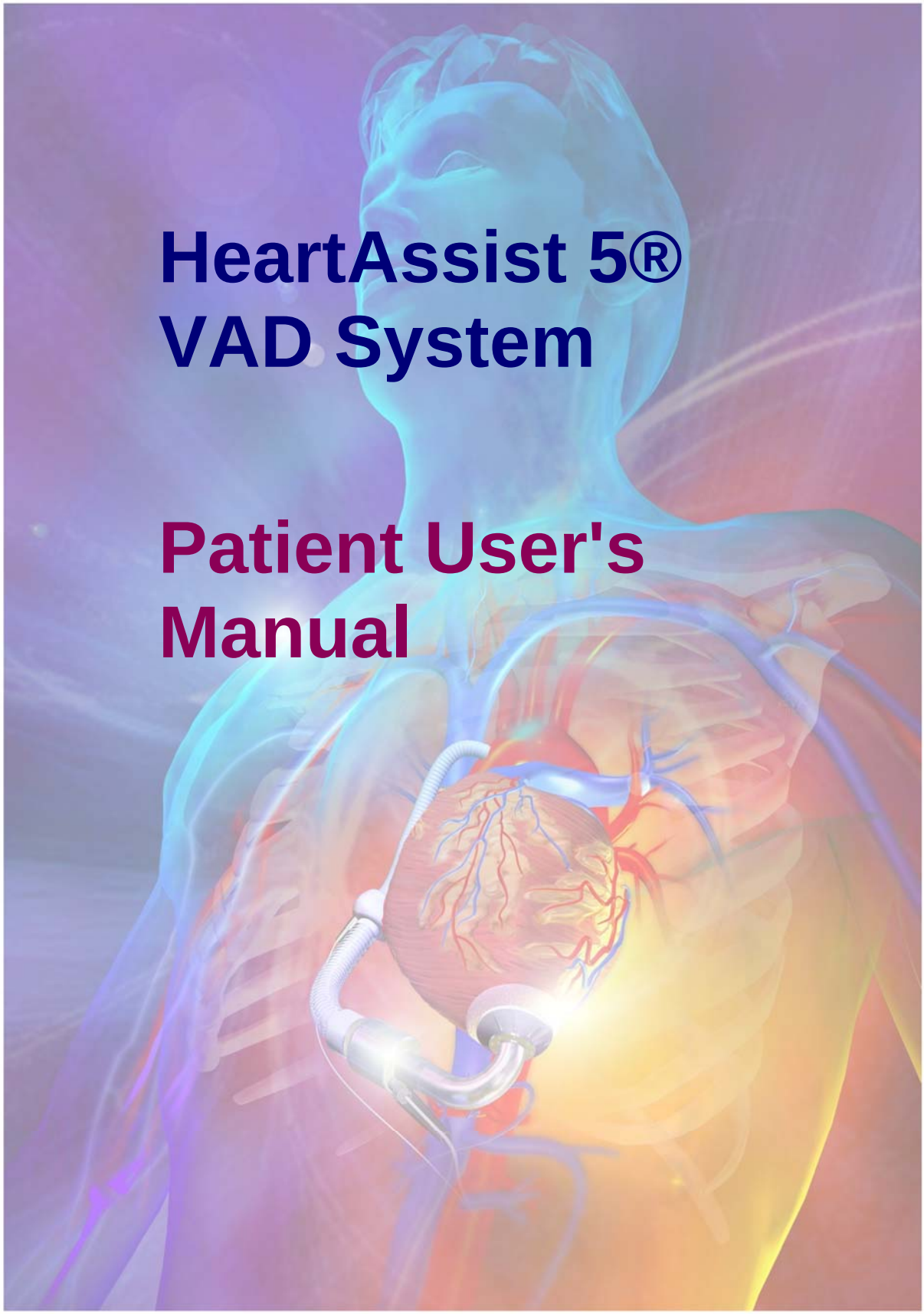
RELIANTHEART



HeartAssist 5®
VAD System

Patient User's Manual

For use with Controller Model: CTL002

L00088-01 Rev R 12/2014

The HeartAssist 5® VAD is a miniaturized ventricular assist technology co-developed with Dr. Michael E. DeBakey, Dr. George P. Noon and the National Aeronautics and Space Administration (NASA).

Federal (USA) law limits the sale and use of HeartAssist 5® VAD to investigational use only.

HeartAssist 5® and HeartAttendant® are registered trademarks of ReliantHeart Inc.

CE **0086** CE marked since November 2013

Customer support

Use the contact information below to reach ReliantHeart.

International

- **ReliantHeart** (Distributor)

  Erfstraat 10A

  5405 BE

  Uden, The Netherlands

  Phone +31 413 245 107

  Fax +31 413 270 504
- **MedPass International Limited (Authorized Representative)**

  Windsor House

  Bretforton

  Evesham

  Worcs, WR117JJ

  United Kingdom
- **Emergency technical and clinical support for medical professionals**

  (24/7 Urgent Support)

  +44 132-386-2836
- **Emergency help for patients**

  Contact your health care provider. (See page 1-2.)
- **Non-emergency technical and clinical support**

  support@reliantheart.com

United States

- **ReliantHeart** (Manufacturer)

  8965 Interchange Drive

  Houston, TX 77054

  Phone: 713-592-0913

  Fax: 713-665-0963
- **Emergency technical and clinical support for medical professionals**

  877-332-2539
- **Emergency help for patients**

  Call 911, or contact your health care provider. (See page 1-2.)
- **Non-emergency technical and clinical support**

  support@reliantheart.com

Contents

Figures

Tables

Warnings

General warnings

The following warnings do not appear elsewhere in this manual.

Warnings indicate possible bodily injury or death.

- **Do not disconnect the HeartAssist 5® VAD (VAD) from the Controller. The VAD will stop. The Controller must be reconnected as quickly as possible to resume VAD function.**
- The Controller's internal capacitors only run the CPU and alarms for approximately three minutes. They do not run the VAD. If both of the batteries are disconnected or depleted, the VAD stops.
- Do not use the Independent Power Supply with ventricular assist devices (VADs) other than the HeartAssist 5® VAD System.
- The Independent Power Supply should not be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- The VAD should not be used adjacent to other equipment or in a stacked configuration with other equipment. The normal operation of the VAD must be verified when used in these configurations.
- Avoid unnecessary pulling or moving of the external portion of the percutaneous lead, especially as the exit site is healing. Pulling on or moving the lead could prolong the healing process or disrupt an already healed exit site. Disruption of the percutaneous lead exit site increases the patient's risk of acquiring a serious infection.
- Avoid prolonged direct contact between the Controller and battery pockets and your skin. The Controller and batteries emit heat that could potentially cause harm if left in direct contact with skin. Limit direct contact with skin to less than one minute.
- Always place the Controller (with battery) in the VADPAK Insert to promote proper cooling of the Controller and to eliminate potential bodily harm.
- Exercise diligent care throughout the course of VAD support to prevent infection and sepsis. Systemic infections and localized infection of the percutaneous lead exit site can occur with use of this device. Infection can contribute to patient morbidity and death.
- Be cautious in the presence of young children as they may not understand the life supporting nature of the system and could damage cables, connectors, or other system components.
- Keep pets and pests away from all HeartAssist 5® VAD System components as they could damage cables, connectors, or other system components.

List of warnings

The following warnings appear sequentially in this manual on the pages indicated.

Cautions

General cautions

The following cautions do not appear elsewhere in this manual.

Cautions indicate possible data loss or equipment damage.

- Federal law restricts this device to sale or to use by or on the order of a physician or properly licensed practitioner.
- Implantable parts of this system must not be reused.
- Do not drop the LVAD Battery Charger, Independent Power Supply, batteries, or the Controller on any hard surface. Dropping these components might damage internal parts causing the device to malfunction.
- Do not expose the LVAD Battery Charger, Independent Power Supply to moisture.
- Do not store the HeartAssist 5® VAD System in environments where temperatures are less than –20 °C (–4 °F) or greater than 55 °C (131 °F).
- Do not store or leave batteries in hot or cold areas (e.g., car trunks, dashboards, window sills, and so forth). These temperatures can damage the battery.
- Do not attempt to make any changes to system software or to use the device as a laptop computer. Any modification of, or attempt to modify, the operating system software could result in rendering this device nonfunctional for its intended use.
- Disconnect the Controller from the Independent Power Supply before unplugging the Independent Power Supply from the power source.
- The percutaneous cable from the patient to the Controller must be handled with care to prevent damage.
- All connectors must be handled with care and kept free of liquid, dust, and debris.
- Clean the LVAD Battery Charger, Independent Power Supply by first disconnecting the equipment from the power source and then wiping it with a damp cloth. Complete the cleaning process by wiping the equipment with isopropanol alcohol to remove contaminants.
- Do not invert the cabinet of the LVAD Battery Charger while installing batteries.
- A spare Controller, a spare battery pocket, and additional batteries must be accessible to the patient at all times.
- When connecting the Controller to the Independent Power Supply, ensure that mains (AC) power is available or that fully charged batteries are installed in the battery pockets.
- Do not obstruct the fan on the back of the LVAD Battery Charger. Obstructing the fan can prevent the batteries from charging properly or cause the LVAD Battery Charger to overheat.
- Using expired or defective batteries can result in reduced operating time or abrupt loss of VAD function.
- Do not set alarm thresholds to extreme values that can render the alarm system useless.

- Do not dispose of any ReliantHeart equipment. Return all equipment to your support team for proper return to ReliantHeart.
- Do not use a battery suspected to be malfunctioning. In the event of a possible battery failure, please remove the faulty battery from battery pocket or charger and replace with a working battery. Contact ReliantHeart if a battery error is suspected.

List of cautions

The following cautions appear sequentially in this manual on the pages indicated.

Chapter 1
Emergency Information

In this chapter

Introduction

This chapter provides a quick reference of your support team's contact information and examples of conditions for calling your doctor or emergency assistance.

Read this entire manual before handling the VAD without supervision.

Support team phone numbers quick reference

Keep a record of your support team's contact information in Table 1-1. To reach ReliantHeart, see "Customer support" on page iii.

Table 1-1. Support team phone numbers

Title	Name	Phone Number
Emergency assistance		
Cardiologist		
Cardiothoracic surgeon		
Nurse		
Technical assistance		

You should always have access to someone trained in the use of and troubleshooting for the HeartAssist 5® VAD System. Your medical care should be monitored by a qualified doctor or medical staff trained in the operation of the HeartAssist 5® VAD System. The name and phone number of this person, your medical doctor, and heart surgeon are listed above.

ReliantHeart recommends that patients who have a limited ability to care for themselves or communicate clearly have a trained companion available.

Conditions for calling emergency assistance

Use the following guidelines to determine whether to call for emergency help.

Your physician's instructions supersede these guidelines. Always follow your physician's orders regarding your care.

Call 911

Call 911 or your local emergency number when any of the following symptoms occur:

- Loss of consciousness
- Seizures or convulsions
- Inability to move or speak
- Sudden collapse

Call your doctor

Call your doctor immediately if you have any of the following symptoms:

- Numbness, tingling or weakness
- Pain
- Redness, swelling, or drainage at the exit site of the percutaneous cable
- Blurred vision
- Speech problems
- Shortness of breath
- Dizziness
- Temperature higher than 38 °C (100.4 °F)
- Unusual bleeding
- Unusual bruising

Chapter 2
About This Manual

In this chapter

Introduction

This manual is intended to supplement formal training provided by your clinician and VAD support team. The VAD should only be operated and monitored by properly trained personnel. Adjustment, maintenance, and repair of this equipment should only be carried out by qualified personnel.

Use this manual as a reference after leaving the hospital.

Purpose of this manual

The purpose of the *HeartAssist 5® VAD System Patient User's Manual* is to serve as a guide for the HeartAssist 5® VAD System for the patient and patient's caregiver.

Scope of this manual

This manual includes information on operating the HeartAssist 5® VAD System, including the Controller, VADPAK, VADPAK Insert, LVAD Battery Charger, Independent Power Supply, and other components.

Intended audience

This manual is intended for the HeartAssist 5® VAD System patients and their caregivers. Medical personnel should refer to the *HeartAssist 5® VAD System Operator's Manual*.

How to use this manual

This manual contains features to assist the reader in finding and comprehending information. These features include a table of contents, a list of figures, a list of tables, an index, chapter-level tables of content, chapter-level numbering, headings and subheadings in the body text, and running headers above the body text that indicate your location in the manual.

This manual uses certain conventions to enhance usability. A description of each of these conventions follows in Table 2-1.

Text conventions

Table 2-1 explains the conventions used in the text of this document.

Table 2-1. Text conventions used in this manual

Format	Meaning	Example
Boldface	The text on the equipment display appears exactly as written in the manual.	The LCD alternates between **PUMP STOPPED** and **PUMP RESTARTED** while restarting.
Boldface Italic	The emphasized words are particularly important.	Do **not** open the inner package outside of the sterile field.
Blue, 10-point text and blue, 10-point initial capped text	• The formatted text is a file format, file name, or file extension. • The formatted, initial capped text indicates a control or window that does not appear on the display as it is written in the manual. (For example, the control or window is not titled on the display or is graphical.)	• YY-MM-DD hh-mm-ssSegX.hol • 11-05-25 10_40_33Seg1.hol • *.hol • Press the Alarm Silence button. 
Italic	• The emphasized words have special meaning. • The emphasized words indicate a book title.	• This method is called *tethered* operation. • Refer to *The HeartAssist 5® VAD System Operator's Manual* for more information.
Magenta text	The formatted text is a link. In the PDF version of the manual, the text is a hyperlink.	www.reliantheart.com

Tips, notes, cautions, and warnings

This manual uses special notices including tips, notes, cautions, and warnings to call out important information. The following sections describe the meaning of these notices.

Tips

Tips convey helpful hints and shortcuts.

Example:

You can only adjust the motor speed (increase or decrease) when the VAD is running.

Notes

Notes convey important information that does **not** pertain to data loss, equipment damage, or personal injury.

Example:

The power adapter is universal for both domestic and European AC input voltages.

Cautions

Cautions indicate possible data loss or equipment damage.

Example:

Connecting batteries other than as described can result in permanent damage to the unit.

Warnings

Warnings indicate possible bodily injury or death.

Example:

Do not store or use the Independent Power Supply near water or any liquid (for example, in the bathroom or kitchen) due to the risk of electrical shock.

Description of chapters

This manual gives you and your caregiver the information that you need to use and manage the HeartAssist 5® VAD System. The manual covers normal use and also explains how to handle emergencies. Read the entire manual before using the HeartAssist 5® VAD System without supervision.

Table 2-2 describes the type of information contained in each chapter. For more information, refer to the appropriate chapter.

Table 2-2. *The HeartAssist 5® VAD System Patient User's Manual* chapter descriptions

Chapter	Title	Description
	Contents	Sequential reference of chapters, headings, and subheadings in this manual
	Figures	Sequential reference of graphics in the manual
	Tables	Sequential reference of tables in the manual
	Warnings	• General warnings for VAD patients • Sequential reference of the warnings that appear in the chapters and appendices of this manual
	Cautions	• General cautions for VAD patients • Sequential reference of the cautions that appear in the chapters and appendices of this manual
Chapter 1	Emergency information	• Who to call for emergencies, equipment service, or general health concerns • When to call for help

Chapter	Title	Description
Chapter 2	About this manual	• How the manual is arranged and what information is presented in each chapter • The conventions used in this manual
Chapter 3	Description of the HeartAssist 5® VAD System	• Why patients need the HeartAssist 5® VAD System and what it does • Names and images of the HeartAssist 5® VAD System components
Chapter 4	Getting started with your HeartAssist 5® VAD System	• Managing the Controller, VADPAK, and power supply • General information about the HeartAssist 5® VAD System
Chapter 5	Everyday use and self care	• Verifying that the VAD is working properly • Steps to perform every day • Allowed and prohibited activities while using this device • Patient care away from the hospital
Chapter 6	Equipment care and maintenance	• Maintaining the VAD and components • Cleaning the components
Chapter 7	The pediatric patient on HeartAssist 5® LBSA VAD support	• Information specific to pediatric patients on HeartAssist 5® LBSA VAD support • Special considerations for children using the HeartAssist 5® LBSA VAD
Appendix A	Troubleshooting	• Appropriate action take in an emergency • Troubleshooting the HeartAssist 5® VAD System
Appendix B	Controller messages and alarms	• Information on the Controller message screens • Controller alarm meanings
Appendix C	System specifications	• General specifications for the HeartAssist 5® VAD system components • Information on the use of connecter cables and power cords, the proper replacement of fuses, and the essential performance of the HeartAssist 5® VAD
Appendix D	Manufacturer guidance for environmental conditions	• Operating temperatures and other environmental conditions for the HeartAssist 5® VAD System • Conditions to avoid while using the HeartAssist 5® VAD System
	Index	Alphabetical reference of major concepts, processes, and system components

