CardioBelt™

System Users Manual

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This product is covered by one or more of the following United States Patents: 6,656,125

Additional patents are pending.

CardioBelt™ is a trademark owned by Monebo Technologies, Inc.

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The Monebo CardioBelt™ complies with the following ANSI/AAMi Standards

EC38

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CardioBelt™

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1. INTRODUCTION – Intended Use

a. Intended Use

The Monebo CardioBelt™ is a single lead ECG acquisition device which uses a Bluetooth radio frequency link to transmit the ECG signals to an associated electrocardiograph monitor. The CardioBelt™ is intended to be used in general electrocardiograph situations where ECG monitoring is deemed necessary and is ordered by a physician. The CardioBelt™ can be applied by the patient, a caregiver, or a clinician following the directions of a physician.

b. Contraindications

The CardioBelt™ must not be used by subjects with known skin reactions to synthetic polymers or silver. Note that some people who display sensitivity to silver jewelry are sensitive to the impurities present in silver alloys, and not to the silver itself. These people may not be sensitive to the high-purity silver used in the silver electrode incorporated into the CardioBelt™ elastic chest belt.

The CardioBelt™ should not be used in the presence of open wounds, rashes, or lesions on the torso of the patient.

The CardioBelt™ should never be used near any flammable compounds, such as anesthetics. The CardioBelt™ should never be used in an explosive or potentially explosive atmosphere.

c. Adverse Reactions

The following adverse reactions may occur where the belt touches the skin, but are generally of short duration:

- Pressure marks
- Localized redness
- Slight itching under the belt

All skin-contacting materials used in the CardioBelt™ have passed tests demonstrating compatibility with normal skin. However, should any of the following conditions occur, discontinue use and contact your doctor or monitoring center immediately.

- Skin rash
- Localized allergic reaction
- Any other undue discomfort
- Open Wounds

d. Defibrillator precautions

The input circuitry of the CardioBelt is not defibrillator protected. The CardioBelt should be removed from the patient if a defibrillator is to be used. Using the CardioBelt to monitor the patient during defibrillator discharges may damage the input stages of the amplifiers. This may result in a safety hazard.

e. Single user belt

The Cardiobelt consists of a reusable electronic and a single patient belt. A single patient may reuse the same belt provided it is kept clean and in working order. Contact your caregiver if the belt appears to be broken or the belt becomes unsafe. The belt should not be shared between patients.

f. Radio Interference

Bluetooth™ communications can be disrupted by higher power radio transmitters in the ISM band like portable telephones, WIFI Networks, cellular phones and other Bluetooth devices. If the device does not connect with the receiving device or has intermittent operations check for interfering devices by turning off other radio devices one at a time or moving the modules to a different location.

2.0 Device Description

The CardioBelt™ is a single lead electrocardiograph (ECG) device.

The CardioBelt™ consists of the following three assemblies:

The Cardiac Signal Processing Unit (CSPU)

The Cardiac Signal Acquisition Belt (CSAB)

The power supply/charger unit.

These three assemblies comprise the complete CardioBelt™ system.

CardioBelt™ Modules			
Description	Model Number	Size	Patient Chest Size
Cardiac Signal Processing Unit	CSPU/3.1		
Cardiac Signal Acquisition Belt	CSAB/3.1S	Small	32” to 39” 81 cm to 99 cm
Cardiac Signal Acquisition Belt	CSAB/3.1M	Medium	38” to 46” 97 cm to 117 cm
Cardiac Signal Acquisition Belt	CSAB/3.1L	Large	45” to 52” 114 cm to 132 cm
Adapter/Charger	CSPU/AC/3.1		

Position of the modified standard Lead I electrodes shall be between left/right anterior axillary line and left/right midaxillary line. The CardioBelt™ should be worn just below nipples (Fig2).

