

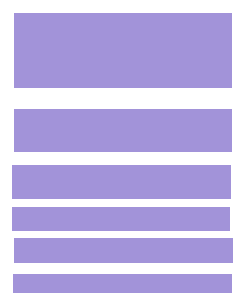
CU – PH1

Operator's Manual

CardioMeter Series



CU Medical Systems, Inc.



Operator's Manual

CU-PH1 ver 1.0



Medical Systems, Inc.

OPERATOR'S MANUAL

Version 1.0

Notice:

This Operator's Manual applies to CardioMeter CU-PH1, the portable ECG monitoring equipment from CU Medical Systems, Inc. The information contained in this manual is subject to change without prior notice.

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Medical Systems, Inc.

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General

Thank you for choosing the CU-PH1. Please read this Operator's Manual carefully and thoroughly before using the CU-PH1. This Manual contains instructions on how to operate and maintain the CU-PH1. The features of the CU-PH1 are all discussed in this Manual.

It is very important for the user to fully understand all the instructions and guidelines discussed in this Manual in order to fully utilize the features of this device and to ensure safe operation.

CU Medical Systems, Inc. designs and manufactures all its products in accordance with international standards (NS-EN ISO9001:2000/ISO13485:1996-MDD 93/42/EEC). This ensures that CU Medical Systems, Inc. provides products of high quality and reliability. In this regard:

- **Only persons authorized by CU Medical Systems, Inc. should do all servicing of the device.**
- **You should ensure that the correct batteries are properly installed before using this device.**
- **You should operate this device in accordance with the instructions specified in this manual.**

To ensure safety and reliability, use only parts and accessories recommended by CU Medical Systems, Inc.

Warranty

- The products of CU Medical Systems, Inc. are designed and manufactured according to international standards (NS-EN ISO9001:2000/ISO13485:1996-MDD 93/42/EEC).

Every device that goes out of the assembly line passes through a battery of reliability tests. In case of problems, our maintenance and exchange policies are in accordance with the relevant consumer protection laws and regulations of the particular country where this device is sold.

- The warranty period of this device is within two years after the date of purchase.
- When the device malfunctions during the warranty period, it will be repaired free of charge at our service centers.
- When you submit the device for maintenance, please specify the details as listed below :

The device model, serial number, date of purchase, name of sales representative, customer information and a brief description of the problems.

| | | | |
|-------------------------------|-------------|----------------------|--|
| Name of Product | CardioMeter | | |
| Model | CU-PH1 | Serial No. | |
| Date of Purchase | | Sales Representative | |
| Customer Information | Name | | |
| | Address | | |
| | Contact No. | | |
| Brief Description of Problems | | | |

Service Request

Only CU Medical Systems, Inc. or its authorized representatives should service the device. If the device is serviced by unauthorized personnel during the warranty period, the warranty will become null and void.

CU Medical Systems, Inc. or its authorized representatives are obliged to service the device free of charge during the warranty period. Damage to the device incurred beyond normal use is not covered by the warranty.

When the device is not functioning properly, it has to be submitted for maintenance immediately.

When any problems are found in the device or when a danger to bodily harm exists, the device has to be repaired immediately by authorized personnel.

When the need for maintenance arises:

- Please contact CU Medical Systems, Inc. or its authorized representatives immediately. Prepare a summary of the problems.

● Contact Us

You can contact us at the following address and telephone number for services and supplies.

Product and Order Inquiries:

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Website: www.amitaliasrl.it

1 How to Use This Manual

1.1 Contents of This Manual

- This Operator's Manual contains all the information a user needs to operate the CU-PH1 properly. The CU-PH1 is designed to acquire, display, and extract the heart rate of the ECG of a patient/user.
- In case you have any problems regarding the operation of the device, please don't hesitate to contact us.
- Specifications and information in this manual are subject to change without prior notice.

1. 2 Safety Messages

Safety messages are used throughout this manual to emphasize important things that must be followed during the operation of the CU-PH1. You must follow the instructions in all the Warnings, Cautions, and Notice messages found throughout this Operator's Manual

In the event that the product is damaged due to misuse or negligence by a user, the manufacturer or its authorized representatives shall not be responsible for the said damage or loss to the product.

WARNING

Conditions, hazards, or unsafe practices that can result in serious personal injury.

CAUTION


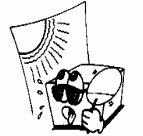
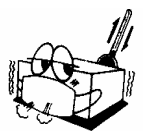
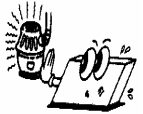
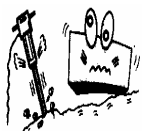


Conditions, hazards, or unsafe practices that can result in minor personal injury, damage to the CU-PH1, or loss of data stored in the device.

NOTICE

These messages are used to denote items that are important during installation, operation, or maintenance of the device.

2 Device Operation Guidelines

2.1 Storage and Operating Environment Guidelines

| | |
|---|---|
|  | <p>Do not operate or store the device in conditions that are beyond the following specified limits.</p> <p>Operating Conditions Temperature 0 °C to 50 °C Humidity 5 % to 95 % (non-condensing)</p> <p>Storage Conditions Temperature -20 °C to 70 °C Humidity 5 % to 95 % (non-condensing)</p> |
|  | <p>Do not store the device in areas that are directly exposed to sunlight</p> |
|  | <p>Do not store the device in areas with highly fluctuating temperatures</p> |
|  | <p>Do not store the device near heating equipment</p> |
|  | <p>Do not store the device in areas where there is high vibration (in excess of Category 10 of MIL-STD-810E)</p> |
|  | <p>Do not operate or store the device in areas with high concentration of dust</p> |
|  | <p>Only personnel authorized by the manufacturer shall open the device for servicing.</p> |

The following are the general guidelines in storage and operating environment conditions.

- Do not expose the device to direct sunlight during storage.
- Do not store the device in locations with temperature and humidity conditions that are beyond the specified safe range
Temperature: -20°C to 70°C
Relative Humidity: 5% to 95% (non-condensing)
- Do not store the device close to heating equipment and appliances.
- Do not store the device near sources of vibration.
- Do not store and operate the device in locations that are exposed to chemicals, explosive gas and solvents.
- Keep the device away from dusty environments.
- There are no user serviceable parts inside the CU-PH1. Only authorized service personnel should open the device for repairs.

The Standard Operating Conditions are as Follows:

- **Temperature: 0 °C to 50 °C**
- **Relative Humidity: 5 % to 95 % (non-condensing)**

The standard storage and shipping conditions are as follows:

- **Temperature: -20 °C to 70 °C**
- **Relative Humidity : 5 % to 95 % (non-condensing)**

2.2 Notes On Electrical Safety

⚠ WARNING

During operation, the device should be placed away from sources of electromagnetic interference such as motors, generators, X-Ray equipment, radio transmitters, cellular mobile telephones and others, as these might interfere with the signals being acquired.

NOTICE

The CU-PH1 is classified as follows:

- It is a Class I, Type BF equipment in terms of electrical shock prevention (EN 60601-1). It is not proper to operate this device around combustible anesthetic or solvents.
- The noise level is "B" Class according to EN 60601-1 (Safety of Electric Medical Equipment), and the noise redemption is "B" level according to the EN 60601-1-2 (Electromagnetic Compatibility Requirements).

