Zio® AT

CLINICAL REFERENCE MANUAL

Rx ONLY

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DESCRIPTION

Zio AT connected continuous ambulatory monitoring system ("Zio AT system") is an electrocardiogram (ECG) monitoring system. It consists of four components: (1) Zio AT patch ECG monitor that records continuously through the entire wear period, (2) Zio AT wireless gateway that provides connectivity between the patch and the iRhythm monitoring center, (3) Zio arrhythmia detection algorithm and (4) ZioSuite clinician portal.

Zio AT system is a single-patient-use ECG monitor that provides a continuous, single-channel recording in addition to symptomatic and asymptomatic data transmission. The Zio AT patch is applied and activated by the patient. Once activated, the patch records ECG without patient interaction, with the goal of improving patient compliance via simplicity of operation. The Zio AT patch, in conjunction with the wireless gateway and the Zio arrhythmia detection algorithm, has arrhythmia auto-detection capabilities. Additionally, patients have the option of pressing a convenient trigger button which marks the continuous record and initiates a wireless transfer of a 90 second ECG strip. The wireless transfer of data is enabled by the Zio AT gateway, which requires proximity to the Zio AT device and cellular reception; however, no patient interaction is required to transmit.

Zio AT is a Mobile Cardiac Telemetry (MCT) monitoring solution designed to optimize battery power in order to offer patients 14 day continuous monitoring without any patient manipulations required. As a result, the device has a maximum threshold of transmitting 100 Patient Triggers and 500 Auto Triggers during wear. When a patient is approaching the limit for either transmission type, iRhythm reaches out to the account to determine whether to send another Zio AT device to the patient.

The patient is encouraged to document symptomatic events, which will support symptom-rhythm correlation in the Zio AT reports. At the conclusion of the wear period, the patient removes the Zio AT patch and returns it, along with the gateway, by mail to an iRhythm data processing center.

Upon receipt of symptomatic/asymptomatic transmissions or downloaded continuous ECG data at iRhythm's Independent Diagnostic Testing Facility (IDTF) Clinical Center, the data is processed by iRhythm's proprietary algorithm before an iRhythm Certified Cardiographic Technician (CCT) reviews the results and generates a report.

Upon explicit request from a clinician responsible for the patient's healthcare, segments of ECG data from the continuous recording on the patch can also be wirelessly retrieved during the wear period.

INDICATIONS FOR USE

The Zio AT ECG monitoring system is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram (ECG) information for long-term monitoring. While continuously recording patient ECG, both patient-triggered and automatically detected arrhythmia events are transmitted to a monitoring center for reporting. After wear, a final report is generated based on beat-to-beat information from the entire ECG recording. It is indicated for use on patients 18 years or older 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. The reports are provided for review by the intended user to render a diagnosis based on clinical judgment and experience. It is not intended for use on critical care patients.

CONTRAINDICATIONS

- Do not use Zio AT for patients with symptomatic episodes where variations in cardiac performance could result in immediate danger to the patient or when real-time or in-patient monitoring should be prescribed.
- Do not use Zio AT for patients with known history of life threatening arrhythmias.
- Do not use Zio AT in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI.
- Do not use Zio AT on patients with a neuro-stimulator, as it may disrupt the quality of ECG data.
- Do not use Zio AT on patients who do not have the competency to wear the device for the prescribed monitoring period.

WARNINGS

- Do not use the Zio AT 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 AT patch on multiple patients. It is a single patient use device. Reuse will cause incorrect patient data and patient may experience cross contamination.
- Do not use Zio AT system on patients residing in areas with limited to no cellular reception.
- Do not modify the Zio AT system.
- The Zio AT system is MR Unsafe!
    - Do not expose the Zio AT patch or gateway to a magnetic resonance (MR) environment.
    - The Zio AT patch or gateway may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
    - Thermal injury and burns may occur due to the metal components of the Zio AT patch that can heat during MR scanning.
    - The Zio AT patch may generate artifacts in the MR image.
    - The Zio AT patch or gateway may not function properly due to the strong magnetic and radio-frequency fields generated by the MR scanner.

If skin irritation such as severe redness, itching or allergic symptoms develop, remove the Zio AT patch from the patient's chest. Call iRhythm Customer Service at 1.888.693.2401.

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

ELECTRICAL SAFETY COMPATABILITY

- CAUTION: The Zio AT system 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 AT system should not be used adjacent to or stacked with other equipment.
- WARNING: The Zio AT system may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSIONS requirements.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Zio AT patch or gateway. Otherwise, degradation of the performance of this equipment could result.

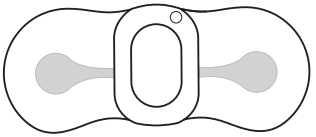
PRECAUTIONS

- Safety and effectiveness of the Zio AT 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.
- Safety and effectiveness of the Zio AT system on pediatric patients (younger than 18 years old) has not been established.
- The Zio AT system includes temperature and humidity limitations when stored/transported. If exposed during storage/transport, patients may experience degradation of adhesive performance causing the Zio AT patch to slip or fall off during the patient wear duration.
- The Zio AT system 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 AT system if package is damaged. Device may not perform as intended.
- Keep device and packaging away from young children. Contents may be harmful if swallowed. Patch contains button cell batteries that are not accessible during normal use but, if exposed, are known choking hazards and may cause severe tissue injury if ingested.

