HeartMate® Universal Battery Charger
INSTRUCTIONS FOR USE (IFU)
for Charging HeartMate 12 Volt NiMH & 14 Volt Li-Ion Batteries

Corporate Headquarters
Thoratec Corporation
6035 Stoneridge Drive
Pleasanton, CA 94588
USA
Business:
Tel.: 925-847-8600
Fax: 925-847-8574
Emergencies:
800-456-1477 (USA HeartLine™)
925-847-8600 (International)
www.thoratec.com

Rx Only

Document # 103771.B
1/2011
Table of Contents

WARNINGS & PRECAUTIONS__________________________________________ 1
Warnings________________________________________________________ 1
Precautions______________________________________________________ 2

INTRODUCTION____________________________________________________ 4
1.0 Overview______________________________________________________ 4
2.0 Setting Up the Universal Battery Charger Prior to Use______________ 5
  2.1 Plugging In and Turning On the Charger__________________________ 5
  2.2 Selecting Language/Display Panel Settings______________________ 9

USING YOUR UNIVERSAL BATTERY CHARGER___________________________ 12
3.0 Charging Batteries____________________________________________ 12
  3.1 Battery Charging (Overview)__________________________________ 12
  3.2 Charging Batteries (Procedure)_______________________________ 15
  3.3 Viewing Battery Information on the UBC Screen_________________ 18
4.0 Calibrating HeartMate Batteries_________________________________ 21

RESPONDING TO ADVISORY MESSAGES________________________________ 24
5.0 Monitoring Performance________________________________________ 24
  5.1 Battery-Related Advisory Messages____________________________ 24
  5.2 Charger-Related Advisory Messages____________________________ 26

INSPECTION, CLEANING & MAINTENANCE_______________________________ 28
6.0 Routine Inspection and Cleaning________________________________ 28
7.0 Product Disposal______________________________________________ 29
8.0 Testing and Classification______________________________________ 29

APPENDICES______________________________________________________ 31
APPENDIX 1: Technical Specifications – HeartMate Universal Battery Charger
  (UBC) (p/n 1440)_____________________________________________ 31
APPENDIX 2: Description of English Text and Graphic Symbols Appearing on
  The UBC Display Panel________________________________________ 33
APPENDIX 3: Graphic Symbols Found on HeartMate UBC
  Labels and Labeling____________________________________________ 34
Warnings and Cautions

Warnings

• Understanding the operating and the safety aspects of HeartMate products is essential for safe and successful use. All users (including clinicians, patients, and caregivers) must be trained on system operation and safety aspects before use.

• A thorough understanding of the technical principles, clinical applications, and risks of left ventricular support is necessary before using this product. Read this entire HeartMate Universal Battery Charger Instructions for Use (IFU) and the corresponding HeartMate II or HeartMate XVE LVAS IFU, Operating Manual, and/or Patient Handbook before use.

• Before using any HeartMate power accessories (Power Module/Power Base Unit, batteries, Universal Battery Charger), all users (including clinicians, patients, and caregivers) must be trained on their use. Manuals for HeartMate power accessories include:
  - HeartMate 12 Volt NiMH Battery Instructions for Use (IFU) (document # 103769)
  - HeartMate 14 Volt Li-Ion Battery IFU (document # 103770)
  - HeartMate Universal Battery Charger IFU (document # 103771)
  - HeartMate Power Module IFU (document # 103772)

• HeartMate batteries must be charged prior to use. Before removing a battery from the Universal Battery Charger (UBC), check that the battery has completed its charge or calibration cycle, then remove the battery and check its charge level using the battery fuel gauge. See Section 3.0, Charging Batteries.

• Ensure you are using the correct batteries before relying on them for power. Using the wrong batteries for an incompatible system will result in pump failure. HeartMate 14 volt lithium ion (Li-Ion) batteries are for use exclusively with the HeartMate II LVAS. They are NOT compatible with the XVE system and cannot power the XVE LVAS. HeartMate 12 volt nickel metal hydride (NiMH) batteries are capable of powering both the HeartMate II and XVE LVAS (see the HeartMate 12 Volt NiMH Battery IFU).

• The HeartMate Universal Battery Charger (UBC) generates, uses, and can radiate radio frequency energy. If not installed and used according to instructions, it may cause harmful interference with other devices in the area. There is no guarantee that interference will not occur in a particular installation/use of the Universal Battery Charger (UBC). Interference can be determined by turning off/on the Universal Battery Charger (UBC) and seeing the affect on devices in the area. If interference is detected, attempt to correct it by:
  - Re-orienting or moving the affected device(s).
  - Increasing the distance between the Universal Battery Charger (UBC) and the affected device(s).
Connecting the affected device(s) to an electrical outlet different from the outlet used to power the Universal Battery Charger (UBC).

Consulting Thoratec’s Technical Services Department for advice and assistance.

Using equipment and supplies other than those specified in this manual or sold by Thoratec for replacement parts may affect the electromagnetic compatibility of the Universal Battery Charger (UBC) with other devices. This may result in potential interference between the UBC and other devices.

