



CLINICAL REFERENCE MANUAL

Rx
ONLY

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DESCRIPTION

The Zio ECG Monitoring System is a ambulatory Electrocardiogram (ECG) monitoring system. The Zio ECG Monitoring System consists of two components: (1) Zio XT monitor ECG Recorder and the (2) proprietary algorithm software.

The Zio XT monitor is a single-patient-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The Zio XT monitor records ECG without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient trigger button and filling out a log to document symptomatic events, which will support symptom-rhythm correlation in the diagnostic report.

After conclusion of the wear period (up to 14 days), the patient removes the Zio XT monitor and returns it by post to iRhythm for processing. After receipt, the data is analysed by iRhythm's proprietary algorithm before a Certified Cardiographic Technician (CCT) reviews the results and generates a report of the key findings.

INTENDED USE

The Zio XT monitor is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring. After wear, ECG data from compatible monitoring devices is processed and analyzed by the ZEUS System. A final report is generated on the beat-to-beat information from the entire ECG recording. The reports are provided for review by the intended user to render a diagnosis based on clinical judgement and experience. It is not intended for use on critical care patients.

INDICATIONS FOR USE

The Zio XT monitor is a prescription-only, single patient use, continuously recording ECG monitor. It is indicated for use on patients who may be symptomatic and asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety.

INTENDED PATIENT POPULATION

Patients 18 years or older who may suffer from transient symptoms such as palpitation, shortness of breath, dizziness, ligh-headedness, pre-syncope, syncope, fatigue, or anxiety and patients who are asymptomatic.

USE ENVIRONMENT

Ambulatory

PRIMARY INTENDED USER

Physician, Healthcare provider; prescribes the monitoring service and may apply the ECG monitor in-clinic.

SECONDARY USER

Patient, who may apply the ECG monitor at home, if prescribed by their physician.

CONTRAINDICATIONS

- Do not use the Zio XT monitor for patients with symptomatic episodes where instance variations in cardiac performance could result in immediate danger to the patient.
- Do not use the Zio XT monitor in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI.
- Do not use the Zio XT monitor on patients with a neuro-stimulator as it may disrupt the quality of ECG data.
- Do not use the Zio XT monitor on patients who do not have the competency to wear the device for the prescribed monitoring period.

ZIO XT MONITOR ANALYSIS

The heart rhythm data captured by the Zio XT Monitor is analysed by iRhythm's UK-based cardiac physiologists on iRhythm's secure analysis platform. iRhythm is registered with, and regulated by, the Care Quality Commission (CQC) as a provider of health services in the UK.

NOTICE OF PRIVACY PRACTICES

iRhythm is committed to upholding patient privacy and protecting personal information, in particular health information collected and processed in conjunction with our Zio Service. We commit to complying with all applicable privacy laws and allowing patients to exercise their rights. For more information, please refer to the Patient Notice which is also available at www.irhythmtech.com/content/privacy-eu.

WARNINGS

- Do not use the Zio XT monitor on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies. Patient may experience skin irritation.
- Do not reuse the Zio XT monitor on multiple patients. It is a single patient use device. Reuse will cause incorrect patient data and the patient may experience skin irritation.
- Prior to monitor application, examine the skin area of the patient for certain skin conditions (such as dermatitis, eczema, rashes/hives), acute/chronic cutaneous infections or irritation.



If skin irritation such as severe redness, itching or allergic symptoms develop, remove the Zio XT monitor from the patient's chest.

Please call 0808 189 3411 for support.

**Rx
ONLY**

CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a physician.



PRECAUTIONS

- The Zio XT monitor includes temperature and humidity limitations. If exposed, patients may experience degradation of adhesive performance causing the device to slip or fall off during the patient wear duration.
- The Zio XT monitor has a shelf-life date. Use of expired device may cause a degradation of ECG signal quality and/or low battery condition.
- Do not use the Zio XT monitor if package is damaged. Device may not perform as intended.
- Safety and effectiveness of the Zio XT monitor on pediatric patients (younger than 18 years old) has not been established.
- Safety and effectiveness of the Zio XT monitor on patients receiving any form of pacing therapy has not been established. Paced cardiac rhythms may not be accurately detected and may be incorrectly classified.