- The Zio AT device has a maximum threshold of transmitting 100 Patient-Triggers and 500 Auto-Triggers during wear, after which point the device no longer transmits for whichever trigger limit has been reached. When the patient is approaching a maximum transmission limit, it is imperative that the Healthcare Provider respond to iRhythm's outreach to confirm whether to send another Zio AT monitor to the patient so we can deliver the expected Zio AT service for continuous cardiac monitoring and reporting.
- Activation of the Zio AT monitor does not initiate monitoring services. A completed patient registration is the prescription order for monitoring services. If you activate a Zio AT monitor before completing the patient registration, notifications of clinically actionable arrhythmias will be delayed until patient registration is complete.
- Registration errors may result in limited functionality or erroneous ECG reporting. Utmost caution should be applied to ensure that patient registration is accurate and complete.

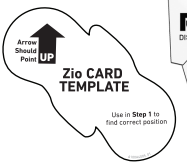
PACKAGE CONTENTS

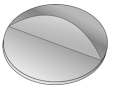
1 Zio AT patch



1 Zio AT gateway, containing:
- 1 postage-paid return envelope

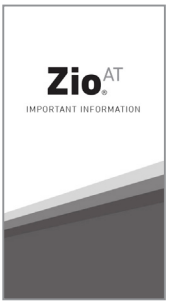
1 Skin preparation kit containing:
- 1 patch card template
- 1 disposable razor
- 1 abrader disc
- 4 alcohol wipes





1 Application instructions

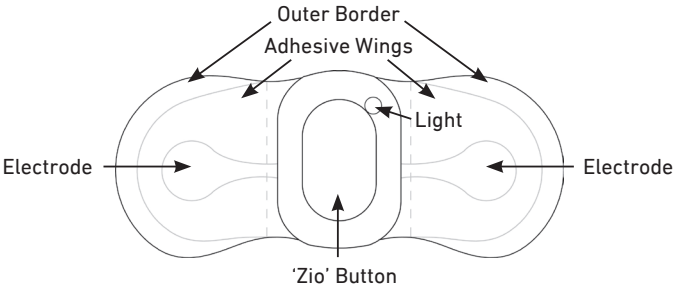
1 Important information pamphlet



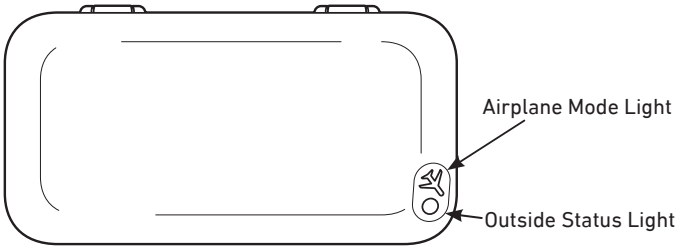
1 Wearing Your Zio manual & button press log containing:
- 1 adhesive remover wipe
- 1 patient consent form
- 1 patient survey

DEVICE DIAGRAMS

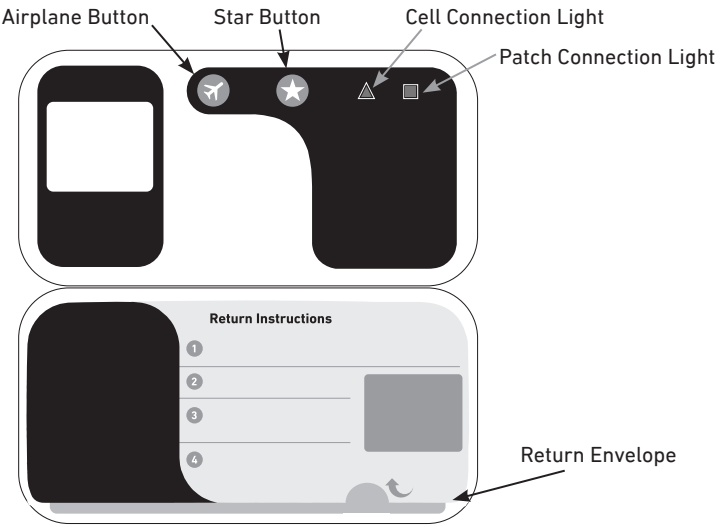
Zio Patch



Zio Gateway Exterior



Zio Gateway Interior



ACCOUNT SETUP

To allow effective use of the Zio system, an account on iRhythm's patient management system (www.ziosuite.com) is assigned to the clinic.

Ensure you can access iRhythm patient management system via provided username and password. If you are unable to access ziosuite.com, please contact iRhythm Customer Service at **1.888.693.2401**.