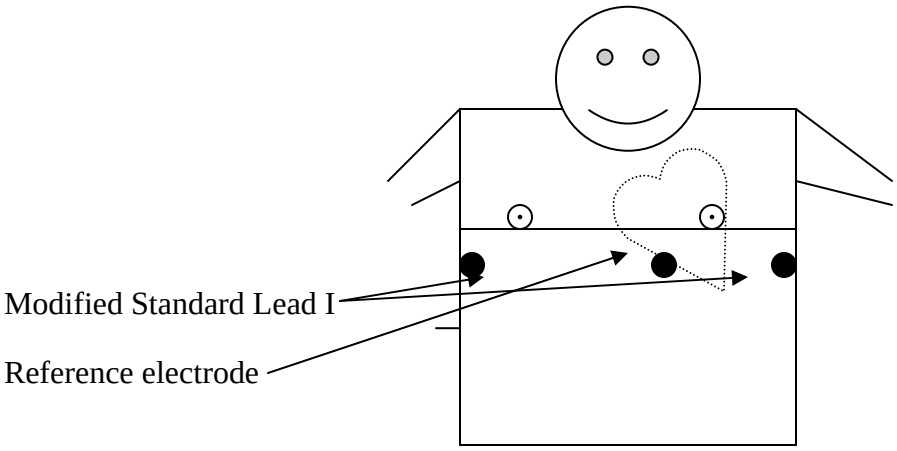


Figure 2

a. Cardiac Signal Processing Unit

The Cardiac Signal Processing Unit, or CSPU, receives the cardiac electrical signals from the sensors in the Cardiac Signal Acquisition Belt. These signals are very low amplitude analog signals detected on the body surface. The CSPU contains signal amplifiers, an analog to digital conversion stage, a controller, and an integrated Bluetooth transceiver. A self contained rechargeable battery powers the electronics.

b. Cardiac Signal Acquisition Belt

The Cardiac Signal Acquisition Belt, also called CSAB, captures the surface electrical signals from the human heart. It consists of three silver chloride metal sensors strategically located in such a way as to represent a modified Standard Lead I. The center sensor is the “common”.

The CSAB is meant to be a single patient use device and should be properly disposed of after use.

c. Power supply/charger

The power supply/charger is used to recharge the self contained battery. It is operable on line voltages from 100 VAC to 240 VAC, 50 or 60 hertz. It cannot be plugged in to the CSPU when the CSPU is connected to the CSAB.

The electrical plug is replaceable and should be selected based upon the connection required to the local electrical system.

3.0 Detailed Description

a. Identification

The CSPU, CSAB, and Power Supply have been uniquely identified with a model and serial number. These are easily identified on the assembly.

b. Standards and Equipment Symbols

The CardioBelt™ conforms to the following electrical standards:

- UL 60601-1
- IEC/60601.1 (amend. 1 and 2)
- IEC/EN 60601.1.2 (EMC)
- CAN/CSA C22.2 No. 601.1 (M90, S1-94, B-90)
- Bluetooth stack v1.1 – Serial Port Protocol - Class 2 (+4-dBm maximum power, with a range limit of approximately 20 m) and and Class 3 (0-dBm maximum power, with a range limit of approximately 10 m)
- FCC ID ED9LMX9820ASM
- Bluetooth Listing LMX980 from National Semiconductor Product ID 3018

The CardioBelt™ is water resistant IPX0 (International Protection Classification). The device is not waterproof and must be removed before bathing, showering, or water activities.

The CardioBelt™ conforms to the following additional standards:

- ISO 10993 (Skin Compatibility).

Regulation Number: 21 CFR 870.2920

Regulation Name: Transmitters and Receivers, Electrocardiograph, Telephone

Regulator Class: II (Two)

Product Code: DXH

At this moment, no performance standards have been developed under FDA regulations for ECG transmitters and receivers.

IEC 60601-1:1988, “Medical Electrical Equipment, General Requirements for Safety”

Specifically 56.3(c) is applicable to any connector or electrode.

