



Zenix[®] EMS Operator's Guide



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

The issue date for the Operator's Guide (**REF** 9650-000421-01 Rev. 2) is April 2024.

Copyright © 2024 ZOLL Medical Corporation. All rights reserved. AccuVent, AutoPulse, CPR-D padz, OneStep, Pedi-padz, Perfusion Performance Indicator, RapidShock, Real BVM Help, Real CPR Help, Rectilinear Biphasic, RescueNet, ResQCPR, See-Thru CPR, Zenix, SurePower, and ZOLL are trademarks or registered trademarks of ZOLL Medical Corporation in the United States and/or other countries. All other trademarks are the property of their respective owners.

Masimo, Pulse CO-Oximeter, Rainbow, SET, SpCO, SpMet, SpHb, SpOC, PVi, ISA are trademarks or registered trademarks of Masimo Corporation in the United States and/or other countries.

Masimo Patents: www.masimo.com/patents.htm.

SunTech Advantage is a registered trademark of SunTech Medical Group.

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:

<http://www.zoll.com/patents>

 **ZOLL Medical Corporation**
269 Mill Road
Chelmsford, MA USA
01824-4105

 **ZOLL International Holding B.V.**
Einsteinweg 8A
6662 PW Elst
Netherlands

 **ZOLL Medical Switzerland AG**
Baarerstrasse 8
6300 Zug
Switzerland


0123

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.

SpO₂ Monitoring

The Zenix device is indicated for use for continuous non-invasive monitoring of arterial oxygen saturation (SpO₂), 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.

CO₂ 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 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 SpO₂, Systolic BP (SBP), and EtCO₂ 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.

CONTENTS

CHAPTER 1 General Information

Product Description	2
Monitoring Features	3
Resuscitation Technologies	4
How to Use This Manual	5
Operator's Guide Updates	5
Conventions	5
Unpacking	6
Symbols Used on the Equipment	7
Intended Use	12
Safety Considerations	13
Summary of Safety and Clinical Performance	13
Warnings	14
General	14
ECG Monitoring	15
Defibrillation	16
Pacing	17
Ferromagnetic Equipment	18
CPR	19
TBI Dashboard	19
Pulse Oximeter	19
Non-invasive Blood Pressure	20
IBP	21
CO2	21
Respiration	22
Battery	22
Operator Safety	22
Patient Safety	23
Cautions	25
FDA Tracking Requirements	26

Notification of Adverse Events	26
Restarting the Device	28
Software License	29
NO IMPLIED LICENSE	29
Service	30
Returning a Device for Service	31
The ZOLL Serial Number	32

CHAPTER 2 Product Overview

The Front Panel	34
Controls and Indicators	35
The Touch Screen Display	36
Navigating the Display Screen	37
Status Bar	38
Navigation Bar	39
Action Bar	40
Rotary Knob	42
Battery Status and Auxiliary Power Indicators	42
Replacing a Battery Pack	43
Patient Connectors	44
Multifunction Cable (MFC)	45
OneStep Connector (Optional)	45
Green Connector (optional)	46
External Paddles	47
Attaching the MFC	47
Auxiliary Power Adapter	49
Connecting Auxilliary Power	49
Common Tasks	50
Setting the Display Mode, Brightness, and Volume	50
Setting the Date and Time	50
Creating a New Patient Case	51
Using Treatment Markers	51
Loading Printer Paper	52

CHAPTER 3 Automated External Defibrillator (AED)

Overview	54
Warnings	54
AED Operation	55
Audio and Display Messages	56
Switching to Manual Mode Operation	58