DURING PATIENT VISIT

REGISTRATION

Register patient online at **www.ziosuite.com**.

iRhythm may contact the patient if any additional information is required.

APPLICATION INSTRUCTIONS

The Zio AT package contains instructions on how to apply the patch and activate the patch and gateway.

DURING MONITORING

During monitoring the Zio AT device will record continuous beat to beat ECG information and transmit patient triggered and asymptomatic ECG to provide accurate arrhythmia detection.

In special circumstances, when patient data needs to be accessed by the physician during the wear period, a Device Data Request can be made. In order to make a Device Data Request, the clinician should call iRhythm at 1.888.693.2401. (Note: Device Data Requests are limited by availability of remaining battery power and may not be successful late in a monitoring period.)

REPORTS

ZIO AT REPORTS

All Zio AT Reports will be available in ziosuite.com.

Note: Transmission time may vary significantly depending on how effectively the patient maintains patch-gateway proximity and gateway cellular reception. Transmission reports will be provided after iRhythm receipt and analysis of ECG strips.

This device is not intended for use in critical care patients because the reporting timeliness is not consistent with life-threatening arrhythmias such as ventricular fibrillation.

ASYMPTOMATIC ARRHYTHMIA DETECTION

Asymptomatic arrhythmia events that are auto-detected (auto-triggered events) and transmitted during wear, are defined in the table below:

Rhythm	Heart Rate	Duration
Atrial Fibrillation	≤40 bpm	≥60 seconds
	Between 40–180 bpm	≥60 seconds until first documentation of AF
	≥180 bpm	≥60 seconds
Ventricular Tachycardia	≥120 bpm	≥30 seconds
	≥150 bpm	≥10 seconds
Supraventricular Tachycardia	≥180 bpm	≥60 seconds
Pause	-	≥4 seconds
	-	≥3 seconds back-to-back
Complete Heart Block	≤50 bpm	≥6 beats
Sinus Tachycardia	≥200 bpm	≥60 seconds
Sinus Bradycardia	≤30 bpm	≥60 seconds

Sensitivity (%) [1]		Positive Predictivity (%) [1]	
AHA	MIT-BIH	AHA	MIT-BIH
98.99	99.31	99.63	99.41

For each of the arrhythmias listed above, the Zio AT patch will transmit up to four ECG strips per hour.

[1] TR00689.01 (On file at iRhythm Technologies, Inc.)

TROUBLESHOOTING

FOR CUSTOMER SUPPORT, CALL **1.888.693.2401**

FREQUENTLY ASKED QUESTIONS

HEALTHCARE PROVIDER QUESTIONS

1. **How long is the patient supposed to wear the Zio AT patch?**

   The patient can use Zio AT for as long as prescribed. Each Zio AT patch can be worn for up to 14 days. For longer monitoring prescriptions, additional Zio AT monitors will be provided.

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

2. **Who should the patient call if they have questions about the Zio AT patch or gateway?**

   The patient can read the Wearing your Zio Manual & Button Press Log or call Customer Service at 1.888.693.2401.

3. **What if the patient does not have symptoms?**

   The Zio AT patch records every heartbeat. It also automatically detects and transmits asymptomatic arrhythmias, even if the patient does not feel them.

4. **Does the patient need to do anything with the Zio gateway to send heart rhythm data wirelessly?**

   The patient only needs to keep the gateway within 10 feet of the patch and within range of good cellular reception. No action is required for the gateway to send symptomatic heart rhythm data other than pressing the Zio button on the patch.

5. **Are there tests or treatments that are not compatible with the Zio AT patch?**

   Yes. The following are not recommended during wear of the Zio AT 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.

6. **Can the Zio AT patch be left on a patient during Cardioversion/ Defibrillation?**

   No, the Zio AT patch should be removed if the patient requires Cardioversion or Defibrillation.

PATIENT QUESTIONS

The Zio AT Monitoring System

7. **What is the patch doing?**

   The patch is recording every heartbeat. Your doctor will use the heart rhythm data from the patch to determine the right course of action.

8. **What is the gateway doing?**

   The gateway sends the heart rhythm data recorded by your patch to iRhythm using a cellular connection. iRhythm analyzes the data and provides a report to your doctor.

9. **How do I know the patch and the gateway are working?**

   Your patch and gateway are designed to be discrete. Once they are activated during the application process, neither the patch nor the gateway will display lights unless there is an interruption with connectivity.

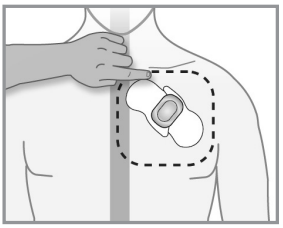
   Please note that the device does not flash lights when the device reaches the maximum limit for patient or auto-triggered transmissions as the device is still functioning and recording ECG data. See the Flashing Lights section for more information).

10. **What happens if I am in an area with poor or no cell reception?**

    If you are in an area with poor or no cell reception, the gateway will not transmit data from the patch. If iRhythm does not receive data for a sustained period of time, our team will reach out to the patient to troubleshoot.