IEC 60601-1-1:2000, “Medical Electrical Equipment – Part 1-1, General Requirements for Safety”; Collateral standard: Safety requirements for medical electrical systems”

IEC 60601-1-2:2001, “Medical Electrical Equipment – Part 1-2; General Requirements for Safety, Collateral Standard: Electromagnetic Compatibility”

IEC 60601-2-25:1993, “Medical Electrical Equipment, Particular requirements for the safety of electrocardiographs”

Symbol	Explanation
	Type BF (Body Floating)
	Lot Number
	Serial Number
	Refer to accompanying documentation
	Direct Current

c. Dimensions

Cardiac Signal Processing Module:

Total Weight: 1.472 oz
Total Length: 2.5 in
Total Width: 1.8 in
Total Height: 0.9 in

Cardiac Signal Acquisition Belt:

Total Width: 1.5 in
Total Length: The disposable belt is available in three sizes: Small (S) 33 in, Medium (M) 39 in, and Large (L). 45 in

d. Composition

The CardioBelt™ electrodes and belt assembly is constructed of latex free materials which have been tested for human skin compatibility.

e. Physical Description

The CardioBelt™ is a single lead device which consists of the combination of the CSPU and the CSAB.

The CardioBelt™ is used without gel or adhesives. It is capable of picking up high quality cardiac electrical signals from unprepared skin, without electrolytic gels or skin abrasion. This enables easy application of electrodes to the body. It also gives greater comfort and freedom for the subject: the absence of gels or adhesives allows easy removal and re-donning without causing skin irritation or skin shear.

All skin-contacting materials used in the CardioBelt™ have passed tests demonstrating compatibility with normal skin. Furthermore, no natural rubber latex is present in these materials. This allows monitoring without skin irritation.

The CardioBelt™ does not transfer energy to the body. The resistive material of the electrode constitutes an electrical barrier between the body and the electrode and any external apparatus to which the electrode may be connected. The adjustable elastic chest belt shown in is designed to hold the electrode assembly snugly against the torso.

f. Usage Environment

The CardioBelt™ is ideal for use in ambulatory and at-home settings. This device complies with electromagnetic compatibility standards (IEC/EN 6060-1-2) and does not cause electromagnetic interference. Note that all ECG activities can occasionally be subject to electromagnetic interference from other external sources such as power-lines, power transformers, and radio transmitting equipment.

If any interference occurs while using the CardioBelt™, consult trouble-shooting guide in section 9 of this manual.

The CardioBelt™ must be removed for bathing, showering and water activities (note that profuse sweating is acceptable). Failure to do so may damage the device.

The CardioBelt™ can be worn at all other times while performing usual activities, at work and at home, day and night.

A PIN number needs to be in the application to connect with the CardioBelt™.

4.0 Patient Counseling

In order to maximize safety, effectiveness, patient comfort, and patient compliance, ensure that patients are instructed on the use of the CardioBelt™. In particular, emphasize the following points:

- Remind the patient that for effective monitoring, the CardioBelt™ should be worn at all times except while bathing, showering or when involved in other water activities.
- Suggest that when the patient removes the CardioBelt™ he/she should take the opportunity to wipe the electrodes with a damp cloth or soapy water. This enhances comfort.
- Remind the patient not to immerse the electrode assembly in water or other liquids.
- Remind the patient that if symptoms occur while the CardioBelt™ is off the body or while disconnected from the recorder, their cardiac event will not be recorded.
- Reassure the patient that, although the CardioBelt™ was designed for comfort, it may take some time to become fully accustomed to the feel of the device on their chest.
- Invite questions and encourage the patient to call your office in case of difficulties.
- Remind the patient that, if undue skin irritation occurs, the patient should discontinue use and contact the monitoring center.
- Review the Patient Guide with the patient and remember to provide a copy of the Patient Guide for the patient to take home.
- Remind the patient to return the CSPU at the end of their monitoring period, and to properly discard the elastic chest belt.

5.0 Directions for Use

Adhere to the following steps to ensure safe and effective use of the CardioBelt™:

- Inspection procedure
- Choice of elastic chest belt
- Cleaning and disinfection
- Assembly
- Patient fit
- Testing
- Patient instructions

a. Inspection Procedures

1) Upon opening the package and before first use, make sure the package contains the following:

- 1 Cardiac Signal Processing Unit (CSPU)
- 1 Cardiac Signal Acquisition Belt (CSAB)
- 1 Power Supply/Charger
- 1 User Manual (This manual)
- 1 Patient Guide

2) Ensure that a choice of elastic chest belt sizes is available for fitting. These are packaged separately and come in three different sizes: Small (S), Medium (M) and Large (L).

