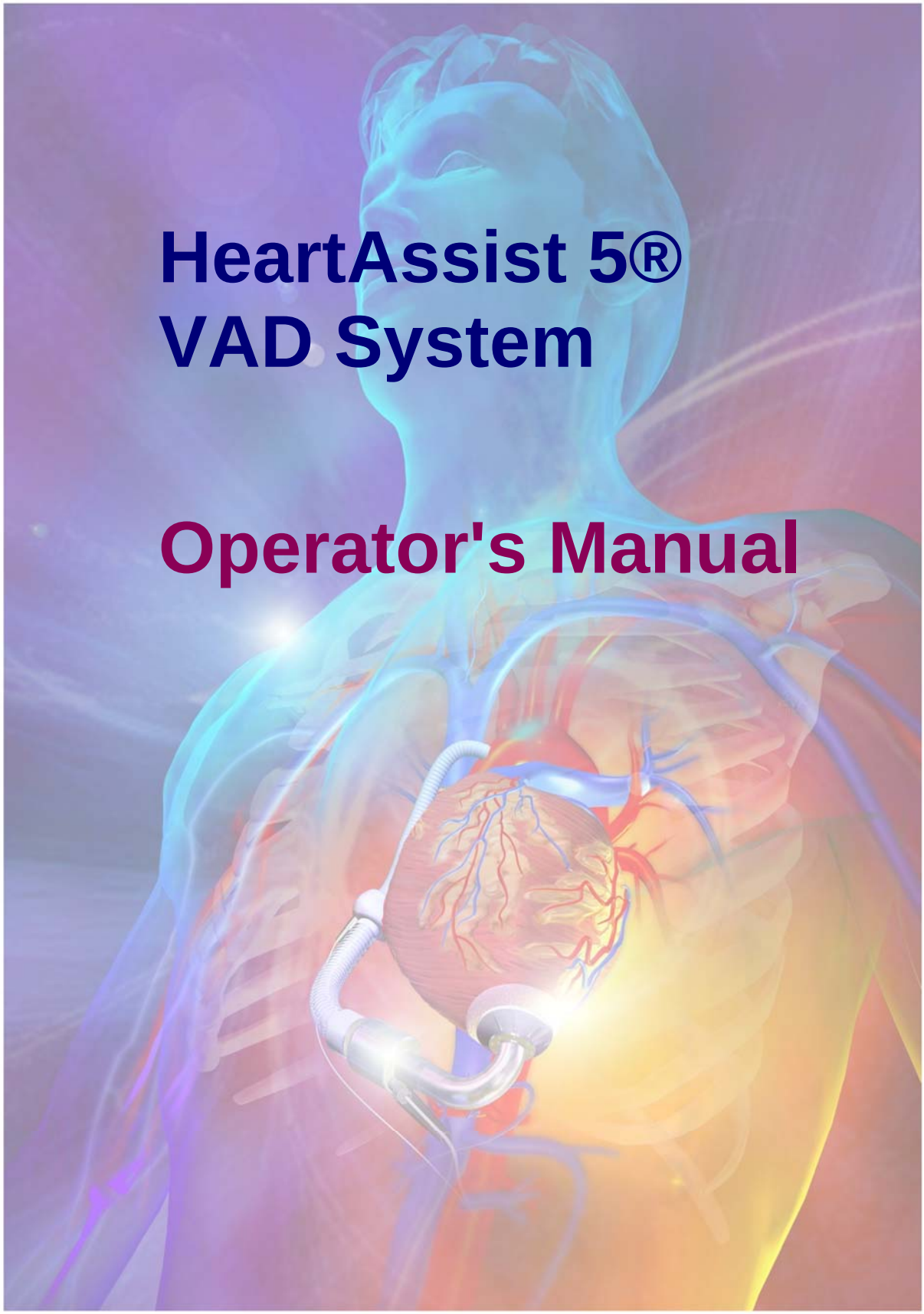
RELIANTHEART



HeartAssist 5®
VAD System

Operator's Manual

For use with Controller Model: CTL001

L00101-01 Rev Z 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.

CE **0086** CE marked since November 2013

Customer support

Use the contact information below to reach ReliantHeart.

International

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  5405 BE

  Uden, The Netherlands

  Phone +31 413 245 107

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

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  Bretforton

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  Worcs WR11 7JJ

  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

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  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

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Warnings

General warnings

The following warnings do not appear elsewhere in this manual.

Warnings indicate possible bodily injury or death.

