

# HeartMate<sup>®</sup> 14 Volt Li-Ion Battery

## INSTRUCTIONS FOR USE

*For use Exclusively with the HeartMate II<sup>®</sup> LVAS*



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# Warnings and Precautions

## 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 14 Volt Li-Ion Battery Instructions for Use (IFU)* and the corresponding *HeartMate II LVAS Instructions for Use, Operating Manual*, and /or *Patient Handbook* before attempting use.
- Before using any HeartMate power accessories (Power Module, batteries, and 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 for North American and EU users)
  - *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770 for North American and EU users)
  - *HeartMate Universal Battery Charger IFU* (document # 103771 for North American users; document # 103841 for EU users)
  - *HeartMate Power Module IFU* (document # 103772 for North American users; document # 103840 for EU users)
- 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 cycle, then remove the battery and check its charge level with the battery fuel gauge. See Section 2.0, *Checking a Battery's Charge Level*.

- ALWAYS connect to AC mains electrical power for sleeping or when there is a chance of sleep. A sleeping patient may not hear System Controller alarms.
- Do NOT touch television (TV) or computer screens. These screens have strong static electricity. A strong electric shock can damage the electrical parts of the system and make the pump stop.
- Avoid activities that may create static electricity, like vacuuming. A strong electric shock can damage the electrical parts of the pump and make the pump stop.
- Do not use damaged, defective, or expired batteries. Using damaged, defective or expired batteries may cut operating time or cause the pump to stop.
- HeartMate 14 volt lithium ion (Li-Ion) batteries are for use exclusively with the HeartMate II LVAS. They are NOT compatible with the HeartMate XVE system and cannot power the HeartMate XVE LVAS. However, HeartMate 12 volt nickel metal hydride (NiMH) batteries are capable of powering both the HeartMate II and the HeartMate XVE LVAS (see the *HeartMate 12 Volt NiMH Battery IFU*). 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.** See **Appendix 1** for 14 volt Li-Ion battery characteristics.
- Use batteries in matching pairs (e.g., two 12 volt or two 14 volt batteries).
- Do NOT charge HeartMate 14 volt Li-Ion batteries in the HeartMate Power Base Unit (PBU).

## Precautions

- HeartMate 14 volt Li-Ion batteries must be **charged at least once by the end of the month marked on the label placed on battery packaging (box and protective bag)**. If a battery is not

charged by this date, battery operating time may be affected, which can cause the pump to stop. Do not use a battery if it has not been charged by the date indicated. Discard it according to local, state, and federal laws; and, contact your VAD Coordinator or hospital contact person for a replacement, if needed.

- Use only the Thoratec-supplied Universal Battery Charger (UBC) to charge HeartMate batteries. Other battery chargers may damage HeartMate batteries. See the *HeartMate Universal Battery Charger IFU*.
- Use only Thoratec-supplied 14 volt battery clips with HeartMate 14 volt Li-Ion batteries. Other clips will not transfer electrical power to the system.
- As batteries get older, they will power the system for shorter periods of time. If a pair of batteries does not give at least four hours of support, remove both batteries from service.
- Make sure the Universal Battery Charger (UBC) is plugged in and turned on (“I”) before placing batteries into the pockets for charging.
- Before inserting a battery into the Universal Battery Charger (UBC) for charging/recharging, inspect the battery for signs of damage. Do not use a battery that seems damaged.
- After approximately 70 uses, HeartMate batteries may need to be recalibrated. The Universal Battery Charger (UBC) will indicate when a battery needs to be recalibrated (see the *HeartMate Universal Battery Charger IFU*). 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 prompted to prevent a backlog of uncalibrated batteries (see Section 4.0, *Calibrating HeartMate Batteries*).
- Leave a calibrating battery in the Universal Battery Charger (UBC) for the entire 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 3.0, *Checking Battery Charge Level*.

- Dirty battery contacts may prevent proper battery charging, which can affect battery operation. The metal contacts on the batteries and inside the battery clip should be cleaned at least once a month. Use a lint-free cloth or cotton swab that has been moistened (not dripping) with rubbing alcohol. Let the alcohol dry before using the batteries or battery clips, or before placing batteries into the Universal Battery Charger (UBC).
- If stored and used within recommended guidelines, HeartMate 14 volt Li-Ion batteries should be usable for approximately 360 use/charge cycles *or* for 36 months from the date of manufacture, whichever comes first. After 360 cycles/36 months, battery performance cannot be guaranteed and batteries should be replaced. See **Appendix 1** for storage/usage guidelines.
- Do not dismantle, open, or shred batteries.
- Do not expose batteries to heat or fire.
- Do not store batteries in direct sunlight. Store batteries within approved temperatures (-10°C to 40°C; 14°F to 104°F for short term storage) (see **Appendix 1** for complete storage guidelines, including storage greater than 30 days).
- To prevent deterioration or damage to batteries:
  - Do NOT drop batteries or hit them against hard objects or each other.
  - Do NOT use batteries in temperatures that are below 32°F (0°C) or above 104°F (+40°C), or the batteries may fail suddenly.
  - Do NOT leave or store batteries in extremely hot or cold temperatures (e.g., in cars or car trunks), or battery life will be shortened.
  - Do NOT directly connect battery contacts to each other.

