

AbioCor[®]

Handheld Monitor

INSTRUCTIONS FOR USE

CAUTION:

IMPORTANT NOTICE: Read the entire *Instructions for Use* before using the Handheld Monitor. The Handheld Monitor is to be used only in accordance with the *Instructions for Use*.

Manufactured by:
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The AbioCor[®] Implantable Replacement Heart System is covered by one or more United States Patents and patents pending.

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About This Manual

This manual provides the *Instructions for Use* for the Handheld Monitor used by patients who have received the AbioCor[®] Implantable Replacement Heart System.

These *Instructions for Use* are intended to be used by clinicians, caregivers, and AbioCor patients.

For more information about the AbioCor System, refer to the *AbioCor Implantable Replacement Heart System - Operator's Manual*; the *AbioCor Console Alarms - User's Guide*; and the *Patient-Carried Electronics [PCE] - Instructions for Use*.

Cautions

NOTE: A caution indicates a situation in which equipment may malfunction, be damaged, or cease to operate.

- Do **not** use the Handheld Monitor close to an operating AbioCor[®] Console. The RF signals from the AbioCor Console and the Handheld Monitor will interfere with each other and **not allow adjustments to be made to the Implanted System**. If RF interference occurs, turn off the Handheld Monitor.
- The Handheld Monitor does **not** use an indicator to display the status of its battery. However, the alarm message “Handheld Battery” is displayed when the battery is low. You should charge the Handheld Monitor battery every night, whether it is used or not.

Overview

The Handheld Monitor is a Personal Digital Assistant (PDA) that communicates with the AbioCor[®] Implanted Controller. This allows you to quickly access important information about the AbioCor without using the Console. You can use the Handheld Monitor to:

- Respond to a Heart Alarm on the PCE Module.
- Check AbioCor[®] status.
- Check AbioCor[®] settings and alarm history.

You *cannot* make changes to Beat Rate, Motor Speed, or Balance settings using the Handheld Monitor. These changes must be made using the Console.

Before using the Handheld Monitor, you must be trained in the operation of the PCE and the Console.

Components of the Handheld Monitor

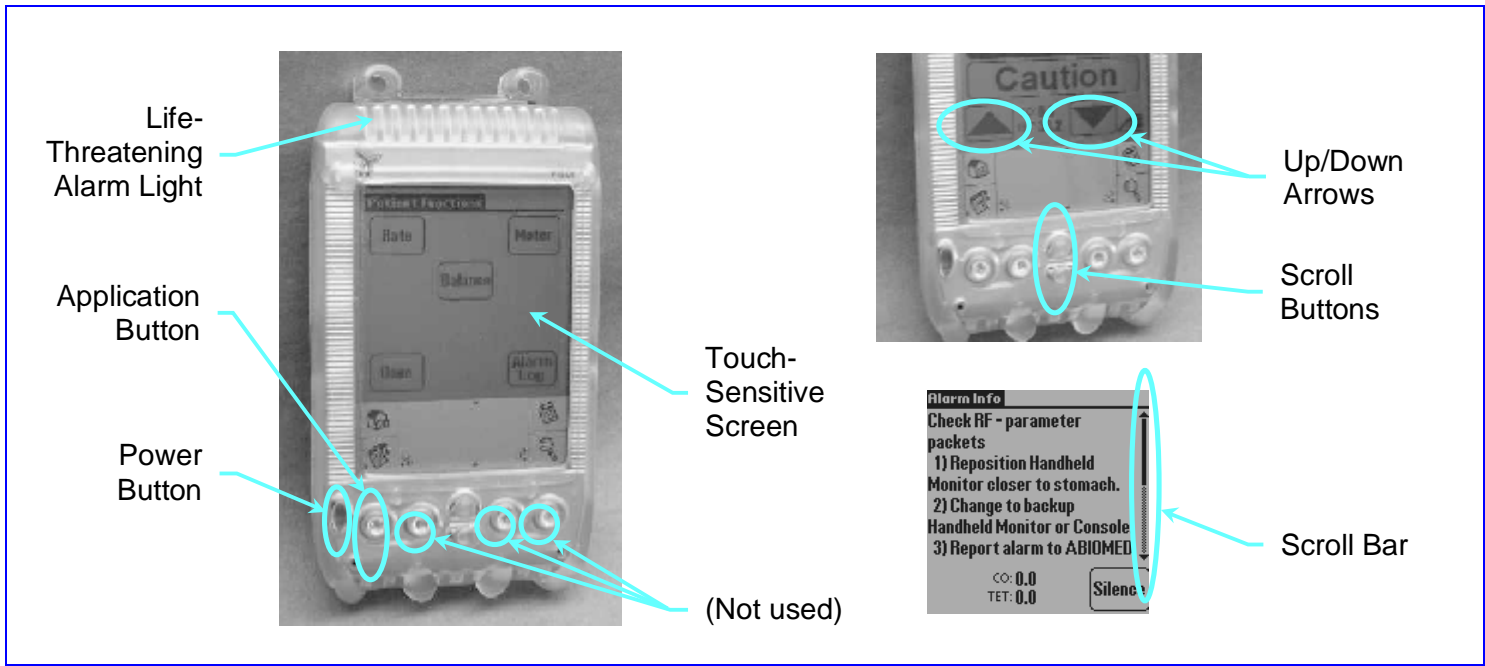
- **RF Expansion Module** – allows the Handheld Monitor to communicate with the Implanted Controller; draws power from the Handheld Monitor's battery (even when the unit is off).
- **Handspring™ Personal Digital Assistant (PDA)** – standard PDA used as the interface component of the Handheld Monitor.
- **Stylus** – used to select items on the screen (fingers can also be used).
- **Charger** – plugs into an AC outlet to charge the Handheld Monitor's battery.