The Universal Battery Charger (UBC) should not be used next to other equipment or stacked on top of or with other equipment. The normal operation of the Universal Battery Charger (UBC) must be verified if the charger is used in these configurations.

Connect the Universal Battery Charger (UBC) (and any peripheral devices) only to properly tested and grounded AC outlets dedicated to battery charger use. Do not use an adapter for ungrounded wall outlets or multiple portable socket outlets (power strips), or the risk of electrocution increases.

Do not connect the Universal Battery Charger (UBC) to electrical outlets controlled by a wall switch, or the charger may be left inoperable.

If traveling internationally, you will need a Thoratec power cord set that is compatible with the local voltage and that meets applicable national plug, rated voltage, rated current, and safety agency marks and specifications. Ask your VAD Coordinator for a Thoratec power cord set, if needed.

Keep the Universal Battery Charger (UBC) away from water or moisture. If the UBC has contact with water/moisture, rain/snow, shower spray, or wet surfaces, you may get a serious electric shock or your Charger may fail to operate properly.

Do not use the UBC near flammable anesthetic agents (such as nitric oxide), or an explosion may occur.

The HeartMate UBC cannot test or charge the black sealed lead acid (SLA) HeartMate batteries originally used with the HeartMate Power Base Unit (PBU) (catalog #2025).

Precautions

- Use only the HeartMate Universal Battery Charger (UBC) to charge HeartMate 12 volt NiMH and 14 volt Li-Ion batteries. Other battery chargers may damage HeartMate batteries.
- Service and maintenance of the HeartMate UBC should be performed only by service personnel who are trained and authorized by Thoratec Corporation.
- Make sure the UBC is plugged in and turned on (“I”) before placing batteries into the pockets for charging.
- After approximately 70 uses, HeartMate batteries may need to be recalibrated. The UBC indicates when a battery needs to be recalibrated. Calibration can take up to 12
hours, and only one battery can be calibrated at a time. Calibrate a battery as soon as possible after being prompted to prevent a backlog of uncalibrated batteries (see Section 4.0, *Calibrating HeartMate Batteries*).

- Leave a calibrating battery in the UBC for the full calibration cycle. Removing a battery before it is fully calibrated may result in a depleted battery (the on-battery fuel gauge will reflect this status) (see Section 4.0, *Calibrating HeartMate Batteries*).

- The metal contacts inside the UBC pockets should be kept clean and dry. Do not expose contacts to water, moisture, dirt, etc. Do not touch these contacts when the charger is connected to AC mains and turned on (“I”).

- Dirty metal contacts inside the battery charging pockets may prevent proper battery charging, which can affect battery operation. The metal contacts inside the pockets should be cleaned at least once a month. Unplug the UBC before cleaning. Use a lint-free cloth or swab that has been moistened (not dripping) with rubbing alcohol. Allow the alcohol to dry before inserting batteries into the pocket(s) for charging. See Section 6.0, *Routine Inspection and Cleaning.*
INTRODUCTION

WARNING! A thorough understanding of the technical principles, clinical applications, and risks of left ventricular support is necessary before using this product. Read this entire HeartMate Universal Battery Charger Instructions for Use (IFU) and the corresponding HeartMate II or HeartMate XVE LVAS IFU, Operating Manual, and/or Patient Handbook before use.

1.0 Overview

The HeartMate Universal Battery Charger (UBC) (Figure 1) is designed to charge the HeartMate batteries used to power the HeartMate II LVAS or HeartMate XVE LVAS during mobile operation. Specifically, the HeartMate UBC can:

- Charge up to four HeartMate 12 volt NiMH batteries or four 14 volt Li-Ion batteries in four hours or less (see Section 3.0, Charging Batteries).
- Monitor the need for calibration and calibrate individual HeartMate 12 volt NiMH batteries or 14 volt Li-Ion batteries (see Section 4.0, Calibrating HeartMate Batteries).
- Perform diagnostic testing on up to four HeartMate 12 volt NiMH batteries or 14 volt Li-Ion batteries at once (see Section 5.0, Monitoring Performance).

CAUTION! Use only the HeartMate Universal Battery Charger (UBC) to charge HeartMate 12 volt NiMH or 14 volt Li-Ion batteries. Other battery chargers may damage HeartMate batteries.
2.0 Setting Up the Universal Battery Charger Before Use

Before using the HeartMate UBC (Figure 1) to charge HeartMate batteries, it must be plugged in and turned on. In addition, you should select the language/display panel setting best for your needs. These steps are described below.

2.1 Plugging In and Turning On the Charger

Follow these steps for setting up the UBC:

1. If not already unpacked, carefully remove the UBC from its product packaging. Place the charger on a flat, sturdy surface.

2. Inspect the charger for dents, chips, cracks, or other signs of damage. Do NOT use a UBC that seems damaged. Contact your VAD Coordinator or hospital contact person for a replacement, if needed.

