SHL

Telemedicine International Ltd.

Cardio Sen'C

Cellular 12 Lead ECG transmitter

User Manual

(DRAFT)

July 2007

	Note
	We strongly recommend that you read this manual carefully and in its entirety before using the device for transmission. A thorough understanding of the operation and use of the CardioSen'C is required for correct and accurate ECG transmission.

In case of any doubts or questions regarding the use of this device, do not hesitate to call our medical call center for support:

800 227 3462

This telephone number can be found at the bottom of each page

Please fill in the telephone number and details of your personal physician in the space provided below:

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1. Conditions for use

Individuals unable to perform ALL of the following tasks should refrain from using the CardioSen'C:

- Operate a hand-held telephone
- Read and understand the user manual
- Place the CardioSen'C against the chest, holding it steadily in place for up to thirty seconds using your left hand
- Operate a simple, push-button device
- Operate the device while sitting

	Caution for carriers of pacemakers or internal cardiac defibrillators
	The CardioSen'C's cover door contains an antenna and cellular modem for transmitting data through the cellular telephone network. To avoid any potential interference when measuring an ECG, users with pacemakers or internal cardiac defibrillators should maintain a minimum of 6 inches (15 centimeters) between the CardioSen'C's open cover door and their implanted device.

2. Indications for use

The CardioSen'C device is intended to condition an electrocardiographic signal so that it can be transmitted digitally over the cellular network or acoustically via telephone to a remote location. The CardioSen'C device is designed to be used by a patient to transmit a 12-lead ECG and rhythm strip in real-time to a physician's office, hospital or other medical receiving center.

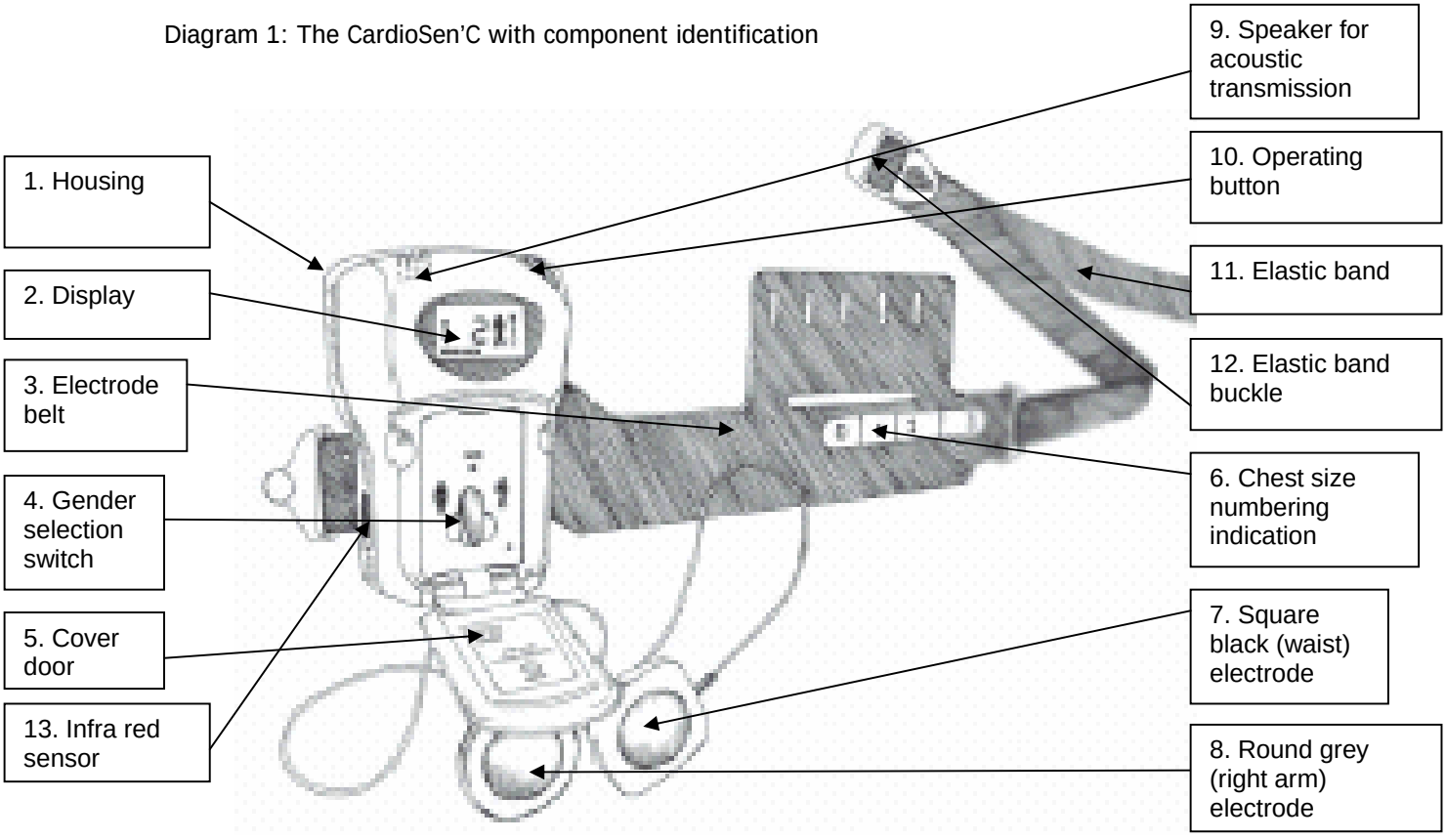
	Caution
	▪ The use of the device should always be in conjunction with a medical center capable of receiving the ECG ▪ The purchase of this device should not substitute for care recommended by your family physician or cardiologist

