zensor Monitoring System

User Manual – Release 2.8.6

zensor

THE ART OF MONITORING

US Federal law restricts this device to sale by or on the order of a Physician.

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CE
0120

Table of Contents

1 About this manual

Purpose

This manual contains the instructions to install and operate the zensor system safely and in accordance with its function and intended use.

If further assistance is required in setting up or maintaining the system or an unexpected operation or event is to be reported, please contact your local Intelesens representative.

Intended audience

This manual is intended for clinical professionals. Clinical professionals are expected to have a working knowledge of medical procedures, practices and terminology, as required for monitoring of ill patients.

Some of the information within this manual is also applicable to the patient, however the information is included in the patient instruction booklet.

Related documents

zensor Clinician Quick Start - provides high level guidance on the use of the zensor system.

zensor online User Guide – provides instructions to use the zensor online analysis tool.

zensor+ User Manual - provides instructions to install and use the zensor+ analysis tool.

zensor Patient Instruction Booklet - provides information to the patient on the use of the zensor system.

Manual conventions

This manual uses the following styles to emphasize text or indicate action.

Item	Description
bold	Indicates menu item.
(7)	Indicates page number reference.

Illustrations and names

This manual uses illustrations as examples only. Illustrations in this manual may not necessarily reflect all settings, features, configurations, or displayed data. Names of persons, institutions, and places and related information are fictitious; any similarity to actual persons, entities, or places is purely coincidental.

Ordering manuals

A printed copy of this manual will be provided upon request. Contact your local Intelesens representative and request the printed manual, using the title on the cover page.

Revision history

The revision number of this manual is at the bottom of each page. The revision number increases whenever the manual is changed.

Equipment information

Intended use of this equipment

The zensor monitoring device is a small, lightweight, wearable, non-invasive, re-chargeable battery operated portable system connected to an electrode accessory (single-use disposable Intelesens zensor electrode) which in turn is in contact with the patient's body.

The device is to be used in the patient's home environment to provide clinicians with patient physiological data, while allowing for patient mobility. The zensor Monitoring System provides full disclosure ECG and cardiac event monitoring for adult patients (18 years+).

The physiological parameters monitored include ECG and respiration waveforms, heart rate and respiration rate, as well as lethal and high acuity arrhythmias (Asystole, Tachycardia, Ventricular Fibrillation, Bradycardia and Atrial Fibrillation).

The zensor monitoring device has the option to store full disclosure ECG & respiration data and/or wirelessly transmit pre-defined event alerts to the Intelesens zensor online system for review by healthcare practitioners. All physiological data stored on the device can be downloaded for viewing on Intelesens zensor+ (*Ambulatory ECG Full Disclosure ECG and Event Viewer*) for later analysis by a clinician.

Any events or variations in physiological readings are not intended to be used to summon emergency care.

Safety messages

Safety message signal words designate the severity of a potential hazard. The signal words danger, warning, caution, and notes are used throughout this manual to point out hazards and to designate a degree or level of seriousness. A hazard is defined as a source of potential injury to a person.

The order in which safety messages are presented in no way implies the order of importance. The following safety messages apply to the system. Safety messages specific to parts of the system are found in the relevant section of this manual.

Danger safety messages

Danger statements indicate a hazardous situation that, if not avoided, will result in death or serious injury. No danger safety messages apply to the zensor system.

Warning safety messages

Warning statements indicates a hazardous situation that, if not avoided, could potentially result in death or serious injury. The following warning statements apply to the zensor system:

WARNING Use only approved accessories (including but not limited to batteries, electrodes, charging docks and cables) supplied for use with the zensor device. Use of any other parts not supplied with the system may result in damage.

WARNING Do not modify this equipment without authorization of the manufacturer.

WARNING No maintenance or service action is to be carried out while the system is in use.

WARNING The battery is not a serviceable part. Do not attempt to dismantle the battery.

WARNING If the battery requires disposal it must be disposed of in accordance with relevant local waste disposal regulations.

WARNING The zensor device, battery or any other system component must not be submerged in water or other liquid. The zensor device is not waterproof.

WARNING Avoid touching the contacts on the battery apart from during cleaning. Doing this will help prevent the buildup of dirt on the contacts.

WARNING Assess the patient for suitability for the zensor system based on the following restrictions:

- Must NOT be used on patients with a pacemaker or an ICD.
- Must NOT be applied to a patient with a skin disorder. Ensure there are no open wounds, lesions, infected or inflamed skin in the area for electrode placement.
- The zensor system is for use on adult patients.
- If any allergic reaction occurs, remove the electrode.

WARNING Electrode wires may cause strangulation. Keep out of reach of small children and babies**.**

WARNING The zensor device and electrode must not be worn when undergoing an MRI scan, X-ray, CT scan, defibrillation or surgical procedure.

WARNING Failure on the part of the responsible hospital or institution using this monitoring equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

WARNING Disconnect the zensor Charging Dock from the AC power before cleaning or disinfecting. Switch off battery-powered equipment before cleaning or disinfecting.

WARNING Always ensure the correct device is assigned to the correct patient in zensor online. Assigning a device that is currently being used by another patient will result in patient data being sent to the wrong patient record.

WARNING Excessive liquid cleaning agents or disinfectant could reach the interior of the zensor device through the battery pins and USB port causing damage. Avoid the application of excess liquid to the device when cleaning and disinfecting.

Caution safety messages

Caution statements indicate a hazardous situation that, if not avoided, could result in minor personal injury or product/property damage. The following caution statements apply to the zensor system:

CAUTION Install the battery charging dock in a suitable location, where it will be protected from damage, liquid ingress, moisture or extreme temperature.

CAUTION Remove the battery from the zensor device when not in use. This will avoid damage to the device in the event of battery leakage.

CAUTION The device and associated accessories should be cleaned after each patient to prevent cross-contamination.

CAUTION Do not use an alcohol wipe on skin where an electrode has already been applied as this may cause irritation.

CAUTION Do not spray, pour, or spill any liquid on the zensor components, accessories, connectors, switches, or into any openings in the case as this may damage the system.

CAUTION When cleaning the zensor device without a battery connected, take care to ensure that the battery connecting pins on the device are not damaged.

CAUTION Do not use the following products when cleaning the zensor components or accessories:

- Conductive solutions that contain chlorides, wax, or wax compounds
- Any type of Ammonium Chloride such as, but not limited to:
    - Dimethyl Benzyl Ammonium Chloride
    - Quaternary Ammonium Chloride solution
- Abrasive cleaners or solvents of any kind
- Acetone
- Ketone
- Betadine
- Sodium salts

CAUTION Do not autoclave or steam clean the zensor components or accessories.

CAUTION Do not connect the zensor device into a mains supply using the USB cable.

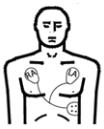
Note safety messages

Notes contain important information that may otherwise be overlooked or missed. Relevant notes are described in each section throughout the manual.

Equipment symbols

The following symbols are associated with the zensor system.

Icon	Description
	Year and month of manufacture
	Manufacturer name and address
	Serial Number
	Product part number and product code
	Attention
	Consult instructions for use
	WEEE Directive compliance Not for general disposal
	CE marked to Medical Devices Directive 93/42/EEC
	Non-ionizing radiation
	Type BF applied part
IP22	Ingress protection to IEC 60529 IP22 Protected against ingress of solid foreign objects ≥12,5 mm diameter (finger) Protected against ingress of dripping water
	Batch code XXXXXXX
Rx Only	US Federal law restricts this device to sale by or on the order of a licensed physician. No modification to the equipment is allowed.
	Use by YYYY / MM
	Temperature limitation for storage conditions
	Do not get wet

Icon	Description
	Electrode positioning
	The zensor electrode is not made with natural rubber latex
	Do not reuse
	Class II double insulated (power supply)
	For indoor use only

Equipment Compliance

CE marking compliance information

The zensor device bears CE mark CE-0120 indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive. The system is in radio-interference protection class B in accordance with EN 55011. The system complies with the requirements of standard EN 60601-1-2 “Electromagnetic Compatibility - Medical Electrical Equipment”.

Compliance	zensor
Type of protection against electrical shock	Transmitter – internally powered Charging dock power supply – Class 2
Degree of protection against electrical shock	Transmitter - Type BF applied part Electrode – Type BF applied part
Degree of protection provided by enclosures	Transmitter - IP22 (EN 60529)
Degree of protection in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide
Method(s) of sterilization or disinfection recommended by the manufacturer	Not applicable
Mode of operation	Continuous operation

FCC declaration

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.

No changes shall be made to the equipment without the permission of Intelesens Ltd. as this may void the user's authority to operate the equipment.

RF exposure

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

The zensor device has been tested and meets the FCC RF exposure guidelines when used against the body under normal usage conditions.

The maximum SAR value reported is 0.646 W/Kg.

This zensor device must be installed in accordance with the operating instructions and must not be co-located or operated in conjunction with any other antenna or transmitter.

2 System Overview

zensor Monitoring System

WARNING Do not modify this equipment without authorization of the manufacturer.

WARNING Assess the patient for suitability for the zensor system based on the following restrictions:

- Must NOT be used on patients with a pacemaker or an ICD.
- Must NOT be applied to a patient with a skin disorder. Ensure there are no open wounds, lesions, infected or inflamed skin in the area for electrode placement.
- The zensor system is for use on adult patients.
- If any allergic reaction occurs, remove the electrode.

NOTE The system is intended to be used to obtain physiological readings for use in routine check-ups. Any events or variations in physiological readings are not intended to be used to summon emergency care.

The zensor system is a 3 lead ECG monitoring system which allows clinicians to record and monitor patient full disclosure ECG, cardiac event, respiration and motion data continuously for up to 7 days, whilst allowing the patient full mobility.

Cardiac events are detected by on-board algorithms or by physical indication by the wearer. Event data is both recorded on board the device, and is transmitted using standard Wi-Fi or mobile hotspot to a remote database. Data transmission can be delayed if the device is out of signal range. Full disclosure ECG data for up to 7 days is continuously recorded on board the device. This data is downloaded, using a USB interface, for analysis or for submission to analysis software.

The zensor system consists of the following components:

- zensor Wearable Transmitter (zensor device)
- Rechargeable Battery
- zensor Electrode
- Battery Charging Dock with power supply and mains lead
- USB cable (USB type A plug to micro USB type B plug)
- zensor App

The zensor system integrates with the following Intelesens software tools:

- Cloud hosted **zensor online** patient database
- PC hosted **zensor+** software to analyze full disclosure ECG data
- **zensor app** located on device and used for device setup and configuration

zensor Wearable Transmitter (device)

WARNING Use only approved accessories (including but not limited to batteries, electrodes, charging docks and cables) supplied for use with the zensor device. Use of any other parts not supplied with the system may result in damage.

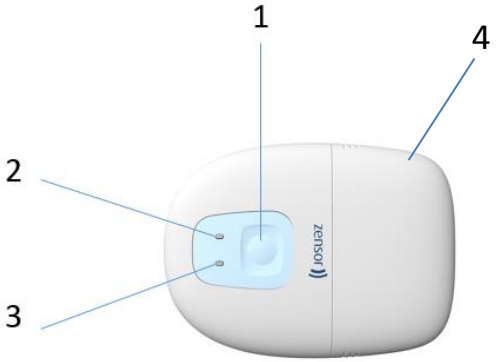
CAUTION Do not connect the zensor device into a mains supply using the USB cable.

zensor device with battery attached

zensor device with battery removed

The zensor device monitors physiological parameters and is a wireless, wearable vital signs device. It is a small, battery-operated system comprised of the zensor monitoring device (a body worn transmitter device) and zensor battery.

