ZOLL®

# X Series™ Operator's Guide




9650-1355-01 Rev. 1

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# Chapter 1
# General Information

## Product Description

The ZOLL® X Series™ unit is an easy-to-use portable defibrillator that combines defibrillation and external pacing with the following monitoring capabilities: ECG, CO-Oximeter, Non-invasive Blood Pressure, IBP, CO2, Temperature, and Respiration. It has been designed for all resuscitation situations and its rugged, compact, lightweight design makes it ideal for transport situations. It is powered by auxiliary power and an easily replaced battery pack that is quickly recharged in the device when it is connected to auxiliary power. In addition, the unit's battery may be recharged and tested using a ZOLL *SurePower™ Battery Charger Station.*

**Note:** The X Series has defibrillation and pacing functionality, but some of the monitoring functions are optional features. See the complete list of options in Fig. 1-1. Optional features are specified as "optional" within this guide.

The product is designed for use in both the hospital and the rugged EMS environment. The device is a versatile automated external defibrillator with manual capabilities and may be configured to operate in Manual, Advisory or Semiautomatic modes. It can be configured to start up in Semiautomatic (AED) mode or manual mode.

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. In Advisory and AED modes, some features of the device are automated and a sophisticated detection algorithm is used to identify ventricular fibrillation and determine the appropriateness of defibrillator shock delivery. Units may be configured to automatically charge, analyze, recharge, and prompt the operator to "PRESS SHOCK", depending on local protocols. The unit is switched from AED mode to Manual mode for ACLS use by pressing the appropriate key on the front panel.

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

Real CPR Help® requires the use of ZOLL OneStep™ CPR electrodes, OneStep™ Complete electrodes, or CPR-D-padz®. When using these pads, the displayed ECG waveforms can be adaptively filtered, using the See-Thru CPR® feature, to reduce the artifact caused by chest compressions.

The unit has a large colorful LCD display of numerics and waveform data that provides easy visibility from across the room and at any angle. ECG, plethysmograph, and respiration waveform traces can be displayed simultaneously, giving easy access to all patient monitoring data at once. The display screen is configurable, so you can choose the best visual layout to fit your monitoring needs. The X Series includes a transcutaneous pacemaker consisting of a pulse generator and ECG sensing circuitry. Pacing supports both demand and fixed noninvasive pacing for adult patients and adolescent, child, and infant pediatric patients.

The X Series has a patient data review and collection system that allows you to view, store, and transfer patient data. The X Series unit contains a printer and USB port, which you can use to print the data and transfer it to a PC.

The X Series unit can send data through a wireless connection to remote locations. The X Series unit can send 12-lead report snapshots (including trend data) to a recipient via a ZOLL server. Full disclosure cases, which also contain trend data, can be automatically retrieved from the X Series unit using ZOLL RescueNet or ePCR software.

## X Series Optional Features

The following features are optional in the X Series unit.

**Figure 1-1 X Series Optional Features**

| Optional Feature |
|---|
| 12-Lead ECG with Interpretation |
| $SpO_2$ (Masimo) with SpCO and SpMet |
| NIBP (with Smartcuf® and SureBP™) |
| EtCO2 (Oridion® Microstream®) |
| Temperature |
| Invasive Pressures (3 Channels) |
| Advanced CPR Help |
| Pacing |

# How to Use This Manual

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

Please thoroughly read the safety considerations and warnings section.

Procedures for daily checkout and unit care are located in the Chapter 24, "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 to determine if additional product information updates are available.

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

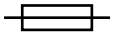
Product documentation is available through the ZOLL website at www.zoll.com. From the Products menu, choose Product Manuals.

# Unpacking

Carefully inspect each container for damage. If the shipping container or cushion material is damaged, keep it until the contents have been checked for completeness and the instrument has been checked for mechanical and electrical integrity. If the contents are incomplete, if there is mechanical damage, or if the defibrillator 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 be used in this manual or on this equipment:

| Symbol | Description |
|---|---|
|  | Dangerous voltage. |
|  | Attention, consult accompanying documents. |
|  | Fragile, handle with care. |
|  | Keep dry. |
|  | This end up. |
|  | Temperature limitation. |
|  | **Conformité Européenne** Complies with medical device directive 93/42/EEC. |
|  | Type B patient connection. |
|  | Type BF patient connection. |
|  | Type CF patient connection. |
|  | Defibrillator-proof type BF patient connection. |
|  | Defibrillator-proof type CF patient connection. |
|  | Fusible link. |

| Symbol | Description |
|---|---|
|  | Equipotentiality. |
|  | Alternating current (ac). |
|  | Direct current (dc). |
|  | Auxiliary power adapter operation. |
|  | Caution, high voltage. |
|  | Earth (ground). |
|  | Negative input terminal. |
|  | Positive input terminal. |
|  | Power On/Off |
|  | Protective earth (ground). |
|  | Contains lithium. Recycle or dispose of properly. |
|  | Keep away from open flame and high heat. |
|  | Do not open, disassemble, or intentionally damage. |
|  | Do not crush. |

| Symbol | Description |
|---|---|
|  | Do not discard in trash. Recycle or dispose of properly. |
|  | Return to a collection site intended for waste electrical and electronic equipment (WEEE). Do not dispose of in unsorted trash. |
|  | Date of manufacture. |
|  | Use by. |
|   | Latex-free. |
|  | Do not reuse. |
|  | Do not fold. |
|   | Not sterile. |
|  | Manufacturer. |
|   | Authorized representative in the European Community. |
|   | Serial Number. |
|   | Catalogue number. |
|  | Consult instructions for use. |

| Symbol | Description |
|---|---|
| Rx ONLY | Prescription only. |
|  | Battery charging status. |

# Conventions

This guide uses the following conventions:

Within text, the names and labels for physical buttons and softkeys appear in **boldface** type (for example, “Press the **Charge** button or press the **Pacer** button”).

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

| | |
|---|---|
| **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 unit. |

# ~~X Series Indications for Use~~

~~The X Series 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 X Series. The X Series 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 usage may be in an ambulance or at the scene of an emergency. It is also intended to be used during the transport of patients. The X Series will be used primarily on patients experiencing symptoms of cardiac arrest or in post trauma situation. It may also be used whenever it is required to monitor any of those functions that are included (as options) in the device. The X Series unit can be used on pediatric patients (as described in the following table) and on adult patients (21 years of age or older) with and 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.~~ |

When the pediatric patient is less than 8 years of age or weighs less than 55 lbs. (25 kg.), use ZOLL pedi-padz® pediatric defibrillation electrodes. Do not delay therapy to determine the patient's exact age or weight.

## Manual Defibrillation

Use of the X Series in the manual mode for external and internal defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness.
- Absence of breathing.
- Absence of pulse.

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

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

The patient population will range from newborn (neonate) to adult.

## Semiautomatic Operation (AED)

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

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

Use of the X Series in the Semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

• Unconsciousness.

• Absence of breathing.

• Absence of pulse.

Specifications for the ECG rhythm analysis function are provided in the section "ECG Analysis Algorithm Accuracy" on page A-32.

When the patient is less than 8 years of age or weighs less that 55 lbs. (25 Kg), you must use ZOLL pediatric defibrillation electrodes. Do not delay therapy to determine patient's exact age or weight.

# Safety Considerations

All operators should review these safety considerations before using the X Series unit.

X Series units are high-energy defibrillators capable of delivering 200 joules. To completely deactivate the unit, press the power switch to turn the unit off.

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

- Press the **Disarm** quick access key.
- Change the selected energy.
- Press the power switch to turn the unit off.

For safety, the X Series automatically disarms if left charged for more than 60 seconds if the shock button (◎) is not pressed.