3. Device Description

The CardioSen'C enables an individual to transmit a 12-lead ECG to a physician's office, hospital or monitoring center. It transmits the ECG measurement via two distinct channels: acoustic and digital. The acoustic transmission uses a standard telephone to transmit acoustically coupled tones produced by the CardioSen'C housing device. These are sent out to healthcare professionals, who are able to convert the tones to a standard 12-lead ECG and interpret the results, providing rapid diagnosis of the user's condition. In addition, the ECG measurement is transmitted digitally by means of a built-in modem via a cellular telephone network. As with the acoustic method the measurement is relayed to qualified healthcare professionals to interpret the data. The total duration of a full 12-lead ECG transmission is roughly twenty-three seconds.

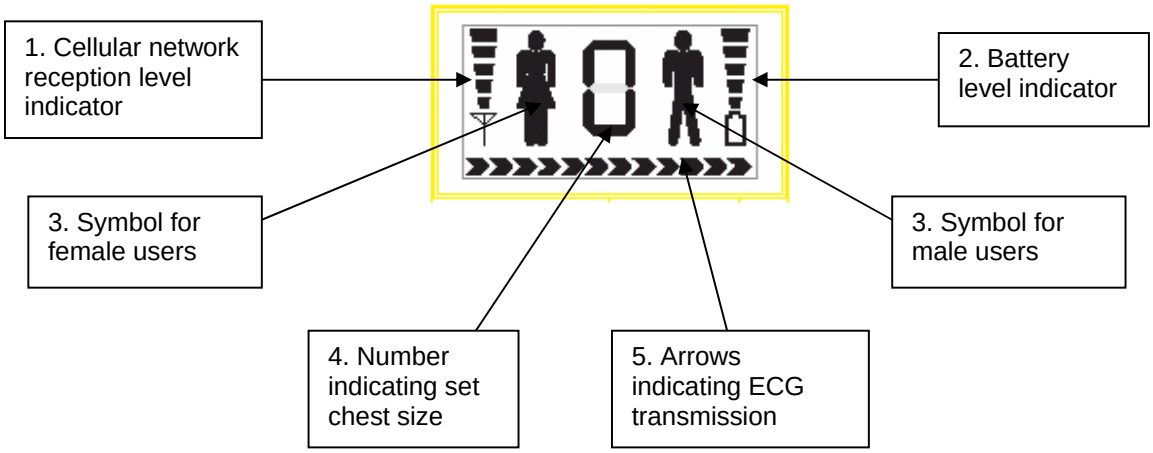
The following diagrams are of the device, its components and related accessories.

