Zenix™ Hospital Operator's Guide

Includes Real CPR Help®, See-Thru CPR®, and Real BVM Help®



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Intended Purpose

The ZOLL Zenix™ monitor/defibrillator is intended to be used on adult and pediatric victims of sudden cardiac arrest or those in post trauma situations. The Zenix device is a portable defibrillator that combines defibrillation, ECG Monitoring, and CPR feedback with additional optional monitoring capabilities that can be configured to meet the needs of a particular application.

Indications for Use

Defibrillator Function

The Zenix device is indicated for defibrillation on adult and pediatric patients neonate and older victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse

The Zenix device Manual mode is indicated for synchronized cardioversion of certain atrial or ventricular arrhythmias. Only skilled personnel trained in Advanced Cardiac Life Support (ACLS) and who are familiar with equipment operation should perform synchronized cardioversion.

The Zenix device Semiautomatic and Manual mode is indicated for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care is incorporated into a medically-approved patient care protocol.

The Zenix device Semiautomatic and Manual mode is indicated for adult and pediatric patients neonate and older.

Electrocardiogram (ECG) Monitoring

The Zenix device is indicated to monitor and/or record 3-, 5-, or 12-lead electrocardiogram (ECG) waveform and heart rate, and to alarm when heart rate is above or below limits set by the operator. ECG monitoring is indicated for adult and pediatric patients neonate and older with and without heart dysfunction.

CPR Monitoring

The Zenix device is indicated to provide visual and audio feedback via the CPR Monitoring function, designed to encourage rescuers to perform chest compressions at the current AHA/ERC guidelines, coaching to rate, depth, and release velocity. The Zenix device is configurable to meet the current and future AHA/ERC guidelines.

External Transcutaneous Pacing

The Zenix device is indicated for temporary external cardiac pacing in conscious or unconscious patients as an alternative to endocardial stimulation. External Pacing is indicated for adult and pediatric patients neonate and older.

SpO_2 Monitoring

The Zenix device is indicated for use for continuous non-invasive monitoring of arterial oxygen saturation (SpO_2), arterial carbon monoxide concentration (SpCO), methemoglobin concentration (SpMet), total hemoglobin concentration (SpHb), Oxygen Concentration (SpOC), Pleth Variability Index (PVi), Perfusion Index (Pi) and pulse rate during both no motion and patient motion conditions for adult and pediatric patients neonate and older.

CO_2 and Respiration Monitoring

The Zenix device is indicated for use in continuous non-invasive measurement and monitoring of end tidal carbon dioxide (EtCO2) and respiration rate in adult, pediatric, and infant patients requiring ventilator support, transport, and anesthesia. It is also used for continuous non-invasive monitoring of respiration rate in intubated and non-intubated patients.

Non-invasive Blood Pressure Monitoring

The Zenix device is indicated for use to make non-invasive measurements of arterial blood pressure for resting adult and pediatric patients in critical care.

Temperature Monitoring

The Zenix device is indicated for use to make continuous temperature measurements of rectal, esophageal, or surface temperatures, and to alarm if the temperature is outside of the limits set by the user. The temperature monitoring feature is indicated for use in adult and pediatric patients neonate and older.

Impedance Pneumography Monitoring

The Zenix device is indicated for use to continuously monitor respiration rate and to alarm if the rate falls outside of the range set by the user. Because the measurement method actually measures respiratory effort, 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 respiration monitoring feature is indicated for use on adult and pediatric patients neonate and older.

Note: The availability of the impedance pneumography feature to measure respiration rate is subject to local regulatory approval and may not be available in all regions, including the United States, at this time. For more information on approvals, please reach out to your local representative.

Invasive Pressure Monitoring

The Zenix device is indicated for use to display and make continuous invasive pressure measurements via a compatible pressure transducer. The invasive pressure monitoring feature is indicated for use on adult and pediatric patients neonate and older.

Ventilation Feedback

The Zenix device Ventilation Feedback function is intended for use to make non-invasive measurements of ventilation rate and inspired volumes of manually delivered breaths. The Ventilation Feedback function is intended for use in adult patients only.

12-Lead Analysis

The Zenix device is indicated for use in acquiring, analyzing, and reporting physiological data via 12-lead ECG Analysis, and to provide interpretation of the data for consideration by caregivers. The 12-lead ECG Analysis feature is indicated for use on adults (> 18 years of age).

TBI Dashboard

The Zenix device is indicated to provide graphical trend data for SpO_2, Systolic BP (SBP), and $EtCO_2$ as well as ventilation assistance relevant to the management of a TBI patient.

RescueNet Live

The Zenix RescueNet Live application is intended for use by trained medical personnel familiar with basic monitoring, vital sign assessment, and emergency cardiac care in order to remotely view near real-time patient and device data transmitted from connected Zenix devices. It requires a clinician at the patient's side next to the Zenix device. The information streamed to the application helps the remote clinician make decisions on patient care supplemental to the clinician on site with the patient.

Semiautomatic Operation Contraindications for Use

The rhythm analysis function may not reliably identify ventricular fibrillation in the presence of an implanted pacemaker. Inspection of the electrocardiogram and clinical evidence of cardiopulmonary arrest should be the basis for any treatment of patients with implanted pacemakers. Do not use the rhythm analysis function during patient movement on a stretcher. A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Cease all movement of the stretcher prior to analyzing the ECG. Do not touch the patient or perform chest compressions during analysis.

General Information

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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CHAPTER 1

General Information

This chapter provides a general overview of product functionality as well as safety considerations to keep in mind while using the Zenix™ defibrillator.

It includes the following sections:

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Product Description

The Zenix™ monitor/defibrillator is an innovative and intuitive resuscitation system designed for use in a hospitalenvironment. Its lightweight and portable design makes it ideal for all resuscitation situations. The device also offers robust vital signs monitoring capabilities that make it valuable for use in patient monitoring situations. You can power the device by auxiliary power as well as through an easily replaceable battery pack. The device has an easy-to-use touch screen interface and a large LCD display that provide maximum visibility.

Monitoring Features

The Zenix device provides an array of standard and optional monitoring parameters to view and monitor the patient's vital signs measurements in a variety of formats. In addition, you can set alarm limits for each measurement.

Note: The features available to you depend on your system's configuration and your purchased options. All features are included in this manual, but only purchased features will be available on your device. Differences in features or functionality are called out where appropriate.

Monitoring Parameter	Description
ECG	The Zenix device offers 3-lead, 5-lead, or 12-Lead ECG monitoring. The device can display up to four ECG waveform traces.
Heart Rate	The Zenix device offers heart rate monitoring from multiple sources. By default the heart rate is derived from the patient's ECG.
Respiration Rate	The Zenix device offers respiration monitoring collected through ECG leads. **Note:** The availability of the impedance pneumography feature to measure respiration rate is subject to local regulatory approval and may not be available in all regions, including the United States, at this time. For more information on approvals, please reach out to your local representative.
Temperature	The Zenix device offers temperature measurements from up to two temperature probes using two separate channels.
Invasive Pressure (IBP)	The Zenix device offers up to three concurrent invasive blood pressure channels.
Non-invasive Blood Pressure (NIBP)	The Zenix device offers NIBP monitoring that measures the patient's systolic, diastolic, and mean blood pressure through an inflatable blood pressure cuff.
Capnography (CO_2)	The Zenix device offers monitoring of end tidal CO_2 ($EtCO_2$). In addition to the waveform and CO_2 numeric, the device also provides breath rate and $FiCO_2$ readings.
Pulse Oximetry (SpO_2)	The device provides monitoring of Pulse Oximetry that measures the oxygen saturation (SpO_2) of arterial blood at a peripheral site such as a finger or toe. Perfusion Index (Pi) is a standard offering along with SpO_2.

Monitoring Parameter	Description
Advanced Masimo® Parameters	The Zenix device offers the following advanced Masimo monitoring capabilities: • SpCO® (carboxhemoglobin saturation) • SpMet® (methemoglobin saturation) • SpHb® (total hemoglobin) • SpOC™ (oxygen content) • PVi® (pleth variability index) • Pi (perfusion index)
Traumatic Brain Injury	The Zenix device offers a dashboard that aids clinicians in monitoring patients with possible traumatic brain injury (TBI).

Resuscitation Technologies

The Zenix device provides resuscitation technologies focused on improving patient outcomes for victims of sudden cardiac arrest and other heart arrhythmias. The Zenix device includes the Real CPR Help® technology which provides real-time feedback on chest rate and depth, CPR Release Indicator, and Perfusion Performance Indicator.

Technology	Description
Manual Defibrillation	When operating in manual configuration, the device operates as a conventional defibrillator where the device's charging and discharging is fully controlled by the operator.
Semiautomatic AED	In Semiautomatic (AED) mode the device guides you through the Rescue Protocol.
Pacing	The Zenix device includes a transcutaneous pacemaker consisting of a pulse generator and ECG sensing circuitry. Pacing supports both demand and fixed non-invasive pacing. This therapy is easily and rapidly applied in both emergency and non-emergency situations when temporary cardiac stimulation is indicated.
Real CPR Help®	The Zenix device can provide rescuers with feedback about the quality of CPR they are delivering to their patients. The device assists caregivers during cardiopulmonary resuscitation (CPR) by evaluating the rate and depth of chest compressions and providing feedback to the rescuer.
Real BVM Help®	The Zenix device includes a Real BVM Help feature which helps guide caregivers to provide effective respiratory assistance through a ventilation dashboard. This feature requires use of the ZOLL AccuVent® sensor and cable.

How to Use This Manual

This manual provides information that operators need for the safe and effective use and care of the 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 monitor care are located in CHAPTER 21 “Maintenance”.

Operator’s Guide Updates

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

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 website at www.zoll.com.

Conventions

This guide uses the following conventions:

Within text, the names and labels for physical buttons and keys appear in **boldface** type (for example, “Select **OK**”).

This guide uses uppercase italics for audible prompts and for text messages displayed on the screen (for example, *ATTACH PADS*).

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

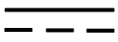
Caution: Caution statements alert you to conditions or actions that can result in damage to the device.

Unpacking

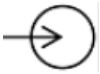
Carefully inspect each container for damage. If the shipping container or cushion material is damaged, keep it until the contents have been checked for completeness and the instrument has been checked for mechanical and electrical integrity. If the contents are incomplete, if there is mechanical damage, or if the device does not pass its electrical self-test, U.S.A. customers should call ZOLL Medical Corporation (1-800-348-9011). Customers outside of the U.S.A. should contact the nearest ZOLL authorized representative. If the shipping container is damaged, also notify the carrier.

Symbols Used on the Equipment

Any or all of the following symbols may appear in this manual or on this equipment:

Symbol	Description
	Class II equipment
	Dangerous voltage
	Dangerous voltage
	General warning: Observe and follow all safety signs
	Fragile, handle with care
	Keep dry
	No flame
	This end up
	Temperature limitation
	Defibrillator-proof type BF patient connection
	Defibrillator-proof type CF patient connection
	Direct current (dc)

Symbol	Description
	Auxiliary power adapter operation
	Earth (ground)
	Negative input terminal
	Non-ionizing radiation
	Positive input terminal
	Power On/Off
	Lock button. Enable/disable touchscreen display.
	Recycle or dispose of properly.
	Contains lithium. Recycle or dispose of properly.
	Do not use if package is damaged.
	Storage humidity limitation
	Atmospheric temperature limitation

Symbol	Description
	Gas inlet
	Input connector
	Video out
	USB connector
	Z-Link™ connector
	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
	Identifies the manufacturer’s batch code.
	Do not reuse
	Not sterile
	Manufacturer
	Authorized representative in the European Community

Symbol	Description
CH REP	Authorized representative in Switzerland
SN	Serial Number
REF	Catalogue number
	Consult instructions for use
	Button location
	Refer to instruction manual/booklet
Rx ONLY	Prescription only
	Alarms are currently enabled
	Alarms are currently disabled
	Alarm audio is currently off
	Alarm audio is currently paused
	Battery charging status
	Battery position

Symbol	Description
	MR unsafe: keep away from magnetic resonance imaging equipment
- - - - -	No physiological signal is being acquired for the displayed monitoring parameter or the acquired signal is inadequate for monitoring patient condition.
	Not for use with children
	Indicates the entity importing the medical device into the locale
MD	Indicates the item is a medical device
UDI	Indicates a carrier that contains Unique Device Identifier information
GTIN	Global Trade Item Number

Intended Use

The Zenix device is intended for use by trained medical personnel who are familiar with basic monitoring, vital sign assessment, emergency cardiac care, and the use of the device. The Zenix device 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 Zenix device will be used on patients experiencing symptoms of cardiac arrest, in post trauma situations and vital signs monitoring. It may also be used whenever it is required to monitor any of those functions that are included (as options) in the device.

The Zenix device can be used on pediatric patients (as described in the following table) and on adult patients (21 years of age or older) with or without heart dysfunction.

Pediatric Patient Subpopulation	**Approximate Age Range**
Newborn (neonate)	Birth to 1 month of age.
Infant	1 month to 2 years of age.
Child	2 to 12 years of age.
Adolescent	12 to 21 years of age.

Use only pediatric electrodes to defibrillate patients under 8 years of age or weighing less than 55 lbs (25kg), and make sure the patient mode is set to pediatric. Use of adult mode with pediatric patients can result in the delivery of excessive energy doses.

⚠ Safety Considerations

All operators should review these safety considerations before using the device.

Zenix devices are high-energy defibrillators capable of delivering 200 joules. To completely deactivate the device, press the power button to turn off the device.

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

- Select **Disarm** on the display screen.
- Change the selected energy.
- Press the power button to turn off the device.

For safety, the device automatically disarms if left charged for more than 60 seconds if the **SHOCK** button  is not pressed.

Summary of Safety and Clinical Performance

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 08479460AYCT.

Warnings

General

- Only appropriately trained, skilled personnel who are familiar with equipment operation should perform emergency defibrillation.
- 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.
- Perform functional test of internal paddles prior to use.
- To ensure protection against the effects of defibrillator discharge, use only ZOLL-approved accessories. Use with ZOLL-approved accessories may show temporary degradation after defibrillator discharge, but shall recover within 3 seconds.
- Do not leave the Zenix device plugged into AC power with a battery installed for extended periods of time.
- The use of external pacing/defibrillation electrodes, accessories, or adapter devices from sources other than ZOLL device is not recommended. ZOLL makes no representation 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.
- These operating instructions describe the functions and proper operation of the Zenix 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 device for patient care.
- Proper operation of the device and correct electrode placement is critical to obtaining optimal results. Operators must be thoroughly familiar with proper device operation.
- Allow ample slack in cables to make sure that cables do not tug at electrodes.
- Do not modify the ZOLL device.
- Do not disassemble the device or accessories. 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 device until it has been inspected by appropriate personnel.
- The ZOLL device might not perform to specifications when stored at the upper or lower extreme limits of storage temperature and then immediately put into use. The device should not be stored or used outside of the environmental limits provided in the APPENDIX A "Specifications".
- Avoid using the Zenix device adjacent to, or stacked on, other equipment. If unavoidable, verify that the device operates normally in this configuration before clinical use.
- The device should be installed and put into service according to the EMC information in the APPENDIX A "Specifications".

- The use of accessories, transducers, and cables other than those specified in this manual and related Zenix option manual inserts may result in increased emissions or decreased immunity of the Zenix device.
- Do not use or place the device in service if the Ready For Use indicator (at the upper right of the front panel) displays a red "X" unless during a code.
- Carefully route patient cables to avoid tripping over them or inadvertently pulling the device onto the patient.
- Always inspect the device 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.
- 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 device and any appropriate device accessories appropriately and remove the batteries. Then dispose of the device and accessories in accordance with your country's regulations for equipment containing electronic parts.
- The Zenix device is MR Unsafe. Keep the Zenix device away from magnetic resonance imaging (MRI) equipment.
- The effectiveness of this sphygmomanometer has not been established in pregnant patients, including pre-eclamptic, as well as in patients with conditions known to affect sphygmomanometer accuracy, such as atrial fibrillation and diabetes.
- To ensure protection against the effects of defibrillator discharge, use only ZOLL-approved accessories.

ECG Monitoring

- Implanted pacemakers might 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 activity. 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 "Pacer" on page 297 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.
- For best performance, ZOLL recommends the use of wet gel electrodes.
- Do not place electrodes directly over an implanted pacemaker.
- The ZOLL device 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.

- Excessive artifact can result due to improper skin preparation of the electrode sites. Follow skin preparation instructions in CHAPTER 8 “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 and distort the ECG signal displayed by the monitor, thereby preventing accurate rhythm analysis. Ensure adequate separation between such emitters, the device, and the patient when performing rhythm analysis.
- Shock Hazard: 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.
- Prior to attempting synchronized cardioversion, ensure that the ECG signal quality is good and that sync markers are displayed above each QRS complex.
- Monitoring ECG through the paddles may result in inaccurate heart rate display due to artifact.
- When using the AutoPulse, stop compressions prior to performing ECG analysis. Compressions can be resumed following the analysis.

  Note: The availability of AutoPulse with Shock Sync technology is subject to local regulatory approval and may not be available in all regions, including the United States, at this time. For more information on approvals, please reach out to your local representative.

Defibrillation

- The Zenix device can deliver 200 joules of electrical energy. If this electrical energy is not discharged properly, as described in this manual, the electrical energy could cause personal injury or death to the operator or bystander.
- To avoid possible damage to the Zenix device, turn off pacing before defibrillating the patient with a second defibrillator.
- After a synchronized cardioversion, the SYNC mode may be cleared after each shock or disarm. The user may have to reselect the **SYNC** key after each synchronized cardioversion shock performed on a patient. In Defib default settings in the Supervisor Setup menu, the Zenix device can be configured to remain in the SYNC mode after each synchronized cardioversion.
- Synchronized cardioversion can be performed in the paddle monitoring mode. However, it is possible that artifact can be produced by the moving paddles, which could cause the defibrillator to trigger on the artifact. It is recommended that monitoring in leads I, II or III be used during synchronized cardioversion. Paddle monitoring should not be used for elective cardioversion procedures.
- To avoid stress to the defibrillator, connected electrodes, or the test plug, never attempt to repeatedly charge and discharge the defibrillator in rapid succession. If a need for repetitive testing arises, allow a waiting period of at least 2 minutes after every third discharge.
- In the 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.

- If conductive gel forms a continuous path between the defibrillator electrodes, delivered energy may be dramatically reduced to zero. In this case, 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 defibrillation gel on paddles, ensure that the gel covers the entire paddle surface, and press firmly against patient's chest.
- If a new energy level is selected after the **CHARGE** button is pressed and while the defibrillator is charging or charged, the defibrillator will disarm. The **CHARGE** button will need to be pressed again to charge to the new energy level.
- Prior to defibrillation, disconnect from the patient any medical electronic device that is not labeled "defibrillation protected."
- Before charging the defibrillator, verify that the energy selected on the display is correct for the therapy.
- Defibrillation takes priority over external pacing. Should the defibrillator be charged during the administration of external pacing, the pacer turns off and the defibrillator charges to the selected energy.
- If the device is in a shock-ready state, and the patient mode needs to be changed, you can either disarm the device manually or wait for automatic disarm of the device. Pressing the **SHOCK** button immediately after changing the patient mode may result in the delivery of energy that is incorrect for the newly selected patient type.
- When using external or internal paddle sets, the device may display the *RELEASE SHOCK BUTTON* message while the device is charging. If you are pressing the paddles' shock buttons when the *RELEASE SHOCK BUTTON* message appears, you must release the shock buttons for the device to become shock-ready. If you are not pressing the paddles' shock buttons when the *RELEASE SHOCK BUTTON* message appears, then the paddles are defective – replace the defective paddles immediately with either another set of paddles or a multifunction electrode. DO NOT attempt to deliver therapy using the defective paddles by pressing the **SHOCK** button on the face of the device. Pressing the **SHOCK** button will NOT deliver therapy; pressing the **SHOCK** button will, however, cause the device to remove the *RELEASE SHOCK BUTTON* message from the display.

Note: When internal or external paddles with buttons are in use, the Shock button on the front panel is deactivated.

Pacing

- 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.
- Non-invasive temporary pacing can cause discomfort of varying intensity, which occasionally can be severe and preclude its continued use in conscious patients.
- Similarly, 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 devices when the anterior electrode was placed too low on the abdomen.
- The pacing rate determination can be adversely affected by artifact. If the patient's pulse and the heart rate display are significantly different, external pacing pulses may not be delivered when required.
- 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 fixed pacing mode if a reliable ECG trace is unobtainable.
- Transcutaneous pacing should not be used to treat V-FIB (ventricular fibrillation). In cases of V-FIB, immediate defibrillation is advised.
- 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.
- 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. In some instances the beat may appear as a relatively normal looking QRS pulse. 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 ensure capture retention. Do not leave the patient unattended when administering external pacing therapy.
- 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 Zenix device.
- Demand external pacing requires independent ECG signal such as leads. Do not attempt pacing without an ECG signal.

Ferromagnetic Equipment

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

- The large magnetic fields generated by an MRI 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.

CPR

- The AHA Guidelines state that optimal chest compressions are best delivered when the victim is on a firm surface. ERC Guidelines suggest that chest compressions should be performed on a firm surface when possible. Always follow local protocols for deciding whether the patient should be moved to a firm surface.
- The patient must be motionless during CPR for accurate CPR measurements.

TBI Dashboard

The TBI Dashboard is not intended for patients showing signs of cerebral herniation.

Pulse Oximeter

- Keep the finger probe clean and dry.
- 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-Masimo sensors, or damaged sensors; in patients with smoke inhalation, or carbon monoxide poisoning, or with patient movement.
- 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 the 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.
- In some instances, such as obstructed airway, the patient's breathing attempts may not produce any air exchange. These breathing attempts can still produce chest size changes, creating impedance changes, which can be detected by the respiration detector. It is best to use the pulse oximeter whenever monitoring respirations to accurately depict the patient's respiratory condition.

Non-invasive Blood Pressure

- Ensure that the NIBP option is operated by qualified personnel only.
- Consult a physician for the proper interpretation of pressure measurements.
- Do not use on patients known to be susceptible to bruising.
- Use caution when using on elderly hypertensive patients, as such patients may be more susceptible to bruising.
- Route patient hoses carefully to avoid patient entanglement, strangulation, or compression of hose.
- Do not select a cuff inflation pressure that exceeds the patient's expected systolic pressure by more than 30-40 mmHg (4.0-5.3 kPa). The factory-installed default adult cuff inflation pressure is 160 mmHg (21.3 kPa) for adult patients and 120 mmHg (16.0 kPa) for pediatric patients, and 85 mmHG (11.3 kPa) for neonatal patients.
- Keep patient, hose, and cuff as still as possible during measurement. Patient movement or vibrations from outside sources, particularly moving vehicles, can degrade measurement accuracy.
- Check patient regularly for signs of skin irritation or impaired circulation in the monitored limb.
- Do not use the NIBP option on a patient when the device is connected to an ECG simulator.
- If an alarm occurs while the audible alarm indicators are disabled, alarms do not sound; rather only the visual alarm indicators are displayed.
- If the accuracy of measurements is suspect, first check the patient's vital signs by alternate means. Then check the cuff, hose, and NIBP option for proper functioning.
- The cuff, hose, and fitting are defibrillation-protected. Using the NIBP option introduces no risk for shock due to defibrillation. The cuff and hose are non-conductive. Using the NIBP option introduces no risk for burns due to electrosurgery.
- Cuff safety and effectiveness have not been proven on pregnant women including pre-eclamptic, patients.
- The Zenix device uses the oscillometric method for measuring NIBP. It is intended for adult, and pediatric patients.
- The NIBP option is not intended for patients with conditions known to affect sphygmomanometer accuracy, such as atrial fibrillation, diabetes, pregnant or pre-eclamptic patients.
- NIBP is a tool to be used in addition to patient assessment. Care should be taken to assess the patient at all times; do not rely solely on the NIBP monitor. NIBP measurements are not indicated for use during patient transport. NIBP measurements taken in the presence of motion artifact should not be relied on for treatment decisions.
- Do not attach the cuff to a limb being used for IV infusions or any other intravascular access, therapy or an arterio-venous (AV) shunt. The cuff inflation can temporarily block blood flow, potentially causing harm to the patient.
- Applying the cuff over a wound can cause further injury.

- For patients that have had a mastectomy, the cuff should be applied to the opposite arm. In the case of a double mastectomy, use the side of the least dominant arm or consider taking the blood pressure on the legs.
- Blood pressure measurements can be affected by the position of the patient, physiologic condition, activity level, improper cuff size/application, environment and use outside of the operating instructions detailed in this manual.
- The NIBP module may not operate correctly if used or stored outside the relevant temperature or humidity ranges described in "NIBP" on page 310.
- Only use cuffs, hoses, and connectors supplied or specified by ZOLL.
- Ensure that the hose is not kinked or obstructed before taking measurement.
- Do not use damaged cuffs, hoses, or connectors.
- Ensure proper cuff selection and placement to avoid inaccurate measurements or patient injury.
- Position the cuff so it is level with the heart during measurement.
- Do not attach the cuff to a limb being used for IV infusion, SpO_2 monitoring, or other monitoring equipment. Cuff inflation might block the infusion, causing harm to the patient or inaccurate SpO_2 measurements.
- When monitoring over an extended time, or at frequent intervals, periodically observe the subject's limb to make sure that the circulation is not impaired. Rapidly repeating measurement can impair circulation in the monitored limb.
- Do not sterilize or immerse the cuffs or hoses.

IBP

- To ensure compatibility and electrical safety, accessory pressure sensors should comply with ANSI/AAMI BP-22 and IEC 60601-2-34 for IBP.
- Follow instructions supplied with any accessory pressure sensor regarding calibration and removal of trapped air.
- Avoid touching metal parts of any transducer while it is in contact with the patient.
- Do not reuse any components that are labeled for single use only.
- Transducers should be rated to withstand an accidental drop of at least one meter onto a hard surface.
- Transducers that are subject to immersion in liquids should be rated as watertight.

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 NomoLine® which permits placement of the monitor outside the MRI suite.
- Use only Masimo CO_2 sampling lines.
- CO_2 sampling lines are labeled for single patient use only. Do not reuse sampling lines.

- CO_2 sampling lines should be replaced between each patient or when the sampling line becomes occluded, as indicated by a red flashing LEGI indicator and an alarm message.
- CO_2 readings and respiratory rate can be affected by sensor application errors, certain ambient environmental conditions, and certain patient conditions.
- IRMA is not designed for MRI environments.
- Use only Masimo IRMA CO2 airway adapters.
- IRMA CO2 airway adapters are labeled for single patient use only. Do not reuse airway adapters.
- IRMA CO2 airway adapters should be replaced between each patient or if rainout/condensation occurs inside the airway adapter, as indicated by a red flashing status LED and an alarm message.

Impedance Pneumography

- When using impedance pneumography, do not use the Zenix device with another respiration monitor that also uses impedance pneumography on the same patient. The respiration measurement signals may interfere with one another and could affect the respiration accuracy.
- The device should not be used as an apnea monitor.
- Do not solely rely on impedance pneumography for detecting cessation of breathing. Follow hospital guidelines and best clinical practices, including monitoring additional parameters that indicate the patient's oxygenation status.
- The use of end tidal CO_2monitoring is always recommended when respiratory monitoring is required in infants. Respiratory monitoring using the impedance pneumography feature has not been clinically validated in this patient population.

Battery

- Although the device can operate with auxiliary power alone, ZOLL strongly recommends that you operate the device with a battery installed at all times. Operating the device with a battery provides a backup in case of AC power shortage, and results in faster defibrillator charge time. The battery can be automatically recharged while it is installed in the device. Keep a fully charged spare battery pack with the device at all times.
- Test battery packs regularly. A battery that does not pass the charger's capacity test might cause the device to shut down unexpectedly.
- If the Low Battery indication occurs at any time during operation, immediately replace the battery pack.
- If the Low Battery icon appears, plug the device into a power source or install a fully charged battery pack. When the warning *REPLACE BATTERY* prompt appears, immediately replace the battery pack with a fully charged pack or plug the device into a power source, as device shut down due to a low battery condition is imminent.
- If mistreated, a battery pack might explode. Do not disassemble a battery pack or dispose of it in fire.
- Batteries that display a fault condition should be taken out of service and replaced immediately.

Operator Safety

- The Zenix device can deliver 200 joules of electrical energy. If this electrical energy is not discharged properly, as described in this manual, the electrical energy could cause personal injury or death to the operator or bystanders.
- Never discharge the device with the defibrillation electrodes or paddles shorted together or in open air.
- 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 with protective earth.
- 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 paddle handles.
- To avoid risk of electrical shock, do not allow patient connectors to contact other conductive parts, including earth.
- For defibrillation using paddles, use only high-conductivity electrolyte gel specified for such use by the gel manufacturer.
- When using paddles for defibrillation, use your thumbs to operate the **SHOCK** buttons. Doing so avoids inadvertent shock to the operator.
- Disconnect all electro-medical equipment that is not defibrillation-protected from the patient prior to defibrillation.
- 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.
- Do not use the Zenix device in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents (such as gasoline). Using the device in such environments might cause an explosion. Turn off oxygen being delivered to the patient before delivering electrical therapy.
- Do not use the device near or within standing water. Electrical safety might be compromised when the device is wet. AHA Guidelines recommend providing CPR as soon as the victim is removed from the water.
- The use of accessory equipment that does not comply with the equivalent safety requirements of the Zenix device 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 and/or IEC (EN) 60601-1-2 harmonized national standards.

- Always check that the equipment functions properly and is in proper condition before use.
- To avoid risk of electrical shock, do not allow printer to come into contact with other conducive 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.
- Use only pediatric electrodes to defibrillate patients under 8 years of age or weighing less than 55 lbs (25kg), and make sure the patient mode is set to pediatric in Advisory mode. Use of adult mode with pediatric patients can result in the delivery of excessive energy doses.
- Neonatal and pediatric defibrillation energy level settings should be based on site-specific clinical protocols.
- Therapy electrodes should be replaced periodically during continuous pacing. Consult electrode directions for proper replacement instructions.
- Prolonged pacing (more than 30 minutes), particularly in neonates or adults with severely restricted blood flow, may cause burns. Periodically inspect the skin under the electrodes.
- ECG electrodes are for rhythm acquisition only; do not use ECG electrodes for defibrillation or pacing.
- To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.
- To ensure patient safety, connect the device only to equipment with circuits that are electrically isolated.
- Use only high-quality ECG electrodes.
- 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 the 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. Remove lotions and medication patches.
- 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 device (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.

Cautions

- If the device is to be stored longer than 30 days, remove the battery pack.
- Do not sterilize the monitor or its accessories unless the accessories are labeled as sterilizable.
- Do not immerse any part of the monitor in water.
- Do not use the monitor if excessive condensation is visible on the device. Wipe only the outside with a damp cloth.
- Do not use ketones (such as acetone or MEK) on the device.
- 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 auxiliary 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 device using battery power only.
- Do not connect to an electrical outlet controlled by a wall switch or dimmer.
- For continued safety and EMI performance, use only the line cord supplied by ZOLL.
- Electrical installation of the room or the building in which the device is to be used must comply with regulations specified by the country in which the equipment is to be used.
- If the integrity of the electrical system in the building is compromised, unplug the power cord from the device and operate using battery power only.
- 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.
- CO_2 readings may be affected by the presence of RF transmitters. See 324.

FDA Tracking Requirements

U.S. Federal Law (21 CFR 821) requires the tracking of defibrillators. Under this law, owners of this defibrillator must notify ZOLL Medical Corporation if this product is:

- Received
- Lost, stolen, or destroyed
- Donated, resold, or otherwise distributed to a different organization

If any such event occurs, contact ZOLL Medical Corporation in writing with the following information:

1. Originator's organization – Company name, address, contact name, and contact phone number
2. Model number and serial number of the defibrillator
3. Disposition of the defibrillator (for example, received, lost, stolen, destroyed, distributed to another organization), new location and/or organization (if known and different from originator's organization) – company name, address, contact name, and contact phone number
4. Date when the change took effect

Please address the information to:

ZOLL Medical Corporation
Attn: Tracking Coordinator
269 Mill Road
Chelmsford, MA 01824-4105
Fax: +1-978-421-0025
Telephone: +1-978-421-9655

Notification of Adverse Events

As a health care provider, you may have responsibilities under the Safe Medical Devices Act (SMDA), for reporting to ZOLL Medical Corporation, and possibly to the FDA, the occurrence of certain events.

These events, described in 21 CFR Part 803, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, ZOLL Medical Corporation requests to be notified of device failures or malfunctions. This information is required to ensure that ZOLL Medical Corporation provides only the highest quality products.

Potential adverse effects (for example, complications) associated with use of defibrillator paddles can include:

- Failure to identify shockable arrhythmia.
- Failure or delay in delivery of a defibrillation shock in the presence of VF or pulseless VT which may result in death or serious injury.
- Inappropriate energy which could cause failed defibrillation or post-shock dysfunction.
- Myocardial damage.
- Fire hazard in the presence of high oxygen concentration or flammable agents.
- Incorrectly shocking a pulse-sustaining rhythm and inducing VF or cardiac arrest.
- Inadvertent user/bystander shock from patient contact during defibrillation.
- Inadvertent user burn during defibrillation.
- Complications in effective rhythm assessment and shock delivery due to interaction with patient ICDs (pacemakers).
- Patient harmed due to device interference with other critical care equipment.
- Skin burns around defibrillation pad/electrode placement area.
- Allergic dermatitis due to sensitivity to materials used in defibrillation pad/electrode construction.
- Minor skin rash.
- Inadequate and/or delayed delivery of CPR therapy.
- Broken ribs and/or compression injury due to over aggressive CPR therapy.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Restarting the Device

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

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

1. Press the **Power** button on the Zenix device front panel to turn it off.
2. If necessary, replace a depleted battery with a fully charged pack, or connect the device to auxiliary power.
3. Press the **Power** button on the Zenix device front panel to turn it back on.

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

If the device is powered off for less than 30 seconds, all patient monitoring parameter settings will be retained. If the device has been powered off for at least 30 seconds, it will be considered a New Patient and all of the patient-specific parameters (alarm limits, 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 Zenix 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.

NO IMPLIED LICENSE

Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

Software Licensing Statement

Some software components included in this product are licensed by ZOLL Medical Corporation under various open source licenses. For more information, see https://info.zoll.com/en/zenix-software-licenses.

Service

The Zenix device requires recalibration of the CO_2 module. Service is required after 20,000 hours of use of the CO_2 module. Appropriately trained and qualified personnel should, however, perform periodic tests of the device functionality to verify proper operation. See the *Zenix Service Manual* for details.

If a device requires service, contact the Technical Service Department.

For customers	Contact
In the U.S.A.	Telephone: • 1-800-348-9011 Web: https://www.zoll.com/en/Service-and-Support/Technical-Support Self Service: www.zoll.com/ExpertCareSupport
Outside the U.S.A.	Call the nearest regional office. To locate an authorized service center, contact the International Sales Department at: ZOLL Medical Canada 3580 Laird Road Unit 1 Mississauga, Ontario L5L 5Z7 Telephone: • 1-866-442-1011 Monday to Friday 8:30 a.m. to 5:30 p.m ET email: intlservice@zoll.com

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

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

Returning a Device for Service

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

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

For customers	Return the device to
In the U.S.A.	ZOLL Medical Corporation 269 Mill Road Chelmsford, MA 01824-4105 Attention: Technical Service Department (*SR number*) Telephone: 1-800-348-9011
In Canada	ZOLL Medical Canada 3580 Laird Road Mississauga, Ontario, L5L 5Z7 Attention: Technical Service Department (*SR number)* Telephone: 1-866-442-1011
In other locations	The nearest authorized ZOLL Medical Corporation representative. To locate an authorized service center, contact the International Sales Department at: ZOLL Medical Canada 3580 Laird Road Unit 1 Mississauga, Ontario L5L 5Z7 Telephone: • 1-866-442-1011 Monday to Friday 8:30 a.m. to 5:30 p.m ET email: intlservice@zoll.com

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, “25” appears for products manufactured in 2025). 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 device.

CHAPTER 2

Product Overview

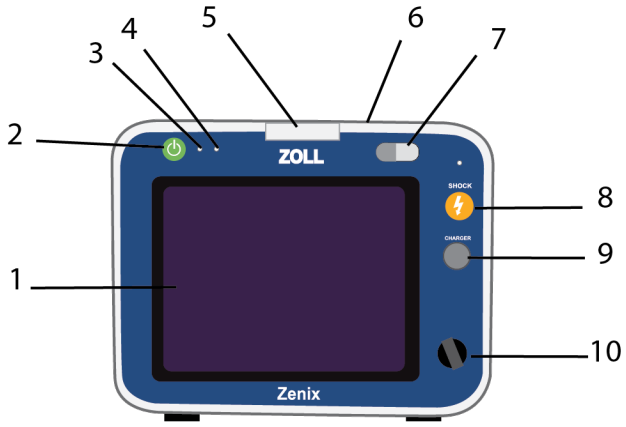
This chapter provides information about the external device such as important indicators and how to use its buttons and touch screen keys. It also contains information about the ports on the device and what connects to them.

It includes the following sections:

The Front Panel 36
Controls and Indicators 37
The Touch Screen Display 38
Navigating the Display Screen 39
Rotary Knob 44
Battery Status and Auxiliary Power Indicators 44
Patient Connectors 46
External Paddles 50
Auxiliary Power Cord 52
Common Tasks 53

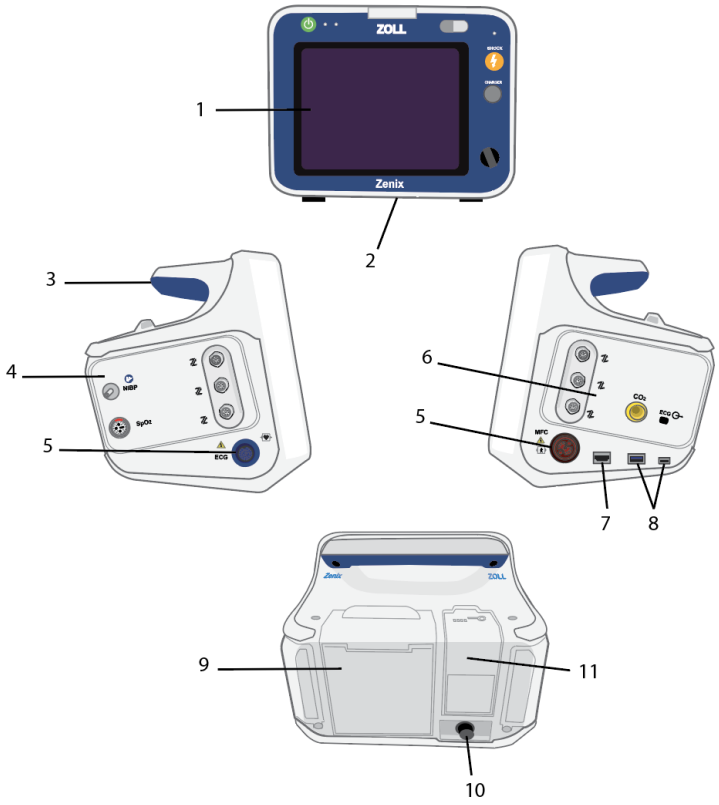
The Front Panel

The front panel of the Zenix device includes the display screen, Power button, rotary knob, battery and auxiliary power indicators, Ready for Use (RFU) indicator, Lock button, and the defibrillation buttons: **CHARGE** and **SHOCK** ( ).



Item	Description
1	Display touch screen.
2	Power button.
3	AC power LED.
4	Battery charge LED. • **Steady yellow:** Battery is charging. • **Steady green:** Battery is charged. • **Alternating green and yellow:** The battery is missing, the battery is faulted, or the battery is not properly installed. • **No light:** The defibrillator is not connected to AC power.
5	Visual alarm and transmission indicators. Lights red or yellow to indicate a patient alert or equipment alert respectively. Lights green to indicate data transmission.
6	Lock button. Use to disable the touch screen. When the touch screen is disabled, a red border appears around the screen with a lock icon in a tab at the top of the screen. Use the rotary knob to maneuver around the display screen. Press the **Lock** button again to unlock it.
7	Ready for Use (RFU) Indicator. A green check ( ) indicates the device is operating correctly. A red X ( ) indicates that the device may not be ready for therapeutic use.
8	SHOCK button. The SHOCK button illuminates when the device is charged and ready. The SHOCK button is only active when using hands-free therapy electrodes or internal defibrillation paddles without a discharge button.
9	CHARGE button. Charges the defibrillator to the selected energy.
10	Rotary knob. An alternative method to using the touch screen.

Controls and Indicators



	Item	Description
1	Front panel	Includes the display touch screen and primary controls.
2	Speaker	Emits R-wave detection beeps and alarm tones.
3	Handle	Integrated carrying handle.
4	Left side (with patient connectors)	For details, refer to "Patient Connectors" on page 46.
5	Patient connectors	
6	Right side (with patient connectors)	
7	Video Out port	Connects to a monitor or television.
8	USB device connectors (A and C)	Connects the Zenix defibrillator to a USB device.
9	Paper compartment	Holds the paper for the printer.
10	Auxiliary power cord	Connects the device to an auxiliary power.
11	Battery compartment	Holds a rechargeable lithium ion battery pack.

The Touch Screen Display

The front panel includes a touch screen display area that shows the following:

- Date and time
- Device mode (color coded)
- Patient type
- Battery status indicator
- Time elapsed (since device was turned on)
- Operator keys
- Waveform source
- Color-coded waveforms and ECG lead identifiers
- Numeric data for parameters: Heart rate, SpO_2, $EtCO_2$, Respiration, Temperature, Non-invasive Pressure, Invasive pressure
- The selected energy, charging status, and delivered energy for defibrillation and synchronized cardioversion
- The output current and stimulus rate for pacing
- Messages and prompts



Navigating the Display Screen

To navigate the display screen:

- Select the screen to navigate to different areas.
- Select the waveforms to select leads, lead size/speed, and the number of waveforms.
- Select the keys on the top of the display screen (Navigation bar) to select mode and patient type.
- Select the keys on the bottom of the display screen (Action bar) to invoke those actions.
- Turn the rotary knob in either direction to move around the screen and press it to make a selection.

To exit a window, select the **X** in the upper right-hand corner or touch outside of the window.

Note: When describing how to move around the display screen or making selections on the screen or in a window, this manual provides instructions for touching the screen. As an alternate method, you can always use the rotary knob.



Status Bar

The status bar area displays the following system status information along the top of the screen:

- Date
- Current time
- Case time
- Shock count
- Transmit status
- Wi-Fi strength signal
- Bluetooth connection status
- USB device connection status
- Battery level

Navigation Bar

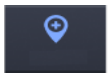
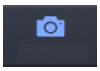
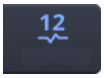
The navigation bar area, located under the status bar at the top of the screen, displays the following controls:

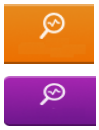
Control	Description
Device Mode: AED, MANUAL, PACER	Changes the device mode by selecting the appropriate key (AED, MANUAL, PACER). The key that is in color indicates the mode that the device is currently in. **Note**: To change to Manual mode from AED mode you may need to enter a password.
Patient Type: ADULT, PEDIATRIC, NEONATE	Changes the patient type by selecting the current patient type key and making the appropriate selection from the drop-down menu.
	Enables/disables audio pause and displays overall alarm status. **Note**: During a patient alarm this key flashes red; during a technical alert, this key flashes yellow.
	Displays in the navigation bar to indicate that the system is not actively monitoring for alarm conditions.
	Displays in the navigation bar when the alarm has been silenced.
	Displays in the navigation bar when an active alarm has been paused.
Status message	Displays the most recent alarm/message.

Control	Description
 (Status list)	Select to display a list of status messages.

Action Bar

The action bar at the bottom of the display screen contains operator keys to access the Zenix functions. The table below provides descriptions of each of the available operator keys.

Operator key	Description
Menu 	Displays the General, Device, and Panels windows to configure settings. When you select this key it turns blue. The Menu key can display the following in the top right corner: • exclamation point for technical alerts • informational icon for informational messages • ellipsis for more than one alert/message
NIBP Cuff 	Starts/stops an NIBP measurement. When you select this key it turns blue.
Marker 	Displays the clinical treatment marker options. When you select this key it turns blue.
Print 	Starts/stops printing of a waveform strip. When you select this key it turns blue.
Snapshot 	Records 24 seconds of numeric and waveform data. When you select this key it turns blue.
12 Lead 	Displays the 12-lead monitoring screen. When you select this key it turns blue.
Sync 	Activates the synchronized cardioversion mode. **Note:** Synchronized cardioversion is disabled when the Zenix device detects that an AutoPulse® Resuscitation System is compressing.
Pause 	Allows you to pause the rescue cycle in AED mode.

Operator key	Description
Analyze 	Initiates ECG analysis to determine whether or not a shockable rhythm is present. Displays orange in Manual Mode and purple in AED mode.
Energy Select  	Displays orange in Manual Mode and purple in AED mode. Manual Mode allows you to adjust the energy level. Once you have made the energy selection, it displays in this area. When you select this key it turns blue. **Note:** The energy indicated on the Energy Select key identifies the energy level currently selected.

Rotary Knob

The rotary knob is an alternate method to using the touch screen. Turning the rotary knob in either direction moves the highlighted area around the elements on the display screen.

Pressing the rotary knob performs a selection related to the highlighted display field.

Battery Status and Auxiliary Power Indicators

The battery status indicator displays various battery icons to indicate the approximate remaining device run time based on the charged state of the battery. Additionally, these icons provide indications of the status of the battery connection and communication with the device. The auxiliary power indicator indicates that the device is being powered by the auxiliary power adapter.

Icon	Status	Indication/Action
	Auxiliary power adapter is connected	The device is being powered by the auxiliary power adapter.
	No battery detected	There is no battery in the device while it is being powered by the auxiliary power adapter.
	Battery communication error	Device cannot detect that the battery is connected.
	Battery is critically low	Replace the battery soon.
	Battery Level 1	The battery has less than one hour of remaining battery run time.
	Battery Level 2	The battery has greater than one hour of remaining battery run time.
	Battery Level 3	The battery has greater than two hours of remaining battery run time.
	Battery Level 4	The battery has greater than three hours of remaining battery run time.
	Battery Level 5	The battery is fully charged.

Replacing a Battery Pack

This section describes how to replace a battery pack on the Zenix device.

To remove a battery pack:

1. Use your thumb to push down on the tab behind the battery.
2. When the battery releases, use your thumb to pull it out of the compartment.

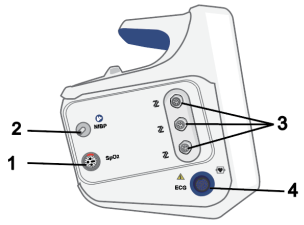


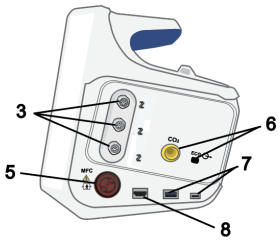
To install a battery pack:

1. Line up the battery so it will slide into the battery well.
2. Push the battery into the battery well until it snaps into place.

Patient Connectors

The left and right sides of the device contain sets of connectors for patient cables. The patient connectors are listed in the table below.





Item	Description
1	SpO_2. For connecting the Masimo SpO_2 cable.
2	NIBP. For connecting the NIBP hose.
3	Z-Link Connector. Provides interchangeable connection for IBP cable(s), Temperature cable(s), or AccuVent.
4	ECG. For connecting 3- or 5-lead ECG cable (12-lead monitoring is optional).
5	Multifunction Cable (MFC). For connecting paddles or hands-free therapy and pacing electrodes.
6	CO_2. For connecting the CO_2 cable. The smaller port is the ECG/Sync Out port.
7	USB (A and C). For connecting the Zenix defibrillator to a USB device.
8	Video Out. For connecting the device to a monitor or television. **Note:** Only Premium Certified Video Out cables are supported.

Note: All cables providing ECG signals meet the ANSI/AAMI Standard EC53:2013 Section 5.3.2, Cable and Leadwire Noise level limits.

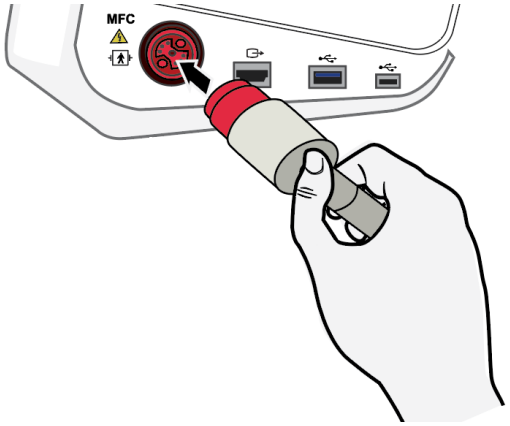
Multifunction Cable (MFC)

The device ships with an MFC that is used to defibrillate the patient. Any other cables that ship with your device depend on your purchased options.

Inserting and Removing the MFC

Line up the cable connector with the therapy input connector on the right side of the device and push it in. Pull the cable connector out to remove it from the device.

Note: The MFC comes with a screw to more securely attach it to the device.



OneStep Connector (Optional)

The OneStep™ connector is for use with OneStep electrodes (in Appendix B) for ECG monitoring and for use with Real CPR Help.

When connecting a OneStep electrode to the OneStep connector, push the two connectors together until the latch clicks.