# Warnings

## General

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

Only appropriately trained, skilled personnel who are familiar with equipment operation should perform emergency defibrillation. The prescribing physician should determine what training, such as Advanced Cardiac Life Support (ACLS) or Basic Life Support (BLS) certification, is appropriate.

Only skilled personnel trained in Advanced Cardiac Life Support (ACLS) and who are familiar with equipment operation should perform synchronized cardioversion. The precise cardiac arrhythmia must be determined before attempting defibrillation.

These operating instructions describe the functions and proper operation of the X Series 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 defibrillator for patient care.

Proper operation of the unit and correct electrode placement is critical to obtaining optimal results. Operators must be thoroughly familiar with proper device operation.

The use of external pacing/defibrillation electrodes, accessories, or adapter devices from sources other than ZOLL is not recommended. ZOLL makes no representations or warranties regarding the performance or effectiveness of its products when used with pacing/defibrillation electrodes or adapter devices from other sources. Defibrillator failures attributable to the use of pacing/defibrillation electrodes or adapters not manufactured by ZOLL might void ZOLL's warranty.

At receipt of shipment, check pacing/defibrillation electrodes to ensure compatibility.

Allow ample slack in cables to make sure that cables do not tug at electrodes.

Do not disassemble the unit. A shock hazard exists. Refer all problems to authorized service personnel.

Follow all recommended maintenance instructions. If a problem occurs, obtain service immediately. Do not use the defibrillator until it has been inspected by appropriate personnel.

The X Series unit might not perform to specifications when stored at the upper or lower extreme limits of storage temperature and then immediately put into use. The X Series unit should not be stored or used outside of the environmental limits provided in Appendix A of this manual.

Avoid using the X Series adjacent to, or stacked on, other equipment. If unavoidable, verify that the unit operates normally in this configuration before clinical use.

The X Series unit should be installed and put into service according to the EMC information in Appendix A of this manual.

Do not use internal paddles while the X Series unit's auxiliary power source is connected to an aircraft AC power operating at a frequency of 400 Hz.

The use of accessories, transducers, and cables other than those specified in this manual and related X Series option manual inserts may result in increased emissions or decreased immunity of the X Series.

Perform functional test of internal paddles prior to use.

Do not use or place the unit in service if the Ready For Use indicator (at the upper right of the front panel) displays a red circle with a line through it.

Carefully route patient cables to avoid tripping over them, or inadvertently pulling the unit onto the patient.

Always inspect the unit for damage if it has been dropped.

Only authorized personnel should use the Supervisor menus.

If uncertain about the accuracy of any measurement, first check the patient's vital signs by alternate means, and then make sure the monitor is functioning correctly.

## 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 spikes. Check the patient's pulse; do not rely solely on heart rate meters. Patient history and physical examination are important factors in determining the presence of an implanted pacemaker. Pacemaker patients should be carefully observed. See "Pacemaker Pulse Rejection:" on page A-15 of this manual for disclosure of the pacemaker pulse rejection capability of this instrument.

Use only ECG electrodes that meet the AAMI standard for electrode performance (AAMI EC-12). Use of electrodes not meeting this AAMI standard could cause the ECG trace recovery after defibrillation to be significantly delayed.

Prior to attempting synchronized cardioversion, ensure the ECG signal quality is good and that sync markers are displayed above each QRS complex.

Do not place electrodes directly over an implanted pacemaker.

The X Series unit detects ECG electrical signals only. It does not detect a pulse (effective circulatory perfusion). Always verify pulse and heart rate by physical assessment of the patient. Never assume that the display of a nonzero heart rate means that the patient has a pulse.

Excessive artifact can result due to improper skin preparation of the electrode sites. Follow skin preparation instructions in Chapter 6: "Monitoring ECG."

## $CO_2$

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 FilterLine® which permits placement of the monitor outside the MRI suite.

When using the monitor with anesthetics, nitrous oxide or high concentrations of oxygen, connect the gas outlet to a scavenger system.

Use only Oridion Microstream $CO_2$ sampling lines.

Microstream $CO_2$ sampling lines are labeled for single patient use only. Do not reuse sampling lines.

If using the $CO_2$ Monitor for extended critical care, replace the airway adapter every 24 hours or when it becomes occluded.

$CO_2$ readings and respiratory rate can be affected by sensor application errors, certain ambient environmental conditions, and certain patient conditions.

## Respiration

Do not operate the X Series with any other monitor with respiration measurements on the same patient. The two devices could affect the respiration accuracy.

The device should not be used as an apnea monitor.

## 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.

## Battery

Although the device can operate with auxiliary power alone, ZOLL strongly recommends that you operate the unit with a battery installed at all times. Operating the unit with a battery provides a backup in case of ac power shortage, and results in faster charge time. The battery can be automatically recharged while it is installed in the unit. Keep a fully charged spare battery pack with the defibrillator at all times.

Test battery packs regularly. A battery that does not pass the ZOLL charger's capacity test might cause the X Series unit 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 X Series unit into a power source or install a fully charged battery pack. When the warning low battery shutdown prompt appears, immediately replace the battery pack with a fully charged pack or plug the X Series unit into a power source, as unit 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.

## Operator Safety

The X Series 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.

Do not use the X Series in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents (such as gasoline). Using the unit in such environments might cause an explosion.

Do not use the unit near or within standing water. Electrical safety might be compromised when the defibrillator is wet.

Never discharge the unit 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 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 manufacturer.

When using paddles for defibrillation, use your thumbs to operate the **SHOCK** buttons. Doing so avoids inadvertent shock to the operator.

The use of accessory equipment that does not comply with the equivalent safety requirements of the X Series defibrillator could reduce the level of safety of the combined system. When choosing accessory equipment, consider the following:

- Use of the accessory in the patient vicinity.
- Evidence that the safety certification of the accessory has been performed in accordance with the appropriate IEC (EN) 60601-1 and/or IEC (EN) 60601-1-1 harmonized national standards.

Always check that the equipment functions properly and is in proper condition before use.

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.

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.

Neonatal and pediatric defibrillation energy level settings should be based on site-specific clinical protocols.

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 X Series only to equipment with circuits that are electrically isolated.

Use only high-quality ECG electrodes. ECG electrodes are for rhythm acquisition only; you cannot use ECG electrodes for defibrillation or pacing.

Do not use therapy or ECG electrodes if the gel is dried, separated, torn or split from the foil; patient burns may result from using such electrodes. Poor adherence and/or air pockets under therapy electrodes can cause arcing and skin burns.

Check the expiration date on the electrode packaging. Do not use electrodes after their expiration date.

Excessive body hair or wet, diaphoretic skin can inhibit electrode coupling to the skin. Clip excess hair and dry any moisture from the area where an electrode is to be attached.

Therapy electrodes should be replaced periodically during continuous pacing. Consult electrode directions for proper replacement instructions.

Prolonged pacing (more than 30 minutes), particularly in neonates or adults with severely restricted blood flow, may cause burns. Periodically inspect the skin under the electrodes.

Carefully route the patient cables away from the patient’s neck to reduce the possibility of patient entanglement or strangulation.

To avoid electrosurgery burns at monitoring sites, ensure proper connection of the electrosurgery return circuit so that a return path cannot be made through monitoring electrodes or probes.

During electrosurgery, observe the following guidelines to minimize electrosurgery unit (ESU) interference and provide maximum operator and patient safety:

- Keep all patient monitoring cables away from earth ground, ESU knives, and ESU return wires.
- Use electrosurgical grounding pads with the largest practical contact area.

Always ensure proper application of the electrosurgical return electrode to the patient.

Check electrical leakage levels before use. Leakage current might be excessive if more than one monitor or other piece of equipment is connected to the patient.

# Cautions

If the unit is to be stored longer than 90 days, remove the battery pack.