UKCA MARK INFORMATION

UK
CA
0086

The Zio® ECG Monitoring System (Zio® XT monitor and ZEUS system) bears the UKCA marking UKCA-0086, indicating its conformity with the provisions in Part II of the UK MDR 2002 (as amended) concerning general medical devices and fulfills the essential requirements of Annex I of EU Council Directive 93/42/EEC.


















The medical device has been assigned to Class IIa in accordance with the classification criteria set out in Annex IX of EU Council Directive 93/42/EEC.

UK
CA

The Exfoliator bears the UKCA marking, indicating its conformity with the provisions in Part II of the UK MDR 2002 (as amended) concerning general medical devices and fulfills the essential requirements of Annex I of EU Council Directive 93/42/EEC.

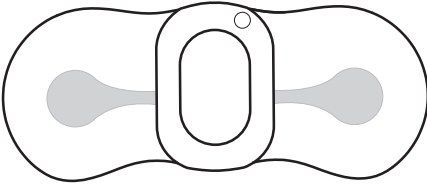
The medical device has been assigned to Class I in accordance with the classification criteria set out in Annex IX of EU Council Directive 93/42/EEC.

SYMBOLS

 <p>Consult instructions for use</p>	 <p>Catalogue number</p>	 <p>Prescription use only</p>
 <p>Manufacturer</p>	 <p>UK Responsible Person</p>	 <p>Date of manufacture</p>
 <p>Serial Number</p>	 <p>Use by</p>	 <p>Net quantity of contents</p>
 <p>Storage Temperature</p>	 <p>Humidity limitations</p>	 <p>Do Not Reuse</p>
 <p>Do not use if package is damaged</p>	 <p>Type BF applied part</p>	 <p>Separate collection</p>
 <p>Caution</p>	 <p>Finger Safe Splash-proof equipment</p>	

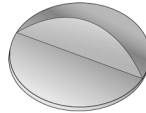
PACKAGE CONTENTS

1 Zio XT monitor



1 Skin Prep & Placement Kit containing:

- 1 disposable razor
- 1 exfoliator disc
- 4 alcohol wipes



1 Patient Instructions & Button Press Log containing:

- 1 adhesive remover wipe
- 1 box seal

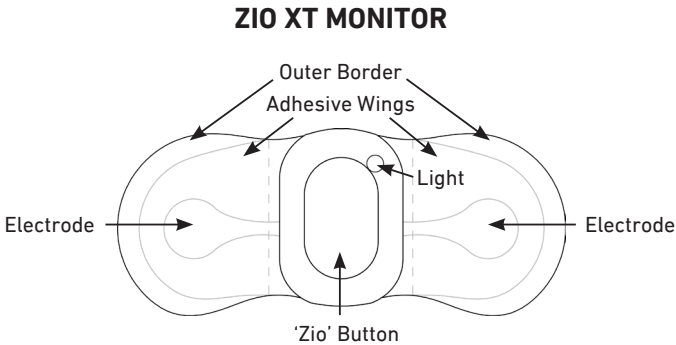
1 Postage-paid return box

Zio^{XT}
PATIENT INSTRUCTIONS
& BUTTON PRESS LOG

PATIENT ID NUMBER: _____
NAME: _____
START DATE: dd / mm / yyyy TIME: _____
REMOVAL: ☐ Physician prescribed duration of _____ days
☐ Patient to wear as long as possible (up to 14 days)
TO BE COMPLETED BY PATIENT
DATE REMOVED: dd / mm / yyyy
SNR STICKER HERE



DEVICE DIAGRAM



GETTING STARTED

The Zio XT monitor is an ECG monitor that continuously records the electrical activity of the heart. It is intended to be worn continuously for a time period specified by a physician for up to 14 days. **Each patient's wear duration may differ due to individual wear experiences.** Excessive sweating may decrease wear duration.

1. Enrol patient in Zio Online Portal - Either Zio Reports or ZioSuite.
Call Customer Service with any questions.
2. Remove the Zio XT monitor from the packaging.
3. On the front of *Patient Instructions & Button Press Log*, write the ID number and initials, start date and time. Instruct the patient to write the date when they remove the Zio XT monitor for return.

