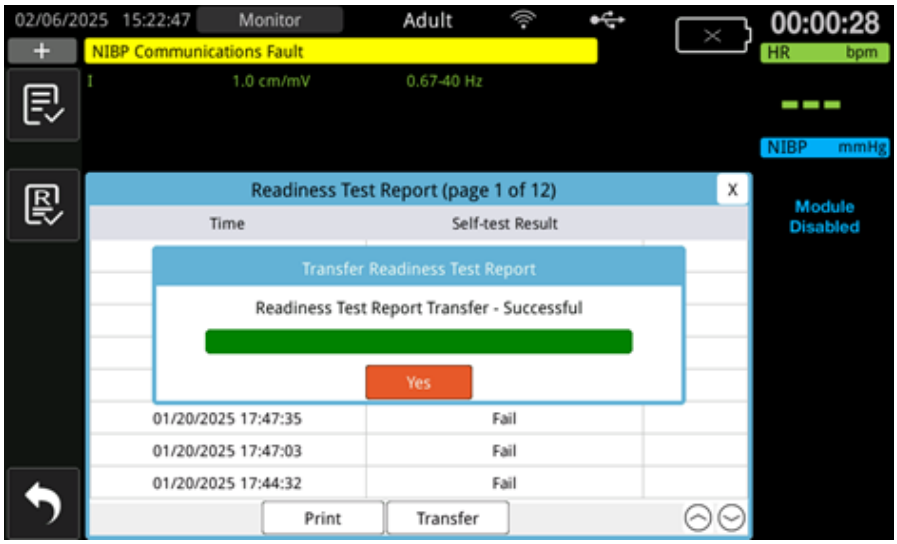
1. Press the **More** quick access key ( ) until the Readiness Test Report quick access key displays.
2. Press the Readiness Test Report quick access key ( ).



3. Rotate the Trim Knob to highlight a Readiness Test Report, then press the knob to select it (a green check marker displays next to the report).



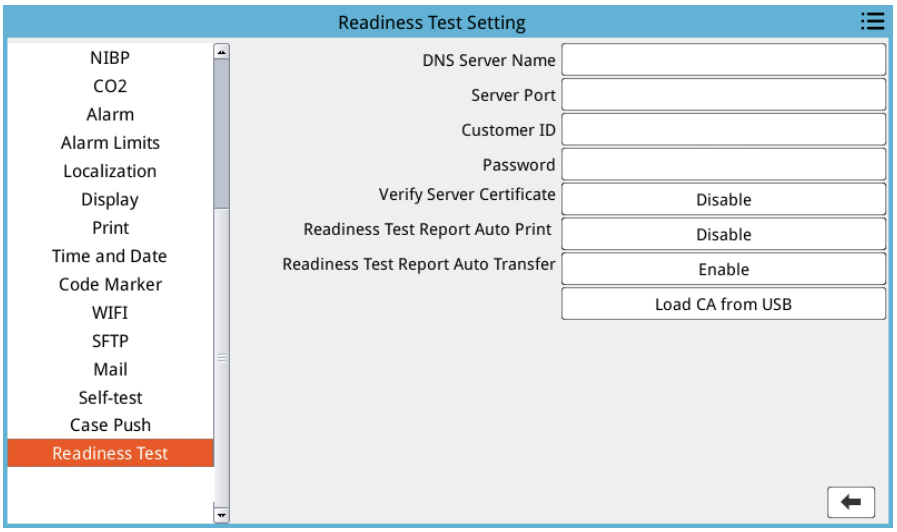
4. Rotate the Trim Knob to highlight either **Print** or **Transfer**, then press the knob to select it. If **Transfer** is selected, a progress bar displays. If **Print** is selected, the M2 unit prints the report.



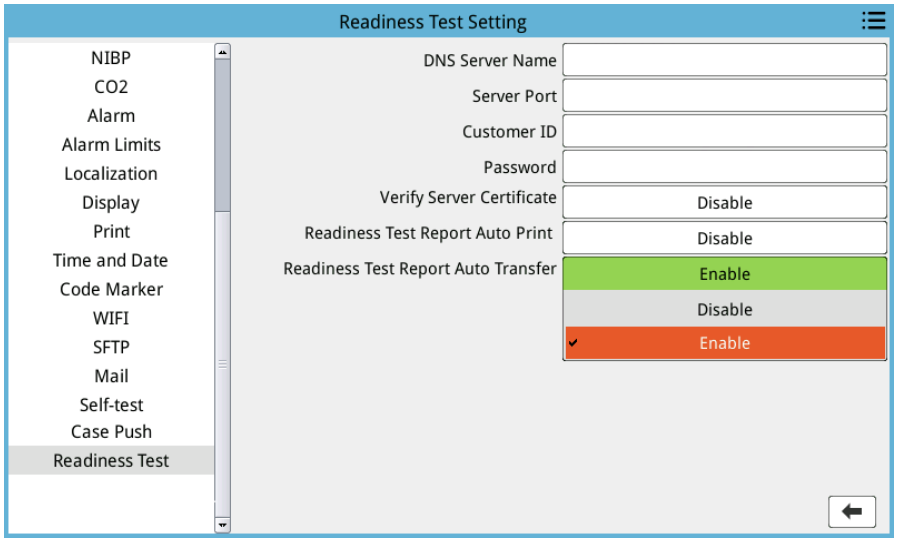
Set up a server for Readiness Test

The ZOLL M2 unit can transmit the Readiness Test Reports to a remote server via Wi-Fi. To set up a Wi-Fi connection, refer to “To Set Up a WiFi Network” on page 17-19. To configure the server, do the following:

1. In the Supervisor menu, press the Trim Knob to select Modify Config.
2. Rotate the Trim Knob to select Readiness Test from the menu on the left side of the window. The Readiness Test setting window displays.



3. Rotate the Trim Knob to move to each field and enter the applicable information. See Table 1 for assistance on entering information in each field.



4. Rotate the Trim Knob to move to the category list icon at the top right corner and press the knob to exit to the Supervisor Menu. Select “Save Config then Exit” to save the configuration and exit the Supervisor menu.

Table 1: Readiness Test Setting Fields

Field	What to Enter
DNS Server name	Use the alpha-numeric keypad to enter server DNS name.
Server Port	Use the numeric keypad to enter the server port number.
Customer ID	Use the alpha-numeric keypad to enter the customer ID number.
Password	Use the alpha-numeric keypad to enter the associated password.
Verify Server Certificate	Rotate the Trim Knob to select either Disable or Enable. If Enabled, the unit connects to the server and verifies the server's certificate and identity before transmitting. If the verification fails, the unit displays an error message. Enabling this option improves the security of the connection by confirming the unit is communicating with the actual server. **Note:** The ZOLL M2 unit has a preloaded certificate to connect to the CaseReview server.
Load CA from USB	If Verify Server Certificate is enabled, the Certificate of Authentication must be uploaded from a USB stick. • Insert a USB device with the certificate into the USB port on the device. • Select the Load CA Certificate in the USB field. A list of available CA certificate files displays. • Select the desired certificate files and press Import. • The message *CA Import Successful* displays. Press the Yes button to return to the Readiness Test Setting menu.
Readiness Test Report Auto Print	Allows automatic printing of readiness test results. Possible values: Enable, Disable Default value: Disable
Readiness Test Report Auto Transfer	Allows automatic transmission of the readiness test results. Possible values: Enable, Disable Default value: Disable

Daily/Shift Check Procedure

Inspection

Equipment and Accessories

- Ensure that the ZOLL M2 unit is clean (with no fluid spills) and free of visible damage.
- Inspect all cables, cords, and connectors for signs of damage or excessive wear (cuts in insulation, fraying, broken wires, dirty or bent connector pins). Replace if damaged.
- Inspect the battery, ECG patient cable, multifunction cable (MFC), SpO_2 sensor, blood pressure cuff and hose, CO_2 sensor(s), and temperature sensors for signs of damage or excessive wear. Replace if damaged.
- Inspect the defibrillator paddles for pitting, gouging, damage, or excessive wear. Check that paddle surfaces are clean and free of electrolyte gel or other contaminants. Verify that all paddle controls operate freely when pressed and released.
- Inspect the external AC power cord and connectors for signs of damage. Replace if damaged.

Supplies

- Verify the presence, proper condition, and appropriate quantities of all disposable supplies (hands-free therapy electrodes, ECG monitoring electrodes, defibrillator gel, recorder paper, alcohol swabs, razors/scissors, etc.).
- Verify that two sets of hands-free therapy pads or Dura-padz and two sets of Dura-padz gel are available.
- Ensure that the therapy and monitoring electrodes and Dura-padz gel are sealed within their packages and within the expiration dates printed on the packages.
- Open the recorder door on the bottom of the ZOLL M2 unit and verify that an adequate supply of paper is available in the unit.

Batteries

- Verify that a fully charged battery is inserted into the battery compartment of the ZOLL M2 unit. Press the button on the battery to see its charged status.
- Ensure that a fully charged spare battery pack is available.

Self-test results

- Check the power-on and 30J self-test results by pressing the Quick Access key and verify that the screen reads All Tests Passed.
- If the ZOLL M2 unit is configured to automatically print the self-test results, verify the All Tests Passed message on the printout.

Note: The ZOLL M2 unit must be plugged in to AC power in order to run the daily self test.

Note: The daily power-on self test can be configured to a specific time of day; refer to the *ZOLL M2 Configuration Guide* for instructions on how to configure the self tests.

Defibrillator/Pacing Test

Note: If a *Low Battery* or *Replace Battery* message appears during any of this testing, the battery is close to depletion and should be recharged or replaced.

Warning! **Keep hands, fingers, and other conductive materials away from paddle electrode plates when discharging the defibrillator, or pacing.**

	Function	Response
1	Connect the external AC cable to a working AC outlet and to the ZOLL M2 rear panel.	Verify that the green AC mains power LED illuminates on the ZOLL M2 front panel.
2	Insert a battery into the unit (if a battery is not already installed).	Verify that the Battery charge LED on the ZOLL M2 front panel illuminates amber. When the battery pack has been fully charged, the battery status indicator light is green.
3	Turn the Mode Selector to **DEFIB**. **Note**: If the ZOLL M2 unit is configured to power up in AED mode, press the **Manual Defib** quick access key. If the unit requires a password, use the Trim Knob to enter the password and then press the knob to select **OK**. The unit then switches to manual mode.	Verify that the unit issues one audio beep and that the red and yellow visual alarm indicators illuminate for 3 seconds. Verify that the unit displays *All Tests Passed*. If the message *Self-Test Failed* appears on the display, contact the appropriate technical personnel or the ZOLL Technical Service Department.
4	Disconnect the external AC mains power from the ZOLL M2 rear panel.	Verify that the unit continues to operate without interruption on battery power and that there is no *Low Battery* or *Replace Battery* message. Verify that no error messages are displayed.
5	With no cables attached to the unit, select Lead I, II, or III as the waveform display source.	Verify that a dashed ECG trace displays in the waveform window.
6	Select **Pads** as the waveform display source and connect the multifunction cable to the unit. (Do not connect the test connector to the MFC.)	Verify that a *Attach Pads* message displays on the screen.
7	Connect the test connector to the multi-function cable (MFC).	Verify that the *Attach Pads* message is replaced by a *Check Pads - Pads Shorted* message, and the SYNC quick access key changes to a 30 Joule Self-test quick access key.
8	Press the 30 Joule Self-test quick access key () on the front panel.	Verify that a periodic tone sounds while the defibrillator is charging. At the completion of the charge cycle, the tone is continuous. The charge time should be less than 7 seconds. Verify that the **SHOCK** button () on the front panel illuminates when the defibrillator is charged.

	Function	Response
9	Press and hold the **SHOCK** button on the front panel until the unit discharges.	Verify that the defibrillator discharges and that a *30J Test Passed* message displays. If the message *30J Test Failed* displays, contact the appropriate technical personnel or the ZOLL Technical Service Department.
10	Turn the Mode Selector to **PACER**. **Note**: If the unit requires a password, use the Trim Knob to enter the password and then press the knob to select **OK**. The unit then switches to manual mode.	Verify that the Pacer Settings display on the screen.
11	Perform the following steps: • Set the Pacer mode to Fixed. • Set the Pacer Rate to 60 ppm. • Set the Output to 100 mA.	Verify that pace markers are printed every 25 mm on the chart recorder printout. **Note**: If a printout does not automatically begin after entry into Pacer mode, press the Print button on the front panel to start a continuous printout. Press the print button again to stop the printout.
12	Press the Print button on the front panel of the unit to stop the printout.	Verify that the Clear quick access key is flashing and that there is an alarm tone. Verify that the pacer status bar displays: *Pacer: Check Pads - Pads Shorted*.
13	Disconnect the test connector from the MFC.	Verify that the pacer status bar alternately displays: *Pacer: Attach Pads and* *Pacer: Check Pads - Pads Shorted*. Verify that the **Clear** quick access key continues to display and the alarm tone continues to sound.
14	Turn the Mode Selector from the **PACER** position to **MONITOR**.	Verify that the Pacer settings are removed from the display, the alarm tone stops, and the **Clear** quick access key disappears and is replaced by the **Diag** quick access key.
15	Reconnect the external AC power to the ZOLL M2 rear panel.	Verify that the green AC mains power LED on the ZOLL M2 front panel is illuminated.

Defibrillator Testing with External Paddles

Prior to testing external defibrillator paddles with the ZOLL M2 unit, complete the testing described in “Defibrillator/Pacing Test” on page 18-9.

Note: If a *Low Battery* or *Replace Battery* message appears during any of this testing, the battery is close to depletion and should be recharged or replaced.

Warning! **Keep hands, fingers, and other conductive materials away from paddle electrode plates when discharging the defibrillator, or pacing.**

	Function	Response
1	Insert a battery into the unit (if battery is not already installed) and disconnect any AC power cable to unit.	Verify that the Battery Charge LED on the ZOLL M2 front panel is not lit when AC mains power is disconnected.
2	Turn the Mode Selector to **DEFIB** to turn the unit on. **Note**: If the ZOLL M2 unit is configured to power up in AED mode, press the **Manual Defib** quick access key. If the unit requires a password, use the Trim Knob to enter the password and then press the knob to select **OK**. The unit then switches to manual mode.	Verify that the unit displays the *All Tests Passed* message.
3	Connect the MFC to the defibrillator and disconnect the patient end of the MFC from any attached accessory (paddles or test connector). Select **Pads** as the waveform display source.	Verify that a *Attach Pads* message displays on the screen.
4	Connect the paddles set to the ZOLL M2 MFC cable. Do not place the paddles electrodes in contact with each other or in the paddle wells.	Verify that the *Attach Pads* message changes to *Apply Paddles to Patient*.
5	Press the **RECORDER ON/OFF** button on the Sternum paddle.	Verify that the recorder begins printing.
6	Press the **RECORDER ON/OFF** button again.	Verify that the recorder stops printing.
7	Press the Apex and Sternum paddle electrodes together (face to face) maximizing the contact area between the electrodes.	Verify that the *Apply Paddles to Patient* message changes to *Check Paddles - Paddles Shorted* and the SYNC quick access key changes to 30 Joule Self-test quick access key.
8	Put the paddles into the paddle wells.	
9	Press the **ENERGY SELECT** (+) button.	Verify that the selected energy increases to the next higher level.
10	Repeatedly press the **ENERGY SELECT** (-) button on the Sternum paddle until 30 Joules is selected.	Verify that the defibrillator window selected energy display decreases to 30 Joules.

	Function	Response
11	Press the **CHARGE** button on the Apex paddle.	Verify that a periodic tone sounds while the defibrillator is charging. At the completion of the charge cycle, the tone is continuous. The charge time should be less than 7 seconds. Verify that the **CHARGE** light on the Apex handle illuminates when the defibrillator is charged and ready to deliver energy.
12	Press the **ENERGY SELECT** (+/-) button on the Sternum paddle to increase or decrease the energy.	Verify that the defibrillator disarms.
13	Press the 30J self test key.	Verify that the defibrillator charges to 30 joules.
14	While the defibrillator is charged, press and hold the **SHOCK** button on the Apex paddle (only).	Verify that the defibrillator does not discharge.
15	While the defibrillator is still charged, press and hold the **SHOCK** button on the Sternum paddle (only).	Verify that the defibrillator does not discharge.
16	While the defibrillator is still charged, simultaneously press and hold both the Apex and Sternum paddle **SHOCK** buttons.	Verify that the defibrillator is discharged and a *30J Test Passed* message displays. If *30J Test Failed* message displays, contact appropriate technical personnel or ZOLL Technical Service Department.

SpO2 Functional Check

This check only needs to be performed if SpO_2 is installed in the unit.

	Function	Response
1	Plug the sensor cable into the SpO_2 receptacle on the back of the ZOLL M2 unit.	
2	Turn the Mode Selector to **MONITOR** to turn on the unit.	
3	Place the SpO_2 sensor onto an appropriately sized finger, and ensure that the sensor's emitter is placed directly over the fingernail and that the sensor is shielded from any bright ambient light sources.	
4	View the SpO_2 plethysmograph waveform.	• Verify that the waveform is present and without signs of artifact. • Verify that the SpO_2 readings are between 95-100%. **Note**: If a reading is less than 95%, check to make sure your finger is fully inserted into the sensor and properly positioned.