Do not sterilize the defibrillator, or its accessories unless the accessories are labelled as sterilizable.

Do not immerse any part of the defibrillator in water.

Do not use the defibrillator 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 defibrillator.

Avoid using abrasives (including paper towels) on the display window.

To achieve the specified level of protection against spilled or splashed liquids, thoroughly dry all exposed surfaces of this device prior to operation or connections to 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 defibrillator using battery power only.

Do not connect to an electrical outlet controlled by a wall switch or dimmer.

To protect the unit from damage during defibrillation, for accurate ECG information, and to protect against noise and other interference, use only internal current-limiting ECG cables specified or supplied by ZOLL.

For continued safety and EMI performance, use only the line cord supplied by ZOLL.

Electrical installation of the room or the building in which the monitor is to be used must comply with regulations specified by the country in which the equipment is to be used.

Dispose of battery packs in accordance with national, regional and local regulations. Battery packs should be shipped to a reclamation facility for recovery of metal and plastic compounds as the proper method of waste management.

Do not place the device where the controls can be changed by the patient.

# Restarting the Defibrillator

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

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

1. Press the power switch on the top of the unit to turn it off.
2. If necessary, replace a depleted battery with a fully charged pack, or connect the defibrillator to auxiliary power.
3. Press the power switch on the top of the unit to turn it back on.

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

If the X Series unit is powered off for less than 2 minutes, all patient monitoring parameter settings will be retained. If the unit has been powered off for at least two minutes, it will be considered a New Patient and all of the patient-specific parameters (alarm limits, defibrillator energy, etc.) will be reset to their default values.

# 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: (978) 421-0025
Telephone: (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.

# Software License

**Note:** Read this Operator's Guide and License agreement carefully before operating any of the X Series 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.

# Service

The X Series only 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 defibrillator functionality to verify proper operation.

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

| For customers In the U.S.A. | For customers outside the U.S.A. |
|---|---|
| Telephone: 1-800-348-9011<br>1-978-421-9655<br><br>Fax: 1-978-421-0010 | Call the nearest authorized ZOLL Medical Corporation representative.<br><br>To locate an authorized service center, contact the International Sales Department at<br><br>ZOLL Medical Corporation<br>269 Mill Road<br>Chelmsford, MA 01824-4105<br><br>Telephone: 1-978-421-9655 |

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

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

### Returning a unit for service

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

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

| For customers | Return the unit to |
|---|---|
| In the U.S.A. | ZOLL Medical Corporation<br>269 Mill Road<br>Chelmsford, MA 01824-4105<br><br>Attention: Technical Service Department (*SR number*)<br><br>Telephone: 1-800-348-9011 |

| For customers | Return the unit to |
|---|---|
| In Canada | ZOLL Medical Canada Inc.<br>1750 Sismet Road, Unit #1<br>Mississauga, ON L4W 1R6<br>Attention: Technical Service Department (*SR number*)<br>Telephone: 1-866-442-1011 |
| In other locations | The nearest authorized ZOLL Medical Corporation representative.<br>To locate an authorized service center, contact the International Sales Department at<br>ZOLL Medical Corporation<br>269 Mill Road<br>Chelmsford, MA 01824-4105<br>Telephone: 1-978-421-9655 |

# The ZOLL Serial Number

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

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

The first two characters of the date-of-manufacture code give the last two digits of the year (for example, “06” appears for products manufactured in 2006). The last character of the date-of-manufacture code gives the month in which the product was manufactured. The month appears in the form of a single alphanumeric character: “A” for January, “B” for February, “C” for March, and so on through “L” for December.

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

# Chapter 22
# Wireless Communications

The X Series unit can send data through a wireless connection to remote locations. The X Series unit can send 12-lead report snapshots (including trend data) to a recipient via a ZOLL server. Full disclosure cases, which also contain trend data, can be automatically retrieved from the X Series unit using ZOLL RescueNet or ePCR software.

You can set up a temporary wireless access point on the X Series unit by selecting the wireless icon on the display screen. Supervisors can set up permanent WiFi profiles (up to 255) in the Setup/Communications menu, which requires a password.

Once you have set up a wireless access point, you can send 12-lead reports to an email or fax recipient. Data can also be retrieved automatically using ZOLL RescueNet or ePCR software.

This chapter describes how to select different recipients and how to set up wireless communications in the X Series unit for different types of recipients.

**Note:** Test all wireless connections after initial setup and prior to use.

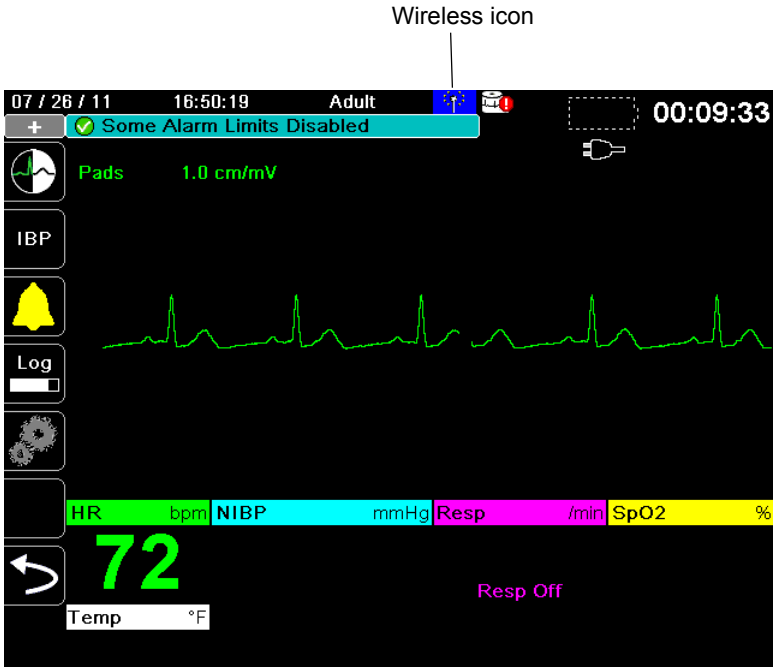
# Wireless Icon

The wireless icon is located to the right of the patient mode in the display screen. It has three possible states shown the table below.

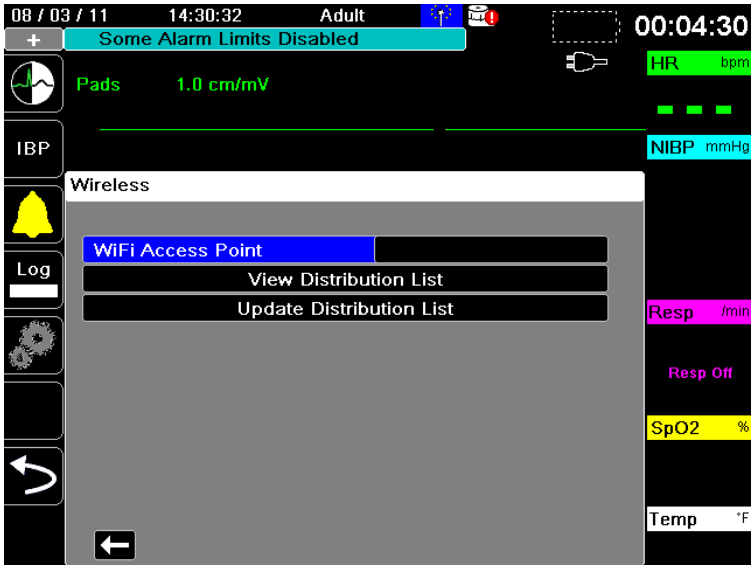
**Note:** If wireless connectivity is disabled, no icon is displayed.

| State | Description |
|---|---|
| Connected  | Wireless connectivity is available. |
| Not connected  | Wireless connectivity is not available due to incorrect configuration or weak/no signal strength. |
| Failed  | Wireless communication hardware has failed. |

You can select this icon to access the Wireless menu and view preconfigured WiFi access points or distribution lists, or to set up a temporary WiFi access point. Use the navigation keys to select the wireless icon.