- Do not store batteries together with keys, coins, or other loose metallic objects. Metal objects touching the exposed battery contacts may cause an accidental short or connection. This can result in battery overheating that may burn you or damage the batteries.
- Avoid touching metal battery contacts with two separate hands, which will increase the chance that battery energy could pass through your body.
- If a battery leaks, do NOT touch the leaking fluid. If the fluid touches your skin or eyes, wash the affected area with plenty of clean, running water and seek medical advice. Never use a battery that is damaged or leaking.
- Keep batteries out of the reach of children.
- Keep batteries clean and dry.
- Dispose of or recycle expired batteries in accordance with local, state and federal laws.

# BEFORE USING YOUR BATTERIES

## **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 HeartMate14 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. See Appendix I for 14 volt Li-Ion battery characteristics.
- Use only Thoratec-supplied 14 volt battery clips to connect with HeartMate 14 volt Li-Ion batteries. Other battery clips will not transfer electrical power to the HeartMate XVE LVAS.



# 1.0 Understanding How They Work

The HeartMate II system uses either electricity or batteries for power. During battery-powered operation, the LVAS is powered by a pair of direct current (DC) batteries that are inserted into battery clips (Figure 1). The batteries and attached clips can be worn in holsters, one under each arm (Figure 2), or in a carrying case worn at the waist.

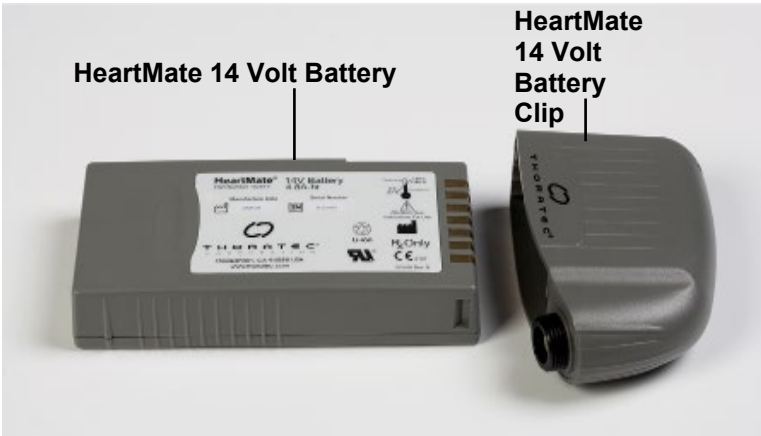
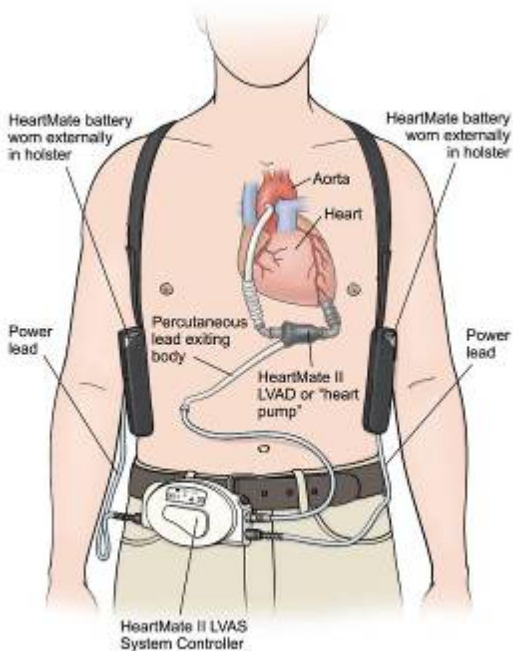


Figure 1 HeartMate 14 volt battery and battery clip



**Figure 2** HeartMate II LVAS using battery power for mobile operation

Using batteries to power the system is called mobile operation, since you are not connected to electricity. Use battery power when you want to be mobile and active. For example, while shopping, running errands, or enjoying activities outside or away from home.

