NUVANT™

Mobile Cardiac Telemetry (MCT) System

corventis

Instructions for Use

Rx Only

FOLLOW THESE INSTRUCTIONS CAREFULLY AND WATCH YOUR INSTRUCTIONAL VIDEO BEFORE USING NUVANT MCT

Customer Service:
USA: 1-877-247-PIIX(7449)

The NUVANT Mobile Cardiac Telemetry (MCT) System is a wearable, wireless arrhythmia detection system that is used to aid clinicians in diagnosing suspected cardiac arrhythmias. It consists primarily of the PiiX® wearable monitoring device, the zLink® portable data transmission device and a Patient Trigger Magnet to enable on-demand collection of ECGs (recordings of heart rhythm). In combination with interpretation services provided by the Corventis Monitoring Center, as well as secure online review of data (for prescribing physicians only), NUVANT MCT enables patient- and physician-friendly arrhythmia detection for up to 30 days at a time.

How NUVANT MCT Works

Once activated, the wearable PiiX sensor continuously monitors the heart and automatically collects ECGs when rhythm abnormalities are detected. Patients can also drive collection of ECGs when they experience cardiac symptoms by using the Patient Trigger Magnet. Data are automatically transmitted from the PiiX to the zLink, which then automatically transmits the data to the Corventis Monitoring Center. Certified cardiographic technicians at the Corventis Monitoring Center review received data and document symptoms reported by patients. Clinical reports, prepared by the Corventis Monitoring Center, are delivered and made available at www.corventis.com to provide data to prescribing physicians for the diagnosis and identification of various clinical conditions, events and/or trends. Prescribing physicians may also be contacted by the Corventis Monitoring Center directly when arrhythmias that meet predefined criteria are detected.

IMPORTANT:

- **The NUVANT MCT System is not intended to be an alarm or to alert patients or physicians, and will not summon emergency response in the event help is needed.**
- **The NUVANT MCT System is not intended to replace direct communication with healthcare providers.**
- **Data provided by the system should be used by physicians along with all other clinical findings and exams to come to a diagnosis.**
- **Patients should talk to their healthcare provider immediately if there are any concerns or if their condition changes.**

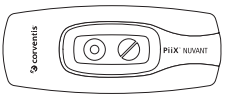
P01281-005 (05/13)

Table of Contents

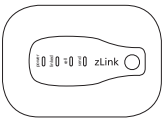
Getting Started 2
Using NUVANT MCT During the Monitoring Period 6
What to do at the End of Monitoring 8
Indications for Use, Contraindications, Warnings 9
Physician Services 10
Specifications, Compliance and Symbols 11
Frequently Asked Questions 15
Contact Information 16

Getting Started

Step 1: Locate the components of the NUVANT MCT System

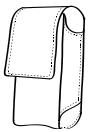


PiiX is a wearable device that collects and transmits physiological data. One or more PiiX devices may be included in the package, depending on the length of the prescription

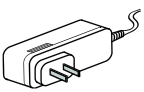


zLink is a device that receives data from the PiiX and transmits it to Corventis

Patient Trigger Magnet is used to collect a record of your heart rhythm (ie, ECG) when symptoms are felt



Link Holster is a wearable holder for the zLink

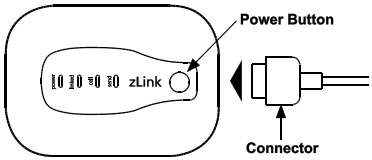


zLink Charger is used to charge the zLink

Prep Wipes are used for cleaning skin before applying the PiiX

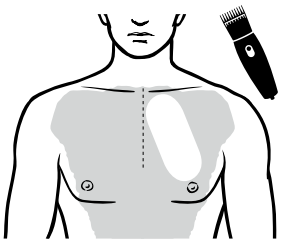
Product Literature including these instructions, an instructional DVD, the Notice of Privacy Practices and a NUVANT MCT patient travel card