When the event transmission mode is used, the zensor device communicates with the zensor online remote database using Wi-Fi access point or a mobile Wi-Fi hotspot.



1	Pushbutton (On/Off and user event trigger)
2	Status and data transfer LED (orange or green)
3	USB connection LED (blue)
4	Battery
5	USB connector

zensor Battery

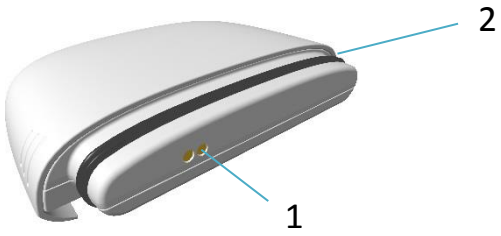
WARNING Use only approved accessories (including but not limited to batteries, electrodes, charging docks and cables) supplied for use with the zensor device. Use of any other parts not supplied with the system may result in damage.

WARNING The battery is not a serviceable part. Do not attempt to dismantle the battery.

WARNING If the battery requires disposal it must be disposed of in accordance with relevant local waste disposal regulations.

WARNING The zensor device, battery or any other system component must not be submerged in water or other liquid. The zensor device is not waterproof.

WARNING Avoid touching the contacts on the battery apart from during cleaning. Doing this will help prevent the buildup of dirt on the contacts.

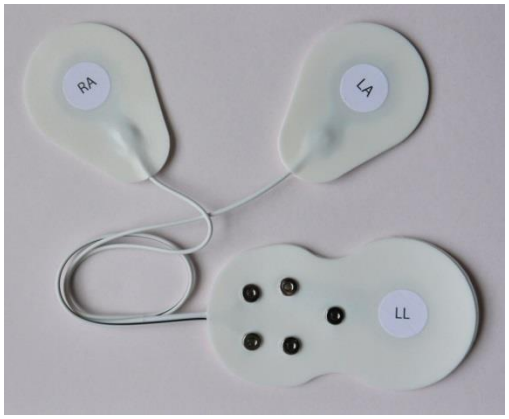


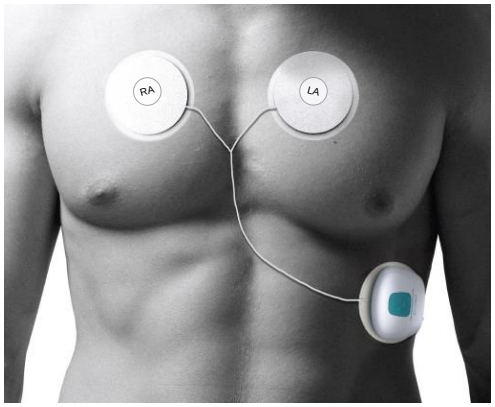
1	Battery contacts
2	O-ring

The zensor battery contains a rechargeable 3.7V lithium ion battery to power the zensor device. The battery has sufficient capacity to power the zensor device for up to 72 hours (3 days) of continuous monitoring. The battery life depends on the monitoring and wireless transmission configuration options selected on the zensor device. Please see Section 4 ‘zensor Battery Life’ for more information.

zensor Electrode

WARNING Electrode wires may cause strangulation. Keep out of reach of small children and babies**.**



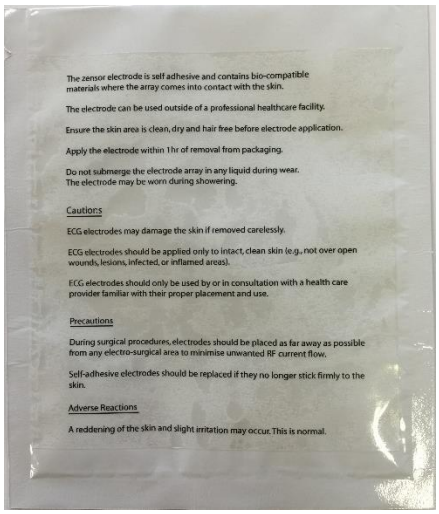


The zensor device is connected to the electrode via magnetic studs, and the electrode is positioned as shown above on the patient's body.

The zensor electrode is a disposable, pre-gelled, single-patient-use, 3 lead ECG and respiration patch that is applied at three specific locations on the patient's body. The zensor electrode is to be used only with the zensor device. The electrode may be worn for a continuous period up to 72 hours.

The zensor electrode consists of three adhesive patch sensors with wire connections. The larger patch has five surface mounted magnetic studs for the attachment of the zensor device. All three patches contain a pre-gelled active measurement area.

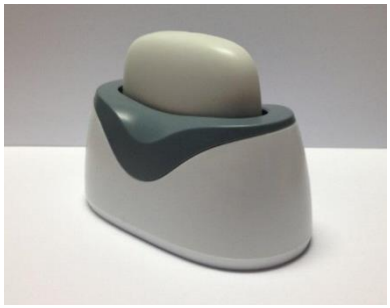
Each electrode comes in a re-sealable plastic bag. The electrode(s) are contained within a sealed pouch (shown below). To open the pouch, tear or cut the seal across the top starting from the incision on the side.



Battery Charging Dock

WARNING Use only approved accessories (including but not limited to batteries, electrodes, charging docks and cables) supplied for use with the zensor device. Use of any other parts not supplied with the system may result in damage.

CAUTION Install the battery charging dock in a suitable location, where it will be protected from damage, liquid ingress, moisture or extreme temperature.



The zensor charging dock is a single bay charging dock, used to charge low zensor batteries. It requires access to a mains power socket within 2 meters of the installation location and is to be used with the charging dock power supply.

The zensor charging dock should be installed in a dry, clean environment.

Charging Dock Power Supply

WARNING Use only approved accessories (including but not limited to batteries, electrodes, charging docks and cables) supplied for use with the zensor device. Use of any other parts not supplied with the system may result in damage.

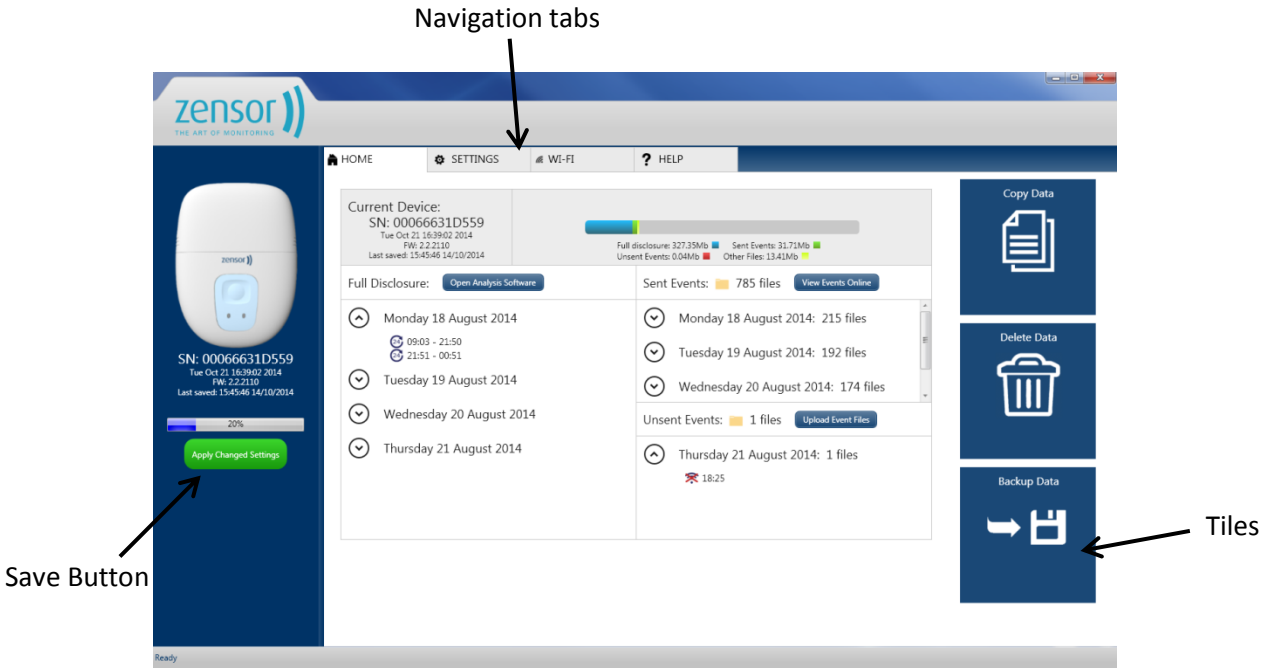
An AC/DC transformer and power lead cable is supplied with the system for connection between the zensor charging dock and the mains supply.

USB Cable

A USB cable is supplied with the system for connection between the zensor device and the PC.

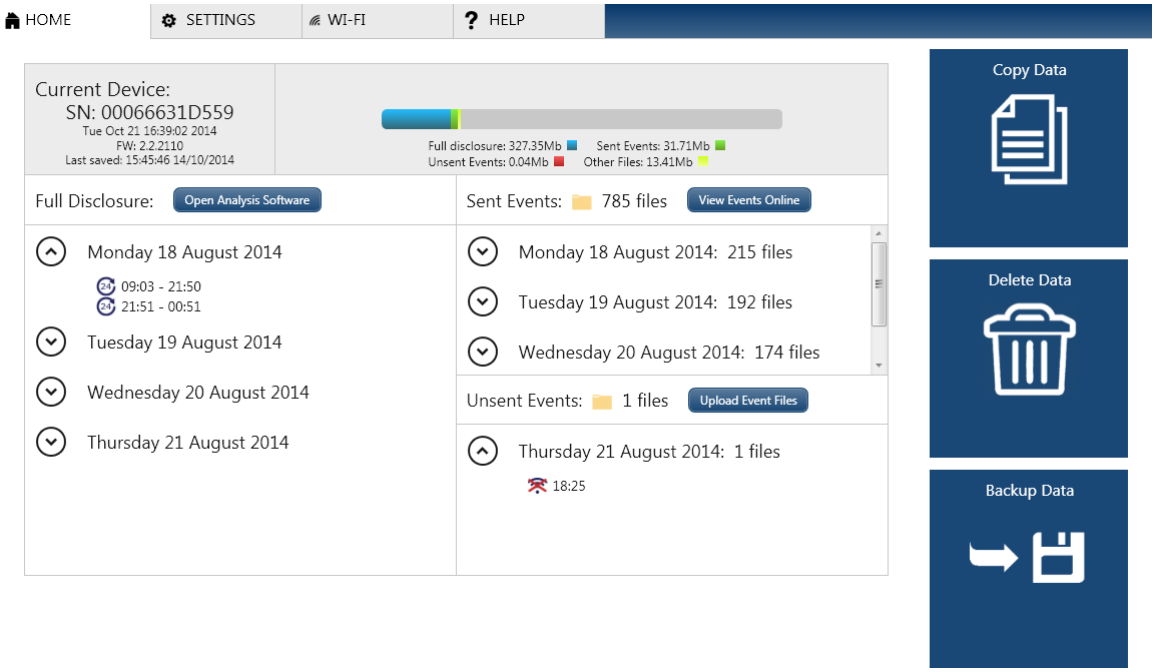
zensor App

The zensor App is used to setup and configure the zensor device. It can be navigated using the tabs to view and configure different elements of zensor, including changing monitoring parameters, backing up and copying recorded data, transferring data to zensor online and accessing both zensor online and zensor+ software analysis tools.