Components of the Handheld Monitor

Controls and Features

- **Life-Threatening Alarm Light** – flashes when a life-threatening alarm condition exists; it also flashes briefly when the RF Expansion Module is inserted.
- **Application Button** – used to access the AbioCor[®] Settings Screens and Alarm History Screen.
- **Power Button** – turns the Handheld Monitor on and off; the screen automatically turns off (to save power) if the unit has not been used for 2 minutes.
- **Touch-Sensitive Screen** – displays information; responds to the stylus.
- **Scroll Buttons, Up/Down Arrows, and Scroll Bar** – used to move through information on the screen.



Resolving Alarms

1

The Handheld Monitor's AbioCor[®] Alarms screen allows you to view two types of alarms: *active* and *inactive*.

- **Active alarm** – an existing alarm that has *not* been acknowledged (“silenced”); indicated by a *flashing* alarm message.
- **Inactive alarm** – an existing alarm that has been acknowledged; becomes active again if it is not resolved within 2 minutes; indicated by a *solid* (not flashing) alarm message.

NOTE: Alarms that have been resolved without action or acknowledgement may be displayed as solid alarm messages.

2

Alarms are divided into three levels: *Life Threatening, Serious, and Advisory*. The following message display methods are used to distinguish each level:

- **Life Threatening** – Active: flashes between black text on light background and light text on black background.
Inactive: solid light text with black background.

NOTE: The Life-Threatening Alarm Light also flashes **red** for Active and Inactive.

- **Serious** – Active: flashes between black text and textured text.
Inactive: solid black text.
- **Advisory** – Active: flashes “INFO” between black text and textured text.
Inactive: solid black text.

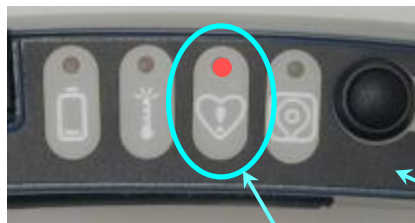
Life-Threatening
Alarm Light



Resolving Alarms (continued)

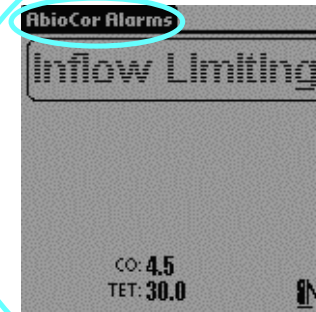
3

When the Heart Alarm (visible and audible) on the PCE Module is activated, move the Handheld Monitor close to the Implanted Controller (stomach area) and turn it on. The AbioCor[®] Alarms screen appears.