Step 2: Charge the zLink



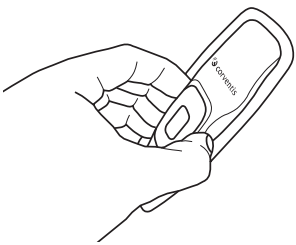
- Connect the zLink Charger connector to the zLink and plug it into a standard electrical outlet
- If the lights on the zLink do not turn on, push the round **Power** button for at least 2 seconds
- Allow the zLink to charge for at least 6 hours

Step 3: Prepare for PiiX Application



- **Trim as much hair as possible** from the intended location *[for men]* on the upper left chest, as seen in the diagram (for example, using an electric razor or hair trimmer). Trim an area slightly larger than the PiiX
- **Using the Prep Wipe provided,** clean the skin where the PiiX will be applied and allow time to dry (clean an area slightly larger than the PiiX)
- Do not use any creams or lotions on your skin before application as this will impact monitoring

IMPORTANT: Monitoring will be affected if hair is not trimmed or if skin is not cleaned with the Prep Wipe. If this happens, you may be required to use another PiiX.

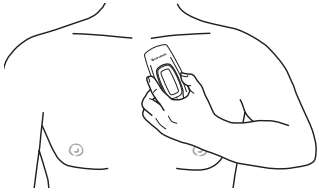


- Remove the PiiX from the foil pouch by tearing at the notch. If you see any lights on the PiiX before application, contact Corventis Customer Service at 1-877-247-PIIX (7449)
- Grasp the top side of the PiiX as seen in the diagram and turn it over to view the underside
- Carefully pull each tab from the underside of the PiiX to expose the adhesive area

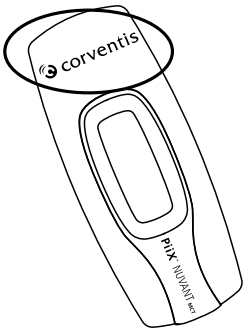
IMPORTANT: Take care not to touch the gel areas and not to fold the fabric on to itself while you handle the PiiX.

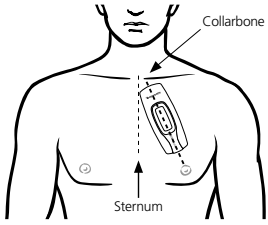
Step 4: Apply the PiiX to your Chest

- Bring the PiiX close to your upper left chest, taking care to hold it only as described in Step 3

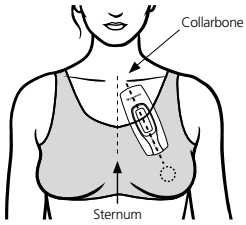


- As seen in the diagrams below, position the end of the PiiX with "Corventis" just below the **collarbone** and angle the device towards the **nipple**. To minimize skin irritation, do not place the PiiX over broken or damaged skin



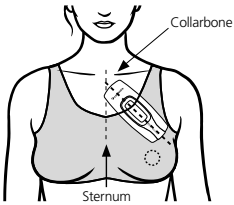


MALE



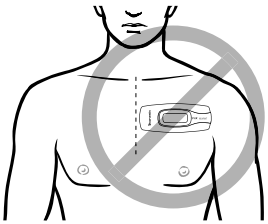
FEMALE

- Petite patients can angle the PiiX slightly away from the nipple and towards the left arm for a comfortable fit, as seen below

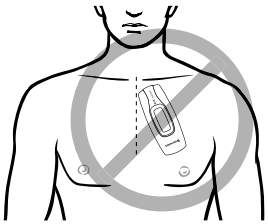


- Once applied, use the palm of the hand to firmly apply pressure across the surface of the PiiX. Then, use your fingers to press the edges of the PiiX onto your skin
- Avoid strenuous motion, activity or showering for 30 minutes after PiiX application

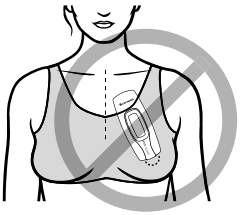
EXAMPLES OF INCORRECT PIIX APPLICATION



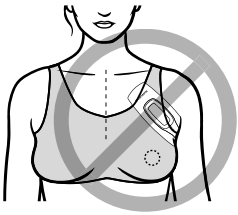
Horizontal



Upside Down



Applied over the nipple

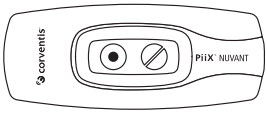


Applied under the arm

IMPORTANT: Monitoring will be affected if the PiiX device is not applied correctly. If this happens, you may be required to use another PiiX.