Diagram 1: The CardioSen'C with component identification



1. **Housing** is placed against the center of the bare chest for electrocardiogram signal detection and contains the necessary electronics and battery**.**
2. **LCD display** indicates network reception, battery level, gender selection and size (see Diagram 2 below for detailed description).
3. **Electrode belt** wraps around the left side of the chest for electrocardiogram signal detection.
4. **Gender selection switch** changes the device for either male or female users.
5. **Cover door** activates and deactivates the device and contains the cellular modem and antenna.
6. **Chest size numbering indication** used for determining the proper chest size setting.
7. **Square black (waist) electrode** is placed at the belt line against the bare skin, halfway from the navel to the left hip for electrocardiogram signal detection.
8. **Round grey (right arm) electrode** is placed under right underarm for electrocardiogram signal detection.
9. **Speaker for acoustic transmission** emits series of tones for the acoustic transmission of the ECG measurement.
10. **Operating button** initiates the ECG transmission.
11. **Elastic band** wraps around the right side of the chest and back in order to keep the housing and electrode belt in place.
12. **Elastic band buckle** adjusts the length of the elastic band and clasps onto the housing device.
13. **Infrared sensor** for maintenances by an authorized technician only.

Diagram 2: Housing LCD display



1. **Network reception level indicator** shows the level of the cellular network reception for digital transmissions
2. **Battery level indicator** shows the level of available battery power
3. **Gender symbols** indicates the user-specific gender to which the CardioSen'C is set
4. **Chest size numbering** indicates the user-specific chest size to which the CardioSen'C is set
1. **ECG transmission process** is indicated by arrows showing the progress status

4. Setting up the CardioSen'C

The CardioSen'C can be used to transmit a 12-lead ECG reading by both males and females, allowing a couple to use a single device. The device has a universal belt that contains contacts to pick up the electrocardiogram signals of the heart. Before use, the device requires a one-time user-specific customization. This setup consists of two simple steps: identifying the appropriate chest size and customizing the device for the user's gender and chest size. Once this customization has been completed, the device is ready for use at any time.

Identifying the appropriate chest size:

a. Apply the CardioSen'C to your chest in the same way as when you would be conducting an ECG transmission (see steps 1 to 7 in *Instructions for transmission* for a detailed description of how to apply the device).
b. Note the different segmented areas on the electrode belt numbering 0, 1, 2 and 3.
c. Draw an imaginary line between the middle of the left underarm and the left hipbone (see Diagram 5).
d. Identify the segment on which the imaginary vertical line intersects with the electrode belt and take note of the number associated with this identified segmented area.

Diagram 3: Segmented areas for the electrode belt size.

