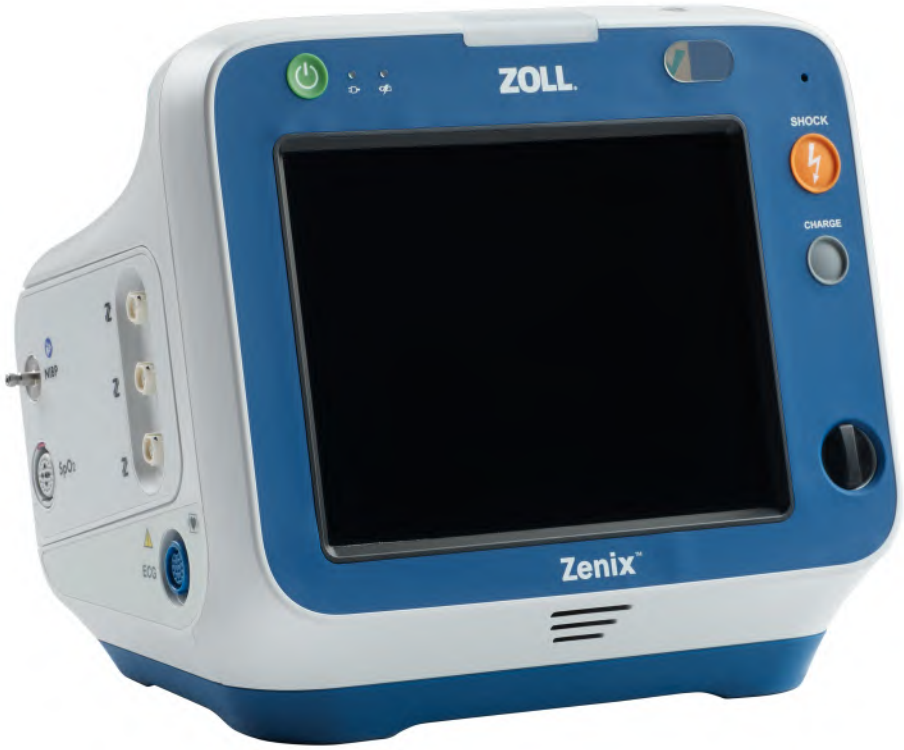
ZOLL®

Zenix® Hospital Operator's Guide



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

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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.

This product and accompanying components are manufactured and sold under one or more patents listed at the following internet address:

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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 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.

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, 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.

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, pediatric, and neonatal patients.

CO_2 Monitoring

The Zenix device is indicated for use in continuous non-invasive measurement and monitoring of end tidal carbon dioxide ($EtCO_2$) and respiration rate in adult, pediatric, and neonatal 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, pediatric, and neonatal patients in critical care and transport.

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 patients from newborn (neonate) to adult.

Respiration 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 patients from newborn (neonate) to adult.

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 patients from newborn (neonate) to adult.

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

APPENDIX B Accessories

APPENDIX A

Specifications

This appendix provides specification information.

It includes the following sections:

Electromagnetic Compatibility Guidance and Manufacturer's Declaration

Note: For EMC limits when using the Zenix with the AutoPulse Plus as a system refer to the latest revision of the AutoPulse User Guide (REF 9650-000723-01).

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 assure 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 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 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 are intended for use in the electromagnetic environment specified below. The customer or user of the Zenix 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, 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; 13.553MHz 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 is used exceeds the applicable RF compliance level above, the Zenix 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.

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.