2.3 Cleaning and Maintenance

When the case is contaminated with dirt, clean the CU-PH1 using a soft, damp cloth moistened with any of the following solvents:

- Soap and water
- 70% solution isopropyl alcohol
- Chlorine bleach and water mixture (30 ml bleach/liter of water)
- Ammonia-based cleaners
- Hydrogen peroxide

CAUTION

Do not immerse any part of the CU-PH1 in fluids.

Do not let any fluid enter the case of the device.

Do not spill liquids on the case of the device.

Do not use strong, acetone-based cleaners in cleaning the device.

Do not use abrasive materials in cleaning the unit, especially the LCD display and the infrared filter on the IrDA port.

Do not sterilize the CU-PH1.

Although there are no user serviceable parts inside the CU-PH1, you can do some maintenance check that will help ensure that the device stays in mint condition.

- Check the case of the device for any apparent damage.
- Check the ports (ECG connector port) to see that it is tightly in place.
- Check the accessories, especially the ECG electrodes, to see that they are in good condition and that they have not yet reached their expiration dates.

NOTICE

A more comprehensive maintenance routine is discussed in the chapter on Maintenance of this User's Manual.

3. INTRODUCTION

3.1 PRODUCT DESCRIPTION

The CU-PH1 is a lightweight, portable, battery operated, 3-lead Electrocardiogram (ECG) monitoring device. It has a bandwidth of 0.3 Hz to 40 Hz.

The CU-PH1 has a high resolution (320x240 pixels) liquid crystal display (LCD). One of the three bipolar limb leads (Lead I, Lead II, Lead III) can displayed at a given time.

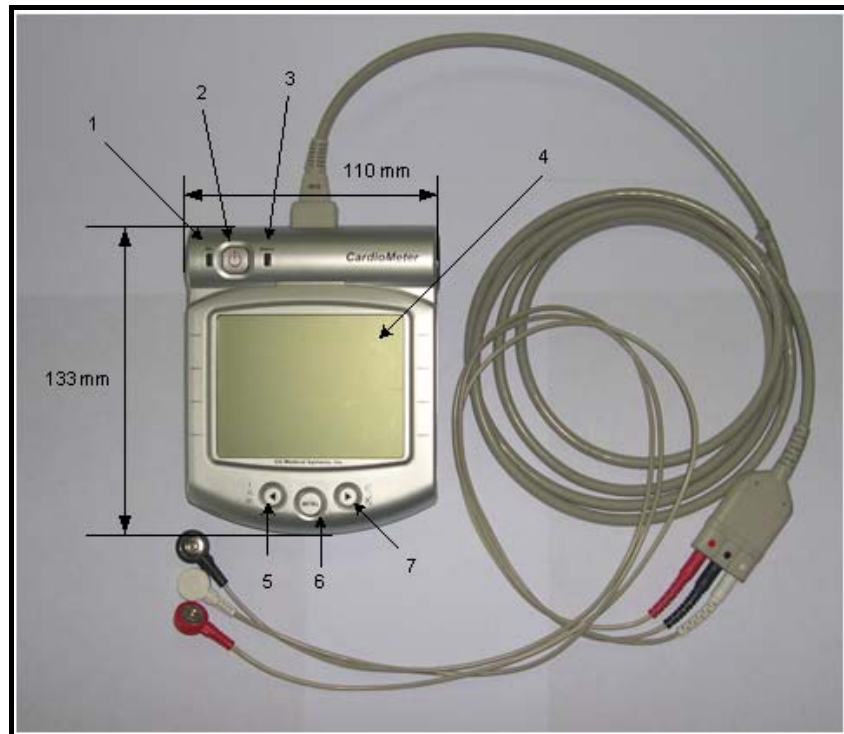
The CU-PH1 runs on two AAA size 1.5V batteries. This makes the device very lightweight and very safe as it is not connected to any power mains.

ECG signal acquisition is achieved through a three-electrode ECG acquisition assembly with disposable electrodes.

User interaction is through three function buttons (LEFT, RIGHT, and MENU). Through these buttons, the settings of the device can be changed.

ECG signals can be recorded in the internal nonvolatile memory of the device. The stored signals can later be reviewed. These recorded signals can also be transferred to a personal computer that is running the CU Expert ECG Data Management Software.

The CU-PH1 analyzes the signal it acquires from the user and determines the heart rate of the user. The device prompts the user through the beeper and the LED alarm indicator if it detects an abnormal heart rate. Abnormal heart rate is any heart rate beyond the normal limits defined by the user.



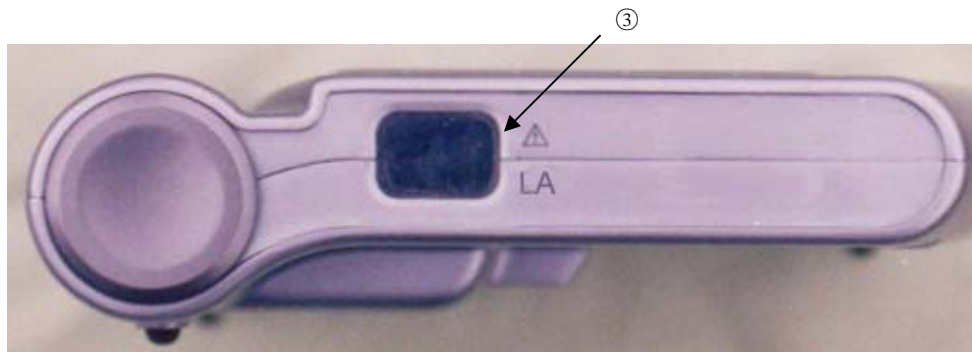
CU-PH1 top view

| | |
|----------------------|---|
| ① Power indicator | Green LED, lit when the device is ON. |
| ② Power switch | Used to turn the device ON or OFF |
| ③ Alarm LED | Red LED, flashes when the device detects an ECG signal with beat rate that is beyond the normal range defined by the user. |
| ④ LCD display | Displays the following: a. ECG signal acquired from the patient b. ECG signal recorded in the memory of the device c. Menu d. Device settings |
| ⑤ RIGHT arrow button | Used to scroll the menu highlight to the right or downward. This button is also used to turn the QRS beeper ON or OFF |
| ⑥ MENU button | Used to activate the menu. When the menu is activated, it is used to select the highlighted menu item |
| ⑦ LEFT arrow button | Used to scroll the menu highlight to the left or upward. This button is also used to change the Lead of the ECG signal being acquired. |



