Rhythm



Record any events during your wear period here, the myZio app or at myzio.com.

Return this booklet, your Zio QX patch and Zio QX gateway after your wear period:





CALL 1.888.693.2401 IF...

- The Zio QX patch falls off.
- You experience severe itching or irritation.

For all other information please see the Troubleshooting and Frequently Asked Questions section of this booklet.

If you feel the need for immediate medical care at any time, call 911. The Zio QX device will not provide any medical assistance and cannot contact medical personnel for you.

For use in the United States only.

iRhythm Technologies, Inc. — Clinical Centers

650 Townsend St., Suite 500 San Francisco, CA 94103 U.S.A.

2 Marriott Drive Lincolnshire, IL 60069 U.S.A.

363 N. Sam Houston Parkway East, Suite 125 Houston, TX 77060 U.S.A.

1.888.6932401 | irhythmtech.com | 🍏 @iRhythmTech



The Zio® QX System consists of three components:

- 1. Zio QX Patch
- 2. Zio QX Gateway
- 3. myZio[™] App and Website

The **Zio QX Patch** records every heartbeat. Each time you press the Patch button or when Zio QX automatically detects an arrhythmia, the **Zio QX Gateway** transmits information to iRhythm for analysis. **myZio** is one way for you to enter your symptoms and verify that your heart data transmission has been received by iRhythm.

APPLYING YOUR ZIO QX

Follow the instructions in the Zio QX Application Instructions guide to apply your Zio QX Patch



It is important that you follow the steps in the Applications Instructions guide to ensure that your Patch sticks to your skin correctly and remains on your skin for the duration of monitoring.

The Patch should only be applied to healthy, unbroken skin that was not previously irritated.

USING YOUR ZIO QX

With the Zio monitor, you can go through your normal daily activities after the first 24 hours.

The Patch needs 24 hours to fully stick to your skin, we recommend showering briefly with your back to the water, and avoid any

activities that cause sweating during this period. After those first 24 hours, you may resume normal activities, including showering and moderate exercise.



The Patch and Gateway will not flash or make noise when they are working correctly, but you can check your transmissions using myZio or www.myzio.com.



Remember:

Each time you feel a symptom, press the button on your Patch. Then note the date, time, and what you felt in this booklet. Or, you may enter your symptoms in the myZio App or on www.myzio.com. See page 6.

If the Patch or Gateway lights are flashing, it does not mean there is a problem with your heart, only that a device may have lost its connection. Turn to the Troubleshooting section or call 1.888.693.2401 for

support.



Keep the Gateway close by when you can, and when you are on the move carry it with you. It is okav if the Gateway is temporarily out of range, but iRhythm will not receive heart rhythm data from your Patch or Gateway while it is out of range. For the Gateway to remain connected it needs to be kept in front of you and within 10 feet of the Patch.

Additional tips:



If your skin around the Patch feels a little itchy, it is okay. If the Patch peels or lifts at the edges, press and hold the Patch to re-stick.



Excessive sweating can cause the Patch to slide, become loose, fall off, and shorten wear time – especially if sweating occurs in the first 24 hours after the Patch is put on.



The Patch is water-resistant but should not be submerged. Brief showering is okay, but no swimming or hot tubs. The Gateway is NOT water resistant. Please do not get it wet.



Do not place the Gateway within 6 feet of transmitting devices, such as wireless routers, baby monitors and TV senders/ transmitters. These devices may cause interference between the Patch and the Gateway.



Sending heart rhythm data through the Gateway may take some time after the Patch button is pressed. Recent transmissions may not be viewable on myZio until several hours later.



Use **myZIO** to enter your symptoms electronically and check transmissions sent from your Gateway.* Through myZio you have easy access to help instructions and videos.

iPhone® users

- 1. Search for 'myZio' in the App StoreSM
- 2. Download app
- 3. Register before entering symptoms

Android™ users

- Search for 'myZio' in the Google Play™
 Store
- 2. Download app
- 3. Register before entering symptoms

Computer users

- 1. Open your web browser
- 2. Navigate to www.myZio.com
- 3. Register before entering symptoms

Supported on iPhone 5 or later (iOS 9+).

Supported on Android 4.4+

iPhone, App Store and the Apple logo are registered trademarks of Apple Inc. $% \begin{center} \end{center} \begin{center} \b$

^{*} Recent transmissions may not be viewable on myZio until several hours later.

TROUBLESHOOTING: GATEWAY



If the light on the outside of your Gateway is flashing, check inside.

SLOW | FLASHING

(once every 3 seconds):

Indicates that the Gateway has lost the connection to your Patch.

To reconnect, hold the star buttonfor 3 seconds until the orange light stays on. If the light then flashes green, the Gateway has reconnected to the Patch.