3. Examine the four battery charging pockets. Make sure the pockets are clean and empty (no batteries), and free of dust or debris. **Note:** Pay particular attention to the metal contacts inside the pockets.
Dirt or objects covering the metal contacts inside the pockets may prevent proper battery charging, which can affect battery performance.

4 Obtain the grey AC power cord from the product packaging.

5 Plug the female end of the power cord into the power entry module in the rear of the charger (Figure 2). Make sure the cord is fully inserted and secure.

6 Plug the male end of the power cord into a properly-tested and grounded (3-prong) AC mains electrical outlet that is not controlled by a light switch. **Note:** If traveling internationally, you will need a Thoratec power cord set that is compatible with the local voltage and that meets applicable national plug, rated voltage, rated current, and safety agency marks and specifications. Ask your VAD Coordinator for a Thoratec power cord set, if needed.

**WARNING!**
- Connect the HeartMate Universal Battery Charger (UBC) only to properly-tested and grounded (3-prong) AC outlets. Do not use an adapter plug or portable, multiple outlet (power strip) for ungrounded wall outlets.
- Ensure the UBC is connected to AC power and is turned “on” before placing batteries into the pockets for charging.

7 Turn on the UBC by pressing the on/off switch in the rear of the charger from the off (“0”) to the on (“I”) position (Figure 3). **Note:** Once the charger is turned on, all lights on the front panel will turn
on (Figure 5), and the charger will beep once. This means the charger is performing a self test. The test takes about 10 seconds. When it is done, all the lights will turn off, unless there is a problem (see Step 8).

8 If the UBC detects a problem during the self test, an error message appears on the display panel screen (Figure 4) and/or the lights and beep will not perform as described above. Note: If you get an error message, and/or the lights or beep are missing or do not perform as described, refer to Section 5.0, Monitoring Performance for how to respond to advisory messages.

OR

8 If the charger passes the self test, “HeartMate CHARGER” appears on the display panel (Figure 6). The charger is now ready for use. Note: Any time the “HeartMate CHARGER” message is displayed, the display panel will slowly dim, turn off for two seconds, and then brighten again to full brightness. This helps to prolong the life of the display (Figure 6). You may use the UBC during this time.
Figure 5 Display panel during self test

Figure 6 "HeartMate CHARGER" message (default screen)
2.2 Selecting Language/Display Panel Settings

The display panel on the front of the HeartMate Universal Battery Charger (UBC) displays messages about how the charger is working or about the status of the battery(ies) in the charging pocket(s).

There are two language/display options for the display panel screen:
- English Text
- Graphic Symbols

“Graphic Symbols” is the default display mode.

Selecting the Language/Display Panel Setting
Before Using the Charger for the First Time

Follow these instructions for switching from the default (“Graphic Symbols”) setting to the “English Text” setting before using the charger for the first time:

1. Unpack and plug in the UBC as outlined in Section 2.1. However, do NOT turn on the charger at this time.
2. At the same time, press and hold buttons #1 and #3 on the front panel of the UBC (Figure 7).

Figure 7 Numbered buttons on front of charger correspond with locations of charging pockets. Note locations of buttons #1 and #3.
3 While still holding buttons #1 and #3, turn on the UBC by pressing the power switch from the off (“0”) to the on (“1”) position.

4 After the “English” display appears (Figure 8), release buttons #1 and #3.

![Figure 8 Display panel showing English language display mode option](image)

5 If “English Text” is the desired display setting, press and release the #1 button. **Note:** After releasing the button, the charger will conduct a self test. If the test is successful, “HeartMate CHARGER” will appear on the screen.

OR

5 If “Graphic Symbols” is the desired setting, press and release the #2 button to scroll down to “Graphics,” then press and release button #1. **Note:** After releasing the button, the charger will conduct a self test. If successful, “HeartMate CHARGER” will appear on the screen.

**Selecting the Language/Display Panel Setting Anytime After Startup**

“Graphic Symbols” is the default display mode. Follow these instructions for changing the display mode anytime after initial setup (see Section 2.0, *Setting Up the Universal Battery Charger (UBC) Before Use)*:

1 Remove all batteries from the charging pockets.

2 Turn off the UBC by pressing the on/off switch from the on (“1”) to the off (“0”) position. **Note:** Do not unplug the charger.

3 At the same time, press and hold buttons #1 and #3 on the front panel of the UBC.

4 While still holding buttons #1 and #3, turn on the charger by pressing the power switch from the off (“0”) to the on (“1”) position.

5 After the display screen appears (Figure 9), release buttons #1 and #3). The UBC will power up.
6 Use the #2 button to scroll down to the desired language/display panel setting.

7 When the desired language/display panel setting appears on the screen, press and release the #1 button. After releasing the button, the charger will conduct a self test. If the test is successful, “HeartMate CHARGER” will appear on the screen.