The diagram shows the front of the Zio XT Patient Instructions & Button Press Log. The form includes fields for Patient ID Number, Name, Start Date, Time, and Removal instructions. It also has a section for the patient to complete, including the Date Removed and a space for the SN Sticker. Arrows indicate where the Office and Patient write.

Zio^{XT}
**PATIENT INSTRUCTIONS
& BUTTON PRESS LOG**

Office Writes →

Patient Writes →

PATIENT ID NUMBER:	
NAME:	
START DATE: dd / mm / yyyy	TIME:
REMOVAL: <input type="checkbox"/> Physician prescribed duration of _____ days	
<input type="checkbox"/> Patient to wear as long as possible (up to 14 days)	
TO BE COMPLETED BY PATIENT	
DATE REMOVED: dd / mm / yyyy	
SN STICKER HERE	

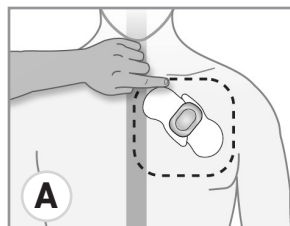
APPLICATION INSTRUCTIONS

1. Have the patient stand with their arms resting at their sides during the Zio XT monitor application.

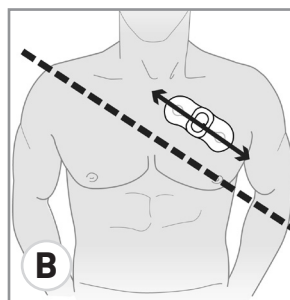
- If the patient cannot stand, have them sit up straight with their arms relaxed at their side.
- Make sure chest area is free of perspiration.

2. Determine placement area.

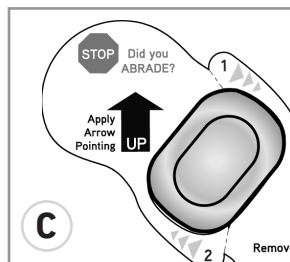
- You may hold the Zio XT monitor up to the patient's **left** chest and use it as a guide to determine the placement area (*Fig. A*).
 - About 1 finger width below the collar bone
 - Edge of the Zio XT monitor next to the sternum
- The recommended placement is similar to a modified Lead II configuration (*Fig. B*).
 - Electrodes should be placed parallel to a line drawn from right shoulder to left nipple.
- The writing on the top label should be parallel to the ground and the arrow should be pointing straight up when the Zio XT monitor is oriented correctly (*Fig. C*).



Prep & Placement Area



Placement Angle

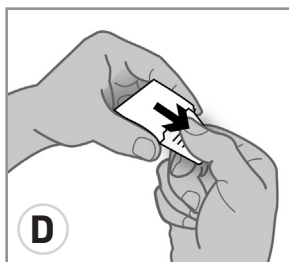


Arrow Points Up

- **Note that the preparation area will need to extend larger than where the Zio XT monitor will be applied.**
 - Due to the nature of the adhesive, the Zio XT monitor may move slightly during the monitoring period. A blue gel may become visible under the wings of the Zio XT monitor.

3. Prepare the patient's skin using the materials from the Skin Prep & Placement Kit:

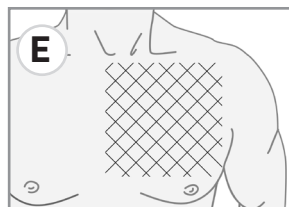
- Remove the razor by holding the cover on the sides and pulling down on the handle (*Fig. D*). **Shave** the placement area. **Do not** add pressure to the razor; shave across the skin lightly.



How to Remove Razor

- **NOTE:** If a cut should occur, treat the site and only continue once bleeding has stopped. After it has stopped, do not place electrode over cut.
- **NOTE:** Dispose of razor in proper sharps container.

- Applying pressure, **exfoliate** the entire area using 40 broad strokes (*Fig. E*).



Exfoliate Skin

- **NOTE:** Be sure to exfoliate the full prep area.

- Using all alcohol pads, **clean** the area thoroughly. Allow skin to dry for 1 minute.
 - At application, any hair, skin oil, residue or moisture present can interfere with the duration and quality of the test.