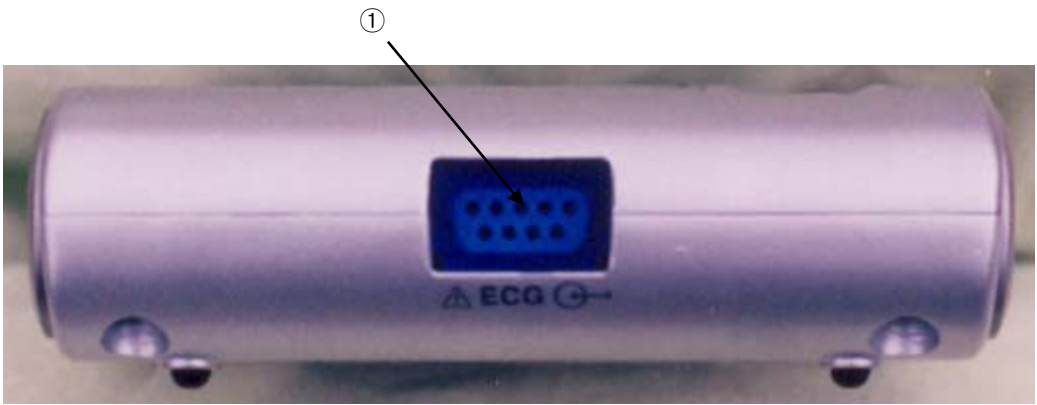
CU-PH1 right side view

| | |
|---------------------|---|
| ① IrDA port | used to transmit data from the CU-PH1 to a personal computer |
| ② RA Hand Electrode | electrode for the right forefinger when the hand electrode system is used instead of the ECG pad and cable system |



CU-PH1 left side view

| | |
|---------------------|--|
| ③ LA Hand Electrode | electrode for the left forefinger when the hand electrode system is used instead of the ECG pad and cable system |
|---------------------|--|



CU-PH1 back view

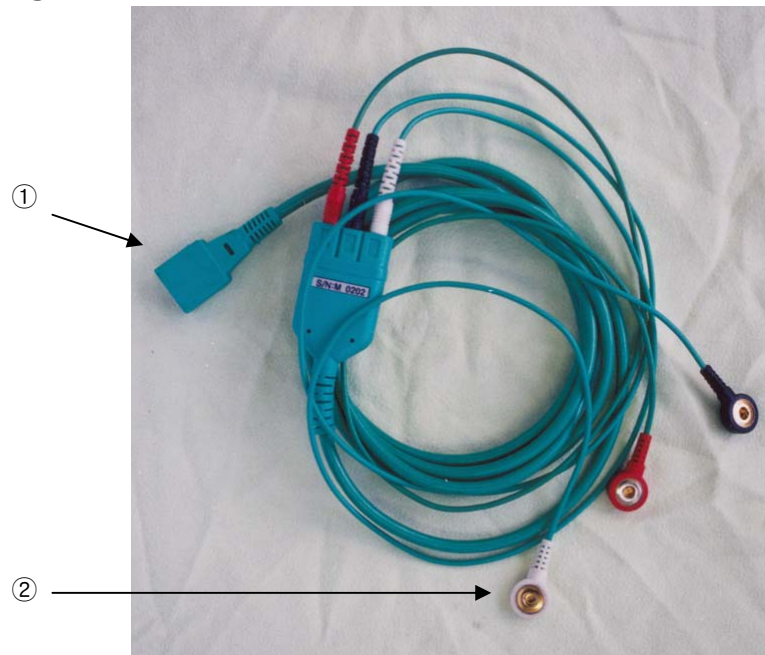
| | |
|----------------------------|---|
| ① ECG Cable Connector Port | used to connect the ECG pads and cable assembly to the CU-PH1 |
|----------------------------|---|



CU-PH1 Bottom View

| | |
|-----------------|---|
| ① Battery Cover | covers the battery compartment. The battery compartment contains the two AAA batteries that are used to power the device. |
| ② LL Electrode | electrode for the right hand middle finger. This is used when the ECG signal is acquired through the hand electrodes. |

ACCESSORIES



Cable and Connector Assembly

| | |
|----------------------------|--|
| ① ECG Port Connector | used to connect the assembly to the CU-PH1 |
| ② Snap Electrode Connector | used to connect the assembly to the disposable ECG electrodes. |



Disposable ECG Electrodes

| | |
|------------------|---|
| ① Snap Connector | used to connect the electrode to the cable assembly |
|------------------|---|



IrDA Com Port Serial Adapter





| | |
|--------------------------|---|
| ① COM Port DB9 Connector | Connected to any COM Port of a personal computer |
| ② IrDA transceiver | Used to receive infrared transmission from the CardioMeter CU-PH1 |

3.2 INTENDED USE AND USERS



The CU-PH1 is intended for ECG signal monitoring. It can indicate whether an ECG signal is normal or abnormal based on a normal range defined by the user. The ECG signal acquired from the user is recorded in the internal flash memory of the device. The signal can be retrieved later for proper diagnosis by a medical professional.

4. OPERATING CONTROLS, INDICATORS, PORTS, AND ACCESSORIES

4.1 OPERATING CONTROLS

| | |
|--|---|
|  ON/OFF Switch | Turns the power of the CU-PH1 ON or OFF. |
|  LEFT BUTTON | <ul style="list-style-type: none">a. Scrolls the Menu highlight UP or to the LEFTb. Scrolls the ECG record to the left (displaying the earlier parts of a recorded ECG) during RECORD REVIEWc. Changes the ECG Lead acquired by the device when pressed during ECG acquisition. |
|  RIGHT BUTTON | <ul style="list-style-type: none">a. Scrolls the Menu highlight DOWN or to the RIGHTb. scrolls the ECG record to the right (displaying the later parts of a recorded ECG) during RECORD REVIEWc. Turns the QRS beep ON or OFF |
|  MENU BUTTON | Used to select an item in a menu |





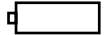

4.2 INDICATOR LAMPS

| | |
|---|---|
| <p style="text-align: center;">On  POWER ON LED</p> | <p>When ON, indicates that the CU-PH1 is ON. This LED is colored green</p> |
| <p style="text-align: center;">Alarm  ALARM LED</p> | <p>When ON, indicates an abnormal ECG. This is used together with the buzzer. This LED is colored RED</p> |

4.3 PORTS

| | |
|---|--|
| <p style="text-align: center;">ECG PORT</p> | <p>Used to connect the ECG cable and connector assembly to the CU-PH1.</p> |
| <p style="text-align: center;">IrDA PORT</p> | <p>Used to transmit data to a personal computer.</p> |
| <p style="text-align: center;">HAND ELECTRODES</p> | <p>Used to acquire ECG signals using the fingers of the patient. RA hand electrode is connected to the right hand forefinger, LL is connected to the right hand middle finger, and LA is connected to the left hand forefinger. Connection is through direct contact</p> |

4.4 Equipment Symbols

| | |
|---|---|
|  | Power ON/OFF Switch |
|  | Attention, consult accompanying documents |
|  | Date of manufacture |
|  | Signal transfer port |
| RA | Right Arm hand electrode; connected with the right forefinger of the patient |
| LA | Left Arm hand electrode; connected with the left forefinger of the patient |
| LL | Left Leg hand electrode; connected with the right middle finger of the patient. |
| IrDA | Infrared data communications port |
|  | Battery state :displayed on LCD screen |
|  | Symbol of data recording :displayed on LCD screen. The number represents the memory partition being used for recording. |

5. OPERATION

5.1 UNPACKING

Upon receiving the device:

- 1) Carefully inspect the packing container for any apparent damage.
- 2) Inspect the unit for apparent damage that it might have sustained during shipping.
- 3) Check the shipping list to ensure that the unit comes with the complete accessories.