Heart
Alarm

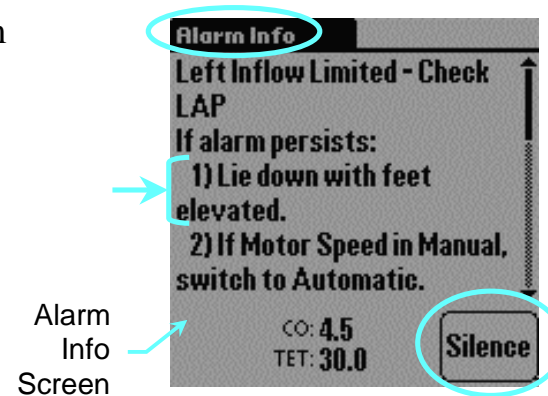
PCE
Module



4

Alarms are listed in order of importance. The most important alarm is at the top of the list.


- a. Using the stylus (or your finger), tap the alarm at the top of the list. The Alarm Info screen appears.
- b. Follow the instructions in the *first step only*.
- c. Tap  to acknowledge the alarm. This returns you to the AbioCor[®] Alarms screen. Check whether the alarm is still listed.



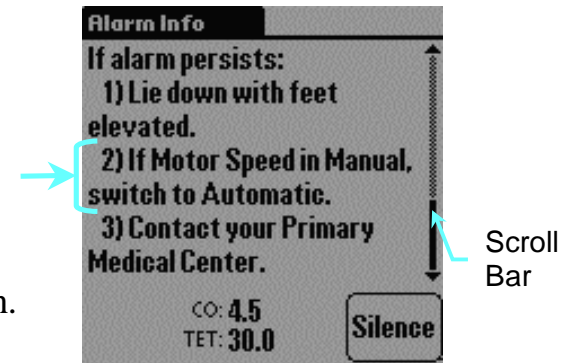
Resolving Alarms (continued)

5

If the alarm is still listed:

- a. Tap the alarm. The Alarm Info screen appears.
- b. Follow the instructions in the *next step only*.
- c. Tap  to return to the AbioCor® Alarms screen.
- d. Continue in this manner, performing *one step at a time*, until the alarm has cleared.

If the alarm is no longer listed, tap the alarm that is now at the top of the list. Begin again with the procedure described on the previous page.



NOTE: Be sure to use the scroll bar to view additional instructions that do not fit on a single screen.

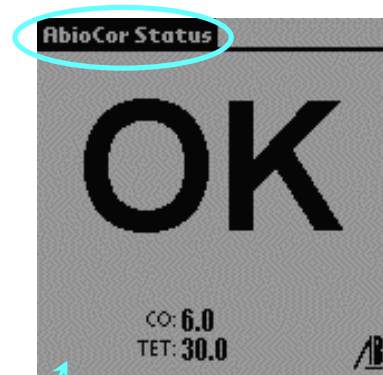
6

When all alarms are resolved, the AbioCor[®] Status screen appears, and the Heart Alarm indicator on the PCE Module turns off.



PCE
Module

Heart
Alarm



AbioCor
Status
Screen

Checking AbioCor[®] Status

1

Turn on the Handheld Monitor. Either the AbioCor Status screen or the AbioCor Alarms screen appears:

- If the AbioCor Status screen appears, proceed to the following page.
- If the AbioCor Alarms screen appears (displaying a “Check RF” alarm), move the Handheld Monitor closer to the Implanted Controller (stomach area). The “Check RF” alarm should clear.