Chapter 3
Description of the HeartAssist 5® VAD System

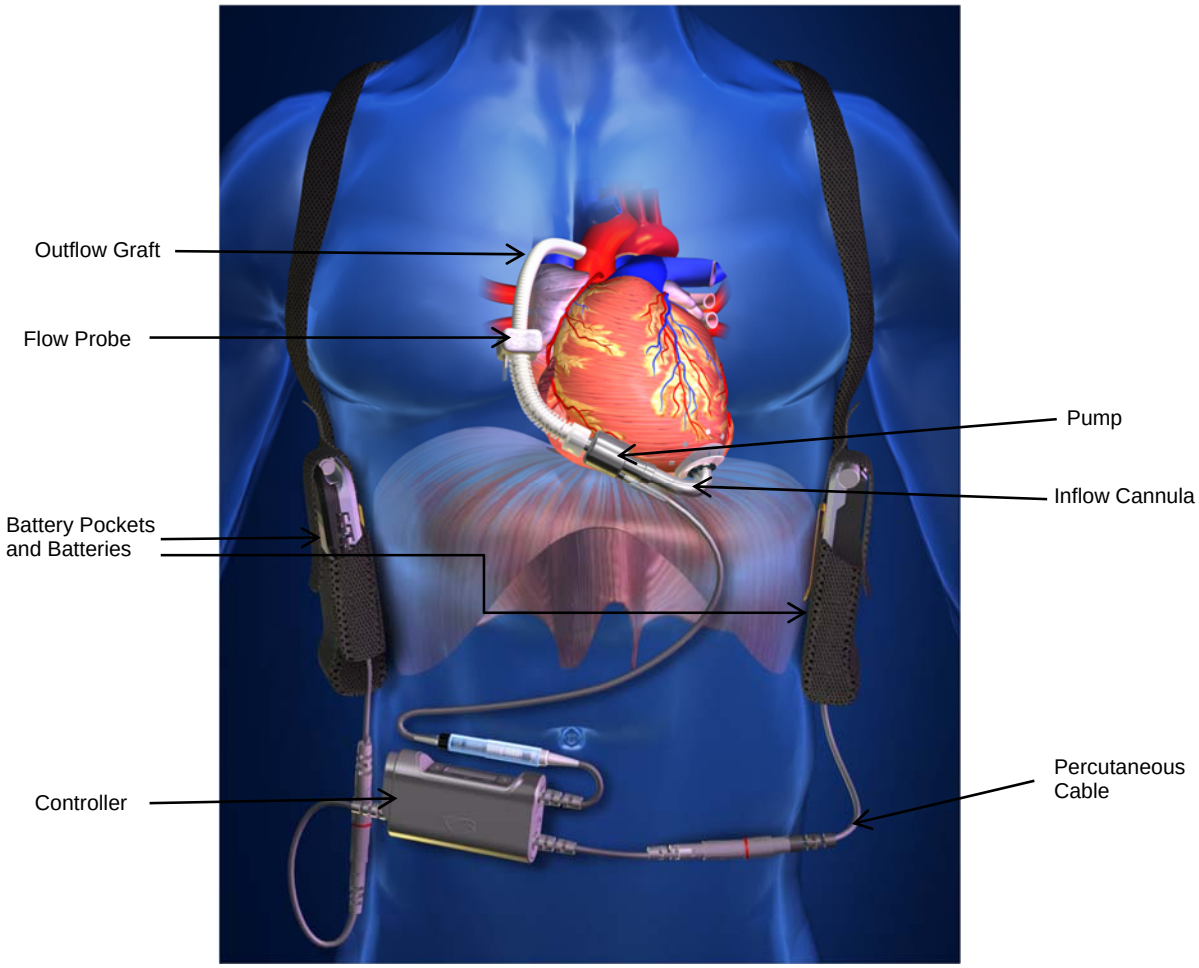
In this chapter

Introduction

The VAD is a miniaturized, auxiliary heart pump, or ventricular assist device (VAD). The VAD is 30 mm x 76 mm, weighs 92 grams (less than 4 ounces), and is designed to provide increased blood flow to patients who suffer from heart failure. It is capable of pumping in excess of 10 liters per minute.

The HeartAssist 5® VAD is intended for patients with a BSA > 1.5, and the HeartAssist 5® LBSA VAD is intended for patients with a BSA < 1.5. All of the material presented in the *HeartAssist 5® VAD System Operator's Manual* is true for both devices.

Figure 3-1. The HeartAssist 5® VAD System



Indications and contraindications for use

The VAD is intended for use in patients with end stage heart failure who would benefit from the implantation of a left ventricular assist device and in whom the device's implantable components fit properly. The HeartAssist 5 VAD is intended for use in the hospital and outside of the hospital, or for transportation of VAD patients via ground ambulance, fixed wing aircraft, or helicopter. .

The VAD is contraindicated in patients who cannot tolerate anticoagulation therapy.

Potential complications

The medical risks associated with the use of the HeartAssist 5® VAD System include the following adverse events:

- Bleeding
- Re-operation
- Hemolysis
- Infection (all causes)
- Renal dysfunction
- Hepatic dysfunction
- Right ventricular dysfunction
- Neurological dysfunction
- Thromboembolism
- Mechanical or electrical failure

Maintenance

The HeartAssist 5® VAD System does not require any user maintenance other than charging batteries. The individual life of a fully charged battery is approximately 4.5 – 7 hours depending on pump speed. Patients must recondition batteries occasionally and recharge batteries regularly.

System components

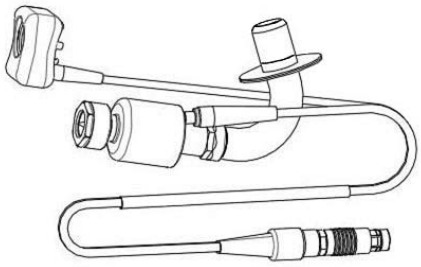
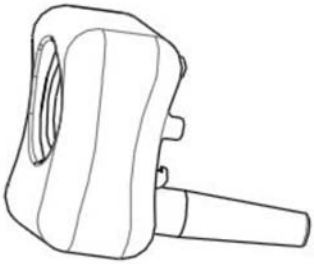
The HeartAssist 5® VAD System consists of implantable components, wearable components, and accessories as well as patient and hospital documentation.

Tables 3-1 through 3-4 list the components that are used throughout your time on VAD support.

Implantable components

Table 3-1 lists the implanted HeartAssist 5® VAD System components.

Table 3-1. Implantable components

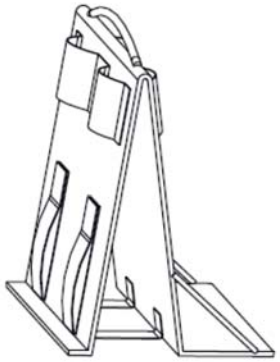
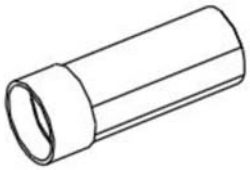
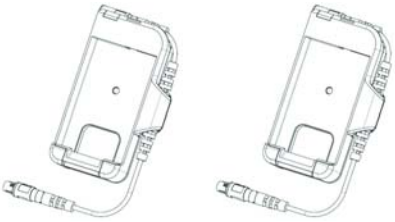
Component	Description	Example
HeartAssist 5® VAD (VAD)	The VAD with inflow cannula, wedge nut, flow probe, and percutaneous cable attached. The VAD is connected to the heart via the inflow cannula, which is inserted into the apex of the left ventricle. A three-phase electric motor is integrated in the VAD and driven by the Controller. The VAD is connected to the Controller via the percutaneous cable that is passed through the skin at the exit site. The VAD is fully implanted in the patient (with the exception of a portion of the percutaneous cable), and thus does not have a user interface. The VAD is the CF Applied part.	
Outflow graft	The outflow graft consists of a pre-clotted gelatin weave graft. It is attached to the distal end of the VAD with the wedge nut and is anastomosed to the ascending aorta.	
Graft protector	The graft protector is a plastic cover that attaches to the flow probe and protects the outflow graft.	
Flow probe	The flow probe is a custom ultrasonic real-time flow sensor. It accurately measures the flow passing through the graft.	
Sewing ring	The sewing ring is a silicone ring wrapped in polyester with drawstring Prolene “0” sutures used to attach the inflow cannula to the apex of the left ventricle.	

Wearable components

Table 3-2 lists the HeartAssist 5® VAD System components that you wear.

Table 3-2. Wearable components

Component	Description	Example
Controller	The Controller regulates the speed and supply of power to the VAD, displays current operating parameters, and provides visual and audible alarms. The Controller contains the power management system, the motor controller, data acquisition memory, software, a microprocessor, and ultrasonic flow measurement system, and a system to provide GSM cell phone connectivity to transmit pump data for remote monitoring. The Controller includes two battery cables and one driveline cable for the VAD connection. ReliantHeart supplies a spare Controller with each patient to allow for Controller exchange in emergency situations.	
Lithium ion	Each battery supplies power to the VAD for up 7.5 hours. The battery includes a button indicator consisting of LEDs which indicate the charge level of the battery.	
VADPAK	The VADPAK carries the VADPAK Insert, which contains the Controller and two battery pockets with batteries inserted.	

Component	Description	Example
VADPAK Insert	The VADPAK Insert is a reinforced fabric organizer for the Controller, battery pockets, batteries, and associated cables. It allows you to easily manage and transport the HeartAssist 5® VAD System during everyday use.	
Defibrillation cover	The defibrillation cover protects the patient from harm if defibrillation is needed. It is **not** intended to secure the percutaneous cable to the Controller cable. The defibrillation cover does not protect against fluid ingress.	
Battery pockets	The battery pockets connect the batteries and all external power sources to the Controller. The battery pockets have an integrated quick release feature to allow for easy removal of the batteries.	

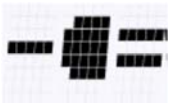
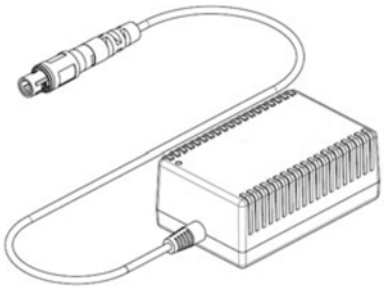
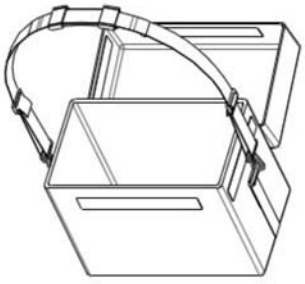
Accessories

Tables 3-3 and 3-4 describe the patient and hospital accessories available for the HeartAssist 5® VAD System.

Patient accessories

Table 3-3 lists the HeartAssist 5® VAD System patient accessories.

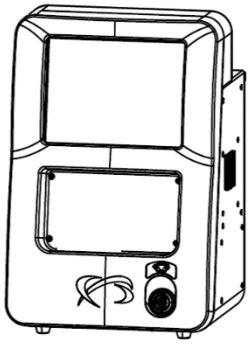
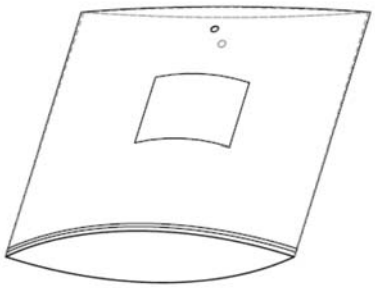
Table 3-3. Patient accessories

Component	Description	Example
LVAD Battery Charger	The LVAD Battery Charger charges and reconditions the system batteries. The charger contains LED status indicators. The charger requires up to 3.5 hours to fully charge a battery and between 10 – 14 hours to recondition a battery.	
Independent Power Supply	The Independent Power Supply provides mains (AC) electricity to the Controller. When you are using the Independent Power Supply, the VAD is not consuming battery power, and the Controller displays the external power indicator (a plug symbol) on the front panel. This symbol indicates that the system is using an external power source: 	
Shower bag	The shower bag protects the VADPAK Insert, Controller, cables, battery pockets, and batteries while you shower.	

Hospital accessories

Table 3-4 lists the components used by the hospital staff.

Table 3-4. Hospital accessories

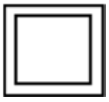
Component	Description	Example
HeartAttendant®	The HeartAttendant® is used to program the Controller, displays VAD performance and data, and provide mains (AC) power to the Controller. It can transmit data via an internet connection. This device is password protected. It is connected to the Controller via the HeartAttendant® connector cable.	
Surgery pouch	The surgery pouch is a non-sterile, disposable pouch that holds the Controller during surgery.	

Symbols used in labeling

Table 3-5 lists the symbols used in ReliantHeart product labeling and provides a description of their meaning.

Table 3-5. Product labeling symbols

Symbol	Description
EC REP	Authorized EC representative in the European Community
LOT	Batch code
	Batteries enclosed
	Battery connection – battery 1
	Battery connection – battery 2
REF	Catalog or reference number

Symbol	Description
	Caution; consult accompanying documents
	CE mark
	Consult operating instructions
	Danger; risk of electrical shock
	Defibrillation proof – type CF applied part
	Diameter
	Do not reuse; applies to single-use devices
	Do not discard in trash
	Do not use if damaged
	Double insulated
	Fire hazard
	For use within temperature limits

Symbol	Description
	Fragile
	General caution
	General warning
	Item showing sterilization method: ethylene oxide
	Latex free
	Manufactured on YYYY-MM *or* Manufactured on YYYY-MM-DD
	Manufacturers name and address
	Nationally recognized safe testing lab label
	Serial number
	Use by YYYY-MM *or* Use by YYYY-MM-DD

Documentation

Table 3-6 lists the documentation available for the HeartAssist 5® VAD System.

Table 3-6. HeartAssist 5® VAD System documentation set

Document	Audience	Description
The HeartAssist 5® VAD System Patient User's Manual (this book)	Patients and caregivers	This manual is a user guide intended for HeartAssist 5® VAD System patients and caregivers. It contains descriptions and usage information for the end user of the HeartAssist 5® VAD System.
The HeartAssist 5® VAD System Operator's Manual	Medical personnel and technical staff	This manual is a user guide intended for HeartAssist 5® VAD System surgeons, technical support staff, and other medical personnel. It contains detailed instructions for surgical procedures and system setup for HeartAssist 5® VAD System medical and technical staff.

Chapter 4

Getting Started with Your HeartAssist 5® VAD System

In this chapter

Introduction

You should practice connecting the components of the HeartAssist 5® VAD System with your support team personnel before you attempt to connect them on your own. This practice allows you to become familiar with each part of your system, how they connect, and what they do. If you have any questions during the system connection, ask your support team personnel for more information.

General considerations

The Controller has alarm sounds and light indicators to alert you about important system conditions and a display that provides textual information about these conditions. For a complete description of these messages and alarms, see Appendix B, “Controller messages and alarms.”

Protect the power cords and equipment cables. Do **not** put them where people walk. Do **not** allow anything heavy to rest on top of or roll over the cables. Avoid pinching cables in doors, drawers, and so forth. To avoid the possibility of electrical shock, contact the support team regarding the replacement of frayed or damaged cords and plugs.

Only use the power cables supplied by ReliantHeart.

Ensure that the mains (AC) input voltage is appropriate for the local power source. *Do not use extension cords.*

All equipment should sit on a hard, flat, stable surface. Do **not** place them on surfaces that could allow them to tip over.

Plug this equipment into grounded outlets only to reduce the risk of shock.

If the power outlets are not grounded, an electrician must install grounded outlets before you can use this equipment outside of the hospital.

To avoid accidentally switching off the power to your VAD, use outlets that are not connected to any wall or light switches. Set up your equipment near outlets that meet these requirements.

Do not block fans or ventilation holes of the equipment. Blocking these openings can cause heat to build up inside and damage the equipment.

Controller

The Controller provides power to run the VAD, and it displays VAD operating parameters such as speed, flow, and power usage. It also displays remaining battery life and wireless

antenna status. The Controller is equipped with an internal radio for one-way wireless transmission of data from the Controller to a secure server.

The Controller is designed to be reliable and easy to operate.

> Users can choose the Controller option to transmit pump data by radio frequency transmission, but activating this option is not required for the device to fulfill its intended use or to meet the indications for use.

Overview

The Controller has two battery cables and one driveline cable for VAD connection. (See Figure 4-1.) A liquid crystal display (LCD) is integrated into the Controller to display the operational parameters of the VAD as well as any emergency or diagnostic alarms that might occur. (See Figure 4-2 on page 4-4.)

Figure 4-1. Controller

Controller display

The Controller front panel allows you manage alarms and to monitor system status.

Controller front panel features

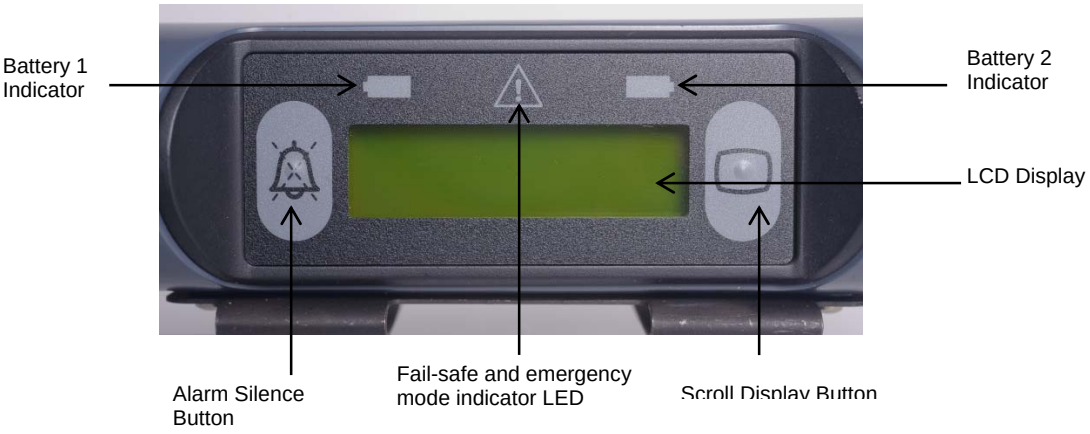
The front panel of the Controller contains the following features:

- LCD display
- Two battery indicator light emitting diodes (LEDs)
- Fail-safe and emergency mode indicator LED

  The indicator LED is red when it activates. It is a solid red for fail-safe alarms, and it flashes red for emergency alarms.
- Alarm Silence button
- Scroll Display button

Figure 4-2 shows an example of the Controller front panel display.

Figure 4-2. Controller front panel



Adjusting Controller front panel brightness

Use the following steps to adjust the Controller backlight display brightness:

1. On the Controller, press the Scroll Display button, and hold it for five seconds.

   The Controller display flashes when five seconds has passed.

2. Release the Scroll Display button.

   The Controller front panel displays the + and – buttons and a slider, indicating the current brightness level.

3. Press the + button to increase the brightness, or press the – button to decrease the brightness.

   The brightness slider indicates the new brightness level.

Controller sounds

The Controller emits three distinct sounds:

- A diagnostic alarm is indicated by a slower beeping sound.
- An emergency alarm is indicated by a faster, loud, ringing two-tone sound.
- A Controller failure is indicated by a continuous tone.

Controller messages and alarms

The LCD screen on the front panel of the Controller displays three types of messages:

- Standard messages
- Diagnostic alarms
- Emergency alarms

Standard messages

You can review seven standard information messages on the front panel of the Controller by pressing the Scroll Display button. With the first press of the Scroll Display button, the LCD backlights, and each subsequent press changes the display from one message to the next in a continuous loop.