5.1.1 Battery Installation

The battery compartment cover of the CU-PH1 is located at its bottom side. Slide the locking mechanism towards the back side of the device and then pull the cover away from the body of the CU-PH1 (see the bottom view figure in section 3.1) The CU-PH1 needs two 1.5V AAA size batteries. The polarities are shown inside the battery compartment.

NOTICE

Avoid storing the batteries at extreme temperatures. Batteries perform best when stored and used between $-15\text{ }^{\circ}\text{C}$ and $55\text{ }^{\circ}\text{C}$

NOTICE

Keep batteries in low humidity locations with low temperature variations.

NOTICE

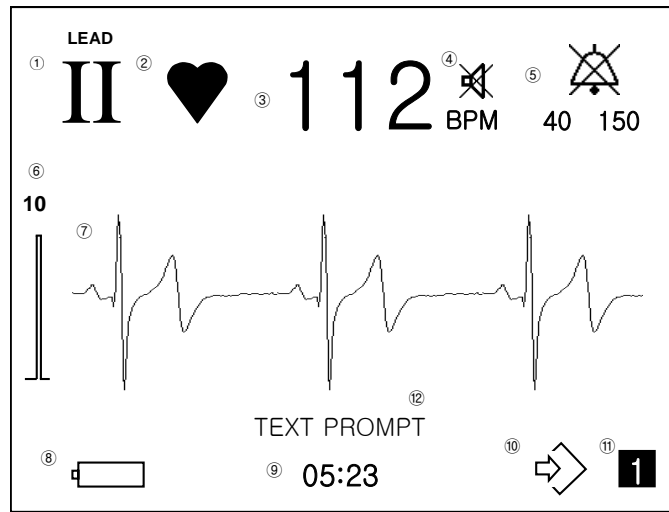
Keep batteries away from direct sunlight.

NOTICE






Do not attempt to recharge non rechargeable batteries.

5.2 SCREEN DISPLAY





Upon turning the device ON, it will display the screen shown below



Screen Display of the CU-PH1

| | | |
|---|---|---|
| ① | LEAD | Indicates the lead number of the ECG signal being displayed |
| | States | I - indicates that LEAD I bipolar limb lead is being displayed |
| | | II - indicates that LEAD II bipolar limb lead is being displayed |
| | | III - indicates that LEAD III bipolar limb lead is being displayed |
| | C - indicates that the device is performing a check of its display function. This is accessible only through the LEFT arrow button. | |
| ② | QRS detection | Indicates the detection of QRS waves in the acquired ECG signal |
| | States | No heart icon - indicates that no QRS wave is detected  - indicates that QRS wave is detected. Heart icon alternates between small and large sizes to simulate heart beat display |
| ③ | BPM display | Displays the heart rate (in bpm) of the acquired ECG signal |
| | States | Heart rate is displayed when it falls within the limits of 30 and 300 bpm --- is displayed when the heart rate is beyond the limits of 30 and 300 bpm |
| ④ | QRS beep | Turns the QRS-synchronized beep ON or OFF |
| | States |  indicates that the QRS-synchronized beep is ON  indicates that the QRS-synchronized beep is OFF |
| ⑤ | Alarm | Indicates whether the bpm alarm is ON or OFF |
| | States |  40 150 indicates that the bpm alarm is ON. If the heart rate is beyond the limits indicated below the alarm icon, the bpm alarm is activated.  40 150 indicates that the bpm alarm is OFF. If the heart rate is beyond the limits indicated below the alarm icon, the bpm alarm is not activated. |

Screen display continued

| | | |
|--|----------------------------|---|
| ⑥ | Sensitivity | Indicates the gain setting of the ECG display in mm/mV |
| | States | 5 the ECG is displayed with a 5 mm/mV gain |
| | | 10 the ECG is displayed with a 10 mm/mV gain |
| | | 20 the ECG is displayed with a 20 mm/mV gain |
| A the ECG is displayed with autoscaled gain. When the peak to peak value of the acquired signal is within 0.3 mV to 1 mV, the ECG is displayed using 10mm/mV. When the acquired signal is beyond the range 0.3 mV to 1 mV, the peak to peak value is displayed as 10 mm on the LCD screen. | | |
| ⑦ | ECG display | Displays the acquired signal from the user. |
| | States | Displays ECG signal in the range 0.05mV to 5.5 mV |
| ⑧ | Battery State Indicator | Indicates the charge status of the batteries The battery life is determined using Duracell batteries. |
| | States |  indicates that the battery has full charge. In this state, the battery can run the device continuously for approximately 5 hours |
| | |  indicates that the battery has medium charge. In this state, the battery can run the device continuously for approximately 3 hours |
| | |  indicates that the battery has low charge. In this state, the battery can operate for approximately one hour |
| | |  indicates that the battery is empty. In this state, the battery can run the device continuously for approximately 15 minutes |
| ⑨ | Time | Displays the time elapsed since the device was turned ON. Format is minutes:seconds |
| | States | The elapsed time from 00:00 to 99:59 is displayed. If the device is ON beyond 99:59, the display wraps around to 00:00 |
| ⑩ | Recording icon | Indicates that the device is recording the acquired ECG in its internal memory |
| | State | The recording function is always ON. As soon as the device is turned ON, the acquired ECG signal is recorded in its internal flash memory |
| ⑪ | Recording memory indicator | Indicates the memory partition where the device is recording the ECG signal being acquired. One memory partition can hold 60 minutes of ECG data. If the ECG data exceeds 60 minutes, the device stops recording the ECG data being acquired. To record to another memory partition, the device must be turned OFF then ON. |
| | States | Displays the number from 1 to 10, depending on the current memory location where the device is recording the acquired ECG signal. |
| ⑫ | Text Prompt | Indicates when the leads are OFF. Displays the prompt "LEAD FAULT" |

5.3 USER INTERFACE

The menu is activated by pushing the MENU button. The highlight can be scrolled sideways or up and down by pushing the RIGHT or LEFT button. The submenu field values are scrolled by pressing the MENU button. The heart rate limit values are incremented/decremented using the RIGHT or LEFT buttons.

For example, to change the BACKLIGHT settings, highlight the BACKLIGHT option and then cycle through the choices (ON, OFF, 5 SEC) by pressing the MENU button repeatedly. When the desired setting is selected, effect the change by moving the highlight away from the BACKLIGHT option using the RIGHT or LEFT key.

There are four main MENU items. These are:

- a. Device – enables the user to change device configuration
- b. ECG – enables the user to change ECG acquisition parameters.
- c. Review – enables the user to review the recorded ECG signals. The average bpm trend can also be tracked under the Review submenu.
- d. Exit – used to exit from the MENU and go back to the ECG display screen.

When the MENU button is pushed while the device is ON, the following is displayed:

| DEVICE | ECG | REVIEW | EXIT |
|----------------------|-----|--------|------|
| BACKLIGHT | | OFF | |
| PC LINK | | | |
| SW VERSION | | 1.0 | |
| RETURN TO UPPER MENU | | | |

The arrow buttons can be used to scroll the highlight across the main menu items: DEVICE, ECG, REVIEW, and EXIT. When the RIGHT arrow button is pushed, the highlight scrolls to the right. When the LEFT arrow button is pushed, the highlight scrolls to the left.