Step 5: Confirm the PiiX has activated

- If you see a single blinking green light within the circle symbol, it means the PiiX is working properly
- If you DO NOT see this light within 15 minutes of application, please call Corventis Customer Service at 1-877-247-PiiX (7449)



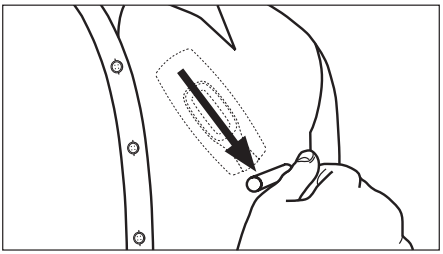
Key Things to Remember

- Wear the PiiX continuously until you see the following two symbols (⊙ and ⊗) appear on the PiiX display
- You can wear the PiiX while you shower (it is water resistant), but do NOT submerge PiiX in water (for example, by swimming or sitting in a hot tub). Avoid excessive rubbing of the PiiX while showering
- Once applied, do not remove and then reapply or reposition the PiiX. If this happens, you may be required to use another PiiX (ie, it is meant for one-time use)
- Keep the zLink close to you at all times (within 9 meters / 30 feet) and charge it daily (for example, each night while you sleep)
- Carry the Patient Trigger Magnet with you at all times and use it when you feel symptoms

Using NUVANT MCT during the Monitoring Period

What to do when you feel cardiac symptoms

Use the Patient Trigger Magnet whenever you feel cardiac symptoms. It will direct the PiiX to collect a record of your heart rhythm (ie, ECG), which will then be automatically transmitted to your zLink and then automatically transmitted to the Corventis Monitoring Center for review by Corventis technicians. This information will then be provided to your physician.



- Position the Patient Trigger Magnet at one end of the PiiX and move it lengthwise, **once**, across the surface and towards the opposite end (for example, as seen in the diagram)
- The Patient Trigger Magnet can be used over light clothing (for example, a shirt or light sweater)
- Carry the Patient Trigger Magnet with you at all times (taking care not to come into contact with credit cards)
- •Do not place the Patient Trigger Magnet in a shirt pocket or on a necklace, as that might cause unnecessary ECG collection

IMPORTANT: You may be contacted by a technician from the Corventis Monitoring Center to discuss symptoms when the Patient Trigger Magnet is used. When you experience any symptoms, please make note of the following to discuss with a technician:

- **Type of symptoms**
- **Time of symptoms**
- **Duration of symptoms**
- **What you were doing**

How to use the zLink

The zLink should be kept within 30 feet (9 meters) of you at all times to allow transmission of data from the PiiX to the zLink

- During the day, carry the zLink with you using the zLink Holster
- At night, keep the zLink close to you while you sleep (for example, on a nightstand)

The zLink should be kept ON at all times to allow transmission of data from the PiiX to the zLink

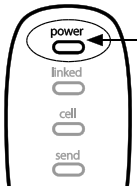
- The zLink may be turned ON and OFF manually by pressing and holding the Power button for several seconds. However, please keep the zLink turned on at all times to ensure transmission

IMPORTANT: If you are out of range of the zLink or required to turn it off (for example, when on an airplane or if asked by Corventis Customer Service), you can continue to use the Patient Trigger Magnet

to document symptoms and wear the PiiX. All of your data will be stored on the PiiX and sent to the zLink when you are again within range or when the zLink is turned back on.