- Surgeons and participating staff members must complete the manufacturer's prescribed training course before implanting the device or managing device patients.
- Do not implant the HeartAssist 5® VAD (VAD) in patients who cannot tolerate anticoagulation therapy.
- Assess female patients of childbearing age for pregnancy prior to implant, and provide counseling for birth control for the duration of the patient's time on VAD support.
- Carefully evaluate patients for the presence of intraventricular thrombus, and when intraventricular thrombus is identified, thoroughly clean the ventricle prior to implanting the VAD.
- Patients with previous sternotomy and patients who are receiving immunosuppressive therapy can have an increased risk of perioperative complications when implanting the VAD.
- VAD implant in patients with vascular impairment of major organ systems can increase technical difficulty of the procedure and adversely affect post-implant outcomes.
- VAD implantation in patients with end-stage renal disease can increase perioperative risks and adversely affect outcome.
- Assess the need for aneurysmectomy and removal of intraventricular thrombus prior to implant in patients with severe left ventricular dilatation (LVID > 85 mm).
- Patients with prosthetic aortic valves might have an increased risk of thromboembolism due to blood flow shunted away from the valve and decreased washing of valve leaflets. Prior to VAD implant, consider valve replacement or repair with a tissue valve for patients with 1.5+ aortic regurgitation or with mechanical prosthetic valves.
- Remove entrapped air from the VAD and conduits prior to releasing the outflow graft cross-clamp in order to reduce the risk of air embolus.
- When beginning to wean the patient from cardiopulmonary bypass, allow a minimum of two liters per minute of blood flow to pass through the ventricle and the pump in order to eliminate the possibility of entraining air.
- Maintain left atrial pressure at a level greater than 10 mm Hg in order to reduce the potential for entrained air.
- Patients can develop hemolysis while on VAD support. Monitor laboratory parameters including hemoglobin, reticulocyte count, plasma free hemoglobin, and serum haptoglobin. In order to minimize the potential for hemolysis, avoid conditions favoring ventricular collapse, and run the pump at the lowest speed that produces the desired hemodynamic result.
- Currently, no validated method for assessing the effects of continuous flow on regional renal blood flow in animals or patients with advanced heart failure is available. Closely monitor patients for potential renal dysfunction and renal infarction throughout device support.

- Use aseptic technique when changing the exit site dressing.
- Always keep the Controller in either the surgery pouch or the VADPAK to prevent thermal injury.
- Avoid prolonged direct contact between the Controller and battery pockets and the patient's 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.
- Do not use the HeartAttendant® near water or during patient bathing due to the risk of electrical shock.
- Do not expose the patient to therapeutic levels of ultrasound energy, as the VAD can inadvertently concentrate the ultrasound field and could cause harm. Medical personnel can safely perform diagnostic ultrasound such as transesophageal echocardiogram and surface echocardiograms of the chest and abdomen.
- If the patient is exposed to diathermy or therapeutic ionizing radiation, you must monitor pump performance during the initial stages of treatment.
- **Do not disconnect the VAD from the Controller. The VAD pump stops. The Controller must be reconnected as quickly as possible to resume VAD function.**
- The Controller's internal capacitors only run the CPU and the alarms for approximately three minutes unassisted by another power source. The capacitors do not run the VAD. If both batteries are disconnected or depleted, the VAD stops (unless it is connected to an external power source such as the HeartAttendant® or the Independent Power Supply).
- Do not use the HeartAttendant® or the Independent Power Supply with ventricular assist devices other than the HeartAssist 5® VAD System.
- Do not use the HeartAttendant® or the Independent Power Supply in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Inspect sterile packages before opening. If the seal is broken, the contents might not be sterile and can lead to infection.
- Ensure adequate left ventricular filling to prevent ventricular collapse.
- Medical personnel can perform defibrillation while the patient is connected to the HeartAttendant® or to the two batteries in the battery pockets or the Independent Power Supply.
- Do not attach the surgery pouch to the bed rail while the surgery pouch contains the Controller. The motion of lowering and elevating the bed rail can damage cables.
- If the VAD stops operating or operates at a speed of less than 7,500 RPM, the patient must seek immediate medical attention to treat the potential physiologic consequences of regurgitant flow. Treatment measures can include heparinization, standard interventions for acutely decompensated congestive heart failure, or surgical exploration.
- Only use batteries supplied by ReliantHeart.
- Disconnect the power cord from the power source before changing fuses in the HeartAttendant®.
- Do not open the back cover of any ReliantHeart device.
- Do not use the HeartAssist 5® VAD System adjacent to other equipment or in a stacked configuration with other equipment. Verify normal operation of the VAD when used in these configurations.
- Before allowing the patient to leave the hospital, ensure that the backup Controller has been preprogrammed to same speed as the main Controller.
- The VAD is a continuous flow device and operates until all power sources are removed.