5.3.1 DEVICE SUBMENU

When the MENU button is pushed while DEVICE is highlighted, the menu goes one level down and the highlight can be scrolled up and down from BACKLIGHT to RETURN TO UPPER MENU. Any sub item is entered by pushing the MENU button while the sub item is highlighted.

DEVICE SUBMENU ITEMS

BACKLIGHT This option turns the backlight of the LCD ON, OFF, or 5 SEC
ON – the backlight is always ON while the device is ON.
OFF - the backlight is always OFF while the device is ON.
5 SEC – whenever any of the keypad buttons is pressed, the backlight turns ON then turns OFF 5 seconds after the

button is pressed. If multiple buttons are pressed in succession, the backlight will be turned OFF 5 seconds after the last button is pressed.

NOTICE

The backlight draws a considerable amount of power. When it is on, the battery will be depleted faster than when the backlight is disabled.

It is recommended that the backlight be turned ON only when absolutely necessary e.g. device operation in dark places

SWVERSION this will indicate the version of the software installed in the device. This is for information purposes only. The user can not change anything in this Sub Menu.

PCLINK

When this is activated, the device will send recorded ECG and patient/user data to a personal computer. The recorded data are saved in 10 memory partitions. The data in each of the memory partitions can be transmitted one by one.

The following screen will be displayed when the MENU button is pressed while the PC LINK submenu item is highlighted

| DEVICE | ECG | REVIEW | EXIT |
|--------|---------|---------|------|
| | DATA 01 | USED | |
| | DATA 02 | USED | |
| | DATA 03 | USED | |
| | DATA 04 | USED | |
| | DATA 05 | USED | |
| | DATA 06 | USED | |
| | DATA 07 | USED | |
| | DATA 08 | USED | |
| | DATA 09 | WRITING | |
| | DATA 10 | UNUSED | |
| | | EXIT | |

The list of memory partitions and their states are shown

SAVED – memory partitions that contain ECG data

WRITING – memory partition that is currently being used by the device to store data

EMPTY – memory partition that has been cleared through an ECG CLEAR operation in the REVIEW submenu.

The memory partition to be transmitted can be chosen by scrolling the highlighter UP or DOWN using the ARROW keys.

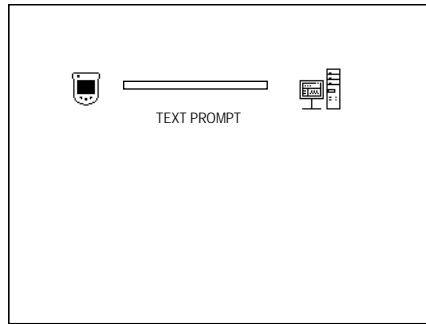
Data Transmission to a Personal Computer

Data is transmitted to a personal computer using the IrDA Com Port Serial Adapter. The CU Expert ECG Data Management Software must also be running on the PC during data transmission.

To transfer data to a personal computer, do the following steps.

1. Connect the IrDA Com Port Serial Adapter to the COM 1 or COM 2 port of the PC.
2. Align the IrDA transceiver of the adapter to the IrDA port of the CU-PH1.
3. Open the CU Expert ECG Data Management Software in the PC. Set the options in accordance with the instructions given in its User's Manual. Make the connection twice. Do this by performing the following steps:
 - a. Open the serial port and click the OK button in the dialog that prompts for the reception to begin.
 - b. Cancel the transmission by clicking on the Disconnect icon in the toolbar.
 - c. Open the serial port again and click the OK button in the dialog that prompts for the reception to begin.

4. In the CU-PH1, choose the memory partition to be transmitted. Do this by activating the menu and going to DEVICE-PC LINK. Highlight the memory partition to be transmitted and then press the MENU button to begin transmission.
5. When transmission begins, the following screen is displayed in the LCD display of the CU-PH1



6. The text prompts indicate the status of the data transmission. The following are the text prompts that the CU-PH1 will display.
 - a. PREPARING FOR TRANSMISSION – the CU-PH1 is preparing for transmission
 - b. TRANSFERRING DATA – data is being transferred through the IrDA port
 - c. TRANSMISSION COMPLETE – the data transmission is finished
 - d. TRANSMISSION ERROR OCCURRED – the data transfer failed
7. As the data transfer proceeds, the data transfer progress will be shown through the progress bar. When the transmission is finished, the "TRANSMISSION COMPLETE" text prompt will be displayed.
8. After the data transmission is finished, turn OFF the CU-PH1.

5.3.2 ECG SUBMENU

When the ECG submenu is highlighted, the following submenu is displayed:

| DEVICE | ECG | REVIEW | EXIT |
|----------------------|-----|------------|------|
| BPM RANGE | | 40 150 BPM | |
| SENSITIVITY | | AUTO | |
| CHANNEL | | LEAD I | |
| ALARM | | OFF | |
| RETURN TO UPPER MENU | | | |

The submenu is entered when the MENU button is pushed while ECG is highlighted.

ECG SUBMENU ITEMS

BPM RANGE sets the range of ECG rate in BPM that the device will consider as normal. Beyond the range, the beeper alarm is activated.

SENSITIVITY sets the display resolution in mm/mV. The sensitivity can be set to 5mm/mV, 10mm/mV, 20 mm/mV, or AUTO (autoscaling -> values between 0.3 mV and 1 mV are displayed using 10 mm/mV, beyond the range, the maximum amplitude is displayed as 10 mm)

CHANNEL sets the ECG Lead acquired, recorded, and displayed on the LCD. The choices are Lead I, Lead II, and Lead III. The default is Lead I.

ALARM sets the beeper ALARM ON or OFF.

The fields of all submenu items, except the BPM RANGE, are changed by highlighting the submenu item and then pushing the MENU button. When the MENU button is pushed repeatedly, the field values are cycled through all their possible values.

When the BPM RANGE is highlighted, pushing the MENU button will highlight the LOWER LIMIT. Another push will highlight the UPPER LIMIT. The values are changed by pushing the RIGHT (increases the value) or LEFT (decreases the value) arrow buttons.

The maximum upper limit is 300 BPM while the minimum lower limit is 30 BPM. The minimum difference between the upper limit and the lower limit is 10 BPM. For example, if the lower limit is set to 30 BPM, the upper limit could go only as low as 40 BPM. If the upper limit is set to 300 BPM, the lower limit could go only as high as 290 BPM.

5.3.3 REVIEW SUBMENU

When the REVIEW submenu is highlighted, the following submenu is displayed:

| DEVICE | ECG | REVIEW | EXIT |
|----------------------|-----|--------|------|
| ECG REVIEW | | | |
| ECG CLEAR | | | |
| TREND | | | |
| TREND CLEAR | | | |
| RETURN TO UPPER MENU | | | |

The submenu is entered when the MENU button is pushed while REVIEW is highlighted.

REVIEW SUBMENU ITEMS

ECG REVIEW A list of the stored ECG records is displayed. The chosen record is then displayed on the LCD display.