How to charge the zLink

- Charge the zLink daily, (for example, every night while you sleep)
- The zLink may take up to 6 hours to fully charge
- With an adequate charge, the zLink can be used for up to 12 hours before needing to be recharged
- The Linked, Cell and Send lights on the zLink are utilized by Corventis Customer Service for troubleshooting. Refer to these lights only if asked by a Corventis Customer Service representative



Power Light:
BLUE ON: Adequate charge
AMBER ON: Low charge
AMBER Flashing: Charging required

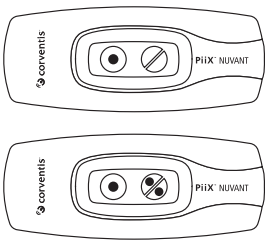
IMPORTANT: If the battery on the zLink runs out, you can continue to use the Patient Trigger Magnet to document symptoms and wear the PiiX. All of your data will be stored on the PiiX and transmitted once the zLink is charged.

When to remove or replace the PiiX

Each PiiX device is designed to operate with normal wear and tear over the course of use for up to 7.5 days. The PiiX is also water resistant. You can keep wearing the PiiX while you shower, but do not submerge it in water (for example, in a bath or hot tub).

Depending on the length of your prescription, you may need to wear more than one PiiX. As seen in the diagram below, the PiiX display will let you know when it should be removed.

- If you see a single blinking green light within the filled circle symbol, this means the PiiX is working properly. You should continue to wear the device.
- If you also see two red lights within the circle with a crossed line symbol, you should remove and replace the device with a new PiiX (unless your monitoring period is over).



IMPORTANT: Each PiiX device should be worn <u>continuously</u> until the two red lights behind the circle with the crossed line are seen. This may take up to 7.5 days, but could be less. Once it has been removed, do not reapply the PiiX as this will affect monitoring (ie, it is meant for one-time use only). Please call Corventis Customer Service at 1-877-247-PIIX (7449) if you have any questions about when to remove the PiiX.

How to remove the PiiX

- Grasp an edge of the PiiX with one hand and begin to peel it away from your skin
- Using the other hand, slowly and gently push the skin away from the PiiX as it is removed

IMPORTANT: Rapid removal can cause skin irritation. If irritation persists after PiiX removal, consult your healthcare provider for topical treatment options.

How and when to dispose of the PiiX

The PiiX has a Lithium battery and must not be disposed of in a fire. Please dispose of your PiiX devices in accordance with local and federal regulations.

IMPORTANT: Please do not dispose your PiiX devices until the end of the monitoring period. This helps to ensure that all of your data are transmitted.

What to do at the End of Monitoring

How to return your zLink

When your prescription is complete, it will be necessary to return the **zLink**, the **zLink Charger**, and the **Patient Trigger Magnet** to avoid being billed for the value of the system. You do NOT need to return used PiiX devices. Follow the steps below to return the materials to Corventis:

- Remove the postal envelope provided in the original packaging.
- Place the zLink, the zLink Charger, and the Patient Trigger Magnet back into the original box.
- Place the box into the postal envelope and seal.
- Place the envelope in the mail. No additional postage is required.

IMPORTANT: Please return your materials only when your prescription is complete. Call Corventis Customer Service at 1-877-247-PiiX (7449) if you need information about the status of your prescription.

Indications for Use, Contraindications and Precautions

Indications for Use

The NUVANT Mobile Cardiac Telemetry (MCT) System is intended to continuously measure, record and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias such as, but not limited to, supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, paroxysmal SVTs), ventricular ectopy, bradyarrhythmias and conduction disorders. The NUVANT MCT System monitors, derives and displays: ECG, Heart Rate

Description of the System

The NUVANT MCT System consists primarily of the PiiX monitoring device, the zLink data transmission device and a Patient Trigger Magnet (to enable on-demand collection of ECGs). Once activated, the wearable PiiX sensor continuously monitors the heart and automatically collects ECGs when rhythm abnormalities are detected. Patients can also drive collection of ECGs when they experience cardiac symptoms by using the Patient Trigger Magnet. Data are automatically transmitted from the PiiX to the zLink, which then automatically transmits the data to the Corventis Monitoring Center. Certified cardiographic technicians at the Corventis Monitoring Center review received data and document symptoms reported by patients. Clinical reports, prepared by the Corventis Monitoring Center, are delivered and made available at www.corventis.com to provide data to prescribing physicians for the diagnosis and identification of various clinical conditions, events and/or trends.