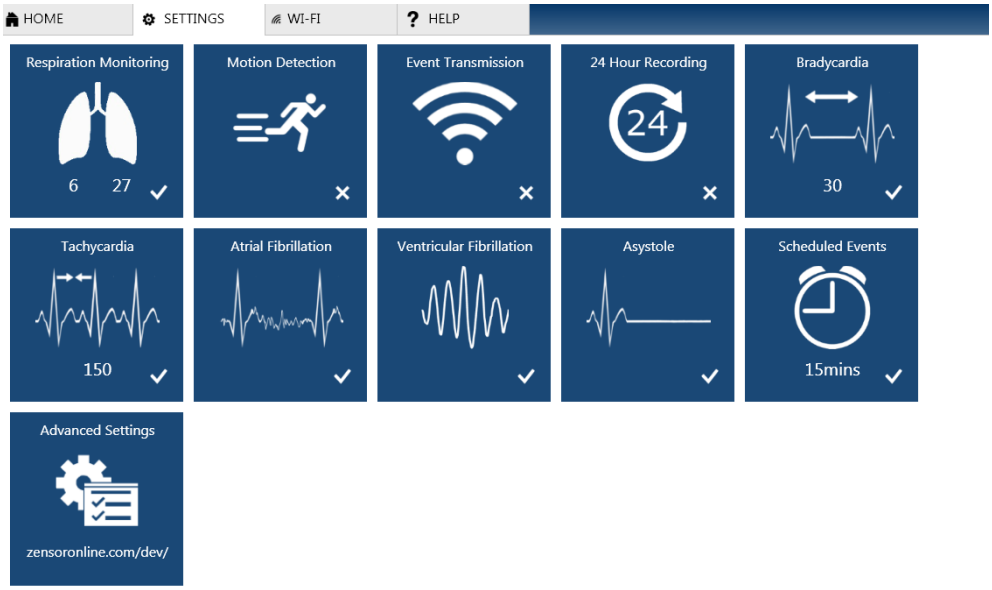
Sidebar - Shows summary of the connected device including serial number, the time the device was connected to the PC, firmware version, last time changes have been saved on the device, a bar displaying currently used storage and the status is displayed at the bottom left of the window.

HOME tab – Displays more detailed information of the files currently stored on the device. Recordings and events are sorted by day and may be expanded by clicking the adjacent arrowhead. Devices files can be copied, deleted and backed-up using the tiles on the right side of the window.

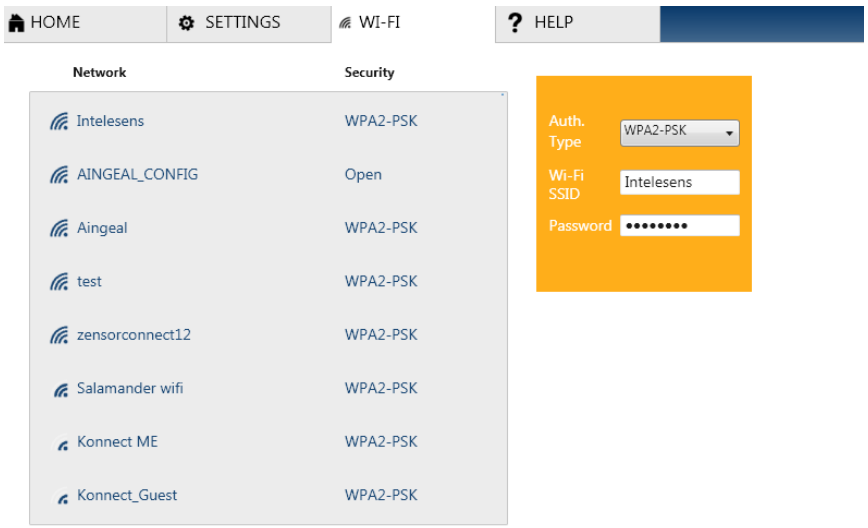


Button	Description
Open Analysis Software	Install full disclosure software. If software has already been previously installed then the software application will be launched instead.
View Events Online	Launch zensor online using the default web browser. An internet connection is required.
Upload Event Files	If there are unsent events on the device that have not yet been uploaded to zensor online, this button will become active. Clicking will upload these events to the website. An internet connection is required.

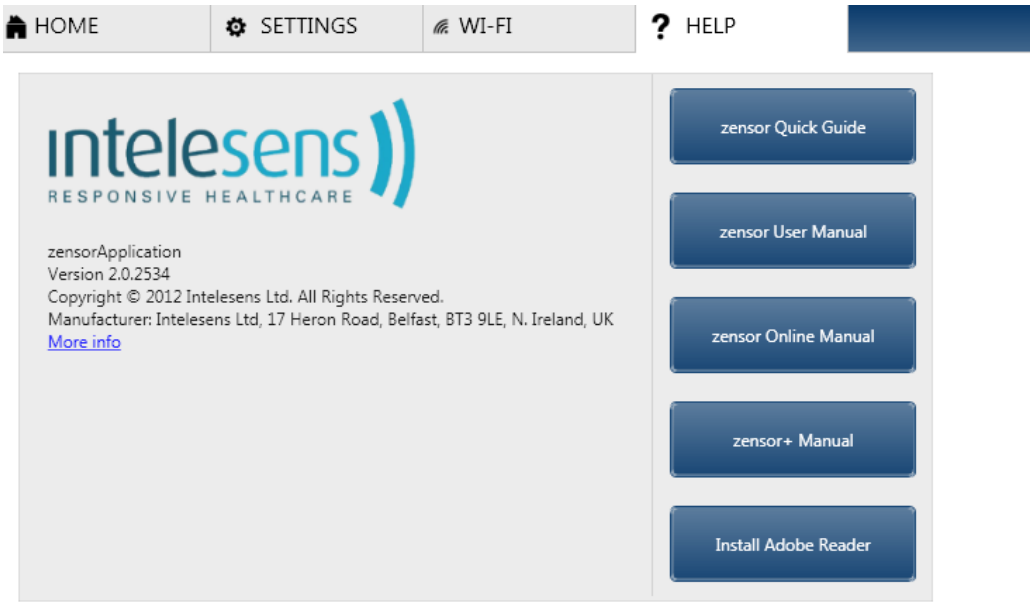
SETTINGS tab – This tab contains a collection of tiles used to configure device modes, events and their associated thresholds to be triggered. A tick at the bottom right corner of a tile signifies that the setting is enabled or and an 'x' signifies the setting is disabled. Further information on each tile can be viewed by selecting the tile.



WI-FI tab – Allows configuration of wireless connection settings. The list of networks will automatically update every 10 seconds. Wireless network details may be entered manually by clicking the tile or automatically by selecting a network from the list. Please note that a password must be entered for a network with a non-open security scheme.



HELP tab – Contains links to PDF resources for zensor related products. Adobe Reader is required to open PDF files, click the Install Adobe Reader to download the software if required (Internet connection required).



Additional Software Tools

Please see the zensor online User Guide and the zensor+ User Guide for further information on these areas.

3 Getting Started

Read through the information below to become familiar with the operation of the device and indicators before using the device on a patient.

Step 1: zensor system Configuration

The zensor device is configured using the zensor app, which is located on the device. Device settings can be configured by connecting the device to the PC, via the supplied USB cable, and opening the zensor app from the device files. The device is configured for the following:

- Device recording mode
- Event detection and reporting
- Data storage and Wi-Fi transmission

Requirements for configuration

PC with the following minimum specification:

- Windows XP, 1Gb RAM, 1GHz CPU
- 30 MB free disk space
- USB 2.0 socket
- .NET 3.5 (SP1)

Connect the zensor Device to PC

Remove the battery from the zensor device and connect the supplied USB cable between the micro USB port on the zensor device and the PC USB socket. The USB connection LED on the zensor device illuminates blue when USB connection is established and the device driver will automatically install. The device App cannot be accessed until the driver has been successfully installed.

Scan and Fix zensor (if required)

The PC may advise a scan and fix of zensor after connection to the PC. If this occurs scan the disk using the recommended option and default settings ('Automatically fix file system errors' only). Once complete, close the pop up window.

NOTE The scan and fix option is recommended when the device has not previously been safely removed from the PC. For further information, please refer to the 'Safe Removal of Device from PC' section on page (24).

Open the zensor App

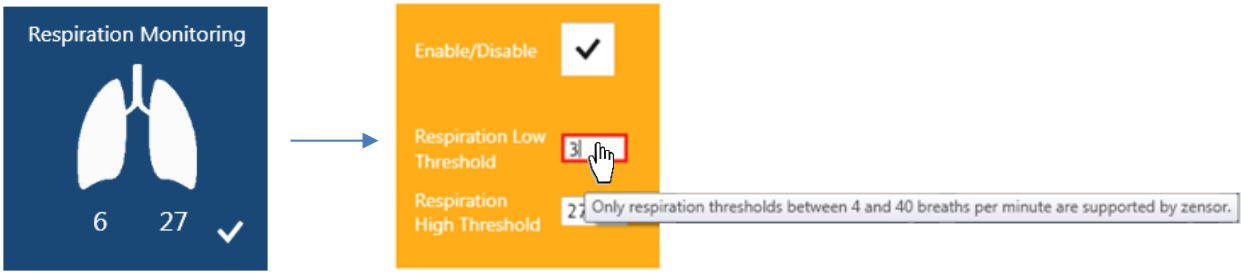
Once connected to the PC and the device driver is installed, the AutoPlay window will appear. (If the AutoPlay feature does not display, go to the ***Windows Start Menu***, ***Computer*** and select ***zensor*** from the Removable Storage section.) Select ***Open folder to view files*** to open the device folder. Locate the ***START*** file on the device and double click to open the zensor App. It will take approximately 20 seconds for the App to load and it will state ***Ready*** in the bottom left corner once it is ready for use.

Delete any Existing Data on zensor Before Monitoring

Ensure there is no previous patient data on the device before monitoring a new patient. If there is data on the device, select the ***Delete Data*** tile and select all three options to remove data from the device before monitoring a new patient. Then select the ***Delete Data*** button, a popup window will appear to confirm you want to delete the files, if correct, select ***Ok***. Once the data is deleted a confirmation box appears confirming the deletion, select ***Ok***.

Configure the zensor Device

1. Select the ***Settings*** tab and select the appropriate tiles to change their associated settings.



NOTE If a tile's field contains a value which is invalid or out of supported range, the area will show a red outline. Position the mouse over the field to view more information on the error.

Tile Name	Configurations
Respiration monitoring	On/Off, High/Low thresholds
Motion detection	On/Off
Event transmission	On/Off
24 hour recording	On/Off
Bradycardia	On/Off, Low threshold
Tachycardia	On/Off, High threshold

Tile Name	Configurations
Atrial fibrillation	On/Off
Ventricular fibrillation	On/Off
Asystole	On/Off
Scheduled events	On/Off, Automatic event period (15 min – 24 hour)
Advanced settings	zensor online URL

2. Select the ***Wi-Fi*** tab and select the appropriate network from the list, or enter the correct network name into the Wi-Fi settings tile. Enter the Wi-Fi password if connecting to a password protected network.

3. Once all the changes have been made, select the ***Apply changed settings*** button and select ***Ok*** when the confirmation box appears.

Step 2: Set Patient up on zensor online

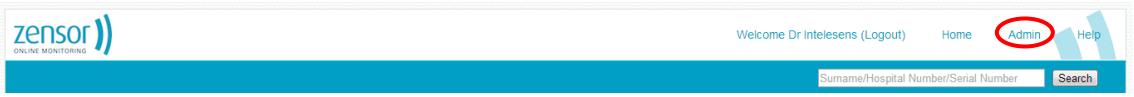
For more detailed information on the use of zensor online outside the following guidance, please see the zensor Online User Manual.

Select ***View Events Online*** button on the Home tab of the zensor App. zensor online will open in the PC's default internet browser. Enter the username and password and select ***Login***.