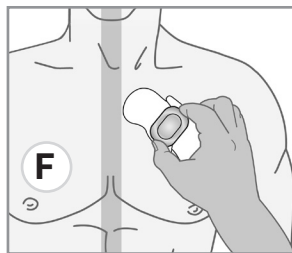


The steps above are critical to achieve good signal quality and adhesion.

4. Holding the Zio XT monitor in the middle, over the top and bottom, pull off the clear backings.

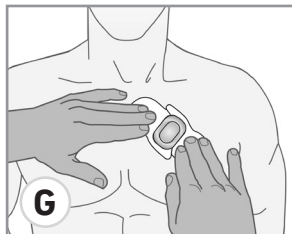
- Be sure not to touch the exposed adhesive.

- 5. Apply the Zio XT monitor to the patient's chest, making sure to place it in the prepared area (Fig. F).**



Place on Chest

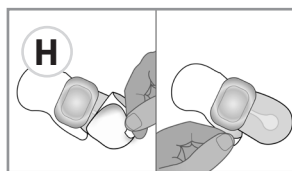
- 6. Apply continuous firm pressure across the wings of the device for approximately 2 minutes (Fig. G).**



Press for 2 Minutes

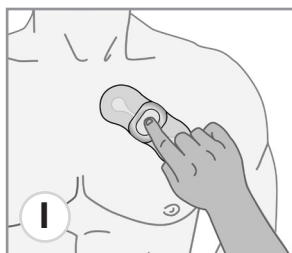
- 7. Remove the top label as illustrated (Fig. H):**

- Hold the tab labeled "1" and peel in the direction of the arrows, tearing along the perforations. Follow with tab "2."



Remove Top Label

- 8. Firmly press the 'Zio' button and release (Fig. I). Watch for the green light to flash 5 times indicating that the monitoring has started.**



Press Button to Turn On

- 9. After you see the green light:**

- Help the patient practice pressing the 'Zio' button. This will familiarise the patient with the action of pressing the button when symptoms are felt. Button presses within the first five minutes of activation will not be captured, however the device will continue to record.

PATIENT USAGE INSTRUCTIONS



Helpful hints to maximize wear time:

- The patient should try to avoid activities that cause excessive sweating as this may cause the Zio XT monitor to slide from its original position or fall off. For this reason, the patient may want to limit exercise while wearing the Zio XT monitor.

- It is normal to experience some itching.

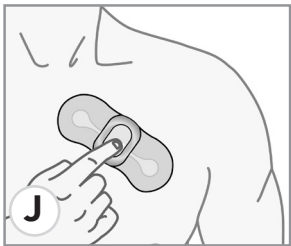
If skin irritation such as severe redness, itching or allergic symptoms develop, remove the Zio XT monitor from the patient's chest.

Please call 0808 189 3411 for support.

- The patient should avoid showering during the first 24 hours of wearing the Zio XT monitor. In general, the patient should keep shower duration short, and if possible, face away from the water.
- The patient should not submerge the Zio XT monitor in water (e.g., pool or hot tub) as this may affect the adhesive strength. Patients may shower and bathe. During a bath, it is important for the patient to keep the device above water.
- The patient should keep soaps and lotions away from the Zio XT monitor.
- After showering the patient should:
 - Hold the Zio XT monitor down with one hand to secure it while towel drying so that it is not accidentally knocked off.
 - Press the Zio XT monitor against skin to secure it.

REVIEW WITH YOUR PATIENT

1. The Zio XT monitor is intended to be worn continuously for up to 14 days, through sleep and showering. (Actual wear time may vary by patient). Should the Zio XT monitor fall-off, instruct the patient **NOT** to re-attach and post back to iRhythm for processing.
2. The Zio XT monitor should not be removed before the end of the prescribed period unless skin irritation or itching is severe or hives or blisters develop (see Removal Instructions on page 13). Please call 0808 189 3411 for support.
3. If symptoms are felt the patient should press the 'Zio' button on the device (Fig. J).
 - This will mark the ECG recording, indicating that the patient felt a symptom.
 - The Zio XT monitor will *not* show a light when the patient presses the button.
 - A click should be felt and/or heard, indicating that the button has been pressed and a symptom has been marked.
4. Each time the patient presses the 'Zio' button to mark a symptom, an entry should be made in the *Patient Instructions & Button Press Log* (Fig. K).
5. The Zio XT monitor can be worn through security screenings. A security statement is provided in the *Patient Instructions & Button Press Log*.