    In the event, the connection is not re-established, data (both auto triggered and patient triggered events) will NOT be transmitted to iRhythm.

11. I think I placed the Zio AT patch in the wrong position. Can I remove it and reposition it?



No. If the Zio AT patch is over the heart in a slight diagonal as shown, the positioning should be acceptable.

DO NOT attempt to reapply the Zio AT patch.

12. The top label was peeled off, but there still seems to be a white label stuck to the wings of the Zio AT patch.

The top label may have separated during the application process and a portion was not removed completely. Although it does not affect the function of your patch, if you don't like the way it looks you can remove the remaining label, beginning with the edge closest to the center button and gently peel it out toward the end of the wings.

13. Do I need to do anything after pressing the patch button to send heart rhythm data wirelessly?

If you were experiencing a symptom when pressing the button, please log your symptom(s) in the MyZio mobile app or patient booklet so your doctor can view this information when reviewing your heart rhythm information. Additionally, to make sure your heart rhythm data is sent promptly, please keep the gateway within 10 feet of you in a place with good cellular connection.

14. Can I carry the gateway in a purse, bag or pocket?

Yes you may carry the gateway in a purse, bag, pocket, or you may also use the provided belt clip to carry the gateway. Keep in mind, for best performance, the gateway should be kept toward the front of your body and within 10 feet of the patch.

15. What can affect wireless connection between the patch and the gateway?

The patch and gateway communicate well as long as they are in close and clear proximity. However, there are some situations that can cause interference. Wireless devices that use 2.4 GHz signals such as baby monitors, TV senders, and wireless routers can interrupt communication between the patch and gateway if used within 6 feet of either the patch or gateway. In addition, do not place objects inside the gateway as this can also cause communication problems.

16. What happens if my patch and gateway are not in close proximity to each other?

Your patch and gateway are designed to continuously send your heart rhythm data as long as they are within a 10 foot range of each other and you are in a place with good cellular reception. Do your best to keep the gateway in front of you and within 10 feet of you. If the patch and gateway are too far apart and not communicating, the patch will not transmit data to the gateway, and data will not transmit to iRhythm. If iRhythm does not receive data for a sustained period of time, our team will reach out to the patient to troubleshoot.

Activities

17. Can I exercise while wearing the patch?

Yes, you may exercise moderately, but excessive sweating may affect the patch adhesive and can cause it to detach before your prescribed wear time is complete.

18. Can I shower with the patch on?

Please avoid showering for the first 24 hours after your patch is applied. After the first 24 hours of wear time, you may take brief showers, but do you best to keep your back to the showerhead, minimizing water directly hitting your patch. After your shower, towel dry carefully around your patch, holding it in place to prevent accidental removal. Always keep the gateway away from all water.

19. Can I take a bath?

Yes, but keep the patch above water. Always keep the gateway away from all water.

20. Can I go into a pool or a hot tub?

No. The patch should not be submerged under water. Always keep the gateway away from all water.

21. Can I travel with the patch on?

Yes. But keep in mind that the gateway will not have cellular connection outside the United States.

22. Can I fly with the gateway?

Yes, the gateway should be placed in “airplane mode.”

23. What activities should I avoid?

Exposure to significant moisture can cause the patch to slide, become loose or fall off. Activities that cause heavy sweating or that may submerge the patch in water should be avoided.

Recording Symptoms

24. What should I do if I feel a symptom?

First, press the button on your patch. Please log your symptom(s) in the MyZio mobile app or patient booklet so your doctor can view this information when reviewing your heart rhythm information. Please choose only one option for recording your symptoms.

25. What if I forget to press the button when I feel a symptom?

Don't worry, your Zio AT patch is always recording your heartbeat and the gateway will transmit the information that is important for your doctor to know.

26. What if I press the button but forget to write down the symptom?

Recording your symptoms and activity gives your doctor additional information about what may have caused the symptom. While this is useful, the button press that indicates the moment you felt a symptom is the most important information.

27. What if I press the patch button while the gateway is not within 10 feet and in line of sight of the patch?

If the patch and gateway are not within 10 feet, they may not communicate in which case the patch will not transmit data to the gateway, and data will not transmit to iRhythm. However, the patch will store the data until the gateway is in range, then the data will be sent.

28. What happens if I press the patch button while the gateway doesn't have cell signal?

If you are in an area with poor or no cell reception, the gateway will not transmit data from the patch. The gateway will store the data until it has cell signal, then the data will be sent. If iRhythm does not receive data for a sustained period of time, our team will reach out to the patient to troubleshoot.

In the event, the connection is not re-established, data (both auto triggered and patient triggered events) will NOT be transmitted to iRhythm.

The Patch

29. What should I do if the patch peels or lifts at the edges?

Press evenly on the wings of the patch for 3 to 5 minutes to re-stick.

30. What should I do if the patch falls off?

Call Customer Service at 1.888.693.2401.