Recommended Minimum Preventive Maintenance Schedule

Operational Tests should be performed at regular intervals. The Operational Tests augment the automated self-tests that the ZOLL M2 unit performs to help ensure readiness. For more information, refer to the Operational Tests in the *ZOLL M2 Service Manual*.

Annual

In addition to Daily/Shift Check Procedure and Operational Tests, the following is recommended:

- Perform NIBP calibration check.
- Perform CO_2 calibration check.
- The NIBP and CO_2 calibration checks should be performed annually or according to local requirements (to be performed by a qualified Biomedical Equipment Technician (BMET)) as described in the *ZOLL M2 Service Manual*.

Guidelines for Maintaining Peak Battery Performance

- Each battery should be identified with a number or letter. An identification mark is useful in tracking battery performance.
- Keep extra batteries in the SurePower Charger Station where you can quickly determine their status.
- Always carry at least one fully charged spare battery. If no other source of back-up power is available, two spare batteries are advisable.
- If a battery is to be stored longer than 30 days, recharge the battery before it is stored. Recharge unused batteries at least every 30 days.
- Do not leave batteries in a partially discharged state.
- Keep discharged batteries separated from spare batteries that are charged. When removing a discharged battery from the monitor, never place it in the location intended to carry a charged spare.

Caution DO NOT leave ZOLL M2 battery packs in a completely discharged state. Damage to the battery packs can occur if they are left in a completely discharged state for more than 14 days.

Cleaning instructions

Cleaning the ZOLL M2 Unit

To clean the ZOLL M2 unit, use a nearly dry cloth containing one of the cleaning agents listed below. DO NOT allow cleaning agent or water to run into the crevices or connector openings at any time. Thoroughly wipe off any excess cleaning solution from the ZOLL M2 unit with a dry cloth.

Note: Do not to clean patient cables or connectors (unit or cables) with any type of bleach solution. It may discolor the cable jackets or cause corrosion of connector pins.

Use only these recommended cleaning agents:

- Distilled water
- Ethanol 96%
- Isopropyl alcohol (Alcohol Spray, 70% concentrate or Clinell Alcohol Wipes)
- Hydrogen peroxide (Lysol with Hydrogen Peroxide Multi-Purpose Cleaner or wipes)
- Water and soap
- Ultra concentrated detergents/water solution 1:10
- 5.25% sodium hypochlorite/water solution 1:10
- Solution containing glutaraldehyde
- Bleach/water solution 1:8
- CaviWipes XL
- Sani-Cloth Plus
- Super Sani-Cloth
- Bleach Germicidal Wipes (for medical equipment surfaces)
- Coverage Spray HB Plus
- Oxivir Tb Wipes

Cleaning the ZOLL M2 Accessories

Use only the following recommended cleaning agents for ZOLL M2 accessories. Use a soft cloth.

- Distilled water
- Ethanol 96%
- Isopropyl alcohol (70% and higher)
- Tap water with liquid soap (10:1 solution)
- Chlorine bleach solution (5.25% - 6.15% sodium hypochlorite) diluted with 1:10 ratio of water
- Hydrogen peroxide solution (3%)
- Wex-cide
- Windex
- Cidex

NIBP Blood Pressure Cuff

Clean the cuff with one of the agents listed above for the ZOLL M2 accessories. Wash gently with the solution, then rinse. DO NOT allow solution to enter cuff tubes. Allow the cuff and hose to completely dry before patient use.

SpO_2 Sensors

Clean the SpO_2 sensors with a cloth that has been slightly dampened with one of the agents listed above for the ZOLL M2 accessories. DO NOT submerge the probe or its connector in any liquids or cleaning agents. Thoroughly wipe off any excess cleaning solution with a dry cloth. Allow the sensor to completely dry before patient use.

CO_2 Sensors

Clean the CO_2 sensors with a cloth that has been slightly dampened with only water or isopropyl alcohol. DO NOT use any other cleaning agents. DO NOT submerge the sensor or its connector in any liquids or cleaning agents. Thoroughly wipe off any excess cleaning solution with a dry cloth. Allow the sensor to completely dry before patient use.

Cleaning and Disinfecting Temperature Probe

Warnings	Use cleaning solutions only as instructed in this operator's manual. Do not clean the sensor with an automated cleaning/ disinfection machine.
Limitations on cleaning/ disinfection	ZOLL recommends replacing the temperature sensor after 300 cleaning/disinfection cycles.
Cleaning and Disinfection Instructions	
Initial treatment at the point of use	Remove contamination from surface immediately after use with soft cloth.
Preparation before cleaning	No particular requirements. Disassembly not required.
Cleaning: Automated	Not applicable.
Cleaning: Manual	To clean the temperature sensors, perform the following steps: 1. Use a non-linting cloth saturated in cleaning solution listed above. 2. Hold the probe in one hand at the connector and gently wipe all surfaces of the probe for 15 seconds. **Note**: Excessive pressure could stretch the cable jacket and break the internal wires, destroying the probe. 3. Allow to air dry completely.

Disinfection	To disinfect esophageal/rectal temperature sensors, perform the following steps: 1. Immerse the sensors in a 10% bleach solution for 3 minutes. Do not immerse the connector. 2. After immersion, rinse the sensors thoroughly with running tap water for 1 minute. 3. Perform a secondary rinse by submerging the sensors in deionized water for one minute. Do not immerse the connector. 4. Remove the device from the deionized water and allow to air dry completely.
Drying	Allow the sensors to completely air dry before using.
Maintenance, inspection, and testing	Check temperature sensors and cables daily for signs of damage or excessive wear. Replace as required.
Packaging	Pack the device with plastic film packaging or equivalent.
Sterilization	Not applicable.
Storage	Store the device as instructed in this operator's manual.
Additional information	If the above-mentioned chemicals are not available, users are obliged to validate their procedure accordingly.
Manufacturer contact	See the Service information in this operator’s manual.

Cleaning Cables and other Accessories

Other cables and accessories can be wiped clean with a damp cloth moistened in a mild detergent solution. Allow time to dry before use.

For important cleaning and sterilization information regarding the autoclavable electrodes, refer to the *Autoclavable Internal Handle and Electrode Operator’s Guide*.

Cleaning the Print Head

To clean the recorder print head, perform the following steps:

1. Press the release button, and allow the printer door to open, then remove any paper.
2. Locate the print head along the top of the printer compartment, just above the release button.
3. Gently wipe the print head with a cotton swab moistened with isopropyl alcohol, and dry any residual alcohol with another dry cotton swab.

Place the paper back into the unit and close the drawer.

Loading Recorder Paper

The unit displays the message *Printer Out Of Paper* when the printer is activated without recorder paper or if the supply runs out during printing.

Note: See the previous section for instructions on how to clean the print head.

To load the recorder paper into the printer:

1. Press the release button and allow the printer door to open, pull out paper tray, then remove any paper.

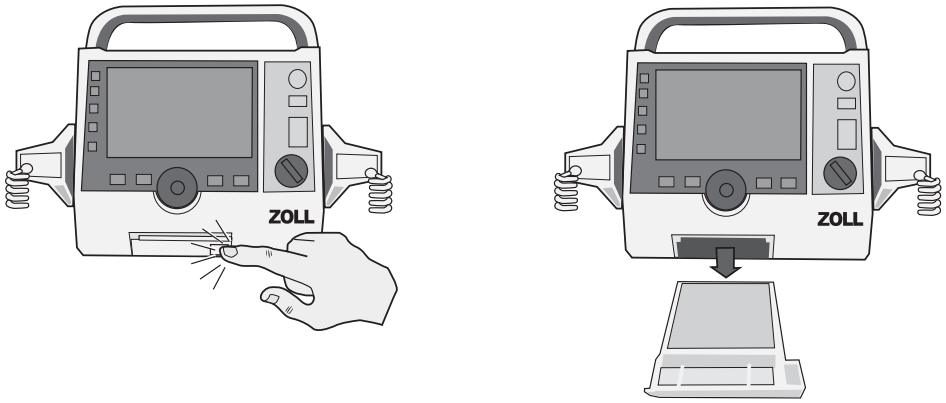
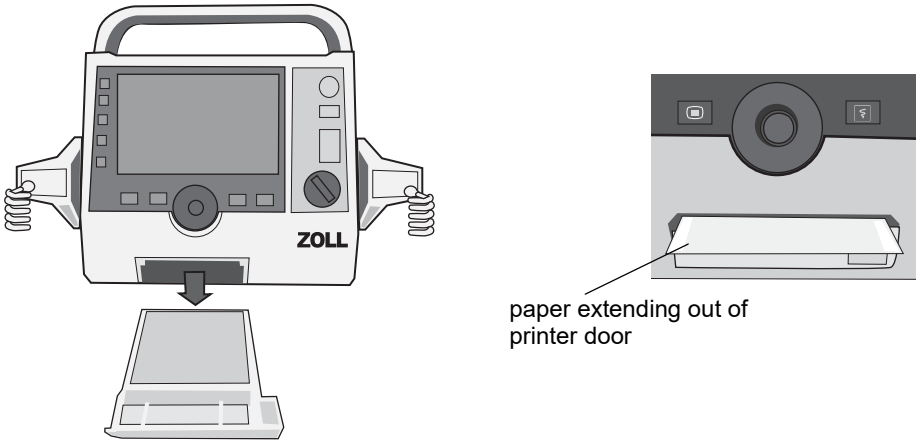


Figure 18-1. Opening the Printer Door and Removing Paper

2. Refer to the illustration inside of the paper compartment for proper paper orientation, and place a new pad of stripchart paper in the tray.

Note: Paper feeds from the top of the stack with gridlines facing up.

3. Pull enough paper off the pad so that paper extends out of the unit when the printer door is closed.



4. Close the printer door. Be sure that the printer door is flush with the bottom front face of the unit.

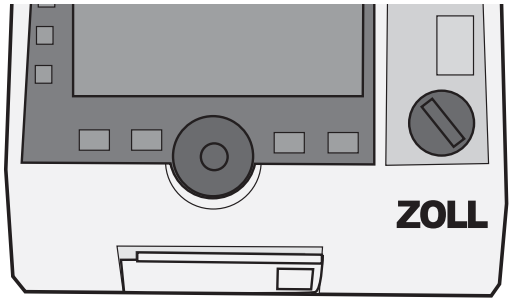


Figure 18-2. Inserting the Paper and Closing Printer Door

5. After the paper is loaded, press the Print key ( ) to resume printing.

Troubleshooting

The troubleshooting information provided in this chapter is intended for use by nontechnical medical personnel during device operation. This chapter answers many of the common problems or questions that may arise during operation.

If trouble persists after consulting this guide, contact the appropriate technical personnel or the ZOLL Technical Service Department.

Note: Most chapters in this guide contain a list of error messages that are specific to that chapter.

Symptom	Recommended Action
General	
The ZOLL M2 does not power on.	• Check that the battery pack is properly installed. • Verify that the device is plugged into AC power. • Replace battery pack with a fully charged battery pack.
Audio is too low or absent.	• Use the System Setting menu to adjust the audio volume. • Contact the appropriate technical personnel or ZOLL Technical Service Department if the issue still exists at the maximum audio volume setting.
Self-test failed	Remove the device from use and contact the appropriate technical personnel or ZOLL Technical Service Department.
Low Battery message.	• Connect the unit to AC power. • Replace battery pack with a fully charged battery pack.
Replace Battery message.	• Immediately connect the unit to AC power. • Replace battery pack with a fully charged battery pack.
Battery error	A battery fault has been detected. Plug the ZOLL M2 unit into an AC power source or install a new battery.
Battery Calibration Required message	The battery has reached a state that requires battery calibration. Calibrate battery using the ZOLL SurePower Charger Station.
Battery communication error	The unit is unable to establish communication with the battery. Check the battery contacts.

Symptom	Recommended Action
Buttons do not respond, e.g., quick access keys do not function.	Turn the ZOLL M2 unit off and then turn it back on to correct the fault. If the fault still exists, contact the appropriate technical personnel or ZOLL Technical Service Department.
The patient data cannot be transferred.	• Connect an undamaged USB drive. • Make sure the USB drive has enough space. • Connect to the available WiFi. • Contact the appropriate technical personnel or ZOLL Technical Service Department.
The device cannot switch modes (non-AED use).	Turn the ZOLL M2 unit off and then turn it back on to correct the fault. If the fault still exists, contact the appropriate technical personnel or ZOLL Technical Service Department.
The ZOLL M2 unit cannot print.	• Close the printer door. • Load paper into the printer. • Verify orientation of paper in the drawer • Take out the jammed paper and insert in proper orientation. • Stop using the printer, and wait until the printer head/motor temperature drops to normal. • Contact the appropriate technical personnel or ZOLL Technical Service Department.
Defibrillation and Pacing Problems	
Excessive Disarms Detected	Wait longer between successive internal discharges (disarm internally instead of to patient).
30 J Test Failed	Turn the ZOLL M2 unit off and then on to correct the fault. Rerun the 30 J test. If the fault still exists, contact the appropriate technical personnel or ZOLL Technical Service Dept.
Defib Disabled message	Turn the ZOLL M2 unit off and then on to correct the fault. If the fault still exists, contact the appropriate technical personnel or ZOLL Technical Service Department.
Button Stuck (Paddles button, front panel Shock button,Charge button,etc.)	Press the stuck button, turn the ZOLL M2 unit off, then turn it back on to correct the fault. If the fault still exists, remove the device from use and contact the appropriate technical personnel or ZOLL Technical Service Department.
Demand Pacing Disabled message	Turn the ZOLL M2 unit off and then on to correct the fault. If the fault still exists, contact the appropriate technical personnel or ZOLL Technical Service Department.
Pacer Disabled message	Turn the ZOLL M2 unit off and then on to correct the fault. If the fault still exists, contact the appropriate technical personnel or ZOLL Technical Service Dept.
Pacer Current Out of Tolerance message	Continue to use Pacer function to treat patient. When finished treating patient, turn the ZOLL M2 unit off and then contact the appropriate technical personnel or ZOLL Technical Service Department.
Defib Charging Failed message	• Plug the device into AC power. • Replace the battery pack with a fully charged battery pack.
ECG	

Symptom	Recommended Action
Poor ECG signal quality (noisy trace, wandering baselines, etc.) from signal acquired through monitoring electrodes/ pads.	• Check that the monitoring electrodes/pads are properly applied. • Check the date on the electrodes/pads and ensure the electrodes/pads are not expired. If necessary, prepare the patient's skin and apply new electrodes/pads. Do not open the electrode package until immediately prior to use. • Relocate or turn off equipment that may be causing radio frequency interference (RFI). Try repositioning the cables/ leads. • Inspect the cables for signs of damage and excessive wear. Replace the cables if necessary.
ECG Communications Fault message	• Turn the ZOLL M2 unit off and on to correct the fault or select PADS/PADDLES as the lead display. • Contact the appropriate technical personnel or ZOLL Technical Service Department.
ECG waveform is not displayed on the screen	• Verify that the cable is properly connected to the unit and to the patient. • Turn the ZOLL M2 unit off and then turn it back on to correct the fault. If the fault still exists, contact the appropriate technical personnel or ZOLL Technical Service Department.
NIBP	
NIBP Measurement Aborted - Measurement Timeout message	• Check the cuff connection. • Take an additional NIBP measurement and ensure there is no patient movement.
The pump operates but the cuff does not inflate or fails to inflate fully.	• Replace the cuff. • Check connections and replace tubing if needed.
NIBP Measurement Aborted - Signal Weak message	Check the cuff placement/connection and tightness, then take an additional NIBP measurement.
NIBP value is not displayed on the screen.	A measurement error occurred. Take an additional measurement.
CO2	
The capnogram does not appear on the display.	• Close one waveform. • Connect the sensor and turn it on using CO_2 quick access key.
FiCO2 value is not displayed on the screen	Go to CO_2 setting menu to turn it on.
CO2 Temperature Out of Range message	The ambient temperature is outside the sensor's normal operating range. Take the device to a place within the normal operating range.
CO2 Disabled - Critical Fault message	A critical fault has been detected in the CO_2 module. Power cycle the unit. If the message persists, replace the sensor/ module.
CO2 Zeroing Required message	The CO_2 module needs to be zeroed.
SpO2	
The SpO_2 value is not displayed.	• Check the sensor connection and cable. • Try another sensor.

Symptom	Recommended Action
SpO2 Communications Fault message	A critical fault has beem detected in the SpO_2 module. Power cycle the unit. If the message persists, replace the sensor/ module.
Check SpO2 Sensor message	Check sensor and then reconnect it to the unit or reapply it to the patient.
SpO_2 signal is unstable.	• Minimize patient movement. • Make sure the sensor cable is not positioned too close to power cables. • Make sure the sensor is properly attached to the patient.
Temperature	
The Temp value is not displayed.	Check sensor and reconnect it.
Recorder/Printer	
White line running along paper.	Clean the print head.
Paper moves but print quality is poor or some dots are missing.	Clean the print head.
Printer Door Opened message	Close the printer door.
Printer Out Of Paper message	Load paper into the printer.
Printer Fault message	One of the following conditions has occurred: • The printer head is overheating. • The printer motor is overheating. • Printer communication is interrupted. If print head/motor has overheated, it will restart when it has cooled down.
Wifi	
Wifi does not connect (timeout or firmware error)	Turn off Wifi, then turn it back on. If still not working, power cycle the unit. Check the Wifi access point setup, correct any error of the setup, then reconnect the Wifi. Ensure that the Wifi access point is within range.