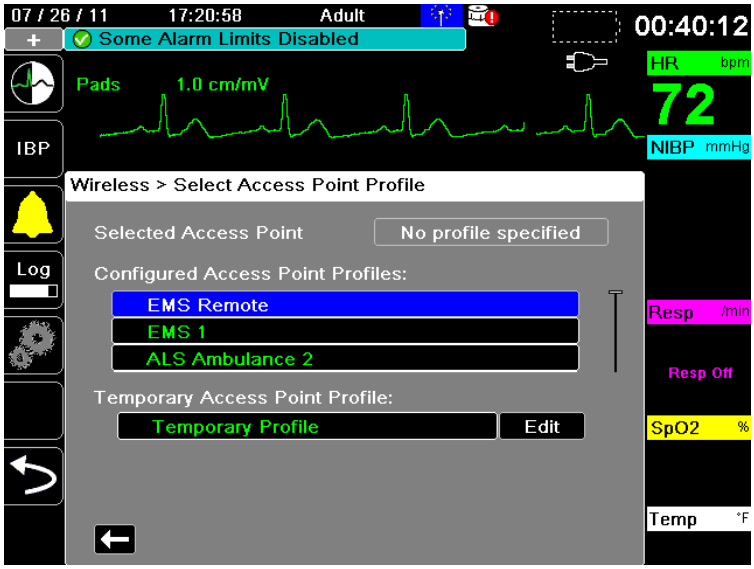


The Wireless menu has three options: **WiFi Access Point**, **View Distribution List,** and **Update Distribution List.** Use the navigation keys to navigate the menu items; press the back arrow (⮌) to exit the wireless menu.



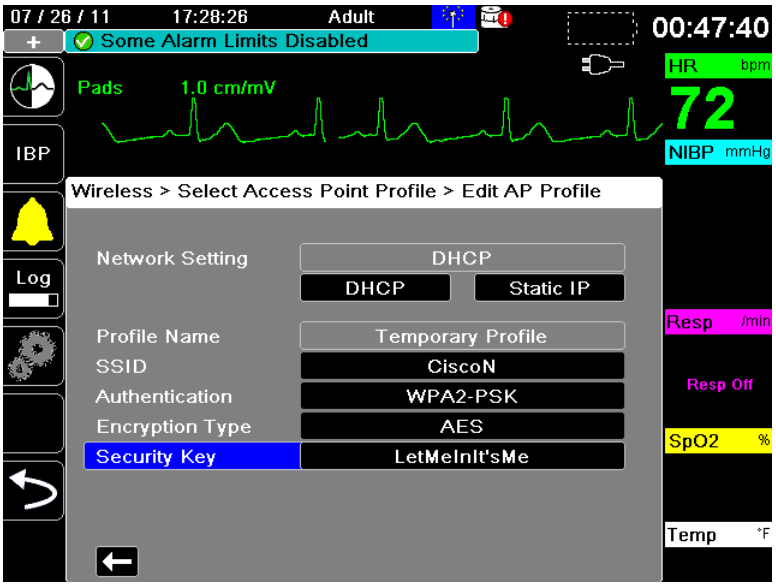

## Selecting and Creating a Temporary Access Point Profile

In the wireless menu, use the navigation keys to highlight and select **WiFi Access Point**. You can now view preconfigured Access Point Profiles.



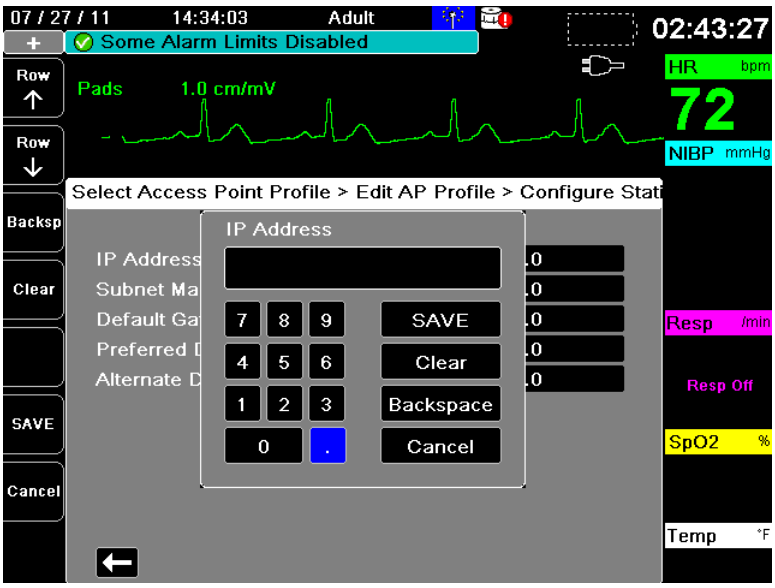

Use the navigation keys to highlight and select **Temporary Profile**. A green check mark appears to show that the profile has been selected.

To edit the profile, use the navigation keys to highlight and select **Edit**. The unit displays the Edit AP Profile menu.




## Network Setting

Use the navigation keys to select either DHCP or Static IP. If you select Static IP, use the numeric keypad to enter values for the IP Address, Subnet Mask, Default Gateway, Preferred SDNS Server, and Alternate DNS Server.

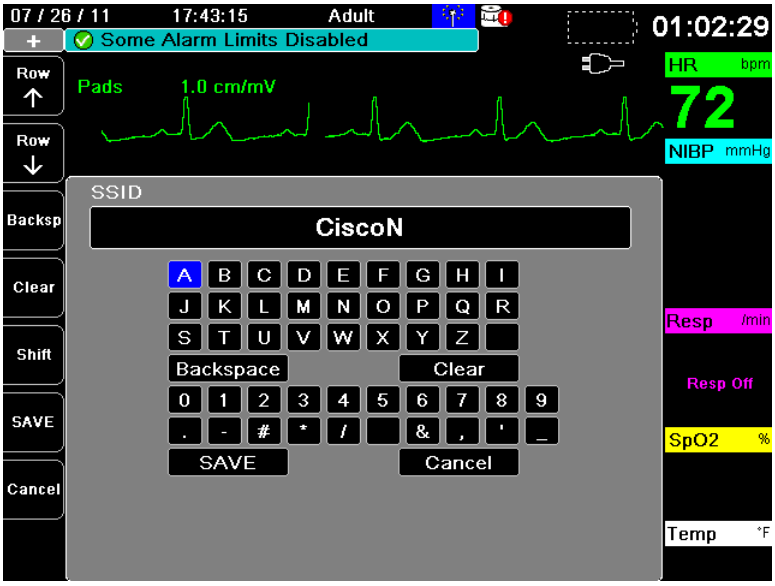



## Profile Name

The profile name is “Temporary Profile” and cannot be changed.

### SSID

Use the alphabetical keypad to enter the SSID name. Press **SAVE** to save changes and return to the Temporary Profile menu; press **Cancel** to return to the Temporary Profile menu without saving changes.