31. I think I see blood under my patch. What should I do?

Call Customer Service at 1.888.693.2401. It is probably due to a small shaving cut when the patch was applied to your chest.

32. Is it normal for the Zio® AT patch wings to become cloudy?

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

33. Is it normal for the patch to move slightly from its original position?

Yes. The patch may move slightly from its original position. A blue gel may be seen under the wings of the patch.

34. Is it normal to experience skin irritation or itchiness in the area of the patch?

Some patients report minor skin irritation and/or itching while wearing the Zio AT patch. If skin irritation such as severe redness, itching or allergic symptoms develop, instruct the patient to remove the Zio AT Patch and call Customer Care at 1.888.693.2401.

Flashing Lights

35. Will the gateway show any lights or make any sounds?

As long as the gateway is able to communicate with the patch and iRhythm, it will not display any lights or make any noise.

36. What if the patch has an orange flashing light while I am wearing it?

If you see a flashing orange light on your patch, this does not mean there is a problem with your heart; it just means that the patch is not well attached and may not be recording or transmitting your heart rhythm data. Try pressing evenly on the wings of the patch for 3 to 5 minutes. If the flashing continues or comes back, call Customer Service at 1.888.693.2401.

37. What should I do if my gateway has an orange flashing light?

If you see the gateway light is flashing orange, this does not mean there is a problem with your heart; it just means that it is unable to send your heart rhythm data to iRhythm. Turn to Troubleshooting or call Customer Service at 1.888.693.2401.

End of the Wear Period

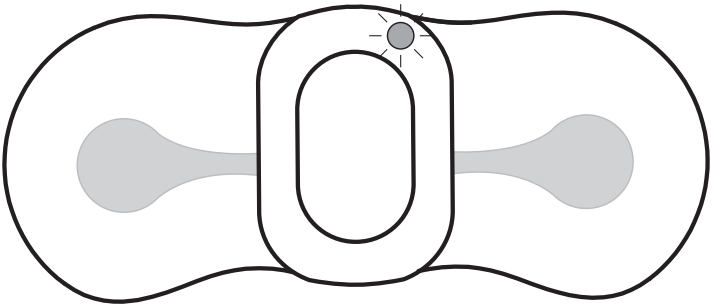
38. How long am I supposed to wear the patch?

Use Zio AT for as long as your doctor prescribed. Each Zio AT patch can be worn for up to 14 days, although your doctor may want to monitor your heart for shorter or longer than 14 days. For longer monitoring prescriptions, additional Zio AT monitors will be provided. NOTE: Each person's wear experience is different and actual wear time may be shorter than prescribed.

39. I have removed the Patch and it is flashing orange. Is this okay?

The light on the patch may flash orange after removal. This does not indicate any problem. It is okay to mail the device while it is flashing. Turn to Patch Removal for return instructions.

TROUBLESHOOTING THE PATCH



SLOW FLASHING (once every 3 seconds):

Indicates that the patch is not making good contact.

To remedy it, press evenly on the wings of the patch for 3 to 5 minutes.

If orange flashing continues, call Customer Service at 1.888.693.2401.

FAST FLASHING (3 times per second):

Indicates that the patch is not recording. Call Customer Service at 1.888.693.2401.

TROUBLESHOOTING THE GATEWAY

SLOW □ (SQUARE) FLASHING (once every 3 seconds):

Indicates that the gateway has lost connection to the patch.

To remedy it, hold the star button for 3 seconds until the orange light stays on. Then, if you see green flashing, the gateway has found connection to the Patch.

If orange flashing continues, call Customer Service at 1.888.693.2401.

SLOW △ (TRIANGLE) FLASHING (once every 3 seconds):

Indicates that the gateway does not have cell signal.

To remedy it, move the gateway to a place with a good cell signal (near a window or outside) and hold the star button for 3 seconds until the orange light stays on.

Then, if you see green flashing, the gateway has found a cell signal. Do not move the gateway until the green flashing stops.

If it does not flash green, move the gateway to a new place and try again.

If orange flashing continues, call Customer Support at 1.888.693.2401.

FAST □ (SQUARE) OR △ (TRIANGLE) FLASHING (3 times per second):

Indicates that the gateway is not working. Call Customer Support at 1.888.693.2401.

ZIO AT SERVICE NOTES

Situation	Note
Patient Timeline – Paper Booklet Diary Entries	For patients with the Zio AT Patch, Ziosuite provides a timeline screen that displays along with Transmission, DDR, Daily, and Final reports, patient provided diary entries. For each diary entry the date and time of the symptom reported is displayed. In the event that a patient does not provide the date/time for a symptom on the paper booklet, the timeline will display a date with a year starting in 3000. Dates that have a year of 3000 or greater indicate that the patient did not provide the timestamp of the symptom experienced. (SYS-2315)

IRHYTHM CLINICAL FACILITY CERTIFICATION

The Zio AT monitoring system 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 (NOPP)

iRhythm is committed to protecting the privacy of your personal information. We are required by the U.S. - EU Safe Harbor Framework to maintain the privacy of your personal information, and to notify you of our privacy practices, our legal duties, and your rights concerning your personal information.