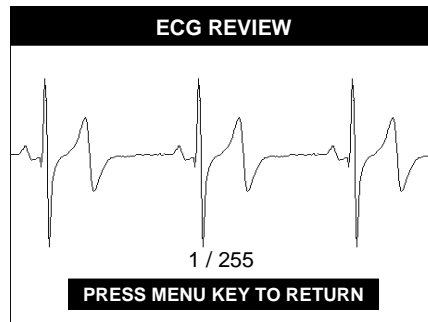
When the MENU button is pressed while the ECG REVIEW submenu is highlighted, the following screen is displayed

| DEVICE | ECG | REVIEW | EXIT |
|---------|-----|---------|------|
| DATA 01 | | USED | |
| DATA 02 | | USED | |
| DATA 03 | | WRITING | |
| DATA 04 | | UNUSED | |
| DATA 05 | | UNUSED | |
| DATA 06 | | UNUSED | |
| DATA 07 | | UNUSED | |
| DATA 08 | | UNUSED | |
| DATA 09 | | UNUSED | |
| DATA 10 | | UNUSED | |
| EXIT | | | |

DATA 01 to DATA 10 indicates the data memory partition number.
WRITING – indicates the memory partition number in which the device is currently writing data.
USED – indicates that the memory partition had been stored with data from previous device uses.
UNUSED – indicates that the memory partition does not contain any recorded data.

Any of the memory partitions can be highlighted by pressing the RIGHT or LEFT button.

When a partition marked USED is highlighted and the MENU button is pressed, the data stored in that particular partition is displayed as shown in the following screen



When a partition marked WRITING is highlighted and the MENU button is pressed, the data stored in the partition currently used for storing is displayed. The display will be in the same format as the display for partitions marked STORED.

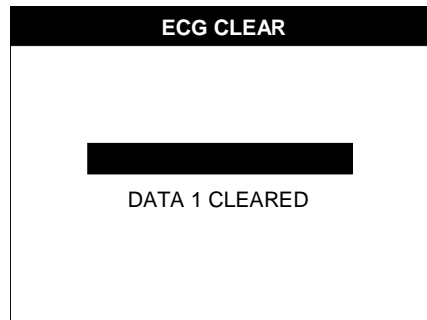
When a partition marked UNUSED is highlighted and the MENU button is pressed, no ECG data is displayed and the screen display stays as it is.

ECG CLEAR

ECG CLEAR is entered when the MENU button is pressed while the ECG CLEAR option is highlighted. The list of memory partitions is displayed after the MENU button is pressed. This is shown in the following screen

| DEVICE | ECG | REVIEW | EXIT |
|--------|---------|---------|------|
| | DATA 01 | USED | |
| | DATA 02 | USED | |
| | DATA 03 | WRITING | |
| | DATA 04 | UNUSED | |
| | DATA 05 | UNUSED | |
| | DATA 06 | UNUSED | |
| | DATA 07 | UNUSED | |
| | DATA 08 | UNUSED | |
| | DATA 09 | UNUSED | |
| | DATA 10 | UNUSED | |
| | EXIT | | |

When it is chosen to clear, partition 1, the menu button should be pressed while partition 1 is highlighted. Upon clearing partition 1, a progress bar is shown. At the end of the clearing process, the prompt "DATA 1 CLEARED" is displayed. This is shown in the following screen



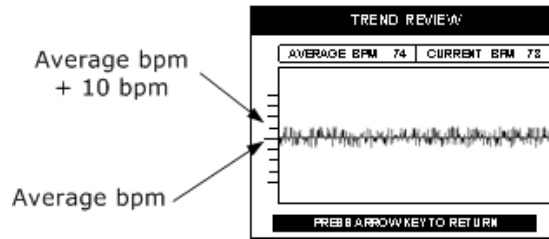
All data memory partitions can be cleared except the memory partition currently being used by the device (the one marked WRITING)

When the ECG CLEAR option is chosen while no memory partition contains any data (except the partition currently being written into), the device will prompt that the memory space has been fully cleared. The following screen will be displayed

| DEVICE | ECG | REVIEW | EXIT |
|--------|----------------------|--------|------|
| | ECG REVIEW | | |
| | FULL CLEARED | | |
| | TREND | | |
| | TREND CLEAR | | |
| | RETURN TO UPPER MENU | | |

TREND

The TREND function of the CU-PH1 graphs the heart rate trend of the input ECG signal. The computed heart rate between two QRS peaks is graphed. A maximum of 300 values can be graphed in one full screen. After 300 points are graphed, the display needs to be cleared. The following screen is displayed when the MENU button is pressed while the TREND option is highlighted.



The AVERAGE BPM is the running average of the graphed bpm values.

The CURRENT BPM is the value calculated from the latest pair of QRS peaks.

The bpm values are graphed as offsets to the average bpm value. Each grid in the vertical coordinate represents 10 bpm.

When the trend graph is full, it can be cleared by going back to the REVIEW submenu.

TREND CLEAR

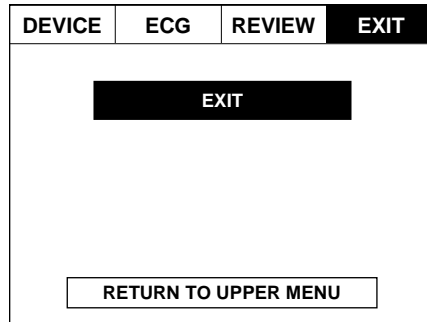
The trend graph is cleared by highlighting the TREND CLEAR option in the REVIEW submenu and then pressing the MENU button.

The TREND CLEAR option is replaced by the CLEARED prompt after the graph is cleared.

If TREND REVIEW is entered again after the trend graph is cleared, a blank graph will be shown. The trend graph will display bpm values as soon as a bpm value is computed.

5.3.4 EXIT SUBMENU

When EXIT is highlighted and the MENU button is pressed, the following submenu is displayed:



- EXIT Pressing the MENU button while EXIT is highlighted will make the device return to ECG display mode.
- RETURN TO UPPER MENU Pressing the MENU button while RETURN TO UPPER MENU is highlighted will take the menu one level higher. The highlight can then be scrolled between the upper menu items (DEVICE, ECG, REVIEW, and EXIT)

5.4 USING THE CU-PH1

5.4.1 ECG Acquisition Using the 3 Electrode ECG Cable Assembly

Step 1: Preparation

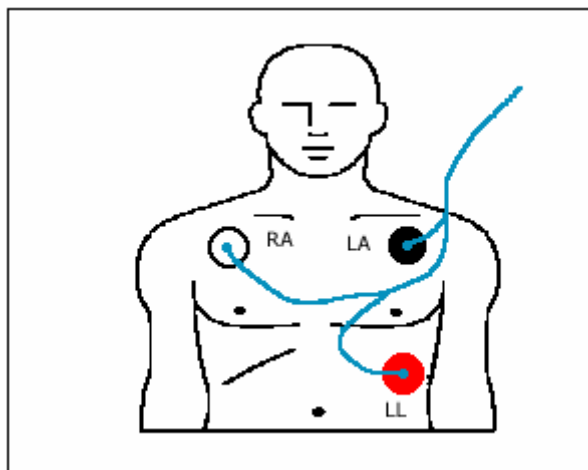
Device Preparation:

Every time you use the CU-PH1:

1. Inspect the physical condition of the device. Ensure that the case, the control buttons, and the ECG port are in good condition.
2. Inspect the ECG cable and connector assembly. Ensure that the cable insulation and the connectors on both ends (electrode side and CU-PH1 side) are not damaged.
3. Make sure that you have the proper electrodes. Electrodes should be in good condition. They must not be past their expiration date. Ensure that the conducting gel has not dried out. **Do not reuse disposable electrodes.**

User/Patient Preparation

1. Ensure that the areas where the electrodes will be attached are free of moisture, grease, or dirt. See the figure below for the position of the electrodes
2. Shave excessive hair.
3. Remove the protective plastic backing of the disposable electrodes. Make sure that the conducting gel has not dried out. Place the electrodes in the positions indicated in the figure below.
4. Ensure that the cable and connector assembly is connected properly. Check for any apparent damage in the cable and connector assembly. The lead connectors should be properly connected to the trunk cable. The connections are color-coded. RA is colored RED, LA is colored YELLOW, and LL is colored GREEN.
5. Attach the electrode connectors to the corresponding electrodes.
6. Attach the other end of the trunk cable to the ECG input port of the CU-PH1.
7. Turn the device ON.