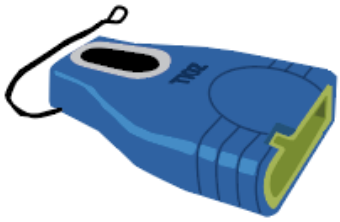


When disconnecting the OneStep electrode and OneStep connector, press down the latch (with the arrow).



Green Connector (optional)

The Zenix Green Connector adaptor is for use with green connector ZOLL electrodes, for ECG monitoring and Real CPR Help.



External Paddles

Paddles are defibrillation-proof Type BF equipment.

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

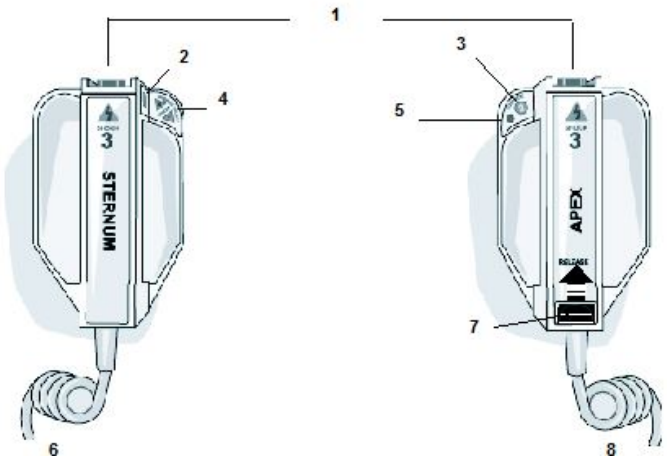
Caution: You cannot use paddles for external transcutaneous pacing.

Attaching the MFC

Attach the MFC from the device to the connector at the base of the 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.

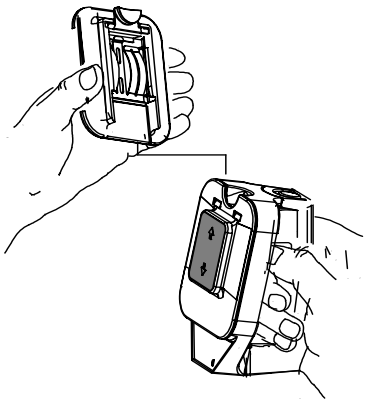


Item	Description
1	Shock Buttons
2	Recorder Button
3	Charge Button
4	Energy Select Buttons
5	Charge Ready Indicator
6	Sternum Paddle

Item	Description
7	Connector and Release Button for MFC or OneStep Cable
8	APEX Paddle

Pediatric-size electrodes are built in to the paddle assembly beneath the standard electrode plates. You 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.



Auxiliary Power Cord

The auxiliary power cord is used as backup power to operate the device. When connected to the device, it powers the device and charges the installed battery. When the power cord is plugged in the auxiliary power LED on the front panel illuminates and the auxiliary power icon ( ) displays at the top of the display screen.

Caution: To ensure continuous operation, always keep a battery installed in the device that is being powered by the auxiliary power cord.

Caution: Allow access to the auxiliary power cord as a means of disconnecting from AC mains power.

Common Tasks

This section contains procedures for the following tasks that you may perform while you are monitoring a patient. It includes:

- Powering on the device
- Setting the Display Mode, Brightness, and Volume
- Setting the Date and Time
- Creating a New Patient Case
- Using Treatment Markers
- Loading Printer Paper

Powering the Device

Power on the Zenix device by pressing the **Power** button on the Zenix device front panel. When you press the **Power** button:

- The ZOLL logo displays while the device boots up.
- The system performs a self-test then displays the results.

  Below is an example of self-test results. Your particular self test results may differ depending on your current installed options.



Note: The rotary dial operation is not part of the power on self-test.

Note: If an error is detected during power on, the system will handle the error and the ZOLL logo may display a second time.

Setting the Display Mode, Brightness, and Volume

The Zenix touch screen display provides, depending on configuration, up to three different brightness modes:

- High Contrast

  In High Contrast mode, the Zenix display uses a white background to make it easier to see in bright sunlight.

- Normal

  In Normal mode, the Zenix display uses color and a black background to make numerics and waveforms easy to read.

- NVG (night vision goggle)

  In NVG mode, the Zenix display uses display and alarm LEDs that prevent interference with goggles.

To select brightness options:

1. Select the **Menu** key  .
2. In the Menu window, select the **Device** key.
3. In the **Display Mode** field, select **Normal**, **High-Contrast** or **NVG**.
4. In the **Brightness** and **Volume** fields, use the **+** and **-** keys to set the appropriate brightness percentage and volume.

   Selecting a higher brightness setting (such as 70%) will deplete the battery pack at a faster rate than when choosing a lower brightness setting (such as 30%).

Setting the Date and Time

You can set the date and time that the Zenix device will use as its internal real time clock.

When the Date and Time is manually adjusted, changes take effect immediately. When the Date and Time are set to automatically update via Auto DST (Daylight Savings Time) or Clock Sync function, the Zenix device will make adjustments to its clock, if necessary, after the device has been off for at least 30 seconds and prior to the start of a new case to ensure that the real time clock never changes during patient treatments.

To set the device's date and time:

1. Select the **Menu** key  . The Menu window displays.
2. In the Device tab, select the **System Settings**. The System Settings window displays.
3. Select **Date & Time**. The Date & Time window displays.
4. Make changes to the Day, Month, and Minute fields by selecting each field and using the **+** and **-** keys then selecting **OK** to confirm choices.
5. Select AM or PM in the **AM/PM** field.
6. In the **DST** field, select **DST** (Daytime Saving Time) or Standard.
7. When you are done making your selections, select **Save** to save settings.

Set Date and Time Screen with Clock Synchronization

Clock Sync is a feature that is Supervisor enabled or disabled. For systems with the Clock Synchronization feature enabled, the Set Date and Time screen indicates the date and time of the Zenix device last synchronization to an external time source. See the *Zenix Configuration Manual* for information on the Clock Synchronization feature.

Note: For systems with Clock Synchronization enabled, avoid changing the device's time manually except at initial configuration.

Creating a New Patient Case

When a new patient is initiated, the Zenix device closes the previous case and creates a new one. At that point, all patient-specific parameters (alarm limits, defibrillator energy, etc.) are reset to their default values.

Note: You can also create a new patient by powering off the device for 30 seconds or longer.

To create a new patient case:

1. Select the **Menu** key  . The Menu window displays.
2. On the **Device** tab, select the **+ New Patient** key at the bottom of the window. The message, *ARE YOU SURE YOU WANT TO START A NEW CASE?* displays.
3. Select **Yes**.

Using Treatment Markers

The Zenix device provides pre-configured treatment markers that contain clinical actions. When you select a treatment marker, it adds a treatment snapshot (which itemizes drugs or treatments administered to the patient) to a Treatment Summary Report.

Access the treatment markers set up for your device by selecting the **Marker** key  . You can customize up to 20 treatment markers for your device.

See the *Zenix Configuration Manual* for information on setting up treatment markers.

Loading Printer Paper

The device displays the message *PRINTER OUT OF PAPER* when the printer is activated without paper or if the supply runs out during printing.

To load the printer paper into the printer:

1. Open the printer door and remove any paper. If necessary, press the paper tray release button on back of device.
2. Insert a new paper pack with the grid facing the front of the device. Paper feeds from the top of the stack.
3. Pull enough paper off the pad so that paper extends out of the device when the printer cover is closed.
4. Make sure the paper tray is pushed down completely.
5. Close the printer door.
6. After the paper is loaded, select the **Print** key () to resume printing.

CHAPTER 3

Automated External Defibrillator (AED)

This chapter describes the recommended method of operation while the Zenix device is in AED mode.

It includes the following sections:

Overview 58

AED Operation 59

Switching to Manual Mode Operation 62



ZOLL hands free therapy electrodes are defibrillation-protected Type BF patient connections.

The device is configured to operate in compliance with the American Heart Association and European Resuscitation Council Guidelines for Adult Basic Life Support and Use of Automated External Defibrillators. If your local protocol requires a different procedure, follow that protocol.

Overview

The Zenix device provides the option to power on the device in AED mode. When configured to start up in AED Mode, the Zenix device guides you through a cardiac event by:

1. Analyzing the patient's ECG rhythm.

   When hands-free therapy electrodes are connected and making good contact with the patient, the analysis of a patient's ECG rhythm analysis occurs automatically.

2. Preparing the device for a shock (if needed) .

   If the analysis determines there is a shockable rhythm present, the device charges and then prompts you to shock the patient at the pre-configured energy level. If the analysis does not detect a shockable rhythm, the device alerts you that no shock is advised.

3. Leading you through a CPR interval.

   The cycle repeats as long as Analysis/CPR Protocol is active and pads are attached to the patient. If pads become detached from the patient or shorted during the Analysis/CPR Protocol, the protocol halts and waits for the pads to be reattached.

Warnings

- 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.
- ECG rhythm analysis does not warn of patient asystole, which is not a shockable rhythm.
- When using the AutoPulse, stop compressions prior to performing ECG analysis. Compressions can be resumed following the analysis.
- Poor adherence and/or air under the therapy electrodes can lead to the possibility of arcing and skin burns.

AED Operation

1. Follow patient protocol to determine if cardiac resuscitation is required.
2. Begin CPR following medical protocols. Request additional assistance.
3. Prepare patient by:
    a. Removing all clothing covering the patient's chest.
    b. Drying chest if necessary.
    c. Removing excessive hair to ensure proper adhesion of the electrodes.
    d. Attaching hands-free therapy electrodes according to instructions on the electrode packaging. Ensure that the electrodes are making good contact with the patient's skin and are not covering any part of the ECG electrodes. When therapy electrodes are not making good contact with the patient, the message *ATTACH PADS* or *CHECK PADS* displays and the energy is not delivered.

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

    e. Connect the hands-free therapy electrodes to the multi-function cable (MFC) if not already connected.
4. Press the power button on the front of the Zenix device.
5. When therapy electrodes are making good contact with the patient, the device automatically begins the analysis of the patient's ECG rhythm and displays a *ANALYZING ECG* message.

    Note: If the device is configured to start with compressions instead of analysis a *PERFORM CPR* message along with a voice prompt for the configured duration before analysis begins. You can start an ECG analysis during the CPR interval by selecting the **Analyze** key on the Zenix display.

6. When the analysis is complete, the Zenix device indicates whether or not a shock is advised.

7. If the Zenix device detects a shockable rhythm:
    a. The **SHOCK** button illuminates and a continuous tone sounds. You must deliver the shock during the time period of the continuous tone or the defibrillator disarms itself within 30 or 60 seconds depending on configuration.

        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.

    b. Press the **SHOCK** button on the Zenix device.
    Observe the patient or ECG response to verify that the shock has been delivered. When a shock is successfully delivered, the shock energy level and the shock number (1) displays on the bottom of the screen.
    c. The Zenix device prompts you to continue CPR. Perform CPR following your local protocols.
    d. After performing CPR for the configured period of CPR, the device issues a **STOP CPR** prompt and restarts the ECG analysis automatically.
8. If the Zenix device does not detect a shockable rhythm, it displays a *NO SHOCK ADVISED* message. Immediately begin chest compressions and continue other treatment per protocol.

Pausing the CPR Cycle

You can select the **Pause** key on the **Zenix** display to temporarily stop the rescue cycle. When you select **Pause**:

- ECG analysis continues in the background.
- The device notifies if a shockable rhythm is detected.

Select the **Analyze** key on the Zenix display to resume the ECG analysis process.

Audio and Display Messages

The Zenix device uses both audio and visual prompts to present critical information to you. The following information describes the device default configuration. If your device has been custom configured, some of the information may be different.

System Message	Cause
ATTACH PADS	Displays and announces when the device is powered on without therapy pads connected to the patient.
ANALYZING ECG/STAND CLEAR	The *ANALYZING ECG* message and the *STAND CLEAR* messages display and announce when the ECG analysis starts automatically or after pressing the **ANALYZE** button. They indicate that an active ECG analysis is in progress.
SHOCK ADVISED	A shockable rhythm has been detected and defibrillation is advised. The selected energy level displays.
PRESS SHOCK	Displays and announces when the ECG analysis has determined that a shock is advised and the selected energy is ready to be delivered.
SHOCKS: XX	Displays the number of shocks that have been delivered by the device since it was powered on. It resets to 0 when the device is off for more than 30 seconds.
NO SHOCK ADVISED	When ECG analysis detects a nonshockable rhythm, this message is announced and displays for 10 seconds following completion of the analysis.
IF NO PULSE, PERFORM CPR	If configured to do so, this message displays and announces in the following situations: • During the CPR interval after a No Shock Advised analysis result • During the start of initial CPR interval (if the device is configured to start with compressions instead of analysis)
PERFORM CPR	If configured to do so, this message displays and announces during the CPR interval after a No Shock Advised analysis result.
STOP CPR	After performing CPR for the configured period, the device issues a *STOP CPR* prompt while it restarts ECG analysis.
PUSH HARDER	Announces when the chest compressions applied during CPR are not deep enough.
GOOD COMPRESSIONS	Announces when the chest compressions applied during CPR are deep enough.
CHECK PADS	Displays and announces when the therapy pads have been disconnected from the patient.
CHECK PATIENT	Displays and announces when the device is paused and detects a shockable rhythm during continuous background ECG analysis. The prompt persists as long as a shockable rhythm is detected. Select the **ANALYZE** button to resume ECG analysis.

Switching to Manual Mode Operation

To enter Manual mode:

1. Select **Manual** on the navigation bar.
2. If prompted, enter the four-digit Manual Mode pass code.

   Note: If the device has not been configured to enter a passcode, the message *OK TO CHANGE TO MANUAL MODE?* displays. Select **Yes** to enter Manual mode.

The Zenix device maintains the current selected energy level when changing from AED mode to Manual mode.

Note: To switch back to AED mode from Manual mode, select **AED** on the navigation bar.

CHAPTER 4

Manual Defibrillation

This chapter describes the recommended method of operation while the Zenix device is in Manual defibrillation mode.

It includes the following sections:

Overview 64

Defibrillation Procedure with Paddles 65

Defibrillation Procedure with Hands-Free Therapy Electrodes 68

Internal Paddles 69

Advisory Defibrillation Overview 70



Paddles are a defibrillation-protected Type BF patient connection.



ZOLL hands-free therapy electrodes are a defibrillation-protected Type BF patient connection.



ECG leads are a defibrillation-protected Type CF patient connection.



Internal paddles are a defibrillation-protected Type CF patient connection.

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.

Overview

Manual Defibrillation mode (or Manual mode) allows you to have full control over defibrillator functions. After determining the need for treatment, this mode allows you to:

1. Select the energy setting.
2. Charge the device.
3. Deliver shock.



If at any time you want to cancel the defibrillation, press the **Disarm** key on the Zenix display. If the defibrillator is not discharged within 60 or 120 seconds (depending on configuration) after reaching the selected energy level, the device automatically disarms itself.

- To avoid risk of electrical shock, do not allow electrode gel to accumulate on hands or paddle handles.
- When defibrillating with paddles, use your 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 - small).
- When using the AutoPulse, stop compressions prior to performing ECG analysis. Compressions can be resumed following the analysis.

Defibrillation Procedure with Paddles

1. **Turn on the Zenix device** by pressing the power button on the front of the device.
2. **Select the desired energy level** by selecting the **Energy Select** key then selecting an energy level from the list that displays. The selected energy level displays at the bottom of the screen.



Note: Neonatal and pediatric defibrillator energy levels should be selected based on local protocols.

The default energy selections for **adult** patients are:

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

The default energy selections for **pediatric** patients are:

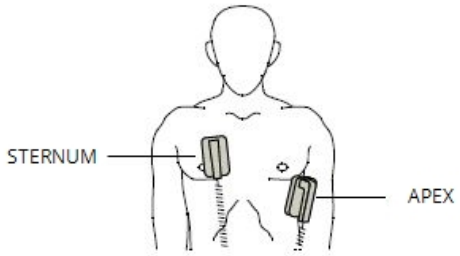
- Shock 1 - 50 joules
- Shock 2 - 70 joules
- Shock 3 - 85 joules

3. **Ensure that the paddles are connected** to the multi-function cable (MFC) and that the cable is connected to the device.
4. **Apply electrolyte gel** evenly to the electrode surface of each paddle.

   Note: You can substitute electrode gel patches for the gel. If you use defibrillator gel pads, make sure that the size of the pad is large enough to cover the entire paddle electrode area.

5. **Apply the paddles** firmly to the anterior wall of the chest.

6. **Apply paddles to the chest** by:
    a. Placing the STERNUM paddle to the right of the patient's STERNUM (patient's right), just below the clavicle.
    b. Placing the APEX paddle on the chest wall just below and to the left of the patient's left nipple along the anterior-axillary line.
    c. Rubbing the paddles against the skin to maximize the paddle-to-patient contact.

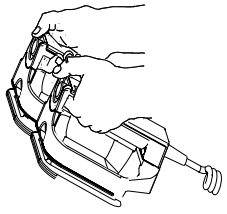


WARNING! Do not permit gel to accumulate between the paddle electrodes on the chest wall (gel bridge). This could cause burns and reduce the amount of energy delivered to the heart.

7. **Charge the defibrillator** by pressing the **Charge** button on the APEX handle or on the Zenix device. When you press the **Charge** button:
    - A charging message displays in the Defib panel on the bottom of the screen.
    - A distinctive charging tone sounds indicating that the device is charging.
    - The energy value in the Defib panel increases while the device is charging.
    - When the device is fully charged, the tone changes to a continuous charge ready tone.
    - The charge indicator on the APEX paddle lights up.

Note: You can increase or decrease the selected energy, if desired, by using the **ENERGY SELECT** buttons on either the STERNUM paddle or the Zenix device front panel. 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.

8. **Deliver shock** by:
    a. Applying a force of 10 - 12 kilograms (22 - 26.4 pounds) to each paddle in order to minimize patient impedance and achieve optimal results.
    b. Using your thumbs, simultaneously press and hold both **SHOCK** buttons (one on each paddle) until energy is delivered to the patient. The delivered energy level displays at the bottom of the screen and the shock number (1) displays at the top of the screen.



Note: If at any time you want to cancel the defibrillation, select the **Disarm** key on the touch screen. If the defibrillator is not discharged within 60 seconds after reaching the selected energy level, the device automatically disarms itself.

Defibrillation Procedure with Hands-Free Therapy Electrodes

1. **Prepare patient** by:
    a. Removing all clothing covering the patient's chest.
    b. Drying chest if necessary.
    c. Removing excessive hair to ensure proper adhesion of the electrodes.
    d. Attaching hands-free therapy electrodes according to instructions on the electrode packaging.
    e. Ensuring 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
2. **Turn on the Zenix device** by pressing the power button on the front of the device.
3. **Select the desired energy level** by pressing the **Energy Select** key () then selecting an energy level from the list that displays. The selected energy level displays at the bottom of the screen.

    Note: Neonatal and pediatric defibrillator energy levels should be selected based on local protocols.

    The default energy selections for **adult** patients are:

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

    The default energy selections for **pediatric** patients are:

    - Shock 1 - 50 joules
    - Shock 2 - 70 joules
    - Shock 3 - 85 joules
4. **Charge the defibrillator** by pressing **Charge** button on the Zenix front panel. A charging message displays at the bottom of the screen, and a distinctive charging tone sounds indicating that the device is charging. When the device is fully charged, the tone changes to a continuous charge ready tone, the highlighted energy bar graph includes the selected energy and the **SHOCK** button lights up.

    Note: You can increase or decrease the selected energy after you have pressed the **CHARGE** button by selecting the **Energy Select** key () on the Zenix display then choosing the desired energy level from the list that displays.

5. **Deliver shock** by pressing the  button on the front panel. Energy is delivered to the patient. The delivered energy level displays at the bottom of the screen and the shock number (1) displays at the top of the screen.

    Note: If at any time you want to cancel the defibrillation, select the **Disarm** key on the Zenix display. If the defibrillator is not discharged within 60 seconds after reaching the selected energy level, the device automatically disarms itself.

Internal Paddles

 ZOLL internal paddles are a defibrillation-protected Type CF patient connection.

The Zenix device is suitable for direct cardiac application via internal paddles.

Internal paddles are designed for use with the Zenix device to defibrillate the heart during open chest procedures. Two types of Autoclavable Internal Handles are available:

- Molded Autoclavable Internal Handles with integrated electrodes
- Autoclavable Internal Handles with removable internal defibrillation electrodes

When an internal handle set is connected to the Zenix device, it automatically limits defibrillator energy output to a maximum of 50 joules.

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*.

Advisory Defibrillation Overview

The Zenix device includes an Advisory Defibrillation function that you can use to guide you through a cardiac event. The Zenix device guides you through a cardiac event by:

- Analyzing the patient's ECG rhythm.
- Determining if a shockable rhythm is present.
- Providing advisory messages to charge the defibrillator and deliver treatment to the patient when required by protocol and patient condition.

The Advisory function is available when:

- The device is in manual mode.
- Hands-free therapy electrodes are properly connected to the patient.
- Valid impedance is detected.
- Patient mode is set to Adult or Pediatric.
- You select the **Analyze** button on the Zenix display.

Your Zenix device may be setup for Single Analysis or CPR Protocol. See the sections that follow for instructions on performing Single Analysis or CPR Protocol.

WARNING! Use only pediatric electrodes to defibrillate patients under 8 years of age or weighing less than 55 lbs (25kg), and make sure the patient mode is set to pediatric in Advisory mode. Use of adult mode with pediatric patients can result in the delivery of excessive energy doses.

Single Analysis

With Single Analysis, the Zenix device guides you through a single ECG analysis. The Zenix device analyzes the patient's ECG rhythm and identifies shockable rhythms. You must read the advisory messages, charge the defibrillator to the preconfigured or user-selected energy level, and deliver treatment to the patient when required by protocol and patient condition.

To analyze the patient's ECG:

1. Select the **ANALYZE** button on the Zenix display. An *ANALYZING* message displays while the patient's ECG is analyzed.
2. When the analysis is complete, the Zenix device indicates whether or not a shock is advised.

3. If the Zenix device detects a shockable rhythm:
    a. A *SHOCK ADVISED* message displays.
    b. Press the **Charge** button on the Zenix display to charge the device to the preconfigured energy level.

        Note: If desired, you can choose a different energy level before pressing the Charge button.

    c. Press the **Shock** button on the Zenix front panel. Energy is delivered to the patient. The delivered energy level displays at the bottom of the screen and the shock number (1) displays at the top of the screen.

    Note: If at any time you want to cancel the defibrillation, select the **Disarm** key on the Zenix display. If the defibrillator is not discharged within 60 seconds after reaching the selected energy level, the device automatically disarms itself.

4. If the Zenix device does not detect a shockable rhythm, it displays a *NO SHOCK ADVISED* message. Immediately begin chest compressions and continue other treatment per protocol. Regardless of the analysis result, you can control the defibrillator manually. For example, you can defibrillate the patient even if the advisory function issues a *NO SHOCK ADVISED* message.

Note: You can restart the analysis, if desired, by selecting the **ANALYZE** button to start an ECG analysis and determine if additional shocks are required.

CPR Protocol

When the Zenix device is set to CPR Protocol, the device can lead you through a cardiac event by analyzing the patient's ECG rhythm, preparing the device for a shock (if needed), and leading you through a CPR interval. The Zenix device will automatically begin an analysis of the ECG rhythm at the end of every CPR period. This cycle repeats as long as CPR Protocol is active and pads are attached to the patient. If pads become detached from the patient or shorted during the Analysis/CPR Protocol, the protocol halts and waits for the pads to be reattached.

To start CPR Protocol:

1. Press the **Analyze** button on the Zenix display. An *ANALYZING* message displays while the patient's ECG is analyzed.
2. When the analysis is complete, the Zenix device indicates whether or not a shock is advised.

3. If the Zenix device detects a shockable rhythm:
    a. A *SHOCK ADVISED* message displays.
    b. Press the **Shock** button on the Zenix front panel. Energy is delivered to the patient. The delivered energy level displays at the bottom of the screen and the shock number (1) displays at the top of the screen.
    c. The Zenix device leads you through a CPR interval and restarts ECG analysis automatically.

        Note: If at any time you want to cancel the defibrillation, select the **Disarm** key on the Zenix display. If the defibrillator is not discharged within 60 seconds after reaching the selected energy level, the device automatically disarms itself.

4. If the Zenix device does not detect a shockable rhythm:
    a. A *NO SHOCK ADVISED* message displays.
    b. The Zenix device leads you through a CPR interval and restarts ECG analysis automatically.
5. Press the **Exit** button on the Zenix Display at any time to end the Analysis/CPR Protocol and return to Manual mode.

CHAPTER 5

Synchronized Cardioversion

This chapter describes how to perform synchronized cardioversion using the Zenix device.

It includes the following sections:

Overview 74

Synchronized Cardioversion Procedure 75



Paddles are a defibrillation-protected Type BF patient connection.



ECG leads are a defibrillation-protected Type CF patient connection.



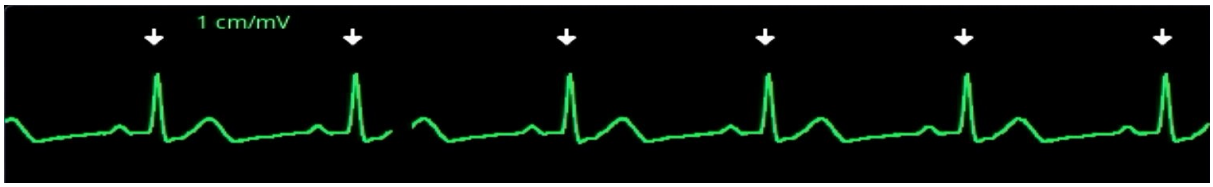
ZOLL hands-free therapy electrodes are a defibrillation-protected Type BF patient connection.

Overview

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.

A synchronizing (SYNC) circuit within the Zenix device detects the patient's R-waves. When the **SHOCK** button (or buttons, if using paddles) is pressed and held, the device discharges with the next detected R-wave, thus avoiding the vulnerable T-wave segment of the cardiac cycle.

When in the SYNC mode, the device displays downward facing arrows on the ECG trace to indicate the points in the cardiac cycle (R waves) where discharge can occur.



Verify that markers are clearly visible on the monitor and their location is appropriate and consistent from beat to beat.

Synchronized Cardioversion Procedure

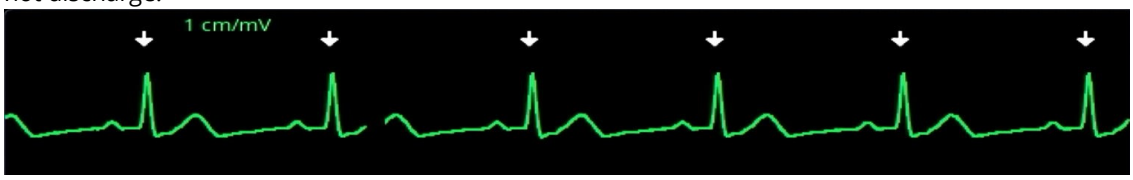
Synchronized cardioversion, available in Manual mode, should only be performed by skilled personnel trained in synchronized cardioversion and familiar with the Zenix device operation. The precise cardiac arrhythmia must be determined before attempting defibrillation or cardioversion. Before attempting synchronized cardioversion, ensure that ECG signal quality is sufficient to minimize the risk of synchronizing on artifact.

Note: The synchronized cardioversion procedure for hands-free therapy electrodes is identical to that for paddles with the exception of the **SHOCK** button location.

To perform synchronized cardioversion:

1. **Determine patient's condition** and provide care following local protocols.
2. **Attach hands-free therapy electrodes** according to instructions on the electrode packaging.

   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 standard 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.
3. **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 paddles are being used for synchronized cardioversion, refer to "Defibrillation Procedure with Paddles" on page 65 . 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.
4. **Enter SYNC mode** by pressing the **SYNC** key on the Zenix display. A downward facing arrow displays above each detected R-wave to indicate where discharge will occur. If the marker does not appear over the R wave, select a different ECG lead. If the sync marker doesn't display, the defibrillator will not discharge.

   Note: Unless otherwise configured, the device automatically exits Sync mode after each shock. To reactivate SYNC mode, press the **SYNC** key on the front panel again. Changing the selected energy levels does not cause the device to leave SYNC mode.
5. **Select the desired energy level** by pressing the **Energy Select** key (120 J) then selecting an energy level from the list that displays. Neonatal and pediatric defibrillator energy levels should be selected based on local protocols.
6. **Charge the defibrillator** by pressing **Charge** button on the APEX handle or on the Zenix front panel. A charging message displays and a distinctive charging tone sounds indicating that the device is charging. When the device is fully charged, the tone changes to a continuous charge ready tone, the selected energy is indicated, and the charge indicator on the APEX paddle lights up.

Note: You can increase or decrease the selected energy, if desired, by using the **ENERGY SELECT** buttons on either the STERNUM paddle or the Zenix device front panel. 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.

7. **Deliver shock** by pressing and holding the **Shock** button on the front panel or by simultaneously pressing and holding both paddle SHOCK buttons. Energy is delivered to the patient. The delivered energy level displays at the bottom of the screen and the shock number (1) displays at the top of the screen.

Note: If at any time you want to cancel the defibrillation, select the **Disarm** key on the Zenix display. If the defibrillator is not discharged within 60 seconds after reaching the selected energy level, the device automatically disarms itself.

CHAPTER 6

CPR Technologies

This chapter describes the CPR technologies available with the Zenix device.

It includes the following sections:

Overview 78

CPR Voice Prompts (Adult Only) 80

CPR Metronome 80

CPR Dashboard 81

CPR Dashboard with AutoPulse 83

AutoPulse with Shock Sync 84

CPR Dashboard with the ResQCPR System 85

See-Thru CPR 86

Real BVM Help 91



Real CPR Help is a defibrillation-protected Type BF patient connection.



WARNING!

- Do not use Adult CPR electrodes with patients under 8 years of age.
- The AutoPulse Resuscitation System is only intended for use on adult patients.

Overview

When configured, the Zenix device can provide rescuers with feedback about the quality of CPR they are delivering to their patients. ZOLL authorized 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 device for processing and display.

The CPR features include:

- **Voice prompts and text messages** (screen prompts), which give rescuers feedback about the depth of chest compressions.
- **CPR Metronome**, which encourages rescuers to perform chest compressions at a rate that falls within AHA/ERC recommended guidelines.
- **FULLY RELEASE prompt**, which instructs rescuers to lift (fully release) their hands from the patient's chest after compressions.
- **Real CPR Help Dashboard**, which displays CPR rate and depth measurements, and graphic indicators for CPR Release and Compression.
- **CPR Compression Bar Graph**, which displays a minimum of 12 seconds of compression depth information.
- **See-Thru CPR**, which enables the rescuer to see a close approximation of the patient's underlying ECG rhythm while performing CPR.
- **Real BVM Help**, which provides ventilation feedback for systems connected to the AccuVent Sensor.

CPR features differ depending on whether you are using ZOLL adult or pediatric CPR electrodes. For electrode compatibility, see APPENDIX B "Accessories". The Zenix device automatically senses which type of ZOLL CPR electrode is attached, and provides the CPR features as follows:

CPR Feature	Adult CPR Features	Pediatric CPR Features
Voice and Text Prompts	+	
CPR Metronome	+	+
FULLY RELEASE Prompt	+	
CPR Rate and Depth Measurements (CPR Dashboard)	+	+
CPR Release Indicator (CPR Dashboard)	+	
CPR Depth Indicator (CPR Dashboard)	+	
CPR Countdown Timer (CPR Dashboard)	+	+

CPR Feature	Adult CPR Features	Pediatric CPR Features
CPR Depth Idle Time Display (CPR Dashboard)	+	+
CPR Compression Bar Graph	+	

The device's CPR features are provided in the following sections.

Note: The CPR features above are modified when the AutoPulse system and the ResQCPR system is in use. See "CPR Dashboard with AutoPulse" on page 83 for details.

CPR Voice Prompts (Adult Only)

When configured, the Zenix device provides voice prompts relating to the depth of chest compressions as feedback to rescuers performing CPR. When chest compressions are detected but their depth is consistently less than the AHA/ERC recommended target depth, the device 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 device issues a "*GOOD COMPRESSIONS*" voice prompt.

CPR voice prompts are only available when patient type is set to Adult.

CPR Metronome

If configured, the Zenix device provides a constant CPR metronome in AED Mode, Manual Mode, or CPR Protocol. The CPR metronome feature encourages rescuers to perform chest compressions at a rate that falls within AHA/ERC recommended guidelines.

Your device may be configured to have the CPR metronome operate in all modes (AED, Manual, and Analysis/CPR Protocol), in AED mode only, or not at all. When activated, the metronome beeps at the configured rate per minute to help rescuers stay within guidelines.

FULLY RELEASE Prompt (Adult Only)

The device can be configured to display the text prompt *FULLY RELEASE*, which instructs rescuers to lift (fully release) their hands from the patient's chest after compressions to allow full recoil. This prompt occurs 45 seconds into the CPR interval.

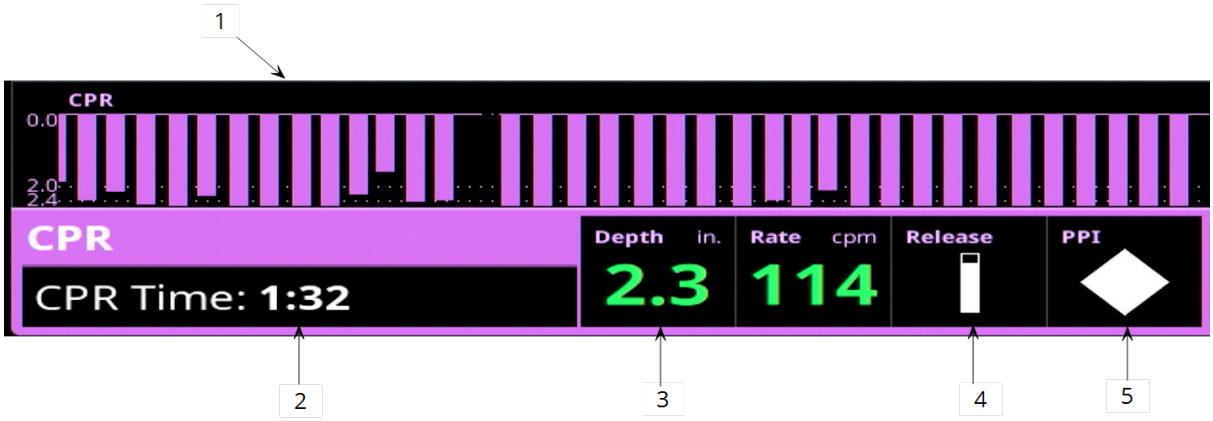
The *FULLY RELEASE* text prompt is only available when using Adult CPR electrodes.

CPR Dashboard

CPR Dashboard™ provides rescuers with detailed real-time visual feedback on CPR quality. Whenever authorized ZOLL CPR electrodes are connected to the Zenix device and the device senses compression, the CPR Dashboard illuminates in the lower portion of the display. The CPR Dashboard contains CPR feedback indicators that provide rescuers with information about the quality of their CPR. The CPR Dashboard provides the following CPR indicators:

- A numeric display of CPR Rate and Depth Measurements
- CPR Release Indicator
- Perfusion Performance Indicator
- CPR Countdown Timer
- CPR Idle Time
- CPR Compression Graph

The CPR indicators available differ depending on whether adult or pediatric CPR electrodes are attached to the device. The table below describes each of the indicators.



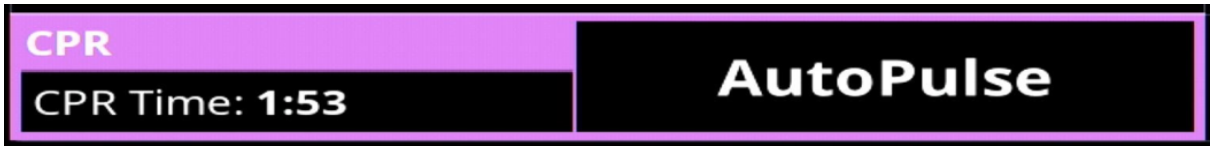
Item	Description
1	Chest Compression Graph (adult only). Available when Adult CPR electrodes are attached, the Chest Compression Graph represents the depth of CPR compression with reference markers at the AHA/ERC recommended guideline of 2.0 (5 cm) and 2.4 inches (6 cm). The device displays a minimum of 12 seconds of compression data at a rate of approximately 133 compressions per minute.
2	Countdown Timer. The CPR Dashboard provides a CPR Countdown Timer that indicates the time (in minutes and seconds) left in the current CPR interval. It decrements the time until it reaches zero.

Item	Description
	CPR Idle Time. The CPR idle timer lets you know how long the patient has been without blood flow. The CPR Idle Time indicates the elapsed time in minutes and seconds since the last detected chest compression. The CPR Idle Time displays three seconds following the cessation of compression. The Zenix device removes the idle time from the dashboard as soon as it detects a new compression. When it detects no compressions for at least 20 minutes, dashes (- - : - -) display in this time field.
3	CPR Rate and Depth Measurements. The display of CPR rate and depth measurements differ depending on whether adult or pediatric CPR electrodes are attached. When adult CPR electrodes are attached, and CPR compressions fall within the AHA/ERC guideline for rate and depth, the CPR numerics display in green. If the device detects that compression rate and depth is consistently outside the AHA/ERC guideline, the depth measurement displays in yellow to indicate that the clinician needs to adjust their CPR compressions appropriately. This color coding assists the rescuer in determining whether they should maintain, increase, or decrease the chest compression rate or depth. When pediatric CPR electrodes are attached, CPR rate and depth measurements *always* display in white.
4	CPR Release Indicator (adult only). The CPR Release Indicator advises the rescuer to fully lift their hands off the sternum during the upstroke of the compression. The release indicator fills when rescuers release compressions quickly and fills partially when chest compression release is slow. When the bar is full, you know you have come completely off the chest to allow for full recoil. The CPR Release Indicator is only available when using Adult CPR electrodes.
5	The Perfusion Performance Indicator™ (adult only). The Perfusion Performance Indicator (PPI) provides a quick, overall indicator of how well the rescuer's combined rate and depth of chest compressions are within the AHA/ERC guidelines for adult CPR. The Perfusion Performance Indicator first displays as an empty diamond then fills as compressions begin. It completely fills when consistent chest compression depth and rate are achieved simultaneously. Should the chest compression rate or depth begin to fall below the target levels, the indicator only partially fills to indicate the need for more rigorous efforts. The goal is to keep the diamond “full.” Following the cessation of compressions, the indicator’s fill level gradually decreases until a hollow outline displays. The Perfusion Performance Indicator is only available when using Adult CPR electrodes.

CPR Dashboard with AutoPulse

When using the AutoPulse with the Zenix device and any authorized CPR electrodes, the following changes automatically occur:

- Voice prompts, text prompts, and the metronome are silenced.
- Compression rate value, compression depth value, and the compression bar graph are removed.
- The Release Indicator and the PPI indicator are removed.
- The message *AUTOPULSE* displays in the CPR Dashboard.
- The CPR Countdown Timer and CPR Idle Timer operate normally.



WARNING! The AutoPulse is only intended for use on adult patients.

AutoPulse with Shock Sync

When using the Zenix device with any authorized ZOLL CPR electrodes and an AutoPulse, the Shock Sync™ technology provides the ability to deliver energy at the relaxation phase of the compression cycle. To utilize Shock Sync, you must:

1. Pause the AutoPulse at the end of the CPR period to analyze the underlying rhythm to determine if it is shockable.
2. Restart the AutoPulse for compressions.
3. Charge the device to the desired joules
4. Press and hold the **Shock** button. The Zenix device automatically discharges the energy at the relaxation phase of the compression cycle.

Note: The availability of AutoPulse with Shock Sync technology is subject to local regulatory approval and may not be available in all regions, including the United States, at this time. For more information on approvals, please reach out to your local representative.

WARNING! The AutoPulse is only intended for use on adult patients.

CPR Dashboard with the ResQCPR System

In order to obtain adequate suction when using the ResQCPR® system:

- Place the authorized ZOLL electrode pads outside the area where the ResQPUMP device will be positioned on the patient's chest.
- In addition, if the electrode has a CPR sensor, detach the CPR sensor from the electrode pad. The CPR sensor will remain connected to the electrode pad via a wire but the sensor can be placed beside the patient, as it is not utilized with the ResQCPR System.

When you select the **ResQCPR** quick-access key ( ) the Zenix device:

- Silences voice prompts, text prompts, and the metronome.
- Removes the compression rate value, compression depth value, and the compression bar graph from the CPR Dashboard.
- Removes the Release Indicator and the PPI Indicator from the CPR Dashboard.
- Displays the message *ResQPump* in the CPR Dashboard.
- Operates the CPR countdown timer and CPR idle timer normally.



See-Thru CPR

See-Thru CPR technology filters out compression artifact so that rescuers can see the underlying heart rhythm during CPR, thereby reducing the duration of pauses in compressions. With See-Thru CPR, you can see a close approximation of the patient's underlying ECG rhythm while performing CPR.

Chest compressions introduce *CPR artifact* into the ECG signal. See-Thru CPR uses a filter that relies on the correlation between CPR compressions, as detected by the ZOLL authorized CPR electrodes, and the CPR artifact to remove much, but not all, of the artifact from the ECG signal. Under some conditions, residual noise after filtering can obscure the ECG rhythm, requiring the rescuer to stop CPR to assess the ECG. For example, in the case of asystole or low amplitude PEA, the residual artifact seen after filtering may look like fine ventricular fibrillation. With See-Thru CPR technology, responders do not have to repeatedly stop CPR for a rhythm check — a filtered signal can be displayed on the screen allowing the rescuer to analyze a patient's heart rhythm while continuous CPR is in progress and monitor the heart rhythm to determine the appropriate time to analyze or stop CPR to check the ECG.

Because the filtered ECG signal may contain residual chest compression and/or filtering artifacts, *a rescuer should always follow the standard procedure of stopping CPR to assess the patient's ECG rhythm before determining treatment*.

- The See-Thru CPR filter works only when the device is monitoring CPR in Manual mode.
- The See-Thru CPR filter is not indicated for use with AutoPulse.
- The See-Thru CPR filter stops if:
    - The device is in pace mode.
    - Patient impedance is invalid.
    - ZOLL CPR electrodes are no longer detected.
- The See-Thru CPR filter will not remove all CPR artifact. Always stop CPR to verify the patient's ECG rhythm before making treatment decisions.
- The See-Thru CPR filter does not operate during ECG rhythm analysis. Always stop chest compressions during ECG rhythm analysis to avoid incorrect results caused by the presence of CPR artifact.
- Diagnostic bandwidth is never applied to the See-Thru CPR waveform.

Using See-Thru CPR

To use See-Thru CPR:

- The device must be monitoring CPR.
- The user must be performing CPR with ZOLL authorized CPR electrodes attached to the device.

When chest compressions begin, the device *automatically* starts filtering the CPR artifact after detecting the first 3 to 6 compressions. The filtered ECG, with the label “FIL,” may be displayed on the first or second trace (by selecting **FILT ECG** in the Trace1 or Trace 2 menu).

See-Thru CPR filtering continues as long as the ZOLL authorized CPR electrodes detect compressions and patient impedance is valid. When no compressions are detected or one of the conditions noted above occurs, See-Thru CPR filtering stops, and unfiltered ECG signals are displayed. When compressions resume, filtering automatically restarts after 3 to 6 chest compressions.

Note: There is a delay of approximately 1/16 second between the See-Thru CPR waveform and the Trace 1 ECG waveform.

Examples

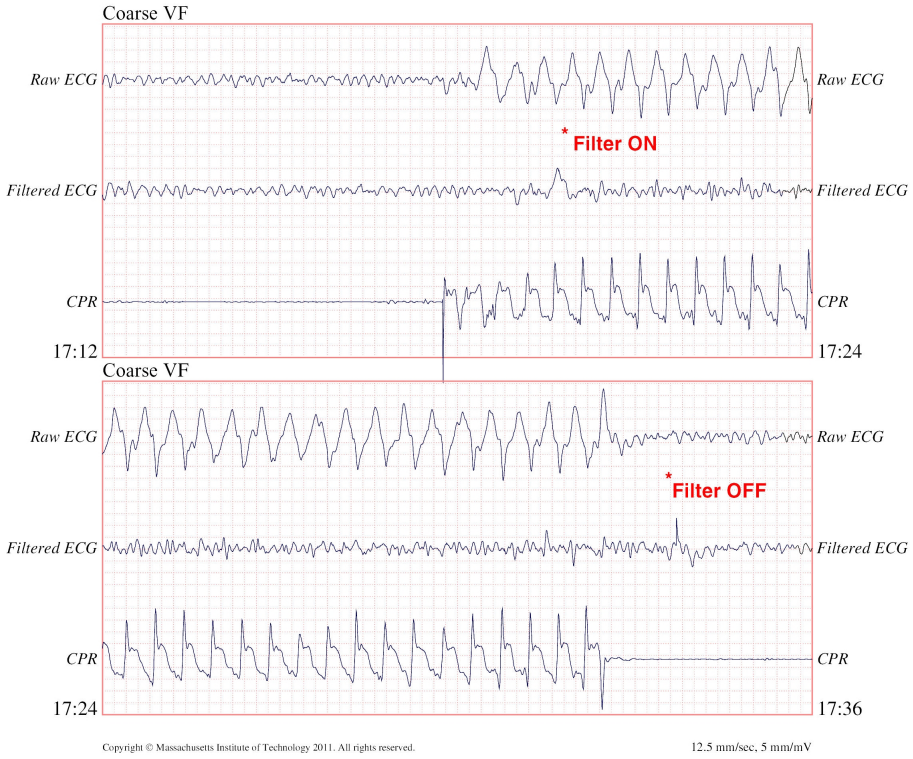
The following examples show the effects of See-Thru CPR filtering on ECG signals contaminated with CPR artifacts.

Each example includes:

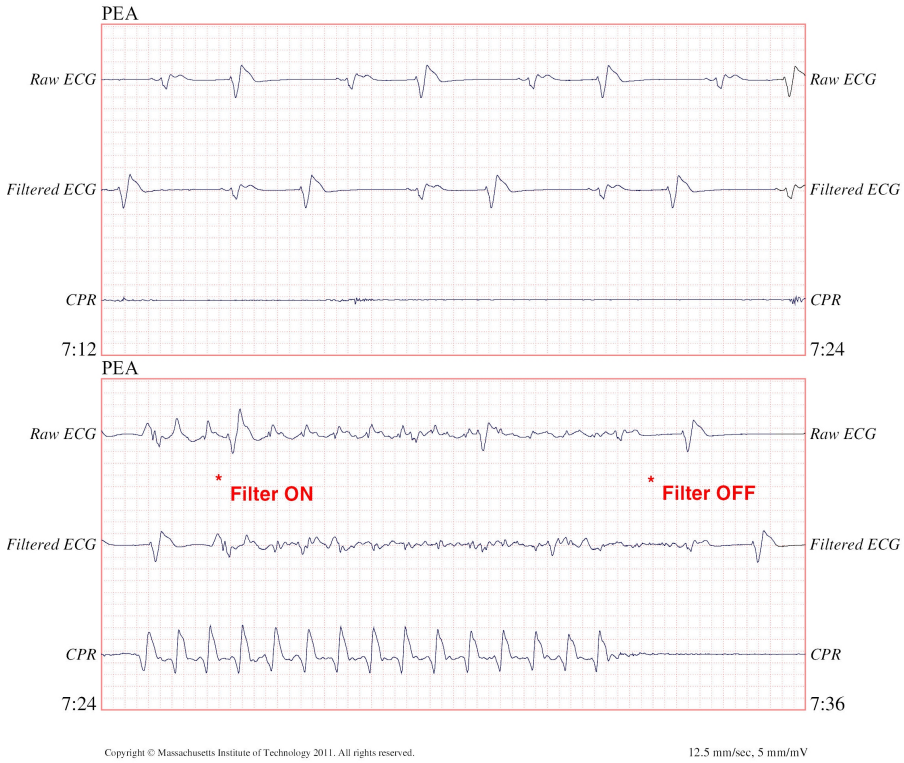
- ECG signal with CPR artifact.
- ECG signal after the See-Thru CPR filter has removed CPR artifact.
- Indication of the period during which See-Thru CPR is active.
- CPR signal to show when CPR activity occurred.

The following figure shows a patient in Fine VF. It is difficult for a rescuer to discern this rhythm during CPR compressions. When the CPR filter turns on, the Fine VF rhythm becomes more obvious.

