

Zio^{XT}[®]

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 Patch ECG Recorder and the (2) proprietary algorithm software.

The Zio XT Patch is a single-patient-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The Zio XT Patch 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 Patch and returns it by mail to iRhythm for processing. After receipt, the data is analyzed by iRhythm's proprietary algorithm before a Certified Cardiographic Technician (CCT) reviews the results and generates a report of the key findings.


















INDICATIONS FOR USE

The Zio XT Patch is a prescription-only, single patient use, continuously recording ECG monitor that can be worn up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue or anxiety.

CONTRAINDICATIONS

- Do not use the Zio XT Patch 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 Patch 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 Patch on patients with neuro-stimulator, as it may disrupt the quality of ECG data.
- Do not use the Zio XT Patch on patients who do not have the competency to wear the device for the prescribed patching period.

SYMBOLS

| | | |
|---|---|---|
|  Serial Number |  Catalogue number |  Prescription use only |
|  Manufacturer |  Date of manufacture |  Net quantity of contents |
|  Temperature limitations |  Use by |  Do Not Reuse |
|  Do not use if package is damaged |  Humidity limitations |  Consult instructions for use |
|  Splash-proof equipment |  Type BF applied part |  Separate collection |
|  Caution |  Magnetic Resonance (MR) unsafe | |

WARNINGS

- Do not use the Zio XT Patch 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 Patch on multiple patients. It is a single patient use device. Reuse will cause incorrect patient data and may experience skin irritation.



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

Rx
ONLY

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



PRECAUTIONS

- The Zio XT Patch 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 Patch 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 Patch if package is damaged. Device may not perform as intended.
- Safety and effectiveness of the Zio XT Patch on pediatric patients (younger than 18 years old) has not been established.
- Safety and effectiveness of the Zio XT Patch 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.

ZIO XT PATCH ANALYSIS

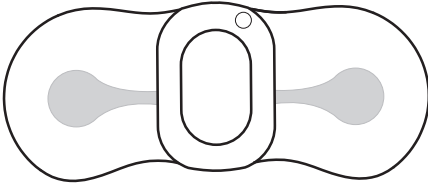
The Zio XT Patch is analyzed at the iRhythm Clinical Center. iRhythm is an Independent Diagnostic Testing Facility (IDTF) dedicated to providing world-class diagnostic service. As an IDTF, we adhere to Medicare Independent Diagnostic Testing Facility Performance Standards. A link to these standards (42 C.F.R.section 410.33) can be found at the iRhythm website www.irhythmtech.com.

NOTICE OF PRIVACY PRACTICES

iRhythm is committed to upholding patient privacy and protecting personal information, in particular Protected Health Information (PHI) 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 via their doctor. Our full Notice of Privacy Practices, found at www.irhythmtech.com, describes our privacy practices, our legal duties, and patients' rights concerning PHI.

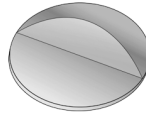
PACKAGE CONTENTS

1 Zio XT Patch



1 Skin Prep & Placement Kit **containing:**

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



1 Patient Instructions & Button Press Log **containing:**

- 1 adhesive remover wipe
- 1 box seal

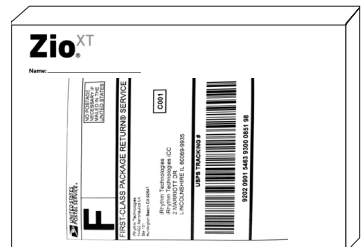
1 Postage-paid return box

Zio^{XT}
PATIENT INSTRUCTIONS
& BUTTON PRESS LOG

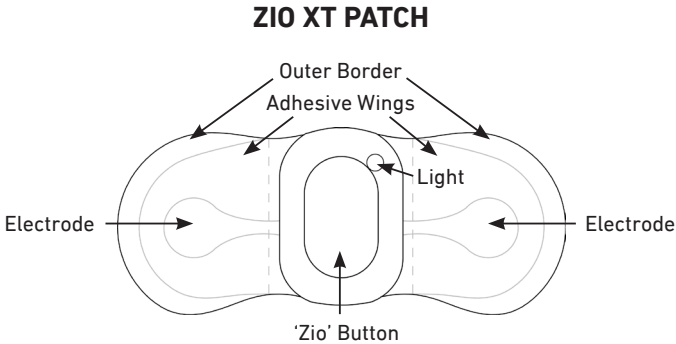
NAME: _____
PHYSICIAN: _____
START DATE: / / TIME: _____
REMOVAL: Physician prescribed duration of _____ days
 Patient to wear as long as possible (up to 14 days)