### Authenication

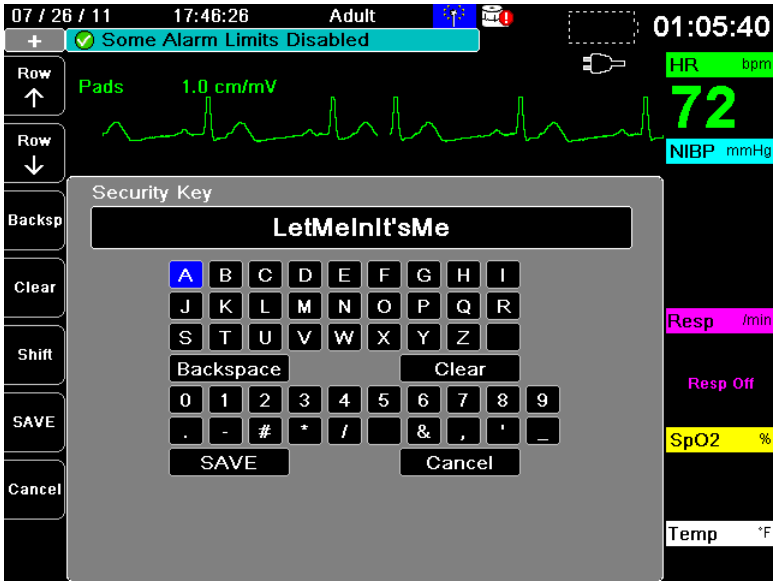
Use the navigation keys to select the authentication type.

### Encryption Type

Use the navigation keys to select the encryption type.

### Security Key

Use the alphabetical keypad to enter the security key. Press **SAVE** to save changes and return to the Temporary Profile menu; press **Cancel** to return to the Temporary Profile menu without saving changes.




When you are done editing the Temporary Profile menu, press the back arrow ( ) to exit the wireless menu.

**Note:** The selected Temporary Profile remains as the default profile until configured otherwise.

# Setting up Communications in the Supervisor Menu

You can set up wireless access profiles in the Communications setup menu. This is located in the Supervisor Setup menu, which requires a password. In this menu, you can set up the following:

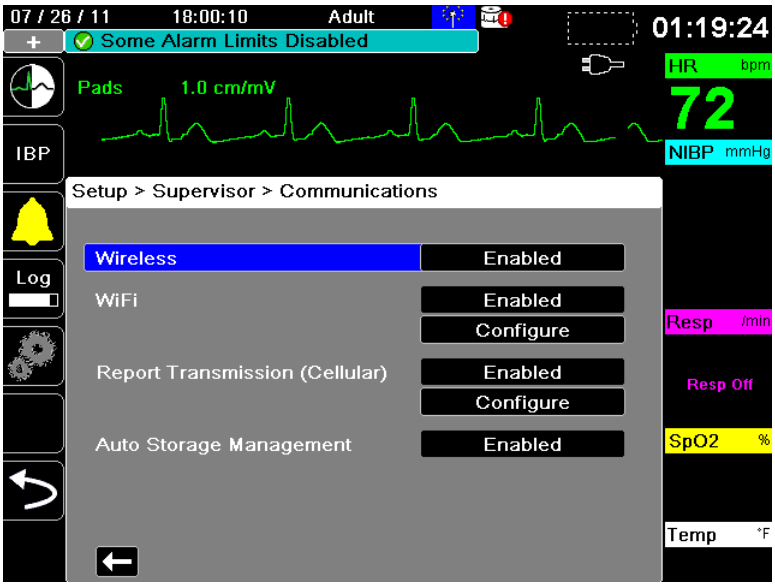
- WiFi access points
- Bluetooth connections using a cellular device
- USB cell modems

**Note:** Communications setup is not available in AED mode.

To access the Communications menu:

1. Press the More quick access key ( ).
2. Press the Setup quick access key ( ). Use the navigation keys to scroll down to **Supervisor.** Press .
3. Enter the password. The Supervisor menu appears.

4. Use the navigation keys to highlight and select **Communications.** The options for Communications are displayed.




### Wireless

Use the navigation keys to enable or disable this function.When disabled, all wireless capabilities are disabled in the X Series unit.

### WiFi

Use the navigation keys to enable or disable this function, and to configure access point profiles (see “WiFi Access Point Profiles” on page 22-8). When disabled, all WiFi access points are disabled in the X Series unit.

### Report Transmission (Cellular)

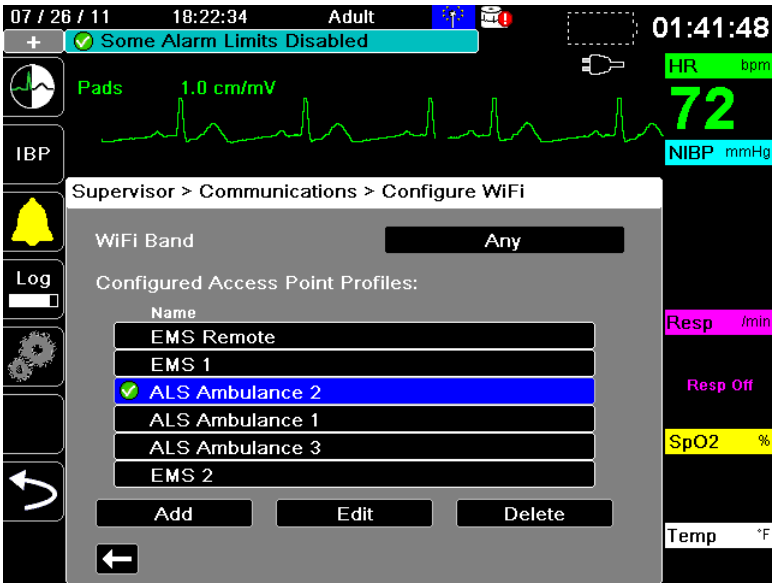
Use the navigation keys to enable or disable this function, and to configure access point profiles (“WiFi Access Point Profiles” on page 22-8). When disabled, all cellular transmission functions (Bluetooth or USB cell modem) are disabled.

### Auto Storage Management

Storage and management of 12-lead reports and full disclosure case files on the X Series unit can be managed from third-party software such as ZOLL RescueNet. When disabled, you cannot access reports that are stored on the unit from outside software.

## WiFi Access Point Profiles

To select and modify WiFi Access Point Profiles, use the navigation keys to highlight and select **Configure WiFi**.

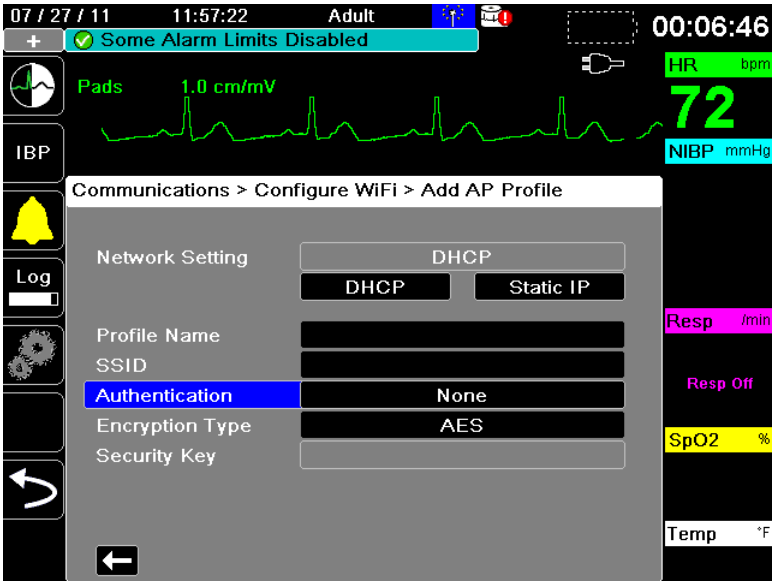



A green check mark indicates the active access point. Use the navigation keys to select a different profile, or to add, edit or delete other profiles.

Use the navigation keys to select the correct WiFi Band. The options are **Any, 5.0 GHz (A/N),** or **2.4 GHz (B/G/N)**.