8 Repeat Steps 1 – 7 any time after initial set up to select or change the desired language/display panel setting.

**Note:** Avoid covering or blocking the vents on the top of the UBC during use. Covering or blocking the vents may affect device performance.
USING YOUR UNIVERSAL BATTERY CHARGER

3.0 Charging Batteries

3.1 Battery Charging (Overview)

The HeartMate Universal Battery Charger (UBC) can charge up to four HeartMate 12 volt NiMH or 14 volt Li-Ion batteries at the same time. It takes up to four hours to charge from one to four batteries, depending on the charge status of the battery(ies) being charged. Be sure to plan battery use and charging with the four-hours in mind.

For best battery performance, leave charged batteries in the charging pockets until ready for use. Leaving charged batteries in the charger will not damage them.

HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries utilize a “smart” technology that measures available battery power and counts battery usage/charge cycles. Once a battery is placed into a charging pocket (Figure 10), the UBC immediately checks that battery’s status by reading the battery’s on board computer chip. Information about the battery (available power and total number of use/charge cycles) can be viewed on the UBC’s display panel by pressing the number button for that pocket (see Section 3.3, Viewing Battery Information on the UBC Screen).

Figure 10 Batteries inserted into Universal Battery Charger pockets #2 and #4. Note yellow lights indicate charge status of batteries (yellow = charging).
Depending on the status of the battery, one of three lights (yellow, green, or red) located near the number button for this pocket will come on (Figure 11). A steady yellow light means that the battery is actively charging. Green means the battery is charged and ready for use. Red means the battery is defective or that there is a problem with the charger. See Table 1 for a complete description of charger pocket light color codes.

![Figure 11 Charge status lights (green, yellow, red) for charging pockets 1 - 4](image)

**UBC Charger Pocket Light Indicators**

<table>
<thead>
<tr>
<th>Light Color</th>
<th>Status/ Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>Battery is charged and ready for use</td>
</tr>
<tr>
<td>Yellow</td>
<td>Battery is undergoing test or charge</td>
</tr>
<tr>
<td>Yellow (Blinking)</td>
<td>Battery requires calibration cycle</td>
</tr>
<tr>
<td>Red</td>
<td>Battery or charging pocket is defective,</td>
</tr>
<tr>
<td></td>
<td>Do not use battery*</td>
</tr>
</tbody>
</table>

* Before assuming that a battery is defective, first remove it from the pocket and then reinsert it into the same pocket. If again there is a red light (or no light), insert the battery into a different pocket. Try cleaning the metal contact on the batteries and inside the pocket (let them dry). If there continues to be a red light (or no light), the battery is defective. Do not
use it. Contact your VAD Coordinator or hospital contact person for help and for a replacement, if needed. See Section 5.0, Monitoring Performance for information on advisory messages and troubleshooting, including how to read alarm codes when a red light comes on

**WARNING!**

- Ensure you are using the correct batteries before relying on them for power. Using the wrong batteries for an incompatible system will result in pump failure.

- The HeartMate 12 volt nickel metal hydride (NiMH) batteries can power both the HeartMate II LVAS and the HeartMate XVE LVAS.

- The HeartMate 14 volt lithium ion (Li-Ion) batteries are NOT interchangeable between the HeartMate II and the HeartMate XVE systems. HeartMate 14 volt Li-Ion batteries are for use exclusively with the HeartMate II LVAS. They are NOT compatible with the XVE system and cannot power the XVE LVAS. Do NOT use HeartMate 14 volt Li-Ion batteries with the HeartMate XVE LVAS.
3.2 Charging Batteries (Procedure)

Follow these instructions for charging HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries:

1. Obtain one or more HeartMate 12 volt NiMH or 14 volt Li-Ion batteries.

CAUTION!

- Do not attempt to test or charge non-HeartMate batteries in the HeartMate Universal Battery Charger (UBC). Doing so may damage the charger or the batteries, or injure the user.
- Do not attempt to test or charge the black sealed lead acid (SLA) HeartMate batteries originally used with the HeartMate Power Base Unit (PBU) (catalog #2025). Doing so may damage the charger or the batteries, or injure the user.

2. Place one of the HeartMate batteries into one of the four battery charging pockets, with the battery fuel gauge on the top and facing forward (Figure 12). **Note:** Do not force a battery into a charging pocket. Batteries will fit only one way into a pocket (with the battery’s battery fuel gauge at the top and facing forward as shown in Figure 12). A beep and one of the pocket lights coming on (red, yellow, or green) confirms the battery is properly placed in the pocket.

![Figure 12 Batteries inserted into charging pockets #2 and #4](image)

3. After hearing the beep, look at the three lights (yellow, green, and red) next to the number button for this pocket (Figure 13). **Note:** The UBC has four charging pockets. Numbers 1 – 4 on the front panel of the charger correspond to the location of each pocket. For example, “1” on the panel stands for the front left pocket; “2” stands for the front right pocket; “3” stands for the rear left; and “4” stands for the rear right pocket.
Identify which of the three lights (yellow, green, or red) comes on for this pocket.

If the yellow light comes on, the battery is actively charging. Do nothing with the battery. Leave the battery in the pocket to continue charging and skip to Step 7. If a blinking yellow light is observed, see section 4.0 Calibrating HeartMate Batteries. **Note:** The yellow light will remain on until the battery becomes charged. Once the battery becomes charged, the yellow light turns off and the green light comes on.