- Ensure that the patient is receiving power from the HeartAttendant®, the Independent Power Supply, or from the two batteries in the VADPAK Insert.
- The use of expired or defective batteries can result in reduced operating time or abrupt loss of VAD function.
- If a power failure is expected to last for an extended period of time, take the patient, the Independent Power Supply, the LVAD Battery Charger, and all batteries to the nearest location with suitable mains (AC) power.
- Keep all liquids away from equipment to avoid accidental spills. Do not put any part of this equipment under water or in or near other liquids. Contact with liquids increases the risk of electrical shock and of damage to the equipment.
- 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 the outlets in the patient's home are not grounded, an electrician must install grounded outlets before the patient can use this equipment outside of the hospital.
- 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 use by or on the order of a physician or properly licensed practitioner.
- Do not attempt to make any changes to system software of the HeartAttendant or Controller or to use the HeartAttendant device as a laptop computer. Any modification, or attempt to modify, the operating system software could render this device nonfunctional for its intended use.
- Do not use the HeartAttendant® outside of the hospital unless the following requirements can be met: 120 volts, 60 Hz, and 3 amps; or 230 volts, 50 Hz, and 2 amps.
- Avoid placing or operating the HeartAttendant® in areas or near appliances that expose it to temperatures outside of its operating range of 10 °C (50 °F) to 40 °C (104 °F).
- 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).
- Avoid placing or operating the Controller or HeartAttendant® in areas or near appliances that expose either device to temperatures outside of the operating range of the device, which is –10 °C (14 °F) to 40 °C (104 °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 obstruct the fans or the ventilation holes on the HeartAttendant® or other components. Keep these areas clear so that air can circulate. Overheating can cause the batteries to take longer to recharge and can cause heat to build up and damage the equipment.
- Rechargeable batteries must be fully charged prior to beginning the implantation procedure to allow patient transfer following the procedure.
- Flow probe wires must point in the direction of the pump when in the implant position.
- If any HeartAssist 5® VAD System device component produces unexpected changes in function, evaluate the environment for sources of electrical or electromagnetic disturbances. If you discover a source of electrical or electromagnetic disturbance, either remove the source of the disturbance or move the patient to a location free of such disturbances.
- Disconnect the battery pockets from the external power source (the HeartAttendant®, the IPS – Independent Power Supply) before unplugging the external power source from the wall or vehicle power receptacle.
- Batteries not being used in the battery pockets should always be charging in the LVAD Battery Charger while the patient is in tethered mode (connected to external power).
- Connecting batteries other than indicated can result in permanent damage to the LVAD Battery Charger.
- Do not invert the cabinet of the LVAD Battery Charger while installing batteries.

- 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.
- The Controller must always be placed in the surgery pouch (with one battery) or the VADPAK Insert to promote proper cooling of the Controller and to eliminate potential harm to the patient.
- Handle the percutaneous cable from the patient to the Controller with care to prevent damage.
- Handle all connectors with care and keep them free of liquid, dust, and debris.
- Do not expose the HeartAttendant® to moisture.
- Do not submerge the VADPAK in liquid or expose it to moisture or heat. Submerging the VADPAK or exposing it to moisture or heat can cause it to malfunction. During showers, the patient must use the shower bag to prevent exposure to moisture.
- Clean the HeartAttendant®, the LVAD Battery Charger, and the Independent Power Supply by first disconnecting the equipment from the power source, then wiping the component with a damp cloth, then wiping the component with another cloth dampened with isopropanol alcohol to remove contaminants.
- Do not drop the HeartAttendant®, the Controller, the LVAD Battery Charger, the Independent Power Supply, or the batteries on any hard surface. Dropping any of these units can damage internal components causing the device to malfunction.
- Ensure that the mains (AC) input voltage is appropriate for the local power source.
- Do **not** use extension cords with any ReliantHeart device.
- Do not service this equipment. Only qualified personnel can service this equipment. If service is required, contact ReliantHeart.
- Do not dispose of any ReliantHeart equipment. Return all equipment to ReliantHeart.
- Do not set alarm thresholds to extreme values that can render the alarm system useless
- 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 2
System Overview