Two types of HeartMate batteries can power the HeartMate II LVAS. Either one pair of:

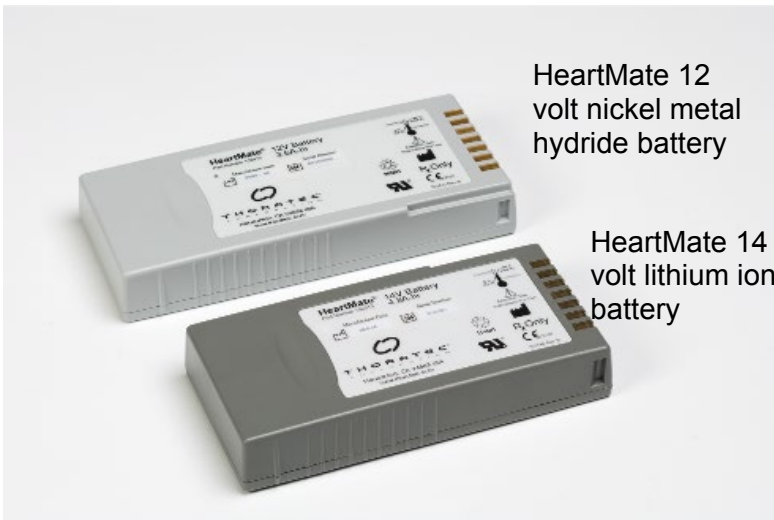
- HeartMate 14 volt lithium ion (Li-Ion) batteries; or
- HeartMate 12 volt nickel metal hydride (NiMH) batteries.

Both 14 volt Li-Ion batteries and 12 volt NiMH batteries work in the same way. However, there are differences in color, size, and weight. Major differences are described below (**Table 1**) (**Figure 3**).

	<b>Catalog Number for Set of 4</b>	<b>Part Number for Single Battery</b>	<b>Size/ Weight</b>	<b>Color</b>
<b>HeartMate 12 Volt NiMH Batteries</b>	2060	102474	L: 180mm (7.1") W: 76mm (3.0") H: 25mm (1.0")  0.65kg (1.44lb)	Light Grey*
<b>HeartMate 14 Volt Li-Ion Batteries</b>	2465	102515	L: 160mm (6.3") W: 76mm (3.0") H: 25mm (1.0")  0.50kg (1.1lb)	Dark Grey*

**Table 1**

\* Batteries and corresponding clips are the same color.



**Figure 3** Different HeartMate batteries

HeartMate batteries only work with matching clips (12 volt NiMH batteries use 12 volt clips and 14 volt Li-Ion batteries use 14 volt clips). HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries and battery clips are NOT interchangeable.

This manual covers 14 volt Li-Ion battery operation. See the *HeartMate 12 Volt NiMH Battery IFU* (document # 103769 for North American and EU users) for detailed warnings, precautions, and instructions on using 12 volt NiMH batteries.

## 2.0 Charging a New 14 Volt Li-Ion Battery

You must charge each HeartMate 14 volt Li-Ion battery (**Figure 4**) before use (this includes the first use). It takes approximately four hours or less to charge a depleted battery. Batteries are charged in the HeartMate Universal Battery Charger (UBC), which can charge up to four batteries at once. **Note:** Depending on how long a battery has been in storage, the on-battery fuel gauge may not work until after the battery goes through its first charge cycle (see Section 3.0, *Checking Battery Charge Level*).

See the *HeartMate Universal Battery Charger IFU*, the *HeartMate II LVAS IFU, Operating Manual*, and/or *Patient Handbook* for instructions on charging HeartMate 14 volt Li-Ion batteries.

### **CAUTION!**

- HeartMate 14 volt lithium ion (Li-Ion) batteries must be **charged at least once by the end of the month marked on the label placed on battery packaging (box and protective bag)**. If a battery is not charged by this date, battery operating time may be affected, which can cause the pump to stop. Do not use a battery if it has not been charged by the date indicated. Discard it according to local, state, and federal laws; and, contact your VAD Coordinator or hospital contact person for a replacement, if needed.
- Before inserting a battery into the Universal Battery Charger (UBC) for charging/recharging, inspect the battery for signs of damage. Do not use batteries that seem damaged.



**Figure 4** HeartMate 14 volt Li-Ion battery


### **WARNING!**

- HeartMate 14 volt lithium ion (Li-Ion) batteries are for use exclusively with the HeartMate II LVAS. They are NOT compatible with the HeartMate XVE system and cannot power the HeartMate XVE LVAS. Do NOT use HeartMate 14 volt Li-Ion batteries with the HeartMate XVE system.
- Ensure you are using the correct batteries before relying on them for power. Using the wrong batteries for an incompatible system will cause the pump to stop.