Why?	As participants in your health care, we are required by applicable federal and state law to maintain the privacy of your Protected Health Information ("PHI"). This notice describes our privacy practices, our legal duties, and your rights concerning your PHI. We will follow the privacy practices described in this notice while it is in effect. We reserve the right to revise this notice and to make the new notice provisions effective for all PHI we maintain. If we revise this notice, we will post the revised notice on this page.
Why?	In providing diagnostic services, the types of information we collect may include: - Name - Gender - Date of Birth - Medicare and Secondary Insurance Information - Address and Phone Number - Prescribing Physician and Office - Primary Indication - ECG Recording - Symptoms and Activities You Report, by Time and Date - Activity Level During Monitoring - Patient Identification Number - Clinical Information and Diagnostic Results
How?	By providing diagnostic services to our patients, we regularly collect information through: - Phone conversations - Patient submitted documents - Prescribing physician submitted documents - Zio Event card transmissions - Return of Zio XT or Zio AT Patches
How We May Use Your Information	
We have the right to use and disclose health information for your treatment, to secure payment for your health care, and to operate our business.	

Without Specific Authorization		Does iRhythm Share?	Can You Limit This Sharing?
To You	We must disclose your PHI to you, as described in the "Your Rights" section of this notice.	Yes	Yes
For Payment	We may use and disclose PHI to obtain payment for services provided to you. We may also disclose your PHI to a health care provider or health plan so that the provider or plan may obtain payment of a claim or engage in other payment activities.	Yes	Yes
For Treatment	We may use and disclose PHI to provide and manage your diagnostic services. That may include consulting with other health care providers about your diagnostic services. For example, we will release the results of your diagnostic services to your prescribing physician, to the physician treating you, or in a medical emergency, if applicable.	Yes	No
For Health Care Operations	We may use or disclose PHI to conduct quality assessment and improvement activities, to conduct fraud and abuse investigations, to engage in care coordination or case management, or to communicate with you about health related benefits and services or treatment alternatives that may be of interest to you. We may also disclose PHI to a health care provider or health plan subject to federal privacy laws, as long as the provider or plan has or had a relationship with you and the PHI is disclosed only for certain health care operations of that provider or plan. We may also disclose PHI to other entities with which we have contracted to perform or provide certain services on our behalf (e.g., business associates).	Yes	No

Without Specific Authorization		Does iRhythm Share?	Can You Limit This Sharing?
For Business Operations	We may use both De-Identified and Limited Data Sets (a data set that, per the Health Insurance Portability and Accountability Act of 1996 regulations, has had patient-identifiable data removed except for dates of service) for development of future products, devices or services. Once information is De-Identified through an approved method, the data is stripped of individual identifiers, at which point iRhythm may share this information without restriction externally to support research, market development, trend analysis, etc. Information containing Limited Data Sets may be provided externally to support market and product development. However, iRhythm will obtain the required data use agreements when transferring Limited Data Sets to external parties.	Yes	Yes
For Public Health And Safety	We may use or disclose PHI to the extent necessary to avert a serious and imminent threat to the health or safety of you or others. We may also disclose PHI for public health and government health care oversight activities and to report suspected abuse, neglect or domestic violence to government authorities.	Yes	No
As Required By Law	We may use or disclose PHI when we are required to do so by law.	Yes	No
For Process And Proceedings	We may disclose PHI in response to a court or administrative order, subpoena, discovery request, or other lawful process.	Yes	No
For Law Enforcement	We may disclose PHI to a law enforcement official with regard to crime victims and criminal activities.	Yes	No
Special Government Functions	We may disclose the PHI of military personnel or inmates or other persons in lawful custody under certain circumstances. We may disclose PHI to authorized federal officials for lawful national security activities.	Yes	No
For Research, Death, And Organ Donation	We may use or disclose PHI in certain circumstances related to research, death or organ donation.	Yes	No

Without Specific Authorization		Does iRhythm Share?	Can You Limit This Sharing?
For Workers' Compensation	We may disclose PHI as permitted by workers' compensation and similar laws.	Yes	No

Without Specific Authorization	Does iRhythm Share?	Can You Limit This Sharing?
You may give us written authorization to use your PHI or disclose it to anyone for any purpose not otherwise permitted or required by law. If you give us such authorization, you may revoke it in writing at any time. Your revocation will not affect any use or disclosure permitted by your authorization while it was in effect.	Yes	Yes
While the law permits us in certain circumstances to disclose your PHI to family, friends and others, we will do so only with your authorization. In the event you are unable to authorize such disclosure, but emergency or similar circumstances indicate that disclosure would be in your best interest, we may disclose your PHI to family, friends or others to the extent necessary to help with your health care coverage arrangements.	Yes	Yes

Your Rights	
Access	With limited exceptions, you have the right to review in person, or obtain copies of, your PHI. We may charge you a reasonable fee as allowed by law to obtain this information.
Amendment	With limited exceptions, you have the right to request that we amend your PHI.
Disclosure Accounting	You have the right to request and receive a list of certain disclosures made of your PHI. If you request this list more than once in a 12-month period, we may charge you a reasonable fee as allowed by law to respond to any additional request.
Use/Disclosure Restriction	You have the right to request that we restrict our use or disclosure of your PHI for certain purposes. We are not required to agree to a requested restriction. We will agree to restrict use or disclosure of your PHI provided that the law allows and we determine the restriction does not impact our ability to operate our business, provide diagnostic services, and comply with the law. Even when we agree to a restriction request, we may still disclose your PHI in a medical emergency and use or disclose your PHI for public health and safety and other similar public benefit purposes permitted or required by law.