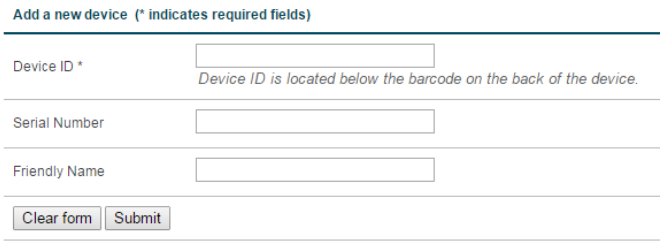
Add a Device to zensor online *(If required)*

NOTE If the device has not been setup on zensor online before, it will need added to the system before use. Each new device will need setup on zensor online once. The user must have device administrator privileges to add a device.

1. Click the ***Admin*** tab at the top right of the page.



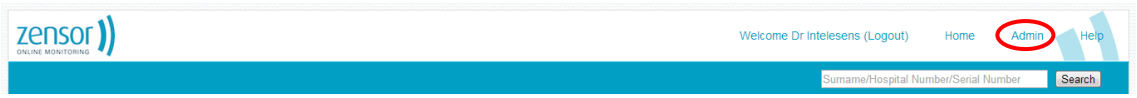
2. Select the ***Add device*** option and enter the device number located below the barcode on the back of the device. A friendly name and serial number can also be entered for each device. When the details have been entered select ***Submit***.



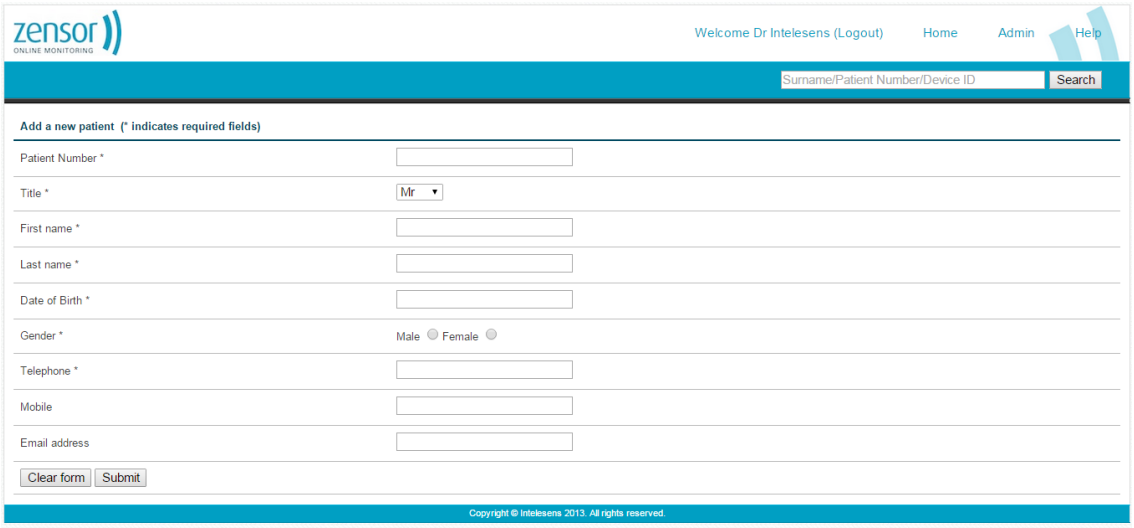
3. The next page will show the device information and confirm that the device has been added.

Add a Patient to zensor online

1. Click the ***Admin*** tab at the top right of the page.



2. Select the ***Add patient*** option and enter the patient's details



3. When the details have been entered select ***Submit***. The next page will show the patient information and confirm that the patient has been added.

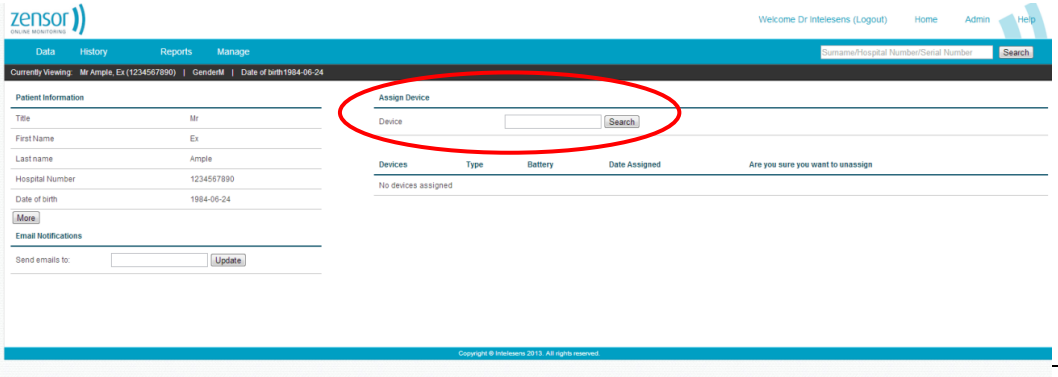
4. Select ***Setup Patient*** to open the patient's ***Manage*** page.

Assign a Device to a Patient

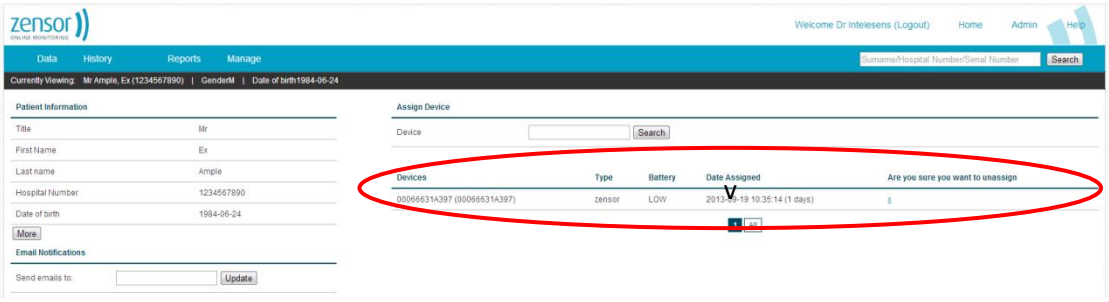
WARNING Always ensure the correct device is assigned to the correct patient in zensor online. Assigning a device that is currently being used by another patient will result in patient data being sent to the wrong patient record.

NOTE If a patient has been added to the system at an earlier time and you wish to assign a device, search for the patient number, select this patient and click on the ***Manage*** tab.

1. Under the ***Assign device*** heading, enter the device number (or friendly name if added during adding a device) for the appropriate zensor device. The device number can be found on the back of the zensor device below the barcode.



2. When the device number has been entered, select ***Search***.
3. Confirm this is the correct device and then select ***Confirm***. The device will be assigned to the patient.



Step 3: Safe Removal of Device from PC

Close the zensor online database and close the zensor App.

The device should be safely ejected from the PC prior to removal. To safely remove the device from the PC click on the Safely Remove Hardware icon ( ) located in the notification area at the far right of the Windows taskbar.

From the list of devices select the device that you want to remove i.e. zensor. Windows will display a notification telling you it's safe to remove the device.

NOTE The zensor device should always be safely removed from the PC using the steps listed. Ensure the zensor app screen has been closed before safely removing the device.

Step 4: Apply the zensor Electrode

WARNING Assess the patient for suitability for the zensor system based on the following restrictions:

- Must NOT be used on patients with a pacemaker or an ICD.
- Must NOT be applied to a patient with a skin disorder. Ensure there are no open wounds, lesions, infected or inflamed skin in the area for electrode placement.
- The zensor system is for use on adult patients.
- If any allergic reaction occurs, remove the electrode.

WARNING The zensor electrode is only intended for use with the zensor device and should not be connected to any other type of ECG monitoring device.

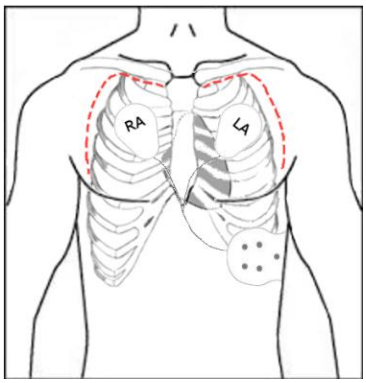
NOTE Minimize the contact of undergarments with the electrode.

NOTE Do not remove the clear plastic covers from the electrode patches until you are ready to apply the electrode to the patient.

Before using the zensor electrodes, check that the zensor electrode packaging is intact and within the use by date.

Follow the key steps below for correct skin preparation and electrode application. The quality of the monitoring session may be reduced if these steps are not carried out.

1. Determine Electrode Location



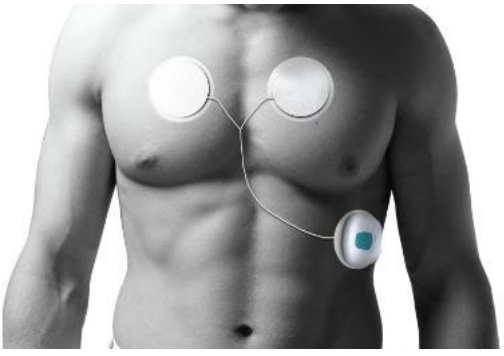
- Determine LL position **before removing the liner**. This will be where the studs will be **flattest on the patient's body** (this may be further forward on the abdomen).
- The RA and LA electrodes should be applied **slightly to the side** to allow the patient to apply a new electrode on an area of new skin during monitoring
- Ensure that the device when attached is easily accessible and will not be pushed off the electrode if the patient lies back.

2. Skin Preparation

CAUTION Do not use an alcohol wipe on skin where an electrode has already been applied as this may cause irritation.

- Carefully remove any hair present using clean scissors or surgical clippers. Shaving the area is not recommended as it can cause skin irritation.
- Clean the skin with an alcohol wipe, paying particular attention to where the circular gelled (active) area on the electrodes will be applied. Ensure cleaning is strong enough to remove top layer of dry skin cells.
- Allow skin to dry before applying electrodes.

3. Electrode Application



- Remove the electrode liner, ask the patient to take and hold a deep breath and smooth each electrode onto the skin, one at a time ensuring there are no creases and there is good contact with the skin. Taking and holding a deep breath during electrode application will maximise comfort during wear.
- Ensure the RA electrode is applied to the patient's right side and LA is applied to the patient's left side otherwise the ECG will be displayed incorrectly.

- Tape excess wire to the patient's skin using appropriate tape.
- Dispose of all electrode packaging carefully to avoid slips.

Step 5: Apply the zensor Device

Before using the zensor device carry out the following checks:

- The zensor device is clean and undamaged (refer to Appendix B).
- The zensor device is configured to record the desired monitoring data (refer to page (21)).
- The available memory on zensor device is sufficient for the intended use.
- The zensor battery/batteries are fully charged.

Clean the Contacts on the Battery

Clean the contacts on the battery before and during monitoring using an alcoholic wipe to ensure good connection between the device and battery.

NOTE It is advised that before inserting the battery into the device, the contacts on the battery should be cleaned with alcohol wipes. Doing this will help to ensure a good connection between the device and battery during wear.

Insert the Battery

Select the fully charged battery from the charging dock.

Holding the zensor device and battery (using the finger grips situated at the sides circled above), locate the battery onto the guide rails and slide it onto the device. A slight pressure is required to secure it into place.

NOTE When sliding the battery on, it is easier to see the guides on the device when it is turned so the label is facing upwards.

Clean the Device and Electrode Studs

Clean the device and electrode studs before and during monitoring using an alcoholic wipe to ensure good quality signal.

NOTE It is advised that the device and electrode studs should be cleaned each day with alcohol wipes. Doing this after showering will help to prevent buildup of soapy water on the studs. This improves signal quality of your signal.