## 3.0 Checking Battery Charge Level

Once properly charged (see instructions in the *HeartMate Universal Battery Charger IFU*), a new HeartMate 14 volt Li-Ion battery should be ready for use. But, before using any battery, first make sure that it has finished charging and check its status with the battery fuel gauge. Follow these steps for using the Universal Battery Charger (UBC) and battery fuel gauge to check a battery's charge status:

- 1 Go to the Universal Battery Charger (UBC); locate a battery inside one of the charging pockets.

- 2 Look at the three lights next to the charging pocket for this battery. A green light means the battery is charged and ready for use. **Note:** A green light next to the pocket is the only assurance the battery is 100% charged. If the yellow light is on, the battery is still charging. If the red light is on, there is problem with the battery – do not use it. See Section 3.0, “Charging Batteries,” in the *HeartMate Universal Battery Charger IFU* for full details.
- 3 If the pocket light is green, remove the battery from the charging pocket.
- 4 Find the battery symbol  on the battery’s fuel gauge (**Figure 5**).
- 5 Press and hold the battery symbol for five second (**Figure 5**).
- 6 If all five of the green fuel gauge lights come on, the battery is between 80 - 100% charged (**Table 2**).

OR

- 6 If four or fewer lights come on, the battery is not yet ready for use. Return it to the pocket for more charging. **Note:** If the fuel gauge continues to show four or fewer lights after additional charging, the battery may be defective. Do not use it. Contact your VAD Coordinator or hospital contact person for information.









**Figure 5** Battery fuel gauge (note battery symbol)



## Understanding Battery Fuel Gauge Displays

The battery fuel gauge on a HeartMate 14 volt Li-Ion battery (**Figure 5**) uses five green lights to show battery power. Each light represents roughly 20% of available power. All five lights come on when the battery is between 80 – 100% charged. Fewer lights come on as power is depleted. When battery power drops below 10%, one blinking light comes on.

Number of Lights Illuminated	Meaning
 5 Lights	Approximately 80 – 100% of power remains
 4 Lights	Approximately 60 – 80% of power remains
 3 Lights	Approximately 40 – 60% of power remains
 2 Lights	Approximately 20 – 40% of power remains
 1 Light (steady)	Approximately 10 - 20% of power remains
 1 Light (blinking)	Approximately 10% or less of power remains. Do NOT use if battery has one blinking light. HeartMate II System Controller will indicate a Low Battery Advisory.

**Table 2** Battery Fuel Gauge Lights

If all of the lights come on, except for one in the middle of the sequence, it may be that the light emitting diode (LED) for this light has broken or burned out. If this happens, call your VAD Coordinator or hospital contact person.

# USING YOUR BATTERIES

## 4.0 Using 14 Volt Li-Ion Batteries to Power the HeartMate II LVAS

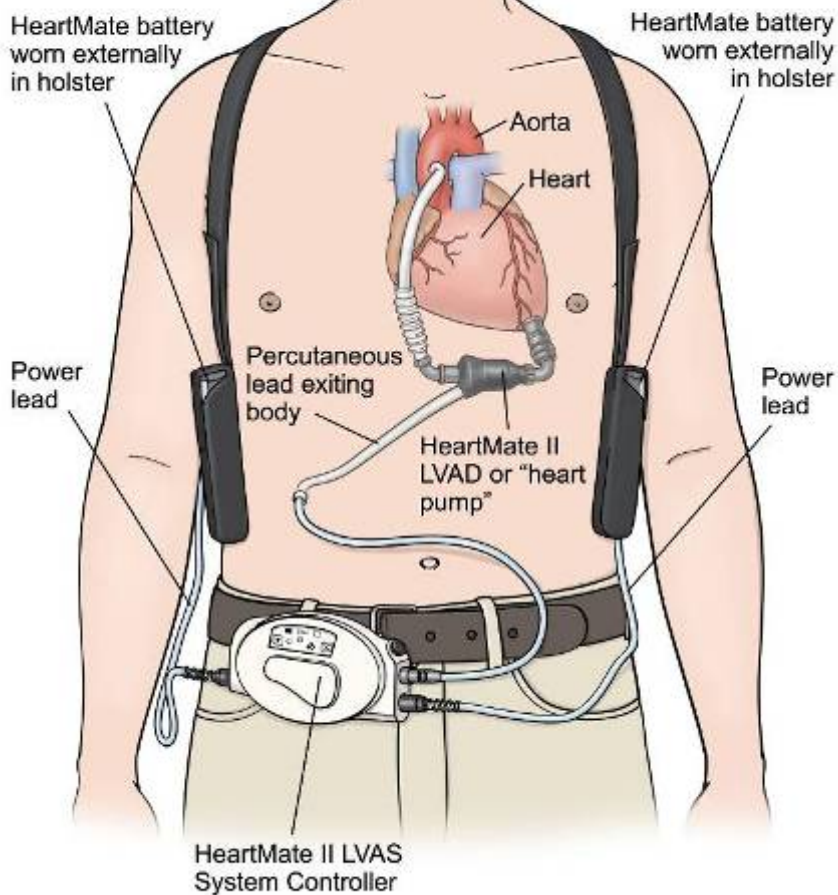
### 4.1. Battery Power (Overview)