ZOLL M2 OPERATOR'S SHIFT CHECKLIST

Date: _____ Shift: _____ Location: _____

Mfr/Model No.: _____ Serial No. or Facility ID No.: _____

At the beginning of each shift, inspect the unit. Indicate whether all requirements have been met. Note any corrective actions taken. Sign the form.

	Okay as found	Corrective Action/Remarks
1. Defibrillator Unit		
Clean, no spills, and casing undamaged		
2. Cables/Connectors		
a. Inspect for damaged insulation, frayed/broken wires, or bent connector pins b. Connectors engage securely		
3. Sensors (pulse oximetry, NIBP cuff and hose, temperature and CO_2 sensors)		
a. Inspect for signs of damage or excessive wear b. Connectors engage securely		
4. Paddles		
a. Clean, not pitted, or damaged. b. Switches operate freely c. Cables and connectors free of damage and engage securely		
5. Supplies and Accessories		
a. Therapy pads in sealed pouches (2 sets, not expired) b. Defib gel, gel pads, or Dura-padz gel c. ECG monitoring electrodes d. Alcohol wipes e. Razors/scissors f. Recorder paper		
6. Batteries		
a. Fully charged battery installed in unit b. Fully charged spare battery available		
7. Operational Checks		
A. Power Up Sequence		
a. Battery charge and AC indicators illuminate with AC power b. Audio beeps heard and Visual Alarm indicators briefly illuminate c. Self Test passed		
B. Hands Free Defibrillation (Test with only battery power)		
a. *Check Pads* and *Pads Shorted* messages display b. Charge time < 7 seconds c. *30J Test Passed*		
C. Pacer Test (Test with only battery power)		
a. Printer prints Pace markers every 25 mm at 60 ppm b. *Pacing: Check Pads and Pads Shorted* message displays-- no error messages at 100 mA c. *Pacing: Check Pads, Pads Shorted* message displays		
D. Paddles		
a. *Apply Paddles to Patient* message displays when paddles are connected to MFC b. Paddle switches functional (Recorder, Energy Select, Charge, Shock) c. *30J Test Passed*		
E. Reconnect Unit to AC Power		
_____ **Major problem(s) identified (OUT OF SERVICE)**		

Signature

Appendix A Specifications

This chapter provides specification information for the ZOLL M2 monitor/defibrillator.

Defibrillator

Waveform: ZOLL Rectilinear Biphasic™ waveform

Energy Selections: 1,2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 85, 100, 120, 150, 200 joules.

Charge Time:

- Less than 7 seconds at rated mains voltage and with a new, fully charged battery.
- Less than 7 seconds with a new, fully charged battery (first 15 charges to 200 joules).
- For the sixteenth discharge at maximum energy, the charge time is less than 10 seconds. Depleted batteries result in a longer defibrillator charge time.
- Less than 15 seconds when operating without a battery, using AC power alone at 90% of the rated mains voltage.
- Less than 25 seconds from the initial power on to charge ready in manual defib mode, with a new, fully charged battery pack (depleted by up to fifteen 200 joule discharges) or when operating without a battery, using AC power alone at 90% of the rated mains voltage.

Rhythm Analysis and Charge Time in AED Mode:

- Less than 20 seconds at rated mains voltage and with a new, fully charged battery.
- Less than 30 seconds with a new, fully charged battery (first 15 charges to 200 joules).
- For the sixteenth discharge at maximum energy, the analysis and charge time is less than 30 seconds. Depleted batteries result in a longer defibrillator charge time.
- Less than 30 seconds when operating without a battery, using AC power alone at 90% of the rated mains voltage.
- Less than 40 seconds from initial power on, with a new, fully charged battery pack (depleted by up to fifteen 200 joule discharges) or when operating without a battery, using AC power alone at 90% of the rated mains voltage.

Patient Impedance Range: 15-300 ohms (external paddles, hands-free therapy electrodes)
7-300 ohms (internal paddles)

Synchronized Mode: Synchronizes defibrillator discharge to the patient's R wave. SYNC is indicated on the display with R wave markers above the ECG waveform on the screen and stripchart. Less than 60 ms delay from R-wave peak to defibrillator discharge.

Display

Active display area:

152.4 mm (width)× 91.4 mm (height)

17.8 cm/7.0 inch (diagonal)

ECG

Sweep Speed: 12.5 mm/sec, 25 mm/sec, 50 mm/sec (user selectable)

Lead Selections: Paddles (Pads), I, II, III, aVR, aVL, aVF, V1-6.

Input: 3-lead, 5-lead, or 12-lead patient cable, paddles, multifunction electrodes.

Frequency Response:

Pads/Paddles:

0.67 to 20 Hz or 0.67 to 40 Hz (configurable, default is 0.67 to 20 Hz)

3/5/12-lead Monitoring (configurable):

0.67 to 20 Hz or 0.67 to 40 Hz (configurable, default is 0.67 to 20 Hz)

0.525 to 40 Hz Diagnostic mode

Per methods a and b of EN/IEC 60601-2-27

Acquired 12-lead snapshots:

0.525 to 40Hz Filtered Diagnostic or 0.525 to 150Hz Diagnostic (configurable, default is 0.525 to 40 Hz)

Per methods a and b of EN/IEC 60601-2-27, methods A and E of EN/IEC 60601-2-25

Common Mode Rejection:

Complies with EN/IEC 60601-2-27

Tall T-Wave Rejection:

Up to 1.2 mV per EN/IEC 60601-2-27 clause 201.12.1.101.17

Diagnostic Signals Applied to Patient Connections (Applied Parts):

Pads/Paddles

Leads off / impedance sensing circuit is < 300 uAmps RMS.

The impedance detector signal frequency is 32 kHz ± 1 kHz.

3/5-Lead

Leads off / active noise suppression sensing circuit is < 0.1 microamps DC.

Heart Rate Range: 20 to 300 BPM.

Heart Rate Accuracy: +/- 3% or +/- 3 BPM, whichever is greater.

Heart Rate Computation: Average of last 5 beat-to-beat intervals

Heart Rate Alarms: User-selectable.

Size: 0.125, 0.25, 0.5, 1.0, 1.5, 2.0, 3.0 cm/mv and auto.

Recovery time after defibrillation: <5s

Heart Rate Meter Response Time:

Responds to a 80-120 BPM step increase in heart rate in less than 6 seconds per EN/IEC 60601-2-27, clause 201.7.9.2.9.101 b) 5). Responds to a 80-40 BPM step decrease in less than 7 seconds per EN/IEC 60601-2-27. Response times include a 1.0-second display in update interval.

Heart Rate Response to Irregular Rhythm: (EN/IEC 60601-2-27)

Ventricular Bigeminy: 76-85 BPM

Slow Alternating Ventricular Bigeminy: 56-66 BPM

Rapid Alternating Ventricular Bigeminy: 112-127 BPM

Bidirectional Systole: 87-102 BPM

Tachycardia Response Time:

Response time to tachycardia alarm is less than 8.0 seconds per EN/IEC 60601-2-27, clause 201.7.9.2.9.101 b) 6). Response times include a 1.0 second display update interval.

Waveform per 60601-2-27	R-Wave Amplitude	Tachycardia Response Time (in seconds)
B1	.5	7.1
	1	5.8
	2	4.5
B2	.5	6.2
	1	7.8
	2	7.9

Pacemaker Pulse Rejection:
(In accordance with IEC 60601-2-27, subclause 201.12.1.101.13)

- Pulses without overshoot: Rejects all pulses with amplitude of ±2 mV to ±700 mV and duration of 0.1 ms to 2 ms.
- May not reject pulses with overshoot.
- A-V sequential pulses: pulses may not be rejected.
- Pulses with a normally paced QRS and T wave: Rejects all pulses with amplitude ±2 mV to ±700 mV and duration of 0.1 ms to 2 ms.
- Pulses with an ineffectively paced QRS pattern: Rejects all pulses with amplitude ±2 mV to ±700 mV and duration 0.1 ms to 2 ms.

Electrosurgery Protection: The ZOLL M2 is protected against malfunction in the presence of electrosurgery as specified in IEC 60601-2-27. Burn hazard protection via a 1 K ohm current limiting resistor contained in each ECG leadwire.

Recovery time after defibrillation: <5 seconds

Impedance Pneumography

Displayed Data: Numeric breath rate, Impedance waveform

Breath rate range: Adult, Pediatric: 2 to 150 breaths / minute and no breath

Breath rate accuracy: +/- 2 breaths / minute (brpm), for breath rate below 100 brpm

+/-3% of the reading for breath rate above 100 brpm

Displayed Breath Rate: Average of last 5 breath-to-breath rates.

Leads: Lead I (RA – LA)

Sweep Speed: 6.25, 12.5, 25 mm/sec

Alarm settings: No Breath, High and low breath rate alarm

Pulse Oximetry (SpO2)

SpO_2 Range: 0% - 100%

SpO_2 Pulse Rate: 25 - 240 beats per minute

SpO_2 Accuracy: 70 - 100 ± 2%, Adult/ Pediatric

SpO_2 Pulse Rate: ±3% of the reading or 2 beats per minute (bpm), whichever is greater, Adult/Pediatric

Resolution: SpO_2: 1%
Pulse rate: 1 bpm (beats per minute)

SpO_2 Wavelength for Sensors:
LED Wavelength
Red 660 nm
Infrared 895nm

Energy (Radiant Power) of light: < 15 mW

SpO_2 and PR Data Averaging Sensitivity/Period: Low (16 sec), Medium (8 sec), High (4 sec), configurable

SpO2 and PR Data Update Period: <30 sec

Bio-Compatibility:
Patient contacting material meets requirements of ISO 10993-1, Biological Evaluation of Medical Device - Part I, for external devices, intact surfaces and short-term exposure

Notes:

- SpO_2 accuracy was determined by testing on healthy adult volunteers in the range of 70-100% SpO_2 against a laboratory CO-Oximeter. Note the SpO_2 accuracy represents the statistical result according to ISO 80601-2-61, i.e., about two-thirds of the SpO_2 readings can be expected to fall within the claimed accuracy (±2%) of the value measured by a CO-Oximeter.
- The SpO_2 sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter.
- The SpO2 sensors have been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator.

Non-Invasive Blood Pressure

Technique: Non-invasive oscillometric method

Operating Modes: Automatic, manual, and STAT (maximum number of measurements allowable in a 5 minute period)

Automatic Intervals: 2.5, 5, 10, 15, 20, 30, 45, 60, 90, and 120 minute intervals.

Pressure Measurement Range:

SYS : 20~265 mmHg (Adult)
20~240 mmHg (Pediatric)

DIA: 10~220 mmHg (Adult)
10~180 mmHg (Pediatric)

MAP: 13~235 mmHg (Adult)
13~200 mmHg (Pediatric)

S**tatic Pressure Accuracy**: +/- 3 mmHg

Default Cuff Inflation Pressure:
Adult: 160 mmHg
Pediatric:120 mmHg

Maximum Cuff Inflation Pressure:
Adult: 280 mmHg
Pediatric:260 mmHg

Overpressure Limit:
Adult: 290mmHg +/- 5 mmHg
Pediatric:270 mmHg +/- 5 mmHg

Typical Determination time without Artifact:30 to 45 seconds

Maximum Determination Time: 175 seconds

NIBP Accuracy: NIBP accuracy has been verified utilizing clinical test methods that meet the requirements of EN ISO 81060-2.

Temperature

Number of Channels: 2

Measurement Range: 0° to 50° C

Accuracy: ± 0.1° C not including probe; ± 0.2° C including probe, from 15.0° C to 50.0° C
± 0.2° C not including probe; ± 0.3° C including probe, from 0° C to 14.9° C

Resolution: 0.1° C

Scale: Fahrenheit or Celsius.

Mode of Operation: Direct mode

Display: T1, T2, ΔT

Minimum Measurement Time (EN 12470-4): <80s

Transient Response Time (ISO 80601-2-56): <60s

CO_2

Range: 0 to 150 mmHg

Accuracy of $EtCO_2$:0~40mmHg,±2 mmHg; 41~70mmHg,±5%; 71-100mmHg,±8%; 101-150mmHg, ±10%; for both mainstream and sidestream modules.

CO_2 Sampling Rate: 100Hz for both mainstream and sidestream modules.

Drift of Measurement Accuracy: Over any 6-hour period, the accuracy claims listed above are maintained for both mainstream and sidestream modules.

Respiration Rate Range: 0 to 150 breaths per minute (brpm) for both mainstream and sidestream modules.

Respiration Rate Accuracy: 0-100, ±1 brpm; 101-150, ±2 brpm for both mainstream and sidestream modules

Flow rate: 50 ml/min -7.5+15 ml/min for sidestream module

Warm-up time: 2 minutes for mainstream module, 30 seconds for sidestream module, at 25° C

Rise time (10 % to 90 %): mainstream module < 250 ms, sidestream module <490 ms

Total System Response Time: mainstream module < 500 ms, sidestream module <3.3 seconds

Notes:

- The CO_2 accuracy is maintained at:
  Mainstream module: BR<80 brpm and I/E ratio (inspiratory/expiratory time ratio) <2:1
  Sidestream module: BR<50 brpm and I/E ratio<1:1; BR<30 brpm and I/E ratio<2:1;
- CO_2 measurements may be inaccurate when measured in the presence of aerosolized pharmaceuticals or anesthetic gases. The additional CO_2 measurement errors caused by the following interfering gases are:

N_2O (<=60%): ±1mmHg
Enf (<=5%): ±1mmHg
Iso (<=5%): ±1mmHg
Sev (<=5%): ±1mmHg
O_2 (<=100%): ±1mmHg

- The rated respiration rate range is determined using a breath simulator at I/E ratio 1:1 according to ISO 80601-2-55, Figure 201.101.

Alarms

Complies with EN/IEC 60601-1-8

Physiological Alarms (Heart Rate, NIBP, SpO2, Resp, CO2, Temp):

Audible: 10 pulse, 660 Hz, triplet tone with a PW of 165 msec, (different interval between each pulse, first and second: 102 ms; second and third: 102 ms; third and fourth: 364 ms; fourth and fifth: 102 ms; fifth and sixth: 950 ms) and a repetition interval of 6 seconds. The lead fault tone repeats at a repetition interval of 14 seconds.

Visual: Heart Rate Alarm causes the heart rate to be displayed in red, with a white background.

The red alarm LED will flash at a rate of 2 Hz.

ECG Lead Off Alarm:

Audible: 3 pulse, 660 Hz triplet tone with a PW of 192 msec, a PRI of 235 msec. The lead fault tone repeats at a repetition interval of 14 seconds.

Visual: Lead Off condition causes a *LEAD OFF* message to be displayed on the ECG trace. The yellow alarm LED will flash at a rate of 0.6 Hz

Invalid Operation Alert Tone:

A short, low-pitched tone is audible when a selected control button is unavailable for use or an invalid entry is detected. Tone frequency is 160 Hz. Duration is 250 msec.

Maximum Alarm Delay (Includes Alarm Condition Delay and Signal Generation Delay):
• if source is ECG, 10 seconds
• if source is SpO2, 10 seconds
• if source is EtCO2: 7 seconds
• if source is FiCO2: 7 seconds
• if source is Temperature: 4 seconds

Alarm signal sound pressure level range: 45-85dB

Characteristics of auditory information signals:

- Alarm off reminder - tone frequency is 650 Hz, duration is 190 msec
- Heart beep - tone frequency is 650 Hz, duration is 40 msec
- Charging tone - tone frequency is 1510 Hz, duration is 150 msec, repetition rate is every 390 ms (2.56 Hz)
- Ready tone - tone frequency is 1510 Hz, continuously
- Indication message tone - tone frequency is 2112 Hz, duration is 68 msec

Recorder

Type: High-resolution thermal array.

Annotation: Time, date, ECG lead, ECG gain, ECG frequency response, heart rate, defibrillation and pacing parameters and treatment summary events.

Paper Width: 80 mm.

Paper Speed: 25 mm/sec, 50 mm/sec

Delay: 6 seconds.

Clinical Data:

Trend Data - A patient's vital signs trend information logged to memory at user configurable intervals.

Summary Report - A collection of snapshot events automatically taken or user initiated during each rescue incident.

Event Log - An abbreviated list of all events recorded during the rescue incident.

Snapshots: Presenting ECG, Shockable ECG Analysis (AED mode only), Shock Delivery, *CHECK PATIENT* Alert, Pacer Startup, Patient Alarm, Recorder Activation, Code Marker, Diagnostic 3/5 Lead ECG, 30J Self-test Report, 12-Lead ECG

Record Modes: Manual and automatic (user-configurable).

Battery

Complies with IEC 62133

Type: *SurePower* Rechargeable Lithium-Ion, 10.8Vdc, 5.8 Ah, 63Wh

Note: The *SurePower* Battery Pack may not perform to specifications when stored at the upper or lower extreme limits of storage temperature and immediately put into use.

Capacity:

With a new, fully charged battery operating at 20° C room temperature:

- At least 4 hours of continuous monitoring of ECG and at least twenty 200 J shocks.
- At least 100 discharges at maximum shock energy (200 joules).
- At least 3.5 hours of ECG monitoring and pacing at 180 ppm and 140 mA.
- At least 10 discharges at maximum shock setting (200 joules) after a Low Battery indication.

Note: Proper battery care is required to maintain maximum available capacity.

Battery Indicators:

5 Battery capacity LED indicators, Fault indicator, Recalibration indicator

Recharge Rate: 100% in 5 hours.