3) Inspect all components of the CardioBelt™ system to ensure that no obvious damage has occurred in transport.

4) The CardioBelt™ system is active right out of the box. The CardioBelt™ is now ready to be fitted to a patient.

b. Patient Fit

In order to ensure proper fit it is important to select the correct size of Cardiac Signal Acquisition Belt. There are three sizes. Measure the patient's chest circumference and select the correct size based upon the following table:

Small – 32" to 39" (81 cm to 99 cm)
Medium – 38" to 46" (97 cm to 117 cm)
Large – 45" to 52" (114 cm to 132 cm)

1) Wrap the assembled belt around the patient's torso, immediately below the breast line.

2) Tighten to a comfortably snug fit using the Velcro ends to secure the belt in place. Do not over tighten.

3) Cardiac Signal Processing Unit should be centered on the patient's chest, in the front with the Monebo logo facing up and outwards.

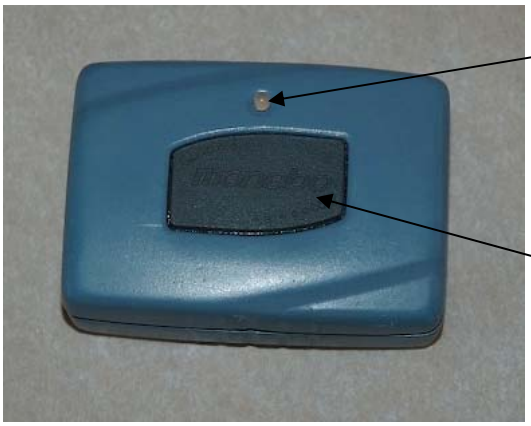
The flat surface of the three CardioBelt™ electrodes should be in direct contact with the patient's skin, and the silver fabric reference indicators "R" and "L" should be position on the right and left side of the patient's chest.

4) Remind patient not to discard the CSPU after their monitoring period, but to return it to the appropriate agency. .

c. Powering on the CardioBelt™

When the CardioBelt™ is correctly positioned on the patient it can be powered on. This is done by depressing the button in the center of the CSPU. The LED will illuminate. If it illuminates yellow, this indicates that the Bluetooth transceiver has not established contact with the Bluetooth base unit. The patient must be within ten (10) meters, thirty (30) feet of the base unit. Once contact is established, the LED will change to green indicating that the link has been established.

When the session has been completed, depress the center button for more than 2 seconds. The LED will change to red and go out indicating that the unit has powered down. The unit also turns itself off when the base unit ends the Bluetooth link.



The LED indicator illuminates in three colors. Yellow indicates that the unit is powered up, but the Bluetooth link has not been established. Green indicates that the link has been established and ECG information is being transmitted. Red indicates that the unit is powering down. Flashing red indicates the battery needs to be charged.

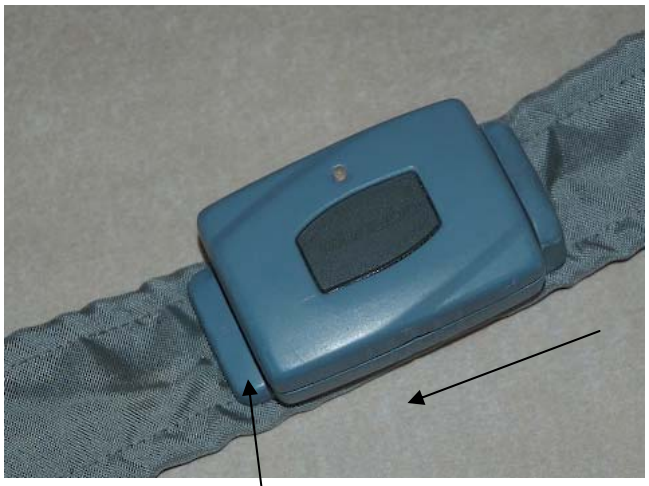
This is the power button. Depress the button to turn the unit ON and OFF.

d. Charging the internal battery

The CSPU is a Internally Powered device. It contains an internal rechargeable battery. The battery is not user serviceable. In the case where the battery needs replacement, this must only be done by a properly qualified technician. If the battery is replaced, it must be disposed of properly by conveying it to an appropriate recycling center.