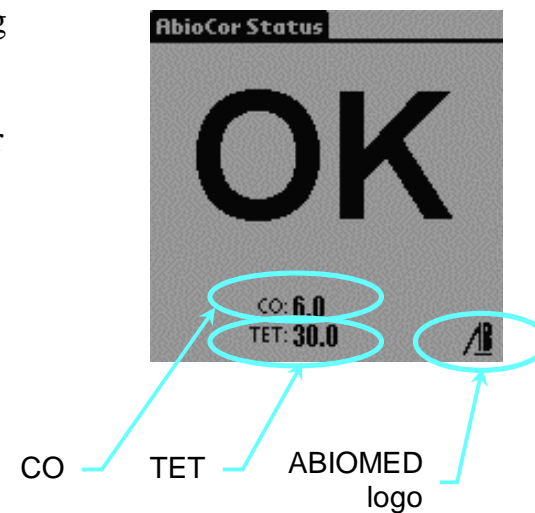


CAUTION: Do **not** use the Handheld Monitor close to an operating AbioCor[®] Console. The RF signals from the Console and the Handheld Monitor will interfere with each other and **not allow adjustments to be made to the Implanted System**. If RF interference appears, turn off the Handheld Monitor.

2

The AbioCor[®] Status screen provides the following information:

- **CO** – indicates AbioCor blood flow in liters per minute (L/min).
- **TET** – indicates system voltage in VDC.
- **ABIOMED[®] logo** – appears to rotate when the program is operating.



Checking AbioCor[®] Settings and Alarm History

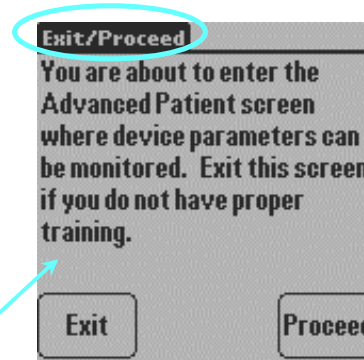
1

Press the application button *twice*. The Exit/Proceed screen appears.

Application
Button



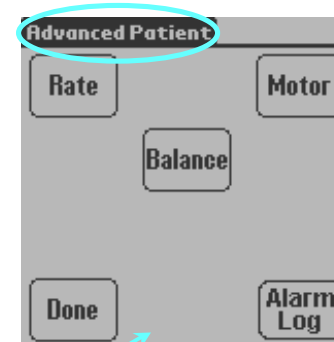
Exit/Proceed
Screen



2

Tap **Proceed** on the Exit/Proceed screen. The Advanced Patient screen appears. This screen allows you to access the following information (see sample screens on the following pages):

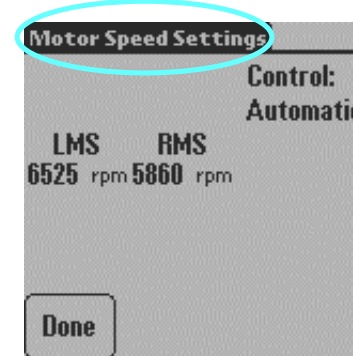
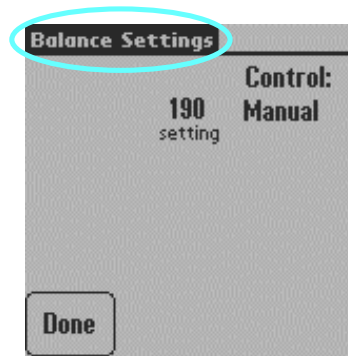
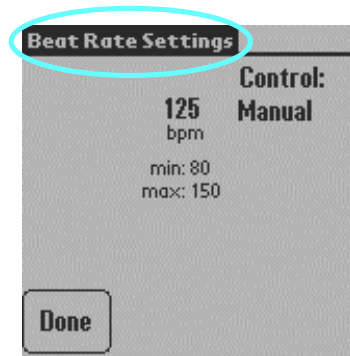
- **Beat Rate** – current, minimum, and maximum settings; control status (manual).
- **Balance** – current setting; control status (manual or automatic).
- **Motor Speed** – current settings; control status (manual or automatic).
- **Alarm History (Log)** – most recent 10 alarms.




