corventis

P00986-002 Rev A

NUVANT™ Mobile Cardiac Telemetry (MCT) System

INSTRUCTIONS FOR USE

Rx only

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. The NUVANT System model monitors, derives and displays:

• ECG
• Heart Rate

The System may also monitor, derive and display:

• Activity
• Posture
• Respiration rate (including RR variability)
• Body fluid status
• Heart rate variability

Description of the System

The NUVANT System includes:

a) PiiX™ - an adherent patient-worn device containing multiple sensors used to track a suite of physiological parameters. The PiiX can also be activated to associate patient symptoms with ECG data using a Patient Trigger Magnet. PiiX can collect approximately 500 ECG episodes. However, PiiX must be replaced after 7.5 days of use or when the end of life indicator appears. An end of life indicator as shown below, will light up when the PiiX needs to be replaced.
b) zLink™- a device that receives data from the PiiX and transmits to the Server.
c) zLink Charger – a charger for the zLink.
d) zLink Holster – a wearable holder for the zLink.
e) Prep wipes – wipes used for cleaning the skin prior to applying the PiiX.

The NUVANT System enables remote monitoring in ambulatory patients to:
a) Detect, store and transmit ECGs and other physiological data.
b) Assist physicians/health practitioners in the diagnosis and identification of various clinical conditions/events/trends through web services and patient reports.

Based on the indications, the NUVANT System may be used for:
a) Patients who require monitoring for known, non-life threatening arrhythmias.
b) 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.
c) Patients with cardiac arrhythmia associated with co-morbid conditions.
d) Obtaining correlation of rhythm with symptoms when symptoms have unknown etiology.
e) Evaluating possible arrhythmias in a) patients recovering from cardiovascular or thoracic surgery; b) survivors of myocardial infarction; c) patients with diagnosed sleep disorder breathing.
f) Evaluating benefits after initiating or discontinuation of anti-arrhythmic drug therapy.
g) Assessing the results of an ablation procedure for an arrhythmia.

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. PiiX should not be used on patients with implantable devices with active minute ventilation sensors.
2. Patient trigger magnet should not be used in patients who have implanted devices with active magnet features in the vicinity of the PiiX.
3. PiiX should be removed prior to external defibrillation or an MRI scan.
4. 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. PiiX is intended for single patient use.
6. PiiX should not be applied to broken, damaged or irritated skin.

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7. 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. PiiX should not be disassembled.
9. Replace the PiiX if it peels off; do not reapply the PiiX.
10. Replace the PiiX if it appears damaged.
11. No creams or lotions should be applied immediately prior to use of PiiX.
12. Store PiiX in a cool, dry location. The device is designed to withstand environmental temperature fluctuations between 0° to 40°C.

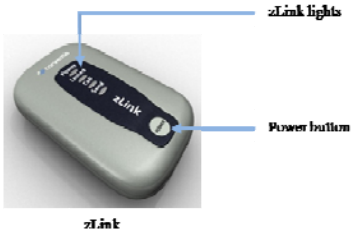
The NUVANT System is not intended to replace direct communication with your healthcare provider. The system data should not be used alone, but should be used along with all other clinical data and exams to come to a diagnosis. The system is not intended to alarm or alert physicians, and will not summon emergency response in the event you need help. Talk to your healthcare provider immediately if you have any concerns, or if your condition changes.

Step-by-step Operating Instructions – NUVANT MCT System

No specific training is needed for the use of this system.
The zLink should be set-up first prior to the PiiX application.

zLink Set-up

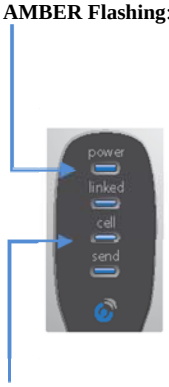
1. Remove the zLink from the box.



2. Connect the charger connector with the zLink
3. Plug the charger into an electrical outlet. zLink will begin charging immediately. If the lights on the zLink do not display, push the round Power button located below the lights to turn on the zLink. The zLink should be kept connected to the charger until the Power light is blue.

zLink Lights

Power Light:
BLUE ON: Full charge confirmed
AMBER ON: Low charge warning
AMBER Flashing: Battery capacity less than 10%. Full charge may take up to 4 hours



Cell Light:
BLUE: Adequate cell coverage
AMBER: No cell coverage. Move zLink to another location

Other lights on zLink are utilized only if troubleshooting is necessary. Refer to these lights only if asked by a Corventis Customer Service representative.

zLink may also be turned ON and OFF manually. To turn zLink ON when zLink is not connected to the charger, press the round Power button located below the lights. All lights will come on, confirming zLink is ON. To turn zLink OFF, press the round Power button for several seconds until all the lights turn off.