TO BE COMPLETED BY PATIENT
DATE REMOVED: / /

5x8 STICKER HERE



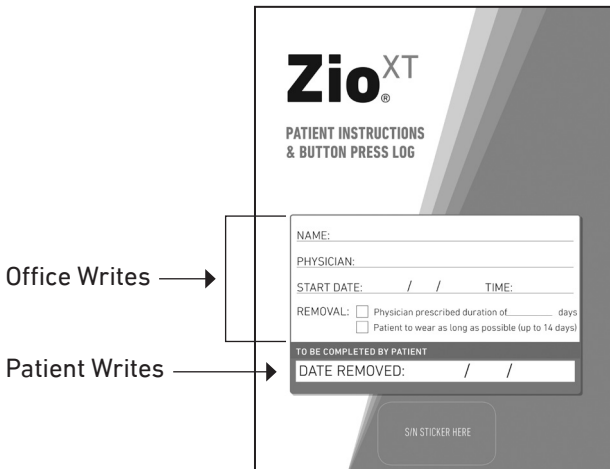
DEVICE DIAGRAM



GETTING STARTED

The Zio XT Patch 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. Enroll patient online at www.zioreports.com.
2. Remove the Zio XT Patch from the packaging.
3. On the front of Patient Instructions & Button Press Log, write the patient's name, physician, start date and time. Instruct the patient to write the date when they remove the Zio XT Patch for return.



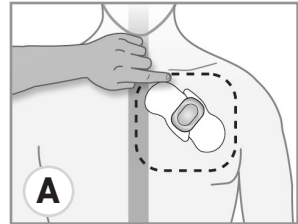
APPLICATION INSTRUCTIONS

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

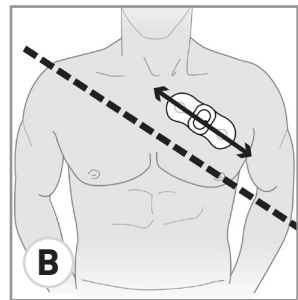
- If the patient cannot stand, have them sit up straight with their arms relaxed at their side.
- Make sure chest area is free of perspiration.

2. Determine placement area.

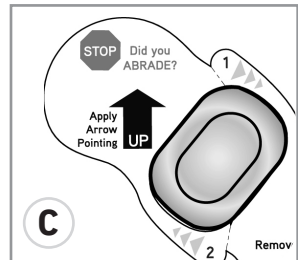
- You may hold the Zio XT Patch up to the patient's **left** chest and use it as a guide to determine the placement area (*Fig. A*).
 - About 1 finger width below the collar bone
 - Edge of the Zio XT Patch next to the sternum
- The recommended placement is similar to a modified Lead II configuration (*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 Patch is oriented correctly (*Fig. C*).



Prep & Placement Area



Placement Angle

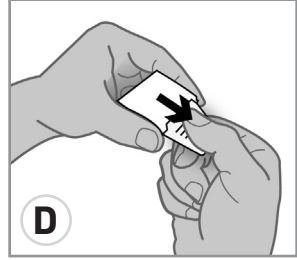


Arrow Points Up

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

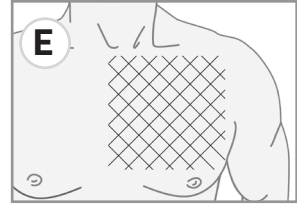
3. Prepare the patient's skin using the materials from the Skin Prep & Placement Kit:

- a. 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.
- **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.



How to Remove Razor

- b. Applying pressure, **abrade** the entire area using 40 broad strokes (Fig. E).
- **NOTE:** Be sure to abrade the full prep area.



Abrade Skin

- c. 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.

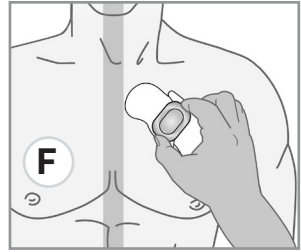


The steps above are critical to achieve good signal quality and adhesion.

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

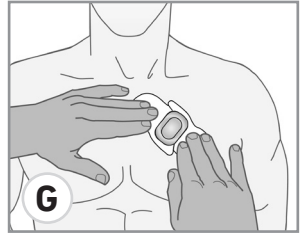
- Be sure not to touch the exposed adhesive.

