corventis

P00873-001 Rev. B

AVIVO™ Mobile Patient Management System

INSTRUCTIONS FOR USE

Rx only

Indications for Use

The AVIVO Mobile Patient Management System is intended to continuously record, store, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. The AVIVO Mobile Patient Management System also monitors, derives and displays:

- ECG
- Heart Rate (including HR variability)
- Activity
- Posture
- Body Temperature
- Respiration rate (including RR variability)
- Body fluid status

Description of the Device

The AVIVO Mobile Patient Management System includes:

a) PiiX™ - an adherent patient-worn device containing multiple sensors used to track a suite of physiological parameters. PiiX can collect up to 72 ECG episodes. However, PiiX must be replaced after 7 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 Base – a charging station 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 AVIVO System enables remote monitoring of physiological parameters in ambulatory patients to:

a) facilitate patient and medical management, and
b) assist physicians/health practitioners in the diagnosis and identification of various clinical conditions/events/trends.

Contraindications

1. PiiX should not be used on patients with known allergies or hypersensitivities to adhesives or hydrogel.

Precautions

1. PiiX should not be used on patients with implantable devices with active minute ventilation sensors.
2. PiiX may cause mild discomfort, skin irritation, redness, itching, rash, 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).
3. PiiX is intended for single patient use.
4. PiiX should be removed prior to external defibrillation or an MRI scan.
5. PiiX should not be applied to broken, damaged or irritated skin.
6. PiiX is water resistant but not waterproof. It should not be submerged in water (showering is acceptable, but swimming and submersion bathing are prohibited).
7. PiiX should not be disassembled.
8. Replace the PiiX if it peels off; do not reapply the PiiX.
9. Replace the PiiX if it appears damaged.
10. No creams or lotions should be applied immediately prior to use of PiiX.
11. This product is recommended for adult use.

The AVIVO Patient Management 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. Additionally, it will not summon emergency response personnel in the event you need help. Talk to your healthcare provider immediately if you have any concerns, or if your condition changes. The AVIVO System is not an emergency response service. Seek medical advice if you experience any symptoms that concern you.

For US distribution (01/10)

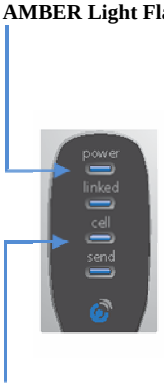
No specific training is needed for the use of this system.
zLink should be set-up first prior to PiiX application.

zLink Set-up

1. Plug the zLink into a standard electrical outlet.

2. Dock zLink into the Base. The lights will automatically come on, confirming zLink is ON.

Power Light:
BLUE Light ON: Full charge confirmed
AMBER Light ON: Low charge warning
AMBER Light 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 the 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 docked in the Base, 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.

3. To initiate use, charge the zLink for a minimum of 4 hours before removing it from the zLink Base

Keep your zLink in the Base 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.

PiiX Application

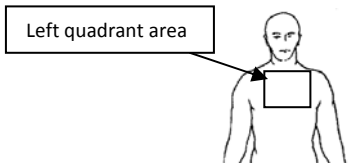
PiiX

First device:

1. **Trim (rather than shave) hair in intended location. Avoid moles and pimples.**
2. **Use alcohol 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.**

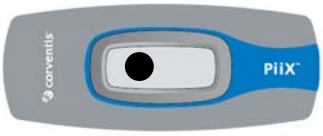
For US distribution (01/10)

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'.**



7. **The PiiX must be in direct contact with the skin. Once applied, press the edges firmly against the skin.**

Look for these indicators to appear on the PiiX display:



FILLED CIRCLE SYMBOL: Indicates the PiiX™ is successfully activated. This symbol will appear when skin contact is made and may blink during duration of use.

CIRCLE MARK WITH LINE: Indicates it is necessary to remove your PiiX™ and replace it with a new PiiX™ (unless your prescription has ended.)

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.**

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:

1. Enter your User Name and Password and click on **Submit** to proceed to the home page.

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Transport and Storage Instructions

Storage temperature: 0°C to 40°C

Instructions on how to safely dispose of the PiiX and zLink

Both PiiX and zLink have Lithium-ion batteries 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 (408) 790-9393.

User Assistance Information

If the AVIVO Mobile Patient Management System is not operating properly, please contact Corventis Customer Service at: +1-877-247-PiiX (7449), or (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.

Label Symbol Definition

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 Manufacturer	 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	

Specifications

	Adherent Device	zLink
Shelf life	4 month	N/A
Battery Capacity	2300mAh	1800mAh @ C/5 Rate @ 23° C
Battery Charger Power Requirement	N/A	100-240VAC, 50/60Hz, 15W
Battery Life	7 days nonrechargable	Provides 12 hrs of function before recharging
Battery Voltage	3.0 Volts	3.7 Volts
Operating Temperature	0^0C to 41^0C	0^0C to 45^0C
Maximum Temperature of the Applied Part	44^0C	N/A
Storage Temperature (power off)	0^0C to 40^0C	0^0C to 40^0C
Operating Humidity	10% to 95%	10% to 95%
Storage Humidity	5% to 95%	5% to 95%
ECG • Sampling Rate • Digital Resolution • Input Dynamic Range • Input Offset Dynamic Range • Timing Accuracy	 200Hz 10bits +/5 mV +/- 300mV +/- 5 ms	 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
Measurement Ranges • Heart Rate • Impedance • Respiration • Posture	 25 to 250 BPM 10 to 150 Ohms 4 to 60 BrPM +/- 2g range in x,y,z direction	 N/A N/A N/A N/A
Data Storage • Capacity • Type	 7 days Digital flash non-removable	 7 days Digital flash non-removable
Weight	50g / 1.8oz max	150g / 5.3oz max
Communication Means	RF Wireless between PiiX and zLink	Cellular Phone between zLink and Server

The heart rate algorithm of the AVIVO™ Mobile Patient Management 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 4 seconds without an R-wave detection.

The arrhythmia detection algorithm of the AVIVO™ Mobile Patient Management 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. The zLink uses RF energy for its internal operations. The RF emission is very low and within IEC 60601-1-2 acceptable limits. It will not likely cause any interference with nearby equipment.

This device complies with Part 15 of the Federal Communications Commission (FCC) Rules – Radio Frequency Devices: Operation is subject to the condition that this device does not cause harmful interference. 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 A 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 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.

User Assistance Number:
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1-877-247-PiiX (7449)
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