The HeartMate II LVAS can be powered either by AC mains electricity (via the Power Module or Power Base Unit), or by battery power, with a pair of rechargeable HeartMate 12 volt NiMH batteries or 14 volt Li-Ion batteries.

Using batteries to power the system is called mobile operation, since you are not connected to AC power. When not connected to the PM, power is provided to the LVAD by two HeartMate direct current (DC) 14 volt Li-Ion batteries. The batteries are inserted into compatible battery clips (**Figure 6**). The battery clips and batteries can be worn in holsters, one under each arm (**Figure 7**), or in a carrying case worn around the patient's waist. See the *HeartMate II LVAS IFU*, *Operating Manual*, and/or *Patient Handbook* for detailed instructions on operating the HeartMate II LVAS.



**Figure 6** Inserting HeartMate 14 volt Li-Ion battery into 14 volt battery clip



**Figure 7** HeartMate batteries inside battery clips and worn in holsters while powering the HeartMate II LVAS

One pair of new HeartMate 14 volt Li-Ion batteries will provide six to ten hours of support under nominal operating conditions for a HeartMate II LVAS (pump speed = 12,000 rpm, flow 6.0 lpm, power 10 watts).

Battery run time could be lower or higher depending upon activity level. Batteries will last for less time if you are more active or emotionally stressed. As batteries get older, they will power the system for shorter periods of time. If a pair of batteries does not give at least four hours of support, remove both from service and tell your VAD Coordinator or hospital contact person. See Section 6.0, *Monitoring Battery Life*, for information on HeartMate 14 volt Li-Ion battery lifespan.

Batteries are used in pairs. However, it is possible to run the system with one battery for a very short period (60 seconds or less). For example, while switching from batteries to Power Module- or PBU-powered operation, or vice versa.

### **WARNING!**

- At least one System Controller power lead must be connected to a power source (batteries, Power Module/PBU, or Emergency Power Pack) at all times. If both System Controller power leads are disconnected at the same time, the pump will stop.
- It is essential that neither System Controller power lead (used to connect the System Controller to a power source) is ever disconnected from power for more than 60 seconds. If disconnected for more than 60 seconds, the risk of pump stoppage increases.

During battery-powered operation, the System Controller shows overall power capacity (for both batteries) on the System Controller's battery fuel gauge. The System Controller's battery fuel gauge will tell you if batteries are running low. If needed, the System Controller will prompt you to replace the batteries or to switch to a different power source (Power Module/PBU or Emergency Power Pack). See the *HeartMate II LVAS IFU, Operating Manual*, and/or *Patient Handbook* for instructions on handling System Controller alerts and alarms.

The charge level of an individual battery can be checked any time by pressing the battery fuel gauge on that battery (see Section 3.0, *Checking Battery Charge Level*). **Note:** An individual battery fuel gauge may show a slightly different charge level than the System Controller's fuel gauge for overall power. Use the System Controller's battery fuel gauge for the most accurate guide to battery power and alarms.

#### **WARNING!**

- HeartMate 14 volt lithium ion (Li-Ion) batteries are for use exclusively with the HeartMate II LVAS. They are NOT compatible with the HeartMate XVE system and cannot power the HeartMate XVE LVAS. Do NOT use HeartMate 14 volt Li-Ion batteries with the HeartMate XVE system. See **Appendix 1** for 14 volt Li-Ion battery characteristics.
- 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.



## 4.2. Replacing Depleted Batteries with Charged Batteries (Procedure)

Replacing used, depleted batteries with a charged pair is a routine procedure. With experience the steps become familiar.