Emergency alarms

When the Controller displays an emergency alarm, the pump is stopped, the back light automatically lights, an audible alarm sounds, and the emergency alarm indicator flashes red. The Controller continues to audibly and visually alarm until you resolve the condition causing the alarm. Pressing the Alarm Silence button has no effect. After you resolve the condition causing the emergency alarm, the alarm automatically clears.

Diagnostic alarms

When the Controller displays a diagnostic alarm message, the back light automatically lights, and an audible alarm sounds. Pressing the Alarm Silence button silences the alarm.

Normal mode

In normal operating conditions with no alarms, the Controller LCD back light is off, and the Controller displays standard message screen 1: battery status.

Battery indicators

The battery indicators on the top corners of the Controller front panel indicate three different conditions for each battery.

For a description of these indicators, see Table 4-2, “Controller battery indicator descriptions,” on page 4-26.

Flow sensor

The Controller contains an integrated flow sensor board that works with the implantable flow probe. The quality of the flow signal is indicated by the received amplitude shown on one of the screens of the Controller. See Figure B-4, “Standard message screen 4: flow probe received amplitude,” on page B-3 as an example.

Any voltage above one volt on either channel A or B indicates that the flow signal quality is acceptable.

Wireless radio antenna

The Controller contains an internal wireless radio antenna for one-way, wireless, machine-to-machine transmission of data from the Controller to a secure server. You can disable the wireless antenna (the equivalent of placing the unit in airplane mode) as needed.

Users have the option to allow the Controller to transmit pump data by radio frequency transmission, but this option is not required for the device to fulfill its intended use or to meet the indications for use.

Use the following steps to enable and disable the wireless antenna:

1. On the Controller, press Alarm Silence button, and hold it for five seconds.

   The Controller display flashes when five seconds has passed.

2. Release the Alarm Silence button.

   The Controller front panel displays the + and – buttons and a wireless antenna symbol. If the wireless radio antenna is disabled, the front panel also displays a circle-backslash symbol.

3. Press the + button to activate the wireless antenna, or press the – button to disable the antenna.

See Figure B-3, “Standard message screen 3: wireless antenna status,” on page B-3 for examples of the wireless antenna Controller display.

Always disable the wireless radio antenna prior to boarding an aircraft.

Automatic fail-safe mode

ReliantHeart equips the Controller with features to provide fail-safe operation in the event of failure of the internal central processing unit (CPU). The fail-safe mode operation bypasses the CPU entirely and runs the HeartAssist 5® VAD at the last set speed. Fail-safe mode operation activates automatically. In this situation, the Fail-safe and emergency mode indicator LED on the Controller front panel changes from off to solid red, and the Controller sounds a continuous high-pitched tone alarm. If these conditions exist, replace the Controller, and contact your support team immediately for instructions.

VAD restart algorithm

The Controller contains a sophisticated restart algorithm that attempts to restart the VAD in case of desynchronization or a VAD stoppage.

Automatic restart

If the VAD becomes desynchronized due to the loss of the back-EMF signal or other momentary VAD stoppage, the Controller attempts to restart the VAD in approximately two seconds. If this attempt occurs, the LCD displays **PUMP STOPPED** then **PUMP RESTARTING** (only while the VAD is attempting to restart).

If the VAD restarts on the first attempt, the LCD screen clears and returns to the standard message screen 1: battery status. If the VAD does not restart on the first attempt, the **PUMP STOPPED** emergency alarm sounds as well as any additional alarms that can diagnose why the VAD has stopped. (Examples of additional alarms include **BOTH BATTERIES DISCONNECTED** or **VAD DISCONNECTED**.)

The Controller attempts to restart the VAD for approximately 60 seconds. First, the Controller attempts to restart the VAD three times with a four-second pause between each attempt. If these initial attempts are unsuccessful, the cycle is repeated two more times with a 10-second pause between each set of attempts. The Controller attempts to automatically restart the VAD up to nine times.

Manual restart

If the nine attempts to automatically restart the VAD are unsuccessful, the Controller ceases any further attempts to restart the VAD. Initiate manual restarts with the following method:

1. Disconnect the battery pockets from any external power sources (such as the Independent Power Supply).
2. Briefly remove both batteries from the battery pockets.
3. Re-insert one of the charged batteries into one of the battery pockets.

   This action activates the restart algorithm, which triggers an additional nine automatic restart attempts.

Only attempt to manually restart the VAD one time. If the VAD does not successfully restart, immediately begin the procedure detailed in the next section, "Controller replacement."

When the pump restarts, the **PUMP STOPPED** emergency alarm automatically clears.

Controller replacement

Replace the Controller only when it is absolutely clear that the existing Controller has malfunctioned.

Read all instructions thoroughly before replacing the Controller.

Setting up the equipment

Use the following steps to replace the Controller.

1. Locate the necessary backup equipment:
   - Backup Controller
   - Independent Power Supply or at least one charged battery

Figure 4-3. Backup equipment for replacing the Controller

2. Remove the VADPAK Insert from the VADPAK.

Figure 4-4. Removing the VADPAK Insert from the VADPAK

3. Arrange all of the components in the VADPAK Insert and all of the backup equipment so that they are easy to access.

Figure 4-5. Arranging the components for easy access

Ensure that there is at least one charged battery or an external power source available.

Connecting the backup Controller

The patient must sit or recline for this procedure.

1. Unscrew the defibrillation cover, by turning it counter-clockwise, to access the driveline connector.

Figure 4-6. Unscrewing the defibrillation cover

2. Slide the defibrillation cover back along the driveline toward the patient.
3. Disconnect one battery pocket (with charged battery) from the Controller.

Figure 4-7. Disconnecting one battery pocket from the Controller

4. Connect the battery pocket to the backup Controller.

   The backup Controller begins to alarm.

Figure 4-8. Connecting the first battery pocket to the backup Controller

5. Pull the ribbed section of the driveline connector to disconnect it from the malfunctioning Controller.

Figure 4-9. Disconnecting the percutaneous cable

6. Align the arrow on the driveline connector to the groove on the backup Controller connector.

Figure 4-10. Aligning the driveline cable to the backup Controller

7. Firmly press the connectors together to connect the backup Controller to the VAD.

   A slight click sounds as the connectors snap into place and become fully seated.

Align the driveline connector and Controller connector properly. Forcing the connectors with improper alignment can damage the equipment. Do not twist a connector plug while inserting it after the connectors are aligned.

The VAD should now be running using the backup Controller.

8. Screw the defibrillation cover to the Controller cable by turning clockwise.
9. Press the Alarm Silence button.
10. Disconnect the second battery pocket from the malfunctioning Controller.

Figure 4-11. Disconnecting the second battery pocket from the Controller

11. Connect the second battery pocket to the backup Controller.

Figure 4-12. Connecting the second battery pocket to the backup Controller

The malfunctioning Controller continues to alarm for approximately three minutes after you disconnect the power. You cannot silence this alarm.

Replacing the SIM card

When you replace the Controller, you must transfer the SIM card from the malfunctioning Controller to the backup Controller. Continue with the following steps to replace the SIM card.

1. Locate and use the screwdriver supplied by ReliantHeart to remove the SIM card cover located on both Controllers.

Figure 4-13. Removing the SIM card cover with the ReliantHeart screwdriver

Figure 4-14. SIM card covers removed from both Controllers

2. Remove the SIM card from the malfunctioning Controller.

Figure 4-15. Removing the SIM card from the Controller

3. Insert the SIM card into the backup Controller.

   The SIM card clicks when it is properly seated.

Figure 4-16. Inserting the SIM card into the backup Controller

4. Reattach the SIM card cover on both Controllers, and secure the cover using the screwdriver.

Figure 4-17. Replacing the SIM card cover

5. Contact your support team immediately.

The Controller replacement is now complete.

Controller safety check

ReliantHeart recommends a periodic safety check of the Controller to ensure continued proper operation.

Perform the following steps to verify the safety of the Controller.

1. Verify that all three connections to the Controller are secure and undamaged.
2. Disconnect the Independent Power Supply from the battery pocket (if connected).
3. Verify that the percent charge of both batteries as displayed on the Controller LCD indicates a charge level above 25%.
4. Remove battery 1 from the battery pocket.
5. Verify that the % charge of battery 1 displays a line: — and that the LED for battery 1 is a flashing amber light.
6. Reinstall battery 1.
7. Verify that the Controller emits three audible beeps and that the Controller LCD displays the % charge for battery 1.
8. Remove battery 2 from the battery pocket.
9. Verify that the % charge of battery 2 displays a line: — and that the LED for battery 2 is a flashing amber light.
10. Reinstall battery 2.
11. Verify that the Controller emits three audible beeps and that the Controller LCD displays the % charge for battery 2.

If the Controller is functioning improperly during the safety check, replace the Controller using the procedure defined in “Controller replacement” on page 4-7, repeat the steps in “Controller safety check,” and contact your support team immediately.

Battery pockets

The battery pockets securely hold the lithium ion batteries that power the HeartAssist 5® VAD System.

Figure 4-18. Battery pocket

Each battery pocket is comprised of the following components:

- Green and amber LED indicators that indicate the status of the battery.
- External interface port that facilitates convenient connection to external power sources (such as the Independent Power Supply).
- Metal belt clip that allows you to rotate the battery pocket 360° for comfortable positioning and for attaching to a belt or the VADPAK Insert for easy mobility.
- Retention clip that safely secures the battery in the battery pocket while providing easy access for battery insertion and removal.

VADPAK

The VADPAK is an ergonomic storage system that allows the patient to carry the Controller, battery pockets, and batteries (Figure 4-19).

Figure 4-19. VADPAK

VADPAK components

The VADPAK is comprised of three components:

- A removable VADPAK Insert that organizes the Controller, battery pockets, batteries, and cables.
- A protective pouch with a padded shoulder strap.
- An emergency information card with appropriate contact information.

Setting up the VADPAK Insert

The VADPAK Insert is a reinforced fabric organizer for the Controller, battery pockets, batteries, and associated cables. It is designed to allow easy management and transport of the HeartAssist 5® VAD System during everyday use.

Figure 4-20. VADPAK Insert

Use the following steps to set up the VADPAK insert.

1. Place the VADPAK Insert on a secure surface near the percutaneous cable exit site.
2. Slide the battery pockets side by side onto the matching fabric straps on the VADPAK Insert using the battery pocket belt clips.

Figure 4-21. Securing the battery pockets in the VADPAK Insert

3. Slide the Controller onto the fabric strap using the Controller belt clip so that the Controller display is facing upward.

Figure 4-22. Securing the Controller into the VADPAK Insert with the Controller display facing upward

4. Secure the battery connectors and cables below the Controller using the Velcro® straps.

Figure 4-23. Securing the battery connectors in the VADPAK Insert

5. Grasp the VADPAK Insert by the handle, and place it in the VADPAK with the Controller display visible in the clear window of the VADPAK.

Figure 4-24. Placing the VADPAK Insert in the VADPAK

Figure 4-25. Viewing the Controller in the clear window of the VADPAK

6. Route the driveline cable to the opening below the end of the zipper in the VADPAK.

Figure 4-26. Routing the driveline cable in the VADPAK

7. Zip the VADPAK all the way to the end of the zipper to prevent the VADPAK Insert from falling out of the VADPAK.

Figure 4-27. Zipping up the VADPAK completely

The VADPAK is now ready to carry using the handle or the shoulder strap.

You can easily remove the VADPAK Insert to aid in replacing batteries or connecting to external power sources.

Connecting to external power

Use the following instructions to connect the Controller to external power sources using the battery pocket's external power connector. These steps are performed while the Controller is in the VADPAK Insert.

> These instructions apply to all external power supply sources. All external power sources share identical connectors.

1. Open the VADPAK to expose the external power connector on the bottom of the battery pocket.

Figure 4-28. Exposing the battery pocket external power connector

2. Visually align the arrow on the power source connector (such as the Independent Power Supply) with the square on the battery pocket external power connector on the bottom of the battery pocket.

Figure 4-29. Aligning the arrow on the power source connector with the square on the battery pocket external power connector

3. Once the arrow and the square are aligned, firmly push the power source connector straight into the battery pocket external power connector.

A slight click sounds, and the connectors snap into place as they become fully seated.

4. When you are connected to a single external power source, the following indications verify your external power connection:
   - The Controller emits three audible beeps.
   - The Controller screen and the connected battery pocket both display a solid green light.
   - The external power indicator (a plug symbol) displays on the Controller screen in place of the charge time remaining for the connected battery pocket.
5. Route the connector cable and the percutaneous cable to the opening below the end of the zipper.

   Figure 4-30. Routing the cables in the VADPAK

6. Zip the VADPAK all the way to the end of the zipper to prevent the VADPAK Insert from falling out of the VADPAK.

   See Figure 4-27, “Zipping up the VADPAK completely” on page 4-20.

The VADPAK is now ready to carry using the handle or the shoulder strap.

Power supply

While you are away from home, the HeartAssist 5® VAD System can draw power from a variety of sources including batteries, the Independent Power Supply.

Batteries

The batteries that power the VAD are lithium ion smart batteries. Each battery powers the VAD for approximately 4.5 – 7.5 hours, providing a combined battery time of approximately 9 – 15 hours.

Figure 4-31 displays an example of a HeartAssist 5® VAD battery.

Figure 4-31. HeartAssist 5® VAD battery

Figure 4-32 displays an example of the charge level indicators on a battery.

Figure 4-32. Battery charge level LED indicators

Each battery contains an integrated charge level indicator display consisting of four LEDs on the face of the battery. The LEDs represent the maximum charge level the battery contains in 25% increments. Table 4-1 describes the LED battery charge level indicators.

- To activate the charge level indicator display on the battery, press the circular **Check** button above the indicator LEDs.

Table 4-1. Battery charge level LED indicators

Charge level indicator LEDs on battery	Percent charged
4	75% – 100%
3	50% – 75%
2	25% – 50%
1 red	10% – 25%
1 flashing red	Below 10%

The battery in Figure 4-32 is 25% – 50% charged.

Battery time can vary from patient to patient depending on the set VAD speed.

Connecting a battery pocket to the Controller

The Controller connects to the battery pockets with connectors that are on the end of cables extending from the units. The Controller has two connectors that connect to the battery pockets, and these connectors are designed for ease of use.

Use the following steps to connect the battery pocket connectors to the Controller connectors.

1. Visually align the arrow on the battery pocket connector with the square on the Controller connector.

Figure 4-33. Aligning the arrow on the battery pocket connector with the square on the Controller connector

2. After you align the arrow and the square, firmly push the battery pocket connector straight into the Controller connector.

- A slight click sounds, and the connectors snap into place as they become fully seated.
- The Controller emits three audible beeps, and the Controller LCD displays the percent charge for the connected battery pocket.
- If the connected battery is either discharged or expired, the battery indicator LED for that battery pocket flashes an amber light, and the Controller emits audible alarms and displays visual alarms.

Figure 4-34. Batteries connected to the Controller

- Alternately, if you cannot visually align the arrow and the square, use the following steps:

a. Gently insert the battery pocket connector 2mm (1/16 of an inch).

b. With ***very little*** pressure applied, rotate the battery pocket connector until it mates with the Controller connector and no longer rotates freely.

c. Firmly push the battery pocket connector ***straight*** into the Controller connector until they are fully seated.

Align all connectors properly. Forcing connectors without proper alignment can damage the equipment. Do not try to force a power source connector into the battery pocket external power connector. When removing a cable, hold the connector, and pull it out. Do not twist the connectors while inserting them or removing them after the connectors are aligned.

Both battery pocket connectors are identical. The Controller automatically switches to draw power from the appropriate battery.

When an external power source (such as the Independent Power Supply) is connected to the battery pocket external power connector, the power source bypasses the battery in the battery pocket and supplies power directly to the Controller port. The Controller displays the external power indicator (a plug symbol) in place of the battery charge percentage.

Interpreting Controller battery indicators

The battery indicators on the top corners of the Controller front panel indicate three different conditions for each battery. See Figure 4-2, “Controller front panel,” on page 4-4 for an example of the battery indicators.

Table 4-2. Controller battery indicator descriptions

Indicator condition	Meaning
Solid green	This battery pocket is connected to external power, and the Controller is using external power from this battery pocket to run the VAD.
Flashing amber[a]	This battery pocket contains either a discharged, an expired, or no battery.
Off	This battery pocket contains a battery with an adequate charge level, which is correctly installed and is in use or is ready for use.

a Flashing amber lights indicate batteries that should be changed. Always change batteries with flashing amber lights before batteries with no lights.

The Controller always uses the battery with the lower charge and continues to use the battery down to a 25% charge level, thus preserving the battery with the highest charge for later use.

You must periodically (every two to three hours) visually inspect the front panel of the Controller to verify battery status in case of a diagnostic audible alarm failure.

Changing a battery

Use the following steps to change a battery.

1. Determine which battery to change by selecting the one with the lower charge using one of the following methods:
   - Use the LCD display on the Controller.

     See Figure B-1, “Standard message screen 1: battery status,” on page B-2.
   - Use the battery indicator LED on the Controller or battery pockets.

     See Table 4-2, “Controller battery indicator descriptions,” on page 4-26.
   - Press the battery charge level indicator **Check** button on each battery to determine its charge level.

     Batteries with adequate charge levels have no indicator lights on the Controller and battery pockets. Batteries with flashing amber indicator lights on the Controller and battery pockets have less than a 25% charge level and should be changed first. See Table 4-2, “Controller battery indicator descriptions,” on page 4-26 for other battery conditions and Figure 4-32, “Battery charge level indicators,” on page 4-23.
2. Ensure that the remaining battery indicates adequate charge on the Controller LCD display.
3. Remove the battery with the lower charge from the battery pocket.

Figure 4-35. Removing the battery from the battery pocket

4. Verify that the battery to be inserted is fully charged by pressing the battery level charge indicator **Check** button on the battery itself.

   See Table 4-1, “Battery charge level LED indicators,” on page 4-23. All four LEDs on the battery should illuminate, indicating a charge between 75% and 100%.

5. Align the connector on the battery with the receptacle in the pocket, and insert the charged battery into the pocket until it clicks.