Location of Button;
Press to Mark Symptom

A diagram of the 'BUTTON PRESS LOG' page. It has a header 'BUTTON PRESS LOG' and a section 'I pressed the button on...' with a date and time field. Below this is a section '...because I felt:' with a list of symptoms and checkboxes. A small circle with the letter 'K' is next to the list. The symptoms listed are: anxious, arm or neck pain/tingling, chest pain or pressure, dizziness, fainted, light headed, pounding, fluttering or racing, short of breath, skipped beat(s), irregular beats, and other (describe).

BUTTON PRESS LOG	
I pressed the button on...	
[] / [] / [] : [] [] AM PM	
...because I felt:	
<input type="checkbox"/> anxious	<input type="checkbox"/> pounding
<input type="checkbox"/> arm or neck pain/tingling	<input type="checkbox"/> fluttering or racing
<input type="checkbox"/> chest pain or pressure	<input type="checkbox"/> short of breath
<input type="checkbox"/> dizziness	<input type="checkbox"/> skipped beat(s)
<input type="checkbox"/> fainted	<input type="checkbox"/> irregular beats
<input type="checkbox"/> light headed	<input type="checkbox"/> other (describe): []

Button Press Log Page

SECURITY SCREENING STATEMENT

(Included in the Patient Instructions & Button Press Log)

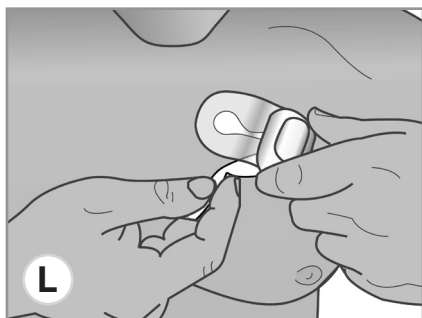
This person is wearing an iRhythm Zio XT monitor prescribed by their physician. This device is currently adhered to the patient's chest, where it is monitoring their heart. It can only be removed under the direction of their physician.

Please call 0808 189 3411 for support.

REMOVAL & RETURN INSTRUCTIONS

REVIEW WITH YOUR PATIENT

1. At the end of the wear period, detach the adhesive remover wipe from the back page of the *Patient Instructions & Button Press Log*.
2. Gently tilt the centre of the Zio XT monitor up. Using the adhesive remover, sweep the wipe between the skin and the Zio XT monitor while peeling the right side from the centre out. Repeat for the other side, peeling from the centre out (*Fig. L*).



Adhesive Remover Aids Removal



If patient has a known allergic reaction to limonene, the active ingredient in the adhesive remover, have them use baby oil or petroleum jelly to aid removal instead of the adhesive remover wipe.

3. Wash skin with mild soap, rinse with water, and pat dry.
4. Stick the Zio XT monitor flat to the area indicated on the last page of the *Patient Instructions & Button Press Log*.
 - The residual adhesive on the Zio XT monitor should be sufficient to affix the device to the page.
5. Place the entire booklet, including the Zio XT monitor, into the postage-paid return box, along with the Patient Instructions & Button Press Log, seal the box with tape, and put it in the post **as soon as possible**.

Please call 0808 189 3411 for support.

TROUBLESHOOTING

APPLICATION

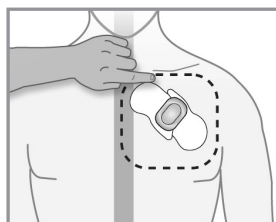
1. **The chest area was prepped and the device was applied. When the 'Zio' button was pressed, it flashed orange (rather than green) five times.**

Press down on the adhesive wings for a moment, so the device makes better contact with the skin. Then, press the 'Zio' button again to attempt activation. If the device does not activate (flash green) on the second attempt, please call 0808 189 3411.

2. **I think I placed the Zio XT monitor in the wrong position.**

Can I remove it and reposition it?