Note

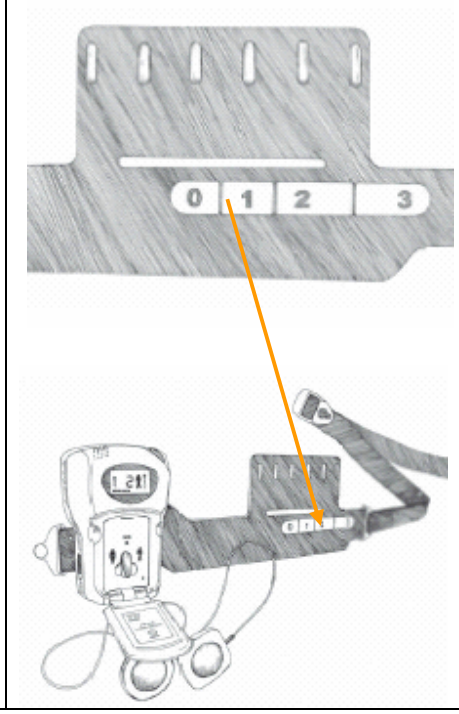


Diagram 4: Position of device against center of the chest

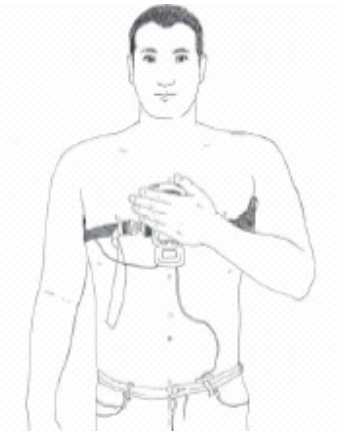
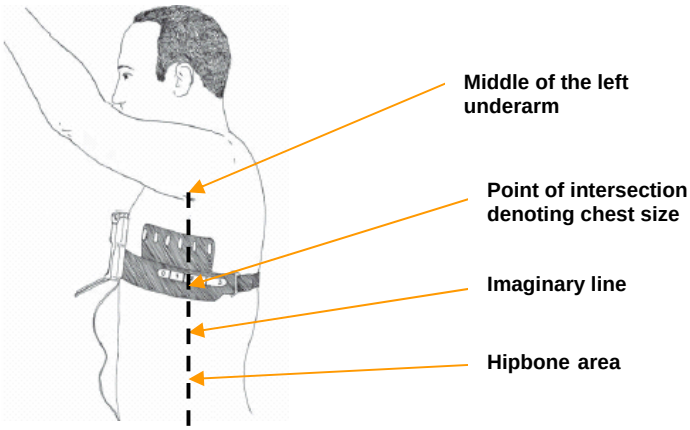


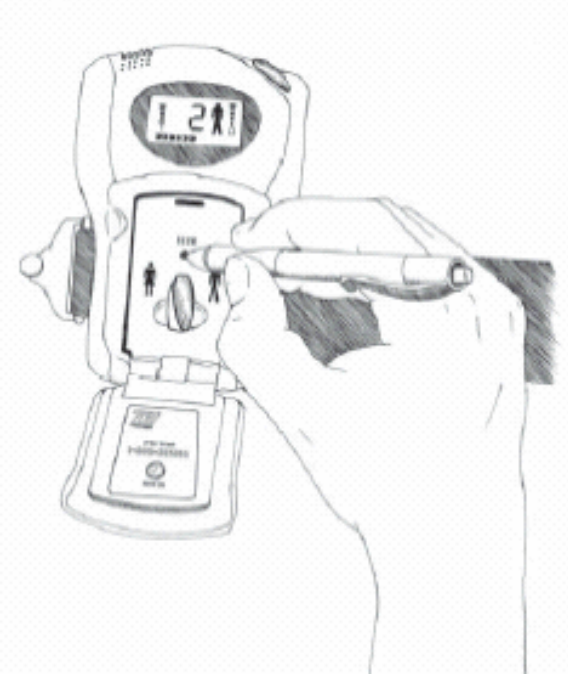
Diagram 5: Imaginary line from underarm to hipbone



Adjusting the CardioSen'C for gender and chest size

a. In order to customize the device for the user, select your gender using the gender selection switch and verify the gender on the LCD display.
b. Select the correct chest size (0,1,2 or 3) by pressing the slightly submerged button located above the gender selection switch using a sharp object (e.g. a pen or sharpened pencil). Verify the chest size selection on the LCD display.
c. The selected combination of chest size and gender will be stored in the device's memory. Couples using the same unit simply have to move the gender switch and their preset chest size will appear on the display.

Diagram 6:



5. ECG transmission

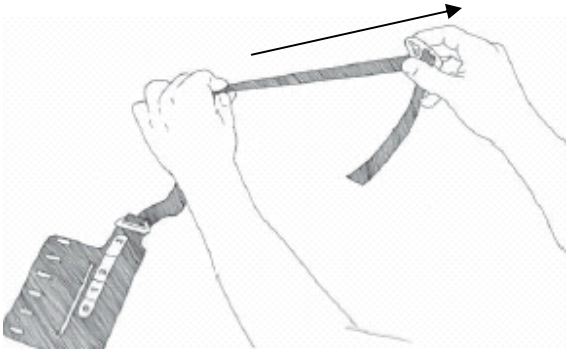
	Caution
⚠	Do not use the CardioSen'C in areas where regulations instruct you to turn off your cellular phone. The CardioSen'C contains a cellular modem that may cause interference with other electronic devices.

Instructions for transmission

1. Remove your shirt or upper garment.
2. Take the CardioSen'C out of its case, unwrap the electrodes and the electrode belt.
3. Open the cover door and check the display to confirm that the correct gender and chest size have been selected. Leave the cover door opened. You will hear a voice message from the CardioSen'C: *"CardioSen'C is ready for transmission"*.