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



Place on Chest

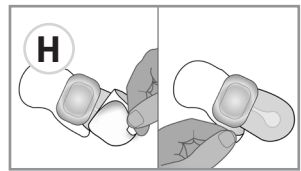
6. **Apply continuous firm pressure across the wings of the device for approximately 2 minutes (Fig. G).**



Press for 2 Minutes

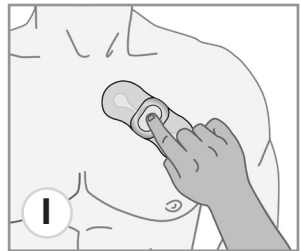
7. **Remove the top label as illustrated (Fig. H):**

- Hold the tab labeled "1" and peel in the direction of the arrows, tearing along the perforations. Follow with tab "2."
- Press firmly across the entire device for 2 minutes, working adhesive into the skin.



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 familiarize 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

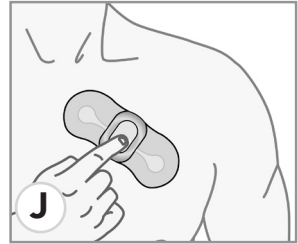


Helpful hints to maximize wear time:

- In the first 24 hours the Zio XT Patch is bonding to the patient's skin. The patient should avoid activities which may cause sweating in the first 24 hours.
- The patient should try to avoid activities that cause excessive sweating as this may cause the Zio XT Patch to slide from its original position or fall off. For this reason, the patient may want to limit exercise while wearing the Zio XT Patch.
 - It is normal to experience some itching, especially during or immediately after exercise and/or excessive sweating. The itching should subside when the patient cools down. If skin irritation such as severe redness, itching or allergic symptoms develop, the patient should remove the Zio XT Patch and call 1.888.693.2401 for Customer Care.
- The patient should avoid showering during the first 24 hours of wearing the Zio XT Patch. 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 Patch 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 Patch.
- After showering the patient should:
 - Hold the Zio XT Patch down with one hand to secure it while towel drying so that it is not accidentally knocked off.
 - Press the Zio XT Patch against skin to secure it.

REVIEW WITH YOUR PATIENT

1. The Zio XT Patch is intended to be worn continuously for up to 14 days, through sleep and showering. (Actual wear time may vary by patient.) Ensure the patient understands the purpose and importance of the device. If the Zio XT Patch falls-off, please call Customer Care, **1.888.693.2401**.
2. The Zio XT Patch should not be removed before the end of the prescribed period unless skin irritation such as severe redness, itching or allergic symptoms develop (see Removal Instructions on page 13). Please call Customer Care, **1.888.693.2401**.
3. If symptoms are felt the patient should press the 'Zio' button on the device (Fig. J).



Location of Button;
Press to Mark Symptom

- This will mark the ECG recording, indicating that the patient felt a symptom.
- The Zio XT Patch 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.

A scan of the 'BUTTON PRESS LOG' page. It has a header 'BUTTON PRESS LOG' and a section 'I pressed the button on...' with a grid for date and time (AM/PM). Below is a section '...because I felt:' with a grid of checkboxes for symptoms like '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)'. A letter 'K' is in a circle in the bottom left corner.

Button Press Log Page

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 Patch can be worn through security screenings. A security statement is provided in the *Patient Instructions & Button Press Log*.

SECURITY SCREENING STATEMENT

(Included in the Patient Instructions & Button Press Log)

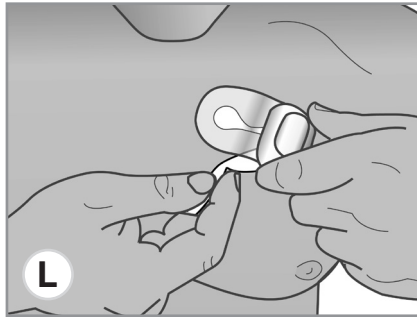
This person is wearing an iRhythm Zio XT Patch prescribed by their physician. This device is currently adhered to the patient's chest, where it is monitoring their heart. It can only be removed under the direction of their physician.

If you have any questions, please contact the iRhythm Customer Care at **1.888.693.2401**, 24 hours/day, 7 days/week.