Confidential Communication	You have the right to request that we communicate with you in confidence about your PHI at an alternative address.
Privacy Notice	You have the right to request and receive a copy of this notice at any time. For more information or if you have questions about this notice, please contact us using the information listed at the end of this notice.
Complaints / Violations	
If you are concerned that we may have violated your privacy rights, you may inquire with us using the contact information listed at the end of this notice. You may also submit a written complaint to the U.S. Department of Health and Human Services. We will provide you with the address for the U.S. Department of Health and Human Services upon request.	
To Limit Our Sharing Or Submit Complaints	Call 1.888.693.2401 - our Customer Service staff will assist you
Questions?	Call 1.888.693.2401
Who We Are	
Who Is Providing This Notice?	This privacy notice is being provided by iRhythm Technologies, Inc., and applies to the diagnostic services offered in connection with prescribed health care.
What We Do	
How Does iRhythm Protect My PHI?	To protect your PHI from unauthorized access and use, iRhythm has implemented security safeguards that comply with federal law to secure physical and electronic information.
Company Contact Details	
Address:	iRhythm Technologies, Inc. 699 8th Street Suite 600 San Francisco, CA 94103 Attn: Privacy Official www.irhythmtech.com
Phone:	415.632.5700
Fax:	415.632.5701

CYBERSECURITY MEASURES AND CONTROLS

As a connected medical device, the Zio AT patch was developed with careful consideration of cybersecurity risks and their compensating controls. Key measures include manufacturing steps to exclusively pair one AT patch with one Gateway, thus preventing Bluetooth communication with any other devices, and to configure encryption of all transmissions between these devices. Similarly, encryption of all cellular communication between the Gateway and the cloud is configured during manufacturing.

iRhythm regularly evaluates the integrity of our cloud-based infrastructure through both vulnerability and penetration testing of all internet-accessible servers. Industry-standard encryption is employed for all data transfers to, from and within the Cloud, and for protecting data at rest.

Patient data is protected during wear through use of proprietary data storage formats and access methods, and physically protected data ports. Once returned to iRhythm for processing, data integrity checks are used to ensure the integrity of all recorded data.

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	0.4 Hz to 40 Hz
ECG Input Impedance	>10 MΩ
ECG Differential Range	3.3 mV p-p
ECG A/D Sampling Rate	200 Hz
ECG Resolution	10 bits
Patch Short-range RF Transmit/ Receive	2.4 GHz Bluetooth Low Energy Effective Radiated Power <1 mW
Frequency Band of Transmission	2.4 GHz
Bandwidth of the Receiver	2400-2480 MHz
Type and Frequency of Modulation	1-Mbps GFSK
Gateway Short-range RF Transmit/ Receive	2.4 GHz Bluetooth Low Energy Effective Radiated Power <1 mW
Gateway Cellular RF Transmit/ Receive	750 MHz LTE Cat M1 Effective Radiated Power < 200 mW

POWER CHARACTERISTICS

Patch Battery Type	2 Lithium Manganese Dioxide Coin Cells
Gateway Battery Type	1 Lithium Polymer Cell
Battery Life	Continuous
Service Life	14 days

PHYSICAL CHARACTERISTICS

Patch Dimensions	5.2 x 2.0 x 0.5 inches
Patch Weight	24.7 g
Gateway Dimensions	6.2 x 3.4 x 0.8 inches
Gateway Weight	158 g

ENVIRONMENTAL CHARACTERISTICS

Operational Temperature	41 to 104 degrees
Operational Altitude	-1,000 to 10,000 ft
Operational & Storage Humidity	10% to 95% (non-condensing)
Shipping (Short-term Storage) Temperature	-4 to 104 degrees F
Long-term Storage Temperature	55 to 85 degrees F
Storage Altitude	-1,000 to 14,000 ft
Patch IP Classification	IP24
Gateway IP Classification	IP22

ESSENTIAL PERFORMANCE

The Zio AT device records and transmits ECG for analysis after receipt of data. In the event it cannot record or transmit in a timely fashion, the Zio AT alerts the patient that functionality is impaired.