   - The Controller emits three audible beeps, and the Controller LCD displays the percent charge for the connected battery. Any flashing amber indicator lights turn off.
   - The **BATTERY DISCHARGED** and **BATTERY DISCONNECTED** alarms clear automatically.

6. Verify the percent charge of the replaced battery on the Controller LCD display.

   See the following section, “Verifying battery charge status.”

Only remove one battery at a time from the battery pockets. Removing both batteries simultaneously causes the VAD to stop (unless you are in tethered mode). The batteries must be reconnected as quickly as possible to resume VAD function.

Do not handle batteries by the connector pins. A strong static discharge can cause the charge level indicator to temporarily malfunction. If the charge level indictor ceases to function, place the battery into a ReliantHeart charger, and recharge the battery.

Verifying battery charge status

Use one of the following methods to check the charge status of either battery:

- Look at the Controller LCD display.
- Press the **Check** button on the battery, adjacent to the battery charge indicator LEDs.

  See Table 4-1, “Battery charge level LED indicators,” on page 4-23 for a description of the LED meanings.

Even when they are connected to an external power source (such as the Independent Power Supply), the batteries located inside the battery pockets drain and lose charge over time. Verify that the two batteries in the battery pockets have sufficient charge levels prior to disconnecting the system from an external power source.

Verifying battery capacity

Battery capacity number refers to the total power available from the battery when fully charged. As the battery ages with normal use, this number decreases.

Verify the total battery capacity using standard message screen 6: battery capacity on the Controller. (See Figure B-6 on page B-3.) The screen displays the maximum battery capacity in milliamp hours. Once a battery displays a total capacity of 6000 milliamp hours or less, contact your support team for a replacement battery.

Obtain replacement batteries from ReliantHeart after the battery capacity indicates less than 6,000 milliamp hours. Only use batteries supplied by Reliant Heart.

A battery that displays less than 6000 milliamp hours is still a good battery; however, the battery might not provide as much total support time as a new battery.

LVAD Battery Charger

Figure 4-36 displays the LVAD Battery Charger. It charges and reconditions batteries used with the HeartAssist 5® VAD System. Table 4-3, “LVAD Battery Charger status lights description,” on page 4-30 describes the charge indicator lights.

With batteries, the LVAD Battery Charger weighs approximately 3.6 pounds (1.7 kg). It is enclosed in a durable case that is both moisture and flame resistant.

Figure 4-36. LVAD Battery Charger

Certain battery charger can only charge or recondition one battery at a time. This is denoted by the recondition arrow solely indicating the left bay as the reconditions lot. Please verify the proper model before following the steps for charging or reconditioning of batteries..

Connecting to a power source

Use the following steps to connect the LVAD Battery Charger to wall power.

1. Plug the main power cord into the AC power input on the LVAD Battery Charger.
2. Connect the plug to an AC power source.

The power adapter is universal for both domestic and European AC input voltages.

Charging batteries

Use the following steps to charge the batteries.

1. Identify the appropriate model, before attempting reconditioning or charging.
2. Inspect the connector end of each battery to ensure that it is clean.
3. Insert one or two batteries into the two bays of the LVAD Battery Charger.
4. Allow 5 – 10 seconds for the LVAD Battery Charger to recognize the battery.

   Depending on model type, the charger can charge one or two batteries simultaneously.. The charging process can take up to 3.5 hours per battery. If the battery status light below the battery bay flashes green, the battery is charging. If a battery status light flashes red, the battery charger is in error mode.

If the battery status lights flash a red color, you must remove both batteries and unplug the power cord. Wait 15 seconds, reinsert the batteries, and reconnect the power cord. If the batteries are warm, wait for 30 minutes before reinserting them.

Always check batteries by pushing the charge level indicator **Check** button on the battery to verify charge level when removing batteries from the LVAD Battery Charger.

Using a battery charger that is not supplied by ReliantHeart could result with batteries that could be charged inappropriately causing an over or under charged condition resulting in discharge times that are noticeably shorter than intended.

Table 4-3 describes the LVAD Battery Charger status lights.

Table 4-3. LVAD Battery Charger status lights description

Light status	Battery status
Off	No battery
Green flashing	Fast charging
Green solid	Fully charged
Amber flashing	Reconditioning
Amber and green	Reconditioned
Amber solid	Standby or Suspend
Red flashing	Error

Reconditioning batteries

To maintain the accuracy of the battery indicators, batteries must occasionally run through a recondition cycle. Use the following steps to recondition batteries.

1. Place the battery into the left bay, for chargers with only one reconditions slot. Use either slot with the charger capable of reconditioning in either position.
2. Press the **Recondition** button on the front label of the charger, directly below the battery slot. The reconditioning process can take up to 9 hours.

Connection other than indicated can result in permanent damage to the LVAD Battery Charger.

Avoid placing or operating the LVAD Battery Charger in areas or near appliances that expose it to temperatures outside of the operating range of the device, which is 0 °C (32 °F) to 50 °C (122 °F).

Independent Power Supply

The Independent Power Supply is a portable power supply that supplies AC power to the VAD via the battery pocket external power connector.

Use this power supply as a backup power source in conjunction with the two battery pockets containing charged batteries.

Figure 4-37. Independent Power Supply

	The Independent Power Supply is for use only by patients who are implanted with the HeartAssist 5® VAD System.
	Do not store or use the Independent Power Supply near water or any liquid (for example, in the bathroom or kitchen) due to the risk of electrical shock.
	The Independent Power Supply contains no user-serviceable parts. Do not open the back cover of the Independent Power Supply. Only qualified ReliantHeart personnel can service this equipment. If service is required, contact your support team.
	Avoid placing or operating the Independent Power Supply in areas or near appliances that expose it to temperatures outside the operating range of the device, which is 0 °C (32 °F) to 40 °C (104 °F) or where relative humidity is noncondensing, less than 10% Rh or greater than 75% Rh.
	Do not trip over the power cord. Instruct persons in the area to prevent tripping.

Connecting the Independent Power Supply to the Controller

Figure 4-38 and the following instructions serve as a guide for connecting the Independent Power Supply to an AC power source and to the Controller.

Figure 4-38. Independent Power Supply connection diagram

Use the following instructions to connect the Independent Power Supply to the Controller.

1. Plug the power cord of the Independent Power Supply into the wall plug. See “1” in Figure 4-38.
2. Plug the power cord into the Independent Power Supply. See “2” in Figure 4-38.
3. Plug the Independent Power Supply connector into the battery pocket external power connector (which is already connected to the Controller; see “Connecting a battery pocket to the Controller” on page 4-24). See “3” in Figure 4-38.

If all connections are secure, and the components are working properly, the Controller emits three audible beeps, the Controller front panel displays the external power indicator (a plug symbol), and the battery indicator LED on the Controller’s front panel displays a solid green light for the connected battery pocket.

When you are using the Independent Power Supply, the Controller uses power from the grounded AC wall outlet. The Controller can also receive backup power from the two charged batteries in the battery pockets if the wall outlet fails. If a power failure occurs, the Controller sounds an audible alarm, notifying you that it is using backup battery power.

Use the Independent Power Supply only with a properly grounded plug. To reduce the risk of electrical shock, plug this equipment into grounded outlets only. If your power outlets are not grounded, an electrician must install grounded outlets before you can use this equipment outside of the hospital.

Chapter 5
Everyday Use and Self Care

In this chapter

Introduction

Hospital staff should initially supervise system management, and then, as appropriate, transfer management to the patient.

Daily status checks

Check the Controller, the primary and reserve batteries, the Independent Power Supply, and the LVAD Battery Charger every day as described below.

Contact your support team if any of the Controller alarms are not working.

Every two – three hours when you are awake (whether you are attached to the Independent Power Supply or not), check the battery status on the Controller front panel.

Upon waking

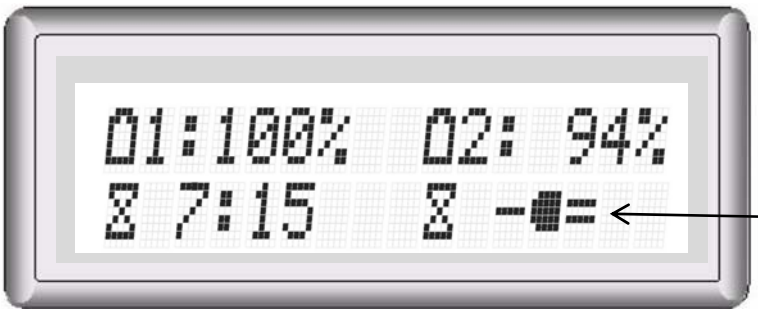
When you awaken in the morning, check the front panel display of the Controller for lighted symbols and messages. If the Controller is displaying alarm messages, see “Emergency alarms” on page B-4 and “Diagnostic alarms” on page B-6.

Before sleeping

Before you go to sleep, ensure that you verify the following statuses:

- Verify that the battery status lights are lit for all reserve batteries in the LVAD Battery Charger.
- Verify that you have two fully charged batteries in the battery pockets.
- Verify that the Independent Power Supply is supplying power to the Controller by performing the following steps:
  a. Verify that the battery LED on the Controller’s front panel is solid green for the battery pocket connected to the Independent Power Supply.
  b. Press the Scroll Display button on the front panel of the Controller to verify that the battery percentage is displaying the external power indicator (a plug symbol) for the battery pocket connected to the Independent Power Supply.

Figure 5-1. Standard message screen 1 display on the Controller front panel when using external power



Daily operation

Always connect the Controller to two power sources. The VAD draws power from one source at a time. The second source serves as backup power. When you are using the two batteries in the battery pockets as the primary and backup power sources, ensure that you check the remaining charge in each battery every hour.

While you are relaxing or sleeping, use the Independent Power Supply in the tethered mode of operation (described in the following section).

When you are active, you usually use the batteries in the battery pockets in the untethered mode of operation. The system is not connected to the Independent Power Supply during this time.

Tethered operation

During times of little activity, such as when you are sleeping or relaxing, you should use the Independent Power Supply. This method is called *tethered* operation. The HeartAttendant® is only used while you are in the hospital and the physician wants to monitor your condition.

The system must be in tethered mode whenever you think you might fall asleep or if charged batteries are not available for use in the battery pockets.

When you use the Independent Power Supply the Controller uses power from the grounded AC wall outlet. The Controller can also receive backup power from the batteries in the battery pockets if the wall fails.

Untethered operation

When active, most patients prefer using the batteries in the battery pockets (*untethered* operation) instead of having the system plugged into the Independent Power Supply in tethered mode.

The battery pockets must contain two fully charged batteries before you switch to untethered mode. The Controller draws power from one battery before drawing power from the second battery. This design ensures that the second battery will have energy remaining when the first battery falls below a 25% charge level.

Each fully charged battery powers the VAD for approximately 4.5 – 7.5 hours, giving a combined battery time of approximately 9 – 15 hours. Higher VAD speeds can reduce battery charge levels. The Controller front panel displays the percent charge level for each battery.

A fully charged battery provides adequate power to run the VAD for 4.5 – 7.5 hours. If the VAD speed is set high, it reduces the amount of time the battery can operate the VAD.

The amount of time that you stay in untethered operation depends on the set VAD speed and the number of reserve batteries available.

Only use batteries supplied by ReliantHeart.

Switching from tethered to untethered operation

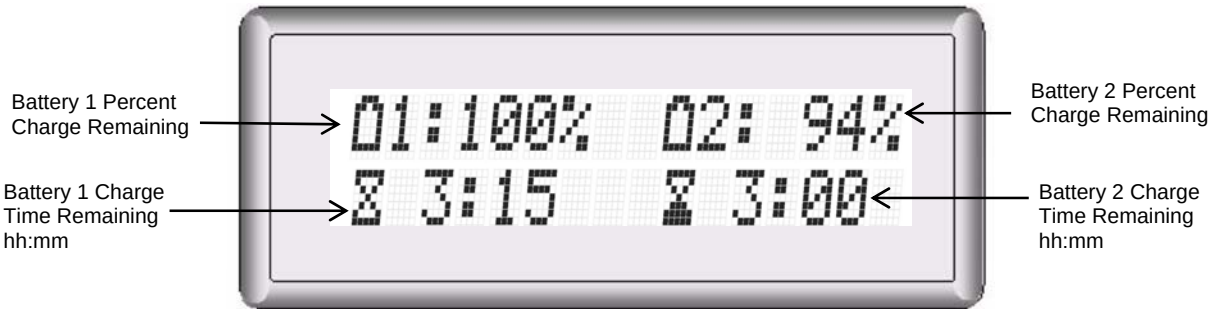
Use the following steps to change the power source from tethered to untethered operation.

Verifying battery charge

Use the following steps before you disconnect from the Independent Power Supply.

Verify that the charge level of the two batteries connected to the Controller is nearly full (>80%) on the Controller front panel.

Figure 5-2. Standard message screen 1 display on the Controller front panel when using battery power



If one or both batteries are not near charge capacity, proceed as follows:

1. Remove one or two fully charged batteries from the LVAD Battery Charger.
2. Check the batteries by pushing the charge indicator button on each battery to verify charge level.
3. Remove only one discharged battery from the battery pocket and insert the fully charged battery.
4. Remove the second discharged battery from the battery pocket and insert the fully charged battery.

Only remove one battery at a time from the battery pockets. Removing both batteries simultaneously causes the VAD to stop (unless you are in tethered mode). The batteries must be reconnected as quickly as possible to resume VAD function.

5. Check the charge level of the new battery connected to the Controller on the Controller front panel.

Disconnecting from the Independent Power Supply

Use the following steps to disconnect the battery pocket from the Independent Power Supply and complete the process of switching to untethered operation.

Disconnect the Independent Power Supply from the battery pocket external power connector as follows:

1. With one hand, firmly hold the battery pocket external power connector.
2. With the other hand, pull the power source connector from the battery pocket external power connector.

   This connection might be tight and might take some force to pull loose.

Do not twist the connector while removing it. Do no pull on the cables..

During untethered operation, check the charge level of both batteries in the battery pockets every hour to ensure that enough power is available..

Always disconnect the Independent Power Supply connector from the battery pocket external power connector ***before*** removing power to or turning off the Independent Power Supply.

Switching from untethered to tethered operation

Use the following steps to change the power source from untethered to tethered operation.

Verifying Readiness

Ensure that the Independent Power Supply is ready to be used.

- Verify that the system status light of the Independent Power Supply is a steady green.

Connecting to the battery pocket external power connector

Use the following general steps to connect the power source connector (Independent Power Supply connector) to the battery pocket external power connector.

1. Visually align the arrow on the power source connector with the square on the battery pocket external power connector.
2. Once the arrow and square are aligned, firmly push the power source connector into the battery pocket external power connector.

   You hear a slight click as the connectors become fully seated.

You can damage the connectors if you force them without proper alignment. After the connectors are aligned, do not twist the power source connector while connecting it.

If all connections are tight and the components are working properly, the Controller emits three audible beeps, the Controller front panel displays the external power indicator (a plug symbol), and the battery indicator LED on the Controller's front panel displays a solid green light for the connected battery pocket.

If a power failure is expected to last for an extended period of time, take the Independent Power Supply, the LVAD Battery Charger, and all batteries to the nearest location with suitable mains power.

Ensure that batteries that are not being used in the battery pockets are always charging in the LVAD Battery Charger while you are in the tethered mode of operation.

Leaving the home

Always travel with fully charged batteries, a spare Controller, a spare battery pocket, the Independent Power Supply, extra batteries and the LVAD Battery Charger. You might need these components in an emergency.

When you travel away from home, carry a card, letter or other medical notification that identifies you as a left ventricular assist device (HeartAssist 5® VAD) patient. This notification should include the name and telephone number of your doctor in case of an emergency.

Before going on extended trips, notify your support team.

Showering with the VADPAK Insert and shower bag

Your doctor will provide instructions for the exit site care before, during, and after showering.

Do not shower with the VAD connected to the Independent Power Supply (in tethered mode). Showering in untethered mode reduces the risk of electrical shock.

Do not submerge the Controller in liquid. Submerging the Controller in liquid might damage internal parts, causing the device to malfunction. Showers and washing are permitted when the clinician approves wound site readiness. During showers, you must use the shower bag. Do not expose the Controller to moisture.

Do not submerge batteries in liquid or expose them to heat or moisture. Submerging the batteries in liquid or exposing them to heat might cause them to malfunction. During showers, you must use the shower bag to prevent exposure to moisture.

Ensure that the VADPAK Insert is properly encased in the provided shower bag before showering.

Use the following instructions to encase the VADPAK Insert with components into the shower bag for showering.

1. Open the top cover of the shower bag.
2. Insert the VADPAK Insert, containing the Controller, battery pockets, two charged batteries, and cables into the shower bag with the VAD percutaneous cable pointing towards the left (as viewed facing the shower bag).

   The percutaneous cable connection must remain dry in the shower bag.

Figure 5-3. Properly inserting the Controller, battery pockets, batteries, and cables in the VADPAK Insert into the shower bag

3. Secure the percutaneous cable to the side of the shower bag using the Velcro® strap attached to the left side of the shower bag.

Figure 5-4. Securing the percutaneous cable to the side of the shower bag

4. Close the lid of the shower bag, and carefully press the sides of the cover inward to secure the Velcro® fasteners located along each face of the shower bag.

Figure 5-5. Properly closing and securing the lid of the shower bag

5. When you are finished showering, carefully dry off the outside of the shower bag, open the top cover of the shower bag, and remove the VADPAK Insert. If water has leaked into the shower bag, contact your support team immediately.

⚠	**Do not use the VADPAK Insert and Controller in the shower bag longer than 30 minutes because the Controller requires air circulation for proper cooling.**
⚠	**Position the shower bag so that it does not tip or drop. Do not allow the shower bag to sit in liquid.**

Activity restrictions

The HeartAssist 5® VAD System lets you move around and be active; however, there are some restrictions associated with the device. The following tables describe prohibited activities.

The activities described in Table 5-1 are always prohibited for your safety and for the function of the device. Ask the doctor what types of activities you are allowed to perform.