**OR**

If the green light comes on, the battery is already charged and ready for use. Either remove the battery for immediate use, or leave the battery in the pocket until needed. **Note:** Leaving charged batteries in the charger will not damage them.

**OR**

If the red light comes on (or no light at all), there is a problem with the battery or the charging pocket. **Note:** Remove the battery and reinser it into the same pocket. If again there is a red light (or no light), insert the battery into a different pocket. If the battery cannot be charged in a different pocket, the battery is defective. Do not use the defective battery. Contact your VAD Coordinator or hospital contact person for help and for a replacement, if needed. See Section 5.0, *Monitoring Performance* for information on advisory messages and troubleshooting, including how to read alarm codes when a red light comes on.

**Figure 13** Charge status lights. Note yellow light for pocket #1. In this case, the battery in pocket #1 is charging.
6 After approximately four hours, look at the three lights near the charging pocket for this battery. **Note:** It takes up to four hours to charge one to four batteries, depending on the original charge status of the battery(ies) being charged.

7 If the **green** light is on, the battery is charged and ready for use. **OR**

7 If the **yellow** light is on, the battery is still charging. **OR**

7 If the **red** light is on, there is a problem with the battery and/or the UBC interrupted the charging cycle for some reason. See Section 5.0, *Monitoring Performance* for how to handle red light conditions.

8 Repeat Steps 2 – 8 for as many as three more batteries, to charge up to four batteries at the same time (**Figure 14**).

**Figure 14** Batteries inserted into all four charging pockets
3.3 Viewing Battery Information on the Universal Battery Charger (UBC) Screen

To check a battery’s charge status, place the battery into a charging pocket, then press and release the number button for that pocket. The following will appear on the display panel (Figure 15):

- Pocket Number
- Battery symbol
- Percentage of available charge

For example, if approximately 50% of the battery’s power is available (i.e., battery is 1/2 charged), half of the battery symbol is filled and “50%” appears on the screen.

After five seconds, the display returns to the default screen (“HeartMate CHARGER”), unless the number button for this pocket is pressed again. Pressing the button a second time brings up the total number of use/charge cycles (see immediately below).

To see how many times a battery has been used/charged, press and release the number button while the Charge Status Screen (Figure 15) is still on. The following will appear on the display panel (Figure 16):

- Pocket Number
- Total number or uses/charges for this battery
- How much power the battery can potentially hold if fully charged (measured in mAh)

After 10 seconds, the display panel returns to the default (“HeartMate CHARGER”) screen (Figure 13).
Figure 15  Viewing available power for the battery in pocket #1 (in Graphics mode). In this case, the battery is approximately 90% charged.

Figure 16  Battery cycle count (in this case 7 cycles) and charger capacity (in mAh) for the battery in pocket #1 (sample only).
If a battery is being calibrated (see Section 4.0, *Calibrating HeartMate Batteries*), the pocket number and a split battery symbol appear on the display panel when the number button for that pocket is pressed (*Figure 17*). **Note:** Five seconds after pressing the button, the display returns to the default (“HeartMate CHARGER”) screen (*Figure 13*).

![Figure 17](image)

*Figure 17* Display panel screen (in Graphics mode) when button is pressed to start battery calibration cycle. In this case, the battery in pocket #4 needs calibration.

See *Appendix 2* for a complete list of display panel symbols and messages.
4.0 Calibrating HeartMate Batteries

HeartMate 12 volt NiMH and 14 volt Li-Ion batteries use a “smart” technology that measures available battery power and counts battery usage/charge cycles. Periodically (approximately every 70 battery uses), the battery may sense that it needs to calibrate its battery fuel gauge. Calibration helps keep the battery’s fuel gauge accurate.

During calibration, the UBC drains the battery of all electrical energy and then recharges it. The battery must be placed into the UBC to be calibrated. Battery calibration can take up to 12 hours, and only one battery can be calibrated at a time. During calibration, the other three HeartMate batteries can be charged as usual.

If a battery needs to be calibrated, the UBC will tell you when that battery is inserted into one of the charging pockets. The following occurs if calibration is recommended:

- The yellow light for this pocket blinks
- A split battery symbol and the pocket number for this battery flashes on the display panel screen (Figure 18). Note: The circled number will switch between a filled and unfilled circle as the display panel screen flashes.

![Figure 18 Calibration prompt (in Graphics mode). In this case, the battery in pocket #4 needs calibration.](image.png)

You have the choice of calibrating the battery when prompted or waiting for another, more convenient time (e.g., at night while sleeping). If you choose to not calibrate at the prompt, after ten seconds, the charger will continue with a normal charge cycle for this battery (see Section 3.2, Charging Batteries). It is OK to use a battery (once recharged) if you delayed its calibration. But, you should calibrate it as soon as possible.

If you choose to calibrate the battery, and then decide to cancel it after the process has already begun, you can cancel calibration by removing the battery from its pocket. **If you do remove a battery before calibration is complete, make sure to recharge and check the battery before using it.** Removing a battery before
calibration ends may result in a depleted battery (the on-battery fuel gauge will reflect this status).