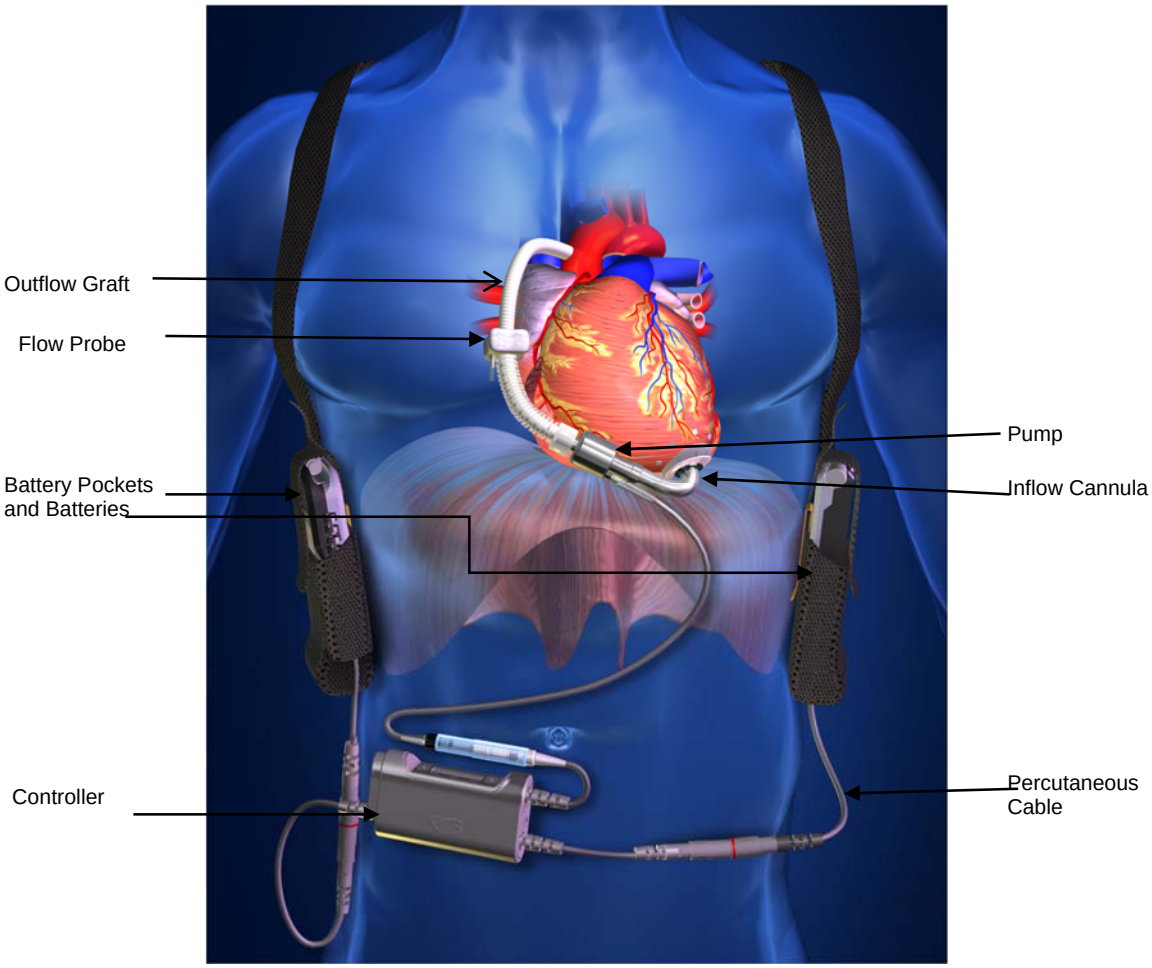
In this chapter

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 2-1. The HeartAssist 5® VAD System



System components

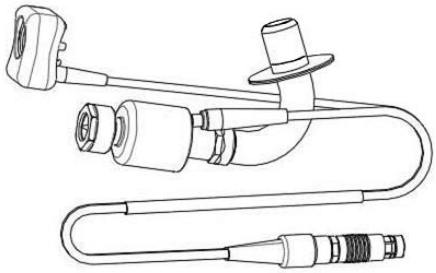
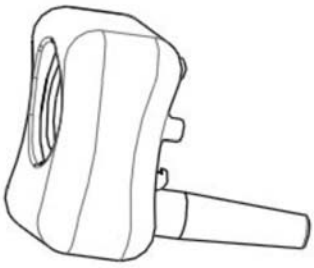
The HeartAssist 5® VAD System consists of implantable components, wearable components, and accessories as well as patient and hospital documentation.

Tables 2-1 through 2-4 list the components that are used throughout your time on VAD support.

Implantable components

Table 2-1 lists the implanted HeartAssist 5® VAD System components.

Table 2-1. Implantable components

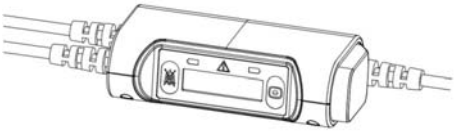
Component	Description	Example
HeartAssist 5® VAD (VAD)	The VAD with inflow cannula, wedge nut, flow probe, and percutaneous cable attached. The VAD is connected to the heart via the inflow cannula, which is inserted into the apex of the left ventricle. A three-phase electric motor is integrated in the 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.	

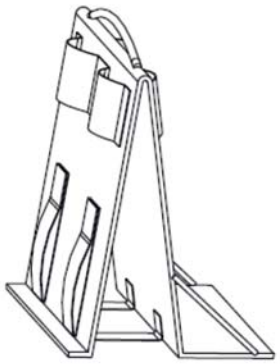
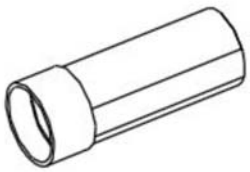
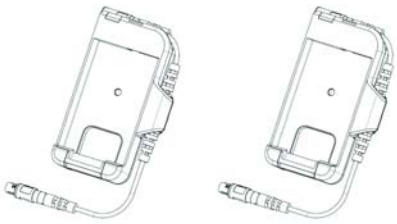
Component	Description	Example
Sewing ring	The sewing ring is a silicone ring wrapped in polyester with drawstring Prolene “0” sutures used to attach the inflow cannula to the apex of the left ventricle.	

Wearable components

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

Table 2-2. 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.	

Component	Description	Example
VADPAK	The VADPAK carries the VADPAK Insert, which contains the Controller and two battery pockets with batteries inserted.	
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.	

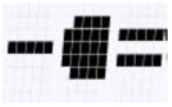
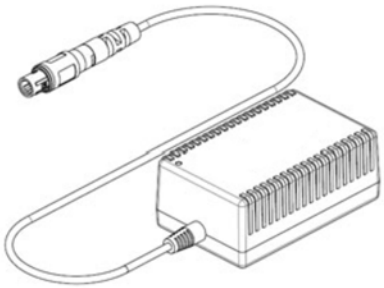
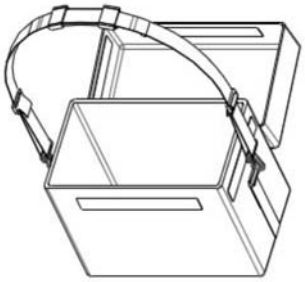
Accessories

Tables 2-3 and 2-4 describe the patient and hospital accessories available for the HeartAssist 5® VAD System.

Patient accessories

Table 2-3 lists the HeartAssist 5® VAD System patient accessories.