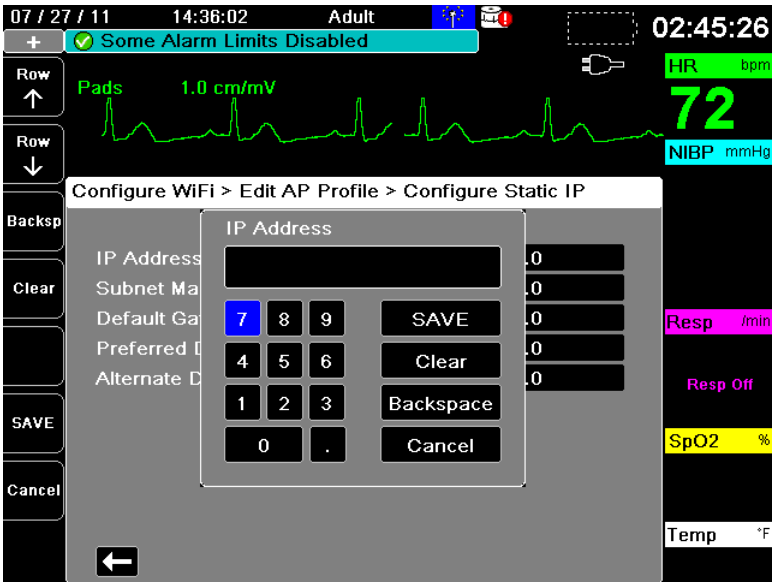
To add a new Access Point Profile:

Use the navigation keys to highlight and select **Add.** You can enter the type of network setting, profile name, SSID, authentication, encryption type, and security key.



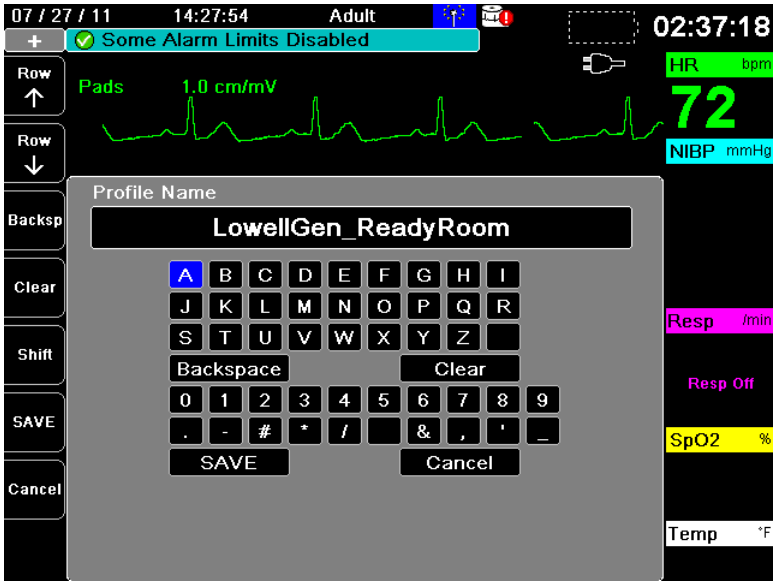

## Network Setting

Use the navigation keys to select either DHCP or Static IP. If you select Static IP, use the numeric keypad to enter values for the IP Address, Subnet Mask, Default Gateway, Preferred SDNS Server, and Alternate DNS Server.



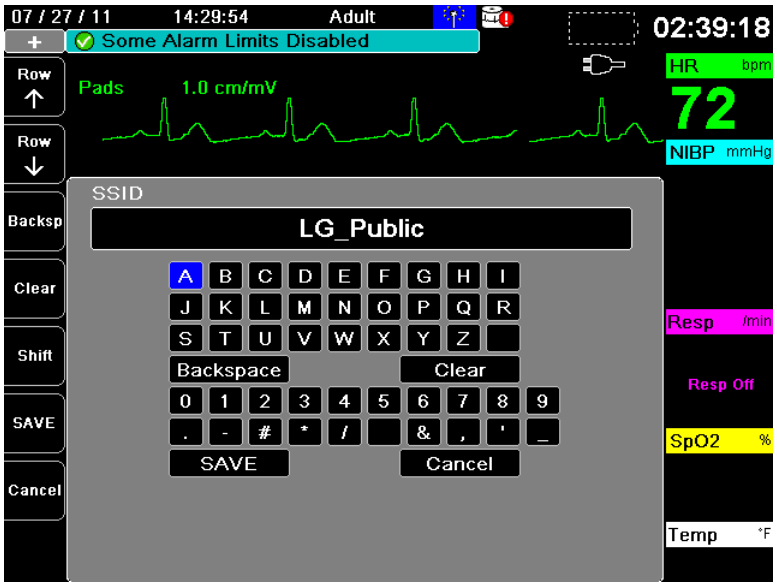
### Profile Name

Use the alphabetical keypad to enter the profile name. Press **SAVE** to save changes and return to the WiFi configuration menu; press **Cancel** to return to the WiFi configuration menu without saving changes.




### SSID

Use the alphabetical keypad to enter the SSID name. Press **SAVE** to save changes and return to the WiFi configuration menu; press **Cancel** to return to the WiFi configuration menu without saving changes.



### Authenication

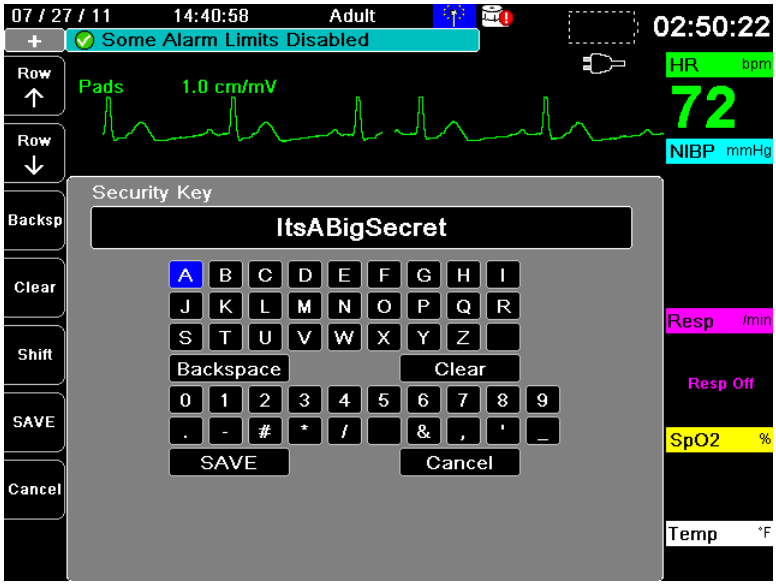
Use the navigation keys to select the authentication type.

### Encryption Type

Use the navigation keys to select the encryption type.

### Security Key

Use the alphabetical keypad to enter the security key. Press **SAVE** to save changes and return to the WiFi configuration menu; press **Cancel** to return to the WiFi configuration menu without saving changes.