**Note:** It is important to calibrate a battery as soon as possible after being prompted to do so. This helps ensure the best possible battery performance. Be sure to have enough charged batteries when planning for calibration, which can take up to 12 hours. For example, under normal conditions, having four charged batteries will allow you to exchange batteries twice during a 12-hour calibration cycle.

Follow these steps to calibrate a HeartMate 12 volt NiMH or 14 volt Li-Ion battery:

1. Receive a calibration prompt from the charger (blinking yellow light, broken battery symbol on display panel screen) (**Figure 18**).

2. If you do not want to calibrate the battery now, do nothing. After ten seconds, the UBC will continue to charge the battery as usual (see Section 3.2, **Charging Batteries**).

**OR**

2. If you do want to calibrate the battery now, within ten seconds of the start of the blinking yellow light, press and release the number button for this pocket.

**Note:** During calibration, the yellow light for this pocket remains on and “HeartMate CHARGER” appears on the display panel screen, unless the number button for this pocket is pressed. Pressing the number button during calibration brings up the calibration status screen for the battery (**Figure 19**). Once calibration is complete, the yellow light turns off and the green light comes on. Green means the battery is charged and ready for use.

**CAUTION!** Leave a calibrating battery in the Universal Battery Charger for the entire calibration cycle. Removing the battery before it is fully calibrated may result in a depleted battery (the on-battery fuel gauge will reflect this status).
Figure 19 Calibration status display (in Graphics mode). In this case, the battery in pocket #4 is calibrating.
RESPONDING TO ADVISORY MESSAGES

5.0 Monitoring Performance

The HeartMate Universal Battery Charger (UBC) is continually monitoring its own performance and that of any battery placed into a pocket. Actual or potential problems, or “faults,” appear as “advisory messages” on the display panel screen.

5.1 Battery-Related Advisory Messages

If the UBC detects a problem with the battery (e.g., battery voltage too high or too low, battery open circuit), the red light for this pocket comes on and a telephone symbol appears on the display panel (Figure 20).

![Figure 20 Advisory message (in Graphics mode) for battery/pocket #1. Note red light.](image)

Before assuming the battery is defective, make sure dirt or debris is not blocking the connection between the battery and charging pocket contacts:

1. Remove the battery. Examine the battery’s metal contact and the contact inside the charging pocket. If there is no dirt, debris, or obstruction, continue with Step 2.

2. Reinsert the battery into the same pocket.

3. If, again, the red light comes on, insert the battery into a different pocket.

4. If the red light comes on in the second pocket, the battery is defective. Do not use it.

5. Obtain the alarm code for this battery, if possible:

   a. Press and hold number button for this pocket to display the alarm code on the screen. **Note:** The battery alarm code will be
one letter followed by four numbers. Alarm codes related to batteries begin with the letter “B.”

b Record the alarm code for this battery (e.g., write it on a piece of paper), check its accuracy, and save the code for future reference, if needed.

6 Call your VAD Coordinator or hospital contact person for help or for a replacement battery, if needed. Note: The VAD Coordinator or hospital contact person may ask for the alarm code.

7 Remove the defective battery from use.

**CAUTION!** Dispose of (or recycle) expired, used, or damaged batteries according to local, state, and federal regulations. Do NOT incinerate.
5.2 Charger-Related Advisory Messages

The Universal Battery Charger (UBC) can detect a problem or “fault” condition with up to four charging pockets at once (with or without batteries inside), or with the entire charger unit. The UBC will alert you immediately of any problems.

Detecting Pocket Faults

If the UBC detects a pocket fault, the red light for the affected pocket(s) (with or without battery(ies) inside) will come on. In addition, the UBC will immediately stop charging or calibrating the battery(ies) inside the affected pocket(s) (if present). If a pocket fault occurs:

1. Remove the battery(ies) (if any) from the affected pocket(s).
2. Record the alarm code for the defective pocket, if possible:
   a. Press and hold the number button for this pocket to display the alarm code on the screen. **Note:** The pocket alarm code will be one letter followed by four numbers. Alarm codes related to pocket problems, begin with the letter “S.”
   b. Record the alarm code for this pocket (e.g., write it on a piece of paper), check its accuracy, and save the code for future reference, if needed.
3. Call your VAD Coordinator or hospital contact person for help. **Note:** The VAD Coordinator or hospital contact person may ask for the alarm code.

**Note:** Do not use the pocket until it is repaired or until the UBC is replaced. You can continue to use the other pockets.