HEART RATE CALCULATIONS

Episode Heart Rates	**Max**	The maximum episode heart rate (i.e., maximum of all instantaneous heart rates within the episode)
	Min	The minimum episode heart rate (i.e., minimum of all instantaneous heart rates within the episode)
	Avg	The average episode heart rate (i.e., average of all instantaneous heart rates within the episode)
Overall Rhythm Heart Rates	**Max**	The maximum overall heart rate (i.e., maximum of all rhythm episode maximum heart rates within the record)
	Min	The minimum overall heart rate (i.e., minimum of all rhythm episode minimum heart rates exclusive of Pause heart rates within the record)
	Avg	The average overall heart rate (i.e., duration-weighted average of all rhythm episode heart rates within the record)

PAUSE DETERMINATION

Pause is defined as an RR interval greater than or equal to 3 seconds.

ELECTRICAL SAFETY AND COMPATIBILITY

- CAUTION: The Zio AT system 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 AT system should not be used adjacent to or stacked with other equipment.
- WARNING: The Zio AT system may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSIONS requirements.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Zio AT patch or gateway. Otherwise, degradation of the performance of this equipment could result.

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

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Zio AT system 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 AT system is suitable for use in all establishments, including domestic establishments.
Harmonic emissions IEC 61000-3-2	Not applicable	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	Not applicable

Table 2: Guidance and manufacturer's declaration—electromagnetic immunity			
The Zio AT system is intended for use in the electromagnetic environment specified below. The customer or the user of the Zio AT system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.w
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 28 V/m 385, 450, 810, 870, 930 MHz 18 Hz pulse 9 V/m 710, 745, 780 MHz 217 Hz pulse 28 V/m 1720, 1845, 1970, 2450 MHz 217 Hz pulse 9 V/m 5240, 5500, 5783 MHz 217 Hz pulse	10 V/m 28 V/m 9 V/m 28 V/m 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Zio AT system , 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: 

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 AT system is used exceeds the applicable RF compliance level above, the Zio AT system 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 AT patch or gateway.

[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 AT system

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

- This system complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This system may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- For body worn operation, this system has been tested and meets FCC RF exposure guidelines when used with an accessory that contains no metal, such as the belt clip provided, and that positions the Gateway a minimum 1 cm from the body. Use of other accessories may not ensurecompliance with FCC RF exposure guidelines.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- The gateway has been tested and meets FCC RF exposure guidelines when used and operated for its intended purpose and as instructed in the manual.

SYMBOLS GLOSSARY

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	DESCRIPTION / EXPLANATORY TEXT
	ISO 15223-1 Clause 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Manufacturer	Indicates the medical device manufacturer.
	ISO 7000-3082	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Date of manufacture	Indicates the date when the medical device was manufactured
	ISO 7000-2497	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 7000-2607	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 7000-2492	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 7000-2493	Graphical symbols for use on equipment		

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	DESCRIPTION / EXPLANATORY TEXT
SN	ISO 15223-1 Clause 5.1.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 7000-2498	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.3.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 7000-0626	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 7000-0632	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.3.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 7000-2620	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.4.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 7000-1051	Graphical symbols for use on equipment		

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	DESCRIPTION / EXPLANATORY TEXT
	ISO 15223-1 Clause 5.4.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 7000-1641	Graphical symbols for use on equipment		
	IEC 60601-1 Table D.1, Symbol 11	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance		
	ISO 15223-1 Clause 5.4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. of reasons, be presented on the medical device itself.
	ISO 7000-0434	Graphical symbols for use on equipment		
	IEC 60601-1 Table D.1, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance		

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	DESCRIPTION / EXPLANATORY TEXT
	BS EN 50419:2006	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE)	Separate Collection	To indicate that the product shall be separated when disposed.
	IEC 60417-5140	Graphical symbols for use on equipment	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of nonionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF lectromagnetic energy for diagnosis or treatment. lectromagnetic energy for diagnosis or treatment.
	IEC 60601-1-2:2007, Clause 5.1.1	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests		
	IEC 60417-5333	Graphical symbols for use on equipment	Type BF Applied Part	To identify a type BF applied part complying with IEC 60601-1.
	IEC 60601-1, Table D.1, Symbol 20	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance		
	ASTM F2503-13	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Magnetic Resonance (MR) unsafe	Keep away from magnetic resonance imaging (MRI) equipment.

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	DESCRIPTION / EXPLANATORY TEXT
IPN1N2	IEC 60601-1, Table D.3 Symbol 2 IEC 60529	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance Degrees of Protection Provided by Enclosures (IP Code)	Degrees of protection provided by enclosure	Manufacturer-determined degree of particle and water ingress protection, where: N1 = Degrees of protection against access to hazardous parts N2 = Degrees of protection against water
IP24				Protected against solid foreign objects of 12,5 mm diameter and greater, and protected against splashing water
IP22				Protected against solid foreign objects of 12,5 mm diameter and greater, and protected against vertically falling water drops when enclosure tilted up to 15°
Rx ONLY	21 CFR 801.15(c)(1)(i)F	Labeling-Medical devices; prominence of required label statements	Prescription only	Requires prescription in the United States

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