



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 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 Cord	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 Mainstream CO₂

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

Mainstream CO2 Setup	149
Attach Probe Interface Cable	149
Turning on CO2 Monitoring	149
Select Mainstream Airway Adapter	149
Attach IRMA Airway Adapter to the CO2 Probe	150
Attach IRMA Airway Adapter to the Airway Circuit	150
The CO2 Settings Window	151
Adjusting CO2 Settings	151
Adjusting CO2 Alarm Settings	152
Measuring CO2	153
CO2 System Messages	154
Zero the Mainstream IRMA Probe	155

CHAPTER 13 Pulse CO-Oximetry (SpO2)

Overview	158
Warnings	159
SpO2 Setup and Use	164
Selecting the SpO2 Sensor	164
Applying the SpO2 Sensor	165
Connecting the SpO2 Sensor	165
Displaying Measurements	166
The SpO2 Settings Window	167
Adjusting SpO2 Settings	167
Adjusting SpO2 Alarm Settings	169
Enabling SpO2 Monitoring Options	170
SpO2 System Messages	171
Functional Testers and Patient Simulators	172
Patents	173
NO IMPLIED LICENSE	173

CHAPTER 14 Monitoring Invasive Pressures (IBP)

Overview	176
IBP Setup	177
Attaching the Invasive Pressure Transducer	177
Zeroing the Transducer	178
The IBP Numeric Display	180
IBP Settings Window	181
Adjusting IBP Settings	181
Adjusting IBP Alarm Settings	183
IBP System Messages	184

CHAPTER 15 Monitoring Temperature

Overview	186
----------------	-----

Temperature Monitoring Setup	187
Selecting and Applying Temperature Probes	188
Connecting the Temperature Probe	189
Displaying Temperature Measurements	189
Temperature Settings Window	190
Identifying Temperature Channels	190
Adjusting Temperature Alarm Settings	191
Temperature System Messages	192

CHAPTER 16 Trends

Overview	194
Displaying/Closing Trends	195
Graphic Trends	195
Changing a Graphic Trend	196
Table Trends	197
Changing a Table Trend	198
Printing an Individual Trend from Table	198
Printing All Trends from Table	198
Printing Trend Summary	199

CHAPTER 17 Alarms

Overview	202
Alarm States	203
LED and Audible Alarm Indicators	204
Patient Alarm Visual Alarm Indicators	205
Technical Alert Visual Alarm Indicators	206
To Display Alert Message:	206
Responding to Active Alarms	207
Re-enabling an Alarm	207
Pausing Alarms	208
Alarm Reminders	208
Life-Threatening Alarms	209
Latching Alarms	209
Alarm Settings	210
General Alarm Settings	211
Respiratory Rate (RR/BR) Alarm Limits	215
Respiration Rate Alarm Limits	215
Heart Rate (HR) Alarm Limits	216
NIBP Alarm Limits	217
SpO2 Alarm Limits	219
SpCO Alarm Limits	219
SpMet Alarm Limits	219
SpHb Alarm Limits	220

SpOC Alarm Limits	220
PVi Alarm Limits	220
Pi Alarm Limits	221
EtCO ₂ Alarm Limits	221
FiCO ₂ Alarm Limits	221
IBP Systolic (SYS) Alarm Limits	221
IBP Diastolic (DIA) Alarm Limits	222
IBP MAP Alarm Limits	222
Δ Temperature Alarm Limits	222
Temperature Alarm Limits	223

CHAPTER 18 TBI Dashboard

Overview	226
Parameter Trend Graphs	227
SBP Trending	227
EtCO ₂ Trending	228
SpO ₂ Trending	228
Ventilation Assistance	229
Ventilation Assistance with Real BVM Help	230
Using the TBI Dashboard	231
References	232

CHAPTER 19 Patient Data Management

Overview	234
Patient Data Storage	235
Data Log Capacity	236
Waveforms	237
Snapshots	238
Manually Captured Snapshots	238
Automatically Configured Snapshots	238
Viewing/Printing/Transmitting 12-Lead Snapshots	240
Reports	241
Continuous Waveform Report	241
Trend Summary Report	241
Treatment Summary Report	241
12-Lead ECG Report	241
Full Disclosure Case Logs	243
Transferring Data to USB Device/Server	244

CHAPTER 20 Communications

Overview	246
Communication Windows	246
Communication Icons	248

Enabling Wireless Features	249
Selecting a Pre-Configured Access Point Profile	249
Viewing and Connecting Bluetooth Devices	250
Distribution	250
Transmitting Data	251
Transmission Status Icons	251
Communications System Messages	253

CHAPTER 21 Maintenance

Overview	256
Daily Visual Inspection	257
Weekly Tests	258
Pacer Test	258
SpO2 Test	258
Guidelines for Maintaining Peak Battery Performance	259
Cleaning Instructions	260
Cleaning or Disinfecting the NIBP Blood Pressure Cuff	261
Cleaning SpO2 Sensors	261
Cleaning IRMA CO2	261
Cleaning Cables and Accessories	262
Cleaning the Print Head	263
Operator's Daily Checklist	264

APPENDIX A Specifications

Defibrillator	271
CPR Monitoring	284
ECG Monitor/Display	285
Impedance Pneumography	288
Alarms	289
Recorder	291
Battery	292
General	293
Pacer	295
IRMA CO2	296
Accuracy	296
Gas Concentration Conversion	296
Electrical	296
Environmental	297
Physical Characteristics	297
Compliance	297
Additional Specifications	298
Pulse Oximeter	301
SpO2 Accuracy Specification	306

NIBP	311
Invasive Pressures	313
Temperature	314
Real Time Clinical Feedback	315
Trending Capability	317
Patient Log Files	318
External Patient Monitor Connections	319
External Data Transfer	320
Clinical Trial Results for the Biphasic Waveform	321
Randomized Multi-center Clinical Trial for Defibrillation of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT)	321
Randomized Multi-Center Clinical Trial for Cardioversion of Atrial Fibrillation (AF)	322
Pre-Clinical Study	323
Published Clinical Data	324
Synchronized Cardioversion of Atrial Fibrillation	325
Electromagnetic Compatibility Guidance and Manufacturer's Declaration	326
Electromagnetic Immunity (IEC 60601-1-2)	327
Electromagnetic Immunity	329
Recommended Separation Distances from RF Equipment for the Zenix Functions	332
ECG Analysis Algorithm Accuracy	334
Clinical Performance Results	334
Shock Conversion Estimator	336
Wireless Output Guidance and Manufacturer's Declaration	338
RF Transmission Emitted (IEC 60601-1-2)	338
FCC Notice	339
ISED Canada Notices	339

APPENDIX B Accessories

APPENDIX A

Specifications

This appendix provides specification information.

It includes the following sections:

Defibrillator	271
CPR Monitoring	284
ECG Monitor/Display	285
Impedance Pneumography	288
Alarms	289
Recorder	291
Battery	292
General	293
Pacer	295
IRMA CO2	296
Pulse Oximeter	301
NIBP	311
Invasive Pressures	313
Temperature	314
Real Time Clinical Feedback	315
Trending Capability	317
Patient Log Files	318
External Patient Monitor Connections	319
External Data Transfer	320
Clinical Trial Results for the Biphasic Waveform	321
Electromagnetic Compatibility Guidance and Manufacturer's Declaration ..	326

APPENDIX A Specifications

ECG Analysis Algorithm Accuracy	334
Wireless Output Guidance and Manufacturer's Declaration	338

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	
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 uninterruptible 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	$d = 0.3 \sqrt{P}$

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 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	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.

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 with 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.