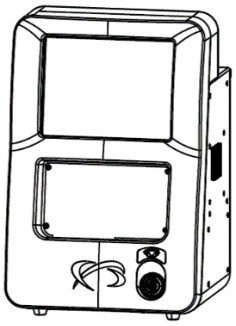
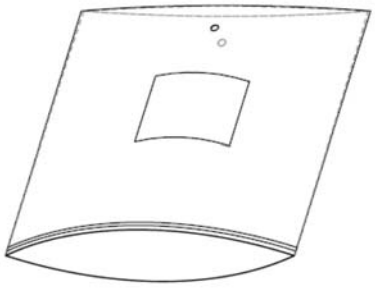
Table 2-3. Patient accessories

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 2-4 lists the components used by the hospital staff.

Table 2-4. Hospital accessories

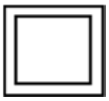
Component	Description	Example
HeartAttendant®	The HeartAttendant® is used to program the Controller, displays VAD performance and data, and provide mains (AC) power to the Controller. It can transmit data via an internet connection. This device is password protected. It is connected to the Controller 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 2-5 lists the symbols used in ReliantHeart product labeling and provides a description of their meaning.

Table 2-5. 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
	CE mark
	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
	Fragile
	General caution
	General warning
	Item showing sterilization method: ethylene oxide

Symbol	Description
	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
	See instructions for use
	If batteries are part of an ongoing clinical trial, contact customer support (see page iii); otherwise, dispose of batteries in accordance with “Disposal”.
	MR Unsafe

Documentation

Table 2-6 lists the documentation available for the HeartAssist 5® VAD System.

Table 2-6. HeartAssist 5® VAD System documentation set

Document	Audience	Description
The HeartAssist 5® VAD System Patient User's Manual	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 (this book)	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 3
Initial Setup, Testing and Surgery

In this chapter

Introduction

This chapter provides information on HeartAttendant® setup; preoperation, operation, and postoperation procedures; patient management; patient discharge; equipment service; and explantation.

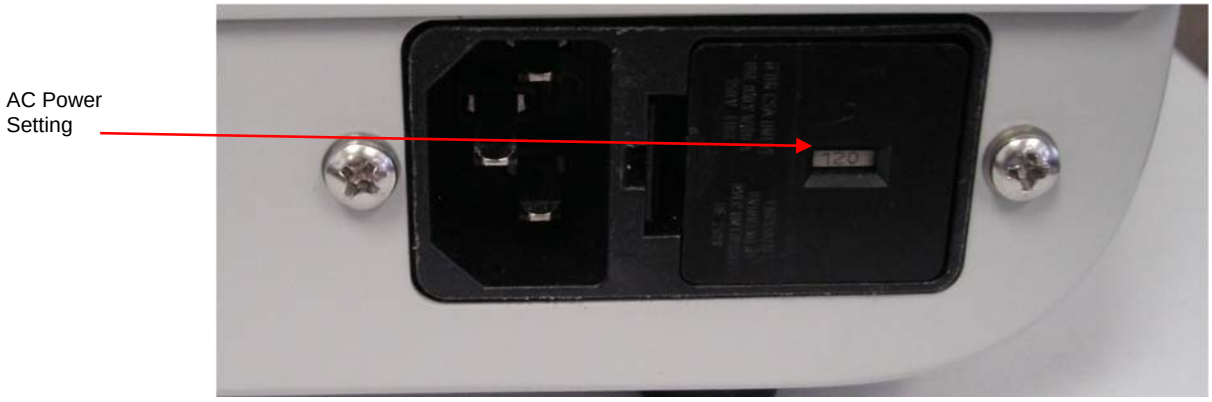
Setting up the HeartAttendant®

The HeartAttendant® ships with the AC power setting appropriate to the country of use, preset for either North America 115VAC or Europe 230VAC. Use the following steps to verify the AC power setting and to activate the HeartAttendant®.

1. Check the AC power input on the back of the HeartAttendant® to ensure that the power setting is appropriate.

   See Figure 3-1. If the setting is not appropriate, contact ReliantHeart.

   Figure 3-1. AC power setting



2. Plug the main power cord into the AC power input on the back of the HeartAttendant®.
3. Plug the power cord into the AC power source.

   The HeartAttendant® should boot up to the **PATIENT** screen within 40 seconds.

Only use power cords supplied by ReliantHeart.

Preparation for implant

Non-sterile preparations for the HeartAttendant®, implant and patient kits for surgery, and the Controllers are outlined in the following sections.

Preparing for implant 24 hours prior to surgery

Perform the following non-sterile tasks 24 hours before implanting the VAD.

Preparing the HeartAttendant®

The operator must verify HeartAttendant® settings prior to surgery. If the settings are not correct, the operator must adjust them. Use the following steps to verify or adjust HeartAttendant® settings.

1. Verify or set the correct date and time. See “Time” and “SYNC TIME button” on page 5-16.
2. Verify or set the tech mode password. See “SET PASSWORD button” on page 5-17.

Preparing the implant and patient kits for surgery

The operator must ensure the contents of the implant kits and the patient kit. A backup implant kit must be present and complete before surgery proceeds.