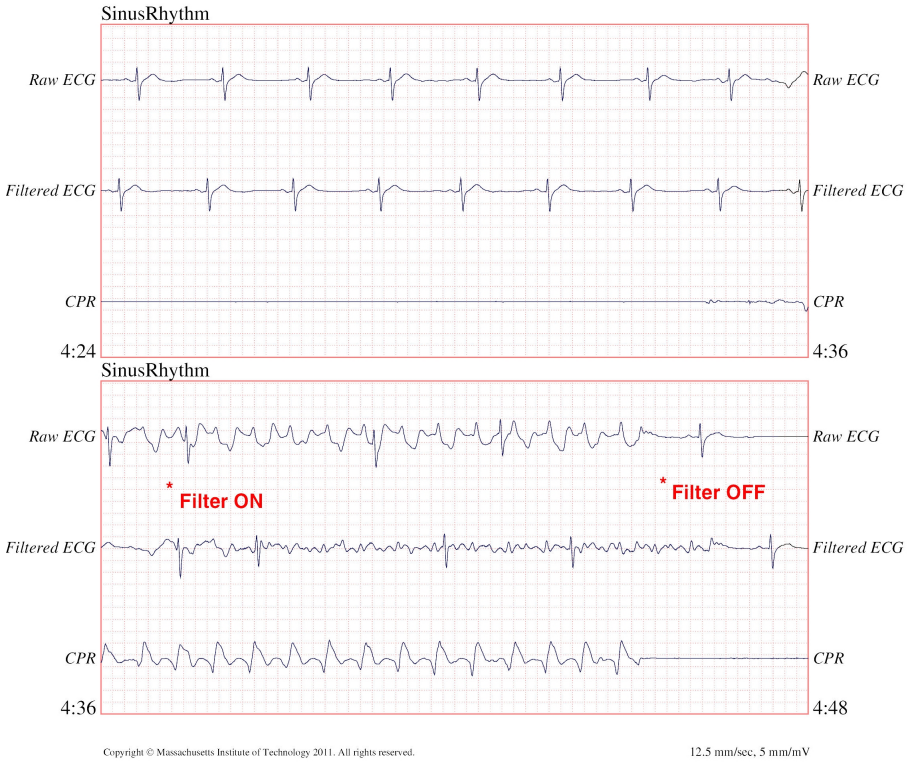
The following figure shows a patient in VF, which, during compressions, is slightly more difficult to discern. When viewing this ECG, it is possible to view the underlying rhythm as the filter is able to reject all of the CPR artifact.



The following figure shows a patient in PEA, which could easily be mistaken for Fine VF because enough of the compression artifact leaks through to distort this signal. When the CPR filter turns on, the PEA is still not obvious because of the left over ripples from the CPR signal. About 14 seconds into this chart, the rhythm changes to asystole, which could easily be mistaken for coarse VF. When the CPR filter turns on, the CPR compression ripples are still obvious, making the rhythm look like Fine VF.



The following figure shows a patient with an organized rhythm where See-Thru CPR effectively filters out artifact created by CPR.



Real BVM Help

The Zenix Real BVM Help feature provides ventilation feedback for systems connected to the AccuVent Sensor. Real BVM Help, available in Manual and AED advanced mode, displays measurements of ventilation rate and inspired volumes of manually delivered breaths.

Real BVM Help does not appear on the Zenix display when the Trend Table Display is open. Navigating away from the above resumes the display. Waveform, numeric data, and timing continues to record whether or not Real BVM Help is displayed.

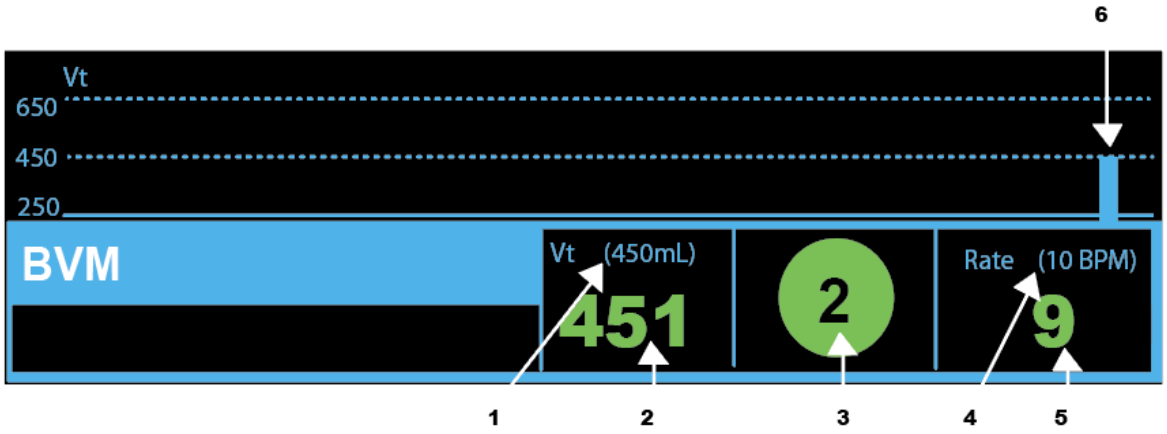
The AccuVent Sensor is for use on Adults only. It is not for use on pediatric patients.

The AccuVent input is Type BF defibrillator proof.

WARNING! The AccuVent Sensor is not approved for use in aircraft.

Real BVM Help Display

The Zenix Real BVM Help display provides ventilation feedback on inspired volume, breath rate, and quality of ventilation of manually delivered breaths. The table below describes the ventilation feedback items that can appear in the Real BVM Help display.

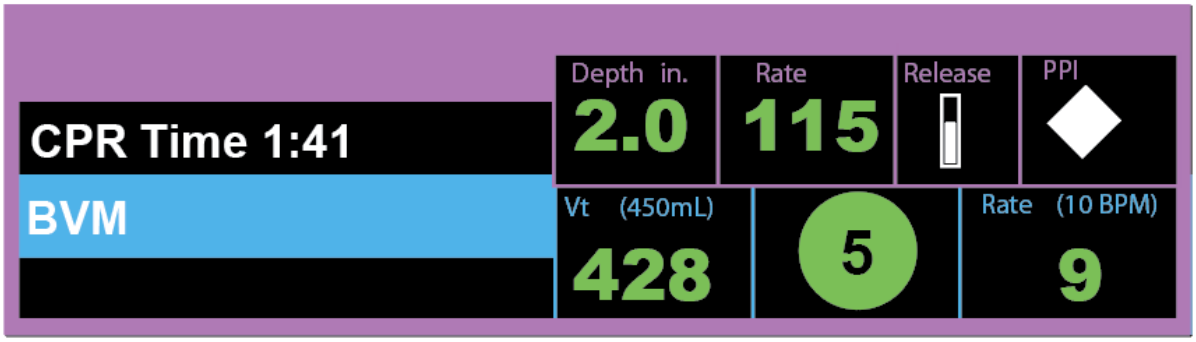


Item	Description
1	Configured Target Volume. Real BVM Help provides feedback on inspired volume by displaying the configured target volume and the current measured volume.
2	Current Measured Volume. Real BVM Help indicates when the measured volume falls within or outside of the configured target volume. The measured volume displays in green if it is within +/- 50 ml of the configured target and in yellow if it is outside that window. **Note:** The connection point of the cable to the sensor also displays in green within the configured target range and yellow outside of configured target range.

Item	Description
3	Ventilation Quality Indicator Ring with Countdown Ventilation Timer. Real BVM Help provides feedback on the quality of ventilation by displaying a ventilation quality indicator ring that fills as a breath completes. The indicator ring fills and changes color according to the quality of ventilation. The quality indicator ring displays in green when the quality of ventilation falls within range of the configured targets. It displays in yellow when it falls outside the configured targets. The ring also contains a timer that counts down to provide guidance to prepare for the next ventilation. The timer resets when it detects a breath.
4	Target Breath Rate. Real BVM Help provides feedback on breath rate by displaying the configured target breath rate and current measured breath rate. The target breath rate can be configured to be continuous or configured to a 30:2 target breath rate. When continuous, a breath is provided continuously at the configured target breath rate. A countdown timer is available in the Real BVM Help window that prompts you to deliver a breath. The timer resets when it detects a breath. A 30:2 target breath rate is based on 30 compressions at a rate of 105 compressions per minute followed by 2 breaths. The measured breath rate does not display in the Real BVM Help window when the ventilation rate is set to 30:2.
5	Measured Breath Rate. Identifies the current measured breath rate. The measured breath rate displays in green in the Real BVM Help display when it falls within range of the configured target and in yellow when it falls outside the configured target. Plus signs display in the Real BVM Help window when the measured breath rate is over 40 BPM. Dashes display when the rate is less than 4 BPM. The measured breath rate does not display in the Real BVM Help window when the target breath rate is set to 30:2
6	Tidal Volume Graph. If configured, Real BVM Help window displays a tidal volume bar graph of volume breath history. The graph automatically displays upon the first breath detection and shows changes in the tidal volume over time. The graph's center value represents the target volume and the minimum and maximum values are +/-200 mL of the target volume. **Note:** The tidal volume bar graph may not display depending on the currently displayed waveforms and their corresponding priority level.

With CPR

If the Zenix CPR Dashboard and Real BVM Help are active at the same time, the CPR dashboard displays above the Real BVM Help dashboard, and the ventilation bar graph displays above the compression bar graph. When either dashboard is removed, the other automatically returns to its original display.

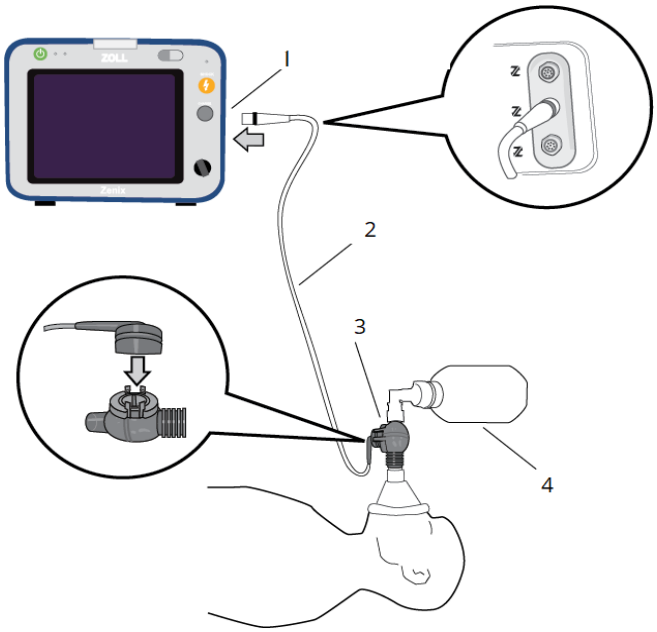


With Pacing

When Pacing and the Real BVM Help feature are active at the same time, the Pacing Dashboard displays on the top of the Real BVM Help dashboard and the ventilation bar graph displays above the Pacing Dashboard.

Using Real BVM Help

1. Connect the AccuVent Sensor to the patient as shown below. For accurate readings, ensure a tight seal between the mask and the patient as the AccuVent Sensor measures flow of air past the sensor.



Item	Description
1	Z-Link connection
2	Interface cable
3	AccuVent Sensor
4	Bag valve mask

Once the sensor and cable are fully connected to the Zenix device, it can take up to 5 seconds for the system to recognize a breath.

Note: The AccuVent Sensor is single use only. Do not use the sensor past its expiration date indicated on the packaging label.

2. Plug the AccuVent interface cable into any of the Z-Link ports located on the Zenix device as shown above. The Real BVM Help window displays with up to three other waveforms.

Note: The Real BVM Help window can be displayed at any time by administering a breath to the patient.

Important: The AccuVent interface cable should be cleaned between uses to prevent pathogen exposure to the patient.

3. Reference the table below for instructions on using Real BVM Help.

If you want to...	Do this...
Remove the Real BVM Help window	1. Select the **Real BVM Help** panel. The BVM Panel Settings window displays. 2. In the Panel tab, select **Remove Panel**. When the Real BVM Help window has been removed, the Zenix device continues to record ventilation information, including numeric, waveform, and timer data.
Add/Remove the Tidal Volume Graph	1. Select the **Tidal Volume Graph**. The Parameter Settings window displays. 2. In the Waveform tab, select **Remove Selected Waveform**. 3. Add the Tidal Volume Graph back to the display by following the steps above and selecting **Vt** from the list that displays.
Change the Target Volume	1. Select the **Real BVM Help** panel. The BVM Panel Settings window displays. 2. In the General tab, change the Target Vt (mL). If the device is powered off for less than 30 seconds, changes to the Target Volume are retained. If the device is powered off for 30 seconds or longer, the Target Volume returns to the default value.
Change the Target Breath Rate	1. Select the Real BVM Help panel. The BVM Panel Settings window displays. 2. In the General tab, change the Target Rate (BPM). If the device is powered off for less than 30 seconds, changes to the Target Breath Rate are retained. If the device is powered off for 30 seconds or longer, the Target Breath Rate returns to the default values. When Real BVM Help is active with a CPR Dashboard the Zenix device uses the Target CPR Breath Rate in the dashboard. **Note:** The measured breath rate does not display in the BVM Dashboard when set to 30:2 ventilation rate.

CHAPTER 7

Non-invasive Pacing

This chapter describes external pacing.

It includes the following sections:

External Pacing Overview 99

Pacing Adult Patients 100

Pacing Pediatric Patients 101

Pacing Messages 101



When ZOLL hands-free therapy electrodes are used, the patient connection is considered to be defibrillation-protected Type BF.



ECG leads are a defibrillation-protected Type CF patient connection.

WARNING!

- Pacing is intended for use on adult patients and on adolescent, child, and infant pediatric patients.
- 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. Consult the electrode directions for specific recommendations.
- Prolonged pacing (in excess of 30 minutes), particularly in adolescent, child, and infant pediatric patients or adults with severely restricted blood flow, may cause burns. Periodic inspection of the underlying skin is recommended.
- Poor adherence and/or air under the therapy electrodes can lead to the possibility of arcing and skin burns.
- Fixed pacing should be performed only in an emergency when no alternative is available.
- Determination of electrical capture should only be performed by viewing the ECG trace on the 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.

External Pacing Overview

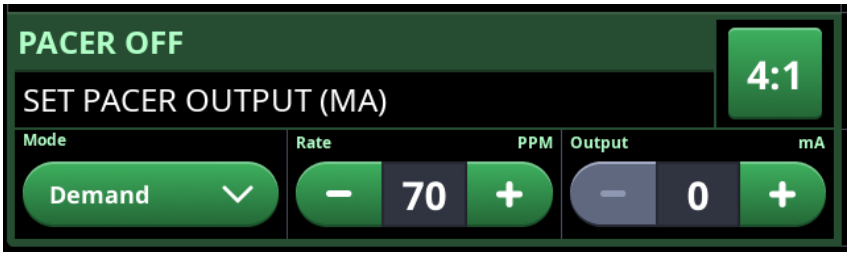
Zenix devices provide the capability for transcutaneous pacing for the emergency treatment of hemodynamically compromising bradycardia, bradycardia with escape rhythms that are unresponsive to pharmacological therapy, refractory tachycardia (supraventricular or ventricular), and bradyasystolic cardiac arrest.

The device offers either demand or fixed pacing options.

- **Demand Mode (default)** – In Demand mode, pacing pulses are inhibited by the patient's QRS complexes that occur during an interval that is dependent on the setting of the rate control. If during that interval no QRS complexes are detected, a pacing pulse is delivered to the patient. In 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.
- **Fixed Mode** – In Fixed mode, pacing pulses are not dependent on the patient's cardiac activity. Fixed pacing should be performed only in an emergency when no alternative is available. The pacer delivers pacing pulses at the selected pacing rate.

Pacing Adult Patients

1. **Prepare patient** and device by:
    a. Removing all clothing covering the patient's chest.
    b. Drying the chest if necessary.
    c. Removing excessive hair to ensure proper adhesion of the electrodes.
    d. Attaching hands-free therapy electrodes according to instructions on the electrode packaging. Proper demand pacing requires a reliable, high quality surface ECG signal.
    e. Ensuring 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.
    f. Connecting the hands-free therapy electrodes to the multi-function cable (MFC) if not already connected.
    g. Selecting the waveform and choose I, II, or III to provide the largest amplitude QRS complex. When the Pacer is on, the lead selection is restricted to Leads I, II, or III.
2. Select **PACER** at the top of the display screen. The Pacer window displays. The mode defaults to Demand.



Note: If desired, change to Fixed mode by selecting the button under Mode and choosing **Fixed**.

3. Set the Pacer rate by using the + and - keys in the **Rate** field. Use 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 5 ppm. Follow local protocol to determine rate.
4. Turn on the Pacer by using the + and - keys in the **Output** field to adjust the output value. You can adjust the pacer output in 5 mA increments. Once the output value is greater than zero, the Pacer turns on. Observe the patient and ECG for evidence of electrical capture. Select the lowest output current that achieves both electrical and mechanical capture. Follow local protocol to determine capture.

4:1 Mode

Pressing the **4:1** key reduces the pacing stimuli to 1/4 of the ppm setting for 10 seconds thereby allowing you to observe the patient's underlying ECG rhythm and morphology. When you press the 4:1 key the background changes to blue with a 10 second countdown timer. When the 10 seconds is up the Zenix device automatically returns to the ppm setting rate.

Pacing Pediatric Patients

Non-invasive 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 55 lbs/25 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 device may display the following messages when pacing.

System Message	Description
PACER PAUSED	The pacer has paused pacing the patient.
PACER	The pacer is pacing the patient.
PACING LEAD SHORT	The pacer output is short circuited due to a test plug connection or a device/MFC fault.
PACING LEAD FAULT	Pads became disconnected while delivering pacing. Reconnect the pace pads.

CHAPTER 8

Monitoring ECG

This chapter describes how to monitor ECG using the Zenix device.

It includes the following sections:

Overview 105

Preparing the Patient for Electrode Application 105

Applying Electrodes to the Patient 106

Connecting the ECG Cable to the Device 108

Configuring the Waveform Display 109

ECG Monitoring and Pacemakers 110

ECG System Messages 111

ECG Lead Fault Identification 112



ECG leads are a defibrillation-protected Type CF patient connection.

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 assure 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 device 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.

Overview

With the Zenix device you can monitor ECG with 3-, 5-, and 12-lead ECG, paddles, and multi-function electrodes. For monitoring and acquisition of a 12-lead diagnostic ECG, see "12-Lead ECG Interpretive Analysis" on page 113.

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 necessary:

1. Clip or shave excess hair at electrode site.
2. Clean the electrode sites with mild soap and water or a non-alcoholic wipe.
3. Rub site briskly to dry.
4. Abrade the skin lightly at electrode site.

Applying Electrodes to the Patient

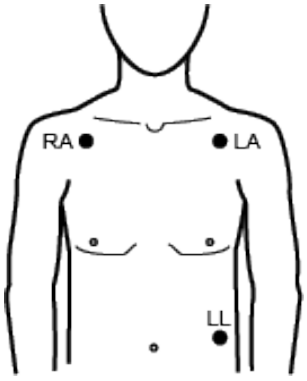
The following sections show where to place electrodes when using 3- and 5-Lead cables to perform ECG monitoring. When applying electrodes to the patient:

- Do not remove electrodes from packaging until they are ready for patient use.
- Do not connect electrodes to lead wires until just before patient application.
- Do not press directly down onto the head of the lead wire when attaching the electrode to the patient.
- Avoid placing electrodes over tendons, major muscle masses or bony prominences.
- Make sure that the ECG electrodes are placed to allow defibrillation, if necessary.
- If using hands-free therapy electrodes for ECG monitoring, attach the hands-free therapy electrodes according to instructions on the electrode packaging.

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.

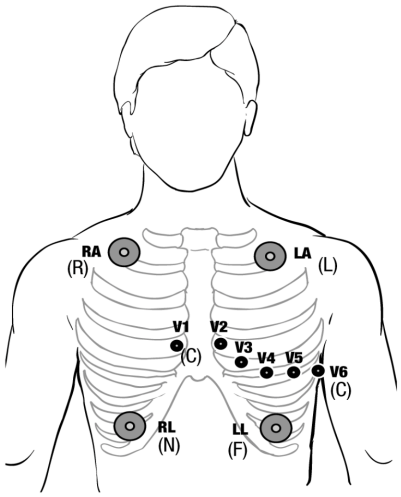
AAMI Color Coding	IEC Color Coding	Placement of Electrodes
RA/White Electrode	R/Red Electrode	Place near patient's right mid-clavicular line, directly below clavicle.
LA/Black Electrode	L/Yellow Electrode	Place near patient's left mid-clavicular line, directly below clavicle.
LL/Red Electrode	F/Green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



5-Lead Electrode Placement

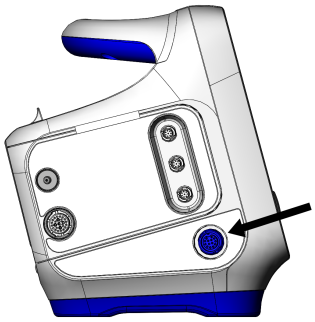
Depending upon local usage, the ECG leads are marked either RA, LA, LL, RL, and V or R, L, F, N, and C. The following table shows the markings and color codes for the different lead sets.

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 - 4th intercostal space at right sternal margin. V2 - 4th intercostal space at left sternal margin. V3 - Midway between V2 and V4 leads. V4 - 5th intercostal space at mid-clavicular line. V5 - Same transverse level as V4 at left anterior-axillary line. V6 - Same transverse level as V4 at left mid-axillary line.



Connecting the ECG Cable to the Device

Connect the ECG cable to the ECG connector on the left side of the device. Make sure that pins are lined up when inserting cable. Push the connector until it clicks.



Configuring the Waveform Display

You can display up to four waveforms on the Zenix device. The first waveform at the top of the display window is always an ECG waveform. When more than two waveforms appear on the waveform display window, the numeric parameter panel displays move to line up with the applicable waveform trace.

You can configure the waveform display in various ways, such as specifying the lead or adding or deleting a waveform. See the table below to perform these functions.

Note: You cannot delete the ECG waveform at the top of the display.

To	Do This
Specify the Lead Source	1. Select the primary ECG waveform. The ECG Settings window displays. The Lead tab displays a list of available ECG waveform sources. 2. Select the lead source from the available options. The device immediately displays the new waveform trace.
Insert a Waveform	1. Select an ECG waveform. The ECG Settings window displays. 2. Select the **Waveform** tab and select the number of ECG waveform traces you want to display from the **Display ECG Waveforms** field. 3. To add a waveform trace from another available monitoring parameter, select a parameter from the list in the **Insert Parameter Waveform** field.
Delete a Waveform	1. Select an ECG waveform. The ECG Settings window displays. 2. Select the **Waveform** tab and select the number of ECG waveform traces you want to display from the **Display ECG Waveforms** field. The bottom ECG waveform trace(s) will be deleted. For example, if you have four waveform traces displayed and select 2, the bottom two traces will be deleted. 3. To remove a waveform trace from another available monitoring parameter, select the parameter waveform trace. The Parameter Settings window displays. 4. Select the Waveform tab and select **Remove Selected Waveform**.
Adjust the Size and Speed of the Waveform Trace	1. Select the ECG waveform. The ECG Settings window displays. 2. Select the **Waveform** tab. Select the size from the drop-down menu in the **Size (cm/mV)** field. 3. Select 25 or 50 from the **Speed (mm/s)** field.

ECG Monitoring and Pacemakers

When the device performs ECG monitoring on a patient with an implantable pacemaker, the device can indicate the occurrence of pacemaker signals.

When the Zenix device Patient Pace Marker setting is **On**, the device 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 accurate QRS detection.
- Displays and prints vertical dashed lines to indicate the detected pacemaker signals.

When the Patient Pace Marker setting is **Off**, the Zenix device does not detect the implantable pacemaker pulses. This means that the pacemaker will be embedded into the ECG waveform. A visual indication in the top trace will identify when this setting is off.

To turn the Patient Pace Marker **On/Off**:

1. On the Zenix display, select the HR numeric.
2. In the HR Settings window, select the **General** tab.
3. In the Patient Pace Marker field, select **On** or **Off** as appropriate. If the patient has a cardiac pacemaker, the Pacer Indicator should be set to **On** indicating that pace pulse detection is on. When you select **On**, the Zenix device will display a pace marker on the top trace when an implanted pace maker pulse is detected.

There are situations where ECG artifact could simulate pacemaker signals which could cause false pacemaker detection and blanking. These situations may cause inaccurate QRS detection and it may be desirable to turn the Patient Pace Marker off. Inversely, when the Patient Pace Marker setting is **Off**, implantable pacemaker signals may cause inaccurate QRS detection and it may be desirable to turn the Pacer Indicator on.

Note: Implanted pacemakers can affect QRS detection. Due to the wide variety of implantable pacemakers, QRS detection may not always be detected by the Zenix device.

ECG System Messages

When monitoring ECG, the device may display the following messages:

System Message	Cause
ECG LEAD FAULT	The current ECG source lead has lost its signal (check lead and replace, if necessary). An unavailable waveform source has been specified for the trace display (check specified waveform source and correct, if necessary). One or more ECG lead(s) is disconnected (check for disconnected lead(s) and reconnect). • When one ECG lead is disconnected (with the exception of RL), the Zenix device displays the ECG Lead Fault message, identifies the disconnected lead, and displays all available waveform traces based on the currently connected electrodes. See “ECG Lead Fault Identification” on page 6-11. The Zenix device does not display available waveform traces when 3 ECG Lead electrode placement is in use and one lead becomes disconnected. If the RL electrode is disconnected or if two or more electrodes are disconnected, the Zenix device displays the message ECG LEAD FAULT - CHECK LEADS.
PAD/PADDLE FAULT or CABLE FAULT	Check the pad, paddle, or cable and replace if necessary.

Note: If an ECG monitoring cable is intentionally disconnected, you can disable the Lead Fault alarm by Pausing (Suspending) the alarm audio. See "Pausing Alarms" on page 212 for more information.

ECG Lead Fault Identification

The following table identifies the lead that displays with the ECG Lead Fault system message when a single identifiable electrode is detached.

Note: The table below applies to 4-Lead, 5- Lead, and 12-Lead electrode placement. No lead identification occurs when 3 ECG Lead electrode placement is in use and one lead becomes disconnected.

		Displayable Leads											
		V1	**V2**	**V3**	**V4**	**V5**	**V6**	**I**	**II**	**III**	**aVR**	**aVL**	**aVF**
Detached Electrode	**LA**								√				
	LL							√					
	RA									√			
	RL												
	V1		√	√	√	√	√	√	√	√	√	√	√
	V2	√		√	√	√	√	√	√	√	√	√	√
	V3	√	√		√	√	√	√	√	√	√	√	√
	V4	√	√	√		√	√	√	√	√	√	√	√
	V5	√	√	√	√		√	√	√	√	√	√	√
	V6	√	√	√	√	√		√	√	√	√	√	√

CHAPTER 9

12-Lead ECG Interpretive Analysis

This chapter describes how to monitor 12-Lead ECG for adult and pediatric patients and how to display 12-Lead ECG Interpretive Analysis information for adult patients.

It includes the following sections:

Overview 114

12-Lead ECG Monitoring Setup 116

12-Lead ECG Window 120



The 12-Lead input is Type CF defibrillator proof.

Overview

12-Lead ECG monitoring allows you to acquire and store 12-Lead information for adult and pediatric patients. In addition, when enabled, post-acquisition Interpretive Analysis is available for adult patients.

With 12-lead ECG monitoring you can:

- Acquire and display 12 Leads of ECG data.
- Print 12-lead snapshots following acquisition.
- Transmit a 12-Lead report to a pre-configured destination.

Warnings

- 12-Lead ECG monitoring is intended for the recording of 12-lead ECG 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 and analysis. Use of the device to acquire ECG signals from moving or shaking patients may produce noisy signals that are difficult to interpret.
- The 12-Lead Interpretive algorithm's interpretive statements are designed to enhance the diagnostic process. They are no substitute for the qualified judgment of a properly trained clinician. As with any diagnostic test, always give consideration to patient symptoms, history, and other relevant factors.
- 12-Lead Interpretive Analysis is for use with adult patients *only*.
- It is important to enter each patient's age and gender prior to performing ECG analysis using the Inovise 12L Interpretive Algorithm. Providing patient age and gender will ensure that highest accuracy of ECG analysis is attained. If age is not provided, a default of 45 years is used. If gender is not provided, the default is male.
- 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.
- When not in use, cover the patient cable's V-lead connector with the supplied plastic cap. Failure to do so may result in a shock hazard during defibrillation attempts.
- To ensure protection against the effects of defibrillator discharge, use only 12-lead cables supplied by ZOLL Medical Corporation.
- Check the operation and integrity of the device and 12-lead cable regularly by performing the Daily Operational Verification Test. See "Daily Visual Inspection" on page 259.
- When attempting to interpret subtle ECG changes (such as ST segments), use only the Diagnostic Frequency Response setting. Other frequency response settings may cause misinterpretation of the patient's ECG.
- Use only ZOLL-approved accessories to ensure the Type CF defibrillator-proof rating of the 12-Lead input.
- 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 ECG Monitoring Setup

Perform the following steps to set up 12-lead ECG monitoring:

1. Enter patient demographic information.
2. Prepare the patient's skin for electrode placement.
3. Apply electrodes to patient.
4. Connect the 12-Lead cable to the device and observe the 12-Lead waveform traces.

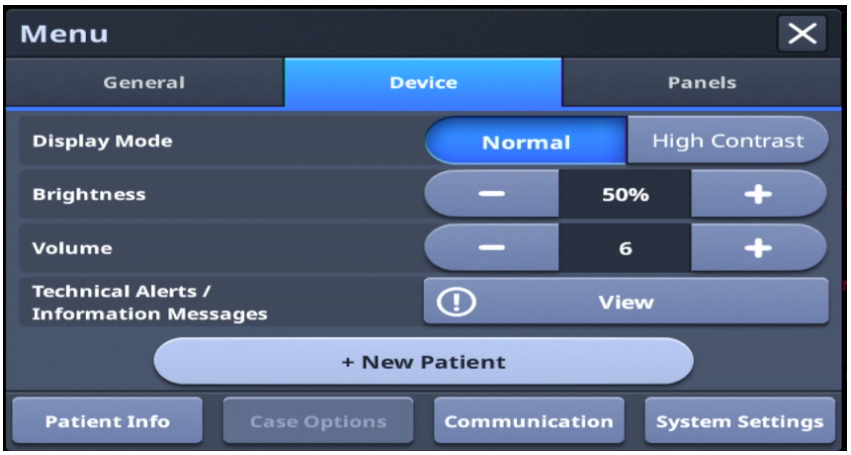
Each of the steps above are described in the following sections.

Enter Patient Information

The Zenix device uses the name that you enter in the Patient Info panel to label the 12-lead ECG monitoring snapshots it saves. It is important that you provide the patient's age and gender prior to performing ECG analysis using the Inovise 12L Interpretive Algorithm. Entering the correct age and gender ensures that the highest degree of ECG analysis is obtained. If you do not provide the patient's age or gender the device uses the default age (45 years) and default gender (male).

To enter patient information:

1. Select the **Menu** key  on the bottom of the display window. The Menu window displays.



2. Select **Patient Info** button on the bottom of the window. The Patient Information window displays,
3. Specify the patient's age by using the **+** or **-** keys in the **Age** field as appropriate. The default patient age is 45.
4. Indicate the patient's gender by selecting the **Male** or **Female** key in the **Gender** field as appropriate.
5. Specify the patient's name by selecting the **Last Name**, **First Name** or **Middle Name** field as appropriate then using alphabetical keypad that displays to enter the name. When you are done entering data, select **X** to exit.
6. When you are finished using the Patient Information window, select the **X** on the top right of window.

Prepare 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 necessary:

1. Clip or shave excess hair at electrode site.
2. Clean the electrode sites with mild soap and water or a non-alcoholic wipe.
3. Rub site briskly to dry.
4. Abrade the skin lightly at electrode site.

Apply Electrodes to the Patient

When applying electrodes to the patient:

- Avoid placing over tendons and major muscle masses.
- Make sure that the ECG electrodes are placed to allow defibrillation, if necessary.
- Refer to the following table for labels and color codes for the different lead sets. Depending on local usage, ECG lead wires are marked with certain labels.

Important: ZOLL-approved ECG cables are not intended for direct cardiac application.

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

To apply electrodes to the patient:

1. Place patient in a resting, supine position.
2. Place the limb electrodes anywhere along the ankles and wrists.

Note: There should be uniformity in the placement of ECG electrodes. If a patient has an amputated limb, ensure similar placement of arm and leg leads. For instance, do not attach one electrode on the right wrist and one on the left upper arm.

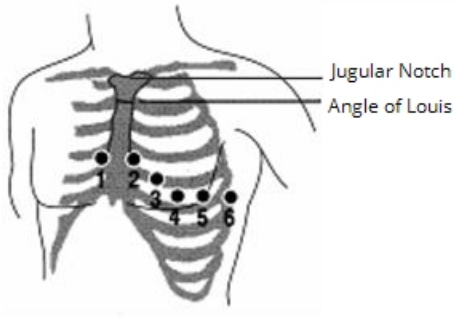
3. Place the precordial electrodes across the chest as follows:

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.

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

a. Place your finger on top of the jugular notch (see figure below).

b. Move your finger slowly downward about 1.5 inches (3.8 centimeters) until you feel a slight horizontal ridge or elevation. This is the "Angle of Louis," where the manubrium joins the body of the sternum.



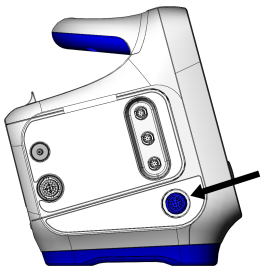
c. Locate the second intercostal space on the patient's right side, lateral to and just below the "Angle of Louis."

d. Move your finger down two more intercostal spaces to the fourth intercostal space which is the V1 position.

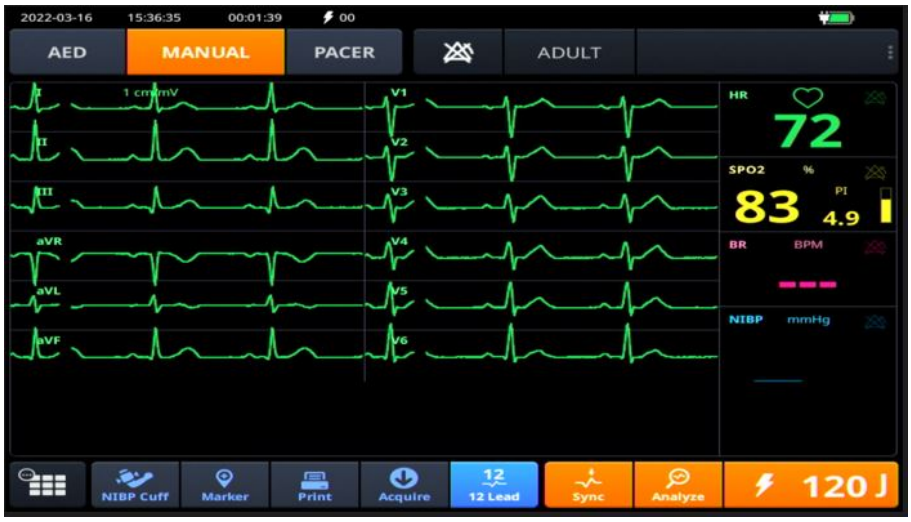
Note: When placing electrodes on female patients, always place leads V3-V6 under the breast rather than on the breast.

Connect the 12-Lead Cable and Observe Waveforms

Connect the 12-Lead ECG cable to the ECG input connector on the left side of the device.



To observe the 12-Lead waveform traces, select the **12-Lead** key  on the bottom of the Zenix display. All twelve waveform traces display in two columns with the size displayed above the waveform traces.



12-Lead ECG Window

The 12-Lead ECG Window allows you to:

- Initiate and review a 12-Lead Interpretive Analysis.
- Print 12-Lead waveform traces.
- Transmit 12-Lead data to a pre-configured destination.

The sections that follow describe how to perform each of the functions above.

12-Lead Interpretive Analysis

If 12-Lead Interpretive Analysis is enabled on your device, after observing the patient's ECG and determining that all 12-lead traces display correctly, you can initiate 12-Lead Interpretive Analysis.

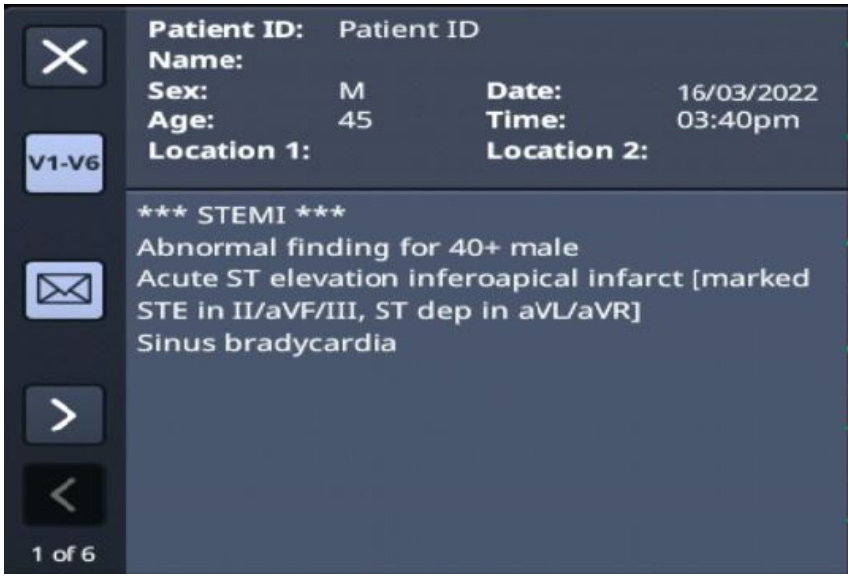
Note: 12-Lead Interpretive Analysis is for patients 18 years of age and older only. It is important that you provide the patient's age and gender prior to performing ECG analysis. If the patient's age and gender are not provided, the device uses the default age (45 years) and default gender (male). See "Enter Patient Information" on page 116.

To begin 12-Lead Interpretive Analysis:

1. Select the **Acquire** key  on the bottom of the display.
2. If the Patient Info window displays,
    a. Verify the patient age and gender as appropriate.
    b. Select **Confirm**.

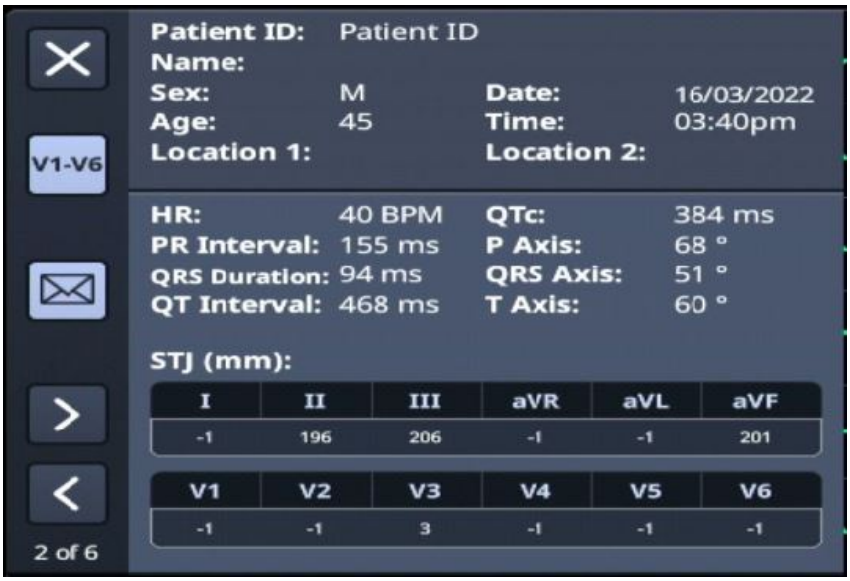
3. The *Acquiring 12-Lead* message displays followed by the *Saving 12-Lead* message. When complete, the first page of 12-Lead Analysis information appears. If Lead Analysis is enabled and Interpretive Text is set to On, the first page of the 12-Lead Analysis information includes interpretive statements. Otherwise, the first page shows the numeric analysis results only.

   In the example below, the interpretive statement, ***STEMI***, indicates the occurrence of ST-Elevation Inferoapical Infarction.



Note: The interpretive statements that the device displays are produced by the Audicor software of Inovise Medical, Inc. For more information on these interpretive statements, see the *Inovise 12L Interpretive Algorithm Physician's Guide* . The 12 lead isoelectric values are used with the STJ point to calculate the STJ values that are presented after the 12 lead Acquisition.

4. To display *Analysis Page 2*, select the Forward **>** key on the left side of the 12-Lead ECG Window. The *Analysis Page 2* displays with measurements.



5. Select **>**, as desired, to view four additional 12-Lead snapshot pages sequentially.

Fault Conditions Affecting 12-Lead Interpretive Analysis

The device will not perform Interpretive Analysis if it detects one of the following fault conditions when attempting to acquire 12-Lead data:

- A pacer signal is present.
- A lead fault is detected in the ECG cable.
- An invalid cable is in use.

If the device detects one of these fault conditions, *Analysis Page 1* indicates that there is *NO DATA AVAILABLE* for Interpretive Analysis and lists the fault condition; all measurements on *Analysis Page 2* appear as *N/A*.

Once you have corrected the fault condition, select the **Acquire** key to confirm the correction and perform the 12-Lead Interpretive Analysis.

12-Lead Print

Your Zenix device may be configured to automatically print upon 12-Lead acquire. If not, the Zenix device allows you to print the 12-lead traces for review and analysis. The 12-Lead information prints in the format currently set up for your device and includes the heart rate, PR interval, QRS duration, QT interval, P axis, QRS axis, T axis, and STJ segment values.

Note: For information on printing previously acquired 12-lead data for the current patient case see "Viewing/Printing/Transmitting 12-Lead Snapshots" on page 242.

To print 12-Lead waveform traces:

1. If necessary, select the **Acquire** key to collect 10 seconds of 12-Lead data for print.
2. Select the **Print** key on the bottom of the Zenix display. The 12-lead snapshot prints in the print format currently setup for your device. The 12-lead printed snapshot includes a header that gives the date, time, and patient information, followed by 2.5 second samples of all twelve waveform traces.
3. When you are done viewing and printing the 12-Lead waveform traces, select the **X** key on the left side of the 12-Lead ECG Window.

Transmitting a 12-Lead Report

Once 12-lead data has been acquired or previously acquired, you can transmit the results to a pre-configured distribution list.

To transmit a 12-Lead Report:

1. Select the **12-lead** key (12).
2. Select the **Acquire** key . The **Verify patient age and gender** screen displays.
3. Verify the patient age and gender then select **Confirm**. The Zenix device collects 10 seconds of 12-Lead data.
4. Select the **Transmit** key. A list of pre-configured distribution lists displays.
5. Use the navigation keys to highlight and select the desired location to transmit the 12-Lead data.
6. Select the **Transmit** button to initiate the 12-lead report transmission.

CHAPTER 10

Monitoring Respiration (RR/BR) and Heart Rate (HR)

This chapter describes how to monitor Respiration (RR/BR) and Heart Rate (HR) on the Zenix device.

It includes the following sections:

Overview 126

The Resp (RR/BR) Settings Window 128

Heart Rate Meter 130

The Heart Rate (HR) Settings Window 131

RESP System Messages 133

Overview

The Zenix device displays Respiration (RR/BR) and Heart Rate (HR) meters. The Respiration and Heart Rate meters display values that the device derives from measurements taken by other monitoring functions.

Respiration Rate/Breath Rate Meter

The respiration meter displays the respiration rate that it derives, by default, from the device's monitoring functions. The device derives respiration rate from EtCO2 monitoring if available and active. If EtCO2 monitoring is not available, the device derives the respiration rate through impedance pneumography if available and active. If no source of respiration rate is available and active then the device 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 ECG electrode Lead I (RA-LA) or Lead II (RA-LL). As the patient inhales and chest volume expands, impedance increases; as the patient exhales, impedance decreases.

Note: The availability of the impedance pneumography feature to measure respiration rate is subject to local regulatory approval and may not be available in all regions, including the United States, at this time. For more information on approvals, please reach out to your local representative.

WARNING!

- When using impedance pneumography, the device automatically rejects cardiovascular artifact (CVA). This function requires accurate ECG R-wave detection. Therefore, always select the ECG lead with the most prominent QRS complex when using impedance pneumography to monitor respiration.
- Impedance pneumography detects respiratory effort through changes in chest volume. However, apnea episodes with continued respiratory effort may go undetected. 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 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.
- Due to susceptibility for motion and vibrations, it may not be appropriate to use impedance pneumography with patients during active transport.
- When using impedance pneumography, do not use the Zenix device with another respiration monitor that also uses impedance pneumography on the same patient. The respiration measurement signals may interfere with one another and could affect the respiration accuracy.

- Impedance pneumography is *not* recommended for use on paced patients, because pacemaker pulses may be falsely counted as breaths.
- Impedance pneumography is not recommended for use with high frequency ventilation.
- Since impedance pneumography uses the same leads as the ECG channel, the Zenix device determines which signals are 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 ignore breaths and trigger a respiration alarm.

The Resp (RR/BR) Settings Window

Select the RR/BR Rate parameter numeric to display the RR/BR Settings window. Use this window to:

- Enable/disable respiration monitoring.
- Select the Resp lead from which the device calculates the respiration rate. Resp Lead selection is independent of ECG Lead selection.
- Enable/disable the Resp alarm and set high/low alarm limits.

Adjusting Resp (RR/BR) Settings

To adjust the Resp (RR/BR) settings:

1. Select the RR/BR numeric on the right side of the window. The RR/BR Settings window displays:



2. In the General tab, select **On** or **Off** as appropriate in the **Resp Monitoring**. When set to **Off**, the device removes the Respiration Rate meter from the display.
3. Select **On** or **Off** as appropriate in the **Resp Waveform** field. When set to **Off**, the device removes the Respiration Waveform from the display.
4. Select the appropriate lead from the **Resp Lead** field. The Zenix device uses this lead to calculate the respiration rate.

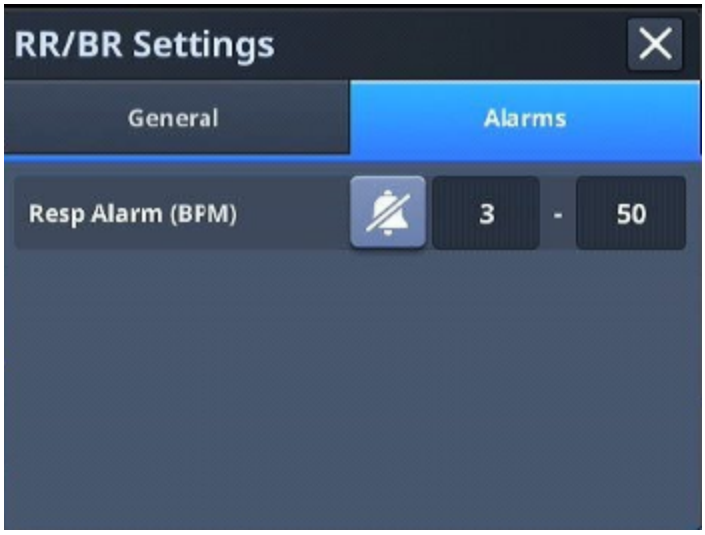
   Note: Resp Lead selection is independent of ECG Lead selection.

5. Select **On** or **Off** as appropriate in the CO_2 Monitoring field. When set to **On**, CO_2 replaces the Breath Rate (BR) meter. When set to **Off**, the BR meter displays.
6. When you are done making adjustments to the RR/BR settings, select **X** to exit the window.

Adjusting Resp Alarm Settings

To adjust the Resp alarm settings:

1. Select the RR/BR numeric on the right side of the window. The RR/BR Settings window displays.
2. Select the Alarms tab. The RR/BR Alarms Settings panel displays.



See the"Respiratory Rate (RR/BR) Alarm Limits" on page 219for default alarm limits and low and high alarm ranges.

3. Enable the Resp alarm by selecting the **Alarm** icon. When enabled, an alarm sounds whenever the patient's respiration rate is above or below the specified limit value.
4. Specify an upper alarm limit value, if necessary, by selecting the upper limit value. Use the keypad and/or up and down arrows to enter the upper limit value. Select **OK**.
5. Specify a lower alarm limit value, if necessary, by selecting the lower limit value. Use the keypad and/or up and down arrows to enter the lower limit value. Select **OK**.
6. When you are done making adjustments to the RR/BR settings, select **X** to exit the window.

Heart Rate Meter

The Heart Rate meter displays the heart rate that it derives from the ECG monitoring function (by default) or from a monitoring function that you specify.

If the ECG (or user-specified monitor function) measurements are not available, the Heart Rate meter derives the heart rate from the following monitoring functions, if they are available, in this order:

- User-selected default source
- ECG
- SpO_2
- NIBP

When the heart rate source is ECG, the device labels the Heart Rate meter HR. It labels the Heart Rate meter PR if any other source is used.



The Heart Rate (HR) Settings Window

Select the HR parameter numeric to display the HR Settings window. Use this window to:

- Specify whether or not an audible tone will sound when a patient's pulse is detected.
- Select the monitoring source from which to derive the heart rate. The device derives the heart rate from the ECG monitoring function (by default) or from a monitoring function that you specify.
- Enable/disable patient pace marker.
- Set HR/PR high/low alarm limits.
- Enable/disable LTA alarms and set Extreme Brady/Tachy alarm limits.
- Display number of waveforms.