Battery charge time from depletion to 90%:

- ≤ 4 hours with the system turned off and plugged into AC mains.
- ≤ 12 hours when operating from AC mains in MONITOR mode.
- Trickle charging when in PACE and DEFIB modes.

General

Weight:

5.8 kg without battery and paper

6.5 kg with battery and paper

Dimensions:

Without Handle: 264.7 x 231.3 x 223.6 mm
With Handle: 264.7 x 231.3 x 274.6 mm

General Environmental Specs

Operating

Humidity: 5 to 95% RH (non-condensing)
Vibration:

- EN ISO 80601-2-61 (per IEC 60068-2-64)
- EN 1789 for ambulance

Shock: IEC 60068-2-27, 100g, 6 ms half sine

Bump: IEC 60068-2-29

Atmospheric pressure: 620 mbar to 1060 mbar (-381 m to 4000 m)
Temperature: 0 to 50° C
Free Fall: EN 1789, 0.75m functional drop

Storage and Transport

Temperature: -30 to 70°C
Humidity: 5 to 95% RH (non-condensing)
Shock/vibration: ISTA 2A

Safety Classification: Class I and internal power per EN/IEC 60601-1

Enclosure Protection (EN/IEC 60529):

Ingress Protection against Particle & Water: IP44

AC Operating Power:

Input: 100-240 V ~ 50/60 Hz, 200 VA

Pacer

Type: External transcutaneous pacing, VVI demand or asynchronous (fixed rate)

Pacer Rate: 30 to 180 ± 2 PPM.

Output Current: 8 to 140 mA ± 5% or 5 mA (whichever is greater)

Modes: Demand and Fixed

Status Indicators:

ECG lead fault, pace marker on monitor and chart.

Pulse Type: Rectilinear, constant current

Pulse Width: 40 ms +/-2 ms

Chest Compression Monitoring

Compression Depth Range: 1.9 - 7.6 cm

Compression Depth Accuracy: ± 0.6 cm

Compression Rate Range: 50 to 150 compressions per minute

Metronome Rate: 105 beeps per minute (configurable)

Prompts: *PUSH HARDER*, *GOOD COMPRESSIONS*, *STOP CPR* (AED Mode only), *PERFORM CPR* (AED Mode only)

WiFi

WiFi Media:

Direct Sequence-Spread Spectrum (DSSS)
Complementary Code Keying (CCK)
Orthogonal Frequency Divisional Mutiplexing (OFDM)

WiFi Media Access Protocol:

Carrier sense multiple access with collision avoidance (CSMA/CA)

Network Architecture Types:

Infrastructure and ad hoc

WiFi Standards:

IEEE 802.11.a, 802.11b, 802.11d, 802.11e, 82.11g, 802.11h, 802.11i, 802.11n

WiFi Data Rates Supported:

802.11a (OFDM): 6, 9, 12, 18, 24, 36, 48, 54 Mbps
802.11b (DSSS, CCK): 1, 2, 5.5, 11 Mbps
802.11g (OFDM): 6, 9, 12, 18, 24, 36, 48, 54 Mbps
802.11n (OFDM,HT20,MCS 0-7): 6.5, 13, 19.5, 26, 39, 52, 58.5, 72.2 Mbps
7.2, 14.4, 21.7, 28.9, 43.3, 57.8, 65 Mbps

Regulatory Domain Support:

FCC (Americas, Parts of Asia, and Middle East)
ETSI (Europe, Middle East, Africa, and Parts of Asia)
MIC (Japan) (formerly TELEC)
KC (Korea) (formerly KCC)

2.4 GHz Frequency Bands:

ETSI: 2.4 GHz to 2.483 GHz
FCC: 2.4 GHz to 2.483 GHz
MIC (Japan): 2.4 GHz to 2.495 GHz
KC: 2.4 GHz to 2.483 GHz

2.4 GHz Operating Channels:

ETSI:13 (3 non-overlapping)
FCC:11(3 non-overlapping)
MIC (Japan):14 (4 non-overlapping)
KCC:13 (3 non-overlapping)

5 GHz Frequency Bands:

ETSI 5.15 GHz to 5.35 GHz
5.47 GHz to 5.725 GHz

FCC 5.15 GHz to 5.35 GHz
5.725 GHz to 5.82 GHz

MIC 5.15 GHz to 5.35 GHz

KC 5.15 GHz to 5.35 GHz
5.47 GHz to 5.725 GHz
5.725 GHz to 5.82 GHz

5 GHz Operating Channels:

ETSI:19 non-overlapping
FCC: 23 non-overlapping
MIC: 8 non-overlapping
KC: 8 non-overlapping

Security:

Standards

Wireless Equivalent Privacy (WEP)
WiFi Protected Access (WPA)
IEEE 802.11i (WPA2)

Encryption

Wireless Equivalent Privacy (WEP, RC4 Algorithm)
Temporal Key Integrity Protocol (TKIP, RC4 Algorithm)
Advanced Encryption Standard (AES, Rijndael Algorithm)

Encryption Key Provisioning

Static (40-bit and 128-bit lengths)
Pre-Shared (PSK)
Dynamic

802.1X Extensible Authentication Protocol Types

EAP-FAST
EAP-TLS
EAP-TTLS
LEAP PEAP-GTC
PEAP-MSCHAPv2
PEAP-TLS
LEAP

Essential performance

The Essential performance of ZOLL M2 unit has met the requirements of the applicable standards (IEC 60601-1, IEC 60601-2-4, IEC 60601-2-27, IEC 60601-1-2, IEC 60601-1-6, IEC 62366-1, IEC 60601-1-8, IEC 80601-2-30, ISO 80601-2-61, ISO 80601-2-55, ISO 80601-2-56, IEC 60601-2-25, IEC 80601-2-49).

Defibrillation

Energy output accuracy, charge time, synchronized cardioversion, sync delay, AED rhythm recognition.

Transcutaneous Pacing

Pacing pulse shape, pulse duration and stability, pulse current, pulse rate and stability.

ECG Monitoring

Input impedance, frequency response, bandwidth, common mode rejection, linearity, dynamic range, noise, channel crosstalk, gain control, sweep speed, baseline reset, pacemaker pulse display capability, QRS detection range, aspect ratio, tall T-wave rejection, heart rate accuracy, low and high heart rate alarms.

NIBP Monitoring

Static pressure accuracy, blood pressure determination accuracy, low and high alarms for blood pressure.

CO_2 Monitoring

CO_2 measurement accuracy, respiration rate accuracy, low and high alarms for CO_2 low and respiration rate.

Temperature Monitoring

Temperature measurement accuracy, low and high temperature alarms.

SpO_2 Monitoring

SpO_2 measurement accuracy, pulse rate accuracy, low and high alarms for SpO_2, and pulse rate.

CPR Feedback

Accuracy of compression depth measurement, visual and audible CPR feedback, proper metronome rate.

Overload Protection

Defibrillation protection, defibrillation energy reduction, electrosurgery protection.

Performance on AC Power

For power interruptions of 30 seconds or less: no change of operator settings shall occur, including the mode of operation, and all stored patient data shall remain available.

For power interruptions longer than 30 seconds, the subsequent operation shall be one of the following: reversion to the manufacturer's default settings, reversion to the supervisor's default settings.

If a battery is installed when mains power is interrupted, the monitor shall automatically switch to battery power, with no change in mode of operation, operator settings, or stored data. There shall be a visual indication that the monitor is operating on battery power.

Performance on Battery Power

Battery capacity, battery shelf life, low battery indication, low battery shutdown.

Electromagnetic Compatibility (EMC)

ESD immunity, immunity to fast transients and bursts, immunity to conducted and radiated RF disturbances, RF emission levels within CISPR B limits, immunity to power frequency magnetic fields.

ZOLL M2 Rectilinear Biphasic Waveform Characteristics

Table A-1 shows the characteristics of the ZOLL M2 Rectilinear Biphasic™ waveform when discharged into 25 ohm, 50 ohm, 75 ohm, 100 ohm, 125 ohm, 150 ohm and 175 ohm loads at the maximum energy setting of 200 joules.

Table A-1. ZOLL M2 Rectilinear Biphasic Waveform Characteristics

	200 J discharged into						
	25Ω	**50Ω**	**75Ω**	**100Ω**	**125Ω**	**150Ω**	**175Ω**
First phase							
Maximum initial current	31.4 A	30.4 A	23.8A	19.7 A	19.4 A	16.7 A	15.6 A
Average current	27.1 A	24.9 A	20.5A	17.5 A	16.2 A	14.4 A	13.2 A
Duration	6 ms	6 ms	6 ms	6 ms	6 ms	6 ms	6 ms
Interphase duration (between first and second phases)	200 µs	200 µs	200µs	200 µs	200 µs	200 µs	200 µs
Second phase							
Initial current	29.2 A	18.8 A	16.9A	15.1 A	13.2 A	12.1 A	11 A
Average current	14.7 A	13 A	13.1 A	12.5 A	11.3 A	10.7 A	9.9 A
Duration	4 ms	4 ms	4 ms	4 ms	4 ms	4 ms	4 ms

Table A-2. Rated Delivered Energy at Every Defibrillator Setting into a Range of Loads

Selected Energy	Load							
	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω	Tolerance
1 J	1 J	1 J	1 J	1 J	1 J	1 J	1 J	+/- 3 J
2 J	1 J	2 J	2 J	2 J	2 J	2 J	2 J	+/- 3 J
3 J	2 J	3 J	3 J	3 J	3 J	3 J	3 J	+/- 3 J
4 J	3J	4 J	4 J	5 J	5 J	5 J	4 J	+/- 3 J
5 J	3 J	5 J	6 J	6 J	6 J	6 J	6 J	+/- 3 J
6 J	4 J	6 J	7 J	7 J	7 J	7 J	7 J	+/- 3 J
7 J	5 J	7 J	8 J	8 J	8 J	8 J	8 J	+/- 3 J
8 J	5 J	8 J	9 J	9 J	10 J	9 J	9 J	+/- 3 J
9 J	6 J	9 J	10 J	11 J	11 J	11 J	10 J	+/- 3 J
10 J	7 J	10 J	12 J	12 J	12 J	12 J	12 J	+/- 3 J
15 J	10 J	16 J	17 J	18 J	18 J	18 J	17 J	+/- 3 J
20 J	14 J	21 J	23 J	24 J	24 J	24 J	23 J	+/- 3 J
30 J	21 J	32 J	35 J	36 J	37 J	36 J	35 J	+/- 15%
50 J	35 J	54 J	59 J	61 J	62 J	61 J	59 J	+/- 15%
70 J	49 J	76 J	83 J	85 J	87 J	86 J	83 J	+/- 15%
85 J	60 J	92 J	101 J	104 J	106 J	104 J	101 J	+/- 15%
100 J	71 J	109 J	119 J	122 J	125 J	123 J	119 J	+/- 15%
120 J	85 J	131 J	143 J	147 J	150 J	147 J	143 J	+/- 15%
150 J	107 J	164 J	180 J	183 J	188 J	184 J	179 J	+/- 15%
200 J	142 J	230 J	249 J	253 J	269 J	261 J	260 J	+/- 15%

The ZOLL M2 Rectilinear Biphasic waveform employs the same first and second phase timing, the same first and second phase currents/voltages, and the same mechanisms for controlling defibrillation waveshape as the ZOLL X Series® and R Series® defibrillators. The X Series and ZOLL M2 defibrillation waveforms are considered substantially equivalent.

Figures A-1 through A-20 show the Rectilinear Biphasic waveforms that are produced when the ZOLL M2 defibrillator is discharged into loads of 25, 50, 75, 100, 125, 150, and 175 ohms at each energy setting.

The vertical axis shows the current in amperes (A); the horizontal axis shows the duration of time in milliseconds (ms).