Apply the zensor Device

Position the zensor device so that the 5 magnetic studs line up with the stud pattern on the electrode. Allow the magnetic studs to connect the device to the electrode.

Connecting one stud, then two and then the remaining studs will help ensure all 5 studs successfully connect. Gently lift the edges of the device to confirm that all five studs are connected.

Step 6: Activate zensor Device

Switch on the device by pressing the pushbutton and verify the start-up sequence on the device:

Device Indication		Buzzer
Device switching on		Ascending tone *(three beeps)*
Device initialising *(approximately 5 s)*		
Device has initialised and normal operation		1 beep

NOTE The zensor device requires a charged battery to be fitted at all times to ensure continuous monitoring.

Step 7: Verify Correct Setup

1. Ask the patient to press the pushbutton on the device to demonstrate understanding and verify correct setup. This creates an event recording which is transmitted to zensor online via the Wi-Fi or mobile hotspot.
2. The device will record 30 seconds of ECG, connect to the wireless network and transmit the data:

Device Indication	
Connecting to wireless network (Connection may be very quick, therefore this indication is not always seen)	Slow flashing green
Data transferring via the wireless network	Fast flashing green

3. After a few minutes the wireless network will have transmitted the ECG data to zensor online server.
4. Log onto zensor online and verify that the event has been successfully transmitted and is of an acceptable quality. Please refer to the zensor online User Manual for further information.

Step 8: Provide Information to Patient

It is important that the patient is aware of the intended system use and performance before monitoring, and that they are appropriately informed of any safety messages contained within this user manual.

Provide a paper copy of the 'Patient Instruction Booklet' as necessary and make the patient aware of the following areas which are detailed in the booklet:

- How to connect the device to the electrode
- How to switch the device off and on
- How to press the event button
- How and when to charge the zensor battery
- How and when to replace the electrodes
- Normal device indications
- Intended use during showering / bathing / sleeping

Before giving a copy of the booklet to the patient, ensure the appropriate contact details of the Health Care Provider have been completed on the back of the patient instruction booklet and inform the patient who and how to contact if in the event they require any more assistance in relation to the system, or want to report an unexpected operation or event, or if they have any further questions.

4 Monitoring with the zensor System

Read through the information for details relating to the zensor system during use. Important areas should be highlighted to the patient ahead of monitoring.

NOTE The system is intended to be used to obtain physiological readings for use in routine check-ups. Any events or variations in physiological readings are not intended to be used to summon emergency care.

zensor Device

WARNING The zensor device and electrode must not be worn when undergoing an MRI scan, X-ray, CT scan, defibrillation or surgical procedure.

WARNING The zensor device, battery or any other system component must not be submerged in water or other liquid. The zensor device is not waterproof.

CAUTION Remove the battery from the zensor device when not in use. This will avoid damage to the device in the event of battery leakage.

- The zensor device must be removed during showers and baths and reconnected as soon as possible thereafter.
- The zensor device can be worn when the patient is asleep.
- The zensor device should be operated at temperatures between 0 °C and 40 °C (32 °F and 104 °F).
- If the battery charge level is low (less than 2 hours remaining) the device sounds a long beep every second. Please refer to the Charging the zensor Battery section on page (35).

NOTE It is advised that the device and electrode studs should be cleaned each day with alcohol wipes. Doing this after showering will help to prevent buildup of soapy water on the studs. This improves signal quality of your signal.

NOTE It is advised that before inserting the battery into the device, the contacts on the battery should be cleaned with alcohol wipes. Doing this will help to ensure a good connection between the device and battery during wear.

zensor Battery Life

The zensor battery life is dependent on the device configuration. The table below details the minimum battery life for the device configurations that will result in the longest and shortest battery lives.

Device Configuration		Minimum Battery Life
ECG ON Respiration ON Accelerometer ON	24hr Full Disclosure Mode ON Wi-Fi Event Transmission Mode ON (Scheduled Events every 15 min)	24 hours
ECG ON Respiration OFF Accelerometer OFF	24hr Full Disclosure Mode ON Wi-Fi Event Transmission Mode OFF (Scheduled Events OFF)	72 hours

Charging the zensor Battery

CAUTION Install the battery charging dock in a suitable location, where it will be protected from damage, liquid ingress, moisture or extreme temperature.

The battery has sufficient capacity to power the zensor device for up to 72 hours (3 days) of continuous monitoring (depending on device configuration, see Section 'zensor Battery Life' for more information). Therefore dependent on the intended monitoring duration the battery may require charge during monitoring.

Remove the low battery from the zensor device and place on charge. Place a fully charged battery in the device and continue monitoring.

Please refer to the 'Charge the Battery' section for further information on page (34).

NOTE It is advised that before inserting the battery into the device, the contacts on the battery should be cleaned with alcohol wipes. Doing this will help to ensure a good connection between the device and battery during wear.

zensor Controls and Indicators

The zensor device provides controls as follows:

Controls	Function
Press pushbutton	Switch device ON
Press and hold pushbutton	Switch device OFF
Press pushbutton when device is ON	Register an event

The zensor device provides visual and audible status indications as follows:

Indication					Buzzer	
Device switching on						Ascending tone
Device initialising						
Device initialised						1 beep
Normal operation						
Device connecting to Wi-Fi		Slow flashing	N/A			
Data transferring via Wi-Fi		Fast flashing	N/A			
Device has stored data which has not been transmitted				Constant flashing		
Button press				At button press		1 beep
Device switching off						Descending tone
Device switched off						
Low battery alert	N/A		N/A			1 repeated long beep
Device error*		Alternate flashing		Alternate flashing		1 repeated short beep

*This indication may last approximately 6 seconds. If the error still exists after 6 seconds the indication will be repeated. In this instance, switch the device off and remove the battery. After 10 seconds reinsert the battery, and switch the device on. Monitoring should then be continued, otherwise contact your local Intelesens representative to discuss a device issue.

Viewing events on zensor online

If event transmission mode is on, events (both automatic and manual) are automatically downloaded to the cloud based zensor online database. Events can be viewed on the zensor online database using a PC, tablet computer or smartphone.

All events are stored both on the device and on zensor online. If an event is unable to send to zensor online due to a loss of wireless network connection during monitoring, it will be stored on the device until a connection is established.

Please refer to the zensor Online User Manual to learn more about the zensor Online features.

zensor Electrode

- Each electrode may be worn for up to 72 hours (3 days). During this time if any of the electrodes become loose or detached remove the electrodes and replace with a new electrode as the quality of the data will degrade.
- To avoid skin irritation, when changing electrode move them slightly from their previous position.
- Excessive exercise will decrease the length of time that the electrode can be worn due to perspiration.
- The electrode can be worn in the shower (excluding power showers) with the zensor device removed. After showering the electrode should be gently dabbed dry with a lint free cloth.
- The electrode should not be submerged in water, for example during a bath or while swimming.

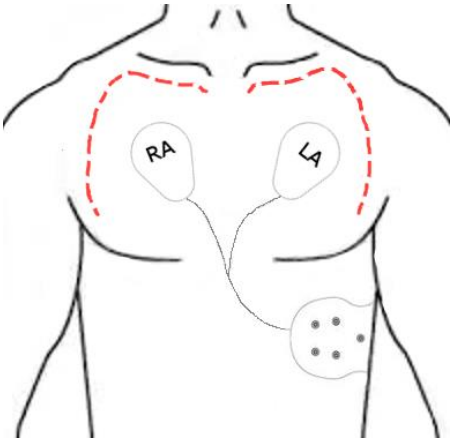
NOTE It is advised that the device and electrode studs should be cleaned each day with alcohol wipes. Doing this after showering will help to prevent buildup of soapy water on the studs. This improves signal quality of your signal.

Replacing the zensor Electrodes

CAUTION Do not use an alcohol wipe on skin where an electrode has already been applied as this may cause irritation.

If the edges of the patches are coming away from the skin by any more than 1 cm, the patches should be replaced.

1. Remove each patch slowly, taking care not to damage the skin
2. Dispose of the used patch with your normal household waste
3. Take a few minutes to determine the best position for each patch before removing the liner:



Right Arm and Left Arm patches:

a. The patches should be applied in a different area to where the previous patches were placed.

b. RA – Right side of chest

LA – Left side of chest

c. The patches should not be placed too close to the red lined area on the diagram.

Larger lower (LL) patch:

a. The patches should be applied where the studs are flattest on the body. This may be further forward on the abdomen.

b. Keep in mind that you do not want to push zensor off the patch if you lie back.

4. Assess the areas for any hair. If hair is long enough to trim, use clean and safe scissors to **carefully** do this.
5. Gently clean each area with mild soap and water ensuring no soap residue remains and pat dry. Allow the skin to breathe for a short while before reapplying the next patch.
6. Ensure the whole area is **clean and dry** before the next patch is applied.
7. Apply the patches ensuring there are no creases.

5 Ending Monitoring

Step 1: Remove the zensor Device

Disconnect the zensor device from the electrode while pressing down on the electrode beside each stud.

Step 2: Turn the zensor Device Off

Turn the zensor device off by pressing and holding the pushbutton for approximately 10 seconds, until 3 descending beeps are heard and the LEDs turn off.

If the device fails to turn on or off refer to the troubleshooting procedure (Appendix C).

Step 3: Remove the zensor Electrode

Remove each electrode slowly, taking care not to damage the patient's skin. Dispose of the electrode after use according to local guidelines.

NOTE It is recommended that a trained healthcare professional clean the application site appropriately.

NOTE Some reddening of the skin is to be expected in the area of the electrode placement.

Step 4: Remove the Battery

WARNING Avoid touching the contacts on the battery apart from during cleaning. Doing this will help prevent the buildup of dirt on the contacts.

Holding the zensor device and battery (using the finger grips situated at the sides circled above), pull the battery away from the device.

Step 5: Clean the zensor Device and Battery

CAUTION When cleaning the zensor device without a battery connected, take care to ensure that the battery connecting pins on the device are not damaged.

CAUTION The device and associated accessories should be cleaned after each patient to prevent cross-contamination.

Clean the device and battery according to Appendix B.

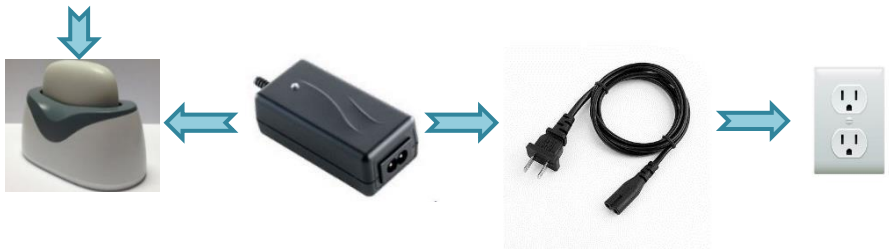
Step 6: Charge the Battery

WARNING Use only approved accessories (including but not limited to batteries, electrodes, charging docks and cables) supplied for use with the zensor device. Use of any other parts not supplied with the system may result in damage.

CAUTION Install the battery charging dock in a suitable location, where it will be protected from damage, liquid ingress, moisture or extreme temperature.

When connecting the charging unit, follow the steps in the order listed:

1. Place the depleted battery in the charging dock, pushing down to ensure there is a good connection.
2. Connect the charging dock power supply to the back of the charging dock.
3. Insert the Figure of 8 lead into the port in the charging dock power supply.
4. Connect the mains lead to the wall socket in your home.
5. Switch on the power at the mains.
6. Check that the charging status LED is red to indicate charging.
7. The battery will fully charge within 4 hours.



Connecting the charging dock and power supply in this order will ensure the battery will charge.

NOTE The battery must be inserted into the charging dock **before** the power supply block is turned on at the mains. The power supply should be disconnected from the mains socket once charging has completed.