Detecting Faults with the Entire Unit

If the UBC detects a fault with the entire charger, all four red lights will come on and all charging and/or calibrating for any inserted batteries will stop. If a fault occurs for the entire unit:

1. Remove all batteries from all pockets.
2. Record the alarm code for the fault condition, if possible:
   a. Press and hold number button for any one of pockets to display the alarm on the screen. **Note:** The pocket alarm code will be one letter followed by four numbers. Alarm codes related to the entire unit, begin with the letter “S.”
   b. Record the alarm code for this fault condition (e.g., write it on a piece of paper), check its accuracy, and save the code for future reference, if needed.
3. Turn off the UBC; unplug it from the electrical outlet.
4. Call your VAD Coordinator or hospital contact person. **Note:** The VAD Coordinator or hospital contact person may ask for the alarm code.
**Note:** Do not use a damaged or defective pocket until it is repaired or until the UBC is replaced. Until you have a safe and reliable way to recharge the batteries, use an alternate power source to power your HeartMate system. For example, use the HeartMate Power Module (PM) or Power Base Unit (PBU) to power the HeartMate XVE or HeartMate II LVAS.

**CAUTION!** Use only the HeartMate Universal Battery Charger (UBC) to charge HeartMate 12 volt NiMH batteries or 14 volt Li-Ion batteries. Other battery chargers may damage HeartMate batteries.
INSPECTION, CLEANING & MAINTENANCE

6.0 Routine Inspection and Cleaning

The HeartMate Universal Battery Charger (UBC) requires little preventive maintenance. However, it should be inspected routinely for the safest and best possible performance:

- **Once a week**, inspect the UBC for signs of physical damage, such as dents, chips, or cracks. Do NOT use the charger if it shows signs of damage. Obtain a replacement from your VAD Coordinator or hospital contact person.

- **Once a week**, inspect the power cord used to connect the UBC to an electrical outlet. Make sure the cord is not kinked, split, cut, cracked, or frayed. Do not use the cord if it shows signs of damage. Obtain a replacement from your VAD Coordinator or hospital contact person.

- **Once a month**, UNPLUG the UBC and then clean the metal contacts inside all four charging pockets with a lint-free cloth or swab that has been moistened (not dripping) with rubbing alcohol. **Note**: Allow the alcohol to dry before inserting batteries into pockets. When re-powering the UBC, make sure that the self-test is completed as described in Section 2.1, Step 7.

- **Periodically and as needed**, UNPLUG the charger and clean the exterior surfaces using a clean, damp (not wet) cloth. You may use a mild, non-abrasive cleaner if necessary. Do NOT immerse the UBC in water or liquid.

- **At least once a year**, bring the HeartMate UBC to an authorized service technician for a thorough safety inspection and cleaning that includes (but need not be limited to) the following:
  - Functional test of device
  - Cleaning and inspection of all internal components

**Note**: Your VAD Coordinator or hospital contact person can coordinate annual UBC inspection/maintenance for you.

---

**CAUTION!** Service and maintenance of the HeartMate Universal Battery Charger should be performed only by service personnel who are trained and authorized by Thoratec Corporation.
7.0 Product Disposal

Dispose of (or recycle) used or damaged UBCs in compliance with all applicable local, state, and federal laws and regulations. Talk with your VAD Coordinator or hospital contact person for guidance, if needed.

8.0 Testing and Classification

The HeartMate UBC complies with the following safety standards:

- CAN/CSA C22.2 No.601.1-M90 (R1997), CAN/CSA C22.2 No.601.1S1-94, and CAN/CSA C22.2 No.601.1B-98 (National Difference for Canada)

The HeartMate UBC has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2004. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The UBC is an unintentional radiator of radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If the HeartMate UBC does cause harmful interference to other devices, 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:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult Thoratec Technical Service for assistance.
# Declaration Concerning General Safety Standards

<table>
<thead>
<tr>
<th>Type</th>
<th>Degree of Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode of Operation</td>
<td>Continuous</td>
</tr>
<tr>
<td>Type of protection against electrical</td>
<td>Class I (grounded)</td>
</tr>
<tr>
<td>shock</td>
<td></td>
</tr>
<tr>
<td>Degree of protection against electric</td>
<td>No Applied Part</td>
</tr>
<tr>
<td>shock</td>
<td></td>
</tr>
<tr>
<td>Degree of safety of application in the</td>
<td>Equipment not suitable for use in the presence of a flammable anesthetic mixture with</td>
</tr>
<tr>
<td>presence of a flammable anesthetic mixture</td>
<td>oxygen or nitrous oxide.</td>
</tr>
<tr>
<td>with air or with oxygen or nitrous oxide.</td>
<td></td>
</tr>
<tr>
<td>Degree of protection against harmful</td>
<td>IPX0</td>
</tr>
<tr>
<td>ingress of water</td>
<td></td>
</tr>
</tbody>
</table>

Medical Electric Equipment with respect to shock, fire, mechanical and other specified hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No.601.1-M90 (R1997), CAN/CSA C22.2 No.601.1S1-94, and CAN/CSA C22.2 No.601.1B-98 (National Difference for Canada)

For more information on Compliance and EMC testing, please refer to the following LVAS System Manuals:

- *HeartMate II LVAS Operating Manual* (document #103884)
- *HeartMate XVE LVAS Operating Manual* (document #103887)

Manuals for HeartMate power accessories include:

- *HeartMate 12 Volt NiMH Battery Instructions for Use (IFU)* (document # 103769)
- *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770)
- *HeartMate Universal Battery Charger IFU* (document # 103771)
- *HeartMate Power Module IFU* (document # 103772)
APPENDIX 1
TECHNICAL SPECIFICATIONS

HeartMate Universal Battery Charger (UBC)        Catalog #1440
(North America)

**ACTIVE FUNCTIONS**
Four pocket simultaneous battery charging for HeartMate 12 volt NiMH batteries (part no. 102474) and 14 volt Li-Ion batteries (part no. 102515).