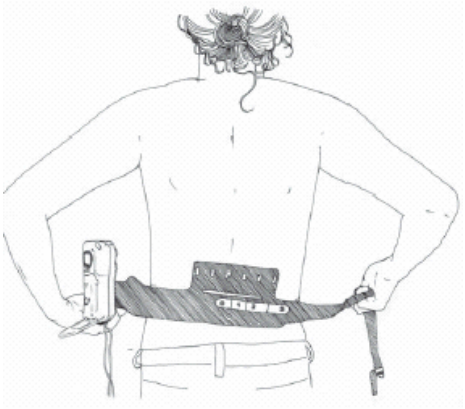
	Note
ℹ	• Take care not to place the device face down while the cover door is open • The cover door should remain open while the ECG is being transmitted

4.



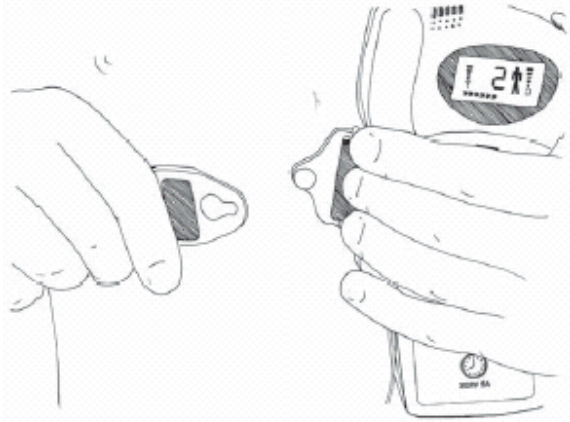
To facilitate attaching the device to your body, slide the elastic band buckle in the direction of the arrow to the end of the elastic band.

5.



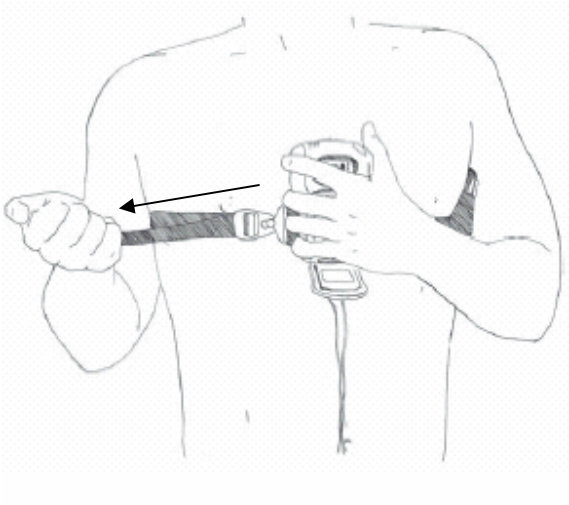
This step is best performed while standing. Hold the housing behind your back with your left hand and the electrode belt with your right hand.

6.



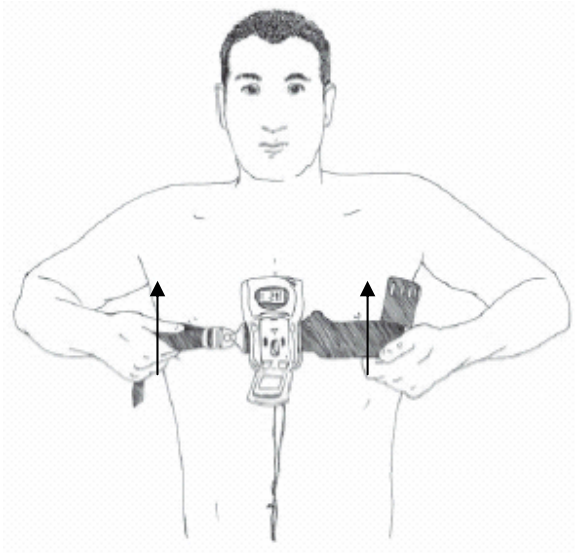
Move the elastic band and buckle to the front and clasp to the right side of the housing.

7.