Adjusting Heart Rate Settings

To adjust the Heart Rate (HR) settings:

1. Select the HR numeric on the right side of the window. The HR Settings window displays:

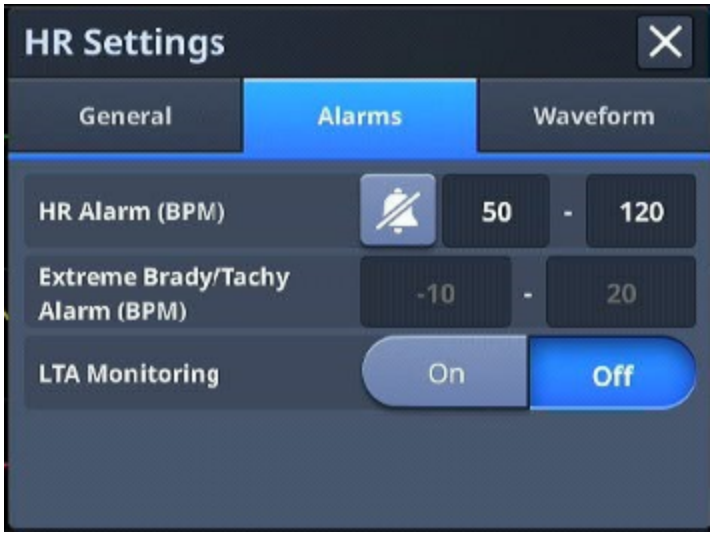


2. In the **HR Tone** field, select **On** or **Off** to enable/disable the option. When set to **On**, an audible tone sounds when a patient's pulse is detected.
3. In the **HR/PR Source** field, select the monitoring source from which to derive the heart rate/pulse rate (ECG, SpO_2, NIPB). The current source displays in the following field.
4. In the **Patient Pace Marker** field, select **On** or **Off** to enable/disable the option. If the patient has a cardiac pacemaker, the Pacer Indicator should be set to **On** indicating that pace pulse detection is On. When you select **On**, the Zenix device displays a pace marker on the top trace when an implanted pace maker pulse is detected.
5. Select the Waveform tab. Select the number of traces you want to display in the **Display ECG Waveforms** field.
6. When you are done making adjustments to the HR settings, select **X** to exit the window.

Adjusting Heart Rate Alarm Settings

To adjust the HR alarm settings:

1. In the HR Settings window, select the **Alarms** tab.



Note: See "Alarms" on page 205 for default alarm limits and low and high alarm ranges.

2. In the **HR Alarm (BPM)** field, enable the alarm by selecting the **Alarm** icon. When enabled, an alarm sounds whenever the patient's rate is above or below the specified limit value.
3. Specify a HR upper alarm limit value, if necessary, by using the keypad and/or up and down arrows to enter the upper limit value.
4. Specify a HR lower alarm limit value, if necessary, by using the keypad and/or up and down arrows to enter the lower limit value.
5. If LTA alarms are enabled, set Extreme Tachy and Extreme Brady alarm limits by doing the following:
    a. Specify an upper alarm limit value by using the keypad and/or up and down arrows to enter the upper limit value.
    b. Specify a lower alarm limit value by using the keypad and/or up and down arrows to enter the lower limit value. See "Adjusting Heart Rate Alarm Settings" above for more information on extreme brady/tachy alarms.
    c. In the **LTA Monitoring** field, select **On** or **Off** to enable/disable the option. When LTA monitoring is enabled, the Zenix device monitors for the following life-threatening ECG rhythms: asystole, ventricular fibrillation, ventricular tachycardia, extreme bradycardia, and extreme tachycardia. See "Latching Alarms" on page 213 for more information on LTA monitoring.
6. When you are done making adjustments to the HR settings, select **X** to exit the window.

RESP System Messages

When monitoring Respiration using impedance pneumography, the Zenix device may display the following message:

System Message	Cause
RESPIRATION FAULT	The impedance measured through the ECG lead is too high for the device to detect Respiration changes, but not high enough to indicate an ECG lead fault (the impedance may vary between 1800 and 2800 ohms).

CHAPTER 11

Monitoring Non-invasive Blood Pressure (NIBP)

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

It includes the following sections:

Overview 136

NIBP Setup 138

NIBP Settings Window 143

Taking Measurements 146

NIBP System Messages 147



The NIBP input is Type BF defibrillator proof.

Overview

The NIBP option non-invasively measures arterial blood pressure and pulse rate in resting adult and pediatric patients.

You can use the NIBP option to:

- Take a single blood pressure measurement.
- Repeat automatic measurements at pre-selected intervals.
- Immediately stop any measurement in progress.
- Set the cuff inflation pressure to adjust automatically based on the previously measured systolic value.
- Display systolic, diastolic, and mean blood pressure on the screen.
- Configure alarms to go off when the device detects blood pressure values above or below user-programmable limits.

How NIBP Works

The Zenix device measures arterial blood pressure using the oscillometric method. In this approach, a cuff placed on the upper arm is inflated and then deflated while the pressure inside the cuff is measured. When the blood pressure cuff and hose are connected to the Zenix device and a blood pressure measurement is initiated, the Zenix device measures the oscillometric pulses transmitted through the blood pressure cuff and hose and uses them to calculate the corresponding systolic, diastolic, and mean blood pressure, as well as the patient's pulse rate.

The Zenix device automatically adjusts the blood pressure measurement procedure in response to certain error conditions such as:

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

The NIBP Numeric Display

When NIBP monitoring has been set up and the device has begun taking NIBP measurements, the systolic, diastolic, mean blood pressure measurements, and alarm status icon appear on the NIBP numeric display as follows:



An asterisk *appears next to the NIBP numeric whenever the Zenix device detects that NIBP measurements (systolic, diastolic, mean) may be inaccurate. The asterisk displays when NIBP measurements are below the specified measurement range for the selected patient type or when the accuracy of NIBP measurements may be compromised by the presence of motion artifact, weak pulses, cardiac arrhythmias, or other blood pressure artifacts.

When reading the blood pressure values, keep in mind that the following conditions can influence NIBP measurements:

- Position of the patient
- Position of the cuff relative to the patient's heart
- Physical condition of the patient
- Patient limb movements
- Convulsions or tremors
- Very low pulse volumes
- Premature ventricular beats
- Vibrations in the cuff or hose caused by moving vehicles
- Improper cuff size or application

NIBP Setup

To take safe and accurate NIBP measurements 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.

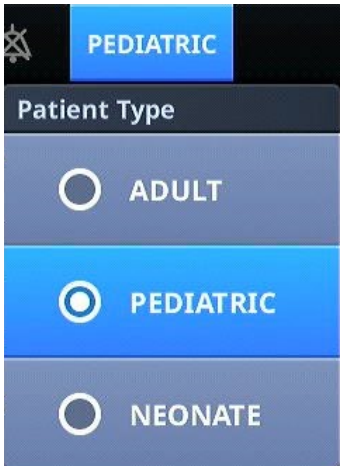
1. Verify the inflation hose is connected and secured to the port on the device.
2. Verify the patient type.
3. Select the correct size cuff.
4. Apply the cuff to the patient.
5. Verify the cuff inflation settings.

Verify Patient Type

It is important that the patient type is correct before performing NIBP measurement as the patient type determines the default cuff inflation pressure, as well as default alarm limits for high/low systolic, diastolic, and mean blood pressure values.

To select a patient type for NIBP measurements:

1. On the Zenix navigation bar, select the current patient type key. The Patient Type drop-down menu displays.



2. Select the appropriate patient type from the drop-down menu.

Select the NIBP Cuff

To take accurate measurements:

- 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 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 40 percent of the limb circumference.

  Caution: Using a cuff that is too small results in measurements higher than the patient’s actual blood pressure. Using a cuff that is too large results in measurements lower than the patient’s actual blood pressure.

  Use the following guidelines when selecting the appropriate hose and cuff:

Cuff	Limb Circumference
Child	12 to 19 cm (4.72 to 7.48 in.)
Small Adult Plus	18 to 29 cm (7 to 11.4 in.)
Adult Plus	28–40 cm (11 to 15.75 in.)
Large Adult Plus	40–55 cm (15.75 to 21.65 in.)

The Zenix device uses the same definitions for Pediatrics and Adults as defined in the AAMI SP10:2002 standard.

With Condition of Hypertension:

Note: The following steps should be taken to obtain accurate routine resting BP measurements for the condition of hypertension, including:

a. Ensure patient is comfortably seated.
b. Ensure legs are uncrossed.
c. Ensure feet are flat on the floor.
d. Ensure the back and arm are supported.
e. Check that the middle of the cuff is at the level of the right atrium of the heart.
f. The patient should relax as much as possible and not talk during the measurement procedure.
g. 5 minutes should elapse before the first reading is taken.

Apply 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 on the floor, and back supported. The limb to use for NIBP measurement should be relaxed, extended, and placed on a smooth surface for support. The operator position is not restricted during NIBP measurement.
2. Squeeze as much air from the cuff as possible before placing it on the patient.
3. Wrap the cuff snugly around the upper arm or thigh of the patient. On the arm, the bottom of the cuff should be approximately 1 inch above the elbow joint.

   WARNING!

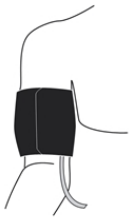
   - Do not place the NIBP cuff on the same arm or leg as an SpO_2 sensor. Inflation of the cuff causes the SpO_2 monitor to read incorrectly.
   - Do not attach the cuff to a limb being used for IV infusion. Cuff inflation might block the infusion, causing harm to the patient.
   - Do not place cuff over 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 to the hand or foot.
5. Check that the cuff ends between the range lines marked on the cuff. If they do not line up, use a different size cuff.
6. Wrap the deflated cuff snugly around the limb without impeding blood flow.
7. Ensure that the hose is routed to avoid 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:



Verify Cuff Inflation Settings

Before taking a measurement, ensure that the cuff inflation settings are appropriate for the patient. During an NIBP measurement, the Zenix device may increase the cuff inflation pressure over the initial value to obtain a systolic reading.

By default, the cuff inflation pressure for the first measurement after device power-up is set as follows:

- 160 mmHg (21.3 kPa) for adult mode
- 120 mmHg (16.0 kPa) for pediatric mode
- 85 mmHg (12.0 kPa) for neonate mode

Use the default setting unless it is clearly inappropriate.

Note: Cuff sizes less than 12 cm are not validated.

To change the cuff inflation pressure:

1. Select the NIBP numeric on the right side of the Zenix display. The NIBP Settings window displays.



2. On the NIBP Settings window's **General** panel, navigate to the **NIBP Cuff Inflation Target** field then select the down arrow **v**. A list of cuff inflation pressures displays.
3. Select the desired cuff inflation pressure.
4. Select **X** to exit the NIBP Settings window and return to the Zenix display.

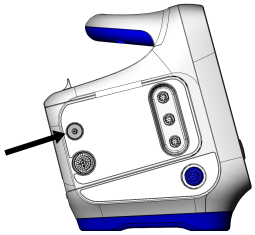
WARNING! Do not set cuff inflation pressure too high, particularly for pediatric, or frail patients. Serious injury can result.

Connect the NIBP Cuff

The NIBP hose has a metal connector on each end. You must attach the NIBP hose to both the Zenix device and the cuff's hose. The NIBP hose metal connectors are reversible.

To connect the hose:

1. Insert the metal connector on one end of the NIBP hose onto the NIBP connector on the left side of the Zenix device and push the connector until it snaps into place.



2. Insert the cuff hose connector into the metal connector on the other end of the NIBP hose.

NIBP Settings Window

Unless you are sure that the cuff inflation and alarm settings are appropriate for the patient, you should always check that they are set properly before taking a measurement. When you first turn on the Zenix device, the NIBP settings are set to their default values. Use the default settings unless they are clearly inappropriate for the patient.

The NIBP Settings window allows you to make adjustments to NIBP settings and alarms. You can:

- Select the NIBP Mode.
- Specify the NIBP Automatic Measurement Interval.
- Set the NIBP display format.
- Set the NIBP Cuff inflation.
- Enable/disable alarms and set high/low alarm limits.

Adjusting NIBP Settings

To adjust the NIBP settings:

1. Select the NIBP numeric on the right side of the display. The NIBP Settings window displays.



2. In the **NIBP Mode** field, select whether to have NIBP measurements acquired automatically at a specific interval or to have single NIBP measurements done manually by selecting the **Auto** or **Manual** key as appropriate.

3. For automatic measurements, in the **NIBP Auto Mode Interval** field, specify the desired measurement interval by selecting the **v** key and selecting an interval from the list that displays. With automatic measurements, the Zenix device take a series of NIBP measurements at the selected interval. For example, with an interval of 15 minutes, the Zenix device immediately takes a NIBP measurement, waits 15 minutes, takes another measurement, waits another 15 minutes, and so on.
4. In the **NIBP Display Format** field, specify format to use for the NIBP Numeric display by selecting the desired format. The display format allows you to choose whether or not you will display MAP measurement (M) with the Systolic (S) and Diastolic (D) measurements in one of the following formats:
    - **SD M** (default)

      For example, 118/79 (96)
    - **M SD**

      For example, (96) 118/79
5. In the **NIBP Cuff Inflation Target** field, set the cuff inflation rate by selecting the down arrow **v** and selecting an inflation pressure from the list that displays. By default, the cuff inflation pressure for the first measurement after device power-up is set as follows:
    - 160 mmHg (21.3 kPa) for adult mode
    - 120 mmHg (16.0 kPa) for pediatric mode
    - 85 mmHg (12.0 kPa) for neonate mode

    Note: As a safety feature, the cuff can never be inflated to more than 300 mmHg (40.0 kPa) in adult or pediatric mode and 150 mmHg (20.0 kPa) in neonatal mode.

    WARNING! Do not set cuff inflation pressure too high, particularly for pediatric, or frail patients. Serious injury can result.
6. When you are done adjusting the NIBP settings, select the **X** on the top right corner of the window to return to the Zenix display.

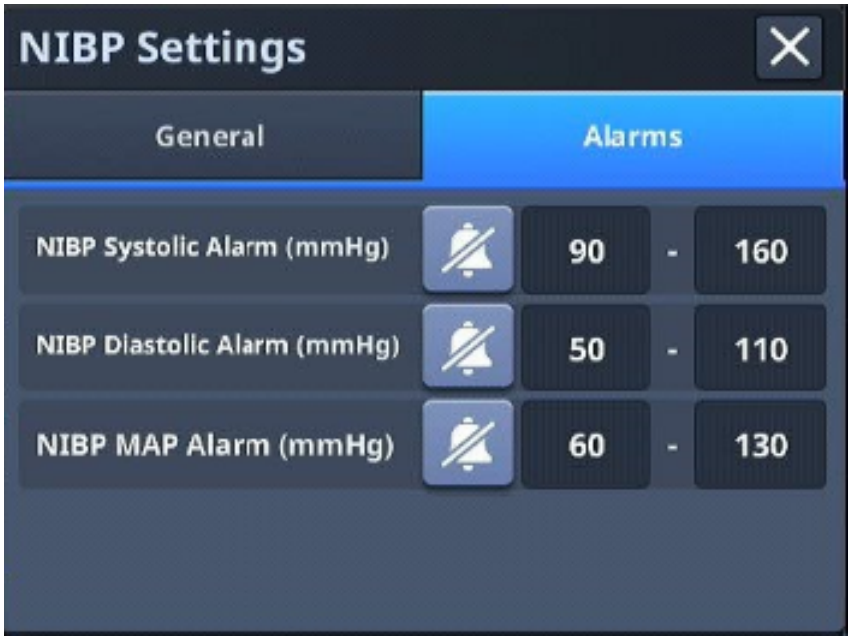
Adjusting NIBP Alarm Settings

Before taking a measurement, ensure that the NIBP alarms settings are appropriate for the situation. In the NIBP Settings window you can enable/disable NIBP alarms and set the following limits so that an alarm sounds whenever NIBP measurements are outside those limits:

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

To set NIBP alarms and limits:

1. Select the **NIBP numeric** on the right side of the display. The NIBP Settings window displays.
2. On the NIBP Settings window select the **Alarms** tab. The NIBP Settings Alarms window displays.



3. In the **NIBP Systolic Alarm (mmHg)** field, select the **Alarm** icon to enable/disable the NIBP Systolic Alarm. Touch the lower and upper limits and use the keypad to change limit values.
4. In the **NIBP Diastolic Alarm (mmHg)** field, select the **Alarm** icon to enable/disable the NIBP Diastolic Alarm. Touch the lower and upper limits and use the keypad to change limit values.
5. In the **NIBP MAP Alarm (mmHg)** field, select the **Alarm** icon to enable/disable the NIBP MAP Alarm. Touch the lower and upper limits and use the keypad to change the values.
6. When you are done adjusting the NIBP settings, select the **X** to exit the window and return to the Zenix display.

Taking Measurements

You can take NIBP measurements in any mode except when the defibrillator is charged or charging.

Depending on how your system is set up, selecting the **NIBP** key 

takes one blood pressure measurement or takes a series of automatic measurements. See "NIBP System Messages" on the facing pagefor information on manual and automatic measurements.

With Automatic measurements, the Zenix device takes a series of measurements at specified intervals. For example, if the Zenix device is set up to take an automatic measurement with an interval of 15 minutes, it immediately takes a measurement, waits 15 minutes, takes another measurement, waits another 15 minutes, and so on.

Note: If the Zenix device is configured to startup with default automatic blood pressure measurements, the automatic measurements begin once you select the **NIBP** key 

. This prevents the Zenix device from inflating the tubing/cuff when a patient is not attached.

You can stop any current measurements by selecting the **NIBP** key 

. The Zenix device immediately stops all measurements and the cuff deflates.

Note: If configured to do so, when an NIBP or heart rate alarm is triggered the device automatically initiates a single blood pressure measurement if configured to do so.

WARNING! If the Zenix device takes a measurement but detects the presence of artifact in the signal (denoted by "*" in the NIBP display area), the measurement may not be accurate. Under such circumstances, perform additional blood pressure measurements. If you repeatedly obtain artifact, use alternate techniques to determine blood pressure prior to taking clinical action.

WARNING! Do not begin NIBP measurements unless the patient type setting is appropriate for the patient. Taking NIBP measurements on a pediatric patient while the device is in adult mode can result in inaccurate measurements and injury to the patient. Taking NIBP measurements on an adult patient while in pediatric mode can result in inaccurate measurements.

WARNING! Possible Inaccurate Blood Pressure Readings. Motion artifact from patient transportation may prolong the measurement process or affect measurement accuracy. Do not use NIBP if environmental motion artifact is present (including vehicular motion, in-hospital transportation, or patient ambulation.

NIBP System Messages

When monitoring NIBP, the following messages may display:

System Message	Cause
READING IN PROGRESS	The unit is taking an NIBP measurement and functioning normally.
READING STOPPED	The unit has stopped an NIBP measurement, because the operator has pressed the **NIBP** button and cancelled the measurement.
NIBP READING FAILED	The patient's pulse is too weak to obtain an NIBP measurement, or the cuff requires adjustment.
NEONATE CUFF DETECTED	The unit has detected a neonate cuff when in Adult mode. Replace cuff or correct patient mode, as appropriate. If the detection is in error, dismiss the alert and reattempt the NIBP measurement.
AIR LEAK	A major air leak is preventing cuff inflation. Check hose and cuff connections, replace a defective hose or cuff, as necessary, and reattempt NIBP measurement.
NIBP DEVICE DISABLED	A system error has occurred, and the unit should be serviced.
PLEASE WAIT	Message displays after initial start.
WEAK PULSE	The patient's pulse is too weak to obtain an NIBP measurement or the cuff requires adjustment.

CHAPTER 12

Monitoring Mainstream CO_2

This chapter describes how to monitor mainstream End Tidal Carbon Dioxide ($EtCO_2$), breath rate, and Fractional Inspired Carbon Dioxide ($FiCO_2$). Refer to the *IRMA Mainstream Gas Analyzer User's Guide* for detailed information and warnings regarding the accessories mentioned in this chapter.

It includes the following sections:

Overview 150

Mainstream CO2 Setup 153

The CO2 Settings 156

Measuring CO2 158

CO2 System Messages 159

Overview

The device uses a mainstream sensor to monitor CO_2 inhaled and exhaled gases.

The IRMA™ airway adapter is inserted between the endotracheal tube and the Y-piece of the breathing circuit. The respiratory gas measurements are obtained through the XTP™ windows in the sides of the adapter. The XTP windows are transparent to light in the wavelength ranges of interest; they are specially designed using the latest advances in material technology to provide a window minimizing the impact of water vapor on light transmission.

The IRMA airway adapter is designed as a non-sterile single patient use disposable for both adult/pediatric and infant applications.

Warnings

- IRMA should only be used for the purpose and in the manner described in this manual.
- Do not adjust, repair, open, disassemble, or modify the IRMA or IRMA Airway Adapters. Damage to the device may result in degraded performance and/or patient injury.
- If for whatever the reason the IRMA device is in direct contact with any parts of the infant's body an insulation material shall be placed between the IRMA and the body.
- The IRMA is not designed for MRI environments.
- Do not use the IRMA Adult/Pediatric Airway Adapter with infants as the Adapter adds 6 ml dead space to the patient circuit.
- Do not use the IRMA Infant Airway Adapter with adults/pediatrics as this may cause excessive flow resistance.
- IRMA should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
- Use only IRMA Airway Adapters manufactured by Masimo.
- Light transmission can be affected by secretions and moisture pooling on the IRMA Airway Adapter XTP™ windows. When using heated humidifiers special care should be paid to position the Airway Adapter in a vertical position and to change Airway Adapter if necessary.
- Do not place the IRMA Airway Adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.
- Do not use IRMA with metered-dose inhalers or nebulized medications as this may affect the light transmission of the IRMA Airway Adapter windows.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.
- Make sure that IRMA is used in the electromagnetic environment specified in this manual.
- Use of high-frequency electrosurgical equipment in the vicinity of IRMA may produce interference and cause incorrect measurements.
- 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 IRMA including cable. Otherwise, degradation of the performance of the IRMA could result.
- Incorrect zeroing of IRMA will result in false gas readings.
- Use of accessories and cables other than those specified or provided could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Replace the airway adapter if rainout/condensation occurs inside the airway adapter.
- Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user’s authority to operate the equipment.

- Do not operate IRMA outside of the specified operating environment.
- Disposal of Product: Comply with local laws in the disposal of the device and/or its accessories
- IRMA Airway Adapters shall be disposed of in accordance with local regulations for biohazardous waste.

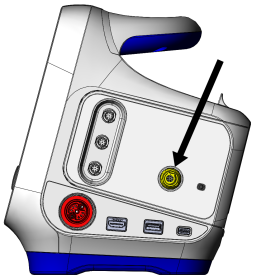
Mainstream CO_2 Setup

To take safe and accurate mainstream CO_2 measurements you must perform the following steps, each of which corresponds to a section in this chapter. Read each section carefully.

1. Attach the IRMA probe interface cable to the Zenix device.
2. Turn on CO_2 monitoring on the Zenix device.
3. Select the IRMA airway adapter.
4. Attach the IRMA airway adapter to the CO_2 probe.
5. Zero the CO_2 probe/airway adapter (if necessary).
6. Attach IRMA airway adapter to the airway circuit.

Attach Probe Interface Cable

Connect the IRMA probe interface cable to the CO_2 connector on the right side of the Zenix device.



Turning on CO_2 Monitoring

To turn on CO_2 monitoring, do the following:

1. Select the Resp/EtCO2 numeric on the right side of the window. The EtCO2 Settings window displays.
2. In the **CO2 Monitoring** field, select **On**.

Select Mainstream Airway Adapter

Select an airway adapter based on the patient's ET tube diameter and monitoring situation.

Airway Adapter Type	ET Tube Diameter
SPU* Pediatric/Adult	> 4.0 mm
SPU* Infant	≤ 4.0 mm

*SPU = Single Patient Use

WARNING! The Airway Adapters are intended for single patient use. They are disposable and shall not be re-used. Reuse of single patient use Adapters can cause cross infection.

Attach IRMA Airway Adapter to the CO_2 Probe

Attach the IRMA airway adapter to the probe, as follows:

1. Snap the IRMA probe on top of the IRMA airway adapter. It will click into place when properly seated.
2. Wait a minimum of 10 seconds. If gas readings does not show 0% or if an unspecified accuracy message is displayed, perform the zeroing procedure. See "Zero the Mainstream IRMA Probe" on page 160 before continuing with this procedure.
3. A green LED indicates that the probe is ready for use.
4. Connect the airway adapter (male connector) to the breathing circuit Y-piece.
5. Connect the airway adapter (female connector) to the patient's endotracheal tube.
6. Verify proper connection of the adapter to the probe.
7. Position IRMA with the status LED pointing upwards, unless IRMA is protected with a Heat Moisture Exchanger (HME).

Attach IRMA Airway Adapter to the Airway Circuit

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

Attach the airway adapter to the breathing circuit as follows:

1. Place the CO_2 sensor/airway adapter assembly 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.

   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 and the airway adapter is occluded, replace the adapter. To prevent moisture from draining into the airway adapter, do NOT place the airway adapter in a gravity dependent position.
2. Check that connections have been made correctly by verifying the presence of a proper CO_2 waveform on the display.
3. The sensor cable should face away from the patient.

The CO_2 Settings

The CO_2 Settings window allows you to do the following:

- Enable/disable the $EtCO_2$ waveform.
- Enable/disable CO_2 monitoring.
- Zero the sensor (when necessary).
- Enable/disable alarms and set high/low alarm limits for $EtCO_2$, $FiCO_2$, and RR/BR.

Adjusting CO_2 Settings

To adjust the Resp/$EtCO_2$ settings:

1. Select the $EtCO_2$ numeric on the right side of the window. The $EtCO_2$ Settings window displays:



2. In the **EtCO2 Waveform** field, enable/disable the $EtCO_2$ waveform by selecting **On** or **Off** as appropriate.
3. In the **CO2 Monitoring** field, enable/disable $EtCO_2$ monitoring by selecting **On** or **Off** as appropriate.

Adjusting CO_2 Alarm Settings

In the $EtCO_2$ Settings window you can enable/disable $EtCO_2$ alarms and set the following limits so that an alarm sounds whenever $EtCO_2$ measurements are outside those limits:

- High and Low $EtCO_2$
- High $FiCO_2$

  Note: For $FiCO_2$, you can only set the upper limit.
- High and Low RR/BR

To set $EtCO_2$ alarms and limits:

1. Select the $EtCO_2$ numeric on the right side of the window. The EtCO2 Settings window displays.
2. In the EtCO2 Settings window, select the **Alarms** tab.



Note: See"EtCO2 Alarm Limits" on page 224 for default alarm limits and low and high alarm ranges.

3. In the **EtCO2 Alarm (mmHg)** field, select the icon to enable/disable the $EtCO_2$ Alarm. Select the lower and upper limits and use the keypad to change limit values.
4. In the **FiCO2 Alarm (mmHg)** field, select the icon to enable/disable the $FiCO_2$ Alarm. Select the upper limit and use the keypad to change limit value.
5. In the **RR/BR (BPM)** field, select the icon to enable/disable the RR/BR Alarm. Select the lower and upper limits and use the keypad to change limit values.
6. When you are done making adjustments to $EtCO_2$ settings, select **X** to exit the window.

Measuring CO_2

Once setup is complete and CO_2 monitoring is enabled, the $EtCO_2$ numeric appears on the screen. The $EtCO_2$ numeric provides the current $EtCO_2$ value, and within seconds the patient's Respiration Rate (in Breaths/Minute identified as **BR**) displays.



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).

CO_2 System Messages

When monitoring CO_2, the device may display the following messages:

System Message	Cause
CO2 AMBIENT PRESSURE OUT OF RANGE	Indicates the ambient pressure measurement is out of range. Verify standard operating conditions according to the gas analyzer's instructions.
CO2 INTERNAL TEMP OUT OP RANGE	Indicates that the internal temperature is out of range. Verify standard operating conditions according to the gas analyzer's instructions.
CO2 OUTSIDE SPECIFIED RANGE	The CO_2 value exceeds the specified range.
CO2 MOTOR SPEED OUT OF BOUNDS	The CO_2 motor speed exceeds the specified range.
CO2 ZERO REF CALIBRATION REQUIRED	Module requires a zero reference calibration.
DEVICE DISABLED	The device was configured for the incorrect CO_2 module or multiple communication errors and/or error messages from the CO_2 module were received.
EQUIPMENT FAILURE	The device has determined that the CO_2 module is not functioning correctly. If the problem persists, the device may require servicing.
FACTORY CAL MISSING	Indicates that the factory calibration is lost or missing in the gas analyzer. If the problem persists, replace the gas analyzer.
HARDWARE FAILURE	Indicates hardware error in the gas analyzer. If the problem persists, replace the gas analyzer.
IRMA MODULE DISCONNECT	The external IRMA was disconnected. Check the IRMA module connection and reconnect the module.
IRMA NO ADAPTER	There is no IRMA adapter. Check that there is an adapter and connect it.
IRMA REPLACE ADAPTER	The adapter needs to be replaced.
SOFTWARE FAILURE	Indicates software error in the gas analyzer. If the problem persists, replace the gas analyzer.
ZEROING	Indicates the device is zeroing the IRMA probe.

Zero the Mainstream IRMA Probe

Zeroing needs to be performed ONLY when an offset in gas values is observed or when an unspecified accuracy message is displayed. Special care should be taken to avoid breathing near the airway adapter before or during the zeroing procedure.

Allow 10 seconds for warm up of a IRMA CO_2 probe after power on before proceeding with the zeroing procedure.

Note: Do not zero the CO_2 probe without an airway adapter installed.

1. Select the $EtCO_2$ numeric on the right side of the Zenix window. The $EtCO_2$ Settings window displays.
2. Select the **Zero Sensor** button to zero the device.
3. The device zeroes the IRMA probe. Zeroing displays in the EtCO2 numeric display instead of the CO2 value.
4. Always verify gas readings and waveforms on the Zenix device before connecting the IRMA Airway Adapter to the patient circuit.

CHAPTER 13

Pulse CO-Oximetry (SpO2)

This chapter describes how to monitor Pulse CO-Oximetry (SpO_2), as well as the optional features: SpCO, SpMet, SpHb, SpOC, PVi, and Pi.

It includes the following sections:

Overview 162
SpO2 Setup and Use 168
Displaying Measurements 170
The SpO2 Settings Window 172
SpO2 System Messages 176
Functional Testers and Patient Simulators 177
Patents 178

The SpO_2 input is Type BF defibrillator proof.

Overview

The pulse CO-Oximeter continuously and non-invasively measures the following at a peripheral site, such as the foot, toe, finger, or ear:

- Oxygen saturation of arterial hemoglobin (SpO_2)
- Carboxyhemoglobin saturation (SpCO)
- Methemoglobin saturation (SpMet)
- Total Hemoglobin (SpHb)
- Oxygen Content (SpOC)
- Pleth Variability Index (PVi)
- Perfusion Index (Pi)

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 non-invasive, continuous, easily applied, and painless.

The pulse CO-Oximetry option is intended for use only with Masimo sensors. The CO-Oximetry sensor contains light-emitting diodes (LEDs) that transmit various visible and infrared light through the body's extremities. The transmitted light is then received by a photodetector, which converts it to an electronic signal. The signal is then sent to the device for processing.

Oxygen-saturated blood absorbs light differently than unsaturated blood. Thus the amount of visible and infrared light absorbed by blood flowing through a suitable peripheral area of the body, typically the finger in adults and the foot in neonates, can be used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood. The monitor displays this ratio as a percent (normal values typically range from 95% to 100% at sea level) alternating with SpCO and SpMet, and SpHb, SpOC, PVi and Pi values if available on your device.

Note: The monitor does not display SpCO values when you use a SpHb sensor and does not display SpHb values when you use a SpCO sensor.

The measurements rely on multi-wave length calibration equations to estimate the following:

- Percentage of carboxyhemoglobin in arterial blood (SpCO).
- Percentage of methemoglobin in arterial blood (SpMet).
- Total hemoglobin concentration present in the blood (SpHb).
- Total oxygen content present in the blood (SpOC).
- Peripheral perfusion changes secondary to respiration (PVi).
- The arterial pulse strength as the percentage of pulsatile signal to non-pulsatile signal (Pi).

Note: The SpO2 sensor's LED wavelength information (Appendix A) may be useful to clinicians.

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 exposure to ambient light. For correct placement and location of the sensors, refer to the *Directions for Use* contained with all Rainbow® oximetry sensor packages.

Warnings

- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the pulse CO-Oximeter or accessories in any position that might cause it to fall on the patient.
- Do not start or operate the pulse CO-Oximeter unless the setup was verified to be correct.
- Do not use the pulse CO-Oximeter during magnetic resonance imaging (MRI) or in an MRI environment.
- Do not use the pulse CO-Oximeter if it appears or is suspected to be damaged.
- Explosion hazard: Do not use the pulse CO-Oximeter in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide.
- 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.
    - Use cleaning solutions only as instructed in this operator's manual.
    - Do not attempt to clean the device while monitoring a patient.
- To protect from electric shock, always remove the sensor and completely disconnect the pulse CO-Oximeter before bathing the patient.
- If any measurement seems questionable, first check the patient’s vital signs by alternate means and then check the pulse CO-Oximeter for proper functioning.
- Inaccurate respiration rate measurements may be caused by:
    - Improper sensor application
    - Low arterial perfusion
    - Motion artifact
    - Low arterial oxygen saturation
    - Excessive ambient or environmental noise

- Inaccurate SpHb and SpOC 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 PaO_2 levels
  - Elevated levels of bilirubin
  - Low arterial perfusion
  - Motion artifact
  - Low arterial oxygen saturation levels
  - Elevated carboxyhemoglobin levels
  - Elevated methemoglobin levels
  - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
  - Vasospastic disease such as Raynaud's
  - Elevated altitude
  - Peripheral vascular disease
  - Liver disease
  - EMI radiation interference
- Inaccurate SpCO and SpMet readings may be caused by:
  - Improper sensor application
  - Intravascular dyes such as indocyanine green or methylene blue
  - Abnormal hemoglobin levels
  - Low arterial perfusion
  - Low arterial oxygen saturation levels including altitude induced hypoxemia
  - Elevated total bilirubin levels
  - Motion artifact

- Inaccurate SpO2 readings may be caused by:
    - Improper sensor application and placement.
    - Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
    - Elevated levels of bilirubin
    - Elevated levels of dyshemoglobin
    - Vasospastic disease, such as Raynaud's, and peripheral vascular disease
    - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etcetera.
    - Hypocapnic or hypercapnic conditions
    - Severe anemia
    - Very low arterial perfusion
    - Extreme motion artifact
    - Abnormal venous pulsation or venous constriction
    - Severe vasoconstriction or hypothermia
    - Arterial catheters and intra-aortic balloon
    - Intravascular dyes, such as indocyanine green or methylene blue
    - Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
    - Birthmarks, tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers, etc.
    - Skin color disorders
- Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
- The pulse co-oximeter should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.
- The pulse co-oximeter is not an apnea monitor.
- The pulse co-oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse co-oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse co-oximeter should not be used for arrhythmia analysis.
- SpCO readings may not be provided if there are low arterial saturation levels or elevated methemoglobin levels.
- SpO2, SpCO, SpMet, and SpHb are empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

- Do not adjust, repair, open, disassemble, or modify the pulse co-oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse co-oximeter for servicing if necessary.
- Tissue damage can result from incorrect application or use of a sensor (for example, wrapping the sensor too tightly, applying supplemental tape, failing to periodically inspect the sensor site). To ensure skin integrity, correct positioning, and sensor adhesion, inspect the sensor site as directed in the *Directions for Use* provided with the sensor.
- Do not allow the sensor to remain on the same site for a prolonged period, especially when monitoring neonates. Check the application site at regular intervals (at least every 2 hours) and change the site if any compromise in skin quality occurs.
- Do not attempt to recycle, recondition, or reprocess disposable sensors or patient cables. This could damage the electrical components, leading to patient harm.
- Optical, pleth-based measurements (SpO2, SpHb, SpOC, SpMet, SpCO) can be affected by the following:
    - Improper sensor application or use of incorrect sensor.
    - Blood pressure cuff applied to the same arm as the sensor site.
    - Intravascular dyes such as indocyanine green or methylene blue.
    - Venous congestion.
    - Abnormal venous pulsations (e.g. tricuspid valve regurgitation, Trendelenburg position).
    - Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g. cardiac arrhythmias, intra-aortic balloon, etc.).
    - Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
    - Moisture, birthmarks, skin discoloration, nail aberration, deformed fingers, or foreign objects in the light path.
    - Elevated levels of bilirubin.
    - Physiological conditions that can significantly shift the oxygen disassociation curve.
    - A physiological condition that may affect vasomotor tone or changes in vasomotor tone.

Cautions

- Do not place the pulse CO-Oximeter where the controls can be changed by the patient.
- 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. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- Do not place the pulse CO-Oximeter on electrical equipment that may affect the instrument, preventing it from working properly.

- If SpO2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
- If the *LOW PERFUSION INDEX* message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
- When the SpO2 probe signal is not sufficient to determine arterial hemoglobin saturation, SpO2 numerical zone displays "- - -".
- Change the application site or replace the sensor and/or patient cable when a *REPLACE SENSOR* and/or *REPLACE CABLE*, or a persistent poor signal quality message is displayed on the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the instrument might read zero for the duration of the active irradiation period.
- The device must be configured to match your local power line frequency to allow for the cancellation of noise introduced by fluorescent lights and other sources.
- To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse CO-Oximeter is used.
- 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.
- Do not submerge the pulse CO-Oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse CO-Oximeter.
- 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 IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.
- Disposal of product: Comply with local laws in the disposal of the instrument and/or its accessories.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse CO-Oximeter.
- Replace the cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.
- Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.

SpO_2 Setup and Use

To take accurate SpO_2 measurements using the Zenix device, 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 Zenix device.
4. Configure alarms and settings (if the current alarms and settings are not appropriate).

Pulse oximetry measurements begin as soon as the sensor is applied to the patient and connected to the Zenix device.

Note: Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the *Cable or Sensor Directions for Use* for the specified duration of the patient monitoring time.

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 APPENDIX B "Accessories" which provides a list of ZOLL-approved reusable and single-use sensors for adult, pediatric, and neonate patients. Before applying the sensor, always familiarize yourself with the *Directions for Use* that the manufacturer provides with the sensor.

Note: An SpHb sensor is required for measuring the optional SpHb and SpOC parameters. The monitor does not display SpCO values when you use a SpHb sensor and does not display SpHb values when you use a SpCO sensor.

Note: Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's *Directions for Use (DFU)*.

Applying the SpO_2 Sensor

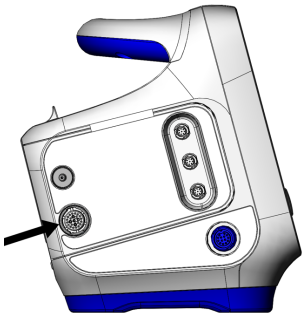
- Choose a site that is well perfused and restricts a conscious patient's movements the least. The ring finger or middle finger of the non-dominant hand is preferred.
- Alternatively, you can use the other digits on the non-dominant hand. Be sure the sensor's detector is fully covered by flesh.
- You can use the great toe or long toe (next to the great toe) on restrained patients or patients whose hands are unavailable.
- 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.
- 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.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor may not allow the Pulse CO-Oximeter to obtain vital sign readings.

Connecting the SpO_2 Sensor

When using a sensor extension cable, inspect the cable before use. Replace the cable if it shows any signs of wear, breakage, or fraying.

To connect the sensor, plug the sensor extension cable into the SpO_2 receptacle on the side of the device.

When using single use sensors, apply the sensor to the patient first and then connect the sensor cable to the SpO_2 receptacle on the device.



Displaying Measurements

When the connection is made between the sensor and the device, the message *INITIALIZING* appears in the display. After a brief delay, the device displays the SpO_2 numeric and plethysmograph normalized waveform. If SpCO and SpMet, or SpHb, SpOC, PVi and Pi are installed and monitoring is on for these parameters, the measurements will alternate. A pulse bar appears on the right side of the SpO2 numeric display window. This tracks the amplitude of the plethysmography normalized waveform.



If the message *SENSOR FAILURE* appears, the sensor is either incompatible with the device or it is not working, and you will need to replace the sensor. A pulse bar appears on the right side of the SpO2 numeric display window to indicate the pulse derived from the plethysmograph normalized waveform. See "SpO2 System Messages" on page 176 for more information about SpO2 related messages that may display.

Note:

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

- Physiological conditions that result in loss of pulsatile signal may result in no SpO2, SpHb, SpOC, SpCO and SpMet readings.
- SpHb and SpOC measurements require an SpHb sensor. The monitor does not display SpCO values when you use a SpHb sensor and does not display SpHb values when you use a SpCO sensor.

The SpO_2 Settings Window

Select the SpO_2 parameter numeric to display the SpO_2 Settings window. In this window you can perform the following functions:

- Enable/disable the SpO_2 waveform display.
- Select the SpO_2 Sensitivity.
- Specify the SpO_2 Averaging Time.
- Enable/Disable SpCO, SpMet, SpHb, SpOC, PVi or Pi monitoring.
- Enable/disable alarms and set high/low alarm limits.

Adjusting SpO_2 Settings

To adjust the SpO_2 settings:

1. Select the SpO_2 numeric on the right side of the window. The SpO_2 Settings window displays:



2. In the **SpO_2 Waveform** field, enable/disable the SpO_2 waveform by selecting **On** or **Off** as appropriate.

3. In the **SpO_2 Sensitivity** field, select **Normal** or **Maximum** as appropriate.

   The Normal sensitivity setting is the recommended setting for most patients. The High sensitivity setting allows you to monitor SpO_2 even under very low perfusion conditions. Such conditions may include severe hypotension or shock. With the High sensitivity setting, however, SpO_2 results are more easily contaminated by artifact. To ensure accurate SpO_2 readings when using the High sensitivity setting, observe the patient carefully and continuously.

   When using the High Sensitivity setting, performance of the *Sensor Off* detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.

4. In the **SpO_2 Averaging Time** field, select **4 secs**, **8 secs**, or **16 secs** as appropriate in the SpO_2 Averaging Time field.

   The averaging period is rarely changed from the 8 second default setting. For high risk patients with rapidly changing SpO_2 conditions, use the 4 second setting. Use the 16 second setting only when the 8 second setting (default) is inadequate due to extremely high artifact conditions.

5. Select the **SpHb** button at the bottom of the window.

   When the SpHb option is installed, you can specify whether to use venous mode (**On**) as the blood sample source or not (**Off**). When **Off**, the device uses arterial as the blood sample source.

   You can choose the time period over which SpHb values will be calculated: **Short**, **Medium**, or **Long**. Averaging time represents the approximate time period the device will use to calculate SpHb values. Longer averaging times allow you to see subtle changes in the SpHb value and tend to improve accuracy.

Adjusting SpO_2 Alarm Settings

1. In the SpO_2 Settings window, select the **Alarms** tab.



2. Select a button on the bottom of the window to display the appropriate alarm options:
   - **SpO_2, SpCO, SpMet**
   - **SpHb, SpOC, PVI**
   - **Pi**
3. Enable the alarm by selecting the **Alarm** icon. When enabled, an alarm sounds whenever the patient's value is above or below the specified limit value. See "SpO2 Alarm Limits" on page 222 for default alarm limits and low and high alarm ranges.
4. Specify an upper alarm limit value, if necessary, by selecting the upper limit value. Use the keypad and/or up and down arrows to enter the upper limit value.
5. Specify a lower alarm limit value, if necessary, by selecting the lower limit value. Use the keypad and/or up and down arrows to enter the lower limit value.

Enabling SpO_2 Monitoring Options

You can only make the changes in this procedure if SpCO, SpMet, SpHb, SpOC, PVi, and Pi are installed.

1. In the SpO_2 Settings window, select the **Monitoring** tab.



2. Select the appropriate button at the bottom of the window (**SpCO, SpMet, SpHb** or **SpOC, PVi, Pi**).
3. Select **On** or **Off** to enable/disable the option.
4. When you are done making adjustments to the SpO_2 settings, select **X** to exit the window.

SpO2 System Messages

The Zenix device may display the following system messages when monitoring SpO_2:

System Message	Cause
INITIALIZING	The SpO_2 pulse oximeter is initializing.
SEARCHING	The device is searching for a pulse.
CHECK SPO2 SENSOR CONNECTION	The SpO_2 sensor has become disconnected from the device. Check sensor and then reconnect it to the device.
SPO2 SENSOR OFF PATIENT	The sensor is no longer on the patient. Check sensor and then reapply it to the patient.
CHECK SPO2 CABLE AND SENSOR FAULT	The SpO_2 sensor/cable are defective. Replace the sensor/cable.
SPO2 CABLE LIFE NEAR EXPIRATION	Adhesive/Sensor/Cable Failure. The adhesive/sensor/cable is nearing expiration. Replace the adhesive/sensor/cable.
LOW PERFUSION INDEX	Signal too small, move to better perfused site.
SPO2 FAILURE	A system error has occurred. The Zenix device cannot take SpO_2 measurements and should be serviced.
SPO2 ONLY	The sensor only provides SpO2 and Pi values.

Functional Testers and Patient Simulators

- Some models of commercially available bench top functional testers and patient simulators can be used to verify the proper functionality of Masimo pulse oximeter sensors, cables and monitors. See the individual testing device's operator's manual for the procedures specific to the model of tester that you are using.
- While such devices may be useful for verifying that the pulse oximeter sensor, cable, and monitor are functional, they are incapable of providing the data required to properly evaluate the accuracy of a system's SpO_2 measurements.
- A functional tester cannot be used to assess the accuracy of the Pulse CO-Oximeter.
- Fully evaluating the accuracy of the SpO_2 measurements requires, at a minimum, accommodating the wavelength characteristics of the sensor and reproducing the complex optical interaction of the sensor and the patient's tissue. These capabilities are beyond the scope of known bench top testers, including known devices which claim to measure sensor LED wavelength.
- SpO_2 measurement accuracy can only be evaluated in vivo by comparing pulse oximeter readings with values traceable to SpO_2measurements obtained from simultaneously sampled arterial blood using a laboratory CO-Oximeter.
- Many functional testers and patient simulators have been designed to interface with the pulse oximeter's expected calibration curves and may be suitable for use with Masimo monitors and/or sensors. Not all such devices, however, are adapted for use with the Masimo digital calibration system. While this will not affect use of the simulator for verifying system functionality, displayed SpO_2 measurement values may differ from the setting of the test device.

  For a properly functioning monitor, this difference will be reproducible over time and from monitor to monitor within the performance specifications of the test device.

Patents

All patent information related to the SpO2 component of the Zenix device can be found at the following:

www.masimo.com/patents.htm

NO IMPLIED LICENSE

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

CHAPTER 14

Monitoring Invasive Pressures (IBP)

This chapter describes how to monitor invasive pressures (IBP).

It includes the following sections:

Overview 180

IBP Setup 181

The IBP Numeric Display 184

IBP Settings Window 185

IBP System Messages 188

The IBP inputs are Type CF defibrillator proof.

Overview

The Zenix device allows you to monitor up to three different invasive pressure channels and view numerics for each of the three channels on the Zenix display and, if configured to display, view IBP waveforms. You can use these channels to measure arterial, venous, or intracranial pressures using invasive transducers with 5uV/V/mmHg sensitivity. Each channel requires its own connector, cabling, and pressure transducer.

Use only ZOLL-distributed interface cables. Use of third party cables may result in inaccurate IBP measurements. See APPENDIX B “Accessories” for a list of compatible transducers. Do not use light-sensitive disposable transducers.

Use the invasive pressure transducers according to your organization’s established clinical protocol and follow the manufacturer’s recommendations. Always refer the manufacturer’s *Directions for Use* before using a transducer.

WARNING!

- If electrocautery is used, always avoid using any transducer with a conductive (metal) case connected to its ground shield. Using a conductive transducer case that is connected to its cable shield risks high-frequency burns at the ECG electrodes if the transducer case becomes grounded to earth.
- Normal alarm functions will detect complete disconnections of invasive pressure transducers; however, the alarm functions will not detect a partial disconnection or the use of some incompatible transducers. Use only approved transducers and ensure that the transducers are connected properly.
- Before using the device on a new patient, always turn it off for at least 30 seconds. This clears the previous patient’s trend values, alarm limit settings, and NIBP cuff inflation pressure.
- Use *only* ZOLL-approved IBP interface cables. Use of third party interface cables may result in inaccurate IBP measurements.

IBP Setup

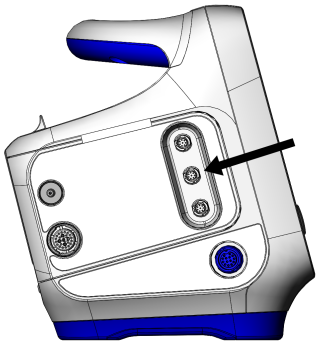
To take safe and accurate IBP measurements using the Zenix device, you must perform the following steps, each of which corresponds to a section in this chapter. Read each section carefully before you perform IBP measurements.

1. Attach the IBP cable to the Z-link port.
2. Attach the transducer to the interface cable.
3. Zero the transducer.
4. Select a label for the invasive pressure channel.

Attaching the Invasive Pressure Transducer

Follow these steps when attaching the invasive pressure transducer:

1. Inspect the transducer cable. If the cable shows any signs of wear, breakage, or fraying, replace the cable. Replace the transducer dome, if necessary.
2. Apply the transducer according to your organization's procedures. Always refer to the manufacturer's *Directions for Use* before using a transducer.
3. If the transducer is a disposable device with a separate cable, connect the transducer to the transducer cable.
4. Connect the transducer cable to one of the Z-Link connectors on either side of the Zenix device. The message *ZERO PROBE* appears in the numeric display window for that IBP channel.