CHAPTER 4 Manual Defibrillation

Overview	61
----------------	----

Defibrillation Procedure with Paddles	62
Defibrillation Procedure with Hands-Free Therapy Electrodes	65
Internal Paddles	66
Advisory Defibrillation Overview	67
Advisory Defibrillation Procedure	68
CHAPTER 5 Synchronized Cardioversion	
Overview	70
Synchronized Cardioversion Procedure	71
CHAPTER 6 CPR Technologies	
Overview	74
CPR Voice Prompts (Adult Only)	76
CPR Metronome	76
FULLY RELEASE Prompt	76
CPR Dashboard	77
CPR Dashboard with AutoPulse	79
AutoPulse with Shock Sync	80
CPR Dashboard with the ResQCPR System	81
See-Thru CPR	82
Using See-Thru CPR	83
Real BVM Help	88
Real BVM Help Display	88
Using Real BVM Help	91
CHAPTER 7 Non-invasive Pacing	
External Pacing Overview	95
Pacing Adult Patients	96
Pacing Pediatric Patients	98
Pacing Messages	98
CHAPTER 8 Monitoring ECG	
Overview	100
Preparing the Patient for Electrode Application	100
Applying Electrodes to the Patient	101
3-Lead Electrode Placement	101
5-Lead Electrode Placement	102
Connecting the ECG Cable to the Device	103
Configuring the Waveform Display	104
ECG Monitoring and Pacemakers	105
ECG System Messages	106
ECG Lead Fault Identification	107

CHAPTER 9 12-Lead ECG Interpretive Analysis

Overview	110
Warnings	111
12-Lead ECG Monitoring Setup	112
Enter Patient Information	112
Prepare the Patient for Electrode Application	113
Apply Electrodes to the Patient	113
Connect the 12-Lead Cable and Observe Waveforms	115
12-Lead ECG Window	116
12-Lead Interpretive Analysis	116
12-Lead Print	119
Transmitting a 12-Lead Report	119

CHAPTER 10 Monitoring Respiration (RR/BR) and Heart Rate (HR)

Overview	122
Respiration Rate/Breath Rate Meter	122
The Resp (RR/BR) Settings Window	124
Adjusting Resp (RR/BR) Settings	124
Adjusting Resp Alarm Settings	125
Heart Rate Meter	126
The Heart Rate (HR) Settings Window	127
Adjusting Heart Rate Settings	127
Adjusting Heart Rate Alarm Settings	128
RESP System Messages	129

CHAPTER 11 Monitoring Non-invasive Blood Pressure (NIBP)

Overview	132
How NIBP Works	132
The NIBP Numeric Display	133
NIBP Setup	134
Verify Patient Type	134
Select the NIBP Cuff	135
Apply the Cuff to the Patient	136
Verify Cuff Inflation Settings	137
Connect the NIBP Cuff	138
NIBP Settings Window	139
Adjusting NIBP Settings	139
Adjusting NIBP Alarm Settings	141
Taking Measurements	142
NIBP System Messages	143

CHAPTER 12 Monitoring Sidestream CO₂

Overview	146
----------------	-----

Sidestream CO2 Setup	148
Selecting the CO2 Sampling Line	148
Connecting the CO2 Sampling Line	148
Apply a Nasal or Nasal/Oral Sampling Line	149
Apply an Airway Adapter Set	150
LEGI Indicator	150
Zeroing	150
The CO2 Settings Window	151
Adjusting CO2 Settings	151
Adjusting CO2 Alarm Settings	152
Measuring CO2	153
CO2 System Messages	154

CHAPTER 13 Pulse CO-Oximetry (SpO2)

Overview	156
Warnings	157
SpO2 Setup and Use	162
Selecting the SpO2 Sensor	162
Applying the SpO2 Sensor	163
Connecting the SpO2 Sensor	163
Displaying Measurements	164
The SpO2 Settings Window	165
Adjusting SpO2 Settings	165
Adjusting SpO2 Alarm Settings	167
Enabling SpO2 Monitoring Options	168
SpO2 System Messages	169
Functional Testers and Patient Simulators	170
Patents	171
NO IMPLIED LICENSE	171

CHAPTER 14 Monitoring Invasive Pressures (IBP)

Overview	174
IBP Setup	175
Attaching the Invasive Pressure Transducer	175
Zeroing the Transducer	176
The IBP Numeric Display	178
IBP Settings Window	179
Adjusting IBP Settings	179
Adjusting IBP Alarm Settings	181
IBP System Messages	182