LED Colour on Mascot Charger	Indication
	Charging
	Fully charged

6 Managing the zensor Data

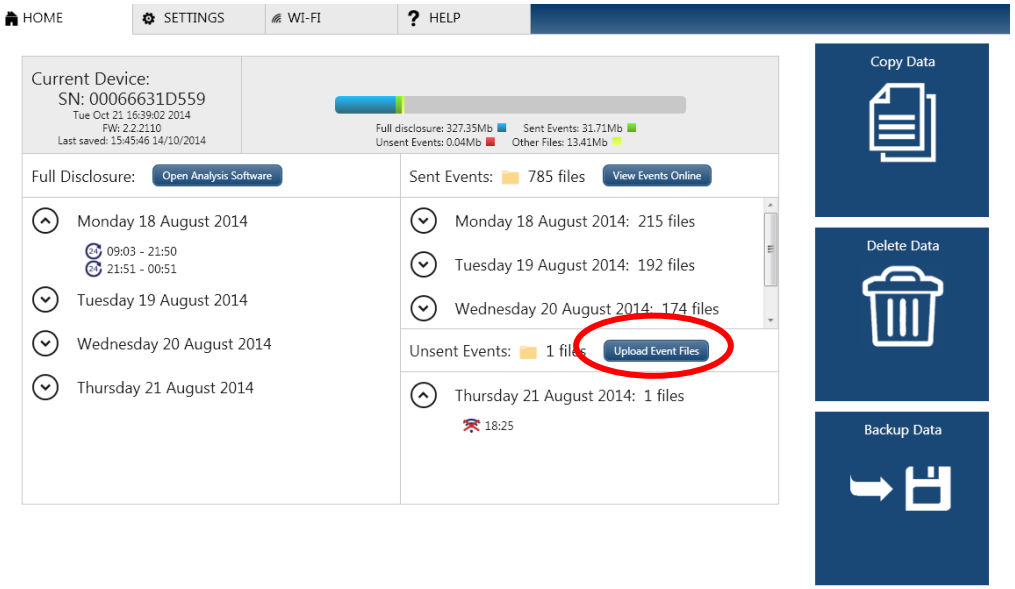
For information on accessing the zensor app please refer back to Section 3 Equipment Setup.

NOTE The zensor device should always be safely removed from the PC using the steps listed. Ensure the zensor app screen has been closed before safely removing the device.

Checking zensor Device Memory Space

The memory space on the zensor device can be reviewed at the right of the home tab by the currently used storage status bar. The remaining available recording time can be calculated approximately by assuming that 1 day full disclosure recording occupies 150 MB of memory space.

Uploading Unsent Events to zensor online



If there are unsent events on zensor online, select ***Upload Event Files*** to push the events to zensor online. A dialog box will confirm that the events have been uploaded, select ***Ok***.

Copying zensor Data to PC

Select the ***Copy Data*** tile and select the files that are to be copied from:

- Documents and manuals
- System configuration files
- Full disclosure data
- Event data

When the data has been selected, select the ***Copy Data*** button. A popup window will then appear; select the location for the backup to be saved and select ***Ok***. A progress bar will appear in the bottom right on the app. When completed a confirmation box will appear, select ***Ok***.

Deleting zensor Data

Select the ***Delete Data*** tile and select the files that are to be deleted:

- Log files
- Full disclosure data
- Event data

When the data has been selected, select the ***Delete Data*** button. A popup window will then appear, select the location for the backup to be saved and select ***Ok***. A progress bar will appear in the bottom right on the app. When completed a confirmation box will appear, select ***Ok***.

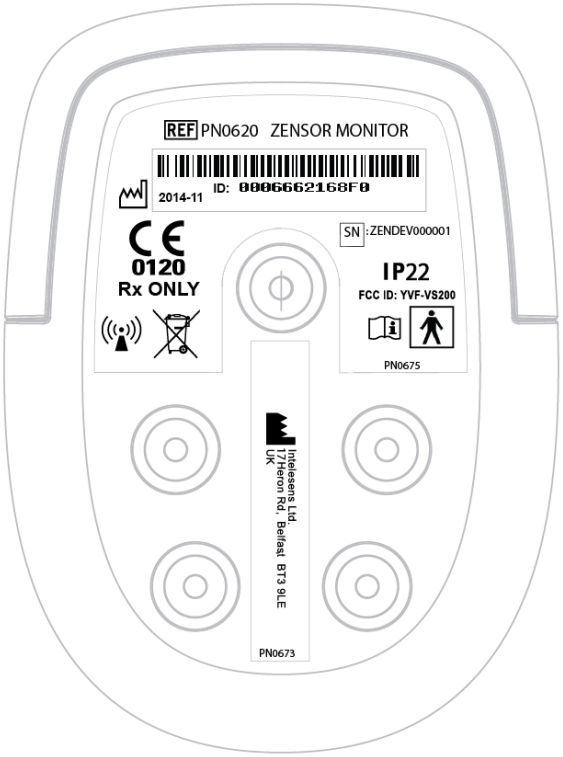
Backing up zensor Data to PC

Select the ***Backup Data*** tile and select the ***Backup device files*** button. A popup window will then appear, select the location for the backup to be saved and select ***Ok***. A progress bar will appear in the bottom right on the app. When completed a confirmation box will appear, select ***Ok***.

Appendix A Equipment Identification

zensor Device

The identification and manufacturing information for the zensor device is shown below. The number below the barcode on the zensor device is the MAC address of the device.



zensor Battery

The identification and manufacturing information for the zensor battery is as follows:

zensor battery barcode label

zensor battery manufacture date

zensor battery certification label

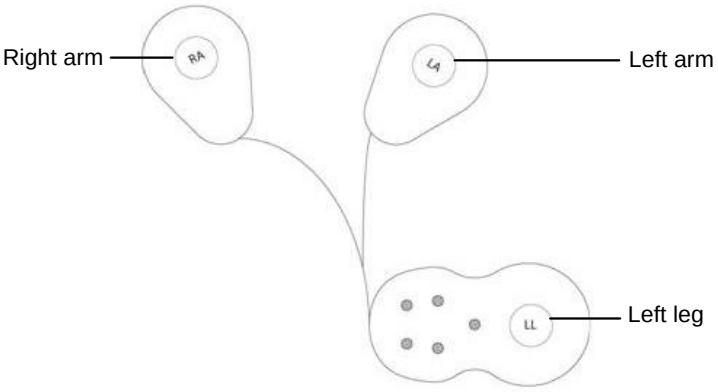
zensor Charging Dock

The identification and certification information for the charging dock is displayed below.

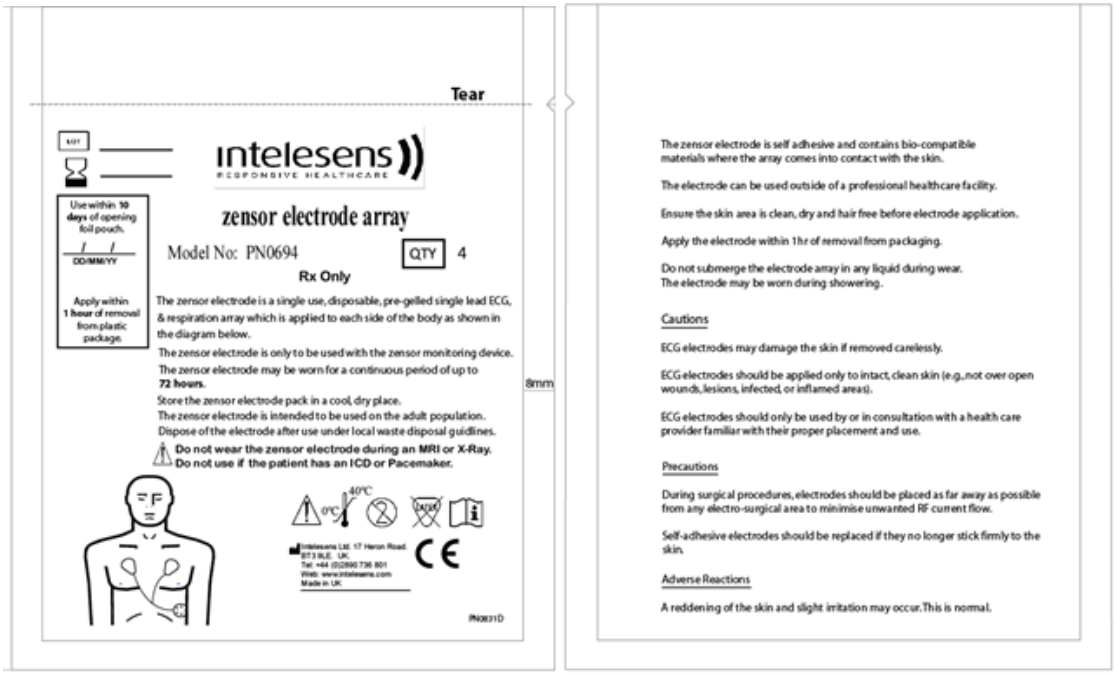
zensor charger manufacture date

zensor Electrode

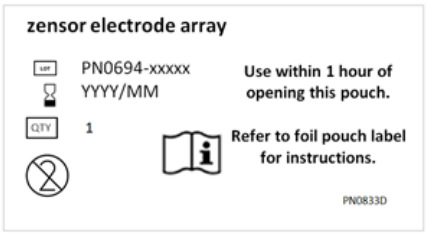
The electrodes are identified as illustrated below:



The following information is printed on the front and back of the electrode pouch:



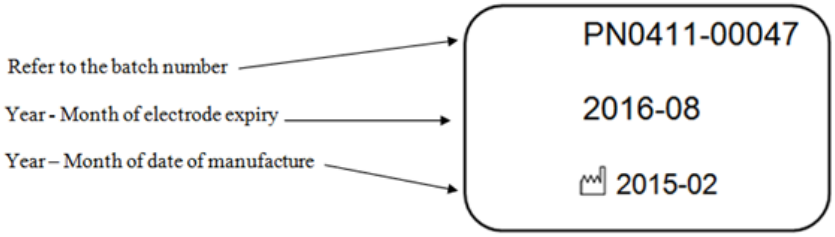
The following information is printed on the inner electrode pouch:



XXXXX – Sequential lot number (derived from zensor electrode batch log)
YYYY/MM – Use by date of electrode (year / month)

The following label is displayed on the front of the electrode pouch for identification and to provide manufacturing information:

Example label with sample information only



zensor Carry Case

Appendix B Service and Maintenance

zensor Battery

CAUTION Remove the battery from the zensor device when not in use. This will avoid damage to the device in the event of battery leakage.

Service Requirements

WARNING No maintenance or service action is to be carried out while the system is in use.

Follow the service requirements listed below:

- Refer equipment servicing to authorized service personnel only.
- Any unauthorized attempt to repair equipment under warranty voids that warranty.
- It is the user's responsibility to report the need for service to Intelesens or to one of their authorized agents.
- Regular maintenance, irrespective of usage, is essential to check that the equipment is always functional when required.

Maintenance Schedule

WARNING Failure on the part of the responsible hospital or institution using this monitoring equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

WARNING No maintenance or service action is to be carried out while the system is in use.

An effective maintenance schedule should be established for the zensor components and accessories. This should include inspection as well as cleaning before and after each patient. The maintenance schedule must comply with the policies of your institution's infection control unit and/or biomedical department.