5. On the Setup IBP Label window, select a desired label for the channel.



Zeroing the Transducer

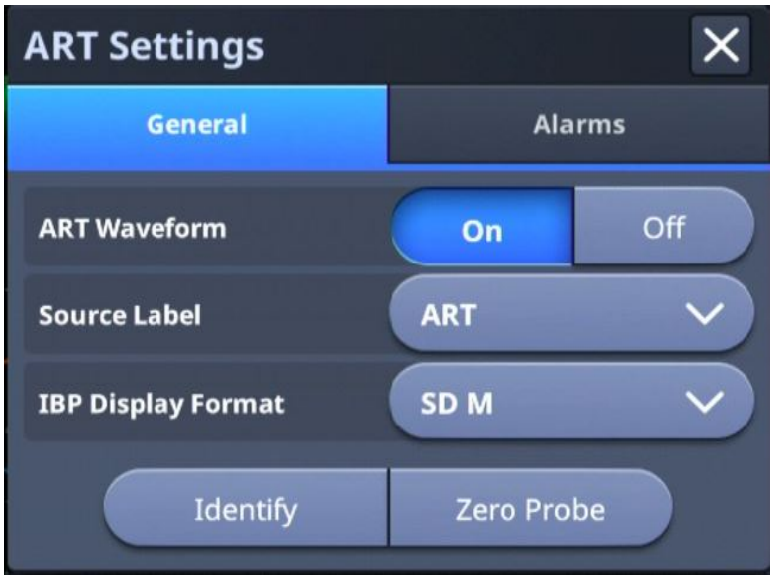
To ensure that the Zenix device measures pressure accurately, you must zero the transducer:

- Before each use.
- If you change or disconnect a transducer.
- If you move a transducer to a different monitor, you must zero the transducer again, even if you have already done so on another device.

In addition to the procedure below, follow the transducer manufacturer's *Directions for Use* and your organization's established clinical protocol.

Once the transducer is placed and ready for monitoring, follow these steps to zero with the Zenix device:

1. Place the transducer at the same height as the patient's left atrium.
2. Close the transducer stopcock to the patient.
3. Open the transducer's venting stopcock to atmospheric air.
4. Allow the transducer a few seconds to settle.
5. Navigate to and select the transducer's IBP Numeric Display. The IBP channel's settings window displays.



6. If necessary, select **Identify** to visually identify the channel. When you select **Identify** a light blinks on the associated transducer cable.
7. Select **Zero Probe**. The device displays the message *ZEROING* in the IBP Channel's numeric display then *ZEROED* if the device is successful.

8. If the device was unable to zero the transducer, the message *ZERO REJECTED* appears in the IBP channel's numeric display. The device will not display pressure values for the IBP channel until it has successfully zeroed the transducer and established an acceptable zero reference.

   Check that the device is open to atmospheric air and that it is properly connected to the device, then try zeroing the transducer again. The Zenix device will not zero the transducer if it detects pulsation in the pressure channel, if there is too much noise in the signal, or if transducer's offset is too great. If you cannot zero the transducer after several attempts, replace the transducer or the transducer cable.

The IBP Numeric Display

After attaching and zeroing a transducer, the device displays the invasive pressure's measurement values in the IBP channel's numeric display along with the alarm status icon. Optionally, the waveform for that IBP channel appears on the Zenix display.

Depending on how your system is setup, the IBP numeric can include the systolic, diastolic, and MEAN or can be set up to display MEAN only.



When reading blood pressure measurements on the IBP numeric display, keep in mind that the following conditions can affect the accuracy of IBP measurements:

- Catheter placement in the vasculature. Artifact such as catheter whip should be handled per your established clinical protocols.
- Position of the transducer stopcock, catheter, and flush port.
- Saline line flushes which will temporarily interrupt accurate pressure measurement.
- Position of the transducer relative to the patient's phlebostatic axis or catheter tip.
- Patient movement.
- Catheter clogging.
- Air bubbles in catheter or transducer dome.
- Electromagnetic interference.

Follow instructions supplied with any accessory pressure sensor regarding calibration and removal of trapped air.

Caution: Flush catheter regularly while taking IBP measurements. Always view the IBP waveform to ensure that pressure measurements are based on a physiological waveform.

IBP Settings Window

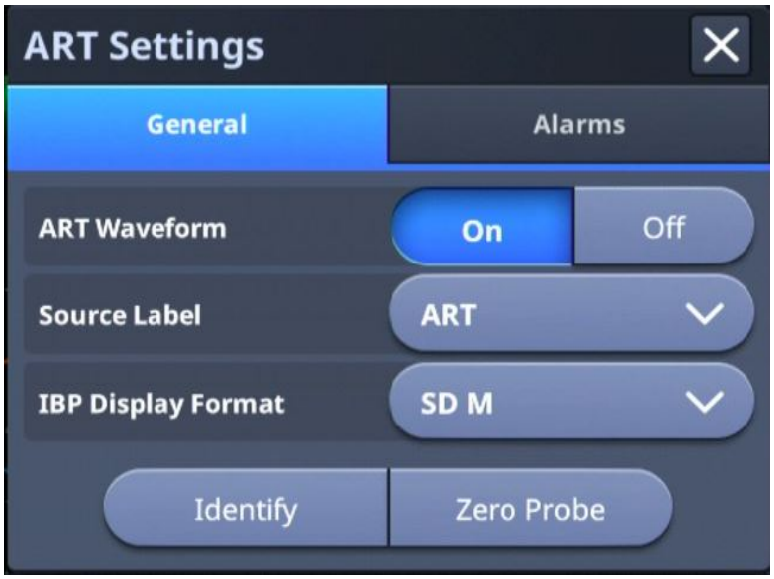
The IBP Settings window allows you to make adjustments to IBP settings and alarms. You can:

- Specify whether to display the IBP waveform.
- Select a label that identifies the source of the channel's IBP measurement. By default, the channels are labeled IBP1, IBP2, and IBP3.
- Set the IBP display format.
- Zero the transducer.
- Identify the transducer.
- Enable/disable alarms and set high/low alarm limits.

Adjusting IBP Settings

To adjust the IBP settings:

1. Select the desired IBP numeric on the Zenix display. The IBP Settings window for that channel displays.



2. In the **ART Waveform** field, select whether to have a waveform for the IBP channel appear on the Zenix display or not by selecting the **On** or **Off** key as appropriate.
3. In the **Source Label** field, specify the source of the channel's IBP measurements by selecting the **v** key and selecting a label from the list that displays.

4. In the **IBP Display Format** field specify the format to use for the IBP Numeric display by selecting the desired format. The display format allows you to choose whether or not you will display MEAN measurement (M) with the Systolic (S) and Diastolic (D) measurements in one of the following formats:
    - **SD M** (default)

      For example, 118/79 (96)
    - **M SD**

      For example, (96) 118/79
    - **M**

      For example, 96
5. Identify the transducer cable for this channel, if desired, by selecting the **Identify** key. A white light flashes on the transducer cable.
6. When you are done making adjustments select **X** to return to the Zenix display.

Adjusting IBP Alarm Settings

It is important that alarm settings are appropriate for the situation. In the IBP Alarm Settings window you can enable/disable the following IBP alarms and set limits so that an alarm sounds whenever IBP measurements are outside those limits:

- High and Low Systolic Pressure
- High and Low Diastolic Pressure
- High and Low Map Alarm

Note: When enabled, any of the low alarms for IBP (systolic, diastolic, or mean) will also provide an alert in the event of a disconnected catheter.

To set IBP alarms and limits:

1. Select the desired IBP numeric on the Zenix display. The IBP Settings window displays.
2. On the IBP Settings window select the **Alarms** tab. The IBP Settings Alarms window displays.



3. In the **Systolic Alarm (mmHg)** field, select the icon to enable/disable the Systolic Alarm. Touch the lower and upper limits and use the keypad to change limit values.
4. In the **Diastolic Alarm (mmHg)** field, select the icon to enable/disable the IBP Diastolic Alarm. Touch the lower and upper limits and use the keypad to change limit values.
5. In the **MAP Alarm (mmHg)** field, select the icon to enable/disable the IBP MAP Alarm. Touch the lower and upper limits and use the keypad to change the values.
6. When you are done making adjustments to IBP alarm settings, select the **X** to exit the window and return to the Zenix display.

IBP System Messages

The device may display the following messages when monitoring IBP:

System Message	Cause
TRANSDUCER FAILURE	The IBP probe is damaged and needs to be replaced.
INCOMPATIBLE TRANSDUCER	The IBP probe is not compatible. See APPENDIX A “Specifications” for a list of ZOLL-approved IBP probes.
CHECK PROBE	The IBP probed has become disconnected.
ZERO PROBE	The IBP probe is connected and needs to be zeroed.
ZEROING	The IBP probe is zeroing.
IBP DISABLED	A system error has occurred, and the device should be serviced.
ZERO REJECTED	The IBP probe was not removed due to a pulsatile pressure signal, excessive IBP artifact, or excessive transducer offset.

CHAPTER 15

Monitoring Temperature

This chapter describes how to monitor temperature.

It includes the following sections:

Overview 190

Temperature Monitoring Setup 191

Selecting and Applying Temperature Probes 192

Connecting the Temperature Probe 193

Temperature Settings Window 194

Temperature System Messages 196

The Temperature inputs are Type CF defibrillator proof.

Overview

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

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 including biocompatibility, use only ZOLL-approved temperature probes.

Temperature Monitoring Setup

To monitor temperature using the Zenix device, perform the following steps, each of which corresponds to a section in this chapter. Read each section carefully before you perform temperature measurements:

1. Select the temperature probe and apply it to the patient.
2. Connect the temperature probe to the Zenix device.
3. Identify Temperature channel(s) and configure Temperature alarms if the current Temperature alarms are not appropriate.

Selecting and Applying Temperature Probes

Use only temperature probes that are approved for use with the Zenix device. 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.

Connecting the Temperature Probe

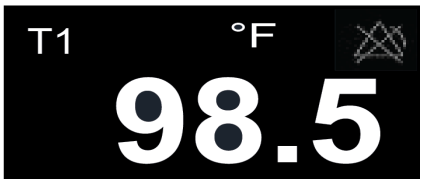
Insert the temperature cable into one of the Z-Link connectors on either side of the Zenix device then connect the temperature probe's 1/4" plug to the end of the cable.



Displaying Temperature Measurements

When the probe is connected, the device displays the temperature after a brief pause. The temperature displays as a numeric value. The Zenix device displays the temperature in °C or °F.

Note: If two probes are connected to a patient, the device alternates displaying the temperature values (T1 and T2) and then displays the difference between the two values (the DeltaT value).



Temperature Settings Window

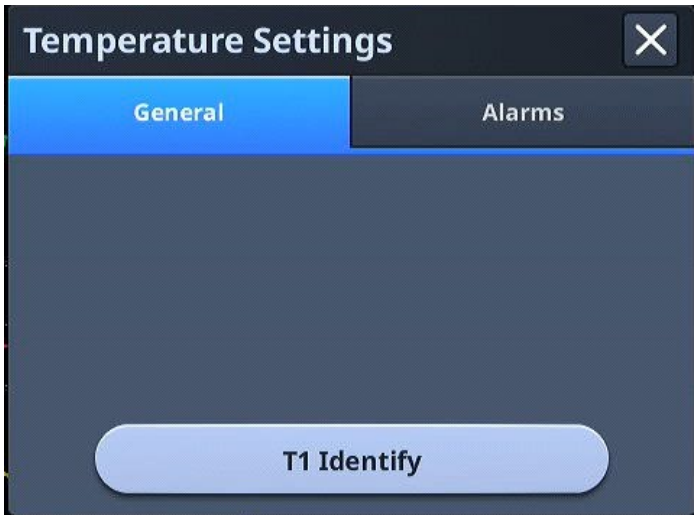
The Temperature Settings window allows you to do the following:

- Identify each temperature channel.
- Enable/disable temperature alarms and set high/low alarm limits.

Identifying Temperature Channels

To visually identify the temperature channel(s):

1. Select the desired Temperature numeric on the Zenix display. The Temperature Settings window displays.



2. Select the **Identify** key (there are two Identify keys if there are two channels). A white light flashes near the temperature probe connection.

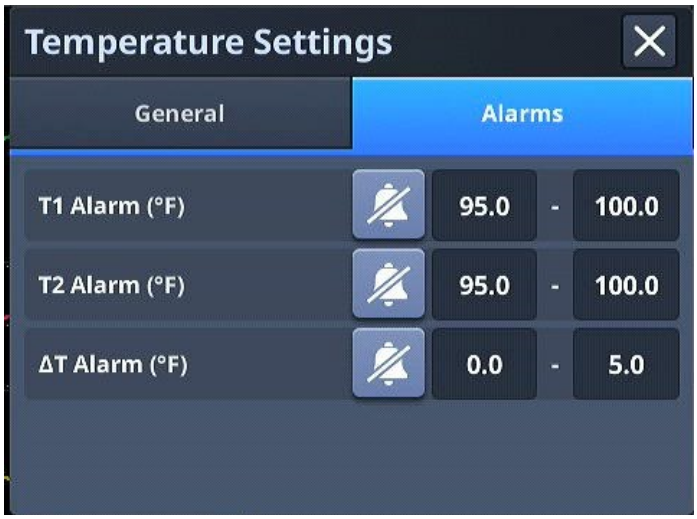
Adjusting Temperature Alarm Settings

In the Temperature Alarm Settings window you can enable/disable the following Temperature alarms and set limits so that an alarm sounds whenever Temperature measurements are outside those limits:

- High and Low Temperature
- High and Low Delta Temperature

To configure Temperature alarm settings:

1. Select the Temperature numeric on the Zenix display. The Temperature Settings window displays.
2. In the Temperature Settings window, select the **Alarms** tab. The Temperature Settings Alarms window displays.



3. In the **T1** or **T2** field, select the **Alarm** icon to enable/disable the Temp alarm. Touch the lower and upper limits and use the keypad to change limit values.
4. In the **ΔT** field, select the **Alarm** icon to enable/disable the Delta Temp alarm. Touch the lower and upper limits and use the keypad to change limit values.
5. When you are done making adjustments to the Temperature alarm settings, select the **X** to exit the window and return to the Zenix display.

Temperature System Messages

The Zenix device may display the following messages when monitoring Temperature.

System Message	Cause
CHECK PROBE	The temperature probe is disconnected. Check probe and reconnect it.
PROBE FAILURE	The temperature probe is defective. Replace the Temperature probe.
TEMP DISABLED	A system error has occurred. The Zenix device cannot take temperature measurements and should be serviced.

CHAPTER 16

Trends

Trends highlight patterns and changes in a patient's vital signs that provide important information for clinical analysis and decision making. This chapter describes the different types of vital sign trends that are accumulated, how they are accumulated, and how to view and print that information.

It includes the following sections:

Overview 198

Displaying/Closing Trends 199

Graphic Trends 199

Table Trends 201

Printing Trend Summary 203

Overview

The Zenix device automatically logs all monitored vital signs and stores them in memory at a user-configurable interval. In addition to the regular interval of logged vital signs, the device can be configured to automatically save a set of vital signs when a blood pressure measurement or an alarm occurs, as well as when a user initiates a snapshot.

The trend data for the patient can be displayed in the Trends Panel on the display screen in a graph or table format. The trends can be viewed in increments from 30 seconds to 60 minutes. You can view and print all logged trend information.

Printed trends are useful for reviewing the patient's vital signs over the last several minutes to the last five hours. You can print vital signs data at one selected time or a trend summary showing vital signs values acquired during the current case (up to the last 24 hours).

Displaying/Closing Trends

The Zenix device displays parameter trend information in the Trends Panel in a graphic or table format, along with a time at which the trend measurements were logged.

1. Select the **Menu** key .
2. In the Menu window, select the **Panels** tab.

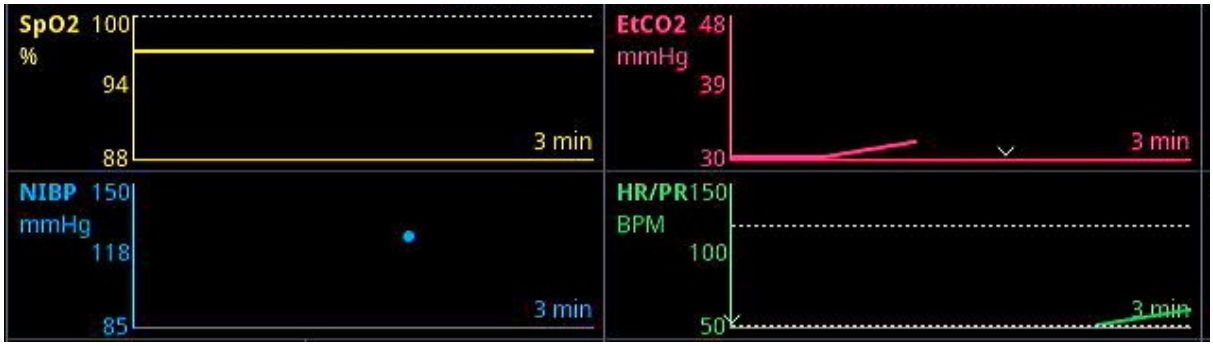


3. In the **Trends Panel** field, select one of the following:
   - **2** or **4** - to display two or four graphic trends
   - **Table** - to display a table trend
   - **None** - to close the current trend
4. When you have made your choice, select **X** to exit the window.

Graphic Trends

Graphic trends are a visual representation that show the parameter trend values on an x and y axis. You can change the time interval and scale of these displayed vital signs. Graphic trends display in the bottom waveform trace (for two trends) or the bottom two waveform traces (for four trends).

The example below shows four graphic trends.



While a graphic trend is being displayed, the Zenix device updates the trend within two seconds of the trend value being recorded.

Trend Values Out of Range

In a graphic trend, configured upper and lower alarm limits are indicated by horizontal white lines. An upward or downward pointing triangle denotes the out of range values. When viewing IBP and NIBP trends, horizontal white lines indicate high systolic and low diastolic alarms limits.

In the example below, the white triangles at the top of the graph show that the HR upper values are out of range.

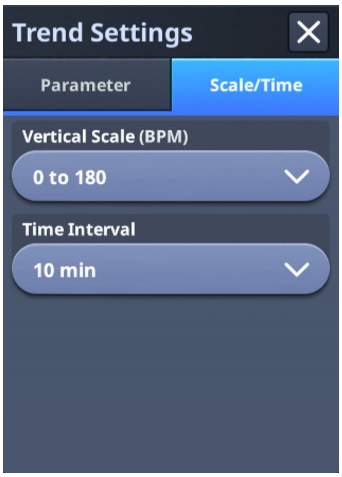


Changing a Graphic Trend

Once graphic trends are displayed on the screen, follow the procedure below to change the trends that are displayed.

1. Select the trend on the display screen. See the table below for details on how to change a graphic trend from the Trend Settings dialog box.





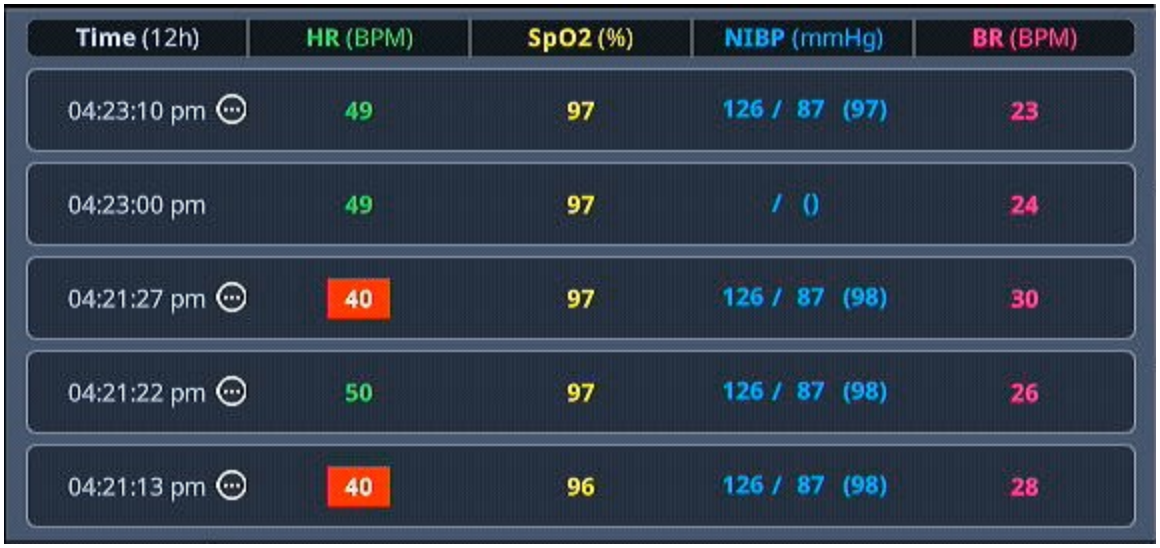
To Change	Do This
Parameter(s)	On Parameter tab, select new parameter to replace current one. **Note**: All parameters that are connected to the device display in this field.
Vertical scale	On Scale/Time tab, select a new vertical scale from the Vertical Scale drop-down menu.
Time Interval	On Scale/Time tab, select new time interval from the Time Interval drop-down menu. **Note**: Selecting a shorter time interval displays the graph format more quickly.

Table Trends

Table trends display numeric values of the vital signs in a tabular format. You can change the time interval of these displayed signs. Table trends display in the three bottom waveform traces, unless another panel is already displayed.

The example below shows a table trend.

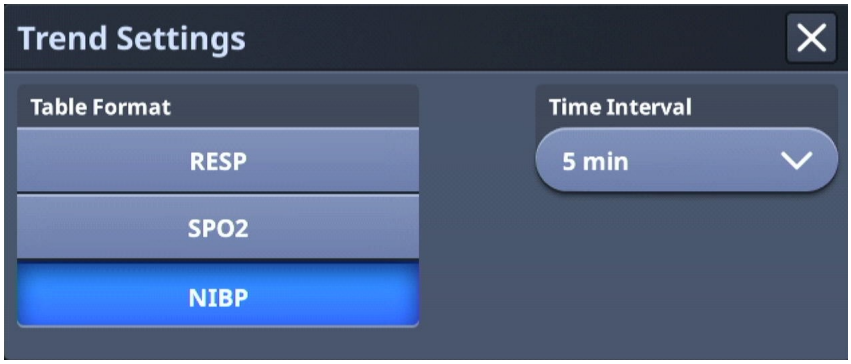
Note: When an alarm occurs, the value displays in red in the table.



The first column shows the time of the reading, followed by a column for each physiological parameter in the trend parameter group. The trend data displays in chronological order, starting with the most recent first. Use the up and down arrows to display additional page(s) of trend data.

Changing a Table Trend

1. Select the **Settings** icon on the left of the trend table. See the table below for details on how to change a table trend from the Trend Settings dialog box.



To Change	Do This
Parameter(s)	In **Table Format** field, select new parameter to replace the current one. **Note**: All parameters that are connected to the device display in this field.
Time Interval	In **Time Interval** field, select a new time interval from the drop-down menu.

Printing an Individual Trend from Table

1. Select a row in the trend table. The trend displays in a snapshot view with the parameters of the selected trend and their values.
2. Select the **Print** button .

Printing All Trends from Table

1. Select the **Print** icon on the left of the table. This prints all current trend displays, from newest to oldest.

Printing Trend Summary

Printed trends are useful for reviewing the patient's vital signs over the last several minutes to the last five hours. You can print vital signs data for a specific time or a trend summary showing vital signs values acquired during the current case (up to the last 24 hours). When printing a trend summary report, the device prints the trend data at the user specified time interval.

To print a trend summary of all trends for the current patient:

1. Select the Menu key  . The Menu window displays.
2. Select the Device tab then select the **Case Options** key at the bottom of the window. The Current Case panel displays,
3. Select **Print** in the Trend Summary field to print the Trend Summary.

CHAPTER 17

Alarms

This chapter describes the Zenix device alarm functionality. It includes how and when patient and equipment alarms display and how to respond to them.

It includes the following sections:

Overview 206
Alarm States 207
LED and Audible Alarm Indicators 208
Patient Alarm Visual Alarm Indicators 209
Technical Alert Visual Alarm Indicators 210
Responding to Active Alarms 211
Pausing Alarms 212
Life-Threatening Alarms 213
Alarm Settings 214

Overview

The Zenix device produces both *patient alarms* and *technical alerts*. Patient alarms are configurable and occur when the vital sign falls outside of the alarm limit. Technical alerts are not configurable and occur when the device or sensors perform differently than expected.

In addition to status/alarm messages that appear on the display, the device illuminates the red or yellow indicator lights on the front panel, displays the alarms active key, and emits an audible alarm to show the priority level of the highest-priority active alarm. This chapter contains more detailed changes on the visual and audible alarm indicators for both patient alarms and technical alerts.

Alarm conditions from patient alarms and technical alerts/information messages are stored in the Event Log and retained with normal power down or total loss of power.

Alarm States

The following alarms display on the device indicating the following:

Alarm	Alarm State
	**Alarms Active** Displays in the navigation bar to indicate that the system is actively monitoring for alarm conditions. Also displays in the parameter control panel if alarms are enabled for that parameter.
	**Alarms Off** Displays in the navigation bar to indicate that the system is not actively monitoring for alarm conditions. Also displays in the parameter control panel if no alarms are enabled for that parameter.
	**Alarm Audio Off** Displays in the navigation bar when the alarm has been silenced.
	**Alarm Audio Paused** Displays in the navigation bar when an active alarm has been paused.

LED and Audible Alarm Indicators

This table shows the LED and audible alarm indicators for patient alarms and technical alerts:

Active Alarm/Alert Priority	LED Alarm/Alert Indicator	Audible Alarm/Alert Indicator
High Priority - Patient Alarm, Life Threatening Alarm (LTA), Replace Battery Alarm	Flashing red indicator light.	Two sets of five short beep tones, repeated at 5-second intervals.
Technical Alert/Information Message	Flashing yellow indicator light.	One set of three longer beep tones, repeated at 15-second intervals.

Patient Alarm Visual Alarm Indicators

When a patient's vital signs measurements trigger an alarm, the following indicators occur on the display:

- The alarm key on the navigation bar flashes red ().
- The alarming parameter appears in white against a red background (185).
- An alarm message displays in the navigation bar.

Note: If there is more than one patient alarm, the Zenix device rotates each message every 4 seconds.

Technical Alert Visual Alarm Indicators

When a problem with the device or an attached sensor triggers an alert, the following indicators occur on the display:

- The alarm key on the navigation bar flashes yellow  .
- The Menu key displays an information icon  .

To Display Alert Message:

1. Select the **Menu** key  .
2. In the Menu window, select the **Device** tab.
3. In the **Technical Alerts / Informational Messages** field, select **View** to see the alarm message. The information icon disappears.

   Note: The alert remains in the Alerts/Messages window and the Alarm key flashes yellow until the alarm is acknowledged by pressing the Alarm key or the error is corrected, for example, a detached lead is reattached.

WARNING! Always respond immediately to a system alarm since the patient may not be monitored during certain alert conditions.

Responding to Active Alarms

Note: There are three special alarms that cannot be disabled: *PACING -LEAD FAULT*, *PACING - PADS LEAD SHORT*, and *IBP PULSATILE TO NON-PULSATILE*.

When a patient alarm is triggered and the alarm tone sounds:

1. Assess the patient and provide appropriate care.
2. Select the red **Alarm** key on the navigation bar to acknowledge the alarm and briefly pause (silence) the alarm (90 seconds). The alarm tone stops and the device displays the **Alarm Audio Paused** key with the countdown timer. The value of the alarming parameter remains highlighted.
3. After caring for the patient, check that the appropriate alarms are set (for more information about setting alarms, see "General Alarm Settings" on page 215).

Note: Selecting the red **Alarm** key pauses (silences) the alarm tone briefly for all active alarms. If the patient's vital signs measurements trigger another, different alarm, the patient alarm tone will sound, even if the first pause (silence) period hasn't expired.

Re-enabling an Alarm

To re-enable an alarm before the alarm pause (silence) period has expired:

1. Select the Alarm Audio Paused key on the navigation bar.
2. In the General tab of the Alarm Settings window, select **Alarm Audio Reset**.

WARNING!
Do not pause (silence) the audible alarm if patient safety may be compromised.

Do not adjust alarm signal volume lower than the ambient noise level if this may impede operator recognition of alarm signals.

Pausing Alarms

If you want to temporarily prevent potential or current patient alarms and equipment alert alarms from sounding when caring for a patient, you can pause alarm audio for 90 seconds or pause the alarm audio indefinitely (Audio Off). Alarms automatically resume after the pause time is up.

To pause patient alarms:

1. Select the **Alarm** key on the navigation bar to acknowledge the alarm (alternatively, you can select the parameter control panel). The alarm tone stops and the device displays the Alarm Audio Paused key with a countdown timer indicating the amount of time the alarms will be paused.
2. If you would like to turn the alarm audio off indefinitely, select the **Alarm Audio Paused** key on the touch screen navigation panel.
3. In the General tab of the Alarm Settings window, select **Alarm Silence**. The **Alarm Audio Paused** key appears on the navigation bar to indicate alarm audio is paused indefinitely for this device.

   Select **Alarm Audio Reset** from the General tab in the Alarm Settings window to clear the display and resume alarm audio.

No alarms will sound while alarms are paused; however, if an alarm occurs during the suspension period, the device will display visual alarm indicators — alarm messages in the message area (white text on a red background) and red/white numeric displays.

Note: Your device may be configured to not allow pausing alarms.

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

Alarm Reminders

The Zenix device may be configured to sound a Reminder Alarm at specified intervals. When the Reminder Alarm is enabled, an alarm sounds every 5 (default), 10, or 15 minutes (depending on configuration) if an Alarm Audio Off condition persists. When a Reminder Alarm is disabled, no reminders are issued if the Alarm Audio Off condition continues. Alarm reminders are Supervisor enabled or disabled.

Life-Threatening Alarms

When LTA monitoring is enabled, the device monitors for the following life-threatening ECG rhythms:

- Asystole
- Ventricular Fibrillation
- Ventricular Tachycardia
- Extreme Bradycardia
- Extreme Tachycardia

Depending upon the Zenix device configuration, visible and audible alarms are generated as needed.

Note: LTA monitoring is not available in AED mode.

Latching Alarms

High priority patient alarms can be configured to be latching or non-latching (default).

When alarms are configured as non-latching, alarm indicators clear when the alarm condition ends, whether or not the alarm was Paused.

Latching alarms are useful in situations where the patient may not be continuously attended by the clinical operator as they make you aware of patient alarm conditions whether or not they are still occurring. Latched alarms must be acknowledged even if the condition no longer exists. When alarms are configured to be latching, alarm indicators (sound, message, color) persist whether or not the condition is present. Life Threatening Rhythm Alarms (LTA) are always latching.

Alarm Settings

The default alarm settings globally for all alarm, alarm limit thresholds, alarm states, and alarm limits by patient type are Supervisor configured. You can, however, make adjustments to alarm settings to accommodate the clinical needs of the current, monitored patient. You can enable/disable alarms, modify alarm limits, and set all alarm limits relative to the patient's current vital signs measurements. The Zenix device returns to the default alarm settings when powered down.

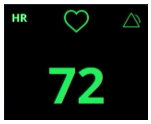
You can access alarm options in two ways:

Select the **Alarm** key:



or

Select the desired parameter numeric:



Note: Each parameter control panel has an alarm icon in the top right corner that is either enabled or disabled so you can quickly see if an alarm is set for that parameter.

WARNING!

- **A potential hazard exists if different alarm limits are used for the same or similar equipment in any single area.**
- **Confirm the alarm limits are appropriate for the patient each time there is a new patient case.**
- **Do not set alarm limits to such extreme values that render the alarm system useless.**

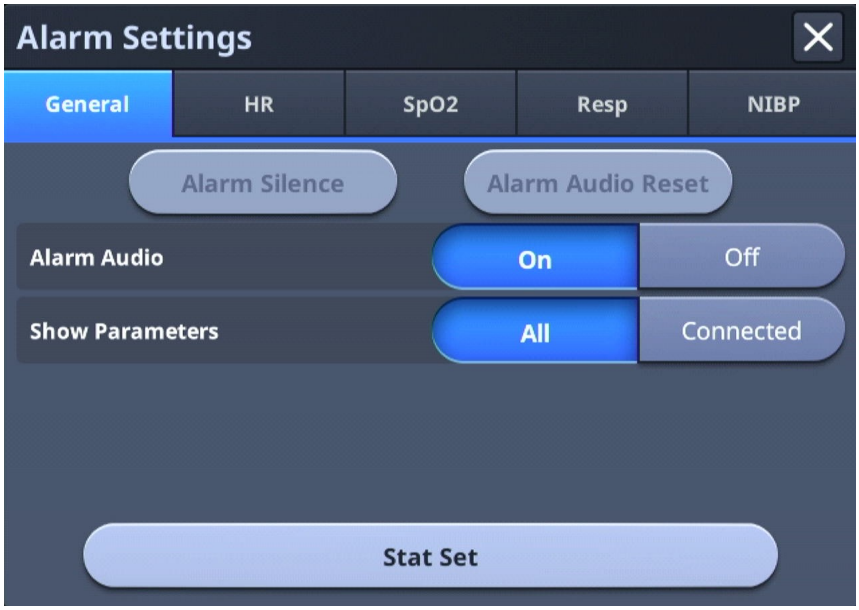
General Alarm Settings

You can specify general alarm settings such as enabling/disabling all alarm audio for all parameters or just those parameters that are connected to the Zenix device.

To configure general alarm settings:

1. Select the **Alarm** key . The Alarm Settings window displays with the General tab selected. See the table below for general alarm settings.

Note: See the specific parameter chapters for details on enabling/disabling individual parameter alarms.



Note: The **Alarm Silence** and **Alarm Audio Reset** settings are for active alarm(s). For more information on how to use these settings, see "Responding to Active Alarms" on page 211and "Pausing Alarms" on page 212.

To	Do This
Enable/Disable only the alarm audio	In the **Alarm Audio** field: • Select **On** to enable alarm audio. • Select **Off** to disable alarm audio. **Note:** When the alarm audio is **Off**, the visual alarms still display.

To	Do This
Show tabs for all parameters or show tabs only for connected parameters in Alarm Settings window	In the **Show Parameters** field: • Select **All** to have tabs for all parameters appear in the Alarm Settings window. • Select **Connected** to only have tabs for the current monitoring parameters appear in the Alarm Settings window.
To enable/disable parameter alarms	• Select the desired parameter tab on the top of the Alarm Settings window. • Select the **Alarm** icon next to the alarm to enable/disable as appropriate. • Set alarm limits, if necessary, by selecting the lower and upper limits and using the keypad to change the values. **Note:** See the specific parameter chapters for details on enabling/disabling individual parameter alarms.

The Stat Set key at the bottom of the window sets all alarm limits relative to the patient's current vital signs measurements. All parameters are set to a new value based on the current values. For more information, see "Setting Alarm Limits Relative to the Patient – Stat Set Option" on the facing page.

Setting Alarm Limits Relative to the Patient – Stat Set Option

The Stat Set key sets all alarm limits relative to the patient's current vital signs measurements. When Stat Set has been selected, these alarm settings remain in effect for the rest of the patient case or the device has been powered down. All parameters are set to a new value based on the current values as follows:

Parameter (devices)	Range	Upper Limit Calculation	Lower Limit Calculation
HR/PR (bpm)	Numeric < 26	Limit is unchanged	Limit = 25
	26 ≤ Numeric ≤ 99	Limit = Numeric x 1.2	Limit = Numeric x 0.8
	100 ≤ Numeric ≤ 250	Limit = Numeric + 20	Limit = Numeric – 20
	Numeric > 250	Limit = 250	Limit is unchanged
IBP (mmHg)	Numeric < 26	Limit = Numeric + 5	Limit = Numeric – 5
	26 ≤ Numeric ≤ 99	Limit = Numeric x 1.2	Limit = Numeric x 0.8
	Numeric > 99	Limit = Numeric + 20	Limit = Numeric – 20
NIBP (mmHg)	Numeric < 26	Limit = Numeric + 5	Limit = Numeric – 5
	26 ≤ Numeric ≤ 99	Limit = Numeric x 1.2	Limit = Numeric x 0.8
	Numeric > 99	Limit = Numeric + 20	Limit = Numeric – 20
RR/BR (/min)	Numeric < 26	Limit = Numeric + 5	Limit = Numeric – 5
	26 ≤ Numeric ≤ 99	Limit = Numeric x 1.2	Limit = Numeric x 0.8
	Numeric > 99	Limit = Numeric + 20	Limit = Numeric – 20
SpO_2 (%)	Entire range	Limit = 100 (Adult and Pediatric) Limit = Numeric + 5 (Neonate)	Limit = Numeric – 5
SpCO (%)	Entire range	Limit = Numeric + 2 Upper limit 40	Limit = Numeric - 2 Lower limit 0
SpMet (%)	Entire range	Limit = Numeric + 2 Upper limit 15	Limit = Numeric - 2 Lower limit 0
SpHb (g/dL)	Entire range	Limit = Numeric + 2	Limit = 0
SpHb (mmo/L)	Entire range	Limit = Numeric + 1	Limit = 0
SpOC (ml/dL)	Entire range	Limit = Numeric + 2	Limit = 0
PVi (%)	Entire range	Limit = Numeric + 5	Limit = Numeric - 5

Parameter (devices)	Range	Upper Limit Calculation	Lower Limit Calculation
Pi (%)	Entire range	Limit = Numeric + 2	Limit = 0
$EtCO_2$ (mmHg)	Entire range	Limit = Numeric + 10	Limit = Numeric - 5 *unless* the numeric falls below the lower alarm limit range (0-145 mmHg), in which case Stat Set sets the lower limit to 15 mmHg.
$FiCO_2$ (mmHg)	Entire range	Limit = Numeric + 5	N/A
Temp (°C)	Entire range	Limit = Numeric + 0.5	Limit = Numeric – 0.5
Temp (°F)	Entire range	Limit = Numeric + 0.9	Limit = Numeric – 0.9

Respiratory Rate (RR/BR) Alarm Limits

Patient Type	Respiration Rate Default	Respiration Rate Range
Adult	Lower: 3 BPM Upper: 50 BPM	Lower: 2 to 145 BPM Upper: 5 to 150 BPM
Pediatric	Lower: 3 BPM Upper: 50 BPM	Lower: 2 to 145 BPM Upper: 5 to 150 BPM
Neonate	Lower: 12 BPM Upper: 80 BPM	Lower: 2 to 145 BPM Upper: 5 to 150 BPM

Heart Rate (HR) Alarm Limits

Patient Type	HR Default	HR Range
Adult	Lower: 50 BPM Upper: 120 BPM	Lower: 30 to 298 BPM Upper: 32 to 300 BPM
Pediatric	Lower: 50 BPM Upper: 150 BPM	Lower: 30 to 298 BPM Upper: 32 to 300 BPM
Neonate	Lower: 100 BPM Upper: 200 BPM	Lower: 30 to 298 BPM Upper: 32 to 300 BPM

You can configure delta values to apply to the HR lower limit alarm and HR upper limit alarm for the Extreme Bradycardia and Extreme Tachycardia LTA alarm detection, respectively. See the following examples below:

Extreme Bradycardia:

- HR lower alarm is configured to 50 bpm.
- Extreme Brady delta value is configured to -10 bpm.
- Extreme Bradycardia LTA detection threshold will be 40 bpm.

Extreme Tachycardia:

- HR upper limit alarm is configured to 120 bpm.
- Extreme Tachy delta value is configured to +20 bpm.
- Extreme Tachycardia LTA detection threshold will be 140 bpm.

Note: You do not have to enable the HR lower and upper limit alarms for the Extreme Bradycardia and Extreme Tachycardia LTA alarm detection to be enabled. The Extreme Bradycardia and Extreme Tachycardia LTA alarms will not activate until 20 seconds after the alarm limit threshold is crossed.

Extreme Bradycardia Alarm Limits

Patient Type	Default	Delta Value Range
Adult	-10 BPM	-5 to -30 in increments of 5
Pediatric	-10 BPM	-5 to -30 in increments of 5
Neonate	-10 BPM	-5 to -30 in increments of 5

Extreme Tachycardia Alarm Limits

Patient Type	Default	Delta Value Range
Adult	+20 BPM	+5 to +30 in increments of 5
Pediatric	+20 BPM	+5 to +30 in increments of 5
Neonate	+20 BPM	+5 to +30 in increments of 5

NIBP Alarm Limits

Patient Type	Alarm Parameter		Default Setting	Range (increments of 5)
Adult	Systolic	High	160 mmHg (21.3 kPa)	80-260 mmHg (10.7-34.7 kPa)
		Low	90 mmHg (12.0 kPa)	40-140 mmHg (5.3-18.7 kPa)
	Diastolic	High	110 mmHg (14.7kPa)	50-200 mmHg (6.7-26.7 kPa)
		Low	50 mmHg (6.7 kPa)	25-100 mmHg (3.3-13.3 kPa)
	Mean	High	130 mmHg (17.3 kPa)	60-220 mmHg (8.0-29.3 kPa)
		Low	60 mmHg (8.0 kPa)	30-120 mmHg (4.0-16.0 kPa)
Pediatric	Systolic	High	145 mmHg (19.3 kPa)	80-160 mmHg (10.7-21.3 kPa)
		Low	75 mmHg (10.0 kPa)	35-140 mmHg (4.7-18.7 kPa)
	Diastolic	High	100 mmHg (13.3 kPa)	50-130 mmHg (6.7-17.3 kPa)
		Low	35 mmHg (4.7 kPa)	20-100 mmHg (2.7-13.3 kPa)
	Mean	High	110mmHg (14.7kPa)	60-140 mmHg (8.0-18.7 kPa)
		Low	50 mmHg (6.7 kPa)	30-120 mmHg (4.0-16.0 kPa)
Neonate	Systolic	High	100 mmHg (13.3 kPa)	60-130 mmHg (8.0-17.3 kPa)
		Low	50 mmHg (6.7 kPa)	25-120 mmHg (3.3-16.0 kPa)
	Diastolic	High	70 mmHg (9.3 kPa)	30-105 mmHg (4.0-14.0 kPa)
		Low	30 mmHg (4.0 kPa)	20-100 mmHg (2.7-13.3 kPa)
	Mean	High	80 mmHg (10.7 kPa)	35-110 mmHg (4.7-14.7 kPa)
		Low	35 mmHg (4.7 kPa)	30-105 mmHg (4.0-14.0 kPa)

SpO_2 Alarm Limits

Patient Type	SpO_2 Limit Default	SpO_2 Limit Range
Adult	Lower: 85% Upper: 100%	Lower: 50 - 98% Upper: 52 - 100%
Pediatric	Lower: 85% Upper: 100%	Lower: 50 - 98% Upper: 52 - 100%
Neonate	Lower: 85% Upper: 95%	Lower: 50 - 98% Upper: 52 - 100%

SpCO Alarm Limits

Patient Type	SpCO Limit Default	SpCO Limit Range	SpMet Limit Default	SpMet Limit Range
Adult	Lower: 0% Upper: 10%	Lower: 0- 98% Upper: 2 - 100%	Lower: 0% Upper: 3%	Lower: 0- 98% Upper: 2 - 100%
Pediatric	Lower: 0% Upper: 10%	Lower: 0 - 98% Upper: 2 - 100%	Lower: 0% Upper: 3%	Lower: 0- 98% Upper: 2 - 100%
Neonate	Lower: 0% Upper: 10%	Lower: 0 - 98% Upper: 2 - 100%	Lower: 0% Upper: 3%	Lower: 0- 98% Upper: 2 - 100%

SpMet Alarm Limits

Patient Type	SpCO Limit Default	SpCO Limit Range	SpMet Limit Default	SpMet Limit Range
Adult	Lower: 0% Upper: 10%	Lower: 0- 98% Upper: 2 - 100%	Lower: 0% Upper: 3%	Lower: 0- 98% Upper: 2 - 100%
Pediatric	Lower: 0% Upper: 10%	Lower: 0 - 98% Upper: 2 - 100%	Lower: 0% Upper: 3%	Lower: 0- 98% Upper: 2 - 100%
Neonate	Lower: 0% Upper: 10%	Lower: 0 - 98% Upper: 2 - 100%	Lower: 0% Upper: 3%	Lower: 0- 98% Upper: 2 - 100%

SpHb Alarm Limits

Patient Type	SpHb Limit Default		SpHb Limit Range
Adult	Lower: 7.0 g/dL 4.0 mmol/L Upper: 17.0 g/dL 11.0 mmol/L		Lower: 0 - 24.9 g/dL 0 - 15.4 mmol/L Upper: 2 - 25 g/dL 2 - 15.5 mmol/L
Pediatric	Lower: 7.0 g/dL 4.0 mmol/L Upper: 17.0 g/dL 11.0 mmol/L		Lower: 0 - 24.9 g/dL 0 - 15.4 mmol/L Upper: 2 - 25 g/dL 2 - 15.5 mmol/L
Neonate	Lower: 7.0g/dL 4.0 mmol/L Upper: 17.0 g/dL 11.0 mmol/L		Lower: 0 - 24.9 g/dL 0 - 15.4 mmol/L Upper: 2 - 25 g/dL 2 - 15.5 mmol/L

SpOC Alarm Limits

Patient Type	SpOC Limit Default	SpOC Limit Range
Adult	Lower: 10 ml/dL Upper: 25 ml/dL	Lower: 0 - 34.9 ml/dL Upper: 0.2 - 35 ml/dL
Pediatric	Lower: 10 ml/dL Upper: 25 ml/dL	Lower: 0 - 34.9 ml/dL Upper: 0.2 - 35 ml/dL
Neonate	Lower: 10 ml/dL Upper: 25 ml/dL	Lower: 0 - 34.9 ml/dL Upper: 0.2 - 35 ml/dL

PVi Alarm Limits

Patient Type	PVi Limit Default	PVi Limit Range
Adult	Lower: 5% Upper: 40%	Lower: 0 - 98% Upper: 2 - 100%
Pediatric	Lower: 5% Upper: 40%	Lower: 0 - 98% Upper: 2 - 100%
Neonate	Lower: 5% Upper: 40%	Lower: 0 - 98% Upper: 2 - 100%

Pi Alarm Limits

Patient Type	Pi Limit Default	Pi Limit Range
Adult	Lower: 0% Upper: 20%	Lower: 0 - 19.8% Upper: 0.2 - 20%
Pediatric	Lower: 0% Upper: 20%	Lower: 0 - 19.8% Upper: 0.2 - 20%
Neonate	Lower: 0% Upper: 20%	Lower: 0 - 19.8% Upper: 0.2 - 20%

$EtCO_2$ Alarm Limits

Patient Type	$EtCO_2$ Limit Default	$EtCO_2$ Limit Range
Adult	Lower: 8 mmHg Upper: 60 mmHg	Lower: 0-145 mmHg Upper: 5-150 mmHg
Pediatric	Lower: 8 mmHg Upper: 60 mmHg	Lower: 0-145 mmHg Upper: 5-150 mmHg
Neonate	Lower: 8 mmHg Upper: 60 mmHg	Lower: 0-145 mmHg Upper: 5-150 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 device in high-altitude environments, it is advisable to adjust $EtCO_2$ alarm settings accordingly.

$FiCO_2$ Alarm Limits

Patient Type	Upper $FiCO_2$ Limit Default	Upper $FiCO_2$ Limit Range
Adult	8 mmHg	2-98 mmHg
Pediatric	8 mmHg	2-98 mmHg
Neonate	8 mmHg	2-98 mmHg

IBP Systolic (SYS) Alarm Limits

Patient Type	IBP Systolic Limit Default	IBP Systolic Limit Range
Adult	Lower: 75 mmHg Upper: 220 mmHg	Lower: -30 to 298 mmHg Upper: -28 to 300 mmHg

Patient Type	IBP Systolic Limit Default	IBP Systolic Limit Range
Pediatric	Lower: 75 mmHg Upper: 145 mmHg	Lower: -30 to 298 mmHg Upper: -28 to 300 mmHg
Neonate	Lower: 50 mmHg Upper: 100 mmHg	Lower: -30 to 298 mmHg Upper: -28 to 300 mmHg

IBP Diastolic (DIA) Alarm Limits

Patient Type	IBP Diastolic Limit Default	IBP Diastolic Limit Range
Adult	Lower: 35 mmHg Upper: 110 mmHg	Lower: -30 to 298 mmHg Upper: -28 to 300 mmHg
Pediatric	Lower: 35 mmHg Upper: 100 mmHg	Lower: -30 to 298 mmHg Upper: -28 to 300 mmHg
Neonate	Lower: 30 mmHg Upper: 70 mmHg	Lower: -30 to 298 mmHg Upper: -28 to 300 mmHg

IBP MAP Alarm Limits

Patient Type	IBP Mean Limit Default	IBP Mean Limit Range
Adult	Lower: 50 mmHg Upper: 120 mmHg	Lower: -30 to 298 mmHg Upper: -28 to 300 mmHg
Pediatric	Lower: 50 mmHg Upper: 110 mmHg	Lower: -30 to 298 mmHg Upper: -28 to 300 mmHg
Neonate	Lower: 35 mmHg Upper: 80 mmHg	Lower: -30 to 298 mmHg Upper: -28 to 300 mmHg

Δ Temperature Alarm Limits

Patient Type	Δ Temperature Limit Default	Δ Temperature Limit Range
Adult	Lower: 0.0 ° F (0.0 ° C) Upper: 5.0 ° F (2.8 ° C)	Lower: 0.0 - 87.8 ° F (0.0 - 47.8 ° C) Upper: 0.2 - 88.0 ° F (0.2 - 48.0 ° C)
Pediatric	Lower: 0.0 ° F 0.0 ° C) Upper: 5.0 ° F (2.8 ° C)	Lower: 0.0 - 87.8 ° F (0.0 - 47.8 ° C) Upper: 0.2 - 88.0 ° F (0.2 - 48.0 ° C)
Neonate	Lower: 0.0 ° F (0.0 ° C) Upper: 5.0 ° F (2.8 ° C)	Lower: 0.0 - 87.8 ° F (0.0 - 47.8 ° C) Upper: 0.2 - 88.0 ° F(0.2 - 48.0 ° C)

Temperature Alarm Limits

Patient Type	Temperature Limit Default	Temperature Limit Range
Adult	Lower: 35 ° C (95.0 ° F) Upper: 37.8 ° C (100 ° F)	Lower: 0.0 - 48.0 ° C (32.0 - 120.0 ° F) Upper: 2.0 - 50.0 ° C (34.0 - 122.0 ° F)
Pediatric	Lower: 35 ° C (95.0 ° F) Upper: 37.8 ° C (100 ° F)	Lower: 0.0 - 48.0 ° C (32.0 - 120.0 ° F) Upper: 2.0 - 50.0 ° C (34.0 - 122.0 ° F)
Neonate	Lower: 35 ° C (95.0 ° F) Upper: 37.8 ° C (100 ° F)	Lower: 0.0 - 48.0 ° C (32.0 - 120.0 ° F) Upper: 2.0 - 50.0 ° C (34.0 - 122.0 ° F)

CHAPTER 18

TBI Dashboard

This chapter describes how to use the Zenix TBI Dashboard. If enabled, the Zenix device provides a specific set of information in a dashboard form to aid clinicians in monitoring patients with possible traumatic brain injury (TBI).