Electrode positions

NOTICE

Make sure that the disposable electrodes are not yet past their expiration date. Do not use electrodes that are past their expiration dates.

NOTICE

If you are using electrodes that are packaged in a pouch, close and reseal the pouch after getting the electrodes that you need. Resealing the packaging pouch will help prolong the life of the electrodes.

NOTICE

Do not reuse disposable electrodes. These are for one time use only.

NOTICE

Some electrode conducting gel may cause skin irritation on some patients/users. If this occurs, switch to electrodes with different conducting gel.

⚠ WARNING

Do not subject the device to defibrillation voltages. The device is equipped with defibrillation protection intended to protect it from accidental defibrillation, however, the manufacturer advises against leaving the device on the patient when the patient is to be administered with defibrillation shocks.

Step 2: ECG SIGNAL ACQUISITION

As soon as the CU-PH1 is properly connected to the patient and turned ON, it will begin ECG signal acquisition and ECG display. It will also automatically begin recording the data in its internal memory.

NOTICE

During ECG data acquisition, the patient or user should keep still to avoid having motion artifacts in the ECG signal. Motion artifact is caused by electrical interference from muscular activity.

As long as the CU-PH1 is acquiring ECG signal, it will do analysis and will indicate the heart rate (in bpm). It will also prompt the user through the alarm beeper if the ECG it has acquired is abnormal. Abnormal ECG is ECG that has a rate outside the range defined by the user.

NOTICE

The CU-PH1 will indicate only the heart rate (in bpm) and whether the ECG signal is normal or not. It will not analyze the ECG signal for arrhythmias or other heart abnormalities.

NOTICE

The CU-PH1 is capable of acquiring any of the three bipolar limb leads (Lead I, Lead II, or Lead III) without having the position of the electrodes changed. However, only the lead chosen in the device setup is acquired, analyzed, and recorded at any given time.

⚠ CAUTION

Do not short the electrodes when the device is ON.

⚠ WARNING

Do not use the device alongside with high frequency electrocautery equipment.

⚠ WARNING

The device is designed to be used only in the acquisition and processing/display of surface ECG's. The device is not to be used in direct cardiac application (i.e. applied directly to the heart during open chest operations)

NOTICE

The device will issue a "LEAD FAULT" text prompt on the LCD when the leads are off. The leads are off when the pads are not properly connected or the cable and connector assembly is damaged

5.4.2 ECG Acquisition Using the Hand Electrodes

The CU-PH1 can also acquire ECG signals using hand electrodes. The hand electrodes are located as shown in section 3.1

The RA hand electrode is connected to the right hand forefinger, the LL hand electrode is connected to the right hand middle finger, and the LA hand electrode is connected to the left hand forefinger. Connection is done through direct contact of the fingers with the corresponding electrodes.

6. MAINTENANCE AND TROUBLESHOOTING

6.1 MAINTENANCE

There are no user-serviceable parts inside the CU-PH1. However, the user can do simple maintenance tasks that will help prolong the life of the device.

The following are the activities, together with their frequencies, that the user can do.

NOTICE

Used consumables (disposable electrodes, batteries) should be disposed of in accordance with local regulations

⚠ CAUTION

Turn the device OFF before removing the batteries during battery replacement

Maintenance Activities

| Activity | Actions to be Taken |
|--|---|
| <p>Check the battery level indicator on the LCD display.</p> | <p>If a message that the battery is low is displayed, replace the batteries. The CU-PH1 runs on two AAA size batteries. The device should be turned OFF before the batteries are removed.</p> |
| <p>Check the expiration date of the disposable electrodes.</p> | <p>If the electrodes are beyond their expiration date, replace them immediately. Dispose of the expired electrodes in accordance with local regulations.</p> |
| <p>Check the case of the CU-PH1 and the accessories for any sign of apparent damage.</p> <p>Check for dirt Contamination.</p> | <p>If there is any apparent damage to the case of the device, consult the manufacturer.</p> <p>If there is dirt contamination, clean the case as suggested in the section on Cleaning of this Manual.</p> |
| <p>When not in use, turn the device OFF to prolong the life of its batteries.</p> | |

6.2 CLEANING THE CU-PH1

If the case is contaminated with dirt, clean the CU-PH1 using a soft, damp cloth moistened with any of the following solvents:

Soap and water

70% solution isopropyl alcohol

Chlorine bleach and water mixture (30 ml bleach/liter of water)

Ammonia-based cleaners

Hydrogen peroxide

CAUTION

Do not immerse any part of the CU-PH1 in fluids

Do not let any fluid enter the case of the device.

Do not spill liquids on the case of the device.

Do not use strong, acetone-based cleaners in cleaning the device.

Do not use abrasive materials in cleaning the unit, especially on the LCD display and the infrared filter on the IrDA port.

Do not sterilize the CU-PH1.

6.3 TROUBLESHOOTING GUIDE

WARNING

There are no user-serviceable parts inside the CU-PH1. For those conditions not specified in this troubleshooting guide, please consult the manufacturer or its authorized representatives.

WARNING

The manufacturer will not be liable for any damage or injury that may arise from an attempt to repair the device beyond what is described in this troubleshooting guide.

NOTICE

Attempts to repair the CU-PH1 beyond what is described in this troubleshooting guide will make the warranty null and void.

| SYMPTOMS/CONDITIONS | CAUSE(S)/POSSIBLE CAUSE(S) | ACTION(S) TO BE TAKEN |
|--|--|--|
| Low Battery Indicator ON | Low Battery | Replace both batteries with fresh batteries; do not use a combination of a fresh battery and a drained battery |
| Noisy ECG signal | The device is operated in electrically noisy environment (near generators, big transformers, big motors) | Do not operate the device in the mentioned environments. |
| Noisy ECG signal | Motion artifact. The user/patient is moving/doing exertion of major muscles | The patient/user should keep still when using the device. |
| Noisy or no ECG signal | One or all of the electrodes are not connected or electrode-skin contact is poor | Check the electrodes. See to it that the electrodes have not dried out during storage. |
| Noisy or no ECG signal | Cable and connector assembly is not properly connected to the CU-PH1. | Check the connection between the ECG cable and connector assembly and the CU-PH1. |
| Faulty connection when using the IrDA port | IrDA port filter is contaminated with dirt | Clean the IrDA port filter as suggested in the Cleaning section of this manual |

6.4 Device Life

The CU-PH1's device life is dependent on the useful lives of its components. When minor components go out of service, they can be replaced in designated service centers. The flash memory device where the program is stored has a maximum life of 20 years. When this period elapses, the memory device will have to be replaced and the system program will have to be downloaded again.