CHAPTER 15 Monitoring Temperature

Overview	184
----------------	-----

Temperature Monitoring Setup	185
Selecting and Applying Temperature Probes	186
Connecting the Temperature Probe	187
Displaying Temperature Measurements	187
Temperature Settings Window	188
Identifying Temperature Channels	188
Adjusting Temperature Alarm Settings	189
Temperature System Messages	190

CHAPTER 16 Trends

Overview	192
Displaying/Closing Trends	193
Graphic Trends	193
Changing a Graphic Trend	194
Table Trends	195
Changing a Table Trend	196
Printing an Individual Trend from Table	196
Printing All Trends from Table	196
Printing Trend Summary	197

CHAPTER 17 Alarms

Overview	200
Alarm States	201
LED and Audible Alarm Indicators	202
Patient Alarm Visual Alarm Indicators	203
Technical Alert Visual Alarm Indicators	204
To Display Alert Message:	204
Responding to Active Alarms	205
Re-enabling an Alarm	205
Pausing Alarms	206
Alarm Reminders	206
Life-Threatening Alarms	207
Latching Alarms	207
Alarm Settings	208
General Alarm Settings	209
Respiratory Rate (RR/BR) Alarm Limits	213
Respiration Rate Alarm Limits	213
Heart Rate (HR) Alarm Limits	214
NIBP Alarm Limits	215
SpO2 Alarm Limits	217
SpCO Alarm Limits	217
SpMet Alarm Limits	217
SpHb Alarm Limits	218

SpOC Alarm Limits	218
PVi Alarm Limits	218
Pi Alarm Limits	219
EtCO ₂ Alarm Limits	219
FiCO ₂ Alarm Limits	219
IBP Systolic (SYS) Alarm Limits	219
IBP Diastolic (DIA) Alarm Limits	220
IBP MAP Alarm Limits	220
Δ Temperature Alarm Limits	220
Temperature Alarm Limits	221

CHAPTER 18 TBI Dashboard

Overview	224
Parameter Trend Graphs	225
SBP Trending	225
EtCO ₂ Trending	226
SpO ₂ Trending	226
Ventilation Assistance	227
Ventilation Assistance with Real BVM Help	228
Using the TBI Dashboard	229
References	230

CHAPTER 19 Patient Data Management

Overview	232
Patient Data Storage	233
Data Log Capacity	234
Waveforms	235
Snapshots	236
Manually Captured Snapshots	236
Automatically Configured Snapshots	236
Viewing/Printing/Transmitting 12-Lead Snapshots	238
Reports	239
Continuous Waveform Report	239
Trend Summary Report	239
Treatment Summary Report	239
12-Lead ECG Report	239
Full Disclosure Case Logs	241
Transferring Data to USB Device/Server	242

CHAPTER 20 Communications

Overview	244
Communication Windows	244
Communication Icons	246

Enabling Wireless Features	247
Selecting a Pre-Configured Access Point Profile	247
Viewing and Connecting Bluetooth Devices	248
Distribution	248
Transmitting Data	249
Transmission Status Icons	249
Communications System Messages	251

CHAPTER 21 Maintenance

Overview	254
Daily Visual Inspection	255
Weekly Tests	256
Pacer Test	256
SpO2 Test	256
Guidelines for Maintaining Peak Battery Performance	257
Cleaning Instructions	258
Cleaning or Disinfecting the NIBP Blood Pressure Cuff	259
Cleaning SpO2 Sensors	259
Cleaning ISA CO2	259
Cleaning Cables and Accessories	260
Cleaning the Print Head	261
Operator's Daily Checklist	262

APPENDIX A Specifications

Defibrillator	269
CPR Monitoring	282
ECG Monitor/Display	283
Impedance Pneumography	286
Alarms	287
Recorder	289
Battery	290
General	291
Pacer	293
Sidestream CO2	294
Accuracy	294
Environmental	294
Physical Characteristics	295
Electrical	295
Compliance	295
Additional Specifications	295
Effects from Water Vapor Partial Pressure on Gas Readings	297
Pulse Oximeter	298
SpO2 Accuracy Specification	303