If orange flashing continues, call Customer Service at 1.888.693.2401.

SLOW FLASHING

(once every 3 seconds):

Indicates that the Gateway does not have a cell signal.

To reconnect, 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.

If the light then flashes green, the Gateway has reconnected. 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.

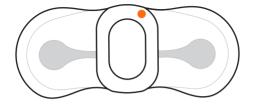
If orange flashing continues, call Customer Service at 1.888.693.2401.

FAST ☐ OR △ FLASHING

(3 times per second):

Fast flashing indicates that your Gateway is not working. Call Customer Service at 1.888.693.2401.

TROUBLESHOOTING: PATCH



SLOW FLASHING

(once every 3 seconds):

Indicates that your Patch is not making good contact with your skin.

To correct this, 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 your Patch is not recording. Call Customer Service at 1.888.693.2401.

FREQUENTLY ASKED QUESTIONS (FAQS)

The Zio® AT monitoring system

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.

What is the Gateway doing?

The Gateway wirelessly sends heart rhythm data from the Patch, each time the Patch button is pressed and each time the system automatically detects an arrhythmia. iRhythm receives and analyzes the data, and provides a report to your doctor.

How do I know the Patch and the Gateway are working?

When they are working normally, the Patch and Gateway do not flash or make noise.

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

No, you only need to keep the Gateway in front of you and within 10 feet of the Patch to stay connected wirelessly after you press the Patch button. The Gateway should also be kept in a place with good cell signal.

Can I carry the Gateway in a purse, bag or pocket?

Yes. However, when carrying the Gateway keep it in line of sight of the Patch. The Gateway will need to be in front of your body and within 10 feet of the Patch.

What can affect wireless connection between the Patch and the Gateway?

Wireless devices that use 2.4 GHz signals such as baby monitors, some cordless home telephones, and wireless routers can interrupt communication between the Patch and Gateway if used within 6 feet. Objects placed inside the Gateway can also cause communication problems.

Your activities

Can I exercise while wearing the Patch?

Yes, you may exercise moderately, but excessive sweating may shorten wear time.

Can I shower with the Patch on?

Yes, but showers should be short and try to keep your back to the shower as much as possible. Keep soaps and lotions away from the Patch. When towel-drying, hold the Patch down with one hand. Press the Patch against your skin to secure it. Keep the Gateway away from all water.

Can I take a bath?

Yes, but keep the Patch above water. Keep the Gateway away from all water.

Can I go into a pool or a hot tub?

No. The Patch should not be put under water. Keep the Gateway away from all water.

Can I travel with the Patch on?

Yes. If questioned during airport security screening, show the statement in the Traveling section. Note that the Gateway will not have cellular connection outside the United States.

Can I fly with the Gateway?

Yes, though the Gateway should be placed in "airplane mode." See Traveling.

What activities should I avoid?

Activities that cause heavy sweating should be avoided. Sweat can cause the Patch to slide, become loose, fall off, and shorten wear time.

Recording symptoms

What should I do if I feel a symptom?

First, press the button on the Patch. Then, fill out a page of the Button Press Log in this booklet, use the myZio App or ff.myzio.com to enter your symptoms. Please choose only one option for recording symptoms but not all.

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

While pressing the button is important to "tag" and wirelessly send an event, the Patch is recording every heartbeat.

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

Recording your symptoms and activity gives your physician additional information about what may have caused the symptom. While this is useful, the more important thing is to press the button.

What if I press the Patch button while the Gateway is not within 10 feet and in line of sight of the Patch?

The Patch will store the data until the Gateway is in range, then the data will be sent.

What happens if I press the Patch button while the Gateway doesn't have cell signal? The Gateway will store the data until it has cell signal, then the data will be sent to iRhythm.

The Patch

What should I do if the Patch peels or lifts at the edges?

Press and hold along the edges to re-stick.

What should I do if the Patch falls off? Call Customer Service at 1.888.693.2401.

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.

Is it normal for the Zio® AT Patch wings to become cloudy?

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

Is it normal for the Patch to move slightly from its original position?

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

Is it normal to experience skin irritation or itchiness in the area of the Patch?

Most patients do not experience skin irritation or itchiness. However, some patients have reported minor skin irritation and/or itching while wearing the Patch. If the irritation or itching is severe or hives or blisters develop, remove the Patch, then call Customer Service at 1.888.693.2401.

Flashing lights

Will the Gateway show any lights or make any sounds?

No. As long as it is able to send data, the Gateway will not flash or make noise.

What if the Patch flashes orange while I am wearing it?

If you see the Patch flashing orange, this does not mean there is a problem with your heart; it just means that the Patch is not well attached. Press 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.

What should I do if my Gateway is flashing orange?