No. If the Zio XT monitor is over the heart in a slight diagonal as shown, the positioning should be acceptable. **Do not** attempt to re-apply the Zio XT monitor.



3. **The top label was peeled off, but there still seems to be a white label stuck to the wings of the Zio XT monitor.**

The top label may have separated. Peel the remaining white labels from the centre of the Zio XT monitor outward.

4. **Are there tests or treatments that are not compatible with the Zio XT monitor?**

Yes. The following are not recommended during wear of the Zio XT monitor:

- Magnetic Field(s): Magnetic Resonance Imaging (MRI); MRI Technician; Any job where the patient may be exposed to a large magnetic field
- Neuromuscular Stimulators: Brain Stimulator; Neurostimulator; Spinal Stimulator; TENS Unit
- External Cardioversion/Defibrillation

5. **Can the Zio XT monitor be left on a patient during Cardioversion/Defibrillation?**

No, the Zio XT monitor should be removed if the patient requires Cardioversion or Defibrillation.

6. Which tests and treatments are okay to have while the patient is wearing the Zio XT monitor?

Wear of the Zio XT monitor will not interfere during the following:

- | | |
|---|---|
| a. Computed Tomography (CAT Scan) | g. Ultrasound |
| b. Electrocardiogram (EKG) | h. Nuclear Stress Test |
| c. Echocardiogram | i. Positron Emissions Tomography (PET SCAN) |
| d. Electron-beam Computed Tomography (EBCT) | j. X-RAY |
| e. Electroencephalogram (EEG) | k. Radiation |
| f. Mammogram | |

NOTE: The image of the Zio XT monitor may be visible if chest fields are being imaged.

PATIENT QUESTIONS

1. How long is the patient supposed to wear the Zio XT monitor?

A patient can wear the Zio XT monitor for up to 14 days or as prescribed.

Note: The Zio XT monitor will not record ECG data after 14 days.

Based on individual wear experiences the patient's actual wear time may be shorter than prescribed.

2. What is the Zio XT monitor doing?

The Zio XT monitor is recording every heartbeat. Pressing the 'Zio' button indicates that the patient felt a symptom at that time.

3. Who should the patient call if they have questions about the Zio XT monitor or if it falls off?

The patient can refer to FAQs in the *Patient Instructions & Button Press Log* or call 0808 189 3411.

4. What should the patient do if they feel a symptom?

Press the 'Zio' button and fill out a page of the *Patient Instructions & Button Press Log*.

5. What if the patient forgets to press the 'Zio' button when they feel a symptom?

While pressing the 'Zio' button is important, the Zio XT monitor is recording every heartbeat.

6. What if the patient presses the 'Zio' button but forgets to write down the information on a Button Press Log page?

While the *Button Press Log* information is useful, pressing the 'Zio' button indicates that the patient felt a symptom at that time.

7. What if the patient does not have symptoms?

That's okay. The Zio XT monitor records every heartbeat.

8. What activities should the patient avoid while wearing the Zio XT monitor?

Activities that cause excessive sweating. This could cause the Zio XT monitor to slide, become loose, fall off, and shorten wear time.

9. Can the patient exercise while wearing the Zio XT monitor?

Yes, but activities that cause excessive sweating may cause the monitor to slide, become loose, fall off, or shorten wear time. In the first 24 hours, the patient should avoid exercise so that the monitor can fully adhere to their skin.

10. Can the patient shower with the Zio XT monitor on?

Yes, but the patient should avoid showering during the first 24 hours of wearing the Zio XT monitor. After that, take brief showers with your back facing the shower head, and keep soaps and lotions away from the Zio XT monitor. When towel-drying, hold down the Zio XT monitor with one hand, and press it against your skin to secure.

11. Can the patient take a bath?

Yes, but the patient should keep the Zio XT monitor above water.

12. Can the patient go swimming or in a hot tub?

No. The Zio XT monitor should not be submerged in water.

13. Is it normal for the Zio XT monitor to move slightly from its original position?

Yes. The Zio XT monitor may move slightly from its original position. A blue gel may become visible under the wings of the Zio XT monitor.