It includes the following sections:

Overview 228

Parameter Trend Graphs 229

Ventilation Assistance 231

Using the TBI Dashboard 233

References 234

Overview

The TBI Dashboard provides graphical trend data and ventilation assistance relevant to management of a TBI patient. The TBI Dashboard is available in Manual and AED mode. When in AED mode, the TBI Dashboard is only available when AED is paused.

The TBI Dashboard is not available during pacing, defibrillation, or CPR. Initiating CPR with ZOLL authorized CPR pads or utilizing any of the **Defib** or **Pacer** buttons removes the TBI Dashboard from the Zenix display. Access to the TBI Dashboard is restricted when the CPR Dashboard is displayed or when the Manual Defibrillation Energy Select control is active.

The TBI Dashboard provides:

- Three panels for viewing the patient's parameter data (SpO_2, Systolic BP (SBP), and $EtCO_2$) in a graphical trend format.
- A ventilation assistance panel that contains a ventilation countdown timer based on a configured target breath rate that prompts users to deliver a breath.



Parameter Trend Graphs

The TBI Dashboard provides graphical trend graphs for SpO_2, Systolic BP (SBP) and $EtCO_2$. The trend graphs plot the patient's physiological parameters over time. When in adult mode, the trend graphs contain supervisor-configured protocol limits so you can easily see if a patient parameter falls outside the recommended value.

Note: Limit values only display in adult mode. They are not available in pediatric or neonate mode. No alarms are set in the TBI Dashboard. Set alarms based on your institution's alarm protocols.

Parameter trend graphs:

- Display numeric protocol limit vertically on the left side of each trend graph.
- Includes a white dashed line across the graph to indicate the protocol limit.
- Trend data from right to left with the most recent data displayed on the right.
- Displays a caret marker where applicable on the appropriate trend graph when a parameter value is above (^) or below (v) the scale range for that graph.



SBP Trending

The TBI Dashboard trends systolic blood pressure (SBP) data over the last 15 minutes and updates whenever a new reading is taken.

The SBP trend graph displays:

- A horizontal dashed line to identify a supervisor-configured protocol limit.
- SBP measurements indicated as circles on the trend graph.
- An asterisk displays in the trend graph whenever a measurement is suspect.
- An out of range marker (^) at the top of the trend graph when an SBP measurement falls above the scale range and an out of range marker (v) at the bottom of the SBP trend graph when it falls below the scale range.

You can change the viewing scale range for the current monitored patient by selecting the SBP trend graph heading and choosing a range from the list that displays. Supervisor configured protocol limits, identified by the dashed horizontal line, cannot be changed.

If NIBP is in manual mode or in automatic mode with an interval greater than 5 minutes, entering the TBI Dashboard automatically sets NIBP measurements to auto mode with a 5 minute interval. If the Zenix device is configured to take NIBP measurements at an interval less than 5 minutes, no change occurs in the interval timing.

$EtCO_2$ Trending

The TBI Dashboard trends $EtCO_2$ data over the last 3 minutes and updates the data every second. The $EtCO_2$ trend graph displays:

- Two horizontal dashed lines to identify supervisor configured upper and lower protocol limits.
- An out of range marker (^) at the top of the trend graph when an $EtCO_2$ value falls above the scale range and an out of range marker (v) at the bottom of the $EtCO_2$ trend graph when $EtCO_2$ value falls below the scale range.

You can change the scale range by selecting the **EtCO2** trend graph heading and choosing a range from the list that displays.

SpO_2 Trending

The TBI Dashboard trends SpO_2 data over the last 3 minutes and updates the data every second. The SpO_2 trend graph displays:

- A horizontal dashed line to identify a supervisor-configured lower protocol limit.
- An out of range marker (v) displays at the bottom of the SpO_2 trend graph when an SpO_2 measurement falls below the scale range.

You can change the scale range by selecting the SpO_2 trend graph heading and choosing a range from the list that displays.

Ventilation Assistance

The top left panel of the TBI Dashboard is for ventilation assistance. The panel contains a configurable target breath rate and a countdown timer that prompts you to deliver a breath. The countdown timer counts down to 0 then turns white to indicate that it is time to deliver a breath.



The target breath rate is set to default whenever the Zenix device is powered off for more than 30 seconds. The default target breath rate is set by patient mode:

- **Adult**: Configurable upon device setup
- **Pediatric**: 20 BPM
- **Neonate**: 25 BPM

The countdown timer resets whenever:

- Countdown timer counts down to 0.
- Target breath rate changes.
- The countdown timer is started after having been paused/stopped.

Ventilation Assistance with Real BVM Help

When used with Real BVM Help, the Zenix device incorporates the Real BVM Help window in the ventilation assistance panel. See "Real BVM Help" on page 91 for information on the Real BVM Help feature.

The BVM dashboard provides the AccuVent target tidal volume and indicates the ventilation quality in an expanding circle with a countdown timer located within the circle. When a breath is complete the circle fills. The quality indicator circle displays in green when the quality of ventilation falls within range of the configured target and yellow when it falls outside the configured target. A timer within the circle counts down to provide guidance to prepare for the next ventilation.



If Real BVM Help was in use prior to entering the TBI Dashboard and the target breath rate is different, the Zenix device displays a pop-up where you can choose whether or not to switch to the TBI breath rate setting. If prior to entering TBI Dashboard the target breath rate was 30:2, the Zenix device alerts you and switches to the TBI Dashboard target breath rate setting.

Note: The Zenix device alerts you only one time per patient case when a target breath is changed. If you exit then return to the TBI Dashboard again, no prompt displays.

Using the TBI Dashboard

Reference the table below for instructions on using the TBI Dashboard.

If you want to...	Do this...
Start/Stop countdown timer	1. Select the **Pause** key to stop the TBI Dashboard countdown timer. The key label changes to **Run**. 2. Select the **Run** key to reset and restart the countdown timer. **Note:** The **PAUSE/RUN** key is not available when the Target Breath Rate is set to **OFF**.
Change the target breath rate	1. On the TBI Dashboard, navigate to and select **Rate**. The TBI BR Settings dialog box displays 2. Select the down arrow then select a breath rate from the list that displays or select **OFF** to turn off the target breath rate and countdown timer in the TBI Dashboard. • When you select **OFF** the pediatric and neonate target breath rate are also turned off and remain off even if the patient mode changes. • The TBI Dashboard uses the current supervisor-configured breath rate for each new patient. • When you change the target breath rate, the countdown timer resets based on the selected rate.
Change a parameter target scale range	1. On the TBI Dashboard, navigate to and select the desired trend graph. The TBI Parameter Settings dialog box displays. 2. Select the down arrow then select a scale range from the list that displays.

References

Badjatia et al. Guidelines for Management of Traumatic Brain Injury 2nd edition. Prehospital Emergency Care. 2007; 12(1 suppl):s1-s52.

Adelson et al. Guidelines for the Acute Medical Management of Severe Traumatic Brain Injury in Infants, Children and Adolescents. Pediatric Critical Care Medicine. 2003; 4(3 suppl): s1- s491.

Excellence in Prehospital Injury Care- Traumatic Brain Injury (EPIC-TBI) Project Blue Book.

CHAPTER 19

Patient Data Management

This chapter describes procedures for viewing, storing, and transferring patient data from the Zenix device.

It includes the following sections:

Overview 236
Patient Data Storage 237
Data Log Capacity 238
Waveforms 239
Snapshots 240
Reports 243
Full Disclosure Case Logs 245

Overview

The Zenix device records important patient event data. The data stored includes demographic information, waveforms, numeric trend data, notations of any alerts or alarms that occurred during the case, as well as user initiated markers to indicate an event. You can review this case data on the Zenix device, transmit the case data for subsequent viewing or transfer the case data to a USB drive.

A patient case begins when the following occurs:

- A new patient event is initiated.
- The Zenix device has been turned off for longer than 30 seconds.
- The patient case reaches 24 hours.

You can retrieve this information in various forms such as waveforms, trends, snapshots, reports, and full disclosure logs while the Zenix device is monitoring the patient or after the patient has been disconnected from the device.

Note: For detailed information on Trends, see CHAPTER 16 “Trends”.

Patient Data Storage

The Zenix device continuously stores information in a full disclosure case log for the patient being monitored. The device can maintain up to 150 full disclosure cases that contain treatment events, trends, ECG and other continuous waveforms, monitoring and event snapshots, and 12-lead snapshots and analysis. The Zenix device can, at a minimum, concurrently store the following information:

250Hz waveforms:

• 4 displayed ECG waveforms

• 2 3D CPR Z axis acceleration waveforms

125Hz waveforms:

• CO_2 waveform (or impedance respiration)

• CPR (calculated) displacement waveform

• Pads Impedance waveform

• 2 AccuVent delta pressure waveforms

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.

Note: The Zenix device retains stored cases even if you turn it off, remove the auxiliary power cord or remove the battery. The Zenix device records the time it was powered down in the case log.

Data Log Capacity

When data storage reaches its capacity where full disclosure is at the 150 case limit (or 99%), the device performs automatic log management by deleting the oldest full disclosure case. If the log is not cleared or transferred as it reaches capacity, the Zenix device continues to delete cases as needed (First in First out) to acquire storage capacity. You should clear the full disclosure log after transferring data to a USB device or when the log is nearing its capacity.

Waveforms

The Zenix device can be configured to display up to four waveforms. You can print displayed waveforms by selecting the **Print** key. When printing an ECG waveform, the device prints the ECG waveform in the first trace window. Waveforms that have invalid data print a dashed line for that trace. When there is no valid ECG waveform data, the printed ECG waveform appears as a dashed line labeled as an ECG Lead Fault.

If configured in the ECG settings, the Zenix device can print the following displayed waveform types:

Waveform Type	Description
ECG	ECG waveforms print with major divisions every 5mm and minor divisions every 1 mm. The ECG waveform always prints if ECG is being monitored.
Invasive Pressure	Pressure waveforms print with major divisions every 5 mm. The pressure scale grids print horizontally.
SpO_2 Plethysmograph	The SpO_2 plethysmograph prints with major divisions every 5 mm.
CO_2	CO_2 waveforms print with major divisions every 5 mm, and the pressure scale grids print horizontally.
RESP	Respiration waveforms print with major divisions every 5 mm. The Zenix device automatically captures and saves physiological waveform and other data that preceded and followed an event. This data capture is called a snapshot. A snapshot recording can be initiated automatically or captured by the user. The recorded data can be printed either during or after the initiating event.

Snapshots

The Zenix device captures and saves physiological waveform and other data that preceded and followed an event. This data capture is called a snapshot. Snapshot recording can be initiated automatically or manually captured by the user. The recorded data can be printed either during or after the initiating event.

Manually Captured Snapshots

Select the **Snapshot** key to capture the monitored 24-second period of numeric and waveform patient data. The device captures 12 seconds proceeding and 12 seconds following the key selection.

Automatically Configured Snapshots

These snapshots must be pre-configured to print. The Zenix device automatically captures a number of seconds of physiological waveform and other data that precede the event and a number of seconds of data that followed the event.

The table below shows the different configured snapshot types and the information that they contain:

Snapshot Type	Description
Defibrillator	Taken when a shock is delivered and includes: • Top trace waveform • Selected defibrillator energy • Delivered defibrillator energy • Transthoracic impedance value • Patient impedance value • 6 seconds of data before the event • 9 seconds of data after the event occurred
AED Presenting Rhythm	Taken at the start of each new rescue and includes: • Primary ECG lead waveform recorded • 6 seconds of data after the first ECG lead connection to the patient
Analysis	Taken during ECG analysis and includes: • 12 seconds of data before the analysis • 12 seconds of ECG data recorded during and after the analysis period • Messages: SHOCK ADVISED, NO SHOCK ADVISED, NOISY ECG, ANALYSIS HALTED

Snapshot Type	Description
Check Patient	Taken when a CHECK PATIENT alert is issued and includes: • Up to 18 seconds of data before the event • CHECK PATIENT annotation with the left edge of the annotation directly above the ECG signals recorded when the alarm occurred
Patient Alarm	Taken when a physiological alarm occurs and includes: • Up to four waveforms • 6 seconds of data before the event • 9 seconds of data after the event
Life Threatening Alarm (LTA)	Taken when one of the following life-threatening alarms occurs: asystole, VF/VT, extreme bradycardia, and extreme tachycardia. It includes: • Identification of alarm type • Up to four waveforms • 6 seconds of data before the event • 9 seconds of data after the event occurred
Printer	Taken when the printer is activated by selecting the **Print** key. It includes: • 6 seconds of data before the event • 9 seconds of data after the event occurred
Patient Treatment	Taken when a patient treatment is entered. It includes: • Up to four displayed waveforms • Patient treatment and the time it was delivered • 6 seconds of data before the event • 9 seconds of data after the event occurred
12-Lead	Taken during 12-lead monitoring and includes: • Current patient demographic data • 10 seconds of 1000Hz ECG data for the eight core leads (I, II, V1, V2, V3, V4, V5, V6), 12-lead analysis results (if enabled), and the trend record

Viewing/Printing/Transmitting 12-Lead Snapshots

To view 12-Lead snapshots for the current monitored patient:

1. Select the **Menu** button  . The Menu window displays.
2. Select the **Case Options** button, then select the **Current Case** tab.
3. Select the **12-Lead Snapshots View** button.
4. Select a snapshot or select **All** to select all displayed snapshots.
5. Select one of the following:
   Open - to view the snapshot. You can then select **Print** or **Send**.
   Print - to print the snapshot(s)/snapshot history.
   Send - to transmit the 12-lead snapshot(s)/snapshot history to a pre-configured destination.

Reports

The Zenix device can produce reports with varying types of patient information. See the sections below for the different types of reports and the information contained in them.

Continuous Waveform Report

This report is a collection of continuous waveform recordings of the current waveform (ECG, IBP, SpO2, CO2, Respiration). If there is an active Life Threatening Alarm (LTA) while printing, the type of LTA will appear at the bottom of the report.

Trend Summary Report

This report is a collection of a patient's monitored vital sign measurements at a user-configurable interval, with the exception of NIBP measurements, which are logged and reported at the times they are taken. SeeCHAPTER 16 "Trends" for more information about Trends.

To print the Trend Summary report:

1. Select the Menu button  . The Menu window displays.
2. Select the **Case Options** button, then select the **Current Case** tab.
3. In the Trend Summary field, select **Print**.

Treatment Summary Report

This report is a collection of snapshot events automatically taken or user initiated during each rescue incident. If configured, it will automatically print when the event occurs. It is helpful to print out this report at the end of a case.

To print the Treatment Summary report:

1. Select the Menu button  . The Menu window displays.
2. Select the **Case Options** button, then select the **Current Case** tab.
3. Select **Treatment Summary** field, select **Print**.

12-Lead ECG Report

This report is a collection of 12-lead analysis results including the heart rate, PR interval, QRS duration, QT interval, P axis, QRS axis, T axis, and STJ segment values.

See "12-Lead ECG Interpretive Analysis" on page 113 for more information on 12-Lead ECG analysis.

Once 12-lead data has been acquired or previously acquired you can transmit the results to a pre-configured distribution list.

To transmit a 12-Lead Report:

1. Select the **12-lead** key ().
2. Select the **Acquire** key  . The **Verify patient age and gender** screen displays.
3. Verify the patient age and gender then select **Confirm**. The Zenix device collects 10 seconds of 12-Lead data.
4. Select the **Transmit**  key. A list of pre-configured distribution lists displays.
5. Use the navigation keys to highlight and select the desired location to which to transmit the 12-Lead data.
6. Select **Transmit** button to initiate the 12-lead report transmission.

Full Disclosure Case Logs

The Zenix device records the CPR sensor and physiological parameter waveforms in a full disclosure case log, which can accommodate at least 24 hours of data. After that time, the device creates a new case log which records the ID of the first case log. These full disclosure case log records include at a minimum:

- Continuous Waveform data
- Treatment and Monitoring Events
- CPR Compression Results
- 12-lead Snapshots
- Monitor Snapshots
- Automatic Snapshots
- Trend Records
- Parameter Numeric Update

For systems with a Disclosure log server configured, the device allows you to send patient disclosure logs (up to 15 cases at one time) to a remote server through a wireless connection.

Note: The device automatically cancels any case disclosure log transmissions when defibrillation is activated

To transmit a Disclosure Log:

1. On the Zenix display, select the **Menu** button.  . The Menu window displays.
2. Select the **Case Options** button. The Case Options window displays.
3. Select the **Case History** button then select the **Case History View** button.
4. Specify whether or not to include the current case in the transfer by navigating to and selecting:
    - **Close Current Case** if you would like to include the disclosure logs for the current case in the transfer. When you select **Close Current Case**, the device closes the current case and generates a new case for the current patient. That way Pacing, Defib, and AED parameter settings for the current patient remain intact following the transfer.
    - **Continue** button to continue the transfer without the current case.

    The Case History window displays with a list of up to 150 most recent cases. You can use arrows on the bottom of the window to move through the list of cases.
5. Use the navigation keys to choose up to 15 cases to include in the transfer. A case is selected for inclusion in the disclosure log transfer when a check mark displays to the left of the case. Alternatively, you can select the **All** checkbox to include all available cases in the transfer.
6. When you are done choosing cases select the:
    a. **Print** button to print.
    b. **USB** button to transfer the Disclosure Log to an attached USB device.
    c. **Send** button to transfer the disclosure log to the configured server.

7. If the Disclosure Log Transfer Failure dialog box displays, use the navigation keys to select **Retry** then the **Select** button. The device continues the transfer from the case that failed. Otherwise, if you would like to end the transfer, use the navigation keys to select the **Cancel** button.

Transferring Data to USB Device/Server

If transferring data to a USB, insert the USB into the USB device port on the Zenix device before starting this procedure.

Note: The Zenix device supports USB flash drives using the FAT32 file system. Windows formats USB flash drives as FAT32 up to 32GB in size but uses other file systems for 64GB and larger. Some available USB flash drives above 32GB are formatted as FAT32, but others are not. Drives not formatted as FAT32 will not be usable by the device.

Note: The Zenix device has ports for both USB A and USB C flash drives. Only connect one flash drive at a time.

WARNING! Do not connect non-isolated equipment to the USB port while monitoring a patient.

1. Select the **Menu** button  . The Menu window displays.
2. Select the **Systems Settings** button. The System Settings window displays.
3. Select **Log Export**.
4. Select one of the following:

- **Export to USB** button to transmit History Log Export or Support Log Export.
- **Upload to Server** button (Support Log Upload) to upload to pre-selected destination.

Note: When transferring data to a USB, do not remove the USB device during the 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 in the vicinity of the patient.

CHAPTER 20

Communications

This chapter describes the Zenix device communication capabilities.

It includes the following sections:

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Communication Icons 250

Enabling Communication Features 251

Transmitting Data 253

Communications System Messages 255

Overview

For devices with the Communication option installed, the Zenix device can send data collected on the Zenix device to a remote recipient through a wireless connection or you can use a USB device to transfer data. The Zenix device can transmit:

- 12-lead report snapshots (including trend data)
- Readiness test logs
- Disclosure logs (up to 15 cases at one time)
- For systems with a RescueNet Live server configured, waveform and physiological data for remote viewing

The Zenix device can communicate to a remote recipient through a:

- Wi-Fi access point
- Bluetooth-equipped device
- USB

Communication Windows

The Zenix device provides the following Communication windows:

Window	Description
Status	The Communication Status window displays the current state of your 12-lead report, case upload, RescueNet Live®, or Readiness test log transmissions. Access the Status window by selecting the **Status** tab on the left side of the Communications window. The Status window provides the date and time of following transmission states: • Complete • In-process • Retrying • Connecting • Connected • Failed For systems with the RescueNet Live feature available, the Status window displays the status of the current RescueNet Live connection.
Wi-Fi Profiles	The Communication Wi-Fi Profiles window allows you to see and choose from a list of up to 255 configured Wi-Fi access point profiles. See "Selecting a Pre-Configured Access Point Profile" on page 251.

Window	Description
Information	Provides details about your current Wi-Fi or Bluetooth connection. The Information window displays the: • Status of Wi-Fi connection • Status of Bluetooth connection • IP Address for connection • MAC address for Bluetooth
Bluetooth	Allows you to see and choose from a list of connected Bluetooth devices. "Viewing and Connecting Bluetooth Devices" on page 252
Distribution	Allows you view and select a destination to which to direct 12-Lead Reports or RescueNet Live transmissions. See "Distribution" on page 252

Communication Icons

The Communication icons appear on the right side of the Zenix display's Status Bar and indicate:

- Wi-Fi strength signal
- Bluetooth connection status
- USB device connection status

Note: If wireless connectivity is disabled, no icon displays.

Icon	Description
	Wireless connectivity is active. The four stacked bars indicate wireless signal strength. The more bars that are filled in, the stronger your wireless connection. No bars are filled if wireless connectivity is inactive, selected network cannot connect due to incorrect configuration or weak/no signal strength.
	Cellular network strength indicator.
	Bluetooth connectivity is active.
	USB storage device connected.
	Transmit icon. Indicates that data is being transmitted from the Zenix device.

Enabling Communication Features

The Zenix device allows you to enable or disable the following Communication options:

- RescueNet Live
- Wi-Fi
- Bluetooth
- Video Out power

To enable or disable Communication features:

1. On the Zenix display, select the **Menu** button  . The Menu window displays.
2. Select the **General** tab.
3. From the General tab, select the **On/Off** button next to a Communication option as appropriate to turn a feature on or off.

Note: When in AED mode, wireless features are only available while paused. Wireless features are always available in Manual mode.

Selecting a Pre-Configured Access Point Profile

You can make a wireless access point active by selecting an access point from a list of pre-configured wireless access point profiles.

To make a Wi-Fi profile active:

1. Select the **Menu** button  . The Menu window displays.
2. Select the **Communication** button on the bottom of the Zenix display. The Communication window displays.
3. Select the **Wi-Fi Profiles** button on the left side of the window. The Zenix device scans for Wi-Fi access points that are within range then displays a list of available pre-configured Access Point Profiles with the current active profile highlighted in blue. Access Point Profiles that are in range appear at the top of the list first then alphabetically by name.
4. Navigate to the **Select Wi-Fi Profile** field and select a profile from the list.

Viewing and Connecting Bluetooth Devices

To view and connect a Bluetooth device:

1. Select the **Menu** button  on the bottom of the Zenix display. The Menu window displays.
2. Select the **Communications** button on the bottom of the Zenix display. The Communications window displays.
3. Select the **Bluetooth** button on the left side of the window. The Zenix device displays a list of available Bluetooth devices.
4. Navigate to the **Select Bluetooth Device** field and select a Bluetooth device to which to connect.

Distribution

The Communication Distribution window allows you to access a Distribution List to which to send 12-Lead Reports or, for systems with a configured RescueNet Live server, to which to stream waveform and physiological data for remote viewing of the patient being monitored. Each Distribution List entry represents a destination to which to send transmissions. Each destination can consist of one or many recipients such as email addresses and fax machines etc.

Note: See the *ZOLL RescueNet® Live User Guide* for information on viewing patient data remotely.

To select a destination to which to direct 12-Lead Report or RescueNet Live transmissions:

1. Select the **Menu** button  . The Menu window displays.
2. Select the **Communication** button on the bottom of the Zenix display. The Communication window displays.
3. Select the **Distribution** button on the left side of the window. The Distribution window displays.
4. Select the **12-Lead Distribution List Update** or **RescueNet Live Distribution List Update** button as appropriate. The Distribution List displays with a list of transmission destinations.
5. Use the navigation buttons on the bottom of the display to move through and select a destination.

Transmitting Data

The Zenix device collects data that is available to transmit to a remote location. The data includes:

- 12-Lead ECG Reports

  Once 12-lead data has been acquired or previously acquired you can transmit the results to a 12-Lead Report to an external 12-Lead Server. See "12-Lead ECG Report" on page 244 for details.

- Readiness test logs

  Your system may be configured to automatically transmit device readiness information to a ZOLL-provided device management server. The Zenix device creates a Readiness Test log whenever a 30 J test is initiated and includes the results of the most recent self-test.

- Full disclosure case logs

  Full disclosure case logs contain the data that the Zenix device continuously stores as it monitors patients. It includes treatment events, trends, ECG and other continuous waveforms, monitoring and event snapshots, and 12-lead snapshots and analysis. You can transmit a single case or up to 15 cases at one time to a remote server. See "Full Disclosure Case Logs" on page 245 for details.

Note: Full disclosure case logs can also be automatically retrieved from the device using RescueNet or ePCR software or saved to a USB device.

While the transmission is in process, the green LED on top of the unit illuminates.

Transmission Status Icons

The Zenix device displays the following icons on the Status bar to indicate the current state of data transmissions.

Icon	Transmission Status
	Indicates that a successful disclosure log transmission has occurred.
	Indicates that a successful 12-Lead snapshot transmission has occurred.
	Indicates that the last disclosure log transmission has failed, including all retries.
	Indicates that the last 12-Lead snapshot transmission has failed, including all retries.
	Indicates that the Zenix device is trying to resend the disclosure log transmission.

Icon	Transmission Status
	Indicates that the Zenix device is trying to resend the 12-Lead snapshot transmission.
	Indicates that a disclosure log transmission is in progress..
	Indicates that a 12-Lead transmission is in progress..

Communications System Messages

The device may display one of the following status messages during the transmission:

System Message	Cause
TRYING TO CONNECT TO NETWORK	The device is connecting to the network.
TRANSMITTING	The data transfer is in progress
TRANSMISSION COMPLETE	The data transfer is complete.
TRANSMISSION FAILED	The data transfer has failed. To correct the problem, check the following: • Verify that wireless communications is enabled on your device. • Verify that the Wi-Fi settings are correct in the Communications setup menu. • Verify that the server is configured correctly. • Verify that your bluetooth device is configured correctly. • Make sure that the device is within range of the wireless server.
INVALID CERTIFICATE FAILURE	The certificate is expired or the trust chain cannot be established.
HOSTNAME MISMATCH	The certificate common name does not match the host name for the server to which you are trying to connect. The server host name and the certificate common name must match exactly. For example, if the server host name is “12lsubsvc.zollonline.com” then the common name must be “12lsubsvc.zollonline.com”. You can use wildcards. So, for the example above, you could use the wildcard “*.zollonline.com”.

CHAPTER 21

Maintenance

This chapter contains maintenance instructions to ensure the readiness and optimum working condition of the Zenix device.

It includes the following sections:

Overview 258

Daily Visual Inspection 259

Weekly Tests 260

Guidelines for Maintaining Peak Battery Performance 261

Cleaning Instructions 262

Operator's Daily Checklist 266

Overview

Resuscitation equipment must be maintained to be ready for immediate use. To ensure the readiness and optimum working condition of the device and accessories, you should perform the following inspections and tests at the specified time period for each test or inspection.

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.

In accordance with the recommendations of the Defibrillator Working Group of the Food and Drug Administration, an operator's shift check list is included in this chapter, which you can copy for use as needed.

Daily Visual Inspection

To ensure the readiness and optimum working condition of the device, the following should be performed at least once daily or per local protocol:

1. Verify that the device is clean, no spills, clear of objects on top, and case intact.
2. Verify the presence, proper condition, and appropriate quantities of all disposable supplies. Some examples include hands-free therapy electrodes, ECG monitoring electrodes, and printer paper. Always follow local protocol for the complete list.
3. Verify that two sets of defibrillation electrodes are available. Verify that they are within the expiration date printed on the package.
4. Inspect the ECG monitoring electrodes for signs of damage. Verify that they are within the expiration date printed on the package.
5. Open the printer door and verify that an adequate supply of paper is available in the unit.
6. Verify that a fully charged battery is installed in the device. If a spare battery is available, check that it is fully charged, or that the unit has ready access to a local AC mains power outlet.
7. Verify that the RFU (Ready For Use) indicator is displaying a Green Check.
8. Connect AC Power and verify Battery Charge and AC indicators illuminate.
9. Turn On unit and verify audio beeps, Alarm LEDs flash and self-test passes.

In addition to the daily check, authorized personnel should complete performance and calibration testing at regularly scheduled intervals, which should not exceed one year.

Note: In accordance with the recommendations of the Defibrillator Working Group of the Food and Drug Administration, an operator's shift check list is included at the end of this chapter, which can be copied as needed.

Weekly Tests

Pacer Test

1. Turn Unit On.
2. Disconnect the AC power.
3. Connect the multifunction cable (MFC) to an unopened set of Zenix CPR electrodes (which have a short in the packaging). If CPR electrodes with a short are not being used, then attach the MFC cable to the test port.
4. Select the **Pacer** mode tab. Verify the Pacer settings and Pacer Off is displayed.
5. Set the Pacer Rate to 60 PPM.
6. Select **Print** and verify the ECG trace shows dashed vertical lines at a 60 PPM rate (every 25 mm).
7. Set the Pacer Output to 25 mA. Verify Pacer On is displayed
8. Set the Pacer Output to 0 mA. Verify Pacer Off is displayed
9. Turn Unit Off.
10. Reconnect AC power.
11. Reconnect electrode to MFC cable (if needed).

Guidelines for Maintaining Peak Battery Performance

The following guidelines should be maintained in order to ensure peak battery performance:

- Identify each battery with a number or a letter. An identification mark is useful in tracking battery performance.
- Keep extra batteries in the SurePower™ Charger Station where their status can be quickly determined. Illumination of the Ready light is the most positive indication of a fully charged battery.
- Always carry at least one fully charged spare battery. If no other source of back-up power is available, two spare batteries is advisable.
- Rotate spare batteries routinely. The charge level gradually diminishes in a battery after it is removed from the charger even if it is not used. Regular battery rotation helps to avoid incidents where a low battery condition is encountered because the battery has not been recharged or used in more than 30 days.
- Recharge a partially depleted battery whenever possible. This can be accomplished following any incident that involves patient monitoring. It ensures maximum operating time for each use, without reliance on spares. The need for a spare can then serve as an alert when an aging battery fails to provide normal operating time.
- 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 battery packs in a depleted state. Damage to the battery packs can occur if they are left in a depleted state for more than 14 days. See your *SurePower 4 Operator's Guide* for additional information.

Cleaning Instructions

Use only the recommended cleaning agents listed below to clean the device. Follow the directions on the product label for use and storage.

DO NOT allow cleaning agent or water to run into the crevices or connector openings at any time.

Always check monitor and connector opening for unusual wear, damage, or dampness while cleaning.

Use only these recommended cleaning agents:

- Warm water
- Liquid soap
- Windex
- Hydrogen peroxide solution
- Opti-Cide Max Wipes
- Sani-Cloth Plus Wipes
- Tuffie 5 Wipes
- Reynard Premier Detergent and Disinfectant Wipes
- V-Wipes
- CaviWipes XL
- Super Sani-Cloth Wipes
- Clinell Universal Wipes
- Optim 1 Wipes
- Rescue Wipes
- Oxivir TB Wipes
- Clorox Healthcare Hydrogen Peroxide Wipes
- WexCide 128 Solution
- PREempt Wipes
- Incidin OxyWipe S Wipes

If your cleaning agent is not in list above, it is at your agency risk to use those agents for cleaning the device and accessories.

Cleaning or Disinfecting the NIBP Blood Pressure Cuff

Follow your local protocols for cleaning or disinfecting the equipment.

Cleaning Procedure

You can clean the hose and reusable cuffs by applying a damp cloth or brush to the surface; air dry before use.

Disinfecting Procedure

It is recommended to disinfect the equipment after each use.

1. Before disinfecting, ensure that no liquid enters tubing by using a plug or taping off.
2. Spray the cuff with Quaternary Ammonium until soaked.
3. Leave to soak for at least 10 minutes.
4. Rinse with distilled water, ensuring that liquid does not enter tube connector.
5. Air dry.

Cleaning SpO_2 Sensors

Reusable sensors can be cleaned as follows:

1. Disconnect the sensor from the patient cable, if appropriate.
2. Wipe the entire sensor clean with a 70% isopropyl alcohol moistened pad.
3. Allow the sensor to air dry before returning it to use.

Cleaning IRMA CO2

Cleaning of the IRMA CO_2 should be performed at regular intervals or in accordance with hospital, as well as local and governmental regulations.

WARNING! To avoid electric shock, always physically disconnect the IRMA and all patient connections before cleaning.

- Never submerge or saturate IRMA in water or any other liquid solution this may cause permanent damage to the IRMA.
- Do not apply excessive pressure on the IR-windows.
- Only perform maintenance procedures specifically described in the manual; otherwise, return IRMA for servicing. Improper maintenance may result in damage to the internal parts. Damage to internal parts may result in no or inaccurate readings.
- Do not clean IRMA with any chemical other than those specified in Maintenance. These substances may affect the device's materials and damage internal parts.
- The IRMA and IRMA Airway Adapters are non-sterile devices. Do not submerge IRMA or IRMA Airway Adapters in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.

- Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended in this manual. Permanent damage to IRMA may occur if other unspecified solutions are used.

The surfaces of the IRMA CO_2 may be cleaned with the following solution(s):

- 70% ethyl alcohol
- 70% isopropyl alcohol
- Quaternary ammonium chloride solution wipe
- Cidex Plus (3.4% glutaraldehyde)
- 0.5% Sodium hypochlorite (1:10 Bleach to water solution)
- Accelerated hydrogen peroxide

Always wipe off residues of disinfection solutions with a wet cloth after exposure. Never saturate IRMA completely with any disinfection solution.

To clean IRMA:

1. Remove the Airway Adapter.
2. Wipe each of the outer surfaces until the surfaces are free of any visible residue, using one of the following solutions:
    - A cloth moistened with 70% Isopropyl Alcohol.
    - A quaternary ammonium chloride solution wipe (for example CaviWipes™). Pay particular attention to crevices and hard to reach areas of the device. Use a soft bristled brush to gently remove any visible residue from crevices as necessary.
3. Repeat the above cleaning step using a fresh cloth or wipe.
4. Allow the IRMA device to dry thoroughly before using again.

Cleaning Cables and Accessories

Clean ZOLL specific accessories (for example, ECG, IBP, MFC and AccuVent cables, temperature probes, and carry case) with the recommended cleaning agents listed above.

Caution: Do not use bleach solution or wipes to clean ZOLL accessory cables. If used, the cable jacket may be discolored.

Cleaning the Print Head

To clean the recorder print head, perform the following steps:

1. Press the **Release** button, 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.
4. Place the paper back into the device and close the door.

Operator's Daily Checklist

Operator's Daily Checklist		
Date:	Location:	Unit Serial No.:
Mfr/Model No.:		
To ensure the readiness and optimum working condition of the unit, the following inspections and tests should be performed *at least once daily or per local protocol.*		
	Okay as Found	**Corrective Action/Remarks**
Daily Visual Inspection		
1. Verify that the device is clean, no spills, clear of objects on top, and case intact.		
2. Verify the presence, proper condition, and appropriate quantities of all disposable supplies. Some examples include hands free therapy electrodes, ECG monitoring electrodes, and printer paper. Always follow local protocol for the complete list.		
3. Verify that two sets of defibrillation electrodes are available and that they are within the expiration date printed on the package.		
4. Inspect the ECG monitoring electrodes for signs of damage. Verify that they are within expiration date printed on the package.		
5. Open the printer door. Verify that an adequate supply of paper is available in the unit.		
6. Verify that a fully charged battery is installed in the device. If a spare battery is available, check that it is fully charged, or that the unit has ready access to a local AC mains power outlet.		
7. Verify that the RFU (Ready for Use) indicator is displaying a Green Check.		
Power Up Sequence		
1. Connect AC Power. Verify Battery Charge and AC indicators illuminate.		

Operator's Daily Checklist		
2. Turn On unit. Verify audio beeps, Alarm LEDs flash and self-test passes.		
Daily Energy Delivery Test with Defibrillation Electrodes (optional if configured for Automatic daily Code Readiness Test)		
1. Disconnect the AC power.		
2. Connect the multifunction cable (MFC) to an unopened set of Zenix CPR electrodes (which have a short in the packaging). If CPR electrodes with a short are not being used, then attach the MFC cable to the test port. **Note:** You need to use an adapter when using legacy ZOLL CPR electrodes. **Note:** The message *Short Detected* displays on the screen to let you know you can safely perform the 30J Self Test.		
3. Verify the 30J Self Test button is displayed on the user interface.		
4. Press the **30J Self Test** button. Verify the device charges, a constant tone sounds and the Shock button illuminates.		
5. ALS Users – Press the **DISARM** control to disarm the device. BLS users – Press **Pause** to disarm the device. Verify the device disarms, the tone stops sounding and the **Shock** button is no longer illuminated.		
6. Press the **30J Test** button. Verify the device charges, a constant tone sounds and the Shock button illuminates.		
7. Press the **Shock** button. Verify the device discharges and that the 30J Self Test Passed message is displayed. **Note:** The energy delivered is shown on the Zenix display. The energy delivered for this test is typically 1-3J.		
8. Turn Unit Off.		
9. Reconnect AC power.		
10. Reconnect electrode to MFC cable (if needed).		

Operator's Daily Checklist		
Daily Energy Delivery Test with External Paddles – ALS Users Only (if applicable)		
1. Turn Unit ON.		
2. Disconnect the AC power.		
3. Ensure paddles are securely inserted into the paddle well on the holder.		
4. Connect the multifunction (MFC) cable to the external paddles.		
5. Verify the SHORT DETECTED message is displayed on the user interface.		
6. Press the **30J Test** button on the unit. Verify the device charges, a constant tone sounds and the Shock LED on the Apex paddle illuminates.		
7. Press the **DISARM** control to disarm the device. Verify the device disarms, the tone stops sounding and the Apex Paddle Shock LED is no longer illuminated		
8. Press the **30J Test** button. Verify the device charges, a constant tone sounds and the Shock LED on the Apex paddle illuminates		
9. Press the **Shock** buttons on both paddle. Verify the device discharges and that the 30J Self Test Passed message is displayed		
10. Turn Unit Off.		
11. Reconnect AC power.		
Weekly Pacer Test - ALS Users Only (if applicable)		
1. Turn Unit On.		
2. Disconnect the AC power.		
3. Connect the multifunction (MFC) cable to an unopened set of Zenix CPR electrodes (which have a short in the packaging). If CPR electrodes with a short are not being used, then attach the MFC cable to the test port.		
4. Press the **Pacer** mode tab. Verify the Pacer settings are displayed and Pacer Off is displayed.		
5. Set the Pacer Rate to 60 PPM.		

Operator’s Daily Checklist		
6. Press **Print** and verify the ECG trace shows dashed vertical lines at a 60 PPM rate (every 25 mm).		
7. Set the Pacer Output to 25 mA. Verify Pacer On is displayed		
8. Set the Pacer Output to 0 mA. Verify Pacer Off is displayed		
9. Turn Unit Off.		
10. Reconnect AC power.		
11. Reconnect electrode to MFC cable (if needed).		

APPENDIX A

Specifications

This appendix provides specification information.

It includes the following sections:

Defibrillator 273
CPR Monitoring 286
ECG Monitor/Display 287
Impedance Pneumography 290
Alarms 291
Recorder 293
Battery 294
General 295
Pacer 297
IRMA CO2 298
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Patient Log Files 316
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Electromagnetic Compatibility Guidance and Manufacturer's Declaration 324

ECG Analysis Algorithm Accuracy 332
Wireless Output Guidance and Manufacturer's Declaration 336

Defibrillator

Charge Time:

Less than 7 seconds with a new, fully charged battery at 25°C for 15 successive charges.

Up to 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, 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 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 the 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 to 300 ohms (hands free electrodes or external paddles)

7 to 300 ohms (internal paddles)

RapidShock®:

Shock/No Shock decision can be made, and the device ready to shock in under 5 seconds from the end of CPR period.

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. When ECG is monitored by the device, meets the EC 60601-2-4 requirement of 60ms maximum time delay between the peak of the R wave and the delivery of energy.

The table below shows the characteristics of the 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.

Rectilinear Biphasic Waveform Characteristics

	200 J discharged into						
	25Ω	**50Ω**	**75Ω**	**100Ω**	**125Ω**	**150Ω**	**175Ω**
First phase							
Maximum initial current	32.0 A	30.7 A	24.3 A	19.6 A	19.5 A	16.8 A	15.6 A
Average current	27.7 A	25.2 A	20.9 A	17.5 A	16.3 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	200 µs	200 µs	200 µs	200 µs	200 µs
Second phase							
Initial current	29.7 A	19.2 A	17.4 A	15.1 A	13.3 A	12.2 A	11.1 A
Average current	15.3 A	13.3 A	13.5 A	12.5 A	11.4 A	10.7 A	9.9 A
Duration	4 ms	4 ms	4 ms	4 ms	4 ms	4 ms	4 ms

Delivered Energy at Every Defibrillator Setting into a Range of Loads

Selected	**Load**							
Energy	**25Ω**	**50Ω**	**75Ω**	**100Ω**	**125Ω**	**150Ω**	**175Ω**	**Accuracy**
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	3 J	4 J	5 J	4 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	9 J	9 J	9 J	±3 J
9 J	6 J	9 J	11 J	10 J	11 J	10 J	10 J	±3 J

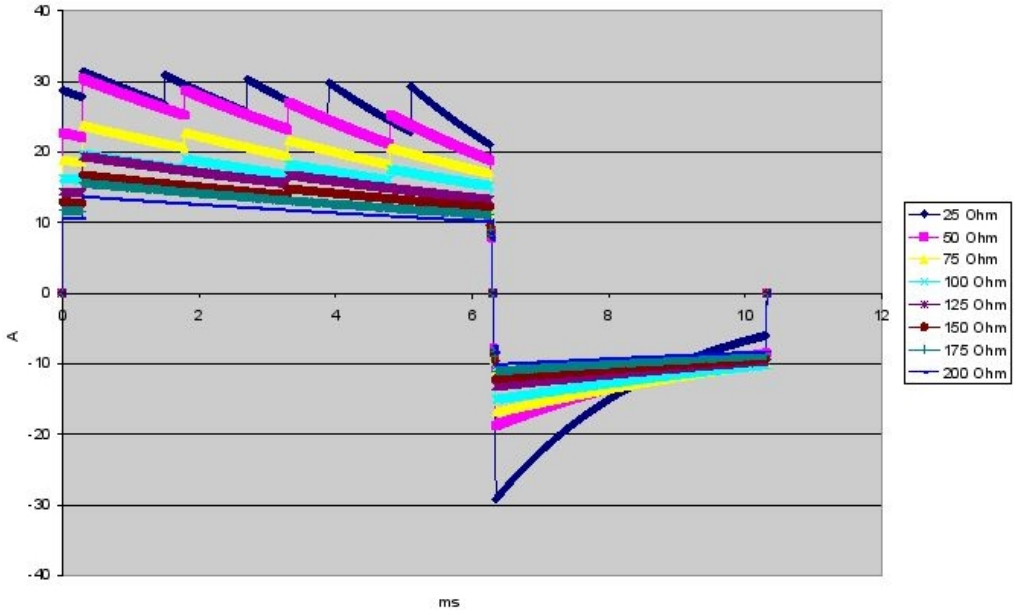
Selected	Load							
Energy	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω	Accuracy
10 J	7 J	11 J	12 J	11 J	12 J	12 J	11 J	±3 J
15 J	10 J	16 J	18 J	17 J	18 J	18 J	17 J	±3 J
30 J	21 J	32 J	36 J	35 J	37 J	36 J	34 J	±15%
50 J	36 J	54 J	60 J	59 J	61 J	60 J	58 J	±15%
70 J	50 J	76 J	85 J	83 J	86 J	84 J	81 J	±15%
85 J	61 J	93 J	103 J	101 J	105 J	102 J	99 J	±15%
100 J	72 J	109 J	122 J	119 J	123 J	120 J	116 J	±15%
120 J	86 J	131 J	146 J	143 J	148 J	145 J	140 J	±15%
150 J	108 J	164 J	183 J	179 J	186 J	181 J	175 J	±15%
200 J	144 J	230 J	254 J	247 J	266 J	257 J	254 J	±15%

For all energy levels, accuracy is equal to either ±15% or 3 joules, whichever is greater .

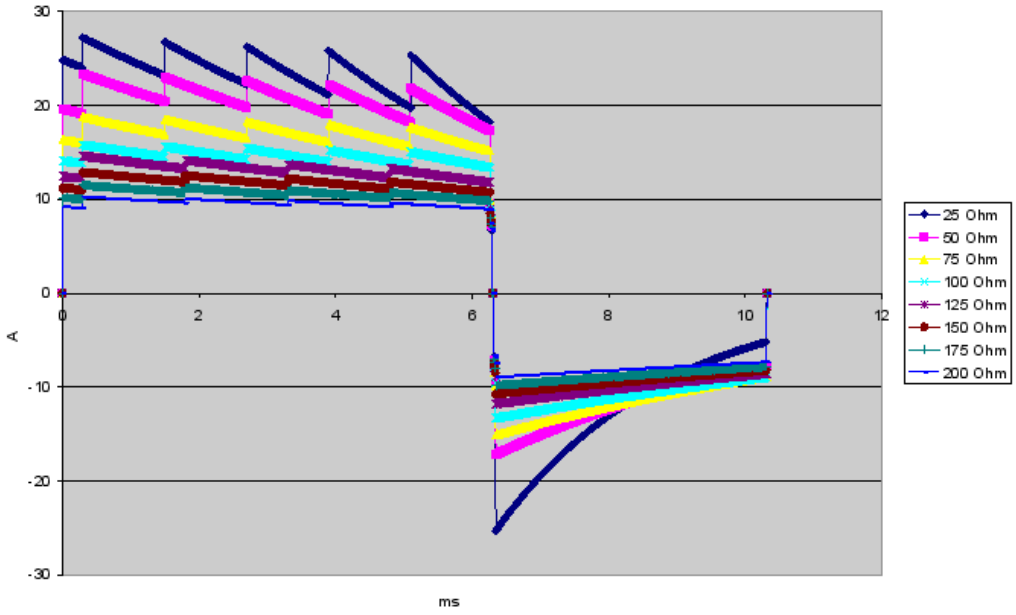
The Rectilinear Biphasic waveform employs the same first and second phase timing, similar first and second phase currents/voltages, and essentially the same mechanisms for controlling defibrillation wave shape as the X Series® defibrillator. The X Series and Zenix defibrillation waveforms are considered substantially equivalent .

The Figures below show the Rectilinear Biphasic waveforms that are produced when the defibrillator is discharged into loads of 25, 50, 75, 100, 125, 150, and 175 ohms at each energy setting.