Battery Chemistry: 12 volt batteries are nickel metal hydride (NiMH) ; 14 volt batteries are lithium ion (Li-Ion).

Battery calibration and diagnostics.

**MONITORING FUNCTIONS**
Battery fault monitoring (with alarm codes)
Battery charger fault monitoring (with alarm codes)

**POWER REQUIREMENTS**
100-240 VAC, 50-60 Hz, 3A (maximum)
Fuse Rating - T5A, 250 V

**DIMENSIONS**
- Length: 370mm (14.5“)
- Width: 216mm (8.5“)
- Height: 227mm (9“)

**WEIGHT**
3.6 Kg (8 lbs)

**OPERATING ENVIRONMENT**

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Acceptable Temperature Range</th>
<th>Relative Humidity</th>
<th>Air Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Universal Battery Charger</td>
<td>0°C to 40°C (32°F to 104°F)</td>
<td>30 to 75%</td>
<td>525 to 795 mmHg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>700 to 1060 hPA (20.7 to 31.3 inHg)</td>
</tr>
</tbody>
</table>
## STORAGE AND TRANSPORT ENVIRONMENT

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Acceptable Temperature Range</th>
<th>Relative Humidity</th>
<th>Air Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Universal Battery Charger</td>
<td>-20°C to 60°C (-4°F to 140°F)</td>
<td>10 to 93%</td>
<td>375 to 795 mmHg 500 to 1060 hPA (14.8 to 31.3 inHg)</td>
</tr>
</tbody>
</table>

# APPENDIX 2
Description of English Text and Graphic Symbols Appearing on the HeartMate UBC Display Panel

<table>
<thead>
<tr>
<th>Meaning</th>
<th>English Mode (on-screen message)</th>
<th>Graphics Mode (on-screen message)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ready</td>
<td>HeartMate CHARGER</td>
<td>HeartMate CHARGER</td>
</tr>
<tr>
<td>Battery Charge Status</td>
<td></td>
<td><img src="image" alt="Battery Charge Status" /></td>
</tr>
<tr>
<td>Battery Information (3rd screen)</td>
<td></td>
<td><img src="image" alt="Battery Information" /></td>
</tr>
<tr>
<td>Charge Complete</td>
<td>READY</td>
<td><img src="image" alt="Charge Complete" /></td>
</tr>
<tr>
<td>Request Calibration</td>
<td>CALIBRATE? PRESS X</td>
<td><img src="image" alt="Request Calibration" /></td>
</tr>
<tr>
<td>Accept Calibration</td>
<td>PROGRESS X: CALIBRATING</td>
<td><img src="image" alt="Accept Calibration" /></td>
</tr>
<tr>
<td>Change Graphics Mode to English</td>
<td>OK ENGLISH ▼</td>
<td><img src="image" alt="Change Graphics Mode to English" /></td>
</tr>
<tr>
<td>Change Graphics Mode to Symbols</td>
<td>OK GRAPHICS ▼</td>
<td><img src="image" alt="Change Graphics Mode to Symbols" /></td>
</tr>
<tr>
<td>Battery Fault</td>
<td>CALL SERVICE</td>
<td><img src="image" alt="Battery Fault" /></td>
</tr>
<tr>
<td>Charger Fault</td>
<td>CALL SERVICE</td>
<td><img src="image" alt="Charger Fault" /></td>
</tr>
<tr>
<td>Battery Fault (Button Push)</td>
<td>CALL SERVICE BXXXX</td>
<td>![Battery Fault (Button Push)]</td>
</tr>
<tr>
<td>Charger or Pocket Fault (Button Push)</td>
<td>CALL SERVICE SXXXX</td>
<td>![Charger or Pocket Fault (Button Push)]</td>
</tr>
</tbody>
</table>
APPENDIX 3

Graphic Symbols Found on HeartMate UBC

Labels and Labeling

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Manufacturer Icon]</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>![SN Icon]</td>
<td>Serial Number</td>
</tr>
<tr>
<td>![REF Icon]</td>
<td>Catalog Number</td>
</tr>
<tr>
<td>![Warning Icon]</td>
<td>Attention, consult accompanying documents before use</td>
</tr>
<tr>
<td>![Rx Only Icon]</td>
<td>Caution: US federal law restricts this device to sale by or on the order of a physician.</td>
</tr>
<tr>
<td>![Operating Conditions Icon]</td>
<td>Operating Environment (temperature)</td>
</tr>
</tbody>
</table>

Operating Conditions:
- 40°C (104°F)