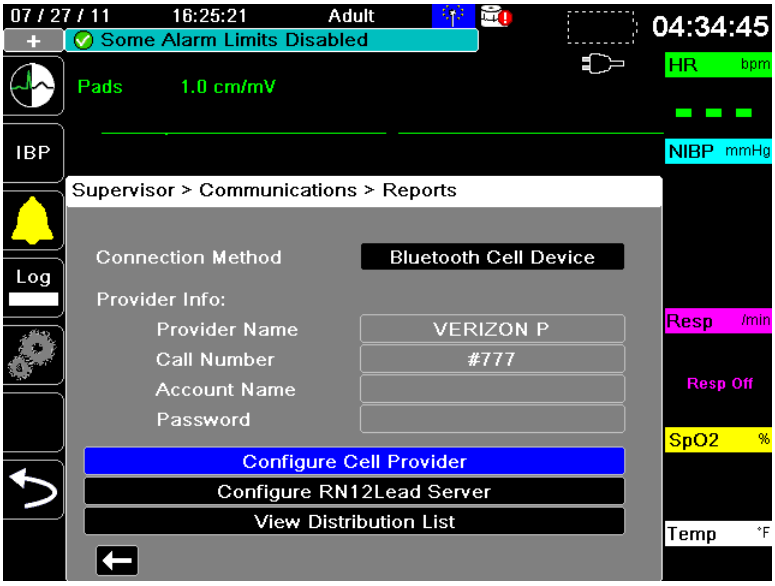



When finished editing your WiFi profile, press the back arrow (⇦) to return to return to the list of configured access point profiles. From this menu you can also edit or delete existing profiles. Press ⇦ to return to the Communications menu.

## Configuring Report Transmissions Via a Cellular Phone

You can send12-lead reports to an email or fax machine using a bluetooth-equipped cellular device or a USB cell modem. You can configure the X Series unit to select a particular device.

To set up your cellular device: In the Communications menu, select Configure Report Transmission (Cellular). The Reports menu displays.




### Communication Method

Select either Bluetooth Cell Device or USB Cell Modem.

### Provider Info

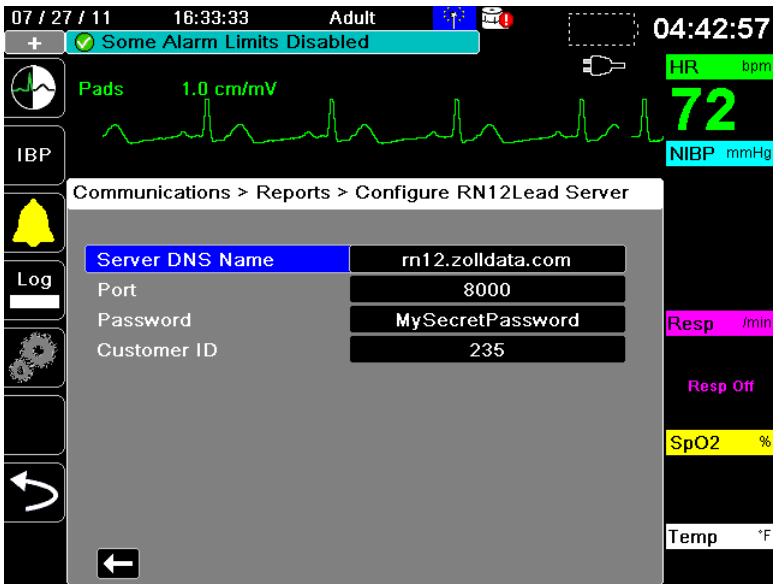
Your current cellular provider information is listed.

### Configure Cell Provider

Use this option to configure your cellular device. Use the alphanumeric keypads to enter the Provider Name, Call Number, Account Name (optional) or Password (optional). Refer to your cellular provider's documentation for details.

## Configure RN12Lead Server

12-lead reports are sent to recipients via a ZOLL server. Use the alphanumeric keypads to enter the correct server information.




## View Distribution List

Use this option to view preconfigured distribution lists.

# Sending a 12-lead report

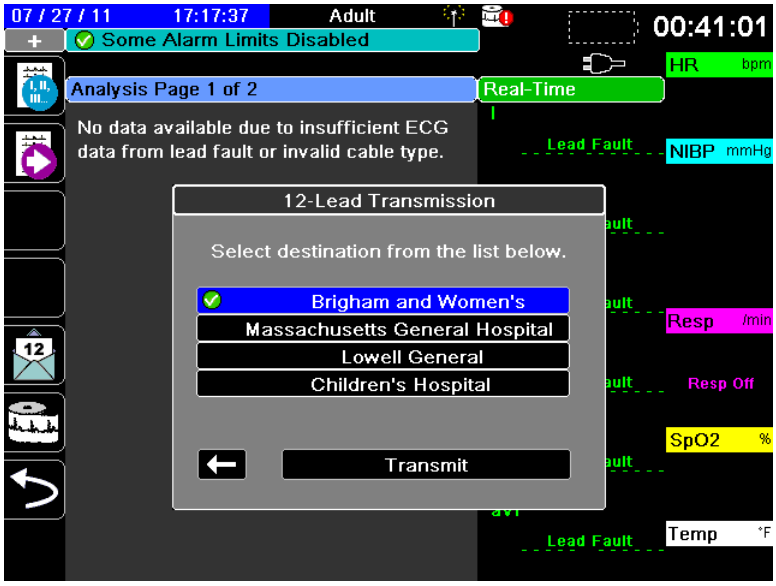
The (connected) wireless icon ( ) at the top of the screen indicates that wireless connectivity is available.

Once a 12-lead report has been acquired (or a previously acquired 12-lead has been selected for review), The Transmit quick access key( ) displays.

To send a 12-lead report to a preconfigured distribution list:

1. Press the 12-lead quick access key( ).
2. If desired, press the snapshot button( ) to take a 12-lead snapshot (see Chapter 14: 12-Lead ECG Interpretive Analysis for more information about acquiring 12-lead data).
3. Press the 12-lead review next quick access key ( ). A list of snapshots appears; select the desired snapshot.

4. Press . A list of preconfigured distribution lists appears.




Use the navigation keys to highlight and select the desired distribution list. A green check box indicates the selected list.When a destination has been selected, the **Transmit** button is enabled.

5. Press **Transmit** to initiate the 12-lead transmission

While the transmission is in process, the green LED on top of the unit is illuminated.

# Communications System Messages

The X Series unit may display one of the following status messages during the transmission:

| System Message | Cause |
|---|---|
| *TRYING TO CONNECT TO NETWORK* | The unit is connecting to the network. |
| *TRYING TO CONNECT TO SERVER* | The unit is connecting to the ZOLL server. |
| *TRANSMITTING* | The data transfer is in progress |
| *TRANSMISSION COMPLETE* | The data transfer is complete. |
| *TRANSMISSION FAILED* | The data transfer has failed.<br><br>To correct the problem, check the following:<br>• Verify that wireless communications is enabled on your X Series unit.<br>• Verify that the WiFi settings are correct in the Communications setup menu.<br>• Verify that the ZOLL server is configured correctly.<br>• Verify that your cellular device is configured correctly.<br>• Make sure that the X Series unit is within range of the wireless server. |

# Appendix A Specifications

This chapter provides specification information for the X Series Monitor/Defibrillator.

# Defibrillator

**Charge Time**:

- Less than 7 seconds with a new, fully charged battery (first 15 charges to 200 joules).
- For the sixteenth discharge at maximum energy, the charge time is less than 10 seconds. Depleted batteries result in a longer defibrillator charge time.
- Less than 15 seconds when operating without a battery, using AC power alone at 90% of the rated mains voltage.
- Less than 25 seconds from the initial power on, 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:** 10- 300 ohms

**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 DF-80:2003 requirement of 60ms maximum time delay between the peak of the R wave and the delivery of energy.

Table A-1 shows the characteristics of the X Series Rectilinear Biphasic™ waveform when discharged into 25 ohm, 50 ohm, 100 ohm, 125 ohm, 150 ohm and 175 ohm loads at the maximum energy setting of 200 joules.