Based on the indications, the NUVANT System may be used for:

1. Patients who require monitoring for suspected or known, non-life threatening arrhythmias
2. Patients with symptoms such as chest pain, syncope, lightheadedness or near syncope, vertigo, dizziness, fall, palpitations, transient ischemic episodes, dyspnea (shortness of breath) that might be due to cardiac arrhythmias.
3. Patients with cardiac arrhythmias associated with co-morbid conditions.
4. Obtaining correlation of rhythm with symptoms when symptoms have unknown etiology.
5. Evaluating possible arrhythmias in a) patients recovering from cardiovascular or thoracic surgery; b) survivors of myocardial infarction; c) patients with diagnosed sleep disorder breathing.
6. Evaluating benefits after initiating or discontinuation of pharmacological therapy (e.g., anti-arrhythmic, beta-blocker, anti-coagulation therapies).
7. Assessing the results of an ablation procedure for an arrhythmia.
8. Providing data to guide treatment decisions (e.g. pharmacological or procedural/device-based treatments) and assessing treatment results in patients with non-life threatening arrhythmias

Contraindications

1. Patients with known allergies or hypersensitivities to adhesives or hydrogel.
2. Patients with potentially life-threatening arrhythmias, or who require inpatient / hospital monitoring.

Precautions

1. Minute ventilation sensing on implantable devices should be disabled for the duration of PiiX usage
2. The Patient Trigger Magnet should not be used when PiiX are applied in the vicinity of implanted devices with active magnet features.

3. The PiiX should be removed prior to external defibrillation or an MRI scan.
4. The PiiX may cause mild discomfort, skin irritation, redness, itching, rash or contact dermatitis in some individuals. The device should be removed if any pain or discomfort occurs. If skin irritation or redness persists after the device has been removed, a topical anti-inflammatory cream may be applied to the area (in consultation with your health care provider).
5. The PiiX is intended for single patient use and should not be reapplied it if peels off or is removed (ie, it is meant for one-time use).
6. The PiiX should not be applied to broken, damaged or irritated skin.
7. The PiiX is water resistant but not waterproof. It should not be submerged in water (showering is acceptable, but swimming and submersion bathing are prohibited).
8. The PiiX should not be disassembled.
9. Do not apply the PiiX if it appears damaged upon receipt.
10. No creams or lotions should be applied to the skin immediately prior to the application of the PiiX
11. Store the PiiX in a cool, dry location. The device is designed to withstand environmental temperature fluctuations between -20° to 65°C (-4° to 149° F).
12. The system has not been fully evaluated for use with infants weighing less than 22 lbs.
13. The system is not designed to detect pacemaker spikes.

Physician Services

Prescription Duration:

After registering with Corventis, physicians can prescribe NUVANT MCT for up to 30 days at a time. As each PiiX is designed to last for up to 7.5 days (unless the memory on PiiX becomes full beforehand), prescription lengths greater than one week will be enabled through the use of more than one PiiX.

Clinical Reports:

Clinicians can receive clinical reports, including Episode, Daily and End of Use Reports, directly from the Corventis Monitoring Center by fax and/or email. Clinical data can also be securely reviewed online at www.corventis.com. Upon clicking on the "LOGIN" link at the Corventis homepage, clinicians will be prompted to input their personal Username and Password information to access the application. Clinicians may download and/or print clinical reports, review collected ECGs and also establish service preferences. For any questions about online use, please contact Corventis Customer Service at 1-877-247-PiiX (7449).