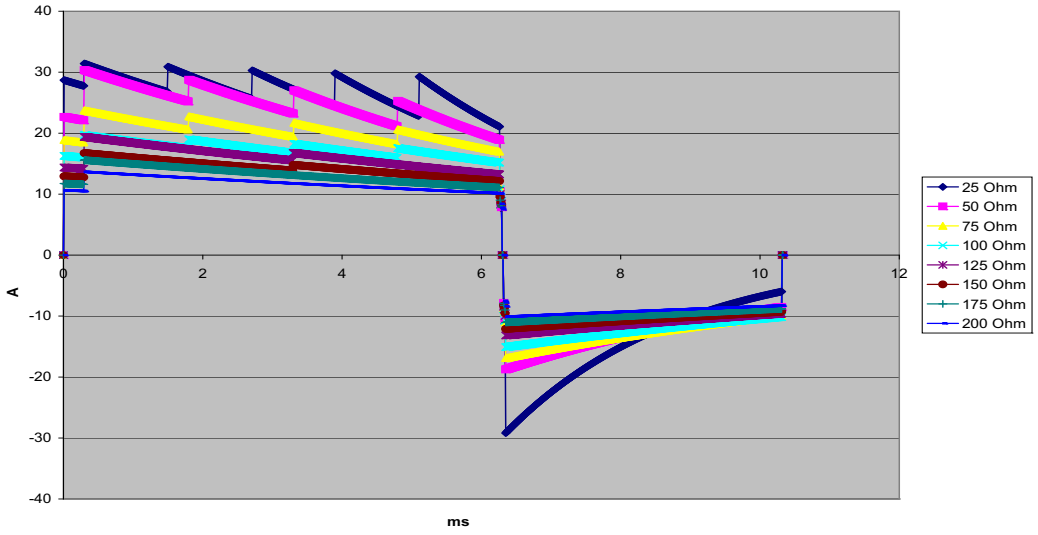


Figure A-1. Rectilinear Biphasic Waveform at 200 Joules

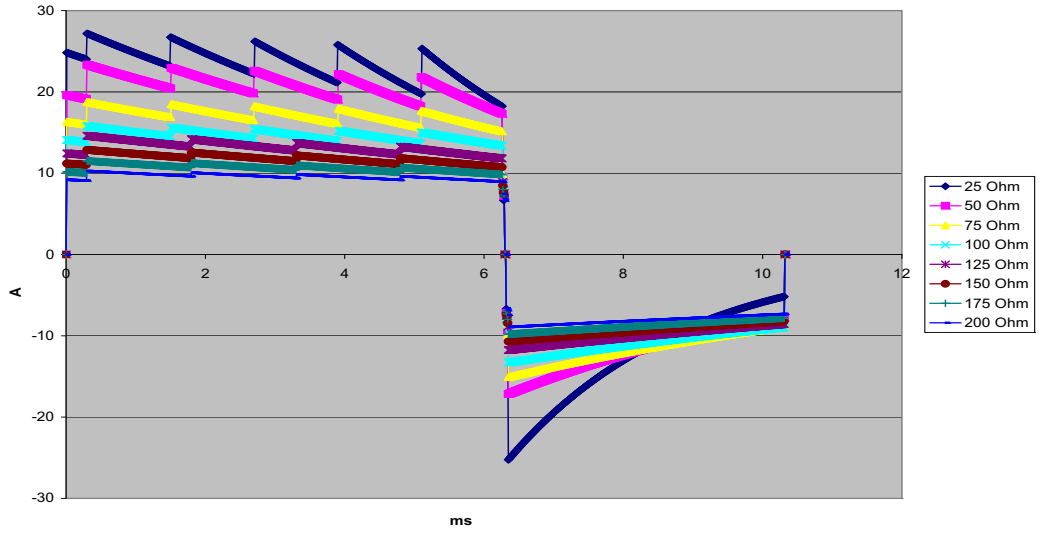


Figure A-2. Rectilinear Biphasic Waveform at 150 Joules

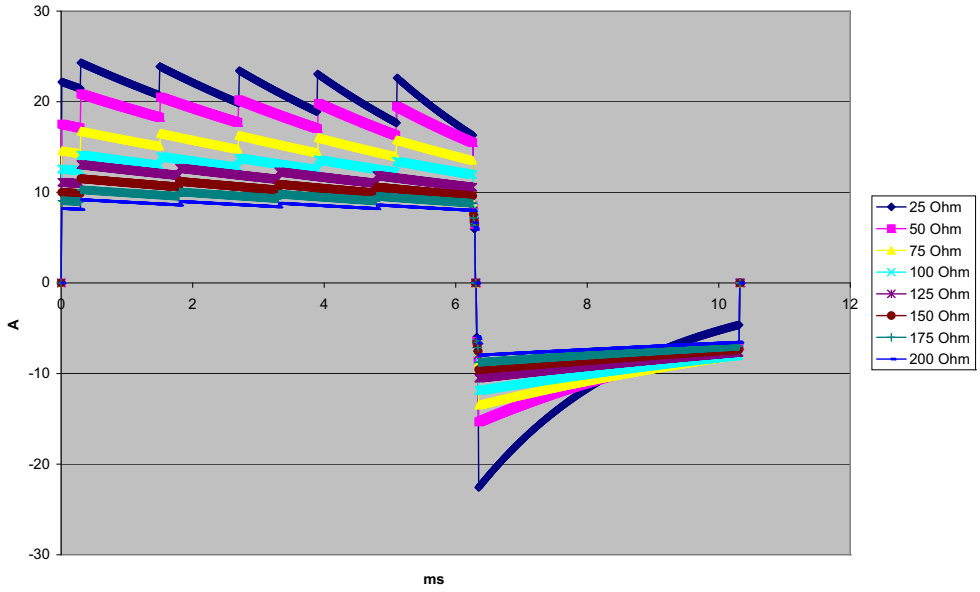


Figure A-3. Rectilinear Biphasic Waveform at 120 Joules

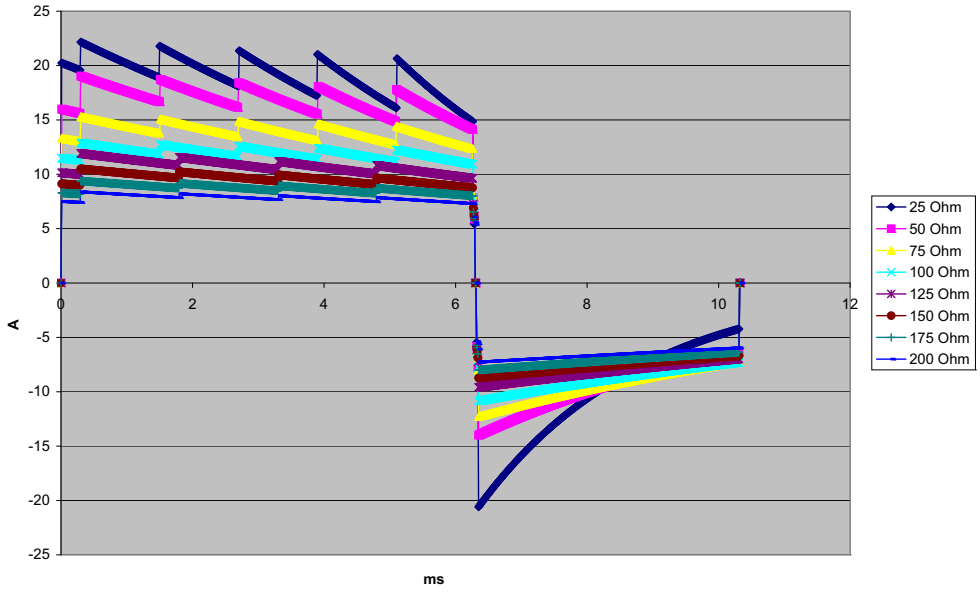


Figure A-4. Rectilinear Biphasic Waveform at 100 Joules

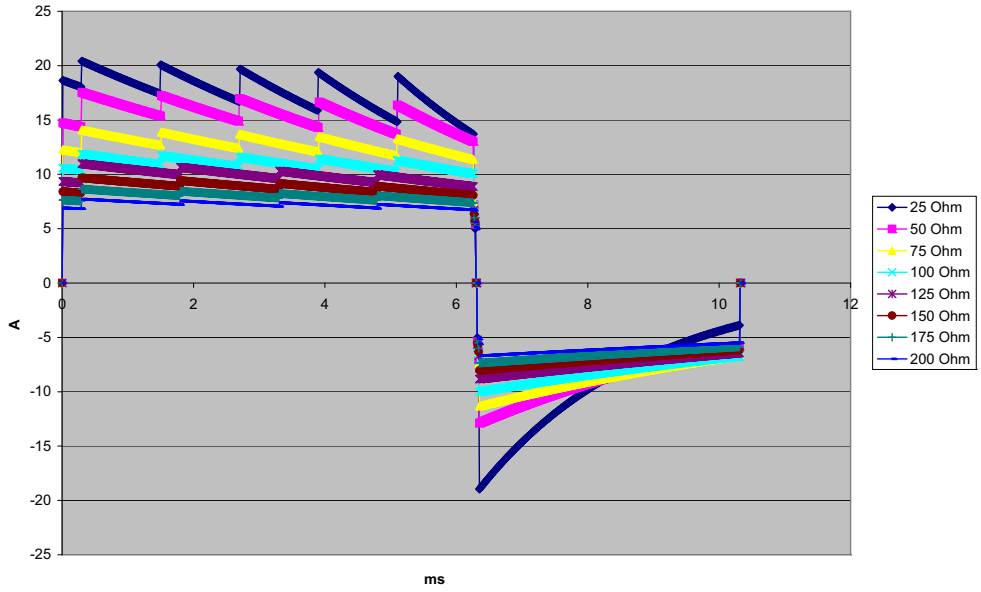


Figure A-5. Rectilinear Biphasic Waveform at 85 Joules

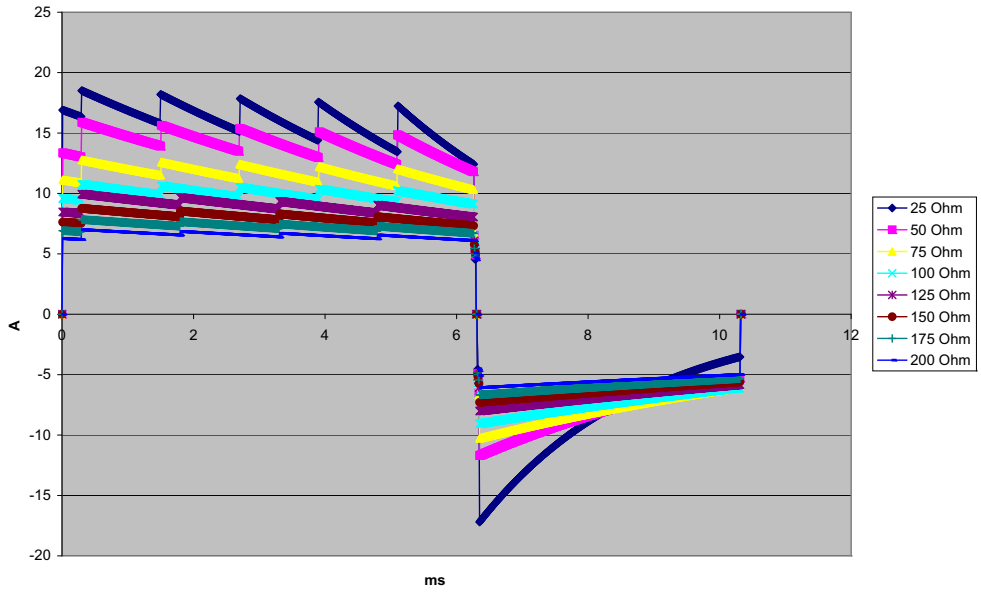


Figure A-6. Rectilinear Biphasic Waveform at 70 Joules

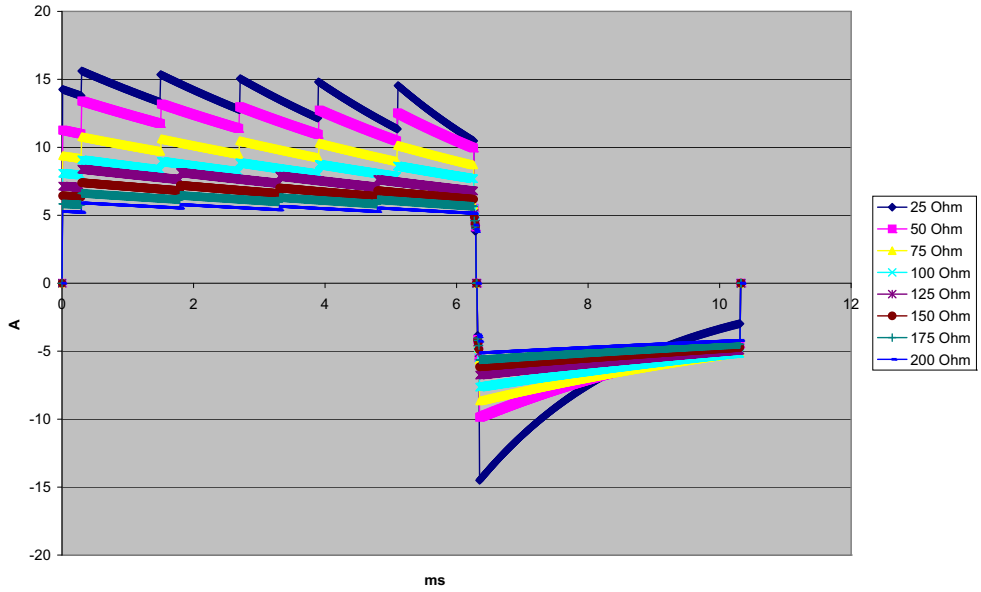


Figure A-7. Rectilinear Biphasic Waveform at 50 Joules

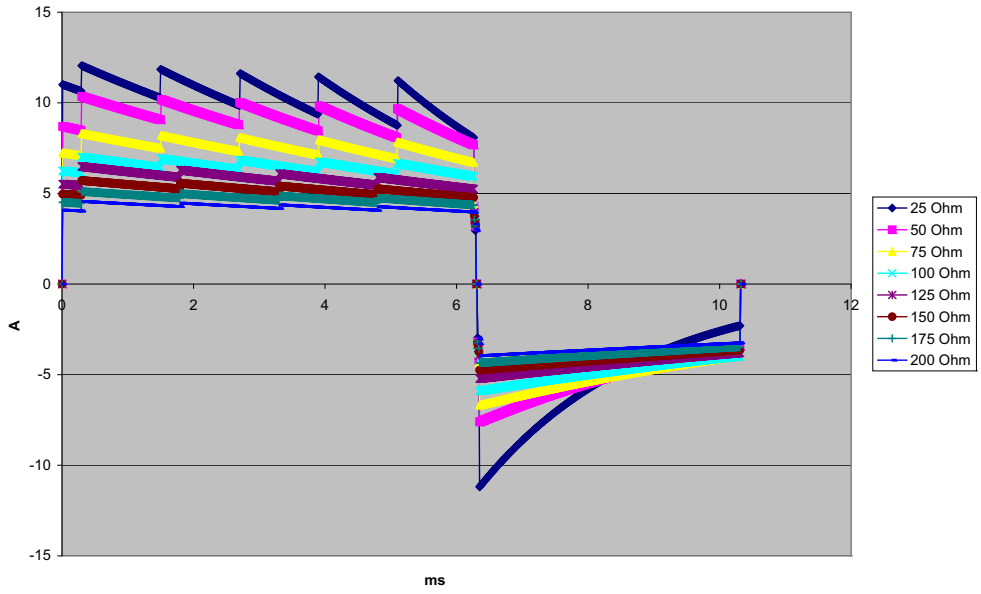


Figure A-8. Rectilinear Biphasic Waveform at 30 Joules

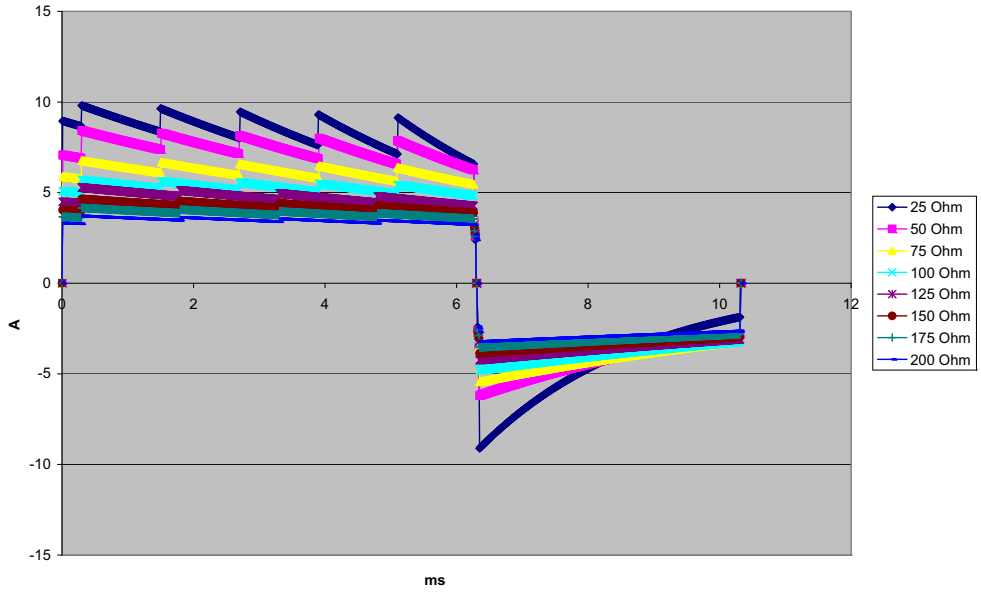


Figure A-9. Rectilinear Biphasic Waveform at 20 Joules

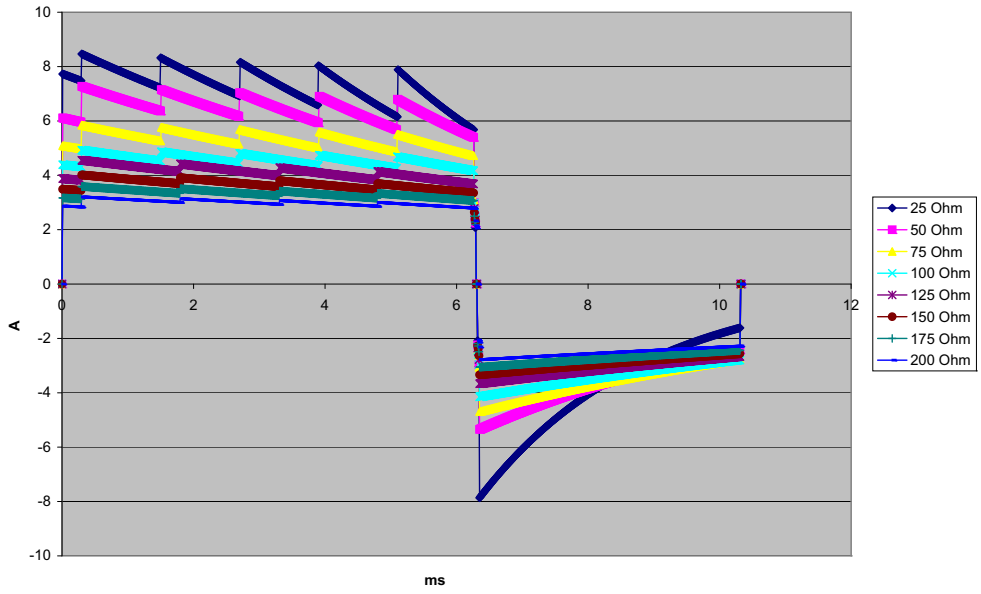


Figure A-10. Rectilinear Biphasic Waveform at 15 Joules

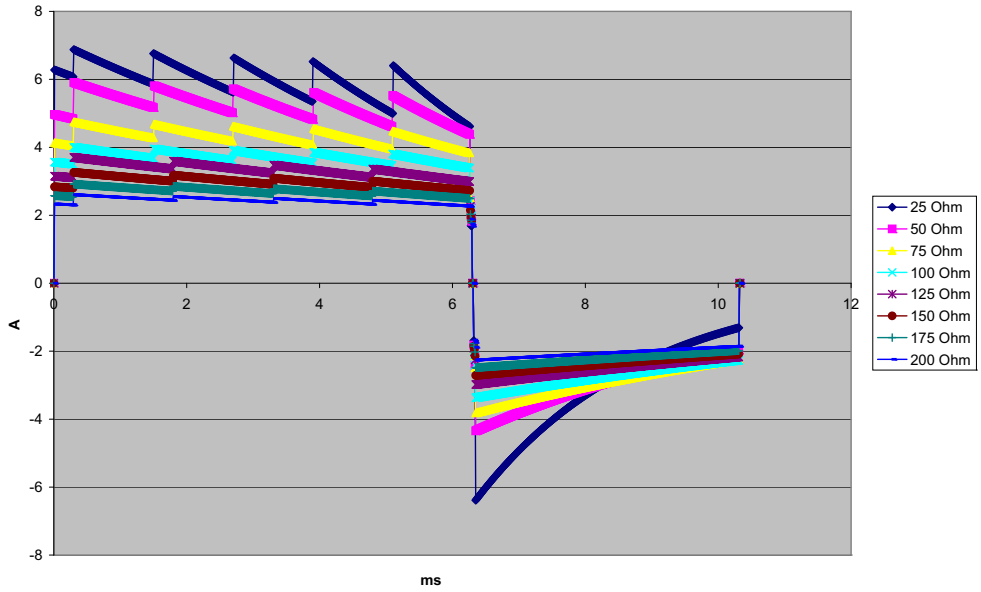


Figure A-11. Rectilinear Biphasic Waveform at 10 Joules

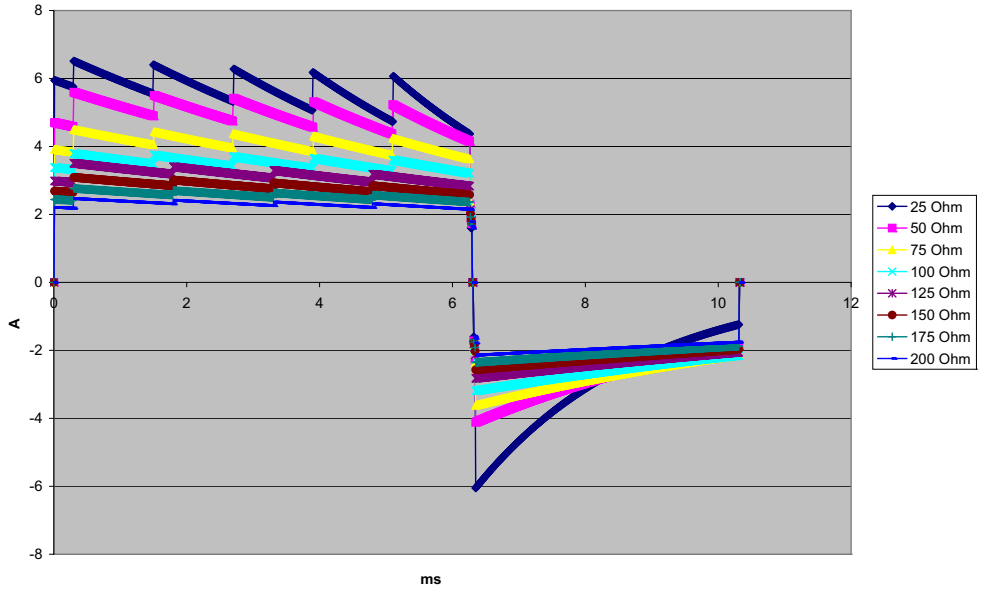


Figure A-12. Rectilinear Biphasic Waveform at 9 Joules

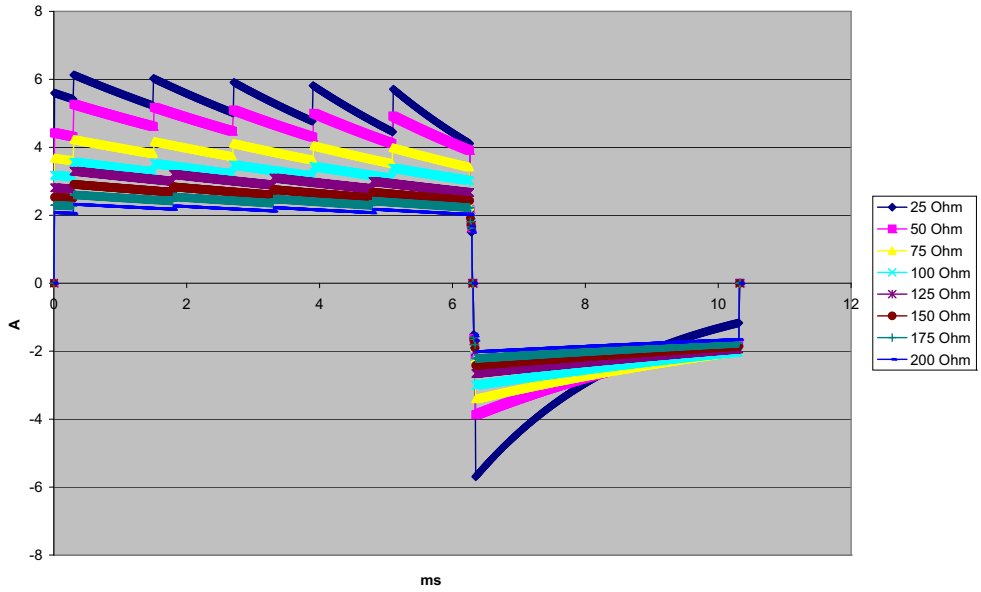


Figure A-13. Rectilinear Biphasic Waveform at 8 Joules

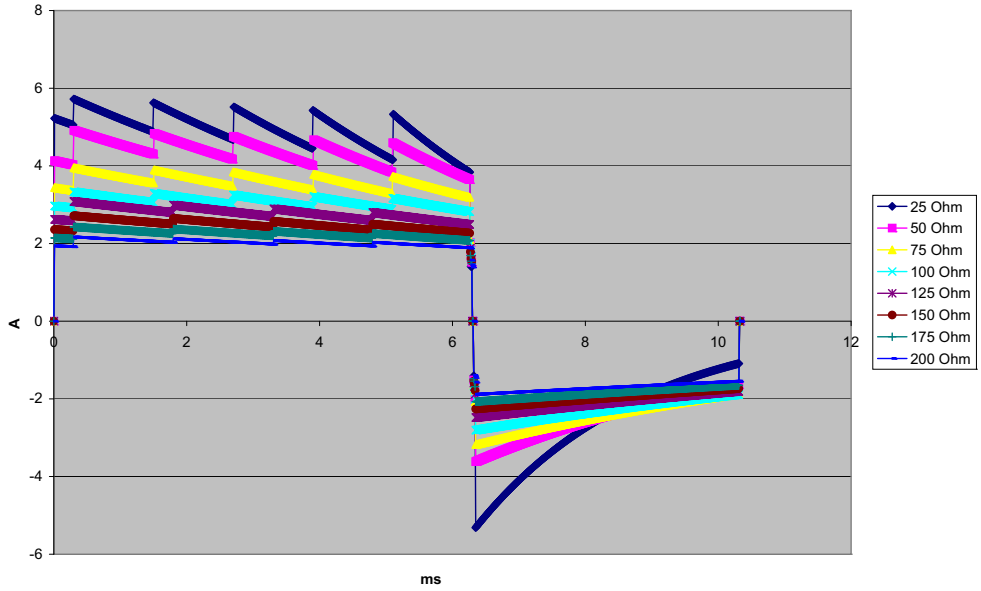