7. INDICATIONS AND SAFETY CONSIDERATIONS

7.1 INDICATIONS

The CU-PH1 is indicated for use on patients for basic heart rate determination without the aid of a physician.

7.2 CONTRAINDICATIONS

The CU-PH1 is not designed to detect and identify particular heart abnormalities (e.g. arrhythmias) on its own without the aid of a qualified physician.

7.3 INTENDED USERS

1. Any user who can operate an electronic device and who can comprehend this User's Manual.
2. Any qualified physician.

7.4 SAFETY CONSIDERATIONS












The user must be aware of the following safety considerations when operating the CU-PH1.

These safety considerations had been stated in other parts of this Manual. These are repeated here for emphasis and easy reference.

The safety concerns are labeled according to the seriousness of the resulting injuries when an accident involving these safety concerns occurs.

- a) **WARNING** – conditions, hazards, or unsafe practices that can result in personal injury.
- b) **CAUTION** – conditions, hazards, or unsafe practices that can result in minor personal injury, damage to the CU-PH1, or loss of data stored in the device.
- c) **NOTICE** - Notes items that are important during installation, operation, or maintenance of the device.

| GENERAL SAFETY CONSIDERATIONS | |
|--------------------------------------|--|
| SAFETY LEVEL | POSSIBLE DANGERS and HAZARDS |
| NOTICE | The user should understand this User's Manual well before attempting to use this device. |
| NOTICE | Make sure that the disposable electrodes are not yet past their expiration date. Do not use electrodes that are past their expiration dates. |
| NOTICE | If you are using electrodes that are packaged in a pouch, close and reseal the pouch after getting the electrodes that you need. Resealing the packaging pouch will help prolong the life of the electrodes. |
| NOTICE | Do not reuse disposable electrodes. These are for one time use only. |
| NOTICE | During ECG data acquisition, the patient or user should keep still to avoid having motion artifacts in the ECG signal. Motion artifact is caused by electrical interference from muscular activity |
| NOTICE | The CU-PH1 will indicate only the heart rate (in bpm) and whether the ECG signal is normal or not. It will not analyze the ECG signal for arrhythmias or other heart abnormalities. However, the device keeps an accurate record of the ECG which can be used by a qualified physician for analysis. |
| NOTICE | The CU-PH1 is capable of acquiring any of the three bipolar limb leads (Lead I, Lead II, or Lead III) without having the position of the electrodes changed. However, only the lead chosen in the device setup is acquired, analyzed, and recorded at any given time. |
| NOTICE | Used consumables (disposable electrodes, batteries) should be disposed of in accordance with local regulations |
| CAUTION | <p>Do not immerse any part of the CU-PH1 in fluids Do not let any fluid enter the case of the device. Do not spill liquids on the case of the device. Do not use strong, acetone-based cleaners in cleaning the device.</p> <p>Do not use abrasive materials in cleaning the unit, especially the LCD display and the infrared filter on the IrDA port.</p> <p>Do not sterilize the CU-PH1.</p> |
| WARNING | There are no user-serviceable parts inside the CU-PH1. For those conditions not specified in this troubleshooting guide, please consult the manufacturer or its authorized representatives. |

| GENERAL SAFETY CONSIDERATIONS | |
|--|---|
| SAFETY LEVEL | POSSIBLE DANGERS and HAZARDS |
|  WARNING | The manufacturer will not be liable for any damage or injury that may arise from an attempt to repair the device beyond what is described in this troubleshooting guide. |
|  NOTICE | Attempts to repair the CU-PH1 beyond what is described in the troubleshooting guide will make the warranty null and void. |
|  NOTICE | Do not operate the device in electrically noisy environments (near big motors, generators, or power transformers) as these will interfere with the signals being acquired. |
|  NOTICE | Some electrode conducting gel may cause skin irritation on some patients/users. If this occurs, switch to electrodes with different conducting gel. |
|  WARNING | Turn the device OFF before removing the batteries during battery replacement |
|  WARNING | Do not short the electrodes when the device is ON |
|  WARNING | Do not subject the device to defibrillation voltages. The device is equipped with defibrillation protection intended to protect it from accidental defibrillation, however, the manufacturer advises against leaving the device on the patient when the patient is to be administered with defibrillation shocks. |
|  WARNING | Do not use the device alongside with high frequency electrocautery equipment |
|  WARNING | The device is designed to be used only in the acquisition and processing/display of surface ECG's. The device is not to be used in direct cardiac application (i.e. applied directly to the heart during open chest operations) |
|  NOTICE | The device will issue a "LEAD FAULT" text prompt on the LCD when the leads are off. The leads are off when the pads are not properly connected or the cable and connector assembly is damaged |
|  NOTICE | The IrDA transceiver is tested and certified by its manufacturer to conform with the provisions of IEC60825-1 |

8. DATA MANAGEMENT AND REVIEW

When the CU-PH1 is turned ON, the data is automatically saved in its nonvolatile, internal memory. The data is then available for review and transfer to external devices.

Data is stored in the memory of the device in 60-minute memory partitions. There are 10 memory partitions for a total recording time of 600 minutes. When the device is operated continuously for more than 60 minutes, only the first 60 minutes of data is recorded. If it is desired to record more than 60 minutes of data, turn the device OFF then ON when it has reached the 60-minute mark. When this is done, the device records on the next blank memory partition.

When all of the memory partitions are full, turning the device ON will make it overwrite the first memory partition. It will always overwrite the first memory partition whenever it is turned ON while all of its memory partitions are full.

9. SPECIFICATIONS

ECG

- Lead I, II, III with 3 Cable Electrodes
- Lead I with hand electrodes
- Bandwidth : 0.3 to 40 Hz : Digital Notch Filter at 50/60 Hz
- ECG Vertical Scales : 5 mm/mV, 10 mm/mV, 20 mm/mV, and AUTO
- ECG Sweep speed : 25 mm/s
- ECG Heart Rate : 30 – 300 bpm
- CMRR : > 90dB
- DC offset correction : ± 300 mV
- Sample resolution : 200 samples / sec, 12 bits

Display

- LCD resolution : 320 × 240 pixel
- Viewing Area : 76 mm × 57 mm
- Backlight : Can be turned ON or OFF or Automatic ON for 5 seconds when any key is pressed
- QRS Beeping : Can be turned ON or OFF
- Screen Information : Heart Rate, Current Lead, Beep Alarm, Low Battery Alarm

Data Control

- Recording Time : max 60 minutes per partition, 10 partitions, total of 600 minutes
- Data Recorded : ECG Waveform
- Data communication : IrDA

Safety Standards

- IEC 601-1, IEC 601-2-25
- MDD 93/42/EEC Annex IV Class IIa Type BF
- Defibrillator Protection when used with 3 Cable Electrodes

Power

- 1.5 V × 2 AAA LR03 type alkaline batteries

Physical

- Length : 133 mm
- Width : 108 mm
- Thickness : 22 mm
- Weight : 230 g excluding electrode assembly, including batteries