Notifications:

The Corventis Monitoring Center may send Episode Reports and contact prescribing physicians directly when arrhythmias that meet pre-defined criteria are identified. Contact information and notification preferences will be established upon registration and can be updated.

IMPORTANT: Patient data are updated for physician display upon detection of a clinical event OR every two hours when no events are detected, assuming a) PiiX is within 30 feet (9 meters) of zLink, b) zLink has been appropriately installed and has sufficient power and c) sufficient cellular coverage for data transmission exists. Analysis of ECGs by the Corventis Monitoring Center may also affect the timing of ECG display.

Specifications, Compliance and Symbols

Specifications

The following performance specifications are at 20°C (68°F) unless otherwise stated

	PiiX	zLink	Patient Trigger Magnet
Shelf life	Refer to PiiX pouch label	N/A	N/A
Battery Charger Power Requirement	N/A	100-240VAC, 50/60Hz	N/A
Battery Life	7.5 days (180 hrs), non-rechargeable	Provides 12 hrs of function before recharging	N/A
Operating Temperature	0˚C to 41˚C (32˚F to 105.8˚F)	0˚C to 45˚C (32˚F to 113˚F)	N/A
Maximum Temperature of the Applied Part	44˚C (111.2˚F)	N/A	N/A
Storage Temperature (power off)	-20˚C to 65˚C (-4˚F to 149˚F)	-20˚C to 65˚C (-4˚F to 149˚F)	N/A
Operating Humidity	10% to 95%	10% to 95%	N/A
Storage Humidity	5% to 95%	5% to 95%	N/A
ECG			
Sampling Rate	200Hz (+/-5%)	N/A	N/A
Digital Resolution	10bits	N/A	N/A
Input Dynamic Range	+/- 5mV	N/A	N/A
Input Offset Dynamic Range	+/- 300mV	N/A	N/A
Impedance Measurements			
Peak current injection	40 uA	N/A	N/A
RMS current injection	29 uA	N/A	N/A
Measurement Ranges, Heart Rate	25 to 250 BPM	N/A	N/A
Data Storage Capacity	7.5 days	N/A	N/A
Weight	50g / 1.8oz max	150g / 5.3oz max	Portable
Communication Means	Bluetooth between PiiX and zLink	Cellular Phone between zLink and Server	N/A

Arrhythmia Detection Algorithms and Automatic ECG Collection

In addition to patient-driven collection of ECGs using the Patient Trigger Magnet, the NUVANT MCT system also uses proprietary algorithms based on rate, rhythm and morphology to continuously analyze rhythm abnormalities and to initiate automatic ECG collection. ECGs are automatically collected upon detection of the following conditions:

- Heart Rate >= 130 bpm
- Heart Rate <= 40 bpm
- Pause >= 3 seconds
- Atrial Fibrillation
- Ventricular Tachycardia/Ventricular Fibrillation

For example, the detection algorithm of the NUVANT MCT System detects the peak of each R-wave and calculates the interval between successive R-waves. The RR intervals are then used to calculate beat-to-beat heart rate values and to initiate collection of ECGs. RR intervals are also aggregated into 5-minute and 24-hour averages to summarize patient heart rate over the monitoring period. For Pause detection, the algorithm monitors the time between successive R-wave peaks. A pause trigger is activated if an internal timer advances to 3 seconds without R-wave detection.