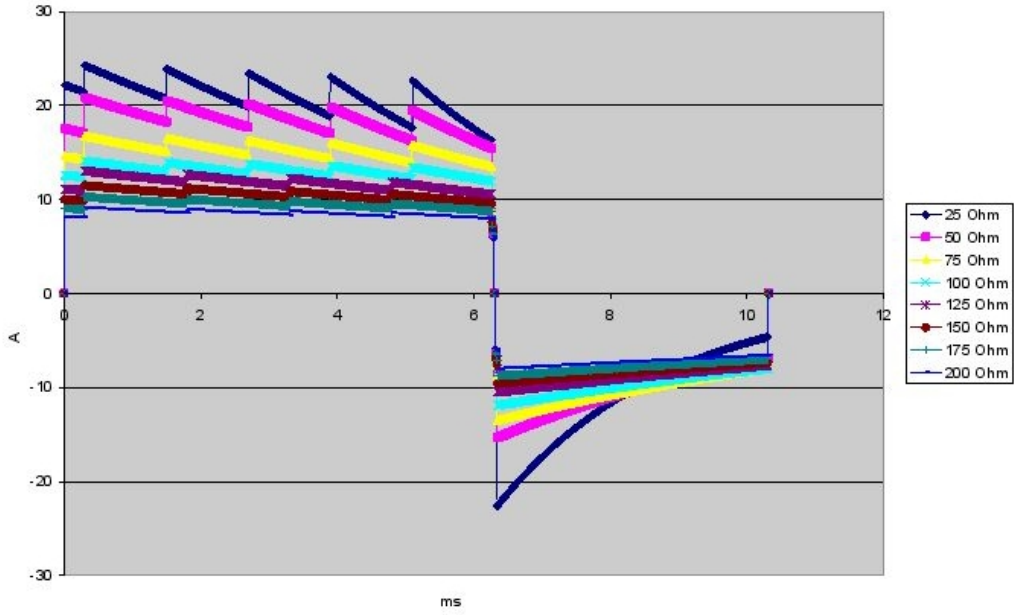
The vertical axis shows the current in amperes (A); the horizontal axis shows the duration of time in milliseconds (ms).



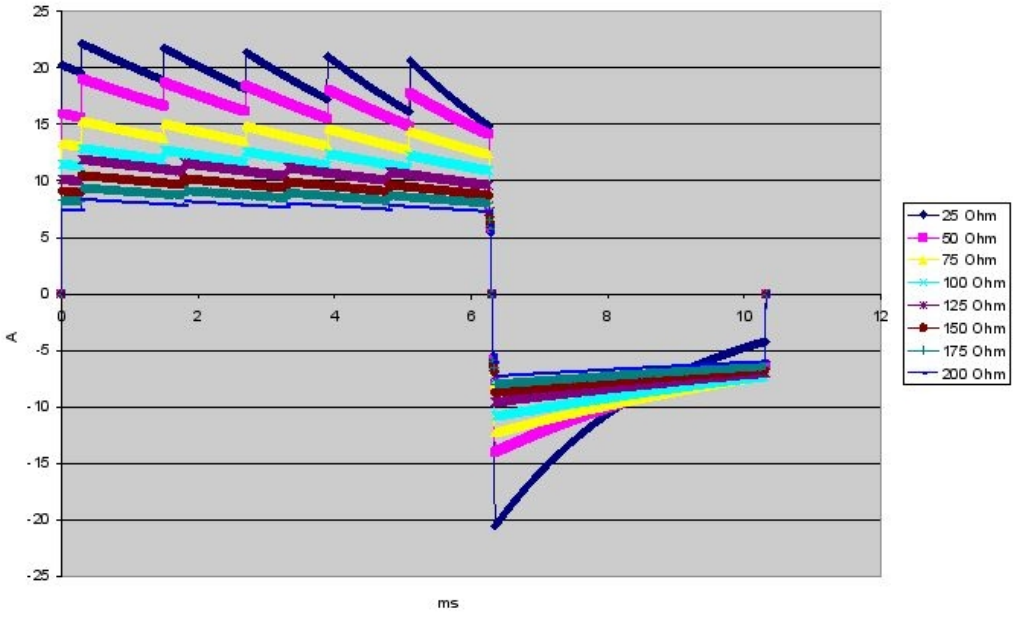
Rectilinear Biphasic Waveform at 200 Joules



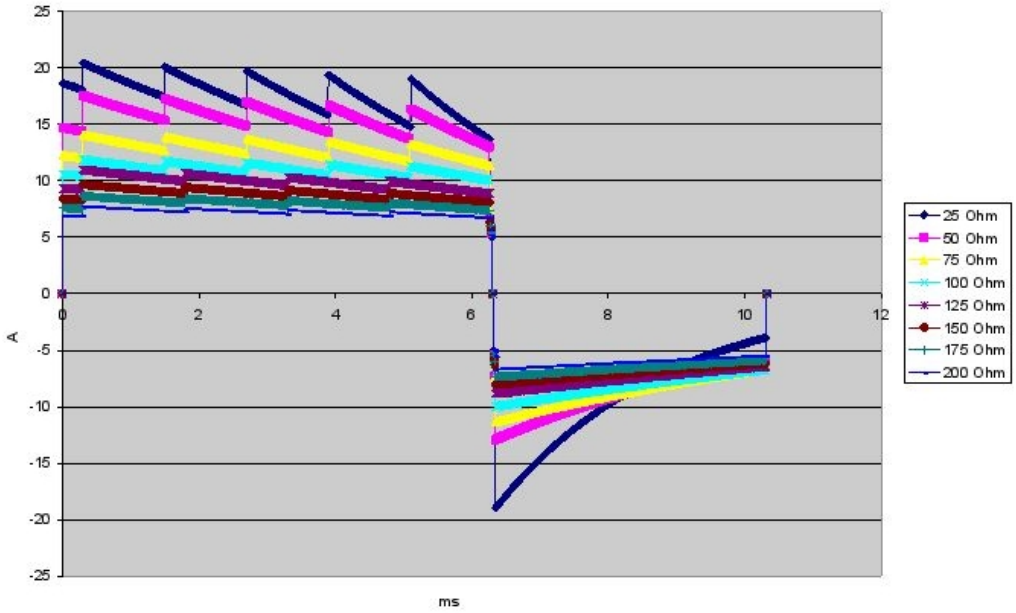
Rectilinear Biphasic Waveform at 150 Joules



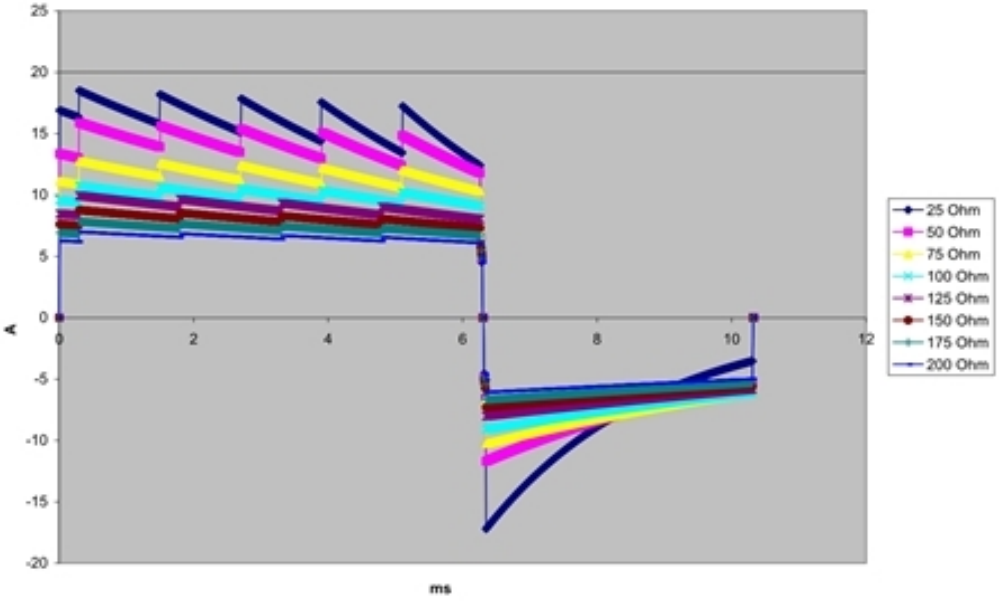
Rectilinear Biphasic Waveform at 120 Joules



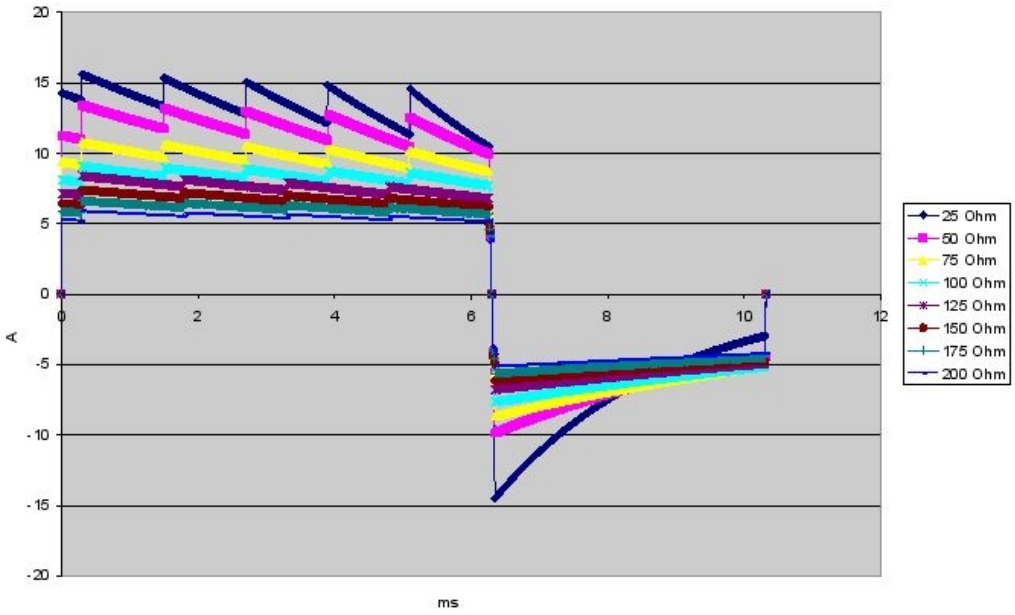
Rectilinear Biphasic Waveform at 100 Joules



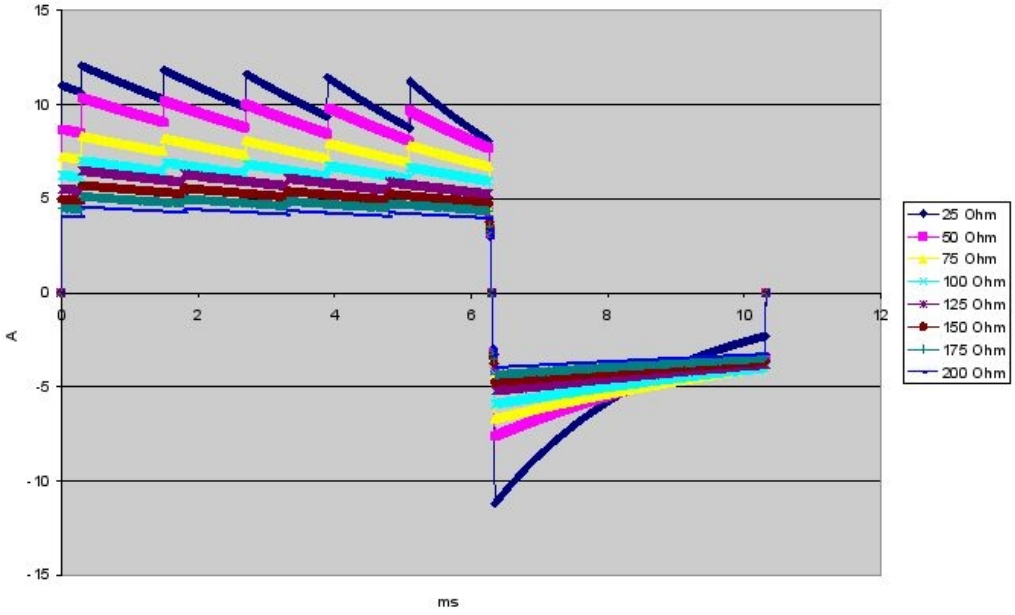
Rectilinear Biphasic Waveform at 85 Joules



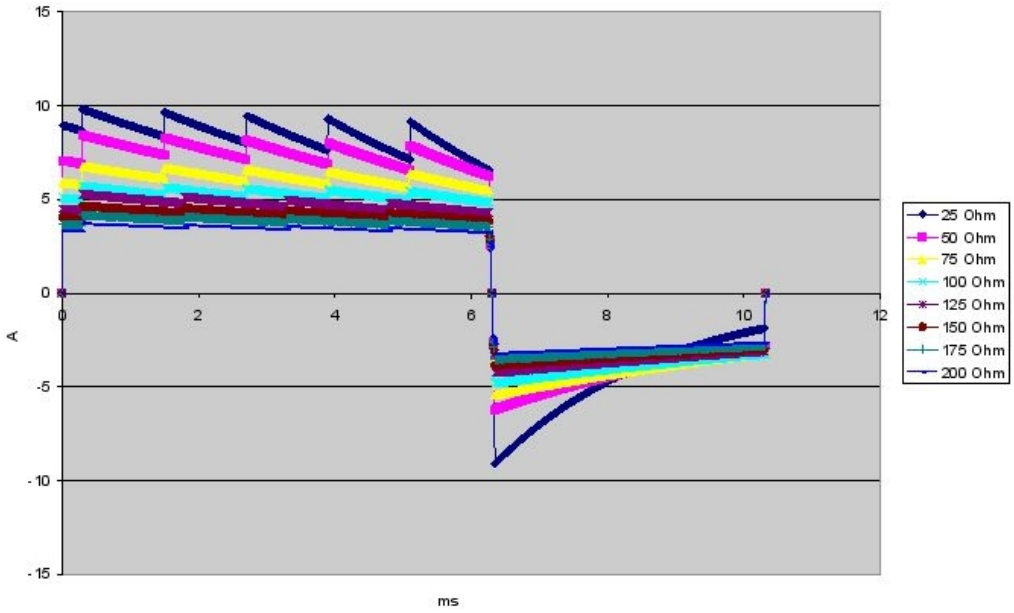
Rectilinear Biphasic Waveform at 70 Joules



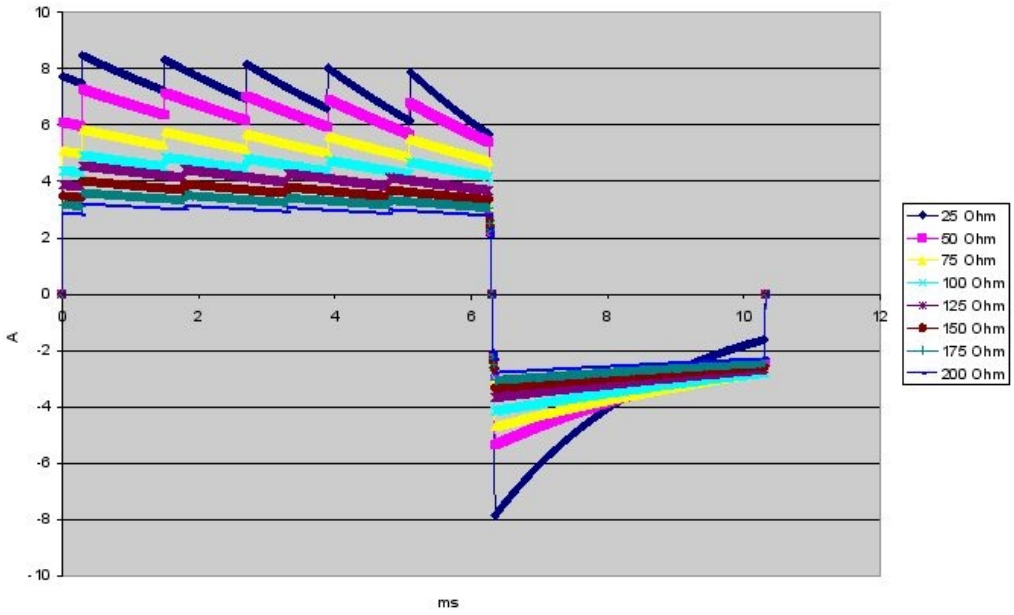
Rectilinear Biphasic Waveform at 50 Joules



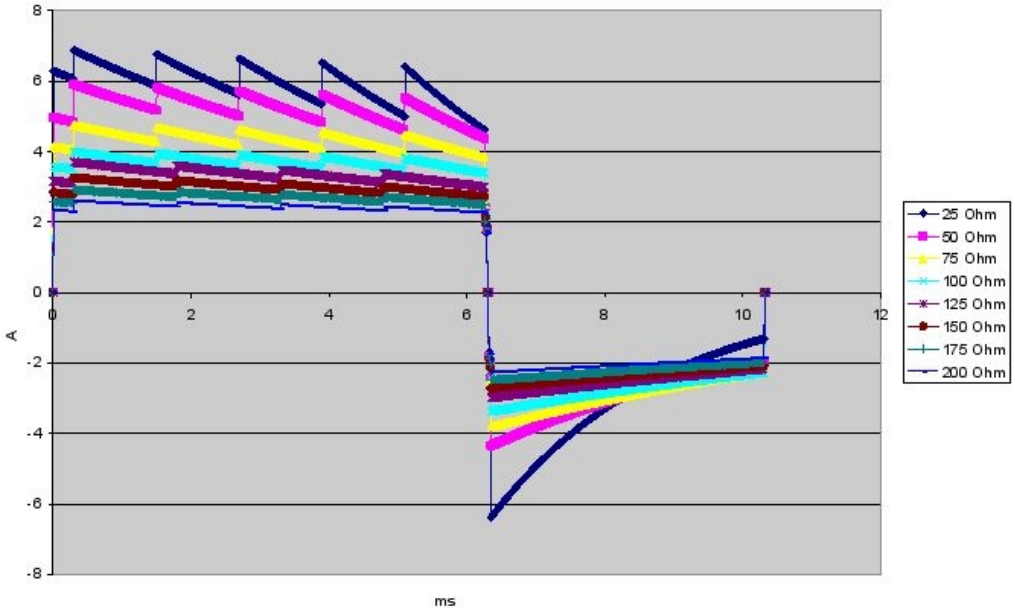
Rectilinear Biphasic Waveform at 30 Joules



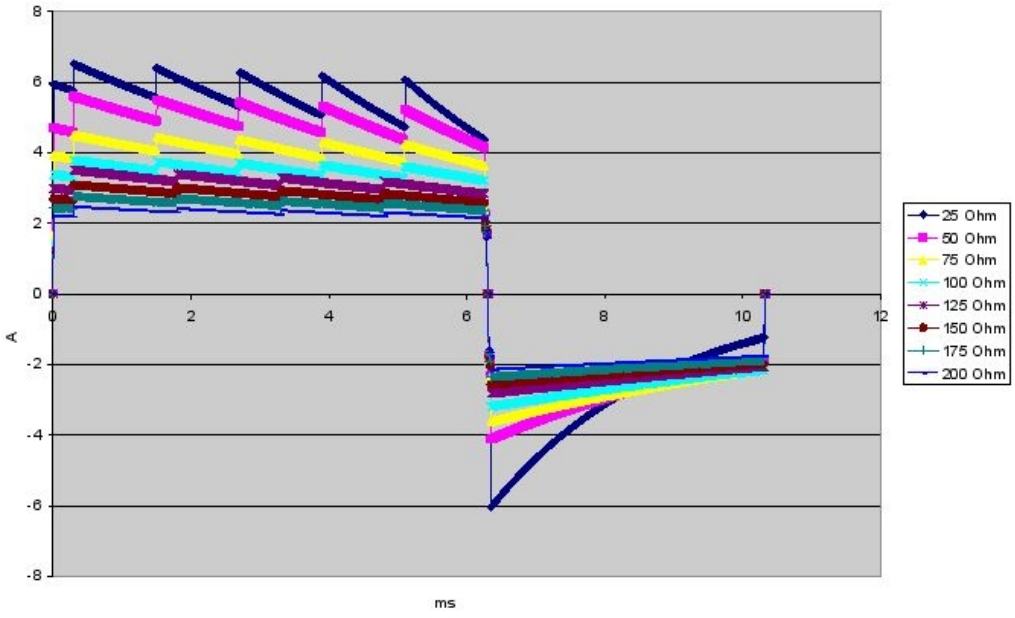
Rectilinear Biphasic Waveform at 20 Joules



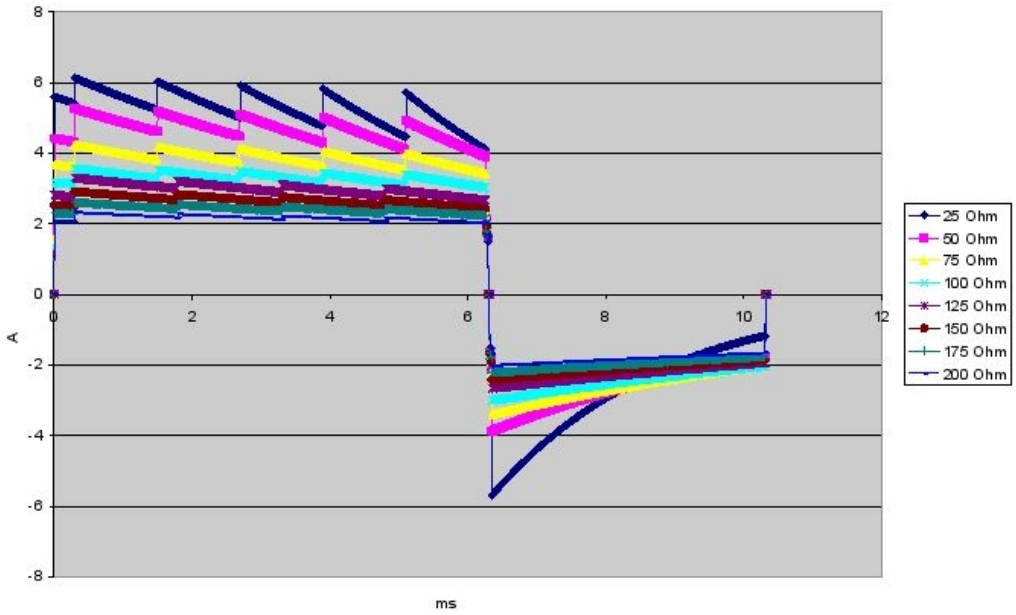
Rectilinear Biphasic Waveform at 15 Joules



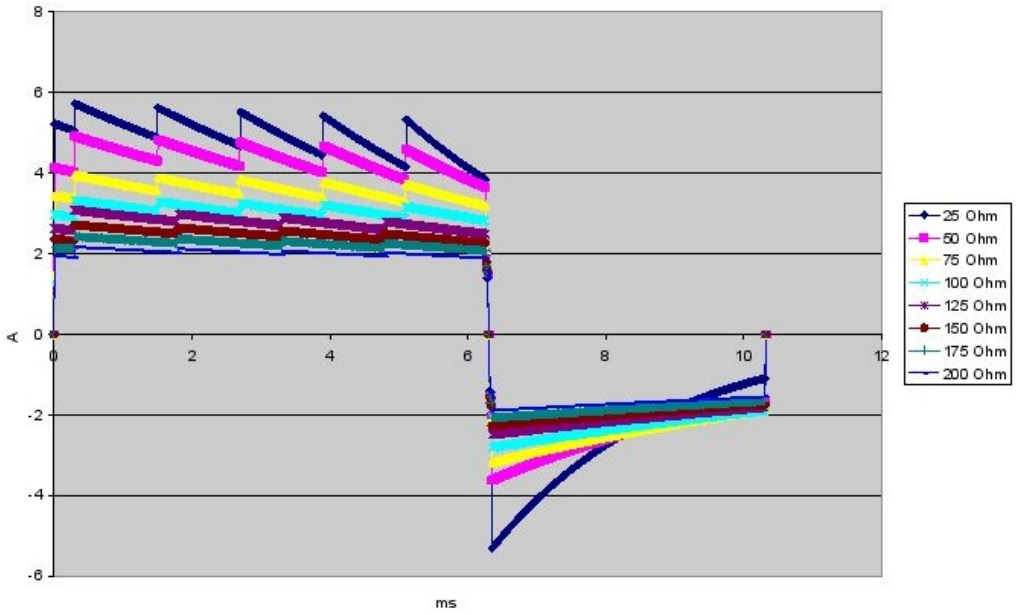
Rectilinear Biphasic Waveform at 10 Joules



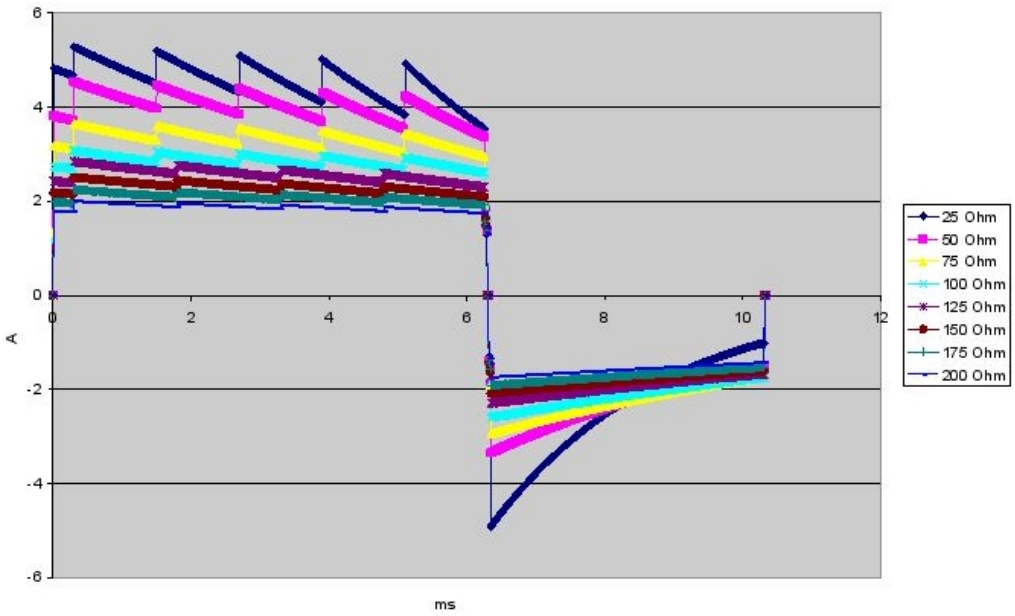
Rectilinear Biphasic Waveform at 9 Joules



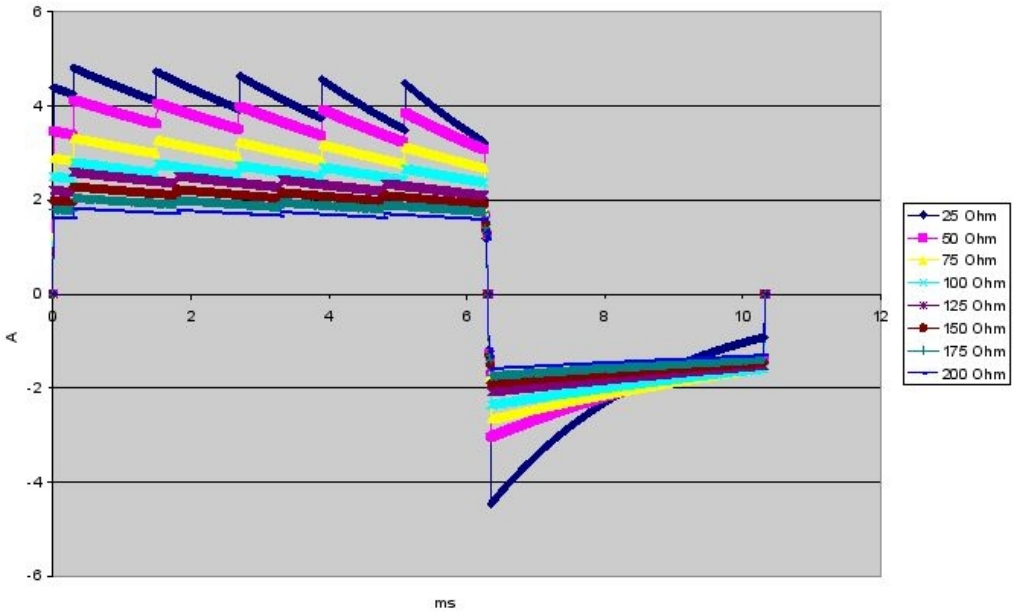
Rectilinear Biphasic Waveform at 8 Joules



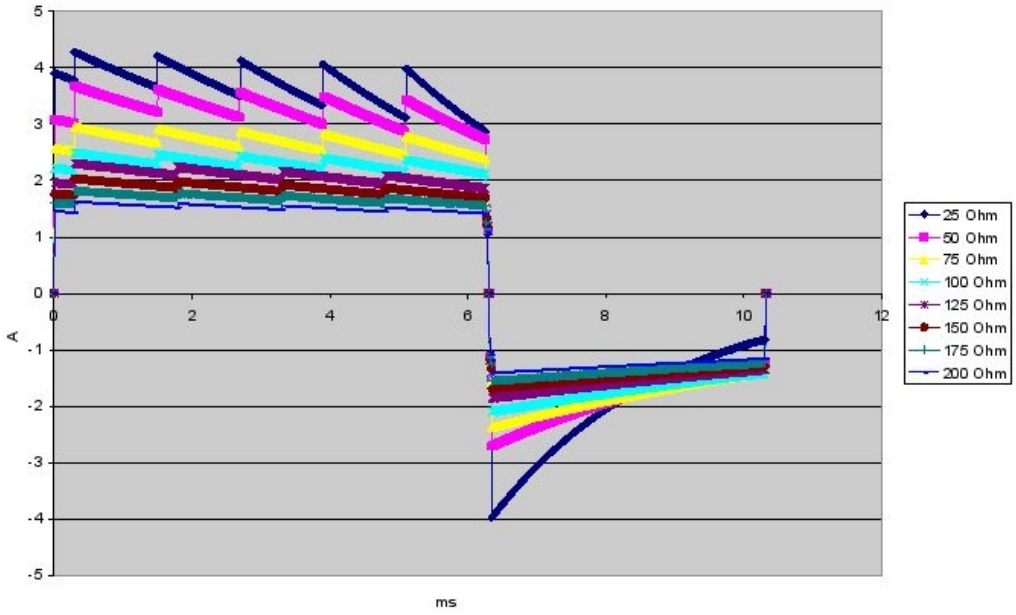
Rectilinear Biphasic Waveform at 7 Joules



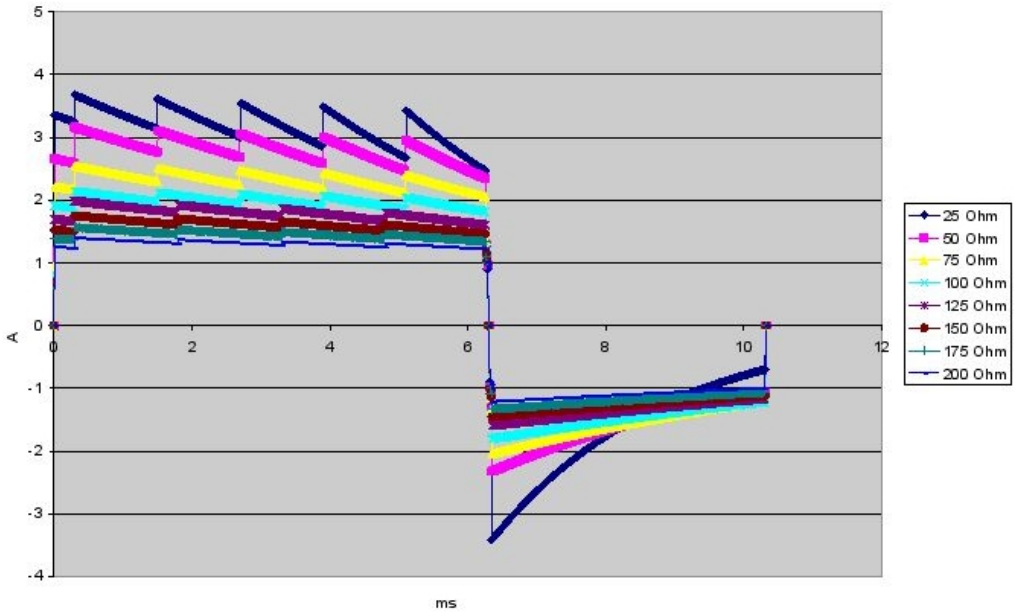
Rectilinear Biphasic Waveform at 6 Joules



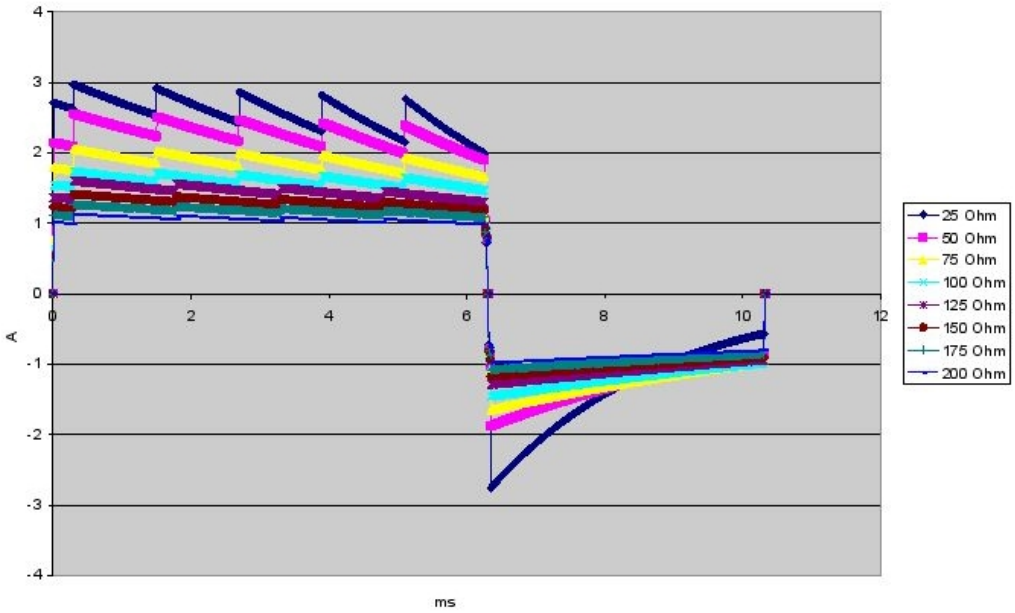
Rectilinear Biphasic Waveform at 5 Joules



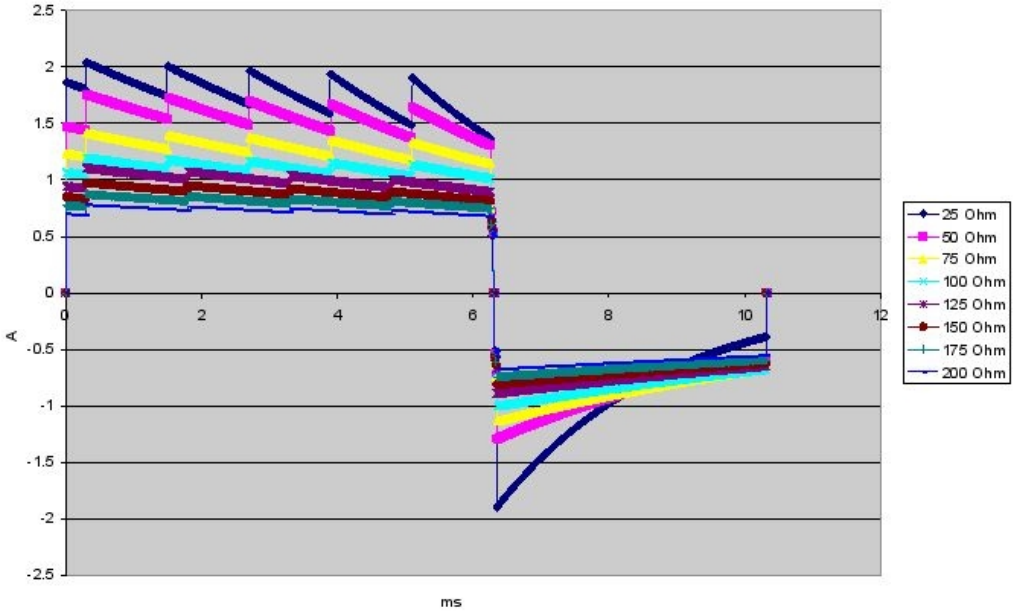
Rectilinear Biphasic Waveform at 4 Joules



Rectilinear Biphasic Waveform at 3 Joules



Rectilinear Biphasic Waveform at 2 Joules



Rectilinear Biphasic Waveform at 1 Joule

CPR Monitoring

Compression depth:

Adult Mode from 0.75 to 4.0 inches

Pediatric Mode from 0.4 to 4.0 inches

Both with accuracy ± 0.25 inch or ± 10% whichever is greater.

Compression rate:

Detected between 50 and 150 compressions per minute (CPM) with an accuracy of ± 3% or ± 3CPM, whichever is greater.

ECG Monitor/Display

Input:

3-lead, 5-lead, 12-lead cables, paddles, therapy electrodes with MFC cable

Type:

Color LCD 800 x 600 Touch screen

8.4 inch diagonal

Sweep Speed:

25 mm / sec or 50 mm / sec (User Selectable)

Lead Selections:

Paddles, Pads, I, II, III, AVR, AVL, AVF, V1-V6, plus P1, P2, P3 with Zenix Complete electrodes

Frequency Response:

Pads/Paddles:

0.67 to 20Hz Limited response

3/5/12 Lead Continuous Monitoring (user selectable):

0.67 to 20Hz Limited response

0.67 to 40Hz Monitor response

Acquired 12-lead snapshots (supervisor selectable):

0.525 to 40Hz Filtered Diagnostic response

0.525 to 150Hz Diagnostic response

Common Mode Rejection:

Complies with IEC60601-2-27:2011 section 201.12.1.101.10

Tall T-Wave Rejection:

Up to 0.6 mV

Diagnostic Signals Applied to Patient Connections:

Heart Rate Range:

20 to 300 BPM

Heart Rate Accuracy:

3 BPM or ±3% , whichever is greater

Displayed Heart Rate:

Average of the last >5 beat to beat intervals

Heart Rate Alarms:

User-selectable

ECG Size Range:

0.25, 0.5, 1, 2, 3, 4 cm/mV

Heart Rate Meter Response Time:

Responds to a 80 to 120 BPM step increase in heart rate in < 4 seconds

Responds to a 80 to 40 BPM step decrease in < 7.5 seconds. Response times include a 1.0-second display in update interval.

Response time to tachycardia alarm is less than 8.0 seconds. 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	14
	1	9
	2	8
B2	5	10
	1	8
	2	8

Heart Rate Response to Irregular Rhythm:

Ventricular Bigeminy: Alternating HR, 76-85 BPM

Slow Alternating Ventricular Bigeminy: Non-alternating HR, 55-66 BPM

Rapid Alternating Ventricular Bigeminy: Non-alternating HR, 112-128 BPM

Bidirectional Systole: Alternating HR, 85-101 BPM

Pacemaker Pulse Rejection:

In accordance with IEC 60601-2-27:2011, 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, with no tail.
- Pulses with overshoot: Rejects all pulses with amplitude of +2 mV to +700 mV and duration of 0.1 ms to 2 ms, with overshoot up to 100 ms.
- A-V sequential pulses: A-V sequential pacemaker pulses may not be rejected.
- Pacemaker pulses may not be rejected if there is no QRS wave.

Electrosurgery Protection:

Zenix device is suitable for use in the presence of electrosurgery as specified in IEC 60601-2-27. Burn hazard protection via a 1K current limiting resistor contained in each ECG lead wire.

Impedance Pneumography

Displayed Data:

Numeric breath rate, Impedance waveform

Breath rate range:

2 to 150 breaths / minute

Breath rate accuracy:

2% or ± 2 breaths / minute, whichever is greater

Displayed Breath Rate:

Average of the breath to breath rate in last minute with a maximum of 10 breaths.

Leads:

Lead I (RA – LA), lead II (RA – LL)

Sweep Speed:

3.13 mm/s, 6.25mm/s, 12.5 mm/s

Alarm settings:

User configurable alarm with high and low limits

Alarms

Heart Rate Alarms:

Audible:

10 pulse, 900 Hz tone, with a PW of 125 msec, a PRI of 125 msec, and a repetition interval of 5 seconds.

Visual:

The heart rate value displays in red with a white background

The red device status LED will flash a rate of 1.5 - 2.8Hz.

Lead Fault Alarm:

Audible:

3 pulse, 680 Hz, triplet tone with a PW of 200 msec a PRI of 200 msec. The lead fault tone repeats at a repetition interval of 15 seconds.

Visual:

Lead Fault condition causes a *LEAD FAULT* message to be displayed on the trace along with a dashed line the width of the trace.

The yellow device status LED will flash a rate of 0.5Hz.

Alarm signal sound pressure level range at 1 meter distance:

High priority:

Minimum (at volume 1): 47.6 dB

Maximum (at volume 11): 87.9 dB

Medium priority:

Minimum (at volume 1): 47.7 dB

Maximum (at volume 11): 89.1 dB

Physiological Alarms (NIBP, SpO_2, Resp, CO_2, IBP & Temp):

Audible:

10 pulse, 900 Hz tone, with a PW of 125 msec, a PRI of 125 msec, and a repetition interval of 5 seconds.

Visual:

Physiological alarms cause the alarming parameter to be displayed in Red with a white background. The red device status LED will flash a rate of 1.4 - 2.8Hz.

Audio Pause (Silence) Duration:

90 seconds

Maximum Alarm Delay (Includes Alarm Condition Delay and Signal Generation Delay):

Heart rate/pulse rate:

if source is ECG, 9 seconds

if source is SpO_2, 10 seconds

if source is IBP, 6 seconds

if source is NIBP, no hold off

SpO2, SpCO, and SpMet Saturation:

10 seconds

$EtCO_2$:

7 seconds

$FiCO_2$:

5 seconds

IBP (Systolic, Diastolic, Mean):

3 seconds

Temperature:

7 seconds

Recorder

Type:

High-resolution thermal array

Annotation:

Snapshots, Alarms, and Treatment Summaries

Paper Width:

80 mm

Paper Speed:

25 mm and 50 mm per seconds configurable

Delay:

6 seconds

Frequency Response:

Automatically set to monitor's frequency response.

Treatment Summary:

The system allows for printing the treatment related events and waveforms for the entire case, or just the events. The user can also select a smaller set of events to print.

Full Disclosure Case Log:

Contains continuous waveform data, treatment markers, CPR data, 12-lead snapshots, monitor snapshots, automatic snapshots, trend records and vital signs numeric updates.

Record Modes:

Manual and automatic (User-configurable)

Battery

Type:

Rechargeable lithium ion, 10.8 Vdc, 8.61 Ah, 93 Wh

Capacity:

With a new, fully charged battery operating at room temperature (18 to 24°C/64.4 to 75.2° F):

- At least 4 hours of continuous monitoring with ECG, SpO2, CO2, three Invasive Pressure channels, two Temperature channels, NIBP measurements every 15 minutes, wireless communication disabled, Display Brightness set to 10%, and Volume set to Medium.
- At least 3.5 hours while pacing with 3/5 lead ECG, SpO2, CO2, three Invasive Pressures channels, two Temperature channels, NIBP measurements every 15 minutes, pacing at 180 ppm and 140 mA, wireless communication disabled, Display Brightness set to 10%, and Volume set to Medium.
- At least 3 hours while AED (Rescue Protocol) monitoring with 3/5 lead ECG, SpO2, CO2, 2 Temperature channels, NIBP measurements every 15 minutes, 2 minute CPR intervals, and 200J shock discharges after every CPR interval, wireless communication enabled and the Display Brightness set to 50%.
- At least 100 discharges at maximum shock energy (200 joules) with worst-case patient impedance.
- 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.

Weight: 1.5 lbs (0.680 kg)

Battery Indicators:

5 capacity indicators + 1 fault + 1 recalibration indicator

Recharge Time: 5 hours to fully charge, max. when charged by the Zenix device

Service Life: Storage 2 years + 5 years' service

General

Weight:

With Battery: 13.2 lbs (5.98 kg)

Dimensions:

9.4 in (23.9 cm) high x 10.3 in (26.2 cm) wide x 8.6 in (21.8 cm) deep

Operating:

Temperature:

0 to 40° C (32 to 104° F)

Humidity:

15 to 95% (non-condensing)

Atmospheric pressure:

572 hPa to 1060 hPa

Vibration:

60068-2-64

Shock:

60068-2-27, 50g, 6ms half sine

Drop:

IEC 60068-2-31, 18" (0.5 meters) functional drop

60601, (2 meter) safety drop

Altitude:

-389 to 4572 meters (-1276 to 15,000 feet)

Transport and Storage:

Temperature:

-20 to 5°C (-4 to 41°F)

5 to 35°C (41 to 95°F) at non-condensing relative humidity up to 90%

>35 to 60°C (95 to 140°F) at water vapor pressure up to 50 hPa

Note: The device may not perform to specifications when stored at the upper or lower extreme limits of storage temperature and immediately put into use. Please wait 1.5 to 2 hours for the unit to come within the specified operation temperature range.

Humidity:

15 to 95% RH (non-condensing)

Atmospheric pressure:

572 hPa to 1060 hPa

Vibration:

60068-2-64

Shock:

60068-2-27, 50g, 6ms half sine

Safety Classification:

Class I and internal power per IEC/EN 60601-1

Enclosure Protection:

Solid Particulate Object:

EN 60529, IP3X, protected against solid foreign objects 2.5 mm diameter or greater

Liquid Ingress:

EN 60529, IPX3, protected against spraying water

AC Auxiliary Operating Power:

Input: 100-240V ∿ 50-60 Hz, 160 VA

Pacer

Type: External transcutaneous pacing

Pacer Rate: 30 to 180 PPM (Fixed mode: ± 1.5%).

Minimum Pacer Output: 10mA

Output Current: 10 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, rate and current indicators on display.

Pulse Type: Rectilinear, constant current

Pulse Width: 40 ms ± 2 ms

Pulse Duration:

Pulse duration is not changed by more than ±10 % over the duration equivalent to the nominal operating time of the battery as specified in the operating instructions.

Pulse duration during AC mains operation is not changed by more than ±10 % over the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions.

Pulse Current:
Pulse current is not changed by more than ±10 % over the duration equivalent to the nominal operating time of the battery as specified in the operating instructions.

Pulse current during AC mains operation is not changed by more than ±10 % over the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions.

Pulse Rate:

Pulse rate is not changed by more than ±10 % over the duration equivalent to the nominal operating time of the battery as specified in the operating instructions.

Pulse rate during AC mains operation is not changed by more than ±10 % over the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions.

Output Protection: Fully defibrillator protected and isolated

IRMA CO_2

Accuracy

Measurement displayed in less than 10 seconds at ambient temperature with full specification in less than 10 seconds.

Accuracy Standard Conditions:

The following accuracy specifications are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa:

Gas	Range*	Accuracy
CO2	0 to 15 vol% 15 to 25 vol%	±(0.2 vol% + 2% of reading) Unspecified

*All gas concentrations are reported in units of volume percent and may be translated into mmHg or kPa by using the reported atmospheric pressure.

Accuracy All Conditions:

The following accuracy specifications are valid with no drift for all specified environmental conditions except for interference specified in the table Interfering Gas Vapor Effect and the section Effects from Water Vapor Partial Pressure on Gas Readings.

Gas	Range*	Accuracy
CO2	0 to 15 vol%	±(0.3 kPa + 4% of reading)

*All gas concentrations are reported in units of volume percent and may be translated into mmHg or kPa by using the reported atmospheric pressure.

Gas Concentration Conversion

Gas concentration is reported in units of volume percent. The concentration is defined as:

%gas = (Partial pressure of gas component)/(Total pressure of gas component) *100

The total pressure of the gas mixture is estimated by measuring the actual atmospheric pressure in the IRMA probe.

Electrical

Item	Specification
Power Supply	4.5-5.5 VDC ≤ 1.0 W (normal operation @ 5V) < 1.8W (power surge @5V can last up to 400 ms when entering measurement mode from sleep mode or during start-up)

Environmental

Environmental Conditions	
Operating Temperature	0°C to 40°C (32°F to 104°F)
Storage/Transport Temperature*	-40°C to 70°C (-40°F to 158°F)
Operating Humidity	< 50 hPa H2O (non-condensing) (68% RH at 40°C)
Storage/Transport Humidity	10% to 95% RH (non-condensing) (95% RH at 40°C)
Operating Atmospheric Pressure	525–1200 hPa (525 hPa corresponding to an altitude of 5211m/17,100 feet)
Storage/Transport Atmospheric Pressure	500 to 1200 hPa (500 hPa corresponding to an altitude of 5572m/18,280 feet)
Transient Operating	The device operates according to specification when exposed to -20°C to 50°C (-4°F to 122°F) for 20 minutes.

* A warm-up period of 15 minutes is required for the IRMA to fulfill the accuracy specification if immediately put into use in 20°C (68°F) ambient temperature after being stored at −40°C (−40°F).

Physical Characteristics

Item	Specification
Dimensions*	38 mm x 37 mm x 34 mm (1.49” x 1.45” x 1.34”)
Weight*	< 25 g (< 0.05 lbs)
Cable Length	2.5m ±0.1m (98" ±4")
Expected Service Life	5 Years

* Excluding cable.

Compliance

Safety Standards Compliance
EN ISO 80601-2-55:2018
EN 60601-1:2006 + A1:2013
EN 60601-1-12:2015 + A1:2021
EN ISO 5356-1:2015

Equipment Classification per IEC 60601-1	
Type of ME Equipment	Hand-Held

Equipment Classification per IEC 60601-1	
Type of Protection	Class II
Degree of Protection of Electrical Shock	Defibrillation proof BF-Applied Part
Degree of protection against solid foreign objects and ingress of water	IP54 (LEMO), Dust-protected and protection against water splashed from any direction. IP55, Dust-protected and protection against water jets from any direction.
Mode of Operation	Continuous operation
Sterility	No part of IRMA is sterile
Type of Equipment	The combination of IRMA and a medical backboard device shall be considered a ME SYSTEM.