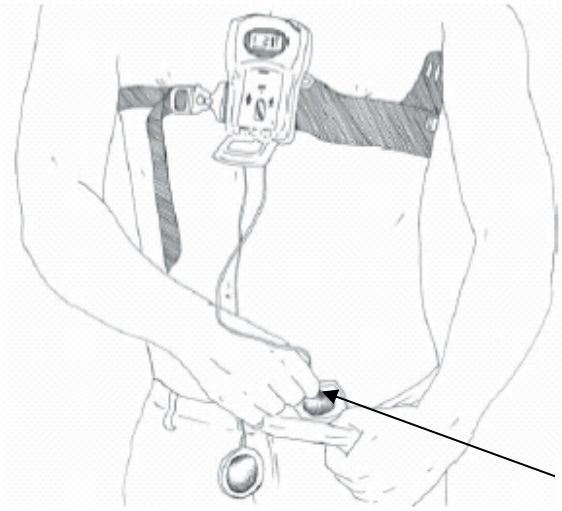
Once the buckle has been clasped, tighten the elastic band until it is tight enough to hold the housing in place. Position the housing in the center of the chest.

8.



Ensure that the **black** arrow on the housing top points to the center of the chest, the housing is positioned firmly against the breastbone and that the electrode belt is not coiled. Make sure the belt's electrodes are in contact with the left side of your body and that the belt is raised all the way up to the left underarm.

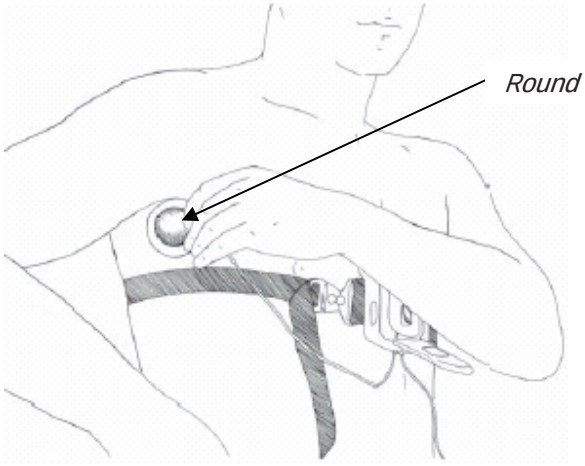
9.



Position the square black (waist) electrode at the belt line (underneath your lower garment) against the bare skin, half way from the navel to the left hip. Make sure this electrode stays in place throughout the transmission procedure.

Square black (waist) electrode

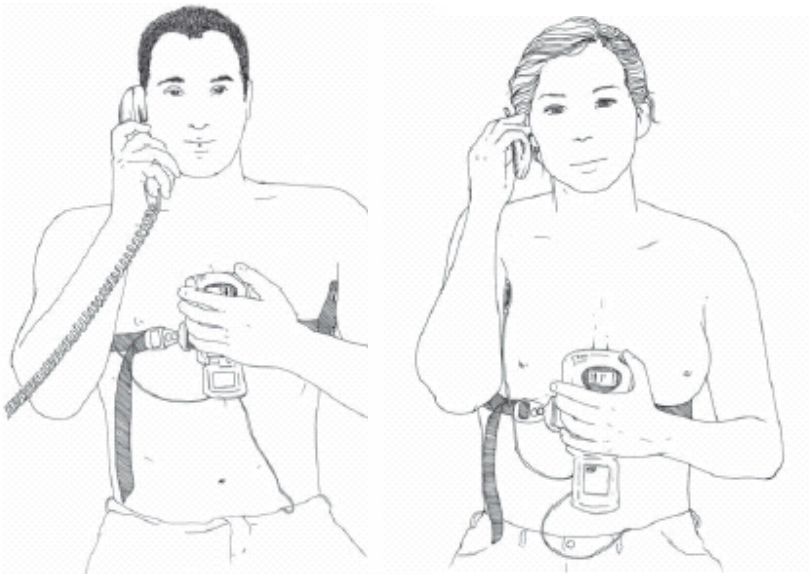
10.



Round grey (Right arm) electrode

Raise your right arm, place the round grey (*Right arm*) electrode under your exposed right underarm against the skin and lower your arm.

11.



Call the medical call center and speak with the medical professional:

800 227 3462

12.

Remote Activated ECG transmission

- When instructed to transmit, position your left arm against the left side of your body while resting your hand on your left thigh (see illustration).
- The transmission will be activated remotely by the medical professional. You will hear a voice message from the CardioSen'C: *"Transmission in process, sit comfortable"*. Immediately you will hear a series of tones for roughly 23 seconds.
- While transmitting you should sit completely still and lean back slightly.
- Once the tones cease and you hear the voice message: *"Transmission completed"*. Resume conversation with the medical professional to receive further instructions.