Table 5-1. Prohibited activities

Activity	Notes
Total body submersion (swimming or bathing)	Do not submerge the Controller or batteries in water. Submerging these components can cause the device to malfunction.
Steam bath or dry saunas	Do not operate the system in environments where the temperature is less than 10 °C or greater than 40 °C.
Participation in contact sports	Hard physical contact with other people or objects could damage the external HeartAssist 5® VAD System hardware, injure internal organs, or interfere with the tissue healing at the exit site.

Consult the doctor and gain prior approval before engaging in the activities described in Table 5-2.

Table 5-2. Restricted activities

Activity	Notes
Showering	Obtain approval from the doctor. A shower bag is also required.
Driving an automobile	Obtain approval from the doctor. In addition, local laws may prohibit persons in your condition from operating motor vehicles.
Flying	Obtain approval from the doctor. In addition, check with the airlines about possible special requirements.
Non-contact sports (golfing, jogging, tennis)	You and your doctor can determine whether participation in a certain sport could cause equipment damage or bodily harm.

The activities described in Table 5-3 have no known risks.

Table 5-3. Permitted activities

Activity	Notes
Careful sponge baths	No total submersion
Sexual activity	
Housework	
Moderate exercise	Walking, gardening, cycling, and so forth
Shopping	

Self care at home

Use the following instructions to care for yourself and HeartAssist 5® VAD System while you are away from the hospital.

Caring for the exit site

The tube (percutaneous cable) that protrudes from your skin contains wires that connect the HeartAssist 5® VAD to the Controller and allow the VAD and Controller to communicate. The area where the percutaneous cable comes out of your skin is called the *exit site*.

The physician's orders supersede these cleaning instructions. You should always follow the physician's orders regarding the care of the exit site and other surgical locations.

Change the percutaneous cable exit site dressing daily using strict aseptic technique (sterile gloves minimally).

1. Gently cleanse the site with a mild disinfectant soap (preferably chlorhexidine solution).
2. Rinse with sterile normal saline solution.
3. Dry the cleansed site using a sterile 4" x 4" gauze pad.
4. Cover the cleansed and dried site with a dry, sterile dressing.

Do ***not*** apply prophylactic topical agents to the exit site wound unless ordered by the physician.

As you clean the exit site each day, examine it for signs of infection such as the following:

- Redness
- Swelling
- Drainage
- Open sores or ulcers
- Pain
- Skin that is warm to the touch

If any sign of infection or break in the tissue is present, contact the doctor immediately.

Caring for the percutaneous cable

It is extremely important that the percutaneous cable is protected from extreme or frequent bending or kinking. Damage to the percutaneous cable, depending on the degree, can cause the VAD to stop.

Follow these recommendations to reduce damage to the percutaneous cable:

- Do **not** severely bend or kink the percutaneous cable.
- Do **not** let the percutaneous cable become twisted.
- Allow for a gentle curve of the percutaneous cable.
- Do **not** severely bend the percutaneous cable multiple times or wrap it tightly.
- Keep the percutaneous cable clean. Wipe off any dirt or grime that appears. If necessary, use a towel with soap and warm water to gently clean the percutaneous cable. However, never submerge the cable or other system components in water or liquid.
- Do **not** pull on or move the cable going through the skin.
- Be aware of the location of the Controller at all times.
- Protect the Controller from falling or from pulling on the percutaneous cable.
- Do **not** allow the percutaneous cable to catch or snag on anything that will pull on or move the cable.
- Check the percutaneous cable daily for signs of damage (such as cuts, holes, or tears).

Caring for the VADPAK

The VADPAK is an ergonomic storage system that allows you to carry the Controller, battery pockets, and batteries. If you are going for a walk, disconnect the Independent Power Supply (possibly the HeartAttendant® if in the hospital).

Taking medications

Your doctor might prescribe an anticoagulant such as warfarin (Coumadin®) and might prescribe other drugs to take while you are on the HeartAssist 5® VAD support. It is important that you take these and other medications according to your doctor's instructions.

Contact your doctor if you have questions about your medications.

Emergencies

An emergency situation can be caused by medical conditions or by mechanical problems that interfere with the pumping ability of the HeartAssist 5® VAD. You and your caregivers must learn how to identify and respond to emergencies. The most important action is to restore power to your HeartAssist 5® VAD.

Local emergency services

You or your caregivers should brief local emergency services about your HeartAssist 5® VAD, and your caregivers should establish a plan to activate these emergency services when needed.

CPR and defibrillation

If defibrillation is required, you can be connected either to battery power, the HeartAttendant®, or the Independent Power Supply. While you are implanted with the HeartAssist 5® VAD, you can receive cardiopulmonary resuscitation (CPR).

Caregivers and health care providers might not be able to feel your pulse, even if the HeartAssist 5® VAD is operating normally, so CPR and defibrillation should **not** be performed if you are awake and responsive, even if a pulse is not apparent.

Power outages

If your current location loses power, and you are not certain when it will be restored, you must temporarily move to a location with power as soon as possible to prevent the HeartAssist 5® VAD from stopping. Bring your Independent Power Supply, LVAD Battery Charger, and reserve batteries with you to the new location.

Chapter 6
Equipment Care and Maintenance

In this chapter

Introduction

The HeartAssist 5® VAD System is made of tough, durable materials, but it does require some basic care as described in the following sections. In addition, support team personnel should perform periodic safety and function checks of your HeartAssist 5® VAD System equipment.

All HeartAssist 5® VAD System components

The following subsections “Environmental conditions,” “Contact with liquids,” “Electromagnetic disturbances,” and “Service” apply to all HeartAssist 5® VAD System components.

Environmental conditions

The HeartAssist 5® VAD System components operate under the following environmental conditions.

- Do **not** operate the Controller where temperatures are less than -10 °C (14 °F) or greater than 40 °C (104 °F), or where the relative humidity is non-condensing, less than 10% Rh or greater than 75% Rh.
- Do **not** operate the Independent Power Supply where temperatures are less than 0 °C (32 °F) or greater than 40 °C (104 °F) or where the relative humidity is non-condensing, less than 10% Rh or greater than 75% Rh.
- Do **not** operate the LVAD Battery Charger where temperatures are less than 0 °C (32 °F) or greater than 50 °C (122 °F), or where the relative humidity is non-condensing, less than 10% Rh or greater than 75% Rh.
- Do **not** store the system in environments where temperatures are less than –20 °C (–4 F) or greater than 55 °C (131 °F).
- Do **not** expose the batteries to moisture or heat.
- Do **not** expose the Controller, VADPAK, VADPAK Insert, battery pockets, Independent Power Supply to moisture.
- The VADPAK carry bag is flame retardant, but you must be careful when using the bag near open flame or embers. Any hot item that falls onto or within the bag must be removed as quickly as possible to prevent scorching or marring of the materials.
- The Controller meets the IP32 rating as designated in IEC 60529 Degrees of protection provided by enclosures. This rating signifies that the Controller case protects the Controller hardware and software from dripping fluid and solid foreign objects ≥ 2.5 mm in diameter.
- Do **not** transport the HeartAssist 5® VAD System in environments where temperatures are less than 0 °C (32 °F) or greater than 55 °C (122 °F).
- Travel should be limited to pressure altitude of 0 – 2000 m (6500 ft).
- The altitude specification does not limit use of the device on fixed wing aircraft, since commercial planes utilize pressurized cabins. For example, when a plane is traveling at 35,000 feet altitude, the pressurized altitude inside the cabin is equivalent to 5,400 feet above sea level.

Contact with liquids

All HeartAssist 5® VAD System components (with the exception of the shower bag) are susceptible to damage by liquids. Keep all liquids away from HeartAssist 5® VAD System components.

Keep all liquids away from equipment to avoid accidental spills. Do not put any part of this equipment under water or in other liquids. Contact with liquids increases the risk of electrical shock and of damage to the equipment.

Electromagnetic disturbances

Laboratory testing suggests that patients have little risk from most devices that might produce electromagnetic disturbances (such as metal detectors, microwave ovens, and cellular phones). However, such devices can affect electronic equipment at very close range. For this reason, observe the recommended separation distances in Tables D-1 through D-4 beginning on page D-2 in Appendix D, “Manufacturer guidance for environmental conditions.”

The HeartAssist 5® VAD has been shown to have acceptable risk regarding electromagnetic disturbances, as specified by international standard IEC 60601-1-2:2007.

The system has not been tested with each possible brand of device, and the possibility of electromagnetic disturbances exists.

If you experience unexpected changes in the speed of the VAD, investigate potential sources of electromagnetic disturbances (such as cellular phones, radio transmitters, or microwave ovens) within a few feet. If you discover disturbances, move away from the potential source, and determine if the VAD operation returns to normal. If it does not return to normal, contact your support team.

Do not subject patients implanted with the VAD to magnetic resonance imaging (MRI). The VAD contains ferromagnetic components, and MRI can cause device failure or patient injury.

Figure 6-1. MRI warning and safety seal

MR unsafe

VAD support equipment was assessed for basic electrical and constructional safety with respect to IEC/EN 60601-1/A2: 1995

UL2601-1: 1997 (North American Deviations to IEC 60601-1)

UL60601-1: 2003 (HeartAttendant®)

CAN/CSA-C22.2 No. 601.1-M90 (with updates 1 and 2 for HeartAttendant®) Service

Service

There are no user-serviceable parts in the Controller, LVAD Battery Charger, or Independent Power Supply. Contact your support team for service of this equipment.

Do not service this equipment yourself. Only qualified personnel can service this equipment. If service is required, contact your support team.

Do not modify this equipment. No modification of this equipment is allowed.

Do not open the back cover of any ReliantHeart device.

Controller

The Controller does not require routine maintenance. You can wipe dust off of the surface of the device with a clean, dry, lint-free cloth, and you can clean spills from the cover with a dampened cloth.

Do not drop the Controller on any hard surface. Dropping the Controller can damage internal parts causing the device to malfunction.

LVAD Battery Charger

The LVAD Battery Charger does not require routine maintenance. You can wipe dust off of the surface of the device with a clean, dry, lint-free cloth, and you can clean spills from the cover with a dampened cloth.

Do not attempt to wipe liquid from the inside of the LVAD Battery Charger battery bays as this action might bend or otherwise damage the connector pins.

Independent Power Supply

The Independent Power Supply does not require routine maintenance. You can wipe dust off of the surface of the device with a clean, dry, lint-free cloth, and you can clean spills from the cover with a dampened cloth.

Chapter 7

The Pediatric Patient on HeartAssist 5® LBSA VAD Support

In this chapter

Introduction

All of the material previously presented in the *HeartAssist 5® VAD System Patient User's Manual* is true for the pediatric patient. It is expected that pediatric patients between 5 and 16 years of age will encounter situations similar to the adult patient as described in this manual. This chapter provides guidance for situations that pediatric patients, especially younger children, might encounter and is written for the child's parents or caregivers.

Parents or caregivers of pediatric patients of any age and children or adolescents with the appropriate skills should read the *HeartAssist 5® VAD System Patient User's Manual* thoroughly before working with the HeartAssist 5® LBSA VAD.

This chapter does not repeat all of the cautions and instructions contained elsewhere in this manual, and this chapter should not be substituted for reading the entire manual.

Implant surgery

The HeartAssist 5® LBSA VAD is placed in your child's chest during surgery. Your child's doctor explains the surgery to both of you. When you and your child are ready after the implant operation, the hospital staff trains you and your child, if he or she is old enough, on how to operate the HeartAssist 5® LBSA VAD.

System description

The Controller, VADPAK, VADPAK Insert, battery pockets, batteries, LVAD Battery Charger, and Independent Power Supply that the pediatric patient uses are the same as described in Chapter 3, "Description of the HeartAssist 5® VAD System."

The VAD your child receives is designed to fit properly in a child's smaller chest. The HeartAssist 5® LBSA VAD operates exactly like the adult HeartAssist 5® VAD. Chapter 3, "Description of the HeartAssist 5® VAD System" describes how the HeartAssist 5® LBSA VAD operates.

Environmental conditions

HeartAssist 5® LBSA VAD system operation and storage is not recommended in certain environmental conditions, as explained in the following subsections.

Temperature

The following guidelines describe temperature controls for the Controller.

Do not operate the Controller where temperatures are less than –10 °C (14 °F) or greater than 40 °C (104 °F) or where the relative humidity is noncondensing, <10% Rh or >75% Rh.

Your child must wear the Controller at all times, or your child's HeartAssist 5® LBSA VAD will not run. Therefore, you must not allow your child to spend time in areas with temperatures outside of the specified range of –10 °C (14 °F) or greater than 40 °C (104 °F) or to place the Controller in locations where this temperature range can be exceeded (for example, near heaters, radiators, or air conditioners).

The batteries, Controller, battery pockets, VADPAK, and VADPAK Insert must not be exposed to moisture or heat.

The batteries must not be exposed to extreme heat. You must monitor his or her temperature when your child is playing in very hot environments such as the beach. Children on HeartAssist 5® LBSA VAD support must not stand in front of or come in contact with sources of heat such as fireplaces, space heaters, stoves, and so forth. As a reminder, your child's LVAD Battery Charger or Independent Power Supply should never be placed close to these types of heat sources.

The VADPAK carry bag is flame retardant, but you must exercise care when using the bag near open flame or embers. Remove any hot item that falls onto or within the bag as quickly as possible to prevent scorching or marring of the materials.

Take special care if your child is around campfires or other sources of open flame. Teach your child to stay a safe distance away from them.

Contact with liquids

All forms of liquid must be kept away from the equipment in order to prevent accidental spills. For example, you might want your child to wear an apron or bib while eating so that food or drinks don't spill on the VADPAK or its components. The equipment must never be submerged in any liquid. Young children might need to be watched carefully when they are near sources of water, such as the bathroom, as they might attempt to put their equipment in places like the toilet. Your child will not be able to swim or take a full bath while supported by the HeartAssist 5® LBSA VAD. Bathing while wearing the HeartAssist 5® LBSA VAD is described in "Showering with the VADPAK Insert and shower bag" on page 5-6.

Whenever your child is mobile or operating in the untethered mode (operating the HeartAssist 5® LBSA VAD on batteries alone), he or she will have two batteries, two battery pockets, and the Controller in the VADPAK, using the VADPAK Insert. The batteries, the battery pockets, and the Controller must not get wet. You must not allow your child to swim or play in water in a way that allows moisture to enter the VADPAK and come in contact with the batteries, the battery pockets, or the Controller.

On days with heavy rains, it might be helpful to ensure that your child is wearing rain gear or the shower bag to protect the VADPAK, the Controller, the batteries, and the battery pockets when he or she goes outside.

Limit the time that the Controller and accessories are in the shower bag and the shower to 30 minutes.

Electromagnetic disturbances

Laboratory testing suggests that there is little risk from most devices that can produce electromagnetic disturbances (such as metal detectors, microwave ovens, and cellular phones) with the HeartAssist 5® LBSA VAD. However, these types of devices can affect electronic equipment at very close range. For this reason, observe the recommended

separation distances in Table D-4, “Recommended separation distance between portable and mobile RF communications equipment and the life-supporting ME equipment and ME systems,” on page D-5. The system has not been tested with each possible brand of these devices, and the possibility of electromagnetic disturbances might exist.

You must observe your child’s HeartAssist 5® LBSA VAD functions, such as flow and speed, closely anytime your child is in the presence of devices that might cause electromagnetic disturbances, including toys that use wireless or radio-controlled technology. If an unexpected change occurs, tell your child to move away from the potential source of interference. If the HeartAssist 5® LBSA VAD function does not immediately return to normal when the source is removed, contact your support team.

Electrostatic discharge

Testing has demonstrated that the HeartAssist 5® LBSA VAD has an acceptable risk regarding electrostatic discharge. However, children often come in close contact with television screens or computer monitors. Although this contact should not affect the operation of the HeartAssist 5® LBSA VAD, consider teaching your child to stay a safe distance from television screens and other sources of electrostatic discharge as an added measure of safety.

Operating the HeartAssist 5® LBSA VAD system

Chapters 4 – 6 explain how to operate and manage your child’s HeartAssist 5® LBSA VAD system. The following additional information is specific to device management for the pediatric patient.

As appropriate for his or her age, help your child to understand the device that is supporting his or her life; in particular, your child should understand that the Controller and other components of the system are not toys and should be handled carefully. Put precautions in place to minimize your child’s ability to play with cables and connections. Teach your child to recognize alarms and to immediately go to you or another caregiver when an alarm occurs. If your child is too young to detect audible alarms reliably, ReliantHeart recommends that your child always be within hearing distance of you or another caregiver.

Batteries

If your child is old enough to participate in his or her care and to understand what to do, you should encourage your child to be responsible for changing batteries. Since the charge duration of the batteries varies according to the HeartAssist 5® LBSA VAD speed, you can only estimate the time interval between battery changes. If your child cannot change his or her batteries, you or another caregiver must always be available around the time that batteries must be changed. If you cannot reasonably estimate the battery charge duration, keep your child within hearing distance so that you can detect the battery discharged alarm. You must make a rule with your child that he or she will always have two charged batteries in the battery pockets.

VADPAK

The VADPAK might be large for your child. Adjust the shoulder strap so that the VADPAK fits securely on your child. If the weight of the VADPAK pulls on your child’s shoulder, additional padding may be placed beneath the shoulder strap to reduce the force. Your child should be taught to keep the VADPAK closed at all times, except when changing a battery or checking the Controller.

Caution active children against upside-down maneuvers on jungle gyms or other apparatus because the VADPAK Insert might come loose from the VADPAK if the zippers are unzipped.

Your child will almost certainly get the VADPAK dirty. You can wipe the exterior of the bag with a slightly damp cloth to clean it, taking care not to get water inside the VADPAK. If your child would like, you can apply stickers to the exterior of the VADPAK, but nothing should be placed in the interior of the bag where equipment is placed. Because sand or dirt particles could easily get into the VADPAK and potentially interfere with connections, keep your child from sitting and playing in sand or dirt. Your child's VADPAK should be exposed to ambient air to allow proper cooling and to prevent the alarms from being muffled. Do not allow your child to wear the VADPAK beneath clothing for extended periods of time.