If you see the Gateway flashing orange, this does not mean there is a problem with your heart; it just means that the Patch cannot send information wirelessly. Turn to *Troubleshooting* or call Customer Service at 1.888.693.2401.

End of the wear period

How long am I supposed to wear the Patch?

Wear the Patch for as long as your doctor prescribed but no longer than 14 days. NOTE: Each person's wear experience is different and actual wear time may be shorter than prescribed.

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

The Patch may flash orange after removal. It is okay to mail the device while it is flashing. Turn to Patch Removal for return instructions.

SECURITY SCREENING STATEMENT

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

If you have any questions, please contact the iRhythm Clinical Center at

1.888.693.2401

24 hours/day, 7 days/week.

TRAVELING WITH YOUR ZIO QX

Flying while wearing a Zio QX is straightforward. Simply show the security statement (opposite) during screening, and remember to put the Gateway in Airplane Mode.



To turn Airplane Mode ON

Press and hold the airplane button inside the Gateway for 3 seconds, until the lights flash orange quickly. The airplane light on the outside of the Gateway will flash as long as it is in "Airplane Mode."

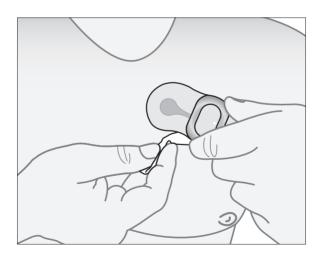
To turn Airplane Mode OFF

Press and hold the airplane button inside the Gateway for 3 seconds, until the lights flash green quickly. The outside airplane light will stop flashing.

REMOVING AND RETURNING THE PATCH

When you have worn the Patch for the time prescribed by your doctor, remove it as described below.

1 Using the adhesive remover from the opposite page, tilt the center of the Patch up and sweep between your skin and the Patch – while lifting one side from the center out. Repeat for the other side, lifting from the center out. Wash the skin with mild soap, rinse with water, and pat dry.



2 Place the Patch inside the Gateway as shown.



3 Lift panel in the Gateway to remove



4 Place only the Patch, Gateway and this booklet inside the envelope and seal. Mail it back via the U.S. Postal Service as soon as possible.*

ADHESIVE REMOVER

*You may be held responsible for the cost of the device if both the Patch and Gateway are not returned.

ABOUT THE ZIO QX

Zio QX data analysis

Your Zio QX data is analyzed at the iRhythm Clinical Centers. 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.

Patient identification

Before placing your device in the prepaid envelope, please write your name on the line above the return address. By writing your name on the envelope you are providing another method of identification for the Patch and Gateway and are consenting to the potential viewing of your name on the envelope. You may choose to not write your name on the envelope.

Notice of privacy practices

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).

Our full Notice of Privacy Practices, found at www.irhythmtech. com, describes our privacy practices, our legal duties, and your rights concerning your PHI.

Indications for use

The Zio QX ECG Monitoring System is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram 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 comprehensive report is generated based on the entire ECG recording. It is indicated for use on patients 18 years or older who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety and patients who are asymptomatic. 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 the Zio QX for patients with symptomatic episodes where variations in cardiac performance could result in immediate danger to the patient.
- Do not use the Zio QX for patients with known history of life threatening arrhythmias.
- Do not use the Zio QX 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 QX on patients with neuro-stimulator, as it may disrupt the quality of ECG data.
- Do not use the Zio QX on patients who do not have the competency to wear the device for the prescribed monitoring period.

Warnings

- Do not use the Zio QX 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 QX Patch on multiple patients. It is a single patient use device. Reuse will cause incorrect patient data and patient may experience skin irritation.
- Do not use the Zio QX on patients residing in areas with limited to no cellular reception.
- No modification of this equipment is allowed.



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



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

Precautions

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

- Safety and effectiveness of the Zio QX 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.
- 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.
- · Device is not intended for infants under 10kg.

The patient is an intended operator

Package Contents

- 1 7in QX Patch
- 1 Zio QX Gateway, containing:
 - 1 postage-paid return envelope
- 1 Skin Prep & Placement Kit containing:
 - 1 patch card template
 - 1 disposable razor
 - 1 abrader disc
 - 4 alcohol pads
- 1 Patient Instructions & Button Press Log containing:
 - 1 adhesive remover wipe
- 1 Zio QX Get Started guide

Symbols



Consult Instructions for Use



Caution



Prescription Use Only



Manufacturer



Date of Manufacture



Serial Number



Use By



Do Not Reuse



Zio Patch Splash-Proof Equipment

95%



Zio Gateway Drip-proof Equipment Protected Against Hazardous Parts with Finger Temperature Limitations



Temperature Limitations



Humidity Limitations



Separate Collection



Do Not Use if Package is Damaged



Type BF Applied Part



RF Transmitter



Net Quantity of Contents



Keep Dry



Do Not Open Until Time of Application

Asymptomatic Arrhythmia Detection

Asymptomatic arrhythmia events, as detected and transmitted during the monitoring period, are defined by the following parameters:

Rhythm	Heart Rate	Duration
Atrial Fibrillation	≤40 bpm	≥60 seconds
Atrial Fibrillation	≤180 bpm	≥60 seconds
Pause	-	≥4 seconds
Ventricular	≥ 120 bpm	≥ 30 seconds
Tachycardia	≥150 bpm	≥15 seconds
Complete Heart Block (day 05:00~23:00)	≤ 50 bpm	≥6 Beats
Complete Heart Block (night 23:00~05:00)	≤ 47 bpm	≥6 Beats
Bradycardia	≤30 bpm	≥60 seconds
Tachycardia	≥ 200 bpm	≥ 60 seconds

PERFORMANCE CHARACTERISTICS

ECG Channels	1 channel
Memory capacity	14 days
Recording Format	Continuous
Service Life	Up to 14 days
Shelf Life	6 months
Out-of-Pouch Shelf Life	1 day

ELECTRICAL CHARACTERISTICS

Medical Equipment Type	BF Applied Part
ECG Frequency Response	0.5Hz to 30Hz
ECG Input Impedance	≥ 10 MΩ
ECG Differential Range	±1.65 mV
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 < 1mW
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 < 1mW
Gateway Cellular RF Transmit/ Receive	800 / 1900 MHz CDMA Effective Radiated Power ≤300mW

POWER CHARACTERISTICS

Patch Battery Type	2 Lithium Manganese Dioxide Coin Cells
Gateway Battery Type	1 Lithium Polymer Cell
Battery 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 F
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	IPX4
Gateway IP Classification	IP22

ESSENTIAL PERFORMANCE

The Zio QX 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 QX alerts the patient that functionality is impaired.

EQUIPMENT CLASSIFICATION INFORMATION

Patch IEC	Gateway IEC
Classifications	Classifications
Internally Powered ME Equipment	Internally Powered ME Equipment
Type BF Applied Part	-
IPX4 -	IP 22
Continuous Operation	Continuous Operation

Heart Rate Calculations

	Max	The maximum episode heart rate (i.e., maximum of all instantaneous heart rates within the episode)
Episode Heart Rates	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)
	Max	The maximum overall heart rate (i.e., maximum of all rhythm episode maximum heart rates within the record)
Overall Rhythm Heart Rates	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 3 seconds.

Electrical Safety and Compatibility

- CAUTION: The Zio QX 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 QX should not be used adjacent to or stacked with other equipment.
- WARNING: The Zio QX 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 QX Patch. Otherwise, degradation of the performance of this equipment could result.

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

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

Emissions test	Compliance	Electromagnetic
		environment -
		guidance

RF emissions CISPR 11	Group 1	The Zio QX device 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 QX device 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	Not applicable	Not applicable

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

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

test test level level environment -	Immunity test	IEC 60601 test level	Compliance level	
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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 %.
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 QX device is intended for use in the electromagnetic environment specified below. The customer or the user of the Zio QX device should assure that it is used in such an environment.

level guidance

			Portable and mobile
	10 V/m 80 MHz to 2.7 GHz 28 V/m 385, 450, 810, 870, 930 MHz	10 V/m	RF communications equipment should be used no closer to any part of the Zio QX device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
	18 Hz	28 V/m	d = 1.2√P
Radiated RF IEC 61000- 4-3	pulse 9 V/m		d = 1.2√P 80 MHz to 800 MHz
	710, 745, 780 MHz 217 Hz pulse 28 V/m 1720, 1845, 1970, 2450 MHz 217 Hz pulse	9 V/m	d = 2.3√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).
		9 V/m	as determined by an electromagnetic site survey, ^a should
	5240, 5500, 5783 MHz 217 Hz pulse	be less than the compliance level in each frequency range. ^b	
		9 V/m	Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

- ^a 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 QX is used exceeds the applicable RF compliance level above, the Zio QX 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 QX 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 7in OX

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

Rated maximum output	Separation distance according to frequency of transmitter			
power of transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	80 MHz to 2.5 GHz	
W	d = 1.2√P	d = 1.2√P	d = 2.3√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 device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

For body worn operation, this device 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 ensure compliance 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.

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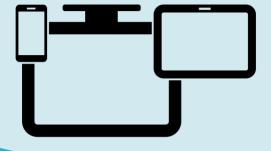
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Enter your symptoms as shown on the sample page, or enter them using myZio[™] or www.myzio.com website and enjoy these additional features:

- Review and edit your symptom history
- Have easy access to help instructions
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- Access and edit your patient profile



See page 6 in the **Wearing Your Zio manual** to get started with myZio







To be completed by patient:

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