Advanced Patient Screen

Checking AbioCor[®] Settings and Alarm History (continued)

3

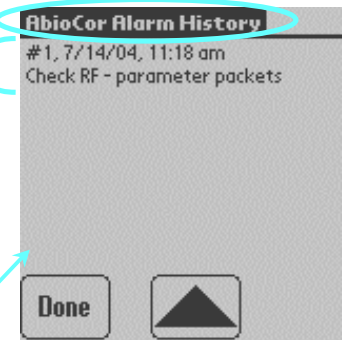


NOTE: Tapping  returns you to the AbioCor Status screen (or, if an alarm exists that has not been acknowledged, to the AbioCor Alarms screen).

4

This information concerns the most recent alarm. Scroll to view the details of the 10 most recent alarms.

AbioCor Alarm History Screen



Charging the Battery

1



CAUTION: *The Handheld Monitor does **not** use an indicator to display the status of its battery. However, the alarm message “Handheld Battery” is displayed when the battery is low.*

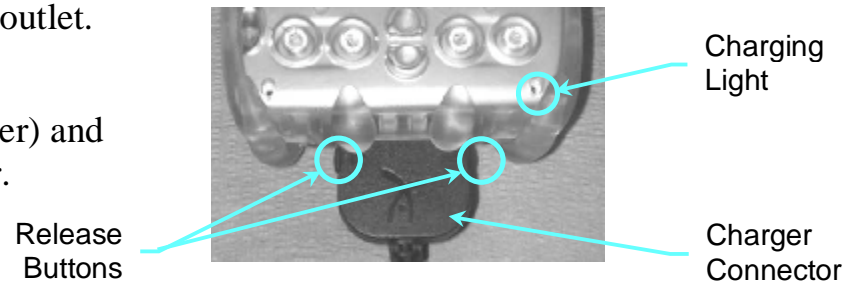
Charge the Handheld Monitor’s battery every night, whether it is used or not. When possible, you should keep the backup Handheld Monitor available while the other unit is charging. It takes about 90 minutes to charge the battery.

NOTE: The screen remains on during charging, even if the Handheld Monitor was turned off prior to charging.


2

To charge the battery:

- a. Plug the charger connector into the Handheld Monitor.
- b. Plug the charger into an AC outlet. The charging light blinks while the battery is charging. When the light stays on, the battery is charged.
- c. Unplug the charger from the outlet.
- d. Squeeze the release buttons (between thumb and forefinger) and unplug the charger connector.



Troubleshooting

Symptom	Solution
<p>The screen is frozen,</p> <p>OR</p> <p>The Handheld Monitor chirps repeatedly.</p>	<ul style="list-style-type: none">• Remove the RF Expansion Module and then reinsert it.• If the screen is still frozen, reset the Handheld Monitor by unscrewing the stylus tip and inserting the smaller end into the RESET hole on the back of the unit.• If the problem still exists, change to the backup Handheld Monitor or AbioCor[®] Console. 

Symptom	Solution
The Handheld Monitor does not turn on.	<ul style="list-style-type: none">• Follow the procedure described in <i>Charging the Battery</i>. Turn on the Handheld Monitor.• If the problem still exists, change to the backup Handheld Monitor or AbioCor[®] Console.

Care and Cleaning

- Be careful not to scratch the screen. Only use the stylus or fingers when touching the screen. Do not use pens, pencils, or other sharp objects on the screen.
- The Handheld Monitor is not waterproof and should not be exposed to rain, moisture, or extremely dusty conditions.
- To prevent damage to the screen, be careful not to drop the Handheld Monitor or subject it to strong impact.
- Protect the Handheld Monitor from extreme temperature environments (such as the dashboard of a closed car during hot weather), heaters, and other heat sources.
- To clean the Handheld Monitor, use a soft, damp cloth. To clean the screen, use a soft cloth moistened with diluted window-cleaning solution.

Appendix: Federal Communications Commission (FCC) Notice

AbioCor Components	Notice
AbioCor® Console	This device complies with Part 18 of the FCC Rules.
PCE Control Module	This device complies with Part 18 of the FCC Rules.
RF Communication Module	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. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Handheld Monitor	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. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Implantable Controller	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. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.



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