NIBP	308
Invasive Pressures	310
Temperature	311
Real Time Clinical Feedback	312
Trending Capability	314
Patient Log Files	315
External Data Transfer	316
Clinical Trial Results for the Biphasic Waveform	317
Randomized Multi-center Clinical Trial for Defibrillation of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT)	317
Randomized Multi-Center Clinical Trial for Cardioversion of Atrial Fibrillation (AF)	318
Pre-Clinical Study	319
Published Clinical Data	320
Synchronized Cardioversion of Atrial Fibrillation	321
Electromagnetic Compatibility Guidance and Manufacturer's Declaration	322
In-Flight Use (RTCA/DO-160):	322
Electromagnetic Immunity (IEC 60601-1-2)	323
Electromagnetic Immunity	325
Recommended Separation Distances from RF Equipment for the Zenix Functions	328
ECG Analysis Algorithm Accuracy	330
Clinical Performance Results	330
Shock Conversion Estimator	332
Wireless Output Guidance and Manufacturer's Declaration	334
RF Transmission Emitted (IEC 60601-1-2)	334
FCC Notice	335
ISED Canada Notices	335

APPENDIX B Accessories

APPENDIX A

Specifications

This appendix provides specification information.

It includes the following sections:

Defibrillator	269
CPR Monitoring	282
ECG Monitor/Display	283
Impedance Pneumography	286
Alarms	287
Recorder	289
Battery	290
General	291
Pacer	293
Sidestream CO2	294
Pulse Oximeter	298
NIBP	308
Invasive Pressures	310
Temperature	311
Real Time Clinical Feedback	312
Trending Capability	314
Patient Log Files	315
External Data Transfer	316
Clinical Trial Results for the Biphasic Waveform	317
Electromagnetic Compatibility Guidance and Manufacturer's Declaration ..	322
ECG Analysis Algorithm Accuracy	330

APPENDIX A Specifications

Wireless Output Guidance and Manufacturer's Declaration	334
---	-----

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).

In-Flight Use (RTCA/DO-160):

The Zenix device complies with RTCA/DO-160, Environmental Conditions and Test Procedures for Airborne Equipment, using the methods in Section 21, Category M for Radiated and Conducted Radio Frequency Energy. The Zenix device is compliant with DO-160 Section 20, Category R for conducted susceptibility and Category Q (ZOLL's defined limits) for radiated susceptibility. Category Q is defined as the following:

- 100-400 MHz, 20 V/m (CW & SW)
- 400-700 MHz, 41.9 V/m (PM)
- 700-1,000 MHz, 50.1 V/m (PM)
- 1.0-1.2 GHz, 54.9 V/m (PM)
- 1.2-8.0 GHz, 61.4 V/m (PM)

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	
RF emissions CISPR 25	Class 1	Interferences may occur in TV Band III & DAB III service bands. If this occurs move Zenix away from sensitive devices.
RF emissions CISPR 25	Class 1, voltage method	For road ambulance use.
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	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	$d = 1.2 \sqrt{P}$
	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 (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	$d = 0.3 \sqrt{P}$

¹The 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.

²The 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.

³Electrodes that may require the use of the 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	3V/m	d = 2.0 √P 433 MHz
	54V/m, 860-960MHz	54V/m	d = 0.1 √P 860-960 MHz
	54V/m, 2.45GHz	54V/m	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.

¹The 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.

²Field 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.

³Over 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 are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Zenix can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Zenix 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, SpO₂, 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
	$d = 1.2\sqrt{P}$	$d = 2.0\sqrt{P}$	$d = 0.6\sqrt{P}$
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
	$d = 1.2\sqrt{P}$	$d = 2.0\sqrt{P}$	$d = 0.3\sqrt{P}$
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

Recommended separation distances between portable and mobile RF communications equipment and the Zenix

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; 13.553 MHz 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.

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, $\pi/4$ DQPSK, 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.