### **WARNING!**

- At least one (1) System Controller power lead must be connected to a power source (batteries, Power Module/PBU, or Emergency Power Pack) at all times. If both System Controller power leads are disconnected at the same time, the pump will stop.
- It is essential that neither System Controller power lead (used to connect the System Controller to a power source) is ever disconnected from power for more than 60 seconds. If disconnected for more than 60 seconds, the risk of pump stoppage increases.
- Never disconnect both batteries at the same time or the pump will stop.
- HeartMate 14 volt lithium ion (Li-Ion) batteries are for use exclusively with the HeartMate II LVAS. They are NOT compatible with the HeartMate XVE system and cannot power the HeartMate XVE LVAS. Do NOT use HeartMate 14 volt Li-Ion batteries with the HeartMate XVE system. See **Appendix 1** for 14 volt Li-Ion battery characteristics.
- 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.

Follow these steps for exchanging HeartMate batteries:

- 1** Obtain two charged HeartMate batteries and place them within easy reach. **Note:** If getting batteries from the Universal Battery Charger (UBC), make sure the light near the charging pockets for each battery is green (i.e., battery ready for use) (see Section 3.0, *Checking Battery Charge Level*).
- 2** Press and hold the battery symbol  on each of the new batteries; make sure they are charged and ready for use (see Section 3.0 *Checking Battery Charge Level*).
- 3** Grasp the battery clip (and attached battery) for one of the two batteries currently powering the system. Remove the clip and attached battery from the holster/carrying case and place it within each reach. **Note:** Do NOT remove the battery from its clip at this time.
- 4** Locate the battery fuel gauge symbol  on one of the batteries that is currently in use (**Figure 8**).



**Figure 8** Battery symbol (close up)

- 5** Press and hold the battery symbol on the 1<sup>st</sup> battery for five seconds to see how much battery power remains for this battery (i.e., count the number of lights that come one).



- 6** Repeat Steps 3 – 5 for the 2<sup>nd</sup> battery currently in use.
- 7** Determine which of the two batteries has the least power (i.e., fewest lights).
- 8** If both batteries have the same amount of power, switch either battery; otherwise, exchange the battery with the FEWEST number of lit lights first:
  - a** Press the battery release button on the battery clip.
  - b** Withdraw the battery from its clip. *The System Controller will sound a once-per-second BEEP and the green power symbol and fuel gauge lights will flash.*
- 9** Pick up one of the charged batteries; locate the orange arrow on the battery. **Note:** Make sure to pick up a charged battery and not one of the old, depleted batteries.
- 10** Line up the orange arrow on the new battery with the orange arrow on the empty battery clip, so that the two arrows are facing each other (**Figure 9**).



**Figure 9** Inserting battery into clip

- 11** Slide one of the new, charged batteries into the empty battery clip. The battery should “click” into place. However, after inserting it, gently pull on the battery and try to remove it from the clip. If properly and fully inserted, the battery will remain inside. In addition, the once-per-second beep and flashing symbols will stop if the battery is properly inserted.  
**Note:** It may take a few seconds for the alarm to stop.
- 12** Repeat steps 9 – 11 to exchange the 2<sup>nd</sup> battery.
- 13** Return the clips (now containing the charged batteries) to holsters or carrying case.
- 14** Make sure the charger is plugged in and turned on (“I”) *before* placing batteries into pockets for charging.

- 15** Place the depleted batteries into the Universal Battery Charger (UBC) for recharging. See the *HeartMate Universal Battery Charger IFU*.

**CAUTION!** Make sure the Universal Battery Charger is plugged in and turned on (“I”) before placing batteries into the pockets for charging.

# CARE & MAINTENANCE

## 5.0 Calibrating HeartMate Batteries

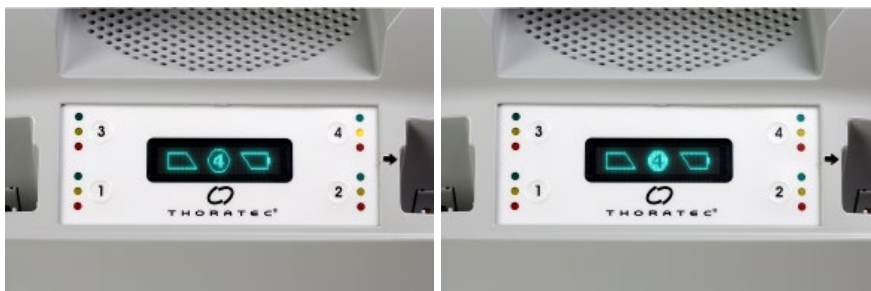
HeartMate 14 volt Li-Ion batteries use a “smart” technology that measures available battery power and counts battery usage/charge cycles. Roughly every 70 battery uses, the battery may sense that it needs to calibrate its fuel gauge. This process completely drains the battery of all electrical energy and then recharges it. The battery must be placed into the Universal Battery Charger (UBC) for calibration. Battery calibration can take up to 12 hours, and the charger will calibrate only one battery at a time. However, during calibration, the other three batteries can be charged as usual.