As a minimum the following guidelines should be observed:

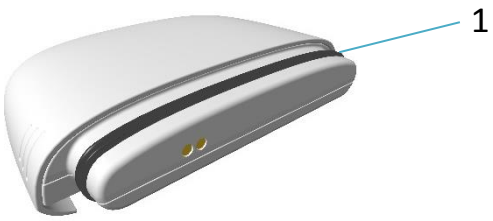
Component	Maintenance Action	Schedule
zensor device	Visual inspection	Before use and during reprocessing
	Reprocess	After each patient use
zensor battery	Visual inspection	During reprocessing
	Reprocess	Before insertion in charging dock
zensor charging dock	Visual inspection	Weekly
	Reprocess	As required / weekly
	Electrical safety test	Annually
zensor electrode	Visual inspection	Before use
	Storage audit	Annually

Visual Inspection

Inspect the zensor components or accessories using the following guidelines. If damage is observed refer the equipment to qualified service personnel.

- Inspect all the equipment for obvious physical damage.
- Inspect the safety labels for legibility.
- Inspect power cords for fraying or other damage.
- Inspect plugs and connectors for corrosion, contamination, bent prongs or pins.
- Inspect cable insulation for cracks, tears, or other damage.
- Inspect the O-ring seal on the battery for damage.
- Inspect the zensor charging dock for objects or contamination within the battery cavity.
- Before opening the zensor electrode inspect that the packaging is intact. Check that the use by date has not been exceeded.

Replacing the Battery O-ring Seal



Replace the O-ring if a visual inspection indicates that the O-ring is damaged. Remove the O-ring on the zensor battery pack as follows:

1. Orientate the battery as indicated.
2. Roll off the O-ring (1) in the direction indicated. If necessary use a blunt tool to free the seal from the locating groove.
3. Discard the O-ring.

Insert a new O-ring seal on the zensor battery pack as follows:

1. Orientate the battery as indicated.
2. Roll on the new O-ring (1) to the locating groove on the battery stub.
3. Check that the O-ring is seated along its entire length.

Cleaning and Disinfecting

WARNING Excessive liquid cleaning agents or disinfectant could reach the interior of the zensor device through the battery pins and USB port causing damage. Avoid the application of excess liquid to the device when cleaning and disinfecting.

WARNING Should zensor become contaminated with blood or body fluids which may contain bloodborne pathogens, the device should by cleaned in line with your institution's procedures. The specific disinfectant contact times should be followed when using disinfectant.

CAUTION When cleaning the zensor device without a battery connected, take care to ensure that the battery connecting pins on the device are not damaged.

All equipment should be cleaned on a regular basis. Comply with the policies of your institution's infection control unit and or biomed department. The decision to disinfect or sterilize must be made per your institution's requirements with an awareness of the effect on the integrity of zensor and its accessories.

Safe and effective device reprocessing is dependent on thorough cleaning of the device (removal of visible dirt or soil) before disinfecting (removal of microbes). Always remove the battery before cleaning to ensure that both components can be completely cleaned.

Cleaning and low level disinfection will ensure effective reprocessing of zensor. Only in exceptional circumstances would intermediate level cleaning be required.

Permitted Cleaning Agents

CAUTION Do not use the following products when cleaning the zensor components or accessories:

- Conductive solutions that contain chlorides, wax, or wax compounds
- Any type of Ammonium Chloride such as, but not limited to:
  - Dimethyl Benzyl Ammonium Chloride
  - Quaternary Ammonium Chloride solution
- Abrasive cleaners or solvents of any kind
- Acetone
- Ketone
- Betadine
- Sodium salts

CAUTION Do not autoclave or steam clean the zensor components or accessories.

Use a solution of 70% alcohol in water for cleaning.

Permitted Disinfecting Agents

Use a solution of 70% alcohol in water for disinfecting.

Cleaning and Disinfecting External Surfaces

zensor Components and Accessories

WARNING Disconnect the zensor Charging Dock from the AC power before cleaning or disinfecting. Switch off battery-powered equipment before cleaning or disinfecting.

CAUTION Do not spray, pour, or spill any liquid on the zensor components, accessories, connectors, switches, or into any openings in the case as this may damage the system.

CAUTION When cleaning the zensor device without a battery connected, take care to ensure that the battery connecting pins on the device are not damaged.

CAUTION The device and associated accessories should be cleaned after each patient to prevent cross-contamination.

For surface-cleaning and disinfecting of the zensor components and accessories (excluding the electrodes), follow your institution's procedures, or the instructions below:

- Disconnect the device from the battery and remove the O-ring from the battery to permit thorough and effective cleaning.
- Surface-clean all components using a soft cloth dampened with a solution of 70% alcohol in water, or any wipe that meets this requirement.
- Ensure any visible dirt or grit is physically removed. Pay special attention to any grooves or slots in the device or battery casing, particularly the inside rim of the battery casing, where the O-ring is placed on the battery and the battery contacts.
- Visually inspect the components to ensure it is clean. If it is determined to not be visually clean at the end of processing, repeat the relevant, previous cleaning steps.
- Disinfect all the components using a new soft cloth dampened with a solution of 70% alcohol in water, or any wipe that meets this requirement.
- Allow the components to dry naturally, or wipe dry using a clean dry lint-free cloth. Do not use forced drying techniques, such as oven, forced heat or sun drying.
- Reapply the O-ring on the battery after cleaning.

Minimize or eliminate delays between steps described, as this may create conditions favorable to microbial growth or colonization, reducing the effectiveness of cleaning and disinfection.

zensor Electrode

The zensor electrode is for single-patient use only. If soiled, the electrode should be discarded.

Results of Using Improper Cleaning Techniques or Materials

- Appearance of false waveform when the device is not connected to a patient.
- Brittle and breaking device case.
- Overall system performance degradation.
- Melting, dulling, or distorting the case.
- Total medical device failure requiring replacement.
- Unit malfunction.
- Void warranty.

Appendix C Troubleshooting

zensor Device

zensor device did not follow normal startup sequence

Indication	Solutions
The LEDs did not turn on	Remove and reinsert the battery. Press the pushbutton down again for approximately 1 second.
The LED stayed orange	Wait for 30 seconds. If it remains orange, turn zensor off and remove battery. After 10 seconds re-insert the battery and turn back on. If the error persists, contact your local Intelesens representative.
Other indication	Review the zensor device indications table and the rest of the troubleshooting section to determine if the indication is covered. If not, contact your local Intelesens representative to report unexpected operation.

zensor will not switch on

Possible Causes	Solutions
The battery is not inserted correctly	Remove and reinsert the battery. When sliding the battery on, it is easier to see the guides on the device when it is turned so the label is facing upwards.
The battery is flat	Confirm the battery is flat by placing in the charging dock. The LED should turn orange if charging.
The button wasn't pressed	Press the button on the front of the device. An ascending tone should be heard when the button is pressed.

zensor will not switch off

Possible Causes	Solutions
The button has not been held down for a long enough period	Hold the button down on the device for over 10 seconds.
No obvious cause	Remove the battery from the device.

zensor monitor is beeping

Possible Causes	Solutions
1 long beep every second: The battery is low	Replace the battery with a charged battery and insert the low battery in the charger
1 short beep every second with orange and blue alternate flashing LEDs: Error indication	See previous Problem Box: **“Blue and orange LED are alternating flashing”**

Cannot remove the battery from the device

Possible Causes	Solutions
The grips on the side of the battery have not been used	Use the grips on the side of the battery to help to remove it.
Do not have the required strength to remove the battery	Seek assistance from a friend or family member to help remove the battery.

zensor exposed to water (bath or shower, etc.)

Possible Causes	Solutions
zensor is not to come into contact with water	Contact your local Intelesens representative.

Cannot connect zensor to the patch

Possible Causes	Solutions
Unable to line the device up with the patch	Use a mirror to help with stud alignment. Line two of the studs up carefully and the rest of the studs should find themselves more easily. If still unsuccessful, seek assistance from a friend or family member.
The patch is not on the flattest surface of the body	Apply a new patch ensuring the studs are on the flattest area of the body.

General Electrode Use

Electrode was submerged in water (bath, swimming, etc.)

Possible Causes	Solutions
Electrode is not to be submerged in water	Replace the zensor electrode.

Consistently poor electrode adhesion

Possible Causes	Solutions
Skin type is resulting in adhesion not lasting as long as normal	If happy to do so, keep replacing the patch when appropriate.

The electrodes are causing a bad skin reaction

Possible Causes	Solutions
Skin has reacted against the patch causing bad irritation	If required, discuss the irritation with the clinician in charge.

Battery Charging

Difficulty charging the battery

Possible Causes	Solutions
Order of battery charging instructions were not followed	Turn the power off and on at the mains switch.
The battery is not inserted into the charger correctly	Remove the battery and reinsert ensuring good connection. Putting slight downward pressure on the battery can help to ensure adequate battery connection with the charger.
The cables are not connected correctly	Remove and reinsert all the charger connections ensuring each one is connected securely.
The power is not switched on at the mains	Turn the power on at the mains switch.

zensor PC User Interface

Device is not recognised by the PC, Device does not appear on the PC

Possible Causes	Solutions
The device is not connected to the PC correctly	Disconnect the cable from the device and PC and reconnect. You may need to reconnect the device multiple times or change the PC USB port to allow for successful connection.

The zensor application crashed

Possible Causes	Solutions
The device has been disconnected from the PC	Ensure the device is attached correctly to the PC and the blue LED is lit.
No obvious reason	Disconnect and reconnect the device to the PC.

Event Button has not been transmitted to zensor online

Wait **30 minutes** and check zensor online again. If the event is still not there, follow the troubleshooting table below.

Indication	Possible Causes	Solutions
 Solid green Flashing blue **OR** button press within the last 15 min:  Solid green	*There is no wireless network coverage*	Move the zensor device within range of the wireless network to allow connection. Ensure the wireless network has good coverage.
 Flashing green Flashing blue **OR**  Flashing green	*Data is currently sending*	The data is transmitting and no action is required.
 Flashing blue Flashing orange  Repeated short beeps **OR**  Solid orange	*There is an error with the device*	If the indication does not stop after 6 seconds, turn zensor off, remove battery. After 10 seconds re-insert the battery and turn back on. If the error persists, contact your local Intelesens representative.
N/A	*No obvious reason*	If the green LED is solid, press the event button again. Pressing the button again, will make the device try and connect to the wireless network again and send the event. N.B. It can take up to 5 minutes for the first event to transmit to zensor online
N/A	*The button wasn't pressed*	Press the event button again. A beep should be heard and a temporary blue LED lit when the button is pressed

No automatic events on zensor online

Indication	Possible Causes	Solutions
 Solid green Flashing blue	*There is no wireless network coverage*	Move the zensor device within range of the wireless network to allow connection. Ensure the wireless network has good coverage.
	*zensor device is off*	Restart zensor (if the battery is flat, replace the battery).
 Flashing green Flashing blue **OR**  Flashing green	*Data is currently sending*	The data is transmitting and no action is required.
 Flashing blue Flashing orange  Repeated short beeps **OR**  Solid orange	*There is an error with the device*	If the indication does not stop after 6 seconds, turn zensor off, remove battery. After 10 seconds re-insert the battery and turn back on. If the error persists, contact your local Intelesens representative.