If any of the contents of the surgical kit packaging are opened, damaged, or compromised before use at surgery, use the backup kit packaging. Return the compromised surgical kit packaging with contents to ReliantHeart.

ReliantHeart ships the HeartAssist 5® VAD within protective packaging. The inner package is sterile while the outer package is not. Do **not** open the inner package outside of the sterile field.

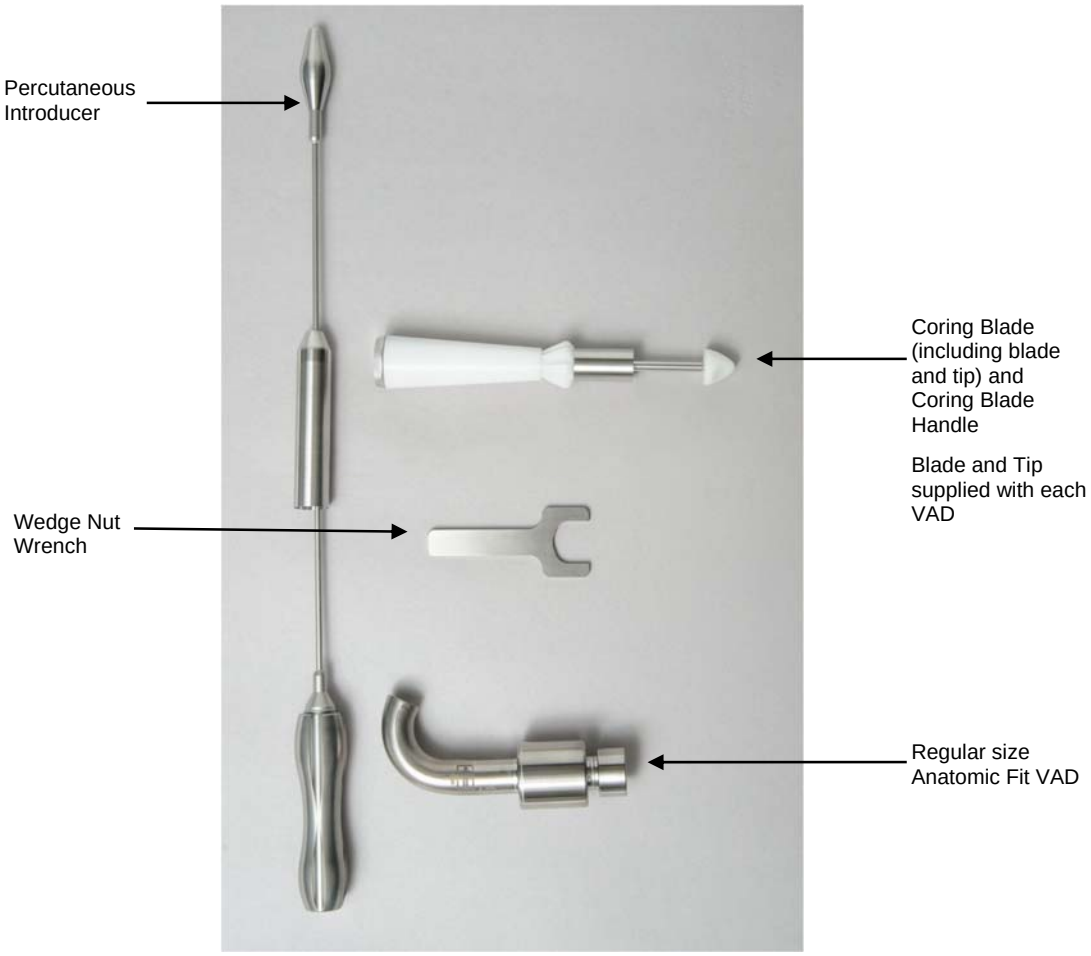
Sterilizing the surgical tools

Perform the following tasks to ensure that the surgical instruments are sterilized properly.

1. Remove the coring blade and tip from the surgical kit packaging and place it in the tool sterilization pouch.
2. Remove the surgical tools and the anatomic fit VAD from the shipping box, if applicable, and place the individual tools in the tool sterilization pouch.
3. Verify that the sterilization pouch contains the following instruments:
   - Percutaneous introducer (4 pieces)
   - Anatomic fit VAD, regular or low BSA (2 pieces)
   - Coring blade (2 pieces)
   - Coring blade handle (3 pieces)
   - Wedge nut wrench (1 piece) See Figure 3-2 for an example of the surgical tools.

   See Figure 3-2 for an example of the surgical tools.

Figure 3-2. Assembled HeartAssist 5® VAD surgical tools



The coring blade and tip are single use items only. Discard previously used blades and tips. The other surgical tools and the anatomic fit VAD components can be used a maximum of 20 times before disposal is recommended.

Figure 3-3. Anatomic VAD Sizer

The anatomic VAD sizers display either a normal human size or small human, surrounded by a box, denoting either normal size or low BSA size, respectively.

4. Steam sterilize disassembled surgical tools in double-pouched paper or Mylar pouches at either 132 °C for ten minutes or at 134 °C for five minutes using parameters in ANSI/AAMI ST42, ANSI/AAMI ST46, ISO 17665-1, and ISO 17664-2004.

   Surgery may not proceed unless backup sterilized tools are available.