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 center of the Zio XT Patch up. Using the adhesive remover, sweep the wipe between the skin and the Zio XT Patch while peeling the right side from the center out. Repeat for the other side, peeling from the center 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 Patch flat to the area indicated on the last page of the *Patient Instructions & Button Press Log*.
 - The residual adhesive on the Zio XT Patch should be sufficient to affix the device to the page.
5. Place the entire booklet, including the Zio XT Patch, into the postage-paid return box, seal the box with tape, and drop it in a U.S. mailbox as **soon as possible**.

TROUBLESHOOTING

FOR CUSTOMER CARE, CALL **1.888.693.2401**

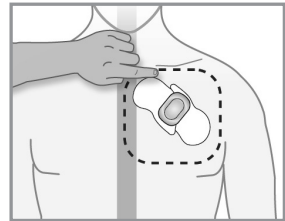
FREQUENTLY ASKED QUESTIONS

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 contact Customer Care at 1.888.693.2401.

- 2. I think I placed the Zio XT Patch in the wrong position. Can I remove it and reposition it?**

No. If the Zio XT Patch is over the heart in a slight diagonal as shown, the positioning should be acceptable. DO NOT attempt to reapply the Zio XT Patch.



- 3. The top label was peeled off, but there still seems to be a white label stuck to the wings of the Zio XT Patch.**
The top label may have separated. Peel the remaining white labels from the center of the Zio XT Patch outward.
- 4. Are there tests or treatments that are not compatible with the Zio XT Patch?**

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

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

NOTE: Data may not be interpretable during the time the stimulators are being used. Usage is at physician's discretion.

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

No, the Zio XT Patch 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 Patch?

Wear of the Zio XT Patch 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 Patch may be visible if chest fields are being imaged.

PATIENT QUESTIONS

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

A patient can wear the Zio XT Patch for up to 14 days or as prescribed. Note: The Zio XT Patch 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 Patch doing?

The Zio XT Patch 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 Patch or if it falls off?

The patient can refer to FAQs in the *Patient Instructions & Button Press Log* or call Customer Care at 1.888.693.2401.

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 Patch 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 Patch records every heartbeat.

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

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

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

Yes, but only after the first 24 hours. This is when the Zio XT Patch is bonding to their skin. After 24 hours, activities that cause excessive sweating may shorten wear time.

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

Yes, but please avoid showering during the first 24 hours of wearing the Zio XT Patch. After that, take brief showers with your back facing the shower head, and keep soaps and lotions away from the Zio XT Patch. When towel-drying, hold down the Zio XT Patch 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 Patch above water.

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

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

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

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

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

Patients have reported skin irritation and/or itching while wearing the Zio XT Patch. If skin irritation such as severe redness, itching or allergic symptoms develop instruct the patient to remove the Zio XT Patch and call Customer Care at 1.888.693.2401.

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

Yes, the wings of the Zio XT Patch 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 Patch?

Instruct the patient to call Customer Care at 1.888.693.2401. 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 Patch is working?

Once the Zio XT Patch 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 Patch flash while the patient is wearing it?

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

Instruct the patient to press evenly on the Zio XT Patch for 3 to 5 minutes. If flashing persists or reoccurs, have the patient call Customer Care at 1.888.693.2401.

19. Can a patient travel with the Zio XT Patch 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 Patch, it is flashing orange. Is this okay?

The Zio XT Patch may blink orange after removal. It is okay to mail the device while it is blinking.

21. Does the device contain latex?

The Zio XT Patch is not manufactured with natural rubber latex.

DEVICE SPECIFICATIONS

PATCH 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

| | |
|------------------------|-----------------------------|
| Medical Equipment Type | BF Applied Part |
| 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 | 64 - 80° F / 18 - 27° 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 Patch 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 Patch should not be used adjacent to or stacked with other equipment.

Table 1: Guidance and manufacturer’s declaration— electromagnetic emissions

The Zio XT Patch is intended for use in the electromagnetic environment specified below. The customer or the user of the Zio XT Patch 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 Patch 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 Patch is suitable for use in all establishments, including domestic establishments. |

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

The Zio XT Patch is intended for use in the electromagnetic environment specified below. The customer or the user of the Zio XT Patch 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 Patch is intended for use in the electromagnetic environment specified below. The customer or the user of the Zio XT Patch 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 Patch, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>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).</p> <p>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</p> <p>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 Patch is used exceeds the applicable RF compliance level above, the Zio XT Patch 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 Patch.
- ^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 Patch

The Zio XT Patch is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Zio XT Patch can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Zio XT Patch 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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