14. Is it normal to experience skin irritation or itchiness in the area of the Zio XT monitor?

If skin irritation such as severe redness, itching or allergic symptoms develop, remove the Zio XT monitor from the patient's chest and call 0800 189 3411.

15. Is it normal for the Zio XT monitor wings to become cloudy in appearance?

Yes, the wings of the Zio XT monitor may become cloudy after a few days of wear.

16. What should the patient do if they think they see blood under the Zio XT monitor?

Instruct the patient to call 0808 189 3411. It is likely due to a small shaving cut when the device was applied to the chest.

17. How will the patient know the Zio XT monitor is working?

Once the Zio XT monitor is applied to the body, and the 'Zio' button is pressed, a green light should flash, indicating that it was turned on. Afterwards, it will not flash or make noise when it is working properly.

18. Will the Zio XT monitor flash while the patient is wearing it?

No. If it is working properly, the Zio XT monitor will not flash or make noise. If the patient sees the Zio XT monitor flashing orange, this does not mean there is a problem with the patient's heart; it just means that the monitor is not well attached.

Instruct the patient to press evenly on the Zio XT monitor for 3 to 5 minutes. If flashing persists or reoccurs, have the patient call 0808 189 3411.

19. Can a patient travel with the Zio XT monitor on?

Yes. If questioned during security screening there is a statement included in the *Patient Instruction & Button Press Log* for them to reference.

20. When the patient removes the Zio XT monitor, it is flashing orange. Is this okay?

The Zio XT monitor may blink orange after removal. It is okay to post back the device while it is blinking.

DEVICE SPECIFICATIONS

MONITOR PERFORMANCE CHARACTERISTICS

ECG Channels	1 channel
Memory capacity	14 days
Recording Format	Continuous
Service Life	Up to 14 days
Shelf Life	6 months

ELECTRICAL CHARACTERISTICS

ECG Frequency Response	0.5Hz to 30Hz
ECG Input Impedance	$\geq 10\text{ M}\Omega$
ECG Differential Range	$\pm 1.65\text{ mV}$
ECG A/D Sampling Rate	200 Hz
ECG Resolution	10 bits
Gain Accuracy	Maximum amplitude error <5%
Gain Stability	<3% over a 24-hour period
Timing Accuracy	< 30sec over 24 hours

POWER SPECIFICATIONS

Battery Type	2 Lithium Manganese Dioxide Coin Cells
Battery Life	14 days

PHYSICAL CHARACTERISTICS

Dimensions	5.20 x 2.02 x 0.53 in / 132 x 51 x 14 mm
Weight	24.5 g

ENVIRONMENTAL SPECIFICATIONS

Operational Temperature	36 to 104° F / 2 - 40° C
Operational Altitude	-1,000 to 10,000 ft / -305 - 3,048 m
Allowable Transit Temperature	-4 - 104° F / -20 - 40° C
Recommended Storage Temperature	55 - 85° F / 13 - 30° C
Storage Humidity	10% - 95% (non-condensing)
Storage Altitude	-1,000 to 14,000 ft / -305 - 4,267 m

ELECTRICAL SAFETY AND COMPATIBILITY

- CAUTION: The Zio XT monitor needs special precautions regarding EMC and needs to be utilized according to the EMC information provided in the following tables.
- CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.
- WARNING: The Zio XT monitor should not be used adjacent to or stacked with other equipment.

Table 1: Guidance and manufacturer’s declaration— electromagnetic emissions		
The Zio XT monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Zio XT monitor should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Zio XT monitor 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 Zio XT monitor is suitable for use in all establishments, including domestic establishments.

Table 2: Guidance and manufacturer's declaration—electromagnetic immunity

The Zio XT monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Zio XT monitor 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 ±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 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3: Guidance and manufacturer's declaration—electromagnetic immunity

The Zio XT monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Zio XT monitor should assure that it is used in such an environment.


Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Zio XT monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Table 3, Continued

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 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 Zio XT monitor is used exceeds the applicable RF compliance level above, the Zio XT monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Zio XT monitor.
- ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the Zio XT monitor

The Zio XT monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Zio XT monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Zio XT monitor 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	80 MHz to 800 MHz	80 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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 MHz and 800 MHz, the separation distance for 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.

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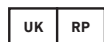
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