The CSPU has an internal battery which can only be charged when the CSPU is separated from the CSAB. To remove the CSPU from the CSAB, take the CardioBelt™ off of the patient. Holding the unit in your hand, depress the latch bar and slide the CSPU to the left.

The CSPU should not be exposed to extreme cold temperatures. The battery capacity will be significantly reduced at temperatures below 40º F (4.4º C).



Depress the latch bar and slide the CSPU to the left

When the CSPU has cleared the lock, it can be removed.

Charging unit should be connected to the CSPU and the charger should then be plugged into the electrical outlet. The unit will begin charging. It should be charged for four hours.

When charging is complete, the CSPU can be reconnected to the CSAB reversing the procedure outlined above.

A fully charged battery will provide approximately 10 hours of continuous transmission. The ability of the battery to hold a charge will diminish with repeated charging. Cold temperature will reduce battery capacity.

e. Cleaning

Cardiac Signal Acquisition Belt

1. Before washing the elastic chest belt, ensure the CSPU module is unsnapped (disconnected) from the belt. DO NOT PLACE CARDIAC SIGNAL ACQUISITION BELT ASSEMBLY IN THE WASHER OR DRYER.

2. Hand wash the elastic chest belt using ordinary laundry detergent.

3. Hang to dry.

4. Wash chest belt as often as needed to enhance comfort.

5. Discard elastic chest belts after 30 days' use.

Cardiac Signal Processing Unit

After the CSPU has been removed from the CSAB, it can be cleaned using a damp cloth. DO NOT use any form of chemical cleaner.

6.0 Maintenance

This equipment does not require any servicing. There are no User Serviceable parts inside the unit. Please return any defective unit to a qualified service center for servicing.

7.0 Cleaning and Disinfectant instructions for the Technologist

Cleaning the elastic chest belt:

- Patient is instructed to hand wash the elastic chest belt using ordinary laundry detergent, and to hang dry or use gentle.
- Discard after each patient.
- Use only new elastic chest belts for new patients.
- Belts are available via your supplier.

Cleaning the Electrode Assembly
NOTE: THIS CLEANING PROCEDURE CONSISTS OF TWO STEPS (A) CLEANING AND (B) DISINFECTION. FOLLOW THESE STEPS CAREFULLY. GOOD CLEANING DURING STEP (A) IS ESSENTIAL FOR PROPER ANTIMICROBIAL ACTION DURING STEP (B).

A) MATERIALS
You will need:
- Two pieces of clean cloth (for best results, micro-fiber is recommended).
- Disinfectant solution: isopropyl alcohol 70% to clean the electrodes
- Soapy water or mild detergent to clean the belt
- A shallow dish.

B) CLEANING PROCEDURE
1. Moisten one piece of clean cloth with soapy water or mild detergent.
2. Wipe any visible residues from the CardioBelt™. Rub electrode surface gently to remove any residues.
3. Allow CardioBelt™ electrodes to dry.

C) DISINFECTANT PROCEDURE
4. Acceptable disinfectant solution is isopropyl alcohol 70%.
5. Moisten fresh piece of cloth with disinfectant solution and hand-wipe the CardioBelt™.
6. Place the cloth in dish and soak it with fresh disinfectant solution.
7. Place electrodes on the soaked cloth with body facing electrode surface on the cloth.

8.0 Manufacturer

The CardioBelt™ is manufactured by:

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9.0 Trouble Shooting Guide

1) There are no user serviceable parts in this unit. If the unit appears damaged please ask you care giver for a replacement.

2) If the unit does not turn on with a yellow or amber light make sure the unit is charged. If the unit still does not turn on ask you care giver for a replacement. If you continue to have issues with communication then ask the caregiver to check for interferences that can prevent communications. Turn off any portable phones or RF enabled devices and check if the device can connect to the acquisition device.

3) If the belt gets torn, dirty or moldy ask you care giver for a replacement

4) If the ECG waveform appear noisy check that the electrodes are located in the proper position and that the electrodes are clean and free of contaminates. If the problem persists, replace the belt.