The medical professional may ask you to repeat the sequence above with your hand left hand placed against the upper part of the housing and pressing lightly.

User Activated ECG transmission

- In case that there is not cellular connection, you will be asked to activate the ECG transmission manually
- Repeat the sequence above and place your left hand against the upper part of the housing and press lightly
- When instructed to do so, press the **orange** operating button with your left thumb until you hear a voice message from the CardioSen'C: *"Transmission in process, sit comfortable"*. Immediately you will hear a series of tones for roughly 23 seconds.
- While transmitting you should sit completely still and lean back slightly.
- Once the tones cease resume the conversation with the medical professional.

13. To shut down the CardioSen'C, close the cover door. You will hear a voice message from the CardioSen'C: *"Thank you for using CardioSen'C"*. Wind the electrode belt around the housing device and return the CardioSen'C to its bag.

	Note
	• Make sure the device and its components are dry and free from any moisture or perspiration.

Recommendations

i. Applying the CardioSen'C to your body before transmission is best done while standing
ii. Adjust the length of the elastic band (while sitting) so that it comfortably fits around your breastbone.
iii. During transmission make sure the electrode belt is pressed against the left part of the body and the housing is pressed firmly against the breastbone. Keeping them in place increases the quality of transmission.
iv. Transmit from a relaxed sitting position, leaning back slightly. No vigorous muscle exertion or tension is required.
v. Conduct the transmission in a quiet room so that any background noise does not interfere with the signal (for acoustic transmissions only)

	**Warning**
	• If you perform a transmission from the CardioSen'C but you are not in phone call communication with the medical center, the transmission will not be able to be completed and you will hear a voice message from the CardioSen'C: *"Please contact monitor center"*.

6. Maintenance information

Cleaning the device

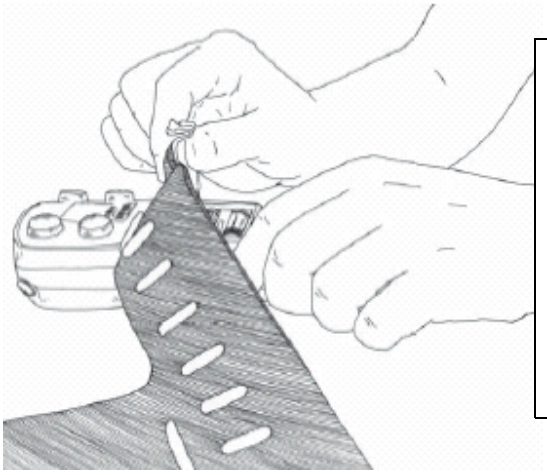
	Note
	The CardioSen'C is not waterproof and should under no circumstance be immersed in water.

- The device generally does not require cleaning.
- Do not attempt to scratch off the brown residue or use abrasive cleaners or abrasive cleaning pads for cleaning. Damage to the electrodes and plastic parts will result.
- If the housing device, belt or electrodes become soiled, clean with lint free cloth lightly dampened with a mixture of rubbing alcohol.
- Clean the CardioSen'C every time it is switched from one user to another.
- In case of any doubt, contact the customer service department for support on: **800 227 3462**

Replacing the battery

- The CardioSen'C contains two AA lithium type (1.5V) batteries. The battery level is displayed on the LCD display.
- Replace the battery when the battery level indicator on the LCD display indicates the battery is almost empty, i.e. when there are two or less bars remaining.
- Alternatively, AA alkaline batteries can be used if lithium batteries are not available. However, beware that the battery life of alkaline batteries is far shorter and should therefore be replaced with lithium batteries at the first possible opportunity.
- To access the battery, making sure the cover door is closed afterwards place the housing device on a flat surface with its front facing downwards. Gently lift the section of the electrode belt that is attached to the housing device, revealing the battery door (see illustration below).
- Lift the battery door by placing your thumb against the submerged groove below the battery door and pushing upwards and outwards simultaneously.
- Remove the old batteries once the battery door has been removed and position new batteries in the recess, according to the markings provided.