In order to provide relevant, exception-based arrhythmia reporting, the NUVANT MCT System's proprietary ECG analysis algorithms proactively manage redundant reporting of ECGs for a select set of arrhythmias when persistently detected:

- Tachycardias with heart rate >= 130bpm and < 165bpm
- Bradycardias with heart rate >= 30bpm and < 40bpm
- Atrial Fibrillation
- Ventricular Tachycardia < 165bpm

For these arrhythmias, the PiiX algorithm detection sensitivity and positive predictive value results, which are obtained from the respective databases in strict accordance with EC-57* and with 0% downtime, are as follows:

Test Rhythm Name	Sensitivity (%)*	Positive Predictive Value (%)*
QRS Detection (average) Including all Tachycardias with heart rate >= 130bpm and < 165bpm, Bradycardias with heart rate >=30bpm and <40bpm	AHA: 98.87 MIT-BIH: 99.77	AHA: 99.61 MIT-BIH: 99.82
AF Duration (gross)	MIT-BIH: 88	MIT-BIH: 82

** as measured by EC-57 standards testing on 10/25/2011*

Redundant reporting of ECGs for this select set of arrhythmias is managed as follows:

- The PiiX will report no more than two (2) ECGs for each of these arrhythmias each hour
- The PiiX will wait ten (10) minutes before allowing a subsequent ECG to be reported for each of these arrhythmias

Note: a) ECGs are reported for all Tachycardias with heart rate >= 165bpm, all Bradycardias with heart rate < 30bpm and all Pauses >= 3 seconds; b) The PiiX keeps a complete count of all arrhythmias that are detected; c) Supplemental ECGs are also reported i) every six (6) hours for prolonged Atrial Fibrillation episodes and ii) every twenty-four (24) hours, irrespective of the presence of an arrhythmia

zLink Maintenance

Please attempt to keep zLink dust free. If necessary, gently wipe the zLink with a soft dry cloth to clean the surface. The zLink is not waterproof and should be kept dry. This device does not have user serviceable components inside. Do not disassemble, crush, puncture, short external contacts or circuits, dispose of in fire or water, or expose the battery pack to temperatures higher than 65˚C (149˚F).

Electromagnetic Interference

This equipment complies with International Standard IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information provided upon request by calling Corventis Customer Service at 1-877-247-PiiX (7449). Portable and mobile RF communication equipment can affect nearby medical electrical equipment.

FCC Compliance

PiiX and zLink devices comply with Part 15 of the Federal Communications Commission (FCC) Rules – Radio Frequency Devices: Operation is subject to the condition that (1) this device does not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by Corventis could void the user's authority to operate the equipment. Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a residential environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications.

Exposure to radio frequency signals

To maintain compliance with FCC RF exposure guidelines when you carry the zlink device on your body, use only the holster equipped with an integrated belt clip that is supplied by Corventis. Use of accessories that are not expressly approved by Corventis might violate FCC RF exposure guidelines.

Specific absorption rate data

The zlink device meets the US Government requirements for exposure to radio waves when used as directed in this section.

The zlink is a radio transmitter and receiver. It is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission (FCC) of the U.S. Government when used as directed in the previous section. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The exposure standard for wireless devices employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg. Tests for SAR are conducted using standard operating positions specified by the FCC. Before a wireless device model is available for sale to the public, it must be tested and certified to the FCC that it does not exceed the limit established by the government-adopted requirement for safe exposure under the recommendations of the International Commission on Non-Ionizing Radiation Protection (ICNIRP).

The FCC has granted an Equipment Authorization for this wireless device model with all reported SAR levels evaluated is in compliance with the FCC RF emission guidelines when the zlink is used as directed in this section.

Label Symbol Definitions

	Consult Instructions for Use		Do Not Reuse
	Follow Instructions for Use		Use-by (Year-month) or (year-month-date)
	Caution: consult accompanying documents		Latex Free
	Batch Number		Serial Number
	Date of Manufacture		Catalogue Number
	Non-Sterile		Manufacturer's Name and Address
	Temperature Limitations		Collection of electrical and electronic equipment
	Type BF applied part; Denotes device is not in direct contact with cardiac muscle		Wireless Transmission Symbol
IP 35	Ingress Protection 3 means protection against objects >= 2.5mm in diameter (tools) 5 means protection against water jets (shower)	Rx only	Federal (USA) law restricts this product to sale by or on the order of a physician.
	Class II Equipment		Conformite Europeenne

Frequently Asked Questions

What is a PiiX?