4. To initiate use, charge the zLink for a minimum of 4 hours.

Keep zLink connected to the charger overnight, every night. With a full charge, the zLink will remain charged for up to 12 hours. Preferably, the zLink should be kept within 30 feet (9 meters) of the patient as much as possible to ensure data transmission.

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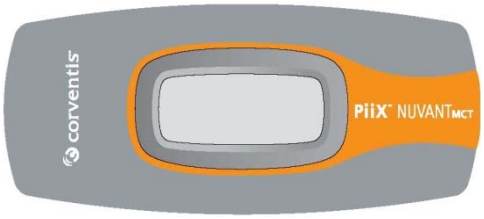
PiiX Application

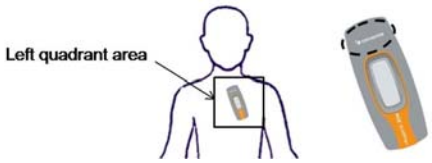


PiiX

First device:

1. Trim (rather than shave) hair in intended location.
2. Use prep wipe provided with PiiX to clean the skin where the device is intended to be applied. Allow the skin to dry.
3. Remove the PiiX from the foil pouch by tearing at the notch and apply immediately.
4. Remove the covers from the underside of the PiiX.
5. Handle the PiiX on the edges until the PiiX is placed on the skin.
6. Place the PiiX in a diagonal position only, oriented with **Corventis** at the top. Noting the picture below, place the device in the chest region, to the left of the sternum and starting at the clavicle (or collarbone) referred to as the 'left quadrant'. Avoid moles and pimples.

FRONT



Note: Apply the PiiX in the position as directed above. The reviewers of the ECG waveform data will not be aware if the user applies PiiX in a location / orientation other than diagonal position in upper left quadrant area of chest.

7. The PiiX must be in direct contact with the skin. Once applied, press the edges firmly against the skin.
8. It is recommended that the PiiX be placed at least ½ inch away from any tight-fitting undergarment to prevent rubbing or chafing.
9. If you experience cardiac symptoms, position the Patient Trigger Magnet just on the surface of the PiiX and move it along the entire length of the PiiX. This will initiate storage of an ECG for subsequent transmission.

Look for these indicators to appear on the PiiX display:

Light behind the filled circle symbol indicates the PiiX is successfully activated. This light will appear when skin contact is made and may blink.

Lights behind the circle with crossed line symbol indicate it is necessary to remove your PiiX and replace it with a new PiiX (unless your prescription has ended).

ECG storage and transmission:

Patient Trigger Magnet

Position the Patient Trigger Magnet just on the surface of the PiiX and move it along the entire length of the PiiX. An ECG will be stored and transmitted and subsequently displayed at the secure Corventis website where your physician can review it.

PiiX Removal

1. Peel back the edge of the PiiX. Slowly and gently push the skin away from the PiiX as it is removed. Rapid removal can cause skin irritation.
2. If the PiiX does not peel easily, soak the device with water to assist in softening the adhesive.
3. If skin irritation persists, leave the area exposed or under light clothing. Consult your healthcare provider for any topical treatment options.

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Physician Web Services
Go to **www.corventis.com** to login. **First time login:** 1. Enter User Name and the Password provided and click **Submit**. 2. Answer the Secret Question. Next, enter new password. Confirm new Password and click Submit. "*Password has been changed*" notification will appear. 3. Click on **Login** to proceed to the Home page. **Subsequent logins:** Enter your User Name and Password and click on **Submit** to proceed to the home page.

Label Symbol Definition: The following symbols may appear on PiiX application, zLink or on the packaging

Symbol and Definition	Symbol and Definition
 Consult Instructions for Use	 Do Not Reuse
 Consult Instructions for Use (Mandatory)	 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
IP34 - Ingress protection 3 means protection against objects >=2.5mm in diameter (tools) 4 means protection against water splashing (shower)	Rx only - Federal (USA) law restricts this product to sale by or on the order of a physician.
 Class II Equipment	

Transport and Storage Instructions

Storage temperature: 0°C to 40°C.