5. Following the sterilization process, assemble the surgical tools in a sterile environment.

Charging the 12-volt Lithium Ion batteries

Fully charge VAD batteries using the LVAD Battery Charger before surgery. ReliantHeart recommends placing the batteries in the charger the night before surgery.

Setting up the Controllers immediately before surgery with the HeartAttendant®

Using the HeartAttendant®, perform the following steps a few minutes before surgery for primary and backup controllers.

Perform the following steps on the HeartAttendant® to set Controller parameters.

1. Connect the HeartAttendant® connector to the backup Controller.

   Initially the HeartAttendant® does not recognize the Controller and displays the message **Patient Data Directory not found. Please enter all required patient data and save.**

2. Enter patient data information for only the first four fields.

   This display consists of a dialog box with seven boxes, four that are editable and three that should **not** be edited. The data specified in these boxes are listed below.

   - Editable boxes include the following:
     - **Patient ID**
       34 character maximum; the following characters are disallowed:
       \ / : ?< > | _ *
     - **Hospital ID**
       10 character maximum
     - **Implant Date**
       8 character maximum in DD/MM/YY format
   - Boxes that should **not** be edited include the following:
     - **Pump ID**
     - **Controller**
     - **Flow Probe Data**

3. When you have completed your entries in the four editable boxes, press the Save button.

   The emergency alarm activates.

4. Temporarily deactivate the alarm using the following steps:

   a. On the Controller, simultaneously press the Alarm Silence button and the Scroll Display button until the Controller emits a beep and the display flashes. The

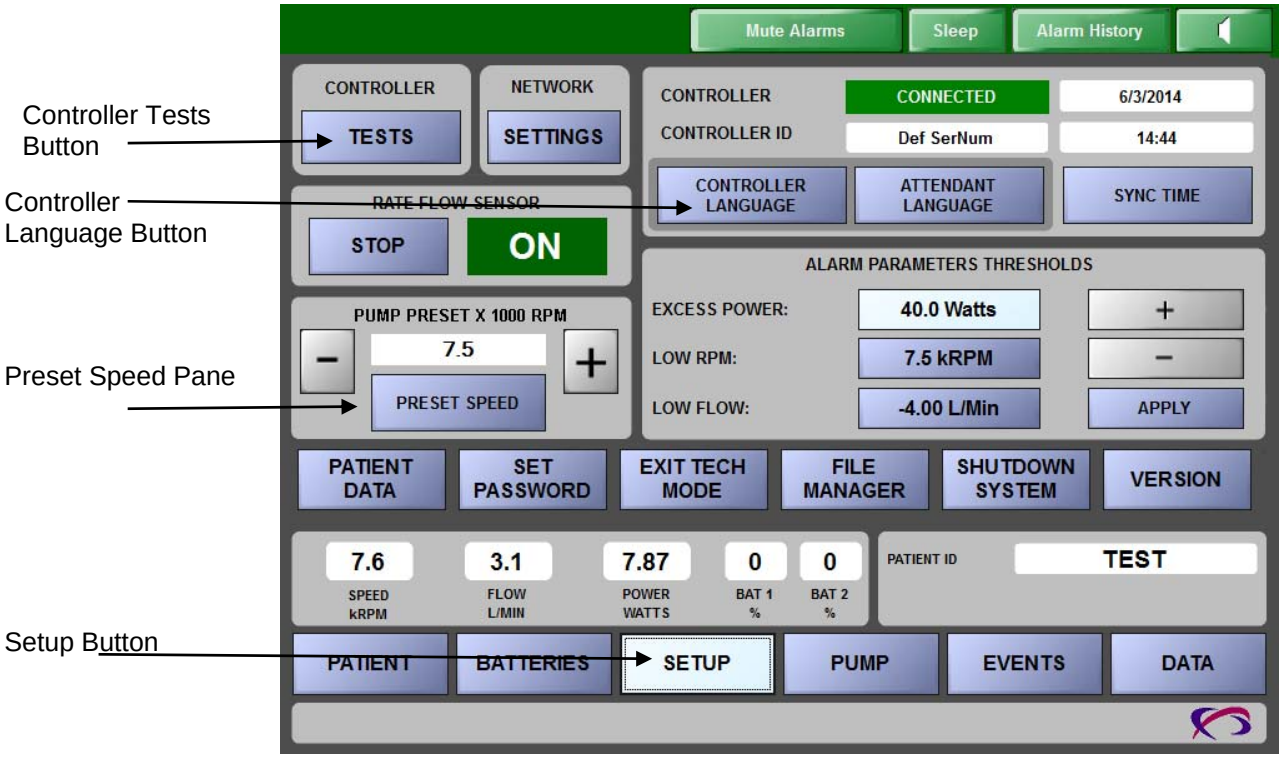
Controller front panel displays the deactivation time options (between 1– 4 hours) and the + and – buttons.

b. Choose the amount of time to deactivate the alarm by pressing either the + or the – button on the Controller front panel. With the alarms silenced, you can prepare the Controller for use.

5. Download your language to the Controller from the **SETUP** screen.

   This process requires a couple of minutes. See “CONTROLLER LANGUAGE button” on page 5-15 for more information.