Figure A-14. Rectilinear Biphasic Waveform at 7 Joules

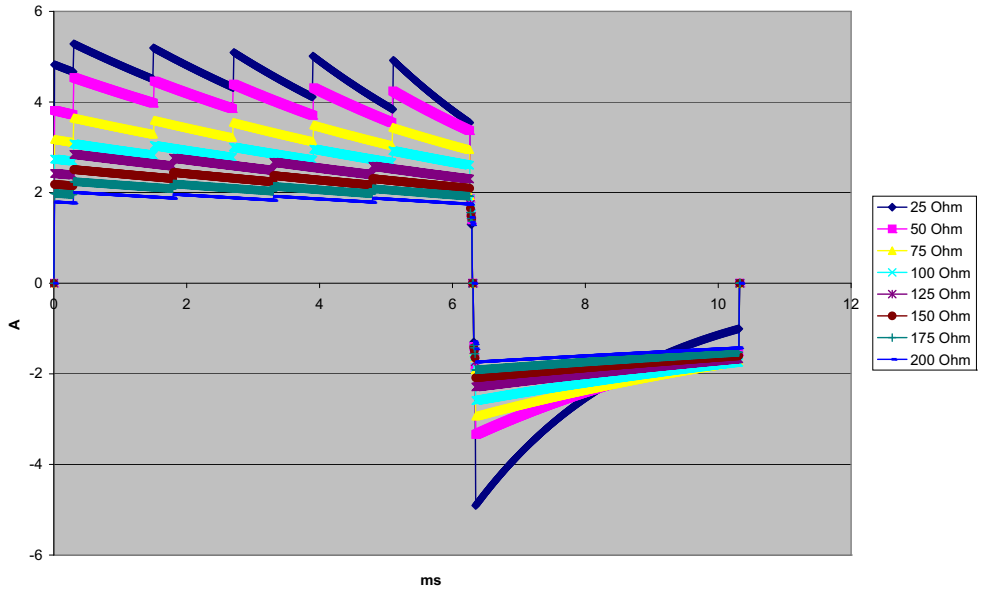


Figure A-15. Rectilinear Biphasic Waveform at 6 Joules

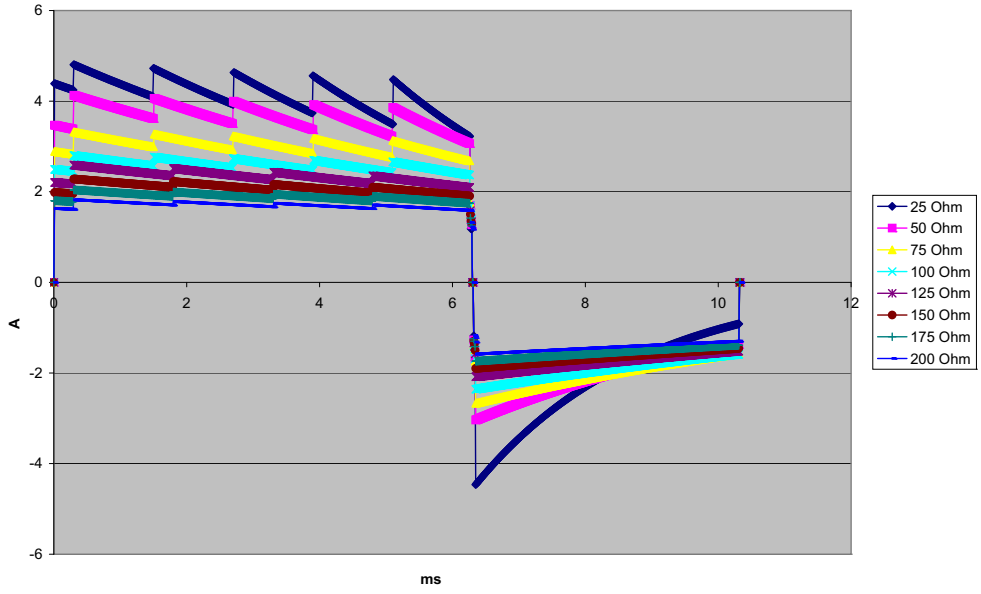


Figure A-16. Rectilinear Biphasic Waveform at 5 Joules

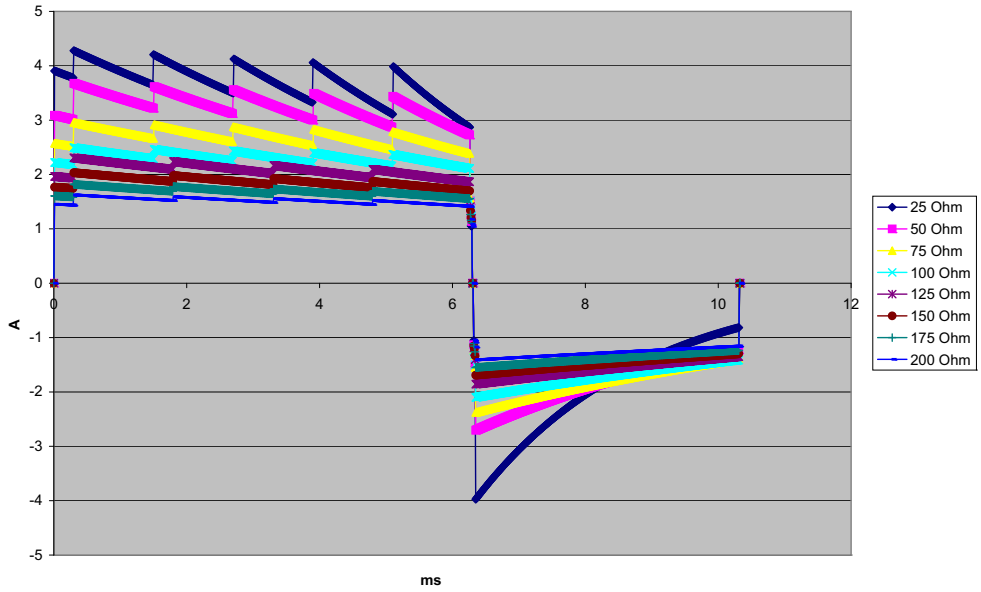


Figure A-17. Rectilinear Biphasic Waveform at 4 Joules

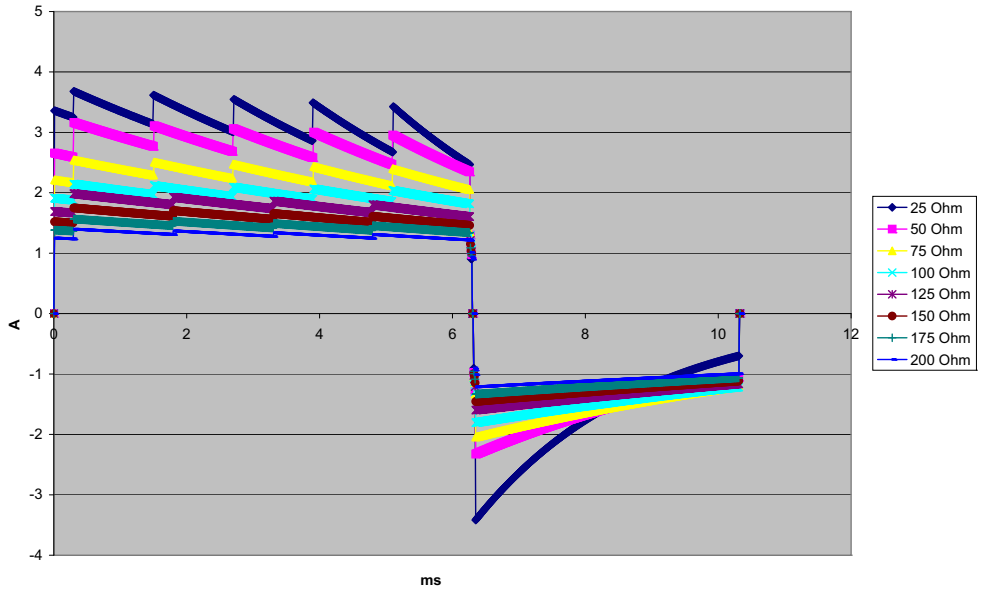


Figure A-18. Rectilinear Biphasic Waveform at 3 Joules

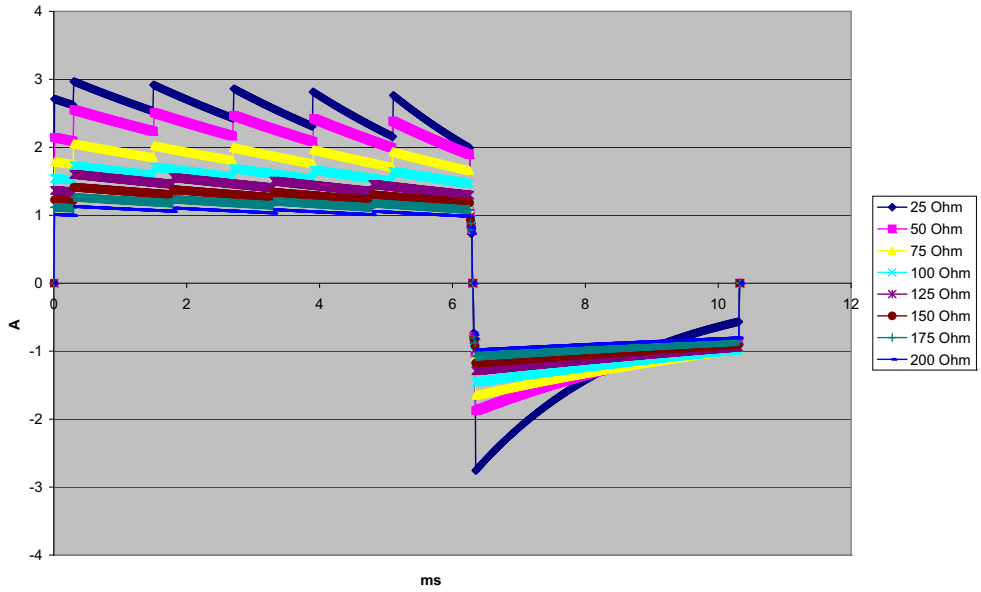


Figure A-19. Rectilinear Biphasic Waveform at 2 Joules

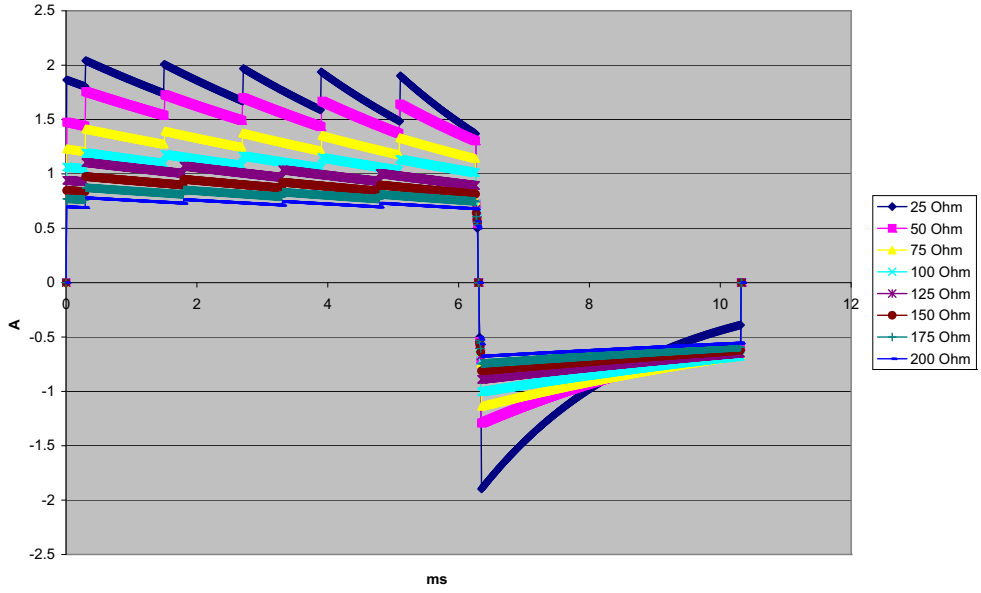


Figure A-20. Rectilinear Biphasic Waveform at 1 Joule

Clinical Trial Results for the Biphasic Waveform

The efficacy of the ZOLL Rectilinear Biphasic waveform has been clinically verified during a study of defibrillation of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT). A feasibility study was performed initially for defibrillation of VF/VT (n=20) on two separate groups of patients to ensure waveform safety and energy selection. Subsequently, a separate, multicenter, randomized clinical trial was performed to verify the waveform's efficacy. A description of this study is provided below. The study was performed using ZOLL defibrillation systems consisting of ZOLL defibrillators, the ZOLL Rectilinear Biphasic waveform, and ZOLL defibrillation electrodes.