Percutaneous cable

The percutaneous cable connection to the Controller should be protected because it links the HeartAssist 5® LBSA VAD inside your child's chest to the equipment that runs that VAD on the outside of your child's body. Even though the HeartAssist 5® LBSA VAD is designed to prevent the cable from catching on objects and being pulled, you should make sure that your child's percutaneous cable is not prone to pulling or disconnection at any point while your child is active. Teach your child not to play with the percutaneous cable or its connection to the Controller because doing so might increase the risk of injury or infection at the exit site or disturb connections.

Daily operation for the pediatric patient

"Daily operation" on page 5-3 discusses the normal, daily use for both the HeartAssist 5® VAD (for adult patients) and the HeartAssist 5® LBSA VAD. The following subsections provide more information that is specific to children on HeartAssist 5® LBSA VAD support.

Leaving the home

Your child must have fully charged batteries whenever he or she leaves the house, and you or your child should always carry a spare Controller, spare battery pocket, and spare batteries. If your child will be away from home for extended periods of time, he or she must travel with an LVAD Battery Charger, reserve batteries, and an Independent Power Supply to charge his or her batteries and provide backup wall power.

If you do not accompany your child, it is very important to teach him or her to carry the required backup equipment. Your child should also have a card, letter, bracelet, or other medical identification that shows that he or she has a HeartAssist 5® LBSA VAD left ventricular support device. This identification should also include your name or another caregiver's name and a method of contact, as well as the name and phone number of your child's physician.

Returning to school

Some children return to school while on HeartAssist 5® LBSA VAD support. Before your child returns to school, the school nurse and classroom teacher or teachers should receive training in the management of your child's device. It is helpful to provide a copy of The *HeartAssist 5® VAD System Patient User's Manual* to school staff. You and your child's teachers should evaluate playground and classroom areas to identify any situations that might cause harm to your child or his or her device.

It is useful to discuss your child's device with his or her classmates before he or she returns to school. Other children who play with your child should be cautioned not to pull your child's VADPAK, straps, or percutaneous cable during play. Classmates and playmates should be reminded to seek adult help as soon as possible if your child doesn't feel well or loses consciousness.

Activities

While on HeartAssist 5® LBSA VAD support, your child may not participate in swimming or contact sports. This restriction is to protect the safety and function of your child's device. With the doctor's permission, your child may participate in moderate activities like jogging, golfing, walking, shopping, and so forth with a low risk of harm to the device.

Travel

Consult your doctor about whether or not your child may travel by car or plane. If your child requires a car seat during travel, you must position the VADPAK to eliminate pulling on the cables or on your child's shoulder. Seat belts should not interfere with travel for older children; however, children might be more comfortable riding on the right side of the vehicle where the belt buckles connect on the left side (because the percutaneous cable and VADPAK are located on the right side of the body).

Sleeping

When sleeping, your child should be tethered to the Independent Power Supply, which provides a continuous power supply and prevents the necessity of waking your child to change batteries. Arrange your child's room so that he or she can take the VADPAK off while sleeping, yet keep it close by so that the percutaneous cable connection is not stretched. You should put things your child might need at night in

Showering and cleansing

Children supported by the HeartAssist 5® LBSA VAD may not take a bath because the VADPAK, VADPAK Insert, Controller, battery pockets, and batteries would be fully submerged in water. Careful sponge baths are suggested in children not yet old enough to shower. If your child showers with the device, the VADPAK Insert must be fully enclosed in the shower bag as described in the section "Showering with the VADPAK Insert and shower bag" on page 5-6.

Emergencies

An emergency situation can be caused by medical conditions or by mechanical problems that interfere with the pumping ability of the HeartAssist 5® LBSA VAD. You and your child must learn how to identify and respond to emergencies. The most important action is to restore power and function to your child's HeartAssist 5® LBSA VAD.

Local emergency services

Local emergency services should be briefed about your child's HeartAssist 5® LBSA VAD, and you should have a plan established with your family to activate these emergency services when needed.

CPR and defibrillation

If defibrillation is required, your child can be connected either to battery power, the HeartAttendant®, or the Independent Power Supply. Children on HeartAssist 5® LBSA VAD support can receive cardiopulmonary resuscitation (CPR). You might not be able to feel your child's pulse even if the HeartAssist 5® LBSA VAD is operating normally, so CPR and defibrillation should **not** be performed if your child is awake and responsive, even if a pulse is not apparent.

Power outages

If your child's current location loses power, and you are not certain when it will be restored, you must temporarily move your child to a location with power as soon as possible to prevent the HeartAssist 5® LBSA VAD from stopping. Bring your child's Independent Power Supply, LVAD Battery Charger, and reserve batteries with you and your child to the new location.

Prevention

Prevention is the key to handling emergencies with children on HeartAssist 5® LBSA VAD support, especially children who are old enough to sometimes be without a parent or caregiver.

Your child should always carry identification as a left ventricular assist device patient with contact information for the caregiver and physician. Your child's teachers, coaches, classmates, friends, and siblings should be educated about the HeartAssist 5® LBSA VAD and taught what to do in the case of emergency.

If your child is not with you, he or she should be accompanied by a responsible person such as a friend or an older sibling, so that someone is available to immediately seek help for your child in the case of an emergency. Children who are too young or unable to respond to device alarms, change batteries, or seek help should always be accompanied by a parent, other caregiver, or an individual knowledgeable in the operation of the HeartAssist 5® LBSA VAD.

Appendix A
Troubleshooting

In this appendix

Emergencies

Emergency situations can be caused by medical conditions or by mechanical problems that interfere with the pumping ability of the HeartAssist 5® VAD. You must learn how to identify and respond to emergencies. The most important action is to restore power and function to the HeartAssist 5® VAD.

You or your caregiver must call 911 or the local emergency number when any of the following symptoms occur:

- Loss of consciousness
- Seizures or convulsions
- Inability to move or speak
- Sudden collapse

If you lose AC power, ensure that fully charged batteries are installed in the battery pockets, disconnect the Controller from the Independent Power Supply, and travel to the nearest source of correct AC power with the Independent Power Supply, reserve batteries, and the LVAD Battery Charger.

Controller troubleshooting

Table A-1 describes troubleshooting for alarm messages displayed on the Controller LCD. For examples of these messages, see “Emergency alarms” on page B-4 and “Diagnostic alarms” on page B-6.

Table A-1. Troubleshooting guide for Controller alarms

Alarm or error	Associated event	Troubleshooting

PUMP STOPPED alarm	The VAD has stopped. The Controller automatically tries restarting nine times within approximately 60 seconds.
	The LCD alternates between **PUMP STOPPED** and **PUMP RESTARTING** while restarting.
		If the first three methods fail to restart the VAD, you can force the VAD to restart by removing both batteries and re-inserting one battery into a battery pocket *while not tethered to wall power* as described in “Manual VAD restart” below.
		• Check for flashing alarms, which can indicate why the VAD has stopped. For example: **VAD DISCONNECTED** or **BOTH BATTERIES DISCONNECTED**.
		• Check for system damage.
		• Attempt to verify that an unknown electrical disturbance is not affecting the Controller by moving to another location. See “Emergency alarm 1: PUMP STOPPED” on page B-4.
		Manual VAD restart
		If the VAD did not restart, perform the manual restart procedure described below:
		1. Disconnect the battery pockets from any external power source.
		2. Briefly remove both batteries from the battery pockets.
		3. Re-insert one of the batteries into one of the battery pockets.
		  • This procedure activates the restart algorithm, which triggers an additional nine automatic restart attempts.
		  • If the VAD does **not** restart, continue with step 4.
		  • If the VAD restarts, disregard the remaining steps. When the VAD restarts, the emergency alarm clears.
		4. If the VAD does not restart after you have performed the manual restart procedure, replace the Controller with the backup Controller.
		5. Contact emergency medical services and your support team.
		  The impeller and the motor Controller can occasionally lose synchronization. When this event occurs, the LCD displays the **PUMP STOPPED** then **PUMP RESTARTING** alarms, then it returns to the default display (assuming no other alarms are present). The audible emergency alarm does not sound for this event, but the event memory is captured. The resynchronization event typically allows the VAD to stop for approximately two seconds.

PUMP RESTARTING alarm	The VAD is attempting to restart.	1. See “Diagnostic alarm 4: PUMP RESTARTING” on page B-7. 2. Contact your support team.

Alarm or error	Associated event	Troubleshooting
REDUCED FLOW RATE alarm	The flow rate measured by the implanted flow probe has dropped below the programmed alarm threshold.	Contact your support team.
EXCESS CURRENT alarm	The VAD is drawing current in excess of the programmed alarm threshold.	Contact your support team.
Fail-safe LED display frozen	The fail-safe LED is lit, the Controller is emitting a high-pitched continuous alarm, the LCD display is frozen, and the battery LEDs are lit. The VAD is running at the last set speed.	1. Replace the Controller with the backup Controller. 2. Contact your support team.
No display	The LCD is off, the LEDs are off, and the Controller is emitting a high-pitched continuous emergency alarm. The Controller has failed internally. Due to potential processor failure, no display is associated with this alarm.	1. Replace the Controller with the backup Controller immediately. 2. Contact your support team.
BOTH BATTERIES DISCONNECTED alarm	Both batteries are disconnected. If the emergency alarm clears, the batteries are connected; disregard further steps. If the alarm does not silence, continue with step 5.	1. Verify that all batteries are fully seated into the battery pockets. 2. Verify that the battery pocket connectors are correctly inserted into the Controller connectors. 3. Verify that the battery pocket cables are not cut or damaged. 4. Verify that at least one of the batteries is charged. 5. Replace the Controller with the backup Controller. 6. Contact your support team.
VAD DISCONNECTED alarm	The VAD has become disconnected from the Controller.	1. Verify that the percutaneous cable is not damaged. 2. Unscrew the white defibrillation cover from the percutaneous cable. 3. Disconnect the driveline from the percutaneous cable and verify that the pins inside the VAD connector are straight and free from debris or liquid. 4. Plug the driveline connector back into the percutaneous cable ensuring that the driveline connector is fully seated with the percutaneous cable connector. If the emergency alarm silences, the VAD is running. If the VAD does not restart, and the message does not clear when the alarm silence button is pressed, replace the Controller with the backup Controller. 5. Screw the white defibrillation cover onto the driveline cable. 6. Contact emergency medical services and your support team.

Alarm or error	Associated event	Troubleshooting
Continuous audible alarm	The Controller is malfunctioning.	1. You must seek immediate medical assistance if the VAD has stopped. 2. Replace the Controller with the backup Controller. 3. Contact your support team.
REDUCED MOTOR SPEED alarm	The RPM of the VAD has fallen below the programmed alarm threshold.	Contact your support team.
BATTERY 1 OR 2 DISCHARGED alarm	The battery in port 1 or 2 has discharged below 25%.	Replace the discharged battery with a charged battery.
BATTERY 1 OR 2 DISCONNECTED alarm	Either battery 1 or 2 has been disconnected.	1. Verify that the battery is firmly seated into the battery pocket. 2. Verify the battery plug is properly seated into battery port of alarm Controller. 3. If alarm does not clear, contact your support team.
BATTERY 1 OR 2 EXPIRED alarm	The battery in port 1 or 2 has discharged below 15%, or the battery voltage is too low.	1. Replace the expired battery with a charged battery. 2. If the battery expired alarm occurred prior to a battery discharged alarm for that battery, contact your support team for a replacement battery.

Non-VAD related troubleshooting

The following tables describe troubleshooting information for the HeartAssist 5® VAD System.

Table A-2. Troubleshooting guide for non-VAD issues

Situation or error	Troubleshooting
The Controller LCD display is unreadable, the battery LEDs respond to battery changes, and the fail-safe mode LED is off. It is likely that the VAD is still running normally.	1. Verify the functionality of the battery LEDs by inserting and removing a fully charged battery into one of the battery ports while the other battery port contains a charged battery. If the LCD is not functional but the battery and fail-safe mode status indicators are still functional and you feel no adverse effects, the VAD is probably still functioning correctly. 2. Replace the Controller with the backup Controller. 3. Contact your support team.
The Controller LCD display is unreadable, the battery LEDs respond to battery changes, and the fail-safe mode LED is on (solid red). It is likely that the VAD is still running in fail-safe mode at the last set speed. Because the motor Controller is separate circuitry from the CPU, the VAD could continue to run in the event of a Controller failure. However, the circuitry that verifies the functionality of the CPU detects a failure in the CPU and sets the motor controller to the last set speed.	1. Replace the Controller with the backup Controller. 2. Contact your support team.
The Controller LCD display is unreadable; the battery LEDs do not respond to battery changes. It cannot be determined whether or not the VAD is operational.	1. Replace the Controller with the backup Controller. 2. Contact your support team.
The Controller is splashed with liquid.	Wipe the liquid from the case of the Controller.
The Controller becomes soiled.	Wipe the Controller with a slightly damp cloth with mild detergent (for example, dishwasher soap). ***Never* spray water or detergent directly onto the Controller. Always apply water or detergent to a soft cloth, wring it out until just slightly damp, and wipe the Controller.**
The Controller becomes submerged in liquid.	1. Replace the Controller with the backup Controller immediately. 2. Contact your support team.

Situation or error	Troubleshooting
A VADPAK with VADPAK Insert is submerged in liquid.	1. Locate your backup Controller, backup battery pocket, a charged battery, and the Independent Power Supply. 2. Insert a charged battery into the backup battery pocket. 3. Power up and connect the Independent Power Supply to the backup battery pocket. 4. Connect the backup battery pocket to the backup Controller. Perform the Controller replacement with the backup. 5. Contact your support team. If the backup battery pocket and the Independent Power Supply are not available, do **not** disconnect the Controller. Try to drain liquid, and contact your support team immediately.  **You must always have extra batteries, a backup battery pocket, and a backup Controller.**
A battery is submerged in liquid.	If the battery is in the battery pocket, replace both the battery pocket and battery with a backup battery pocket and a spare battery. If the battery is not in the battery pocket, do **not** attempt to use or recharge this battery. Do **not** attempt to use or recharge any battery that becomes submerged in liquid. Contact your support team for a replacement battery and battery pocket.

Situation or error	Troubleshooting
An external power source, such as the Independent Power Supply (IPS), is connected to the battery pocket external power connector, but the power source is not indicated on the Controller display.	1. Verify that the connector cable is correctly inserted in the battery pocket connector. If the Controller display does not indicate that the IPS or APS is connected, continue with steps 2–5. 2. Using the Controller display, check the battery status for both battery pocket batteries to ensure adequate charge levels. See Figure B-1 on page B-2. 3. With the IPS or APS connected to the battery pocket, disconnect the battery pocket from the Controller. See “Disconnecting from the Independent Power Supply” on page 5-4. 4. Press the Alarm Silence button on the Controller front panel. If you do not press the Alarm Silence button on the sounds, notifying you that it is disconnected. 5. Disconnect the IPS or APS from the battery pocket connector, and connect the IPS or APS directly into the Controller connector. **You can damage the connectors if you force them without proper alignment. Do not twist the connectors while inserting them after the connectors are aligned.** • If the Controller front panel displays the external power indicator (a plug symbol), the battery pocket external power connector is malfunctioning. Replace the battery pocket with a backup battery pocket, and contact your support team for a replacement. • If the Controller front panel is **not** displaying the external power indicator, the IPS or APS is malfunctioning. Reconnect the battery pocket, and contact your support team for a replacement IPS or APS.

Appendix B
Controller Messages and Alarms

In this appendix

Standard message screens

The Controller has seven standard message screens that continuously display information while scrolling with the Scroll Display button.

Figures B-1 – B-6 display the seven messages shown on the Controller.

Figure B-1. Standard message screen 1: battery status

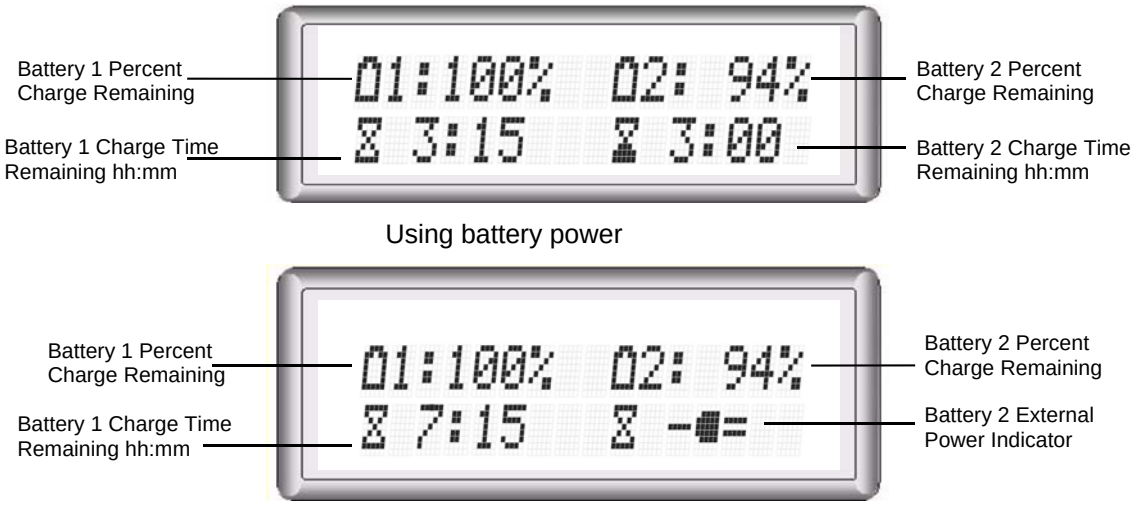


Figure B-2. Standard message screen 2: current VAD parameters

When the system is plugged in to external AC or DC power (for example with the Independent Power Supply), the battery charge time remaining that is displayed in standard message screen 1 is replaced by the external power indicator (a plug symbol), as shown in Figure B-1.