A PiiX is a patient-worn medical device designed to comfortably adhere to the skin. The device contains sensors that collect your ECG waveform (a tool for analyzing the activity of your heart).

How long will my PiiX last?

Each PiiX device is designed to last up to 7.5 days (unless the memory fills up beforehand). However, inappropriate PiiX application, or removal and reapplication of the PiiX during use, will affect monitoring. If this happens, you may be required to use another PiiX.

What information is transmitted to my physician?

Your heart activity is monitored 24 hours a day, 7 days a week. Any unusual heart activity is recorded, and transmitted for review to your physician.

What do I do when I feel symptoms?

Whenever symptoms occur, trigger the PiiX to record your heart activity by using the Patient Trigger Magnet (provided). Swipe the magnet along the entire length of the PiiX, once, at a uniform rate. An ECG will be collected by the PiiX, transmitted to the zLink and then transmitted to the Corventis Monitoring Center for review and delivery to your physician.

How can I report my symptoms?

Technicians from Corventis will occasionally call you to discuss your symptoms. Please make note of the type of symptoms, the duration of symptoms, when they happened and what you were doing so it can be discussed with a technician.

Should I keep the Patient Trigger Magnet with me at all times?

Yes, you should always carry the Patient Trigger Magnet with you. Please keep the Patient Trigger Magnet away from your credit cards or identity cards as the magnet may erase them. Also, please do not place the Patient Trigger Magnet in a shirt pocket or on a necklace, as that might cause unnecessary ECG collection.

Can I take a shower while wearing my PiiX?

Yes, the PiiX is water resistant so you can shower while wearing it. However, do NOT submerge PiiX in water by swimming or sitting in a hot tub. In addition, avoid excessive rubbing of the PiiX during showering.

Should I carry the zLink with me when I travel?

Yes, take zLink with you at all times. zLink will remain charged for up to 12 hours. If you plan to be away for longer than 12 hours, take the zLink charger with you.

Will I need to change the battery in the zLink or the PiiX?

Battery replacement is not required for the PiiX and the zLink. However, we recommend that you charge the zLink every night.

How close must I be to zLink to ensure that the data collected by my PiiX are transmitted?

Remain within 30 feet (9 meters) of zLink for successful data transmission.

How often do I need to change the PiiX device?

When both of the following two symbols ⊙ and ⊗ appear on the PiiX display, you should remove PiiX. Please apply a new PiiX if your monitoring period has not ended.

What if PiiX causes my skin to itch?

If you experience skin irritation while wearing PiiX, speak with your physician.

Will I need to notify airline security screeners about my PiiX?

Although PiiX and zLink devices may trigger airport detectors, they will not be damaged. Carry the NUVANT MCT patient travel card provided as part of your NUVANT MCT System when traveling or entering high security areas. Simply notify airport personnel that you are wearing a PiiX medical device and show them your patient card.

Can I wear a PiiX through a shoplifting detector in a store?

Yes, the PiiX will not set off store detectors and will not be damaged by them.

Can I use microwave ovens or TV remotes while wearing a PiiX?

Yes, it is safe to operate these devices as they will not affect performance of the PiiX.

Can I be close to wireless phones, WiFi, or other electromagnetic devices?

Yes, although some sources of Electromagnetic Interference (EMI) may temporarily disrupt data transmission.

Can I carry my cellphone while wearing PiiX?

Yes, but do not place your cellphone in a pocket directly over PiiX. Some cellphones have magnets that can lead to unintended ECG collection.

Will hot or cold environments affect PiiX performance?

PiiX provides accurate and reliable performance in a temperature range of 32˚ F to 105.8˚ F (0˚ C to 41˚ C).

Are my medical data protected during transmission?

Your data are transmitted securely to the Corventis Monitoring Center and securely stored.

Contact Information

Corventis Customer Service
1-877-247-PiiX (7449)

Corventis, Inc.
1410 Energy Park Drive
St. Paul, MN 55108

corventis™

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