Randomized Multicenter Clinical Trial for Defibrillation of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT)

Overview: The defibrillation efficacy of the ZOLL Rectilinear Biphasic waveform was compared to a monophasic damped sine waveform in a prospective, randomized, multicenter study of patients undergoing ventricular defibrillation for VF/VT during electrophysiological studies, ICD implants, and test. A total of 194 patients were enrolled in the study. Ten patients who did not satisfy all protocol criteria were excluded from the analysis, leaving a study population of 184.

Objectives: The primary goal of this study was to compare the first shock efficacy of the 120 J rectilinear biphasic waveform with a 200 J monophasic waveform. The secondary goal was to compare all shock (three consecutive 120, 150, and 170 joules) efficacy of the rectilinear biphasic waveform with that of a monophasic waveform (three consecutive 200, 300, and 360 joules). A significance level of p=0.05 or less was considered statistically significant using Fischer's Exact test. Also, differences between the two waveforms were considered statistically significant when the customary 95% or AHA-recommended 90%[1] confidence interval between the two waveforms was greater than 0%.

Results: The study population of 184 patients had a mean age of 63±14 years. Of these, 143 patients were male. 98 patients were in the biphasic group (ventricular fibrillation/flutter, n=80; ventricular tachycardia, n=18) and 86 patients were in the monophasic group (ventricular fibrillation/flutter, n=76; ventricular tachycardia, n=10). There were no adverse events or injuries related to the study.

The first shock, first induction efficacy of biphasic shocks at 120 J was 99% versus 93% for monophasic shocks at 200 J (p=0.0517, 95% confidence interval of the difference of –2.7% to 16.5% and 90% confidence interval of the difference of –1.01% to 15.3%).

	Monophasic	Biphasic
First shock efficacy	93%	99%
p-value	0.0517	
95% confidence interval	–2.7% to 16.5%	
90% confidence interval	–1.01% to 15.3%	

1.Kerber RE, et al., "Automated External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety," *Circ J Am Heart Assoc.* 1997;95:1677-1682.

"… the task force suggests that to demonstrate superiority of an alternative waveform over standard waveforms, the upper boundary of the 90% confidence interval of the difference between standard and alternative waveforms must be <0% (ie, alternative is greater than standard)."

Successful defibrillation with rectilinear biphasic shocks was achieved with 58% less delivered current than with monophasic shocks (14±1 amperes versus 33±7 amperes, p=0.0001).

The difference in efficacy between the rectilinear biphasic and the monophasic shocks was greater in patients with high transthoracic impedance (greater than 90 ohms). The first shock, first induction efficacy of biphasic shocks was 100% versus 63% for monophasic shocks for patients with high impedance (p=0.02, 95% confidence interval of the difference of –0.0217% to 0.759% and 90% confidence interval of the difference of 0.037% to 0.706%).

	Monophasic	Biphasic
First shock efficacy (high impedance patients)	63%	100%
p-value	0.02	
95% confidence interval	–0.021% to 0.759%	
90% confidence interval	0.037% to 0.706%	

A single patient required a second biphasic shock at 150 joules to achieve 100% efficacy versus six patients for whom monophasic shocks of up to 360 joules were required for 100% total defibrillation efficacy.

Conclusion: The data demonstrate the equivalent efficacy of low energy rectilinear biphasic shocks compared to standard high energy monophasic shocks for transthoracic defibrillation for all patients at the 95% confidence level. The data also demonstrate the superior efficacy of low energy rectilinear biphasic shocks compared to standard high energy monophasic shocks in patients with high transthoracic impedance at the 90% confidence level. There were no unsafe outcomes or adverse events due to the use of rectilinear biphasic waveform.

Randomized Multi-Center Clinical trial for Cardioversion of Atrial Fibrillation (AF)

Overview: The defibrillation efficacy of ZOLL's Rectilinear Biphasic Waveform was compared to a monophasic damped sine waveform in a prospective randomized multi-center study of patients undergoing cardioversion of their atrial fibrillation. A total of 173 patients entered the study. Seven (7) patients who did not satisfy all protocol criteria were excluded from the analysis. ZOLL disposable gel electrodes with surface areas of 78 cm^2 (anterior) and 113 cm^2 (posterior) were used exclusively for the study.

Objective: The primary goal of the study was to compare the total efficacy of four consecutive rectilinear biphasic shocks (70J, 120J, 150J, 170J) with four consecutive monophasic shocks (100J, 200J, 300J, 360J). The significance of the multiple shocks efficacy was tested statistically via two procedures, the Mantel-Haenszel statistic and the log-rank test, significance level of p=0.05 or less was considered statistically significant. The data are completely analogous to the comparison of two "survival" curves using a life-table approach where shock number plays the role of time.

The secondary goal was to compare the first shock success of rectilinear biphasic and monophasic waveforms. A significance level of p=0.05 or less was considered statistically significant using Fisher Exact tests. Also, differences between the two waveforms were considered statistically significant when the 95% confidence interval between the two waveforms was greater than 0%.

Results: The study population of 165 patients had a mean age of 66±12 years with 116 male patients.

The total efficacy of consecutive rectilinear biphasic shocks was significantly greater than that of monophasic shocks. The following table displays the Kaplan-Meier (product-limit) "survival" curves for each of the two waveforms. As all patients begin in the failure mode, the estimated life-table probabilities refer to the chance of still being in failure after the k^{th} shock (k=1,2,3,4):

Table A-3. Kaplan-Meier Estimate for the Probability of Shock Failure

Shock #	Biphasic	Monophasic
0	1.000	1.000
1	0.318	0.792
2	0.147	0.558
3	0.091	0.324
4	0.057	0.208

As can be seen from the table, the Biphasic experience is superior over the entire course of shocks delivered. The one degree of freedom chi-square statistic for the Mantel-Haenszel test is 30.39 ($p<0.0001$). Similarly, the log-rank test, also a one degree of freedom chi-square statistic, is 30.38 ($p<0.0001$). The residual number of patients not successfully treated after four shocks is 5.7% for biphasic compared to 20.8% for monophasic.

There was a significant difference between the first shock efficacy of biphasic shocks at 70J of 68% and that of monophasic shocks at 100J of 21% ($p=0.0001$, 95% confidence interval of the difference of 34.1% to 60.7%).

Successful cardioversion with rectilinear biphasic shocks was achieved with 48% less delivered current than with monophasic shocks (11±1 vs. 21±4 A, $p<0.0001$).

One half of the patients who failed cardioversion after four consecutive escalating monophasic shocks were subsequently successfully cardioverted using a biphasic shock at 170J. No patient was successfully cardioverted using a 360J monophasic shock after the patient had failed cardioversion with biphasic shocks.

Conclusion: The data demonstrate the superior efficacy of low energy rectilinear biphasic shocks compared to high energy monophasic shocks for transthoracic cardioversion of atrial fibrillation. There were no unsafe outcomes or adverse events due to the use of Rectilinear Biphasic Waveform.

Electromagnetic Compatibility Guidance and Manufacturer's Declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The ZOLL M2 unit is intended for use in the electromagnetic environment specified below. The customer or the user of the ZOLL M2 unit should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Group 1	The ZOLL M2 unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CSPR 11	Class B	The ZOLL M2 unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 6100-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.		

Electromagnetic Immunity (IEC 60601-1-2)

Guidance and manufacturer's declaration – electromagnetic immunity		
Immunity test	**IEC 60601 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	± 15 kV air ± 8 kV contact	± 15 kV air ± 8 kV contact
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines 100 kHz PRF	± 2 kV for power supply lines ± 1 kV for input/ output lines
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth 0°, 90°, 180°, 270°	± 1 kV line to line ± 2 kV line to ground
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle at 0° 70% UT for 25/30 cycles at 0° 0% UT for 250/300 cycles	0% UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle at 0° 70% UT for 25/30 cycles at 0° 0% UT for 250/300 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
Note: U_T is the AC mains voltage prior to application of the test level.		

Electromagnetic Immunity: Professional Healthcare Facility and Home Healthcare Environments

Functions of the ZOLL M2 include: ECG waveform monitoring from leads or pads, the pacing pulse output, QRS detection, defibrillation energy discharge, and shock advisory functions.

Guidance and manufacturer's declaration – electromagnetic immunity – for equipment and systems		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 Vrms
	6 Vrms 150 kHz to 80 MHz in ISM bands[a]	6 Vrms
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 20 V/m
	20 V/m (only for Defibrillation)	
NOTE 1: At 80 MHz the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.		

a. The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Electromagnetic Immunity: Professional Healthcare Facility and Home Healthcare Environments

The following table provides test specifications for Enclosure Port Immunity to RF wireless communications equipment.

Test Frequency (MHZ)	Band [a] (MHZ)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1kHz sine	2	0,3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1720	1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5500						
5785						

ECG Analysis Algorithm Accuracy

Sensitivity and specificity are expressions of ECG analysis algorithm performance when compared to ECG interpretation by a clinician or expert. Sensitivity refers to the algorithm's ability to correctly identify shockable rhythms (as a percentage of the total number of shockable rhythms). Specificity refers to the algorithm's ability to correctly identify non-shockable rhythms (as a percentage of the total number of non-shockable rhythms). The data in the following table summarizes the accuracy of the ECG analysis algorithm as tested against ZOLL's ECG Rhythm Database.

The algorithm sequence takes 6-12 seconds and proceeds as follows:

- Divides the ECG rhythm into three-second segments.
- Filters and measures noise, artifact, and baseline wander.
- Measures baseline content ('waviness' at the correct frequencies **—** frequency domain analysis) of signal.
- Measures QRS rate, width, and variability.
- Measures amplitude and temporal regularity ('auto-correlation') of peaks and troughs.
- Determines if multiple 3 second segments are shockable then displays *SHOCK ADVISED* message.

Clinical Performance Results

The performance of the incorporated analysis algorithm in a single analysis sequence satisfies the applicable requirements specified in IEC 60601-2-4 (subclause 201.7.9.3.103) and the recommendations by Kerber et al. (Circulation. 1997;95(6):1677).

Table A-4. Clinical Performance Results of ECG Analysis Algorithm with Adult Patients

Rhythms	Sample Size	Performance Goal	Observed Performance	90% Lower Confidence Limit
Shockable		**Sensitivity**		
Coarse VF	536	>90%	>99%	>99%
Rapid VT	80	>75%	>98%	>94%
Non-shockable		**Specificity**		
NSR	2210	>99%	>99%	>99%
AF, SB, SVT, Heart block, idioventricular, PVCs	819	>95%	>99%	>99%
Asystole	115	>95%	>99%	>97%
Intermediate		**Sensitivity**		
Fine VF	69	Report Only	>90%	>85%
Other VT	28	Report Only	>98%	>85%

Table A-5. Clinical Performance Results of ECG Analysis Algorithm with Pediatric Patients

Rhythms	Sample Size	Required Performance	Observed Performance	90% One-sided Lower Confidence Limit
Shockable		**Sensitivity**		
Coarse VF	42	>90%	>99%	>93%
Rapid VT	79	>75%	>99%	>96%
Non-shockable		**Specificity**		
NSR	208	>99%	>99%	>98%
AF, SB, SVT, Heart block, idioventricular, PVCs	348	>95%	>99%	>98%
Asystole	29	>95%	>99%	>90%
Intermediate			**Sensitivity**	
Fine VF	0	Report only	NA	NA
Other VT	44	Report only	>80%	>69%

References:

Young KD, Lewis RJ: “What is confidence? Part 2: Detailed definition and determination of confidence intervals”. Annals of Emergency Medicine, September 1997; 30; 311-218

William H. Beyer, Ph.D.: “CRC Standard Mathematical Tables 28th Edition,” CRC Press, Inc, Boca Raton, FL., 1981, Percentage Points, F-Distribution Table, pg 573.

Wireless Output Guidance and Manufacturer's Declaration

RF Transmission Emitted (IEC 60601-1-2)

The ZOLL M2 unit complies with IEC 60601-1-2 for medical electrical equipment and medical electrical systems that include RF transmitters as specified below.

Transmit Power			
Note: Transmit power varies according to individual country regulations. All values nominal, +/-2 dBm. **Note**: Laird 45 series radios support a single spatial stream and 20 MHz wide channels for N rates.	802.11a:	6 Mbps 54 Mbps	15 dBm (32 mW) 12 dBm (16 mW)
	802.11b:	1 Mbps 11 Mbps	16 dBm (40 mW) 16 dBm (40 mW)
	802.11g:	6 Mbps 54 Mbps	16 dBm (40 mW) 12 dBm (16 mW)
	802.11n (2.4 GHz):	6.5 Mbps (MCS0) 65 Mbps (MCS7)	16 dBm (40 mW) 12 dBm (16 mW)
	802.11n (5 GHz):	6.5 Mbps (MCS0) 65 Mbps (MCS7)	15 dBm (32 mW) 12 dBm (16 mW)

Appendix B
Accessories

The following accessories are intended for use with the ZOLL M2 monitor/defibrillator. To order any of these items, contact your local ZOLL representative.

Warning! **The use of accessories, transducers, and cables other than those specified in this manual may result in increased emissions or decreased immunity of the ZOLL M2 monitor/ defibrillator.**

Defibrillation, Pacer, CPR Cables and Electrodes
ZOLL M2, 3-Lead ECG Cable, AAMI
ZOLL M2, 3-Lead ECG Cable, IEC
ZOLL M2, 5-Lead ECG Cable, AAMI
ZOLL M2, 5-Lead ECG Cable, IEC
ZOLL M2, 12-Lead ECG Cable, AAMI
ZOLL M2, 12-Lead ECG Cable, IEC
ZOLL M2 MFC
ZOLL M2 CPR-D MFC
External Paddle Assembly Apex/Sternum with Controls and Built-in Pediatric Electrodes
Sterilizable Internal Handle with Integrated Paddles, with Switch (Paddle Options: 1.0", 1.6", 2.0", 2.7", 3.0")
Sterilizable Internal Handle with Integrated Paddles, without Switch (Paddle Options: 1.0", 1.6", 2.0", 2.7", 3.0”)
Dura-padz Gel
CPR Dura-padz Reusable Defibrillation Electrode

CPR Stat-padz® Electrode (case of 8)
CPR-D-padz® One Piece Electrode Pad with Real CPR Help
CPR Uni-padz® *
OneStep Green Connector CPR AA
OneStep Green Connector Basic
OneStep Green Connector Pediatric
CPR Connector
Stat-padz Electrode (case of 12)
Stat-padz Electrode (single)
Pro-padz Biphasic w/LVP Gel Electrode
Pro-padz Sterile w/10 ft Leadwire
Pro-padz Radiolucent Solid Gel Electrode
Pro-padz Cardiology w/LVP Gel Electrode
Pro-padz Radiolucent Liquid Gel Electrode
Pedi-padz® Multi-Function Liquid Gel Electrode
Pedi-padz Radiolucent Solid Gel Electrode
Pedi-padz II Electrodes
Pedi-padz Solid Gel Electrodes, w/10 ft Leadwire
Pedi-padz Multi-Function Solid Gel Electrode
Stat-padz II Electrode (single)
Stat-padz II (case of 12)
Pedi-padz II, AED PLUS (case of 10)
Defibrillator Gel – 12 Tubes (250 grams)
* **Note**: CPR Uni-padz electrodes are not indicated for use in noninvasive pacing.
SpO2 Sensors
ZOLL M2, Reusable SpO_2 Sensor, Clip, Adult, 2m
ZOLL M2, Reusable SpO_2 Sensor, Soft Tip, Pediatric, 2m
ZOLL M2, Reusable SpO_2 Sensor, Clip, Adult, 3m
ZOLL M2, Reusable SpO_2 Sensor, Soft Tip, Pediatric, 3m
Temperature Sensors
ZOLL M2, Temperature Sensor, Reusable, Adult Skin
ZOLL M2, Temperature Sensor, Reusable, Adult Esophageal/Rectal
ZOLL M2, Temperature Sensor, Reusable, Pediatric Skin

ZOLL M2, Temperature Sensor, Reusable, Pediatric Esophageal/Rectal
NIBP Cuffs/Hose
ZOLL M2, NIBP Cuff, Reusable, Adult Thigh, 46-66cm
ZOLL M2, NIBP Cuff, Reusable, Large Adult, 33-47cm
ZOLL M2, NIBP Cuff, Reusable, Adult, 25-35cm
ZOLL M2, NIBP Cuff, Reusable, Small Adult/Child, 18-26cm
ZOLL M2, NIBP Cuff, Reusable, Pediatric, 10-19cm
ZOLL M2, Blood Pressure Hose, 3m
ZOLL M2, Blood Pressure Hose, 2m
EtCO2
Note: Some items are only available as part of a kit.
CO_2 Mainstream Sensor
CO_2 Sidestream Sensor
Mainstream Airway Adapter, Single Use, Adult/Pediatric, box of 10
Mainstream Airway Adapter, Single Use, Infant, box of 10
Sidestream Nasal Sampling Line, Single Use, Adult, box of 10
Sidestream Nasal Sampling Line, Single Use, Pediatric, box of 10
Water Trap, Single Use, box of 10
L Tube/T Tube Sampling Line, Single Use, box of 10
L Tube Connector, Single Use, Adult/Pediatric/Infant, box of 10
T Tube Connector, Single Use, Adult/Pediatric/Infant, box of 10
Sidestream Nasal Sampling Line Kit, Single Use, Adult, box of 10
Sidestream Nasal Sampling Line Kit, Single Use, Pediatric, box of 10
Sidestream Sampling Line Kit (L Tube), Single Use, Intubated Adult/Pediatric/Infant, box of 10
Sidestream Sampling Line Kit (T Tube), Single Use, Intubated Adult/Pediatric/Infant, box of 10
L Tube/T Tube Sampling Line with Dryer, Single Use, box of 10
Sidestream Sampling Line Kit with Dryer (L Tube), Single Use, Intubated Adult/Pediatric/Infant, box of 10
Sidestream Sampling Line Kit with Dryer (T Tube), Single Use, Intubated Adult/Pediatric/Infant, box of 10
Sidestream Nasal Sampling Line Kit with Dryer, Single Use, Adult, box of 10
Sidestream Nasal Sampling Line Kit with Dryer, Single Use, Pediatric, box of 10
Battery
SurePower Battery
Power Cords
ZOLL M2 Power Cord — EU Plug
ZOLL M2 Power Cord — Chinese Mainland Plug

ZOLL M2 Power Cord — UK Plug
ZOLL M2 Power Cord — US Plug
ZOLL M2 Power Cord — Brazilian Portuguese Plug
Paper
ZOLL M2 Paper, 80 mm Thermal Paper with Gridlines (single pack)
Kit/Bag
ZOLL M2 Bed Hook Kit
ZOLL M2 Carry Case, Rear Bag
ZOLL M2 Carry Case, Side Bag

Appendix C
Messages

This appendix lists the patient (physiological) alarms, equipment (technical) alarms, and indication messages that you may see displayed on your ZOLL M2 monitor/defibrillator.