	Note
	If lithium batteries are not available, alternatively AA alkaline batteries can also be used. However, beware that the battery life of alkaline batteries is far shorter and should therefore be replaced with lithium batteries at the first possible opportunity.



Lifting the battery door for battery replacement

	Note
	• Check to see if the batteries have been replaced correctly by opening the cover door and viewing the battery level indicator on the display. If the indicator does not detect the new batteries, remove the battery and repeat the sequence above. In case of doubt contact the customer service department for support: **800 227 3462** • Do not dispose of old or used batteries in a fire

7. Equipment classification

CE 0344	The CardioSen'C is in conformity with the essential requirements of council directive 93/42/EEC of the 14th June 1993 concerning medical devices as assessed by notified body #0344
Type of Protection Against Electrical Shock	Type BF: 
Internally battery powered and isolated equipment	No mains or earth connections provided or required.
Mode of operation	Intermittent
Degree of protection against ingress of liquids	Not protected (IP30)
Degree of protection against flammable gases	The equipment is not protected against the presence of a flammable anesthetic mixture of air, oxygen or nitrous oxide

	Caution
	• The CardioSen'C should not be used in the presence of electromagnetic interference or power overload caused by electrosurgical diathermy instruments. • The CardioSen'C should not be used in conjunction with an external defibrillator. • The CardioSen'C should not be used in the presence of flammable anesthetics. • The CardioSen'C is not designed against the ingress of liquids. Do not submerse during cleaning.

	FCC Standard FCC ID: U6VCBSENC
	• 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. • The FCC requires the user to be notified that any changes or modifications made to this device that are not expressly approved by SHL Telemedicine International Ltd. may void the user's authority to operate the equipment. • 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 in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: o Reorient or relocate the receiving antenna o Increase the separation between the equipment and receiver o Connect the equipment into an outlet on a circuit different from that to which the receiver is connected o Consult the dealer or an experienced radio or television technician for help

	SAR certification information
	• This product emits radio frequency energy, but it has been tested and the SAR levels are far bellow the FCC limits. While there may be differences between the SAR levels of various devices and at various positions, they all meet the government requirement for RF exposure. For body-worn operation, the device meets FCC RF exposure guidelines provided that it is used with a non-metallic accessory. Use of other accessories may not ensure compliance with FCC RF exposure guidelines. Nevertheless, the device should be used in such a manner that the potential for human contact with the antenna during normal operation is minimized. • The highest SAR value for the CardioSen'C is 0.072 W/kg averaged over ten grams of body tissue.

8. Operating and storage conditions

Storage	Temperature	-40° C to +70° C (-40° F to +158° F)
	Relative Humidity	10-100% non condensing
	Atmospheric Pressure	500hPa - 1060hPa
Operating	Temperature	+10° C to +40° C (+50° F to +104° F)
	Relative Humidity	30-70% non condensing
	Atmospheric Pressure	700hPa - 1060hPa

Note

- Always keep the device in the original carrying bag when not in use
- Do not leave the device in an enclosed and warm space

9.Technical specifications

Battery	2 AA lithium/iron disulfide (1.5V)
Current Drain	▪ Transmission: 1 A Max ▪ Shut down mode: <20μA. ▪ Standby: 260mA typical
Amplifier	CMRR: 80dB min Frequency Response: 0.05-150Hz min System Noise: < 40μV r.t.i.
FM Output	On three channels
Transmissions	• 12 seconds of continuous rhythm strip (lead II). • 2.5 seconds of leads: I, II, III, V1, V2, V3, V4, V5, V6. AVR, AVL and AVF are reconstituted at receiver
Total Transmission Time	23.0 seconds acoustic transmission time Cellular connection time- network dependent (typical 20-30 seconds) Cellular transmitting time- network dependent (typical 20 seconds)
Cellular network connection	GPRS

10. Limited warranty

The CardioSen'C is warranted, under normal use, to be free from any manufacturing defects for one year from the date of purchase. Limitations related to this warranty are as follows:

- Tampering with the CardioSen'C device or opening the device by anyone other than a qualified SHL technician voids the warranty
- The warranty is only extended to the original purchaser, i.e. it is not transferable

In the event of a failure of the CardioSen'C, contact the medical call center at **800 227 3462** to confirm the device's malfunctioning and arrange to receive a replacement.

Manufacturer:
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