**CAUTION!** Leave a calibrating battery in the Universal Battery Charger for the entire 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).

If a battery needs to be calibrated, a prompt will appear on the UBC’s display screen (**Figure 10**). You have a choice of calibrating when prompted or waiting for a more convenient time. If calibration is not selected within ten seconds of the prompt, the charger continues with a normal charge cycle for this battery. The next time that battery is inserted into the charger, you will again be prompted to calibrate it. To calibrate a battery, follow the steps outlined in Section 4.0 of the *HeartMate Universal Battery Charger IFU*.

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. Calibration can take up to

12 hours and only one battery can be calibrated at a time. Be sure to have enough charged batteries on hand when planning for calibration. For example, under normal conditions, having four charged batteries will allow you to exchange batteries twice during the 12-hour calibration cycle



**Figure 10** Display panel screen with calibration prompt for battery pocket #4 (using Graphics display mode).The circled number will alternate between an unfilled and filled circle as the display panel flashes.

## 6.0 Monitoring Battery Life

A number of factors influence battery life for a HeartMate 14 volt Li-Ion battery. The two most important are the number of uses and the number of months since the battery was manufactured. The month and year of manufacture appears on every HeartMate battery label.

**Note:** See Section 3.3 of the *HeartMate Universal Battery Charger IFU* for instructions on viewing the number of use/charge cycles for a battery.

If a battery is stored and used according to the recommended guidelines (see **Appendix 1**), it should be useable for approximately 360 cycles **or** 36 months from the date of manufacture, whichever comes first. After this time, battery performance cannot be guaranteed. Contact your VAD Coordinator or hospital contact person when either of these milestones is reached for a HeartMate 14 volt Li-Ion battery.

## 7.0 Inspecting and Cleaning HeartMate 14 Volt

### Li-Ion Batteries and Battery Clips

HeartMate 14 volt lithium ion (Li-Ion) batteries need periodic inspection and cleaning for the best possible performance. Follow these steps for inspecting and cleaning batteries:

- **Once a week**, inspect batteries for physical damage. Do NOT use batteries that seem damaged. Damaged batteries must be replaced.
- **Once a month**, check the manufacture date on the label on all batteries to see if any batteries are older than three years. If it has been three years or more since a battery was manufactured, that battery has expired. Do NOT use expired batteries. Expired batteries must be replaced.
- **Once a month**, check the number of use/charge cycles for each battery to see if the batteries have exceeded 360 cycles. Do NOT use batteries that have exceeded 360 cycles. Batteries that have exceeded 360 cycles must be replaced. **Note:** Insert a battery into the Universal Battery Charger (UBC) to read the number of cycles. This information will be displayed on the charger's display panel screen (see Section 3.3 of the *HeartMate Universal Battery Charger IFU, Viewing Battery Information on the UBC Screen*).
- **Periodically and as needed**, clean the outside surfaces of batteries (EXCEPT the contacts) using a clean, dry cloth. Do NOT use liquids (e.g., water or liquid cleaning solvent) to clean batteries. Do NOT immerse batteries in water or liquid.

- **Once a month**, clean the metal battery contacts and the contacts inside the battery clips. Use a lint free cloth or cotton swab that has been moistened (not dripping) with rubbing alcohol (**Figure 11**). Do NOT clean batteries while using them to power the system. **Note:** Allow the alcohol to dry before using batteries or clips, or before placing batteries into the Universal Battery Charger (UBC).



**Figure 11** Cleaning metal battery contacts and contacts inside of battery clip

## 8.0 Extended Storage of HeartMate 14 Volt Li-Ion Batteries

HeartMate 14 volt Li-Ion batteries must be **charged at least once by the end of the month marked on the label placed on battery packaging (box and protective bag)**. If a battery is not charged by this date, battery operating time may be affected, which can cause the pump to stop.

Do not use a battery if it has not been charged by the date indicated. Discard it according to local, state, and federal laws; and, contact your VAD Coordinator or hospital contact person for a replacement, if needed.

For the best battery performance, for long term storage (more than 30 days), store 14 volt Li-Ion batteries within a temperature range of 15°C to 25°C (59°F to 77°F). **Note:** See **Appendix 1** for complete storage/usage guidelines.