Figure B-3. Standard message screen 3: wireless antenna status

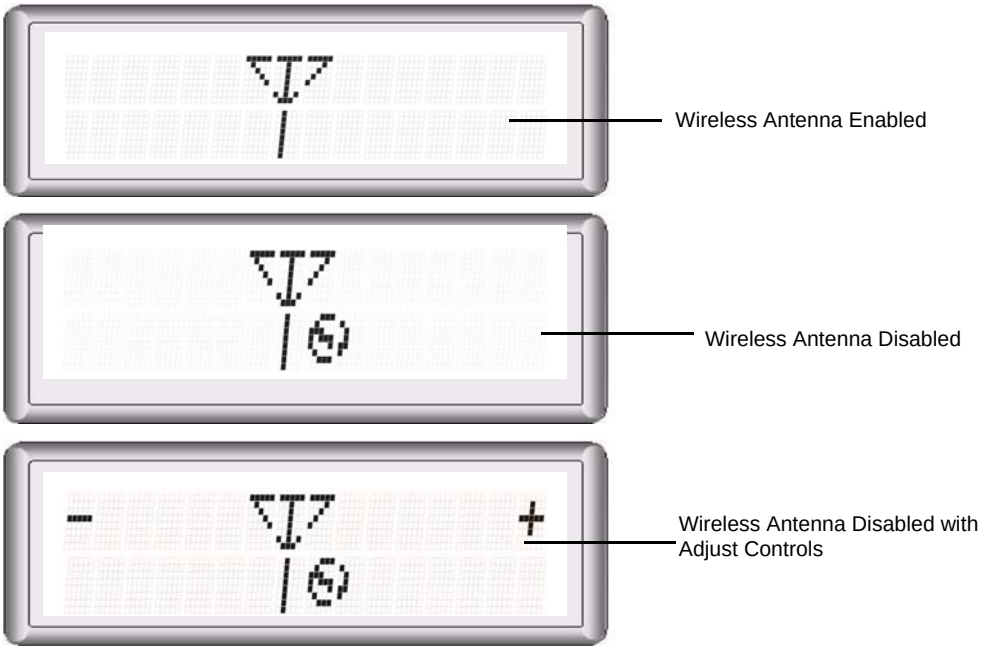


Figure B-4. Standard message screen 4: flow probe received amplitude

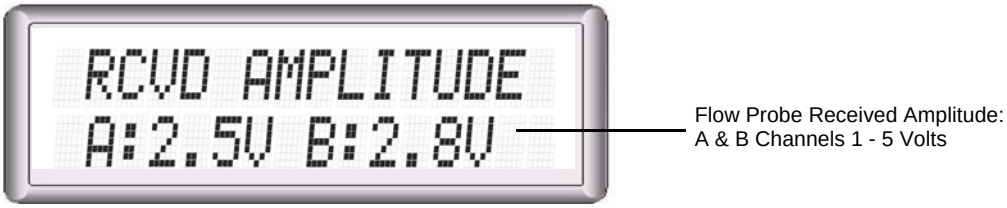


Figure B-5. Standard message screen 5: flow sensor status

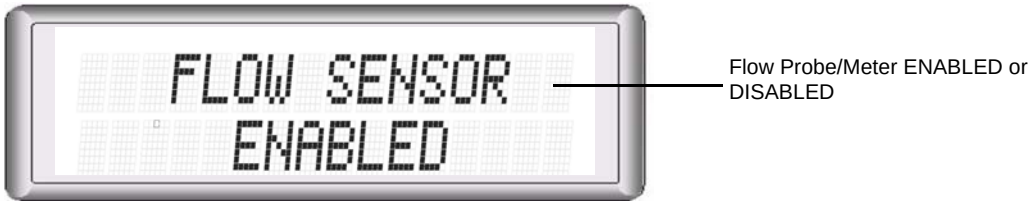


Figure B-6. Standard message screen 6: battery capacity

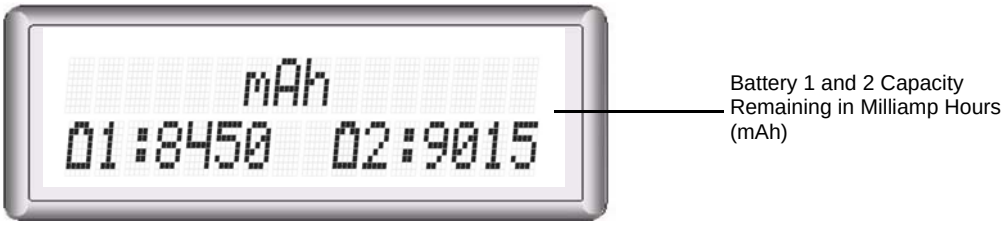
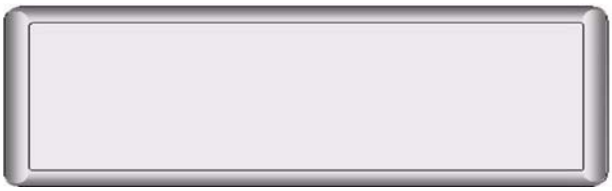


Figure B-7. Standard message screen 7: not used



Emergency alarms

The following subsections describe emergency alarms.

> The Controller indicates an emergency alarm with a fast, loud, two-tone ringing sound.

Emergency alarm 1: PUMP STOPPED

The VAD has stopped. The Controller immediately activates the restart algorithm for approximately 60 seconds. The LCD alternates between **PUMP STOPPED** and **PUMP RESTARTING** while the restart algorithm is activated.

> If the pump successfully restarts, the emergency alarm automatically clears.

Example

Figure B-8 displays an example of emergency alarm 1, **PUMP STOPPED**. This alarm indicates that the VAD is not running.

Figure B-8. Emergency alarm 1: PUMP STOPPED

User response

If the **PUMP STOPPED** alarm displays, take the following actions:

1. Allow the automatic restart algorithm to complete its cycle (within 60 seconds).
2. If the VAD does not restart automatically after 60 seconds, perform the following manual restart procedure:
   a. Disconnect the battery pockets from any external power sources (such as the Independent Power Supply).
   b. Briefly remove both batteries from the battery pockets.
   c. Re-insert one of the batteries into one of the battery pockets.

This procedure activates the restart algorithm, which triggers an additional nine automatic restart attempts.

3. If the VAD does not restart after performing the manual restart procedure, replace the Controller with the backup Controller.
4. Contact your support team immediately.

Emergency alarm 2: BOTH BATTERIES DISCONNECTED

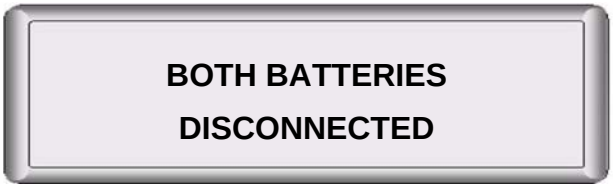
The Controller is not receiving power from either of the batteries.

Example

Figure B-9 displays an example of emergency alarm 2, **BOTH BATTERIES DISCONNECTED**.

This alarm indicates that either the batteries are not properly inserted in the battery pockets, the cables connecting the battery pockets and Controller are not secure or are damaged, or that the Controller is malfunctioning. The VAD is not running when this alarm is present.

Figure B-9. Emergency alarm 2: BOTH BATTERIES DISCONNECTED



User response

If the **BOTH BATTERIES DISCONNECTED** alarm displays, take the following actions:

1. Confirm that both batteries are properly inserted into the battery pockets.
2. Verify all cable connections.
3. If the VAD does not start, and the alarm does not clear automatically, replace the Controller with the backup Controller.

   This alarm clears automatically when the VAD restarts.

A Controller that is not receiving power alarms for approximately three minutes. This alarm cannot be silenced.

Emergency alarm 3: VAD DISCONNECTED

The VAD is not connected to the Controller.

Example

Figure B-10 displays an example of emergency alarm 3, **VAD DISCONNECTED**. This alarm indicates that the VAD is not running and is not connected to the Controller.

Figure B-10. Emergency alarm 3: VAD DISCONNECTED

User response

If the **VAD DISCONNECTED** alarm displays, take the following actions:

1. Unscrew the white defibrillation cover from the driveline cable.
2. Verify and, if necessary, reconnect the driveline cable to the Controller.
3. Verify that the VAD has restarted successfully.
4. If VAD does not restart, and the alarm does not clear automatically, replace the Controller with the backup Controller.
5. Contact your support team immediately.

Diagnostic alarms

The following subsections describe diagnostic alarms.

The Controller indicates a diagnostic alarm with a slow beeping sound.

Diagnostic alarm 1: EXCESS CURRENT

The VAD is drawing current in excess of the programmed alarm threshold.

This alarm does not silence or clear automatically. Press the Controller Alarm Silence button to clear this alarm.

Example

Figure B-11 displays an example of diagnostic alarm 1, **EXCESS CURRENT**.

Figure B-11. Diagnostic alarm 1: EXCESS CURRENT

User response

If the **EXCESS CURRENT** alarm displays, contact your support team immediately.

Diagnostic alarm 2: REDUCED FLOW RATE

The flow rate measured by the implanted flow probe has decreased below the programmed alarm threshold.

> This alarm does not silence or clear automatically. Press the Controller Alarm Silence button to clear this alarm.

Example

Figure B-12 displays an example of diagnostic alarm 2, **REDUCED FLOW RATE**.

Figure B-12. Diagnostic alarm 2: REDUCED FLOW RATE

User response

If the **REDUCED FLOW RATE** alarm displays, contact your support team immediately.

Diagnostic alarm 3: REDUCED MOTOR SPEED

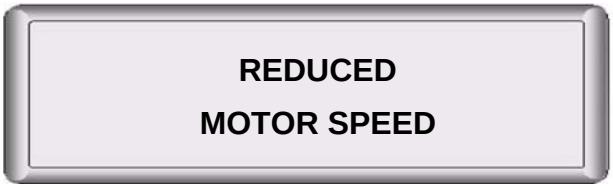
The speed (RPM) of the VAD has fallen below the programmed alarm threshold.

> This alarm does not clear automatically. Press the Alarm Silence button to clear this alarm.

Example

Figure B-13 displays an example of diagnostic alarm 3, **REDUCED MOTOR SPEED**.

Figure B-13. Diagnostic alarm 3: REDUCED MOTOR SPEED



User response

If the **REDUCED MOTOR SPEED** alarm displays, contact your support team immediately.

Diagnostic alarm 4: PUMP RESTARTING

The VAD has stopped and is attempting to restart. The message **PUMP RESTARTING** displays briefly during the restart attempt alternating with the **PUMP STOPPED** message.

Example

Figure B-14 displays an example of diagnostic alarm 4, **PUMP RESTARTING**.

Figure B-14. Diagnostic alarm 4: PUMP RESTARTING

User response

If the **PUMP RESTARTING** alarm displays, take the following actions:

1. Every two to three seconds, press the Alarm Silence button on the Controller, and verify that the flow rate, RPM, and power are normal.

   See Figure B-2 on page B-2. If the alarm silences, the VAD has restarted successfully.

2. Contact your support team immediately.

Diagnostic alarm 5: BATTERY 1 DISCONNECTED

Battery 1 is disconnected from the battery pocket as indicated on the Controller with a blinking amber light and an audible diagnostic alarm.

Example

Figure B-15 displays an example of diagnostic alarm 5: **BATTERY 1 DISCONNECTED**.

Figure B-15. Diagnostic alarm 5: BATTERY 1 DISCONNECTED

User response

If the **BATTERY 1 DISCONNECTED** alarm displays, take the following actions:

1. Verify that the battery is firmly seated into battery pocket 1.
2. Verify that the battery pocket connector is firmly inserted into the Controller connector for battery 1. This alarm clears automatically after you reconnect battery 1.
3. If alarm does not clear, contact your support team.

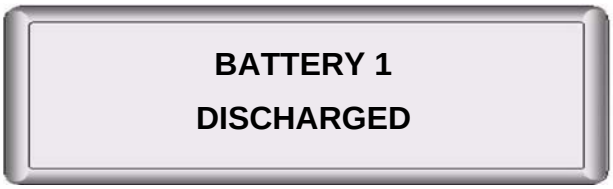
Diagnostic alarm 6: BATTERY 1 DISCHARGED

The battery plugged into battery pocket 1 has discharged below a 25% charge level, as indicated on both the Controller and the battery pocket with a blinking amber light and an audible diagnostic alarm.

Example

Figure B-16 displays an example of diagnostic alarm 6, **BATTERY 1 DISCHARGED**.

Figure B-16. Diagnostic alarm 6: BATTERY 1 DISCHARGED



User response

If the **BATTERY 1 DISCHARGED** alarm displays, take the following actions:

1. Replace the battery in battery pocket 1 with a fully charged battery.
2. Recharge the discharged battery.

This alarm clears automatically when you replace the discharged battery with a charged battery.

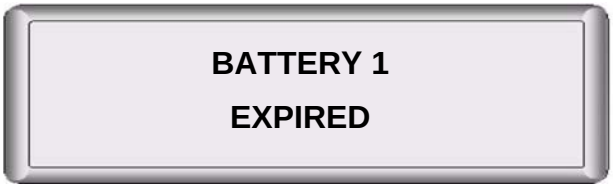
Diagnostic alarm 7: BATTERY 1 EXPIRED

The battery plugged into battery pocket 1 has discharged below 15%, or its voltage is too low, as indicated on both the Controller and battery pocket with a blinking amber light and an audible diagnostic alarm.

Example

Figure B-17 displays an example of diagnostic alarm 7, **BATTERY 1 EXPIRED**.

Figure B-17. Diagnostic alarm 7: BATTERY 1 EXPIRED



User response

If the **BATTERY 1 EXPIRED** alarm displays, take the following actions:

1. Replace the expired battery in battery pocket 1 with a fully charged battery.
2. Recharge the expired battery.

This alarm clears automatically after you replace the expired battery with a charged battery.

Diagnostic alarm 8: BATTERY 2 DISCONNECTED

Battery 2 is disconnected from the battery pocket as indicated on the Controller with a blinking amber light and an audible diagnostic alarm.

Example

Figure B-18 displays an example of diagnostic alarm 8, **BATTERY 2 DISCONNECTED**.

Figure B-18. Diagnostic alarm 8: BATTERY 2 DISCONNECTED

User response

If the **BATTERY 2 DISCONNECTED** alarm displays, take the following actions:

1. Verify that the battery is firmly seated into battery pocket 2.
2. Verify that the battery pocket connector is firmly inserted into the Controller connector for battery 2.

   This alarm clears automatically after you reconnect battery 2.

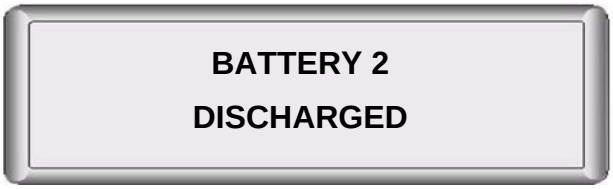
Diagnostic alarm 9: BATTERY 2 DISCHARGED

The battery plugged into battery pocket 2 has discharged below a 25% charge level, as indicated on both the Controller and the battery pocket with a blinking amber light and an audible diagnostic alarm.

Example

Figure B-19 displays an example of diagnostic alarm 9, **BATTERY 2 DISCHARGED**.

Figure B-19. Diagnostic alarm 9: BATTERY 2 DISCHARGED



User response

If the **BATTERY 2 DISCHARGED** alarm displays, take the following actions:

1. Replace the battery in battery pocket 2 with a fully charged battery.
2. Recharge the discharged battery.

   This alarm clears automatically when you replace the discharged battery with a charged battery.

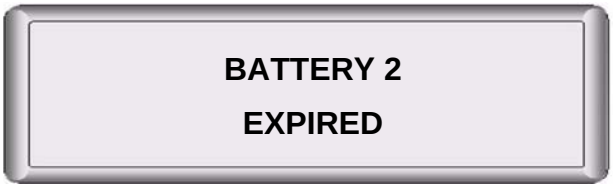
Diagnostic alarm 10: BATTERY 2 EXPIRED

The battery plugged into battery pocket 2 has discharged below 15%, or its voltage is too low, as indicated on both the Controller and the battery pocket with a blinking amber light and an audible diagnostic alarm.

Example

Figure B-20 displays an example of diagnostic alarm 10: **BATTERY 2 EXPIRED**.

Figure B-20. Diagnostic alarm 10: BATTERY 2 EXPIRED



User response

If the **BATTERY 2 EXPIRED** alarm displays, take the following actions:

1. Replace the expired battery in battery pocket 2 with a fully charged battery.
2. Recharge the expired battery.

   This alarm clears automatically when you replace the expired battery with a charged battery.

Controller failure alarms

The following section describes alarms that occur when the Controller ceases to function.

> Controller failure alarms are indicated by a continuous tone.

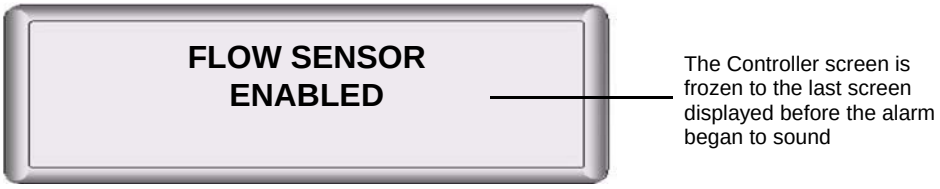
Controller failure alarm 1: fail-safe alarm

The fail-safe LED is lit solid red, a high-pitch continuous alarm sounds, the LCD display is frozen, and battery LEDs are lit. The VAD continues to run at the last set speed.

Example

When this alarm sounds, the Controller continues to display the same screen that was present when the fail-safe alarm began to sound.

Figure B-21. Controller failure alarm 1: fail-safe alarm (display frozen)



User response

1. Replace the Controller with the backup Controller.
2. Notify your support team of this event, and request a Controller replacement.

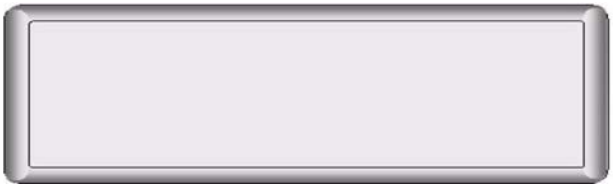
Controller failure alarm 2: Controller failure alarm

The LCD is off, the LEDs are off, and the Controller emits a high-pitch continuous alarm (not a beeping alarm). The Controller has failed internally. ***The VAD has stopped.***

Example

Figure B-22 displays an example of the Controller failure alarm. The Controller has a blank display when emitting this alarm.

Figure B-22. Controller failure alarm 2: (no display)



User response

1. Replace the Controller with the backup Controller immediately.
2. Notify your support team of this event immediately, and request a Controller replacement.