**Table A-1. X Series Rectilinear Biphasic Waveform Characteristics**

| | **200 J discharged into** | | | | | |
|---|---|---|---|---|---|---|
| | **25Ω** | **50Ω** | **100Ω** | **125Ω** | **150Ω** | **175Ω** |
| **First phase** | | | | | | |
| Maximum initial current | 31.4 A | 30.4 A | 19.7 A | 19.4 A | 16.7 A | 15.6 A |
| Average current | 27.1 A | 24.9 A | 17.5 A | 16.2 A | 14.4 A | 13.2 A |
| Duration | 6 ms | 6 ms | 6 ms | 6 ms | 6 ms | 6 ms |
| | | | | | | |
| **Interphase duration** (between first and second phases) | 200 μs | 200 μs | 200 μs | 200 μs | 200 μs | 200 μs |
| **Second phase** | | | | | | |
| Initial current | 29.2 A | 18.8 A | 15.1 A | 13.2 A | 12.1 A | 11 A |
| Average current | 14.7 A | 13 A | 12.5 A | 11.3 A | 10.7 A | 9.9 A |
| Duration | 4 ms | 4 ms | 4 ms | 4 ms | 4 ms | 4 ms |

### Guidance and Manufacturer's Declaration – Electromagnetic (IEC 60601-1-2 Table 202)

The X Series unit is intended for use in the electromagnetic environment specified below. The customer or the user of the X Series 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 | ± 6 kV contact<br>± 8 kV air | ± 6 kV contact<br>± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical Fast Transient / Burst IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input/ output lines | ± 2 kV for power supply lines<br>± 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 differential mode<br>± 2 kV common mode | ± 1 kV differential mode<br>± 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<br>40% $U_T$ (60% dip in $U_T$) for 5 cycles<br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><5% $U_T$ (>95% dip in $U_T$) for 5 sec | <5% $U_T$ (>95% dip in $U_T$) for 0.5 cycle<br>40% $U_T$ (60% dip in $U_T$) for 5 cycles<br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><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 X Series unit requires continued operation during power mains interruptions, it is recommended that the X Series unit be powered from an uninterruptible power supply or a battery. |
| Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| **Note:** $U_T$ is the AC mains voltage prior to application of the test level. | | | |

## Guidance and Manufacturer's Declaration – Electromagnetic Immunity (IEC 60601-1-2 Table 203)

The X Series unit is intended for use in the electromagnetic environment specified below. The customer or the user of the X Series should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance IEC 60601-1-2 |
|---|---|---|---|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the X Series unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| | | | Recommended Separation Distance |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz<br>outside ISM bands[a] | 3 Vrms | d = 1.17 $\sqrt{P}$ |
| | 10 Vrms<br>150 kHz to 80 MHz in<br>ISM bands[a] | 10Vrms | d = 1.2 $\sqrt{P}$ |
| Radiated RF<br>IEC 61000-4-3 | 10 V/m<br>80 MHz to 2.5 GHz | 10 V/m | d = 1.20 $\sqrt{P}$<br>80 MHz to 800 MHz<br>d = 2.30 $\sqrt{P}$<br>800 MHz to 2.5 GHz |
| | 3 V/m<br>80 MHz to 2.5 CHz<br>(IEC 60601-2-34) | 3 V/m<br>(IBP only) | d = 4 $\sqrt{P}$<br>80 MHz to 800 MHz<br>d = 7.67 $\sqrt{P}$<br>800 MHz to 2.5 GHz |
| Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).[b]<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d].<br>Interference may occur in the vicinity of equipment marked with the following symbol:  | | | |

**Note 1:** At 80 MHz and 800 MHz, the higher frequency range applies.
**Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

**a.** The ISM (industrial, scientific, and medical) bands between 150 KHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
**b.** The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 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.
**c.** 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 ZOLL X Series unit is used exceeds the applicable RF compliance level above, the X Series unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the X Series unit.
**d.** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [$V_1$] V/m.

## Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the X Series (IEC 60601-1-2 Table 205)

The X Series unit is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the X Series unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the X Series unit as recommended below, according to the maximum output power of the communications equipment.

**Separation Distance According to Frequency of Transmitter (meters)**

| **Rated maximum output power of transmitter W** | **150 kHz to 80 MHz outside ISM bands** $d = [3.5/3]P$ | **150 kHz to 80 MHz in ISM bands** $d = [12/3]P$ | **80 MHz to 800 MHz** $d = [12/10]P$ | **800 MHz to 2.5 GHz** $d = [23/10]P$ |
|---|---|---|---|---|
| **0.01** | 0.12 | 0.40 | 0.12 | 0.23 |
| **0.1** | 0.37 | 1.26 | 0.38 | 0.73 |
| **1** | 1.17 | 4.00 | 1.20 | 2.3 |
| **10** | 3.69 | 12.65 | 3.79 | 7.27 |
| **100** | 11.70 | 40.00 | 12.00 | 23.00 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) 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 (W) according to the transmitter manufacturer.

**Note 1:** At 80 Hz 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:** An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

**Note 4:** 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 ZOLL's ECG Rhythm Database.

The algorithm sequence takes approximately 9 seconds and proceeds as follows:

- Divides the ECG rhythm into three-second segments.
- Filters and measures noise, artifact, and baseline wander.
- Measures baseline content ('waviness' at the correct frequencies — frequency domain analysis) of signal.
- Measures QRS rate, width, and variability.
- Measures amplitude and temporal regularity ('auto-correlation') of peaks and troughs.
- Determines if multiple 3 second segments are shockable then displays *SHOCK ADVISED* message.

### Clinical Performance Results

The performance of the incorporated analysis algorithm in a single analysis sequence satisfies the applicable requirements specified in ANSI/AAMI DF80 (section 6.8.3) and the recommendations by Kerber et al. (Circulation. 1997;95(6):1677).

**Table A-4. Clinical Performance Results**

| Rhythms | Sample Size | Performance Goals | Observed Performance | 90% One-sided Lower Confidence Limit |
|---|---|---|---|---|
| **Shockable** | | **Sensitivity** | | |
| Coarse VF | 536 | >90% | >99% | >99% |
| Rapid VT | 80 | >75% | >99% | >96% |
| **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 | >89% | >81% |
| Other VT | 28 | Report only | >96% | >84% |

## References:

Young KD, Lewis RJ: "What is confidence? Part 2: Detailed definition and determination of confidence intervals". Annals of Emergency Medicine, September 1997; 30; 311-218

William H. Beyer, Ph.D.: "CRC Standard Mathematical Tables 28th Edition," CRC Press, Inc, Boca Raton, FL., 1981, Percentage Points, F-Distribution Table, pg 573.

# Wireless Output Guidance and Manufacturer's Declaration

## RF Transmission Emitted (IEC 60601-1-2)

The X Series unit complies with IEC 60601-1-2 for medical electrical equipment and medical electrical systems that include RF transmitters as specified below.

| Standard | Frequency Range | Effective Radiated Power | Modulation Type | Data Rates |
|---|---|---|---|---|
| 802.11b | 2412-2472 MHz | 100 mW | DSSS | 1, 2, 5.5, 11 Mbps |
| 802.11g | 2412-2472 MHz | 32 mW | OFDM | 6, 9, 12, 24, 36, 48, 54 Mbps |
| 802.11n | 2412-2472 MHz | 32 mW | OFDM | 6.5, 13, 19.5, 26, 39, 52, 58.5, 65 Mbps |
| Bluetooth | 2400-2483.5 MHz | 10 mW | FHSS; GFSK/ DQPSK/8DPSK | 1, 3 Mbps |
| 802.11a | 5180-5320 MHz<br>5500-5700 MHz<br>5745-5825 MHz | 32 mW | OFDM | 6, 9, 12, 24, 36, 48, 54 Mbps |
| 802.11n | 5180-5320 MHz<br>5500-5700 MHz<br>5745-5825 MHz | 32 mW | OFDM | 6.5, 13, 19.5, 26, 39, 52, 58.5, 65 Mbps |

## 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 device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. See 47 CFR Section 15.19(a)(3).

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.

## Canada, Industry Canada (IC) Notices

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.