Additional Specifications

Data Output

Data Output	Specification
Breath detection	Adaptive threshold, minimum 1 vol% change in CO2 concentration.
Respiration rate*	0 to 150 ± 1 breaths/min. The respiration rate is displayed after three breaths and the average value is updated every breath.
Fi and Et*	Fi and Et are displayed after one breath and have a continuously updated breath average. The following method is used to calculate end-tidal (Et) values: • The highest concentration of CO2 during one breathing cycle with a weight function applied to favor values closer to the end of the cycle. EtCO2 will be within specification for all respiratory rates up to 150 bpm.

Gas Analyzer

Gas	Specification
Data Display Rate	100 Hz
Sampling Rate	0 to 150 ± 1 breaths/min. The respiration rate is displayed after three breaths and the average value is updated every breath.
Compensation	Automatic pressure, temperature, and full spectral interference correction.
Calibration	No span calibration is required.
Warm-up time	< 10 seconds (concentrations reported and full accuracy).
Warm up time after storage at −40°C (−40°F)	A warm up period of 15 minutes is required for IRMA to fulfill the accuracy specification if immediately put into use in 20°C (68°F) ambient temperature after being stored at −40°C (−40°F)*.
Cool down time after storage at 70°C (158°F)	In operation and full accuracy within 10 s.
Rise time** (@ 10 l/min)	CO2 ≤ 90 ms

Gas	Specification
Analyzer System Response Time***	< 1 second

* A ”Change Adapter” message may appear if immediately put into use after being stored at −40°C (−40°F); the message can be ignored if automatically restored after the warm up period.

** Measured at 10 l/min with gas concentration steps corresponding to 30% of total measuring range for each gas.

*** Measured according to EN ISO 80601-2-55.

Airway Adapters

Type	Specification
Disposable adult/pediatric	• Adds less than 6 ml deadspace. • Pressure drop less than 0.3 cm H2O @ 30 LPM.
Disposable infant*	• Adds less than 1 ml deadspace. • Pressure drop less than 1.3 cm H2O @ 10 LPM.

* Infant Airway Adapter recommended for Tracheal Tube ID size ≤ 4 mm

Effects from Water Vapor Partial Pressure on Gas Readings

The table illustrates that the gas concentrations in the alveoli, where the breathing gas is saturated with water vapor at body temperature (BTPS), are 6.2% lower than the corresponding concentrations in the same gas mixture after removal of all water vapor (ATPD).

Temp [°C]	RH [%]	P [hPa]	H2O part. press[hPa]	err rel [%]	err rel ATPD [%]	err rel [%] BTPS
10	20	1013	2	0	-0.2	6.0
20	20	1013	5	0	-0.5	5.7
25	0	1013	0 (ATPD)	0	0	6.2
25	23	1013	7.3	0	-0.7	5.5
25	50	1013	16	0	-1.6	4.6
30	80	1013	42	0	-4.1	2.0
37	100	1013	63 (BTPS)	0	-6.2	0
37	100	700	63	0	-9.0	-2.8

Interfering Gas Vapor Effect

Gas or Vapor	Gas level	CO^2
N2O [4]	60 vol%	_ [1] & [2]
HAL[4]	4 vol%	_ [1]
ENF, ISO, SEV[4]	5 vol%	+8% of reading [3]

Gas or Vapor	Gas level	CO^2
DES [4]	15 vol%	+12% of reading [3]
Xe (Xenon) [4]	80 vol%	-10% of reading [3]
He (Helium) [4]	50 vol%	-6% of reading [3]
Metered dose inhaler propellant [4]	Not for use with metered dose inhaler propellants	
C2H5OH (Ethanol) [4]	0.3 vol%	_ [1]
C3H7OH (Isopropanol) [4]	0.5 vol%	_ [1]
CH3COCH3 (Acetone) [4]	1 vol%	_ [1]
CH4 (Methane) [4]	3 vol%	_ [1]
CO (Carbon Monoxide) [5]	1 vol%	_ [1]
NO (Nitrogen Monoxide) [5]	0.02 vol%	_ [1]
O2 [5]	100 vol%	_ [1] & [2]

[1]Negligible interference, effect included in the specification “Accuracy, all conditions” above.

[2]For probes not measuring NO2 and/or O2 the concentrations shall be set from host. (IRMA CO2 measures neither N2O nor O2)

[3]Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO2 and 50 vol% Helium, the actual measured CO2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO2.

[4]According to the EN ISO 80601-2-55 standard.

[5]In addition to the EN ISO 80601-2-55 standard.

Pulse Oximeter

Display Range

- Oxygen Saturation (% SpO_2) 0% - 100%
- Pulse Rate (bpm) 25 - 240 beats per minute
- Carboxyhemoglobin Saturation (% SpCO) 0% - 99%
- Methemoglobin Saturation (% SpMet) 0% - 99%
- Total Hemoglobin (g/dL SpHb) 0 – 25 g/dL, 0-15.5 mmol/L, 0-250 g/L
- Total Oxygen Content (% SpOC) 0 – 35 ml/dL
- Perfusion Index (% Pi) 0.02% - 20%
- Pleth Variability Index (% PVi) 0.02% - 100%

Accuracy (Arms)*

- SpO2, No Motion:
  - 70-100%, 2%, adults/pediatrics/infants
  - 70-100%, 3%, neonates
- SpO2, Motion: 70-100%, 3% adults/pediatrics/infants/neonates
- SpO2, Low Perfusion: 70-100%, 2%, adults/pediatrics/infants/neonates
- Pulse Rate, No Motion: 25-240 bpm, 3 bpm, adults/pediatrics/infants/neonates
- Pulse Rate, Motion: 25-240 bpm, 5 bpm, adults/pediatrics/infants/neonate
- Pulse Rate, Low Perfusion: 25-240 bpm, 3 bpm, adults/pediatrics/infants/neonates
- SpCO : 1-40%, 3%, adults/pediatrics/infants
- SpMet :1-15%, 1%, adults/pediatrics/infants/neonates
- SpHb: 8-17 g/dL, 1 g/dL adults/pediatric

Resolution:

- SpO_2: 1%
- Pulse rate: 1 bpm (beats per minute)
- SpCO: 1%
- SpMet: 0.1%
- SpHb: 0.1 g/dl, 0.1 mmol/L, 1 g/L

Measurements

- Perfusion Index (Pi)
- Total Oxygen Concentration (SpOC)
- Pleth Variability Index (PVi)

Mechanical

- Material: Polycarbonate/ABS Blend

Environmental

- Operating Temperature: 41 to 104ºF (5 to 40ºC)
- Storage Temperature: -40 to 158ºF (-40 to 70ºC)
- Relative Storage Humidity: 10 to 95% non-condensing
- Operating Altitude:
    - Pressure: 500 – 1,060 mbar
    - Altitude: -1,000 – 18,000 ft (-304.5 - 486m)

Mode & Sensitivity

- SpO2 Averaging Mode: 4, 8, and 16 seconds
- SpO2 Sensitivity: APOD, Normal, Maximum

Alarms

Alarm with high and low limit for each of the following:

- SpO2
- SpCO
- SpMet
- SpHb
- SpOC
- PVi
- Pi

Data Display and Indicators

- SpO2 (%)
- Pulse rate (bpm)
- SpCO (%)
- SpMet (%)
- SpHb (g/dl or mmol/L)
- SpOC (ml/dl)
- Perfusion Index - Pi (%)
- Pleth Variability Index - PVi (%)
- Pleth waveform
- Low Confidence Indicator

Compliance

- EMC Compliance: EN 60601-1-2, Class B
- Electrical Safety: IEC 60601-1, 3rd Edition; UL 60601-1
- Type of Protection (AC Power): Class 1
- Type of Protection (battery power): Internally Powered
- Degree of Protection-Patient Cable: Type BF – Applied Part
- Mode of Operation: Continuous

Footnotes*

1. SpO2, SpCO and SpMet accuracy was determined by testing on healthy adult volunteers in the range of 60-100% SpO2, 0-40% SpCO, and 0-15% SpMet against a laboratory CO-Oximeter. SpO2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7-135 days old and weighing between 0.5-4.25 kg. Seventy-nine (79) data samples were collected over a range of 70-100% SaO2 and 0.5-2.5% MetHb with a resultant accuracy of 2.9% SpO2 and 0.9% SpMet.
2. The Masimo 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% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
3. The Masimo sensors have been validated for 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% SpO2 against a laboratory CO-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
4. The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
5. The Masimo 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. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
6. SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8-17 g/dl SpHb against a laboratory CO-Oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.

7. The following substances may interfere with pulse CO-Oximetry measurements:
    - Elevated levels of Methemoglobin (MetHb) may lead to inaccurate SpO2 and SpCO measurements.
    - Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO2 measurements.
    - Very low arterial Oxygen Saturation (SpO2) levels may cause inaccurate SpCO and SpMet measurements.
    - Severe anemia may cause erroneous SpO2 readings.
    - Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
    - Elevated levels of total bilirubin may lead to inaccurate SpO2, SpMet, SpCO and SpHb readings.
8. RRp performance has been clinically validated on 28 healthy, adult volunteers, 59 hospitalized adult patients, and 28 hospitalized pediatric patients (> 2 years of age). The clinical testing included non-randomized studies comparing RRp measurements against manual, clinician-scored capnograms. The clinical testing on hospitalized adult and pediatric patients was conducted using convenience sampling and did not necessarily include all patient conditions found in hospitals and hospital-type settings. The clinical testing results may not be generalized to all patient conditions. RRp performance was validated across the entire range of 4 to 70 RPM through bench testing. The RRp feature utilizes the same pleth waveform data from the same sensors used in SpO2 monitoring to detect the signals used for determining a respiration rate.

Data Update Period:

- MX7: <30 seconds

SpO_2 Wavelength for Sensors:

- The wavelengths for all of the sensors are identified as follows:

LED	Wavelength
Red	660 nm
Infrared	905 nm

LED	Wavelength
Red	660 nm
Infrared	905 nm

- For SpO2 calculations with a rainbow sensor, the wavelength values shown in the above tables are the same. For rainbow parameter measurements, sensors use light emitting diodes in both the visible and infrared spectrum from the 500 nm to 1400 nm range.
- Energies (Radiant Power) of light for Rainbow Sensors at 100 mA pulsed: ≤ 25 mW

SpO2 Accuracy Specification

RD SET DCI and DCIP Adult and Pediatric Reusable Sensors

Clinical Study Results – SpO2 Accuracy				
Sensor Tested	RD SET DCI			
Sensor Represented	RD SET DCI and RD SET DCIP			
Justification	Masimo RD SET Adult and Pediatric Reusable sensors have the same optical and electrical properties and differ by finger pad shape to accommodate smaller fingers (Adult vs Pediatric).			
Patient population tested	Clinical Study Results – SpO2 Accuracy Patient population tested Male and female healthy volunteer subjects with light to dark skin pigmentation			
Number of Subjects	Male	8	Dark	6
	Female	10	Light	12
	Total	**18**		
SpO2 Accuracy by SaO2 range				
		Bias	Arms	Data pairs
SpO2 Accuracy in range of 70-100%		0.34	1.90	492
SpO2 Accuracy in range of 90-100%		0.35	1.44	162
SpO2 Accuracy in range of 80-90%		0.64	2.30	172
SpO2 Accuracy in range of 70-80%		0.01	1.84	158
SpO2 Accuracy by Pigmentation				
		Bias	Arms	Data pairs
Dark		0.71	2.34	163
Light		0.16	1.64	329
SpO2 Accuracy by Gender				
		Bias	Arms	Data pairs
Male		-0.07	1.66	295
Female		0.96	2.21	197

RD SET Adult and Pediatric Disposable Sensors

Clinical Study Results – SpO2 Accuracy				
Sensor Tested	RD SET Adt			
Sensor Represented	RD SET Adt RD SET Pdt RD SET Inf RD SET Neo RD SET NeoPt			
Justification	Masimo RD SET Adult, RD SET Infant/Pediatric and RD SET Neonatal disposable sensors have the same optical and electrical properties and differ only by: - spacing of the optical components to better conform to smaller pediatric, infant and neonatal digits.			
Patient population tested	Clinical Study Results – SpO2 Accuracy Patient population tested Male and female healthy volunteer subjects with light to dark skin pigmentation			
Number of Subjects	Male	13	Dark	12
	Female	12	Light	13
	Total	**25**		
SpO2 Accuracy by SaO2 range				
		Bias	Arms	Data pairs
SpO2 Accuracy in range of 70-100%		-0.01	1.15	1493
SpO2 Accuracy in range of 90-100%		-0.24	0.83	563
SpO2 Accuracy in range of 80-90%		0.19	1.11	534
SpO2 Accuracy in range of 70-80%		0.05	1.53	396
SpO2 Accuracy by Pigmentation				
		Bias	Arms	Data pairs
Dark		0.08	1.10	683
Light		-0.08	1.19	810
SpO2 Accuracy by Gender				
		Bias	Arms	Data pairs
Male		0.29	1.18	736
Female		-0.30	1.12	757

NICU Convenience Blood Samples - Neonates	
Patient population tested	Neonates with gestation age of 28 weeks to full term, age of 2 days to 31 days, and weights ranging from 1,200 g to 4,400 g under motion.
Number of Neonates	19
Number of Data Pairs	19
Convenience Results in Range of 85-100% (Crms) under motion*	1.40*

* The Clinical Root Mean Squared (CRMS) was calculated using the error RMS equation provided as part of ISO 80601- 2-61, Annex EE. However, since this is a convenience sample study that used non-Masimo clinical personnel for data collection and blood samples processed in a clinical setting using the hospital's reference equipment, the calculated CRMS value from this test report is for reference use only and should not be confused or compared with Accuracy RMS (ARMS) from validation accuracy studies.

NIBP

Measurement method	Oscillometry		
Measurement types	Sys, Dia		
MAP	1/3 SYS + 2/3 DIA		
Range of measurement	Adult	SYS	40~260 mmHg
		DIA	20~200 mmHg
	Child	SYS	40~160 mmHg
		DIA	20~120 mmHg
Pressure Accuracy Static Clinical	 ±3 mmHg ±5 mmHg average error 8 mmHg standard deviation		
Unit	mmHg, kPa		
Recovery time after defibrillation	<5s		
Pulse rate range	30 ~ 220 bpm		
Pulse veracity	2bpm or 3%, whichever is greater		
Inflation time for cuff	<75s		
Measurement protection time	Adult: <180s		
	Child: <180s		
Initial inflation pressure	Adult: 120~280mmHg，default 160mmHg		
	Child: 80~280mmHg，default 140mmHg		
Intervals for AUTO measurement time	5min-240min		
Overpressure Protection Adult Child	Hardware and software double protections <300 mmHg <300 mmHg		
Alarm indication	Three levels of alarms: sound-light alarms, color change in alarm limits area, and alarms with text prompts.		
Measurement Mode	Adult	Manual, Auto	
	Child	Manual, Auto	

Invasive Pressures

Number of Channels: 3

Pressure range: -30 to 300 mmHg

Pressure Accuracy: ± 2 mmHg or 2% of reading, whichever is greater, plus transducer error.

Pulse Rate Range: 25 to 250 BPM

Pulse Rate Accuracy: ± 3 BPM, or ± 3% of value whichever is greater

Pulse Rate Display: Average of last 5 beat-to-beat intervals.

Warm up Time: <15 seconds

Zero Adjust: + / - 200 mmHg

- Sensitivity: 5uV/V/mmHg
- Offset: ± 125 mmHg including offset
- Excitation Impedance Range: 150 to 10,000 ohms
- Excitation Voltage: 4.75 ± 0.25 VDC

Temperature

Number of Channels: 2

Measurement Range: 32 to 122° F (0 to 50° C)

Accuracy: +/- 0.1° C of reading + transducer accuracy

Units: Fahrenheit or Celsius

Probe: YSI 400 and 700 series

Display: T1, T2, ΔT

Minimum Measurement Time: 20 seconds. The Zenix device does not add any clinically significant time to obtain accurate readings.

Real Time Clinical Feedback

Real CPR Help:

Chest Compression Detection Technology:

Accelerometer

Compression Monitoring Range:

Depth: Adult Mode from 0.75 to 4.0 inches; Pediatric Mode from 0.4 to 4.0 inches.

Rate: Detected between 50 and 150 compressions per minute (CPM).

Compression Monitoring Accuracy:

Depth: Both Adult and Pediatric modes ± 0.25 inch or ± 10%, whichever is greater.

Rate: ± 3% or ± 3 CPM, whichever is greater.

Chest Compression Feedback:

Configurable audio and visual prompts for chest compression rate and depth issued when compressions fall outside of AHA/ERC recommendations. Only available in Adult mode.

Chest Compression Release Bar:

Provides feedback on the user release off of the chest

CPR Idle Time Display:

Indicates elapsed time since the last detected chest compression

Perfusion Performance Indicator (PPI):

Integrates compression depth and rate in order to rapidly visualize CPR performance per AHA/ERC recommendations

Real CPR Help Dashboard:

Real-time depth and rate feedback. CPR Dashboard: Numeric readout of pediatric and adult depth and rate, release indicator, perfusion performance indicator (PPI)

See-Thru CPR:

Removes compression-related artifact from the ECG via an adaptive filtering technique

Real BVM Help:

AccuVent sensor provides ventilation feedback including rate and tidal volume in mL

Range:

Inspiratory Volume: 200 to 1000 mL delivered nominally over 1 second

Breath Rate: 4 – 40 BPM

Accuracy:

Volume: Greater of ±50 mL or ± 20% of target. +/-25% at altitudes above 10,000 ft (3048 m)

Breath Rate: ± 3 BPM

Environmental:

Operating Temperature: 0º to 50º C (32º to 122º F)

Storage Temperature: -30º to 70º C (-22º to 158º F)

TBI Dashboard:

Provides graphical trends for SpO2, Systolic BP and EtCO2

EtCO2: data over last 3 minutes and updates every second

Trending Capability

Type: Tabular and Graphical

Trend Interval:

30s, 1 min, 5 min, 10 min, 15 min, 20 min, 60 min (Tabular)

30s, 1 min, 5 min, 10 min, 15 min, 20 min, 60 min (graphical)

Graphical Trend Viewing Time: 3, 5, 10, 15, 30 60 min

Automatic: All vital signs trended at 30 second interval for patient log file, plus when NIBP measurement is taken. User configurable option for when physiological alarms occur.

Patient Log Files

Full Disclosure Data Log:

Contains continuous waveform data, treatment markers, CPR data, 12-lead snapshots, monitor snapshots, automatic snapshots, trend records and vital signs numeric updates.

Full Disclosure Data Storage:

Up to 150 patient cases with FIFO storage or to the maximum storage capability.

External Patient Monitor Connections

Sync Marker Out:

0 to 5 V (TTL level), pulse, active high, 12ms (+/- 2ms) in duration; leading edge of the marker out occurs within 35ms of the peak R-wave.

ECG Output:

1.0V/cm of deflection on recorder; <25ms delay from patient ECG input Not for EMS devices Driven by the top ECG trace on the display with less than 25ms delay from patient ECG.

External Data Transfer

Data Transfer Port: USB (Type A and C), WIFI, Bluetooth

Monitor Port: Video Out

WIFI: 802.11 a, b, g, n and ac

Bluetooth: 5.0

Clinical Trial Results for the Biphasic Waveform

The efficacy of the 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 defibrillation systems consisting of defibrillators, the Rectilinear Biphasic waveform, and defibrillation electrodes.

Randomized Multi-center Clinical Trial for Defibrillation of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT)

Overview: The defibrillation efficacy of the Rectilinear Biphasic waveform was compared to a monophasic damped sine waveform in a prospective, randomized, multi-center 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. 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%).

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%).

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[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)."

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 the 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):

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.

Pre-Clinical Study

To support pediatric usage for the ZOLL Rectilinear Bi-Phasic Waveform, ZOLL submitted pre-clinical data to the FDA as part of a 510(k) submission for its AED Plus device (cleared by the FDA under K033474). The protocol for this pre-clinical study, along with a summary of the results, have been submitted to FDA under AED Plus PMA application (P160015). A summary of this study is presented below.

To demonstrate the safety and efficacy of our Rectilinear Bi-Phasic Waveform when used to treat pediatric VF patients, ZOLL conducted a study using a porcine model of pediatric patients less than 8 years of age. This study included 18 piglets in three (3) size groups (two (2) animals weighing 4 kg, eight (8) animals weighing 8 kg, and eight (8) animals weighing 16 kg) and compared the defibrillation dose/response curves observed using proposed biphasic waveform with those observed using a standard monophasic damped sine wave (DSW) defibrillator to treat short duration (~ 30 seconds) ventricular fibrillation. The study demonstrated that the biphasic waveform defibrillates pediatric pigs with equal efficacy but lower energy (on a Joules/kg basis) than traditional monophasic damped sine wave defibrillators. To confirm the safety of the proposed biphasic waveform in pediatric patients, we studied and compared measures of cardiac function before and after both DSW and Rectilinear Bi-Phasic Waveform defibrillation shocks over a range of relevant energies. The study demonstrated that the biphasic defibrillation produced equivalent or milder disturbances of cardiac function when compared to traditional DSW defibrillation at the same energies.

Another animal study compared the ZOLL rectilinear biphasic (RLB) waveform to a biphasic truncated exponential (BTE) waveform. The study, using an immature porcine model (n=21), was a prospective, randomized, controlled design to determine the dose response curves for the RLB and BTE defibrillation waveforms. A weight range from 4 to 24 Kg for an animal represented a pediatric patient. The weight ranging from 4 to 8 Kg represented a patient less than 1 year old (infant subgroup), and the weight range from 16 to 24 Kg represented a pediatric patient between the ages of 2 and 8 years (young children subgroup).

The ZOLL RLB waveform demonstrated a superior capability to defibrillate a porcine pediatric model with < 90% of the D50 energy required for a BTE waveform (D50 energy: RLB 25.6 ± 15.7 J, BTE 28.6 ±17.0 J, P ? 0.0232; D90 energy: RLB 32.6 ± 19.1 J, BTE 37.8 ± 23.2 J, P ? 0.0228).

The ECG ST segment changes (mV) and LV pressure changes (dP/dt) following a defibrillation shock were compared between the RLB waveform to the BTE waveform. The RLB waveform had an average ST segment increase above baseline of 0.138 ± 0.136 mV (N=401 shocks) compared to the BTE waveform's average increase of 0.146 ± 0.148 mV (N=396 shocks). The RLB waveform had an average dP/dt at the 40 mmHg threshold (the point in time when an animal's blood pressure exceeded 40 mmHg spontaneously) of 1987 ± 411 mmHg/s (N=496 shocks) compared to the BTE waveform's average dP/dt of 2034 ± 425 mmHg/s (N=496 shocks).

Published Clinical Data

Additional clinical data was included with PMA application P160015 to support out-of-hospital use of ZOLL's Rectilinear Bi-Phasic defibrillation waveform. The data reported by Hess et al in Resuscitation (82 (2011) 685–689) is considered sufficient to support ZOLL's defibrillation waveform in the out-of-hospital environment. The resulting clinical paper, "Performance of a rectilinear biphasic waveform in defibrillation of presenting and recurrent ventricular fibrillation: A prospective multicenter study," was included with PMA application P160015. A summary of the study is presented below:

Objectives: The study tested the hypothesis that shock success differs with initial and recurrent episodes of ventricular fibrillation (VF).

Methods: From September 2008 to March 2010 out-of-hospital cardiac arrest patients with VF as the initial rhythm at 9 study sites were defibrillated by paramedics using a rectilinear biphasic waveform. Shock success was defined as termination of VF within 5 s post-shock. The study used generalized estimating equation (GEE) analysis to assess the association between shock type (initial versus defibrillation) and shock success.

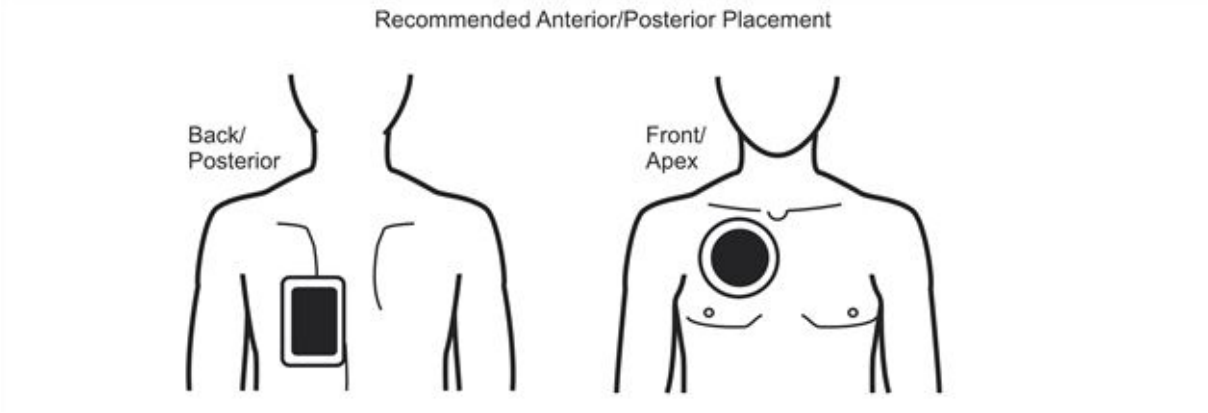
Results: Ninety-four patients presented in VF. Mean age was 65.4 years, 78.7% were male, and 80.9% were bystander-witnessed. VF recurred in 75 (79.8%). There were 338 shocks delivered for initial

(n = 90) or recurrent (n = 248) VF available for analysis. Initial shocks terminated VF in 79/90 (87.8%) and subsequent shocks in 209/248 (84.3%). GEE odds ratio (OR) for shock type was 1.37 (95% CI 0.68–2.74). After adjusting for potential confounders, the OR for shock type remained insignificant (1.33, 95% CI 0.60–2.53). The study observed no significant difference in ROSC (54.7% versus 52.6%, absolute difference 2.1%, p = 0.87) or neurologically intact survival to hospital discharge (21.9% versus 33.3%, absolute difference 11.4%, p = 0.31) between those with and without VF recurrence.

Conclusions: Presenting VF was terminated with one shock in 87.8% of cases. The study observed no significant difference in the frequency of shock success between initial versus recurrent VF. VF recurred in the majority of patients and did not adversely affect shock success, ROSC, or survival.

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 M Series Biphasic Defibrillator Waveform demonstrated that high conversion rates are achieved when defibrillation pads are placed as shown in the following diagram.



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.

Electromagnetic Compatibility Guidance and Manufacturer's Declaration

Note: For EMC limits when using the Zenix device with the AutoPulse Resuscitation System refer to the latest revision of the AutoPulse User Guide.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Zenix device is intended for use in the electromagnetic environment specified below. The customer or the user of the Zenix device should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Zenix device 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 CISPR 11	Class B	The Zenix device 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 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity (IEC 60601-1-2)

The Zenix device's essential performance is defibrillation (Defib), pacing, ECG, SpO2, CO2 (respiration), NIBP, IBP, and temperature (TEMP) as specified in this Appendix. The Zenix device meets basic safety and essential performance when it is operated in the electromagnetic environment specified in the following tables.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Zenix device is intended for use in the electromagnetic environment specified below. The customer or the user of the Zenix device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	The relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Zenix device requires continued operation during power mains interruptions, it is recommended that the Zenix device be powered from an un-interruptible power supply or a battery.

Guidance and manufacturer's declaration – electromagnetic immunity			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity Magnetic Fields IEC 61000-4-39 AIM 7351731	8 A/m, 30kHz 65 A/m, 134.2kHz 7.5 A/m, 13.56MHz 5 A/m, 13.56MHz 12 A/m, 13.56MHz	8 A/m 65 A/m 7.5 A/m 5 A/m 12 A/m	
Note: U_T is the AC mains voltage prior to application of the test level.			

Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The functions of the Zenix device are intended for use in the electromagnetic environment specified below. The customer or user of the Zenix device should ensure that it is used in such an environment. Portable and mobile RF communications equipment should be used no closer to any part of the Zenix device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity test	IEC 60601 test level	Compliance level	Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	3 Vrms[3]	$d = 1.2 \sqrt{P}$
	6 Vrms 150 kHz to 80 MHz in ISM bands[1] and amateur radio bands[2]	6 Vrms[3]	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000- 4-3 (OneStep Electrodes)	3 V/m 80 MHz to 2.7 GHz	3 V/m	$d = 2.0 \sqrt{P}$
Radiated RF IEC 61000-4-3 (Pacing, ECG, SpO_2, CO_2, NIBP, IBP and TEMP)	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 0.6 \sqrt{P}$
Radiated RF IEC 61000-4-3 (Defib)	20 V/m 80 MHz to 2.7 GHz	20 V/m	$d = 0.3 \sqrt{P}$

[1] 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.

[2]The amateur radio bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz; 3.5 MHz to 4.0 MHz; 5.3 MHz to 5.4 MHz; 7.0 MHz to 7.3 MHz; 10.1 MHz to 10.15 MHz; 14 MHz to 14.2 MHz; 18.07 MHz to 18.17 MHz; 21.0 MHz to 21.4 MHz; 24.89 MHz to 24.99 MHz; 28.0 MHz to 29.7 MHz; and 50.0 MHz to 54.0 MHz.

[3]Electrodes that may require the use of the OneStep or Green connector may be susceptible to these test levels. Failure to maintain appropriate separation distances as described may cause the electrodes to become susceptible. If this occurs, please move cabling away from the electrode cable.

Guidance and manufacturer's declaration – electromagnetic immunity			
RFID Electric Fields AIM 7351731	3V/m, 433MHz 54V/m, 860-960MHz 54V/m, 2.45GHz	3V/m 54V/m 54V/m	d = 2.0 √P 433 MHz d = 0.1 √P 860-960 MHz d = 0.1 √P 2.45 GHz
Radiated RF IEC 60601- 1-2, (wireless communications)	27 V/m for TETRA 400 service	27 V/m	d = 0.3 m minimum
	28 V/m for GMRS 460, FRS 460, GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5, GSM 1800, CDMA 1900, GSM1900, DECT, LTE Band 1, 3, 4,and 25, UMTS, Bluetooth, WLAN,802.11 b/g/n, RFID 2450, and LTE Band 7 services	28 V/m	d = 0.3 m minimum
	9 V/m for LTE Band 13 and 17, and WLAN 802.11 a/n services	9 V/m	d = 0.3 m minimum

Guidance and manufacturer's declaration – electromagnetic immunity
where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters. [1] Field strengths from fixed RF transmitters, as determined by electromagnetic site survey,[2] should be less than the compliance level in each frequency range.[3] Interference may occur in the vicinity of equipment marked with the following symbol:    **Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. At 80 MHz and 800 MHz, the higher frequency range applies.

[1] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[2] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Zenix device is used exceeds the applicable RF compliance level above, the Zenix device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Zenix device.

[3] Over the frequency ranges 150 kHz to 80 MHz field strength should be less than 3 V/m.

Recommended Separation Distances from RF Equipment for the Zenix Functions

Recommended separation distances between portable and mobile RF communications equipment and the Zenix			
The functions of the Zenix device are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Zenix device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Zenix device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of equipment (in watts)	Separation distance according to frequency of transmitter (in meters) for pacing, ECG, SpO_2, CO2, NIBP, IBP and temperature functions		
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands and amateur radio bands	80 MHz to 2.7 GHz
	d = 1.2√P	d =2.0√P	d = 0.6√P
0.01	0.12	0.20	0.06
0.1	0.38	0.63	0.19
1	1.2	2.0	0.60
10	3.8	6.3	1.9
100	12	20	6
Rated maximum output power of equipment (in watts)	Separation distance according to frequency of transmitter (in meters) for defibrillation functions		
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands and amateur radio bands	80 MHz to 2.7 GHz
	d =1.2√P	d =2.0√P	d =0.3√P
0.01	0.12	0.20	0.03
0.1	0.38	0.63	0.09
1	1.2	2.0	0.3
10	3.8	6.3	0.95
100	12	20	3

Recommended separation distances between portable and mobile RF communications equipment and the Zenix			
Rated maximum output power of equipment (in watts)	**Separation distance according to frequency of transmitter (in meters) for OneStep electrodes**		
	150 kHz to 80 MHz outside ISM bands	**150 kHz to 80 MHz in ISM bands and amateur radio bands**	**80 MHz to 2.7 GHz**
	d =1.2√P	d =2.0√P	d =2.0√P
0.01	0.12	0.20	0.20
0.1	0.38	0.63	0.63
1	1.2	2.0	2.0
10	3.8	6.3	6.3
100	12	20	20

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3: The amateur radio bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz; 3.5 MHz to 4.0 MHz; 5.3 MHz to 5.4 MHz; 7.0 MHz to 7.3 MHz; 10.1 MHz to 10.15 MHz; 14 MHz to 14.2 MHz; 18.07 MHz to 18.17 MHz; 21.0 MHz to 21.4 MHz; 24.89 MHz to 24.99 MHz; 28.0 MHz to 29.7 MHz; and 50.0 MHz to 54.0 MHz.

NOTE 4: An additional factor of 10/3 is used in calculating the recommended separation distances for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 5: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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 's ECG Rhythm Database.

The algorithm sequence takes approximately 9 seconds and proceeds as follows:

1. Divides the ECG rhythm into three-second segments.
2. Filters and measures noise, artifact, and baseline wander.
3. Measures baseline content ('waviness' at the correct frequencies — frequency domain analysis) of signal.
4. Measures QRS rate, width, and variability.
5. Measures amplitude and temporal regularity ('auto-correlation') of peaks and troughs.
6. 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 (sub-clause 201.7.9.3.103) and the recommendations by Kerber et al. (Circulation. 1997;95(6):1677).

Clinical Performance Results with Standard 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	>94%	>87%

Rhythms	Sample Size	Performance Goal	Observed Performance	90% Lower Confidence Limit
Other VT	28	Report Only	>99%	>89%

	Shockable	Non-shockable
Shock	680	1
No Shock	5	3171

Clinical Performance Results with Standard Analysis Algorithm with Pediatric Patients

Rhythms	Sample Size	Performance Goal	Observed Performance	90% 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	>81%	>69%

	Shockable	Non-shockable
Shock	121	10
No Shock	0	619

Clinical Performance Results with RapidShock

Rhythms	Sample Size	Performance Goals	Observed Performance	90% Lower Confidence Limit
Shockable		**Sensitivity**		
Coarse VF	342	>90%	>99%	>96%
Rapid VT	58	>75%	>98%	>94%

Rhythms	Sample Size	Performance Goals	Observed Performance	90% Lower Confidence Limit
Non-shockable		**Specificity**		
NSR	419	>99%	>99%	>99%
AF, SB, SVT, Heart block, idioventricular, PVCs	1631	>95%	>98%	>98%
Asystole	841	>95%	>99%	>99%
Intermediate			**Sensitivity**	
Fine VF	50	Report only	>89%	>80%
Other VT	51	Report only	>92%	>82%

	Shockable	Non-shockable
Shock	440	24
No Shock	>10	2918

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.

Shock Conversion Estimator

Use of a defibrillator shock is currently the best option for terminating ventricular fibrillation and restoring a life sustaining ECG rhythm [1]. Maintaining blood flow through the heart via cardiopulmonary resuscitation (CPR) has been shown to improve the chances of a successful defibrillation [1]. The cessation of blood flow through the heart that occurs when CPR is stopped decreases the likelihood of a successful shock in proportion to the amount of time that has elapsed without CPR [1]. The repeated use of defibrillator shocks that do not restore a life sustaining rhythm may cause additional damage to the myocardium and reduce the patient's chances for survival. The use of an accurate shock outcome predictor can help reduce the duration of CPR interruptions and the number of ineffective (non-converting) shocks delivered.

Properly performed CPR has been shown to increase blood flow to the heart and increase the neurologically intact patient survival rate [2]. The rescuer must stop CPR while the patient's rhythm is analyzed to determine whether it is shockable. If the rhythm can be identified as unlikely to convert, CPR can be resumed faster rather than delivering ineffective shocks. This reduction in total shocks delivered reduces the damage sustained by the heart during resuscitation.

The Shock Conversion Estimator (SCE) is applied to the analysis result. SCE computes a Shock Prediction Index (SPI) number which measures the probability that a shockable rhythm will be successfully converted by immediate defibrillation. The SPI number is directly related to the AMSA measure developed by the Weil Institute of Critical Care Medicine [3].

The Shock Conversion Estimator algorithm was developed and tested using data collected from a registry of AED Pro® and AED Plus® defibrillator field cases. Since the AED Pro and AED Plus defibrillators are first responder devices, all patient records correspond to first responder cardiac arrest situations. The defibrillator shock results from these cases were annotated as “converted” if a transient return of spontaneous circulation (tROSC) occurred following the shock. tROSC was defined as post shock ECG rhythms meeting both of the following characteristics:

1. Spontaneous ECG rhythms lasting at least 30 seconds that began within 60 seconds after shock delivery; and
2. Rhythms exhibiting a heart rate of 40 beats per minute or more.

The post shock rhythm was annotated as “non-converted” if it exhibited any other conversion outcome, e.g. VF, VT, and asystole.

The development database consisted of 149 patients containing 335 shocks. The SPI threshold of 4.5mV-Hz was selected to achieve sensitivity of 95% in development database.

The testing database consisted of 320 patient records containing 698 shocks. When evaluated against the testing database the threshold of 4.5mV-Hz resulted in sensitivity and specificity of 96% and 50% respectively.

The preferred treatment for non-converting rhythms may be the delivery of aggressive CPR. The use of the SPI measure to determine when shock treatments are likely to succeed will help minimize time between the advisory decision and the start of CPR. Minimizing non-perfusing time during resuscitation is a key contributor to improving patient outcomes [4].

$$\text{Sensitivity} = \frac{\text{Number of ECG Rhythms with SPI} \geq \text{Threshold that were successfully converted}}{\text{Total number of ECG rhythms that were successfully converted}}$$

$$\text{Specificity} = \frac{\text{Number of ECG rhythms with SPI} < \text{Threshold that did not convert}}{\text{Total number of ECG rhythms that did not convert}}$$

References

[1] Eftestol T, Sunde K, Steen PA. Effects of Interrupting Precordial Compressions on the Calculated Probability of Defibrillation Success during Out-of-Hospital Cardiac Arrest. Circulation 2002; 105:2270-2273.

[2] Sota Y, Weil MH, Sun S, Tang W. Xie J, Noc M, Bisera J. Adverse effects of interrupting precordial compression during cardiopulmonary resuscitation. Critical Care Medicine 1997; 25:733-736.

[3] Young C, Bisera J, Gehman S, Snyder D, Tang W, Weil MH. Amplitude spectrum area: measuring the probability of successful defibrillation as applied to human data. Critical Care Medicine 2004; 32:S356-S358.

[4] Wik L. Rediscovering the importance of chest compressions to improve the outcome from cardiac arrest. Resuscitation 2003; 58:267-269.

Wireless Output Guidance and Manufacturer's Declaration

RF Transmission Emitted (IEC 60601-1-2)

The Zenix device complies with IEC 60601-1-2 for medical electrical equipment and medical electrical systems that include RF transmitters as specified below.

Zenix - RF Transmitter Characteristics					
Wireless Standard & Mode	**Frequency Range**	**Effective Radiated Power (Max.)**	**Effective Radiated Power US/CAN (Typ.)**	**Effective Radiated Power EU (Typ.)**	**Modulation Type**
802.11b	2412-2472 MHz	21.5dBm	18.0dBm	13.5dBm	DSSS (DBPSK, DQPSK, CCK)
802.11g/n 20MHz	2412-2472 MHz	21.0dBm	15.0dBm	15.0dBm	OFDM (BPSK, QPSK, 16QAM, 64QAM)
802.11g/n 40MHz	2422-2462 MHz	19.0dBm	10.5dBm	15.0dBm	OFDM (BPSK, QPSK, 16QAM, 64QAM)
Bluetooth	2402-2480 MHz	4.0dBm	0.5dBm	0.5dBm	GFSK, π/4DQPSK, 8DPSK
802.11a/n/ac 20MHz	5180-5825 MHz	13.5dBm	11.0dBm	11.0dBm	OFDM (BPSK, QPSK, 16QAM, 64QAM)
802.11n/ac 40MHz	5190-5795 MHz	12.5 dBm	10.0dBm	10.0dBm	OFTEN (BPSK, QPSK, 16QAM, 64QAM)
802.11ac 80 MHz	5210-5775 MHz	12.0dBm	9.0dBm	9.0dBm	OFDM (BPSK, QPSK, 16QAM, 64QAM, 256QAM)

FCC Notice

ZOLL Medical Corporation has not approved any changes or modifications to this device by the user. Any changes or modifications could void the user's authority to operate the equipment. See 47 CFR Section 15.21.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

The user is cautioned to maintain 20cm (8 inches) of space from the product to ensure compliance with FCC requirements.

This device is limited to indoor use in the 5150MHz to 5250MHz band.

Note: Harmful Interference is defined by the FCC as follows: Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance FCC rules.

ISED Canada Notices

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

APPENDIX B

Accessories

The following accessories are compatible for use with the Zenix device. To order any of these items, contact your local ZOLL representative.

Batteries and Chargers

- SurePower™ 4 Battery
- Charger Adapter SurePower 4
- SurePower Single Bay Charger
- SurePower 4 Bay Charging System

Power Cables

- Power Cord, NA, 10A, 125V
- Power Cord, 10A, 250VAC, 50Hz Continental Euro
- Power Cord, 10A, 220V, Swiss
- Power Cord, 10A, 250VAC, UK
- Power Cord, 10A, 250V, Australia
- Power Cord, 2.5M, 12A, 250V, Japanese

MFC Cables

- MFC, Zenix, Cable Assembly
- Assembly, Green Connector, Zenix
- Assembly, OneStep Connector, Zenix

ECG Cables

- Zenix 12-Lead ECG Cable, AAMI
- Zenix 12-Lead ECG Cable, IEC

- Zenix Chest Lead ECG Cable, AAMI
- Zenix Chest Lead ECG Cable, IEC
- Zenix 3-Lead ECG Cable, AAMI
- Zenix 3-Lead ECG Cable, IEC
- Zenix 5-Lead ECG Cable, AAMI
- Zenix 5-Lead ECG Cable, IEC
- Zenix Limb Lead ECG Cable, AAMI
- Zenix Limb Lead ECG Cable, IEC

AccuVent

- AccuVent Sensors

Z-Link

- Z-Link AccuVent Cable Assembly
- Z-Link IBP Cable Assembly, Edwards
- Z-Link IBP Cable Assembly, Abbott
- Z-Link Temperature Cable Assembly

Cases and Paddle Mounts

- Zenix Carry Case
- Zenix Defibrillator Paddle Mount

NIBP

- Hose, Air, 3m NIBP
- Cuff, Child, 12-19 cm
- Cuff, Small Adult Plus, 18-29 cm
- Cuff, Adult Plus, 28-40 cm
- Cuff, Large Adult Plus, 40-55 cm

EtCO2

- IRMA Airway Adapter Adult
- IRMA Airway Adapter Infant
- IRMA CO2 (External)

SPO2 Masimo

- RD SET Adt, Adult SpO2 adhesive sensor
- RD SET Pdt, Pediatric SpO2 adhesive sensor

- RD SET Inf, Infant SpO2 adhesive sensor
- RD SET Neo, Neonatal/Adult SpO2 adhesive sensor
- RD SET NeoPt, Neonatal SpO2 adhesive sensor
- RD SET NeoPt-500, Neonatal SpO2 non-adhesive sensor
- RD SET E1 Ear Sensor, 3 Ft
- RD rainbow SET-2 Adt 8λ SpHb, Adult Single-Patient-Use Pulse CO-Oximetry Sensor
- RD rainbow SET-2 Pdt 8λ SpHb, Pediatric Single-Patient-Use Pulse CO-Oximetry Sensor
- RD rainbow SET-2 Inf, infant (SpHb, SpO2, SpMet) adhesive sensors
- RD rainbow SET-2 Neo 8λ SpHb, Neonatal/Adult Single-Patient-Use Pulse CO-Oximetry Sensor
- RD rainbow Adt 8λ SpCO, Adult Single-Patient-Use Pulse CO-Oximetry Sensor
- RD rainbow Pdt 8λ SpCO, Pediatric Single-Patient-Use Pulse CO-Oximetry Sensor
- RD rainbow Inf 8λ SpCO, Infant Single-Patient-Use Pulse CO-Oximetry Sensor
- RD rainbow Neo 8λ SpCO, Neonatal/Adult Single-Patient-Use Pulse CO-Oximetry Sensor
- RD SET DCI Adult Sensor, 3 ft
- RD SET DCIP Pediatric Sensor, 3 ft
- RD SET DBI Adult Soft Sensor, 3 ft
- Red 25RA MNC Adapter Cable, 4 ft.
- RD rainbow SET RA25-04, EMS Cable, 4 ft
- RD rainbow SET RA25-05, right angle patient Cable, 5 ft
- RD rainbow SET RA25-12, right angle patient Cable, 12 ft
- LNCS-II rainbow DCI 8λ SpCO Adult Sensor

Temp

- Reusable Adult Esophageal/Rectal Temperature Probe
- Reusable Pediatric Esophageal/Rectal Temperature Probe
- Reusable Adult Skin Temperature Probe
- Reusable Pediatric Skin Temperature Probe

External Paddles

- Defibrillator Gel - 12 Tubes
- External Paddle Assembly Apex/Sternum with Controls and Built-In Pediatric Electrodes
- Anterior Posterior Paddle Assembly
- Steam Autoclavable Defibrillation Paddles, Front Panel Discharge

ECG Electrodes

- ZOLL ECG Rectangular Electrodes
- ZOLL ECG Round Electrodes
- ZOLL ECG Square Electrodes
- ZOLL ECG Radiolucent Round Electrodes
- ZOLL ECG Pediatric Round Electrodes

Zenix Device Compatible Therapy Electrodes

Therapy Electrode	Connector Required	Electrode Connection
Zenix CPR A/A	N/A	Zenix Multi-Function Electrode
Zenix CPR A/P	N/A	Zenix Multi-Function Electrode
Zenix CPR Pediatric	N/A	Zenix Multi-Function Electrode
OneStep Basic	N/A	White
Stat-Padz	N/A	White
Pedi-Padz Multi-function Liquid Gel	N/A	White
Pedi-Padz Solid Gel	N/A	White
Pedi-Padz Radiolucent Solid Gel	N/A	White
Pedi-Padz Solid Gel w/10 ft Lead Wire	N/A	White
Pro-Padz Radiolucent Liquid Gel Electrode	N/A	White
Pro-Padz Biphasic Electrode	N/A	White
Pro-Padz Radiolucent Solid Gel Electrode	N/A	White
Pro-Padz Sterile w/10 ft Lead Wire Electrode	N/A	White
OneStep CPR	OneStep Connector	OneStep
OneStep CPR-A/A	OneStep Connector	OneStep
OneStep Pediatric	OneStep Connector	OneStep
OneStep Pediatric CPR	OneStep Connector	OneStep
OneStep Pediatric CPR Gemini	OneStep Connector	OneStep
Zenix CPR Complete	N/A	Zenix Multi-function Electrode
OneStep CPR Complete	OneStep Connector	OneStep
OneStep Pacing	OneStep Connector	OneStep
CPR-D Padz	Green Connector	Green
CPR Stat-Padz	Green Connector	Green

Therapy Electrode	Connector Required	Electrode Connection
OneStep Basic GC *	Green Connector	Green
OneStep CPR A/A GC *	Green Connector	Green
OneStep Pediatric GC *	Green Connector	Green
CPR Uni-Padz	Green Connector	Green
Stat Padz II	Green Connector	Green
Pedi Padz II	Green Connector	Green
Sterilizable Internal Handles with Integrated Paddles with Switch, 10 ft Cable **	N/A	Autoclavable
Sterilizable Internal Handle with Integrated Paddles without Switch, 10 ft Cable **	N/A	Autoclavable
Sterilizable Internal Handles with Integrated Paddles with Switch, 7 ft Cable **	N/A	Autoclavable
Sterilizable Internal Handles Non-Integrated without Switch, 8 ft Cable **	N/A	Autoclavable
Sterilizable Internal Handles Non-Integrated with Switch, 8 ft Cable **	N/A	Autoclavable
Sterilizable Internal Handles Non-Integrated with Switch 16 ft Cable **	N/A	Autoclavable
Sterilizable Overmold Internal Paddles (multiple diameter sizes) **	N/A	N/A
External Paddles w/buttons	N/A	External Paddles
A/P Paddles w/buttons	N/A	External Paddles
Sterlizable External Paddles w/no buttons	N/A	Autoclavable

*Not available in the USA.

** Refer to the sterilizable internal handles instructions for use for available paddles diameter configurations.

Training Electrodes

- Zenix CPR A/A Training
- Zenix CPR A/P Training
- Zenix Pediatric CPR, Training
- OneStep Pediatric CPR Training Kit,

- OneStep Training Cable and replacement pads
- OneStep Training CPR A/P Electrodes and replacement pads
- Training CPR Stat-padz
- Training Electrodes, Stat-padz II
- CPR-D padz Demo/Training Electrodes

Training Miscellaneous

- 12-Lead ECG Simulator with IBP Channel
- See-Thru CPR Simulator
- 12-Lead ECG Simulator

Recorder Paper

- Zenix Fan Fold Paper