Appendix C
System Specifications

In this appendix

Introduction

This chapter presents information on the specifications for the HeartAssist 5® VAD System components. This chapter also presents information on the use of connecter cables and power cords, the proper replacement of fuses, and the essential performance of the HeartAssist 5® VAD.

The service life of the Controller and all accessories is three years.

HeartAssist 5® VAD specifications

Table C-1 describes the general specifications of the HeartAssist 5® VAD.

Table C-1. HeartAssist 5® VAD general specifications

General property	Specific property	Specification
Weight (without cannula)		92 grams
Size		30 mm x 76 mm
Material	VAD and internal components	Titanium
	Bearings	Ceramic
	Graft	Vascutek Gel Weave® (with titanium ring)
	Flow probe	Titanium, polyurethane, epoxy, polycarbonate polyurethane
	Percutaneous cable	Polycarbonate-polyurethane
	Graft protector	Ultra-high molecular-weight polyethylene
Flow accuracy		±10% when flow > 3 L/min; 0.3 L/min when flow is < 3 L/min
Range		–4.0 L/min to 10.0 L/min

Controller specifications

The following subsections describe the properties of the Controller.

General specifications

Table C-2 describes the general specifications of the Controller.

Table C-2. Controller general specifications

Property	Specification
Classification	Internally powered, type CF, defibrillation proof
Ingress protection	IP32
Weight	2.7 kg (6 lbs) – (with two battery pockets & two batteries)
Dimensions	16.5 cm x 8.9 cm x 5.1 cm (6.5 in x 3.5 in x 2.0 in)
Programmed pump speed	7500 (±200) to 12500 (±200) RPM
Battery type	Lithium Ion (Li-ON)
Power required	Range: 0 – 40 W ±10%
Alarm sound pressure	60 – 80 db

Interface features

Patients, caregivers, and support staff use the Controller by interacting with the following features.

- Battery indicators
- Fail-safe and emergency mode indicator LED
- LCD display
- Programmable language
- Real-time clock
- Alarm Silence button
- Scroll Display button
- Battery status indicators

Safety features

The Controller includes the following features to ensure patient safety.

- Automatic fail-safe and emergency mode LED (with status)
- Automatic pump restart algorithm
- Automatic diagnostic tests at start-up
- Diagnostic visual and audible alarms
- Emergency visual and audible alarms
- Built-in data acquisition
- Patient information stored in nonvolatile memory

Wireless antenna specifications

You can use the wireless antenna in all markets where Quadband GSM (850/900/1800/1900 MHz) is available.

The wireless transmission of data is not a requirement for the Controller to fulfill its intended use or to meet its indications for use.

HeartAttendant® specifications

The following subsections describe the HeartAttendant® properties.

General specifications

Table C-3 describes the general specifications of the HeartAttendant®.

Table C-3. HeartAttendant® general specifications

Property	Specification
Weight	11.34 kg (25 lbs)
Dimensions	55.88 cm x 48.25 cm x 45.72 cm (22 in x 19 in x 18 in)
External indicators	LED display
External control	Touch screen

Safety features

The HeartAttendant® includes the following features to ensure patient safety.

- Fault tolerant operating system
- 5,000 volt defibrillation protection
- Password protection to VAD controls and operating system

Electrical specifications

Table C-4 describes the HeartAttendant® electrical specifications.

Table C-4. HeartAttendant® electrical specifications

Property	Specification
Input voltage	120/240 VAC 60/50 Hz
Maximum current	3.0/1.5 A
Equipment type	Type CF, defibrillation proof, Class 1
EMI/RFI	Class A device
Operation	Continuous duty

Replacement and accessory part list (fuses)

Table C-5 lists the HeartAttendant® replacement and accessory parts and their part numbers. See “Connecter cables, power cords, and fuses” for instructions on obtaining replacement fuses.

Table C-5. HeartAttendant® part list

Part description	Part number
Fuse (US)	5 x 20 mm 120 V / 4 AMP slow blow
Fuse (Europe)	5 x 20 mm 240 V / 3 AMP slow blow

VADPAK and VADPAK Insert specifications

Table C-6 describes VADPAK and VADPAK Insert properties.

Table C-6. VADPAK specifications

Property	Specification
VADPAK Bag	
Weight	1.81 kg (4.0 lb) (with batteries, battery pockets and controller)
Dimensions	27.94 cm x 10.16 cm x 21.59 cm (11 in x 4.0 in x 8.5 in)
Materials	Cordura 500D Black, Cordura 500D Foliage, Soft Tex Skid Resistant
VADPAK Insert	
Weight	1.81 kg (4 lb) (with batteries, battery pockets and controller)
Dimensions	25.4 cm x 20.32 cm x 17.78 cm (10 in x 8 in x 7 in)
Materials	Cordura 500D Black, 0.125 Corrugated Plastic

Independent Power Supply specifications

The following subsections describe the Independent Power Supply properties.

General specifications

Table C-7 describes the general properties of the Independent Power Supply.

Table C-7. Independent Power Supply general specifications

Property	Specification
Weight	0.45 kg (1 lb)
Dimensions	4.80 cm × 12.07 cm × 7.62 cm (1.89 in × 4.75 in × 3.00 in)
External indicators	Power indicator light (green LED)

Property	Specification
Ingress protection	IPX1

Safety features

The Independent Power Supply includes output protection from short circuit and overload to ensure patient safety.

Electrical specifications

Table C-8 describes the Independent Power Supply electrical specifications.

Table C-8. Independent Power Supply electrical specifications

Property	Specification
Input voltage	90-264 VAC; 47-63 Hz; 60 W
Maximum voltage	13.5 Vdc; 4.3 A
Equipment type	Type CF; Defibrillation proof; Class 1
EMI/RFI	Class B device
Operation	Continuous duty

Lithium ion battery specifications

The following subsections describe the lithium ion battery properties.

General specifications

Table C-9 describes the general properties of the lithium ion battery.

Table C-9. Lithium ion battery general specifications

Property	Specification
Weight	0.45 kg (1 lb)
Dimensions	14.05 cm × 8.86 cm × 2.00 cm (5.53 in × 3.49 in × 0.79 in)
External indicators	LED indicator icon (fuel gauge)
Charge percentage	Range: 0 – 100% ±10%
Charge time remaining	Range: 0:00 – 7:30 hours ±10%
Battery capacity	Range: 6000[a] – 7800 mAh ±10%

a Recommended battery replacement level specified by ReliantHeart.

Safety features

The lithium ion battery includes a discharge cutoff of 9.0 V to ensure patient safety.

Electrical specifications

Table C-10 describes the lithium ion battery electrical specifications.

Table C-10. Lithium ion battery electrical specifications

Property	Specification
Input voltage	10.8 V
Maximum voltage	4000 mA (under 30 °C) 3000 mA (over 30 °C)
Equipment type	Type BF
Operation	Continuous duty

LVAD Battery Charger specifications

The following subsections describe the LVAD Battery Charger properties.

General specifications

Table C-11 describes the general properties of the LVAD Battery Charger.

Table C-11. LVAD Battery Charger general specifications

Property	Specification
Weight	0.71 kg (1.56 lb)
Dimensions	17.15 cm × 11.05 cm × 5.03 cm (6.75 in × 4.35 in × 1.98 in)
External indicators	LED indicators (green and amber)
External control	Recalibration button

Electrical specifications

Table C-12 describes the LVAD Battery Charger electrical specifications.

Table C-12. LVAD Battery Charger electrical specifications

Property	Specification
Input voltage	18 VDC
Maximum current	1.8 A
Equipment type	Type BF, Class III
EMI/RFI	Class III
Operation	Intermittent duty

Connecter cables, power cords, and fuses

Only use ReliantHeart-supplied power cords and connecter cables with the HeartAssist 5® VAD System. Contact ReliantHeart to obtain the proper replacement power cords or connecter cables for your geographical area.

Ensure appropriate fuse usage by obtaining replacement fuses from ReliantHeart. See “Customer support” on page iii for contact information.

Essential performance of the HeartAssist 5® VAD

The HeartAssist 5® VAD operates, without stoppage, at the preset speed.

Appendix D

Manufacturer Guidance for Environmental Conditions

In this appendix

Introduction

The following sections outline the ReliantHeart manufacturer's guidance and declarations for the components of the HeartAssist 5® VAD System.

Electromagnetic emissions

The HeartAssist 5® Controller, HeartAttendant®, battery pockets, batteries, Independent Power Supply, and Controller connector cable are intended for use in the electromagnetic environment specified in Table D-1. The customer or the user of these components must ensure that they are used in such an environment.

Table D-1. Electromagnetic emissions guidance and manufacturer's declaration for all ME equipment and ME systems

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	These components use RF energy only for their internal functions. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	These components are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

The Controller, HeartAttendant®, battery pockets, batteries, Independent Power Supply and Controller connector cable are intended for use in the electromagnetic environment specified in Table D-2 and Table D-3. The customer or the user of these components must ensure that they are used in such an environment.

Table D-2. Electromagnetic immunity guidance and manufacturer's declaration for all ME equipment and ME systems

Immunity test	IEC 60601 test level	Compliance	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±15 kV air	The relative humidity should be at least 10%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance	Electromagnetic environment—guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T[a] (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of this equipment requires continued operation during power mains interruptions, ReliantHeart recommends powering this equipment from an uninterruptible power supply (UPS) or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	10 *A/m*	60 *A/m*	Based on the compliance level of 60 *A/m* for power frequency magnetic field, the appropriate separation distance can be calculated based upon the current in the power risers using the following formula: $r = \frac{I}{377}$ Where I is the maximum current in amperes in the mains cable, and *r* is the recommended minimum separation distance (in meters). An example for calculating the separation distance for a *100 A* power bus would be as follows: $r = \frac{100\,A}{377}$ In the example above, the recommended separation distance would be about 27 cm.

a U_T is the AC mains voltage prior to application of the test level.

Table D-3. < Radio Frequency Susceptibility (Radiated and Conducted) and Electrostatic Discharge >

Immunity Test	RTCA/DO 160F Test Level	Compliance
Radiated Susceptibility RTCA/DO-160F Section 20	20V/m 100 to 400 MHz	Yes
Radiated Susceptibility RTCA/DO-160F section 20	150V/m 400 MHz to 8 GHz	Yes
Air Discharge RTCA/DO-160F Section 25	15kV	Yes

Compliance indicates that the device did not malfunction while subjected to the listed test levels.

Table D-4. Electromagnetic immunity guidance and manufacturer's declaration for all life supporting ME equipment and ME systems

Immunity test	IEC 60601 test level	Compliance	Electromagnetic environment—guidance
			Portable and mobile RF communications equipment should be used no closer to any part of this equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 *Vrms* 150 kHz to 80 MHz Outside ISM bands[a]	3 *V*	Recommended Separation Distance $d = 1.2\sqrt{P}$
	10 *Vrms* 150 kHz to 80 MHz in ISM bands[a]	10 *V*	Recommended Separation Distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 *V/ m* 80 MHz to 2.5 GHz	10 *V/ m* 80 MHz to 400 MHz	Recommended Separation Distance: 80 MHz to 400 MHz $d = 1.2\sqrt{P}$
		20 *V/ m* 400 MHz to 3.5 GHz	Recommended Separation Distance: 400 MHz to 800 MHz $d = 1.2\sqrt{P}$
			Recommended Separation Distance: 800 MHz to 3.5 GHz $d = 0.6\sqrt{P}$
			Recommended Separation Distance: 800 MHz to 3.5 GHz $d = 1.2\sqrt{P}$
			Where *P* is the maximum output power rating of the transmitter in watts (*W*) according to the transmitter manufacturer, and *d* is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [c]; should be less than the compliance level in each frequency range[d]. Interference can occur in the vicinity of equipment marked with the following symbol: 

a The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 27,957 MHz to 27,283 MHz; and 40.66 MHz to 40.70 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

Immunity test	IEC 60601 test level	Compliance	Electromagnetic environment—guidance

c No accurate theoretical prediction of field strength from fixed transmitters such as base stations for radio, cellular and cordless telephones, land mobile radios, amateur radios, AM and FM radio broadcasts, and TV broadcasts is possible. To assess the electromagnetic environment due to fixed RF transmitters, consider an electromagnetic site survey. If the measured field strength in the location in which this equipment is used exceeds the applicable RF compliance level listed in Table D-3, observe the equipment to verify normal operation. If you observe abnormal performance, additional measures might be necessary, such as reorienting or relocating this equipment.

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

At 400 MHz and 800 MHz, the higher frequency range applies.

These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Recommended separation distance between portable and mobile RF communications equipment and the Controller, HeartAttendant®, battery pockets, Independent Power Supply, and batteries

This equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile communications equipment (transmitters) and this equipment as recommended in Table D-4, according to the maximum output power of the communications equipment.

Table D-5. Recommended separation distance between portable and mobile RF communications equipment and the life-supporting ME equipment and ME systems

Separation distance according to frequency of transmitter *m*					
Rated maximum output power of transmitter	**150 kHz to 80 MHz outside ISM bands**	**150 kHz to 80 MHz in ISM bands**	**80 MHz to 400 MHz**	**400 MHz to 800 MHz**	**800 MHz to 3.5 GHz**
W	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 0.6\sqrt{P}$	$d = 1.2\sqrt{P}$
0.01	0.12	0.12	0.12	0.06	0.12
0.1	0.38	0.38	0.38	0.19	0.38
1	1.2	1.2	1.2	0.6	1.2
10	3.8	3.8	3.8	1.9	3.8
100	12	12	12	6	12

For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in meters (***m***) can be determined using the equation applicable to

the frequency transmitter, where ***P*** is the maximum output power rating of the transmitter in watts (***W***) according to the transmitter manufacturer.

	At 400 MHz and 800 MHz, the separation distance for the higher frequency range applies.
	The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40.66 MHz to 40.70 MHz.
	An additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile or portable communications equipment could cause interference if it is inadvertently brought into patient areas.
	These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
	The HeartAttendant® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the HeartAttendant® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HeartAttendant® as recommended in Table D-4, according to the maximum output power of the communications equipment.
	Use of equipment and supplies other than those specified in this manual or sold by ReliantHeart for replacement parts could affect the electromagnetic compatibility of the HeartAssist 5® VAD with other devices, resulting in potential interference between the HeartAssist 5® VAD and other devices.
	The HeartAttendant® must be kept at least one foot away from electrical appliances (such as kitchen appliances).

Requirements applicable to ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation (60601-1-2, 5.2.2.5)

For ME EQUIPMENT and ME SYSTEMS that intentionally receive FR electromagnetic energy for the purpose of their operation, the ACCOMPANYING DOCUMENTS shall include the following information:

a. Each frequency or frequency band of reception; the preferred frequency or frequency band, if applicable, and the bandwidth of the receiving section of the ME EQUIPMENT or ME SYSTEM in those bands.

The conquest controller may receive the following frequency ranges:

- 869.2 MHz to 894.2 MHz

- 935 MHz to 960 MHz
- 1805.2 MHz to 1879.8 MHz
- 1930.2 MHz to 1989.8 MHz

For operation in North America, the conquest controller will be fitted with an antenna which is optimized to receive frequencies in the GSM 850 and GSM 1900 frequency bands which have a range of 869.2 to 894.2 MHz and 1930.2 to 1989.8 MHz.

Use of equipment and supplies other than those specified in this manual or sold by ReliantHeart for replacement parts could affect the electromagnetic compatibility of the HeartAssist 5® VAD with other devices, resulting in potential interference between the HeartAssist 5® VAD and other devices.

Requirements applicable to ME EQUIPMENT and ME SYSTEMS that include RF transmitters (60601-1-2, 5.2.2.6)

For (Conquest Controller) ME EQUIPMENT and (VAD System) ME SYSTEMS that include RF transmitters, the ACCOMPANYING DOCUMENTS shall include each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the EFFECTIVE RADIATED POWER.

RF Power Output 850MHz band

Limit: FCC: Nominal Peak Output Power < 38.45 dBm (7W)

IC: Nominal Peak Output Power < 40.60 dBm (11.5W) GSM Cellular 850 (GMSK Mode)

Frequency (MHz)	Radiated Power ERP (dBm)
824.2	30.5
836.6	31.2
848.8	30.3

RF Power Output 1900MHz band

Limit: Nominal Peak Output Power < 33 dBm (2W) GSM PCS 1900 (GMSK Mode)

Frequency (MHz)	Radiated Power EIRP (dBm)
1850.2	29.1
1880.0	29.3
1909.8	27.7

The HeartAssist 5® VAD System has been tested and found to comply with IEC 60601-1-2:2007 Medical Electrical Equipment - Part 1-2 General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility. This testing shows the device provides reasonable protection against interference in a typical medical installation.

The HeartAssist 5® VAD can generate, use, and radiate radio frequency energy and, if not installed and used in accordance with the instructions, can cause interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference to other devices or is negatively impacted by other devices, the user is encouraged to attempt to correct the interference by one or more of the following measures:

- Reorient or relocate devices.
- Increase the separation between devices.

- Connect the equipment to an outlet on a different circuit.
- Consult the manufacturer or technical support engineer for help.

The HeartAssist 5® VAD System requires special precautions regarding electromagnetic compatibility (EMC), and you must install it and put it into service according to the EMC information provided in this appendix.

Portable and mobile RF communications equipment can affect the HeartAssist 5® VAD System.

FCC statements

ReliantHeart has issued the following statements regarding the HeartAssist 5® VAD System wireless transmitter.

The following FCC statements apply to Model: CTL002

FCC ID: 2AB4ZCTL002.

Statement according to FCC part 15.19

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.

Statement according to FCC part 15.21

Modifications not expressly approved by, ReliantHeart could void the user's authority to operate the equipment.

Statement according to FCC part 15.105

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Radio frequency radiation exposure information:

This phone has been tested and meets the FCC RF exposure guidelines for body worn operations with zero distance. It shall be used with the ReliantHeart accessories supplied or designated for this product and as documented within this manual. Use of other accessories may not ensure compliance with the FCC RF exposure guidelines.

R&TTE Declaration of Conformity

Hereby, ReliantHeart declares that the Controller is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

To obtain an English copy of the Declaration of Conformity, write to the address below:

ReliantHeart
8965 Interchange Drive
Houston, TX 77054

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