Alarm Message	Alarm Type	Priority	Cause
ΔT High	Patient	High	The ΔT value exceeds the selected high temperature limit.
ΔT Low	Patient	High	The ΔT value is below the selected low temperature limit.
12-Lead Button Stuck	Equipment	Medium	The front panel quick access key self-test failed.
30 J Self-Test Button Stuck	Equipment	High	The front panel quick access key self-test failed.
4:1 Button Stuck	Equipment	Medium	The front panel quick access key self-test failed.
AED Button Stuck	Equipment	High	The front panel button self-test failed.
AED Functions Disabled	Equipment	Medium (Monitor/Pacer/ Manual mode); High (AED mode)	The streaming communication test failed.
Alarm Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The front panel button self-test failed.

Alarm Message	Alarm Type	Priority	Cause
Analyze Button Stuck	Equipment	Medium (if “Restart analysis after CPR” in the Supervisor menu is disabled); High (if “Restart analysis after CPR” in the Supervisor menu is enabled).	The front panel button self-test failed.
Attach Pads	Equipment	Medium	Pads are not connected to the patient (when Pads is selected as primary ECG waveform in Monitor mode or Manual Defib mode).
Battery Calibration Required	Equipment	Low	The battery has reached a state that requires battery calibration.
Battery Communications Fault	Equipment	Low	Battery communication fault.
Battery Error	Equipment	Low	A battery fault has been detected.
BR High	Patient	High	The BR value exceeds the upper alarm limit selected.
BR Low	Patient	High	The BR value exceed the lower alarm limit selected.
Cardioversion Using Leads ECG - Disabled	Equipment	High (Pacer mode); Low (Defib/Monitor mode)	The ECG module or power supply self-test failed.
Check CO2 Airway Adapter	Equipment	Medium	The airway adapter is blocked, contaminated, contains too many secretions, or is not connected properly to the mainstream module.
Check CO2 Sampling Line	Equipment	Medium	The sampling line and water trap may not be connected to sidestream module; the sampling line may be blocked, pinched, or kinked; or the airway adapter is blocked or otherwise compromised.
Check Pads - Pads Shorted	Equipment	Medium (Defib mode); Low (Monitor mode)	Pads shorted (when Pads are selected as the primary ECG waveform in Manual Defib/Monitor mode).
Check Patient	Patient	High	A VF/VT signal is detected in Monitor/ Manual Defib mode when the HR alarm is on.
Check RESP Electrodes	Equipment	Medium	The patient’s respiratory impedance is out of range.
Check SpO2 Sensor	Equipment	Medium	The SpO_2 sensor has been disconnected from the unit, or the sensor is no longer attached to the patient.
Clear Button Stuck	Equipment	Medium	The front panel quick access key self-test failed.

Alarm Message	Alarm Type	Priority	Cause
CO2 Ambient Pressure Out of Range	Equipment	Medium	The CO_2 ambient pressure is outside of the specified operating range.
CO2 Button Stuck	Equipment	High (Defib mode); Medium (Pacer/Monitor mode)	The front panel quick access key self-test failed.
CO2 Disabled - Critical Fault	Equipment	High	The CO2 module has a critical software or hardware fault.
CO2 Out of Range	Equipment	Medium	The CO2 value is out of the measurement range.
CO2 Temperature Out of Range	Equipment	Medium	The operating temperature of CO_2 module is lower than 0° C or higher than 50° C. The accuracy of the CO_2 value may be out of the specified range.
Code Marker Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The front panel quick access key self-test failed.
Connect Therapy Cable	Equipment	High	The MFC cable is not connected to the unit (when Pads/Paddles are selected as primary ECG waveform in Monitor mode after Lead On).
Defib Disabled	Equipment	High (Defib mode); Low (Pacer/Monitor mode)	Cannot finish the defibrillator charge in low battery condition.
DEFIB DISABLED - SERVICE REQUIRED	Equipment	High (Defib mode); Low (Pacer/Monitor mode)	Defibrillator critical fault.
Defib Service Recommended	Equipment	Low	The total count of the shock greater than or equal to 120 Joules delivered exceeds 5000 shocks.
Demand Pacing Disabled	Equipment	High (Pacer mode); Low (Defib/Monitor mode)	The power supply self-test failed, Pace/Defib blank self-test failed.
Diag Button Stuck	Equipment	Medium (Monitor mode with 3/5 lead function)	The front panel quick access key self-test failed.
Disarm Button Stuck	Equipment	High	The front panel quick access key self-test failed.
ECG Asystole	Patient	High	The limb lead ECG HR detects asystole.
ECG C Lead Off	Equipment	Medium	The ECG C lead is not connected to the patient when other leads are connected.
ECG C1 Lead Off	Equipment	Medium	The ECG C1 lead is not connected to the patient when all ECG limb leads are connected.
ECG C2 Lead Off	Equipment	Medium	The ECG C2 lead is not connected to the patient when all ECG limb leads are connected.

Alarm Message	Alarm Type	Priority	Cause
ECG C3 Lead Off	Equipment	Medium	The ECG C3 lead is not connected to the patient when all ECG limb leads are connected.
ECG C4 Lead Off	Equipment	Medium	The ECG C4 lead is not connected to the patient when all ECG limb leads are connected.
ECG C5 Lead Off	Equipment	Medium	The ECG C5 lead is not connected to the patient when all ECG limb leads are connected.
ECG C6 Lead Off	Equipment	Medium	The ECG C6 lead is not connected to the patient when all ECG limb leads are connected.
ECG Communications Fault	Equipment	Medium	There is an ECG communication fault.
ECG Lead Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The front panel quick access key self-test failed.
ECG Lead Off	Equipment	High (when there is pacer pulse output in Demand Pacer mode); Medium (when in Monitor mode/Defib mode/Fixed Pacer; and when there is no pacer pulse output in Demand Pacer mode).	One or more ECG limb leads or the ECG cable are not connected to the patient or to the ZOLL M2 unit.
ECG Over Load	Equipment	Medium	The DC (direct current) noise is too high.
ECG V Lead Off	Equipment	Medium	The ECG V lead is not connected to the patient when other leads are connected.
ECG V1 Lead Off	Equipment	Medium	The ECG V1 lead is not connected to the patient when all ECG limb leads are connected.
ECG V2 Lead Off	Equipment	Medium	The ECG V2 lead is not connected to the patient when all ECG limb leads are connected.
ECG V3 Lead Off	Equipment	Medium	The ECG V3 lead is not connected to the patient when all ECG limb leads are connected.
ECG V4 Lead Off	Equipment	Medium	The ECG V4 lead is not connected to the patient when all ECG limb leads are connected.
ECG V5 Lead Off	Equipment	Medium	The ECG V5 lead is not connected to the patient when all ECG limb leads are connected.

Alarm Message	Alarm Type	Priority	Cause
ECG V6 Lead Off	Equipment	Medium	The ECG V6 lead is not connected to the patient when all ECG limb leads are connected.
EtCO2 High	Patient	High	The $EtCO_2$ value exceeds the upper alarm limit selected.
EtCO2 Low	Patient	High	The $EtCO_2$ value exceeds the lower alarm limit selected.
Excessive Internal Discharges Detected	Equipment	Low	Excessive internal discharges are detected.
External Pace Pulse Rejection Failed	Equipment	Low (Monitor/Deifb mode); High (Pacer mode)	The Pacer/Defib module cannot receive the ECG module QRS sync signal.
FiCO2 High	Patient	High	The $FiCO_2$ value exceeds the upper alarm limit selected.
FiCO2 Low	Patient	High	The $FiCO_2$ value exceeds the lower alarm limit selected.
Front Panel Charge Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The front panel button self-test failed.
Front Panel Communications Fault	Equipment	Medium	There is a front panel communication fault.
Front Panel Energy Down Btn. Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The front panel button self-test failed.
Front Panel Energy Up Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The front panel button self-test failed.
Front Panel Recorder Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The front panel button self-test failed.
Front Panel Shock Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The front panel button self-test failed.
HR High	Patient	High	The patient heart rate is above the upper alarm limit.
HR Low	Patient	High	The patient Heart rate is below the lower alarm limit.
Low Battery	Equipment	High	The battery has reached a low battery state.
Manual Defib Button Stuck	Equipment	High	The front panel quick access key self-test failed.
Menu Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The front panel button self-test failed.

Alarm Message	Alarm Type	Priority	Cause
Multiple Paddle Buttons Stuck	Equipment	High (Defib mode); Medium (Monitor/Pacer mode)	Multiple paddle buttons self-test failed.
Next Page Button Stuck	Equipment	Medium (Monitor/Pacer mode; High (Defib mode)	The front panel quick access key self-test failed.
NIBP Button Stuck	Equipment	High (Defib mode); Medium (Monitor/Pacer mode)	The front panel quick access key self-test failed.
NIBP Calibration Recommended	Equipment	Medium	The NIBP module's calibration data has failed or corrupted.
NIBP Communications Fault	Equipment	Medium	Communication to the NIBP module has failed.
NIBP Diastolic High	Patient	High	The NIBP diastolic value exceeds the upper alarm limit selected.
NIBP Diastolic Low	Patient	High	The NIBP diastolic value exceeds the lower alarm limit selected.
NIBP Disabled - Critical Fault	Equipment	High	A critical fault has occurred with the NIBP module.
NIBP Hose Blocked	Equipment	Medium	The NIBP hose is blocked, pinched, or kinked.
NIBP Inflation Timeout	Equipment	Medium	The NIBP pump running time has exceeded the limit.
NIBP MAP High	Patient	High	The NIBP MAP value exceeds the upper alarm limit selected.
NIBP MAP Low	Patient	High	The NIBP MAP value exceeds the lower alarm limit selected.
NIBP Measurement Aborted - Artifact	Equipment	Medium	Excessive artifact is preventing the NIBP measurement.
NIBP Measurement Aborted - Check Hose/Cuff	Equipment	Medium	The cuff or hose is defective or not installed correctly.
NIBP Measurement Aborted - Cuff Over Pressure	Equipment	Medium	The cuff pressure has exceeded safety limits.
NIBP Measurement Aborted – Cuff/Hose Leak	Equipment	Medium	A major air leak is preventing cuff inflation.
NIBP Measurement Aborted – Hose Blocked	Equipment	Medium	The NIBP hose is blocked, pinched, or kinked.
NIBP Measurement Aborted - Measurement Timeout	Equipment	Medium	The measurement was not completed in the allowed maximum time.
NIBP Measurement Aborted - Over Range	Equipment	Medium	The NIBP measurement is out of the patient's measurement range.
NIBP Measurement Aborted - Signal Weak	Equipment	Medium	The patient's pulse is too weak to obtain an NIBP measurement.
NIBP Measurement Aborted - Zero Failed	Equipment	Medium	The zeroing of the NIBP module's pressure system failed during the measurement.

Alarm Message	Alarm Type	Priority	Cause
NIBP Pressure Measurement Error	Equipment	Medium	The pressure between the NIBP safety and master subsystems do not match.
NIBP Systolic High	Patient	High	The NIBP Systolic value exceeds the upper alarm limit selected.
NIBP Systolic Low	Patient	High	The NIBP Systolic value exceeds the lower alarm limit selected.
No Breath	Patient	High	The time since the last detected breath exceeds the configured No Breath time.
Pacer/Defib Application Software Invalid	Equipment	High	The Pacer/Defib module software is invalid.
Pacer Disabled	Equipment	High (Pacer mode); Low (Defib/Monitor mode)	The unit is in a low battery condition, or a critical pacing fault
PACER DISABLED - SERVICE REQUIRED	Equipment	High (Pacer mode); Low (Defib/Monitor mode)	Pacer critical fault.
Paddle Buttons Shorted	Equipment	High	Shorted paddle switch for more than 90 seconds.
Paddle Charge Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The paddle button self-test failed.
Paddle Energy Down Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The paddle button self-test failed.
Paddle Energy Up Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The paddle button self-test failed.
Paddle Fault - Replace Paddles Or Use Pads	Equipment	Medium (Monitor Mode); High (Manual Defib mode)	The accessory connected to the MFC port is unrecognized.
Paddle Fault - Use Pads	Equipment	High	The accessory connected to the MFC port is unrecognized.
Paddle Recorder Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The paddle button self-test failed.
Paddle Shock Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The paddle button self-test failed.
Pads/Paddles ECG Disabled	Equipment	High (AED mode); Medium (Pacer/Manual Defib/ Monitor mode)	The streaming communication test failed.
Pads/Paddles Sync Disabled	Equipment	Medium	Streaming communication test failed in SYNC mode while Pads is selected as the primary lead.

Alarm Message	Alarm Type	Priority	Cause
PR High	Patient	High	The pulse rate value exceeds the upper alarm limit selected.
PR Low	Patient	High	The pulse rate value exceeds the lower alarm limit selected.
Printer Door Opened	Equipment	Medium	The printer door is open.
Printer Fault	Equipment	Medium	The printer head/motor is overheating or the printer communication is interrupted.
Printer Out Of Paper	Equipment	Medium	The printer is out of paper.
Red Highlighted Button Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The front panel quick access key self-test failed.
Release 4:1 Button	Equipment	Medium	4:1 button shorted while switching to Pacer mode from another mode.
Replace Battery	Equipment	High	The battery needs to be replaced.
Replace Paddles Or Use Pads	Equipment	Medium in Monitor mode when detected during power on self-test, otherwise High.	Shorted paddle switch for more than 90 seconds; paddle button self-test fail.
RESP Communications Fault	Equipment	Medium	The impedance respiration detection function has failed.
RR High	Patient	High	The respiration rate value exceeds the upper alarm limit selected.
RR Low	Patient	High	The respiration rate value exceeds the lower alarm limit selected.
SpO2 Communications Fault	Equipment	Medium	The unit has not received any data from SpO_2 module for 5 seconds.
SpO2 Disabled - Critical Fault	Equipment	High	The SpO2 module has malfunctioned and is now disabled.
SpO2 High	Patient	High	The SpO_2 value exceeds the upper alarm limit selected.
SpO2 Low	Patient	High	The SpO_2 value exceeds the lower alarm limit selected.
SpO2 Sensor Fault	Equipment	Medium	The sensor has malfunctioned.
Sync Button Pressed	Equipment	High	The SYNC button shorted while switching from Manual Defib mode to another mode.
SYNC Button Stuck	Equipment	High	The front panel quick access key self-test failed.
T1 High	Patient	High	The T1 value exceeds the selected high temperature limit.

Alarm Message	Alarm Type	Priority	Cause
T1 Low	Patient	High	The T1 value is below the selected low temperature limit.
T1 Out of Range	Equipment	Medium	The T1 value is outside the measurement range.
T1 Sensor Fault	Equipment	Medium	The T1 sensor is shorted.
T1&T2 Out of Range	Equipment	Medium	The temperature values of T1 and T2 are outside the measurement range.
T1&T2 Sensor Fault	Equipment	Medium	The T1 and T2 sensors are both shorted.
T2 High	Patient	High	The T2 value exceeds the selected high temperature limit.
T2 Low	Patient	High	The T2 value is below the selected low temperature limit.
T2 Out of Range	Equipment	Medium	The T2 value is outside the measurement range.
T2 Sensor Fault	Equipment	Medium	The T2 sensor is shorted.
TEMP Communications Fault	Equipment	Medium	The unit has not received any data from the TEMP module for 5 seconds.
TEMP Disabled - Critical Fault	Equipment	High	The temperature monitoring function has malfunctioned and is now disabled.
Trim Knob Stuck	Equipment	Medium (Monitor/Pacer mode); High (Defib mode)	The front panel button self-test failed.