## 9.0 Disposing of Batteries

HeartMate 14 volt Li-Ion battery cells do NOT contain lead. Dispose of or recycle them in compliance with all applicable local, state, and federal laws and regulations. Never incinerate discarded HeartMate batteries.



# 10.0 Testing and Classification

HeartMate 14 volt lithium ion (Li-Ion) batteries comply with the following safety standards:

- IEC 62133
- UL 2054

HeartMate 14 volt Li-Ion batteries have 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.

Type	Degree of Protection
Degree of protection against electric shock:	No Applied Part
Degree of protection against ingress of water:	IPx0
Degree of safety in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide:	Not suitable
Mode of operation:	Continuous

**Table 3** Declaration Concerning General Safety Standards



For more information on Compliance and EMC testing, please refer to the *HeartMate II LVAS Operating Manual* (#103884).

Manuals for HeartMate power accessories include:

- *HeartMate 12 Volt NiMH Battery Instructions for Use (IFU)* (document # 103769 for North American and EU users)
- *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770 for North American and EU users)
- *HeartMate Universal Battery Charger IFU* (document # 103771 for North American Users; document # 103841 for EU users)
- *HeartMate Power Module IFU* (document # 103772 for North American Users; document # 103840 for EU users)

# APPENDIX 1

## Technical Specifications

**14 Volt Li-Ion  
Batteries**

**Catalog # 2465 (set of 4)  
Part Number (single  
battery) 102515**

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### PERFORMANCE DATA

<b>Type</b>	14 volt, lithium in (Li-Ion) batteries.
<b>Capacity</b>	4.8 amp-hour each.
<b>Discharge Time</b>	One pair of new HeartMate 14 volt batteries will provide six to ten hours of support under nominal operating conditions for a HeartMate II LVAS (pump speed = 12,000 rpm, flow 6.0 lpm, power 10 watts) to the power advisory alarm.
<b>Fuel Gauge</b>	5-LED, button activated
<b>Charge Time</b>	Four (4) hours max. (using HeartMate Universal Battery Charger).
<b>Calibration</b>	Required approximately every 70 use/charge cycles (using the HeartMate Universal Battery Charger).
<b>Cycle Life</b>	360 cycles (as reported when the battery is inserted in to a charging pocket of the HeartMate Universal Battery Charger) or three (3) years from the date of manufacture, whichever comes first.

### DIMENSIONS

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Length	160mm (6.3")
Width	76mm (3.0")
Height	25mm (1.0")

### WEIGHT

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0.50Kg (1.1lb) System accommodates two batteries

### **OPERATING ENVIRONMENT**

<b>Equipment</b>	<b>Acceptable Temperature Range</b>	<b>Relative Humidity</b>	<b>Air Pressure</b>
14 Volt Li-Ion Battery	0°C to 40°C (32°F to 104°F)	30 to 75%	525 to 795 mmHg 700 to 1060 hPA (20.7 to 31.3 inHg)

### **SHORT TERM STORAGE & TRANSPORT ENVIRONMENT**






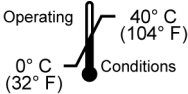


<b>Equipment</b>	<b>Acceptable Temperature Range</b>	<b>Relative Humidity</b>	<b>Air Pressure</b>
14 Volt Li-Ion Battery	-10°C to 40°C (14°F to 104°F)	10 to 93%	375 to 795 mmHg 500 to 1060hPA (14.8 to 31.3 inHg)

### **EXTENDED STORAGE ENVIRONMENT (greater than 30 days)**

<b>Equipment</b>	<b>Acceptable Temperature Range</b>	<b>Relative Humidity</b>	<b>Air Pressure</b>
14 Volt Li-Ion Battery	15°C to 25°C (59°F to 77°F)	30 to 75%	525 to 795 mmHg 700 to 1060 hPA (20.7 to 31.3 inHg)

# APPENDIX 2

## Graphic Symbols Found on HeartMate 14 Volt Li-Ion Battery Labels and Labeling

	Date of manufacture
	Manufacturer
	Batch Code
	Serial Number
<p>Part Number</p>	Part Number
	Attention, consult accompanying documents before use.
<p>R<sub>x</sub> Only</p>	Caution: US federal law restricts this device to sale by or on the order of a licensed physician.
	Operating Environment (temperature).
	Contains Li-Ion, recycle in accordance with local, state and federal laws.
	Charge By date. HeartMate 14 volt Li-Ion batteries must be charged at least once by the end of the month marked on the label affixed to battery packaging (box and protective bag).