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Instructions on how to safely dispose of the PiiX

The PiiX has a Lithium-ion battery and must not be disposed of in a fire. If unable to properly dispose of the product or components in accordance with local and federal regulations contact Corventis at 1-877-247-PiiX (7449) or 1 (408) 790-9393.

Maintenance Instruction for zLink

For cleaning, gently wipe with a soft dry cloth. Please attempt to keep zLink dust free. zLink is not waterproof and should be kept dry. This device does not have serviceable components. Please call Corventis Customer Service number if the device does not appear to be working properly. Do not disassemble, crush, puncture, short external contacts or circuits, dispose of in fire or water, or expose a battery pack to temperatures higher than 60˚C. Please refer to Patient Guide for zLink return instructions.

Specifications

The following performance specifications are for the PiiX and the zLink. All specifications are at 20°C (68°F) unless otherwise stated.

	PiiX	zLink	Magnet
Shelf life	4 months	N/A	N/A
Battery Capacity	2300mAh	1800 mAh @ C/5 Rate @ 23° C	N/A
Battery Charger Power Requirement	N/A	100-240VAC, 50/60Hz, 15W	N/A
Battery Life	7.5 days (180 hrs), non-rechargeable	Provides 12 hrs of function before recharging	N/A
Battery Voltage	3.0 Volts	3.7 Volts	N/A
Operating Temperature	0^0C to 41^0C	0^0C to 45^0C	0^0C to 45^0C
Maximum Temperature of the Applied Part	44^0C	N/A	N/A
Storage Temperature (power off)	0^0C to 40^0C	0^0C to 40^0C	0^0C to 40^0C
Operating Humidity	10% to 95%	10% to 95%	10% to 95%
Storage Humidity	5% to 95%	5% to 95%	5% to 95%
ECG • Sampling Rate • Digital Resolution • Input Dynamic Range • Input Offset Dynamic Range • Timing Accuracy	 200Hz 10bits +/- 5mV +/- 300mV +/- 5 ms	 N/A N/A N/A N/A N/A	N/A
Sampling Rate • ECG • Impedance • Accelerometer	 200 Hz (+/- 5%) 4 Hz 0.25 Hz (+/- 2%)	 N/A N/A N/A	N/A
Measurement Ranges • Heart Rate • Impedance • Respiration • Posture	 25 to 250 BPM 10 to 150 Ohms 4 to 60 Breaths per minute +/- 2g range in x,y,z direction	 N/A N/A N/A N/A	N/A
Data Storage • Capacity • Type	 7.5 days Digital flash non-removable	 7.5 days Digital flash non-removable	N/A
Weight	50g / 1.8oz max	150g / 5.3oz max	Portable
Communication Means	RF Wireless between PiiX and zLink	Cellular Phone between zLink and Server	N/A

The heart rate 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, which are then aggregated into 5-minute and 24-hour averages for display. The pause algorithm monitors the time between successive R-wave peaks. A timer is reset upon each R-wave peak detection, and a pause trigger is activated if the timer advances to 3 seconds without an R-wave detection.

The arrhythmia detection algorithm of the NUVANT MCT System was tested according to ANSI/AAMI EC57 (Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms) for ventricular tachycardia and ventricular fibrillation and determined to have an average sensitivity of 96.9% and an average positive predictive value (PPV) of 85.3%.

This equipment complies with International Standard IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipments. 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) / 1 (408) 790-9393, or at www.corventis.com. Portable and mobile RF communication equipments can affect nearby medical electrical equipment.

PiiX and zLink complies 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. (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 ~~commercial~~ 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.

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Exposure to radio frequency signals

To maintain compliance with FCC RF exposure guidelines when you carry the zlink device on your body, use only 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.

To reduce radio frequency (RF) exposure consider these safety guidelines:
Use hands-free operation if it is available and keep the zlink device at least 0.98 in. (25 mm) from your body (including the abdomen of pregnant women and the lower abdomen of teenagers) when the device is turned on and connected to the cellular network.

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~~, IC, and The Council of the European Union~~ 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 as in compliance with the FCC RF emission guidelines when the zlink is used as directed in this section.

User Assistance Number:
If the NUVANT System is not operating properly, please contact Corventis Customer Service:
1-877-247-PiiX (7449)
1 (408) 790-9393

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Patents pending
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