Poor signal quality on zensor online

Possible Causes	Solutions
The patch is coming away from the skin	Replace the patch ensuring correct skin preparation takes place in accordance with guidelines in the patient information booklet
The RA and LA patches have been applied the wrong way round	
The patches have been applied in the incorrect location	
The patches have been worn for a long period (>3days)	
The patches were replaced without proper skin preparation	
Issues experienced with attaching zensor to the patch	Use a mirror to help with device alignment to the patch. Line two of the studs up carefully and the rest of the studs should find themselves easier. Seek assistance from a friend or family member. If patch is not on the flattest surface of the body, follow the instructions to replace a patch ensuring the stud area is on the flattest surface near to the optimum position as shown in the patient information booklet
zensor / patch studs are dirty	Clean zensor and patch studs using the alcohol wipes provided

No ECG waveform present in automatic events on zensor online

Possible Causes	Solutions
zensor device is not attached correctly to the patch	Reconnect zensor to the patch. If issues are experienced, try these possible solutions: • Use a mirror to help with zensor alignment to the patch • Line two of the studs up carefully and the rest of the studs should find themselves easier • Seek assistance from a friend or family member • If patch is not on the flattest surface of the body, follow the instructions to replace a patch ensuring the stud area is on the flattest surface near to the optimum position as shown in the patient information booklet
There is an error with the device	If the indication does not stop after 6 seconds, turn zensor off, remove battery. After 10 seconds re-insert the battery and turn back on. If the error persists, contact your local Intelesens representative.
No obvious reason	Restart the zensor device and press the pushbutton to trigger an event to check data. If the issue persists, contact your local Intelesens representative.

Appendix D Product Security

The zensor device conforms to the Wi-Fi security parameters below.

Configuration	Default Value	Description/Options
Wi-Fi		
SSID	SSID	Wireless network name that zensor will connect to
Security key	-	Wireless access key for the network above
Security type	Open	Type of security of wireless network: Open WEP-128 WPA1 Mixed WPA1 & WPA2-PSK WPA2-PSK

zensor data files are subject to strong encryption and compression techniques. Files are only readable by Intelesens applications to protect patient confidentiality.

Appendix E Product life and disposal

Product Life

The design lifetime of the zensor device and zensor charging dock is 3 years from the date of manufacture shown on the barcode label.

The design lifetime of the zensor battery is 500 charging cycles.

The shelf life of the electrodes are 1.5 years from manufacture as shown on the electrode pouch label.

Product Disposal

At end of device life the zensor device and system components are to be returned to the manufacturer for safe disposal in accordance with the WEEE Directive.

The zensor battery must be disposed of in accordance with relevant waste disposal regulations.

Electrodes can be disposed of in normal household or clinical waste.

Appendix F Technical Specifications

zensor Device

The zensor device indications table is located in the zensor Controls and Indicators section in Section 4 Monitoring with the zensor System.

Performance (Wi-Fi)		
Protocol	IEEE 802.11b	IEEE 802.11g
Frequency	2402 ~ 2480MHz	
Modulation	DSSS(CCK-11, CCK-5.5, DQPSK-2, DBPSK-1)	OFDM (default)
Data rate	1 - 11Mbps	6 - 54Mbps
Channels	1 - 13	
Channel Interval	5MHz	
Receive sensitivity	-85dBm	
Output level (Class1	+18dBm	
Output power	63mW	
Compliance standard	IEEE 802.11 b/g	

Environment	
Operating Conditions	
Operating Temperature	0 to 45°C (32 to 113°F)
Relative Humidity	10 to 95% (non-condensing)
Altitude	-16 to 3011m (-52 to 9879 ft)
Transport and Short Time Storage Conditions	
Temperature	-20 to 70°C (-4° F to 158° F)
Relative Humidity	5 to 95% (non-condensing)

Handling	
zensor device with battery	Impact resistant to IEC 60601-1 Clause 15.3.3 and 15.3.5.
	Water resistant to IEC 60529 IP22 rating (when zensor device and battery are correctly connected and a tight seal created)

Dimensions	
Height	9.6 cm (~3.8 inches)
Depth	1.8 cm (~0.7 inches)
Width	7.1 cm (~2.8 inches)
Weight (with battery)	80g (2.9oz)

zensor Battery

Performance	
Type	Lithium-ion
Capacity	1 Ah
Battery operating cycle	844 hours operation
Recharge time (100%)	4 hours (max)
Battery life	500 cycles of 844 hours

Environment	
Operating Conditions	
Operating Temperature	0 to 45°C (32 to 113°F)
Relative Humidity	45 to 85% (non-condensing)
Altitude	-16 to 3011m (-52 to 9879 ft)
Transport and Storage Conditions	
Temperature	Charge: 0 to 45°C (32 to 113°F) Discharge: -20 to 60°C (-4 to 140°F)
Storage life and capacity recovery rate	1 year @ 15° to 35°C (59°F to 95°F) >85%
	3 months @ -10°C to 45°C (14°F to 113°F) >90%
	< 1 month @ -20°C to 45°C (-4°F to 113°F) >90%
	Protect from liquids at all times
Relative Humidity	5 to 95% (non-condensing)
Altitude	-382 to 5,572m (-1,253 to 18,280 ft)

Dimensions	
Height	4.8 cm (~1.9 in)
Depth	1.8 cm (~0.7 in)
Width	7.1 cm (~2.8 inches)

Charging dock and Power Adaptor/Power Cord

Indicators (Power Supply)	
AC power connected	LED indicates GREEN
Battery charge state	ORANGE indicates battery charging GREEN indicates battery fully charged

Performance (Power Supply and Power Cord)	
Voltage input	100 – 240VAC
Frequency	50 to 60 Hz
Output voltage	4.2V
Output current	0.55A

Environment	
Operating Conditions	
Operating Temperature	0 to 45°C (32 to 113°F)
Relative Humidity	10 to 90% (non-condensing)
Altitude / Air Pressure	-16 to 3000m (-50 to 9842 ft) / 106 kPa to 70 kPa
Transport and Short Time Storage Conditions	
Temperature	-20 to 85°C (-4° F to 185° F)
Relative Humidity	10% to 85% (non-condensing)
Altitude / Air Pressure	-16 to 3000m (-50 to 9842 ft) / 106 kPa to 70 kPa
Transport and Long Time Storage Conditions	
Temperature	5 to 35°C (41° F to 95° F)
Relative Humidity	10% to 75% (non-condensing)
Altitude / Air Pressure	-16 to 3000m (-50 to 9842 ft) / 106 kPa to 70 kPa

Dimensions		
	Power supply	Charging dock
Height	3.2 cm (1.3 in)	10.9 cm (4.3 inches)
Width	4.5 cm (1.8 in)	4.9 cm (1.9 inches)
Length	9 cm (3.5 in)	1.6 cm (0.6 inches)
Weight	0.115 kg (0.25 lb)	0.088kg (0.19 lbs)

zensor Electrode

These specifications refer to the electrode when it is enclosed in the sealed foil pouch.

Environment	
Transport and Storage Conditions	
Temperature	0 to 40°C (32 to 104°F)
Altitude	-382 to 5,575m (-1,253 to 18,280 ft)
Relative Humidity	5 to 95% (non-condensing)
Storage Life	1.5 years

Dimensions	
Width	15.2 cm (5.9 in)
Length	18.3 cm (7.2 in)
Depth	1.3 cm (0.5 in)
Weight	0.15 kg (0.33 lb)

Regulatory Disclosures

Arrhythmias Monitored by Device

The ***Heart Rate*** averaging computation is as follows: The average of the last 12 seconds R-to-R intervals (up to 16 intervals) for rates greater than or equal to 60BPM and average of last 8 R-to-R intervals for rates below 60BPM, the update rate of the Heart Rate on the display is once per update interval period.

Asystole is a state of no cardiac electrical activity. The device is calibrated to trigger this arrhythmia when it is present for 10 consecutive seconds. Pause episodes are short term events (less than 10 seconds) which are not detected by the device.

Tachycardia is a fast heart rhythm, the device will trigger this arrhythmia when the average heart rate is continuously higher than a user configured threshold (default 150BPM) for a 30 second confirmation period. Episodes shorter than this are not recorded.

Bradycardia is defined as a slow resting heart rate, the device will trigger this arrhythmia when the average heart rate is continuously lower than a user configured threshold (default 50 BPM) for a 30seconds confirmation time. Episodes shorter than this are not recorded.

Ventricular Fibrillation is a condition in which there is uncoordinated contraction of the cardiac muscle of the ventricles in the heart, making them quiver rather than contract properly and resulting in a random and chaotic fluctuation in the ECG signal of the patient. The device will trigger this arrhythmia when it is present for at least 20 consecutive seconds of clean signal or at least 29 consecutive seconds of signal with high noise levels. Episodes shorter than this are not recorded.

Atrial Fibrillation is a cardiac arrhythmia (abnormal heart rhythm) that involves the two upper chambers (atria) of the heart. Its name comes from the fibrillating (i.e., quivering) of the heart muscles of the atria and it is characterised by an irregular heart rate. The device is will trigger this arrhythmia when it is present for at least 15 consecutive seconds. Episodes shorter than this are not recorded. This algorithm is designed to detect and record Atrial Fibrillation and is not suitable for the detection of Atrial Flutter episodes.

The zensor device is NOT suitable for ***ST segment*** analysis.

Disclosure

All arrhythmia algorithms have been tested according to ANSI/AAMI EC57:1998, *Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms*, as well as some additional test results for arrhythmias not included in EC57. Testing is carrying out on the MIT-BIH, AHA and Creighton University (CUDB) databases as required by EC57. During the testing an additional set of results are produced which exclude episodes which do not match the above descriptions to confirm operation as designed. Reasons for excluding events are:

- Arrhythmia episodes with duration too short to confirm event.
- Asystole events triggered during flat (or very low amplitude) signals where no cardiac activity can be detected but have not been marked as Asystole by signal reviewers.
- Bradycardia or Tachycardia episodes in the CUDB where QRS activity is obscured by chest compressions marked up as noise (‘n’ in CUDB annotation).

Certification

UL/IEC/EN 60601-1 : 2006	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC/EN 60601-1-2 : 2007	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC/EN 60601-1-11 : 2010	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
93/42/EEC	CE marked to the Medical Devices Directive

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The information contained in this section (such as separation distances) is in general specifically written with regard to the zensor. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes:
Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the remainder of the instructions for use for this device.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Cables and accessories not specified within the instructions for use are not authorized. Using other cables and/or accessories may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity).

Guidance and manufacturer's declaration – electromagnetic emissions		
The Inteleholter (zensor) is intended for use in the electromagnetic environment specified below. The customer or the user of the Inteleholter (zensor) should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11	Group 1	The Inteleholter (zensor)uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Inteleholter (zensor)is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC/EN 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC/EN 61000-3-3	Not Applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Inteleholter (zensor) is intended for use in the electromagnetic environment specified below. The customer or the user of the Inteleholter (zensor) 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/EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±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/EN 61000-4-4	±2kV for power supply lines ±1 kV for input/output lines	Not Applicable	Not Applicable
Surge IEC/EN 61000-4-5	±1kV differential mode ±2 kV common mode	Not Applicable	Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 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	Not Applicable	Not Applicable
Power frequency (50/60 Hz) magnetic field IEC/EN 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 a.c.mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Inteleholter (zensor) is intended for use in the electromagnetic environment specified below. The customer or the user of the Inteleholter (zensor) should assure that it is used in such an environment			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Inteleholter (zensor), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	Not Applicable	Not Applicable
	3 Vrms 150 kHz to 80 MHz in ISM bands[a]	Not Applicable	Not Applicable
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	d = 1.2 √P…80MHz to 800 MHz d = 2.3 √P…800 MHz to 2.5GHz 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 metres (m)[b] 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. 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 has been incorporated into the formulae 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 Inteleholter (zensor) is used exceeds the applicable RF compliance level above, the Inteleholter (zensor) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Inteleholter (zensor).

Recommended Separation Distances - Electromagnetic Interference

Recommended separation distances between portable and mobile RF communication equipment and the Inteleholter (zensor)

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	Not Applicable	Not Applicable	0.12	0.23
0.1	Not Applicable	Not Applicable	0.38	0.73
1	Not Applicable	Not Applicable	1.2	2.3
10	Not Applicable	Not Applicable	3.8	7.3
100	Not Applicable	Not Applicable	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae 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.