Figure 3-4. SETUP screen



6. Run all Controller tests from the HeartAttendant® **SETUP** screen by pressing the **TESTS** button then pressing the **Execute Test** button.

7. Preset the VAD RPM to 7,500. Wait 16 seconds after pressing this button before initiating any other HeartAttendant® commands. See “Presetting VAD speed” on page 5-16 for more information.

8. Disconnect the Controller from the HeartAttendant®, and repeat steps 1 – 7 for the primary Controller.

9. Leave the primary Controller attached, and follow the steps in the next section, “Setting up the primary Controller.”

Setting up the primary Controller

Using the HeartAttendant®, perform the following steps to prepare the primary controller and VADPAK a few minutes before surgery.

1. Connect the battery pockets to the primary Controller.

   See “Connecting a battery pocket to the Controller” on page 4-24.

2. Insert the fully charged batteries into the battery pockets.

See “Changing a battery” on page 4-26.

3. Place the Controller and battery pockets, containing the fully charged batteries, into the VADPAK Insert.

   See “Setting up the VADPAK Insert” on page 4-16.

4. Place the VADPAK Insert into the plastic bag provided in the surgery kit.
5. Insert the tie wrap through the hole in the bag and the handle on the VADPAK Insert.
6. Close the bag around the cables coming out the bottom of the bag.
7. Move the HeartAttendant® to a convenient position near the operating table.
8. Hang the surgery pouch on the right-hand side of the operating table near the site where the percutaneous cable will exit the patient.

   Leave the HeartAttendant® connected to the Controller with the HeartAttendant®-to-Controller cable draping below the operating table.

The Controller is now ready to be connected to the patient in stop mode.

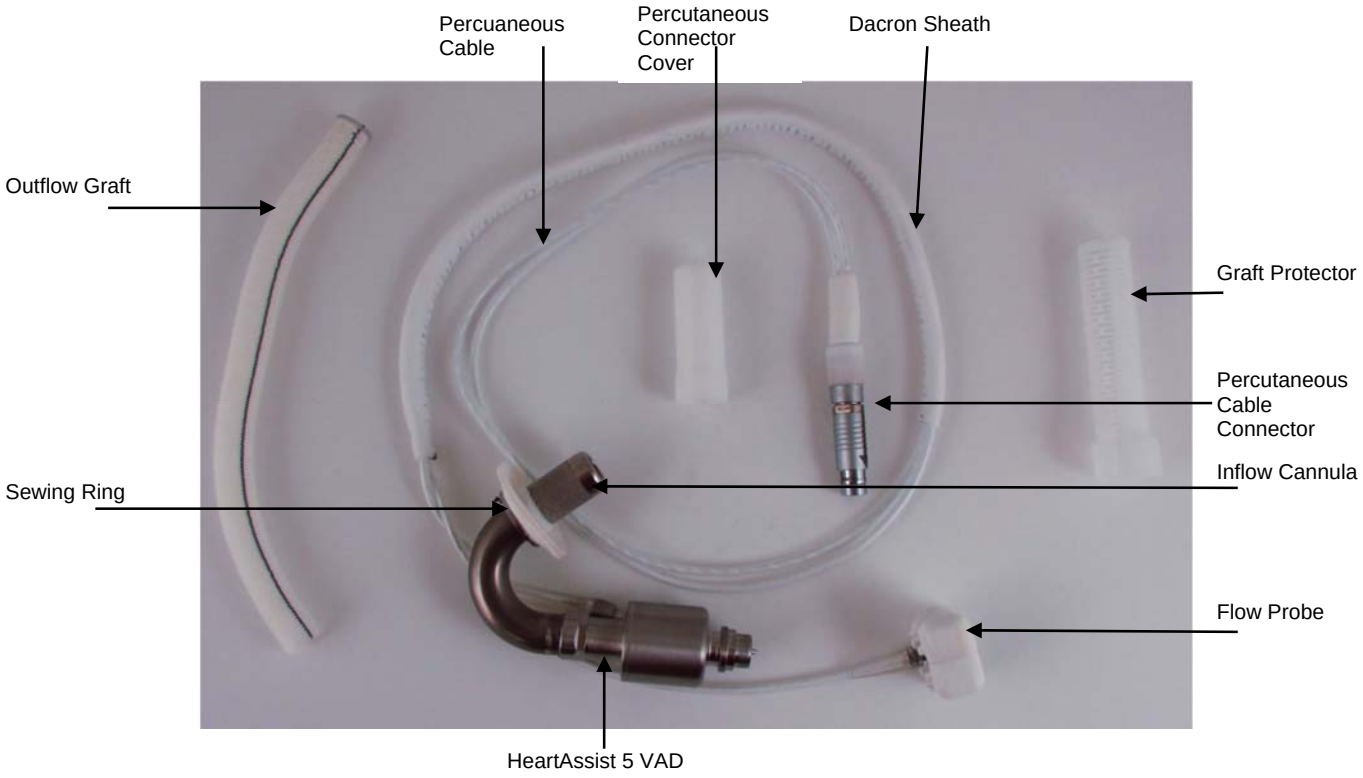
The *primary* Controller to be connected to the patient should be powered up and attached to the operating table in stop mode (**PUMP OFF** on the alarm status bar).

The wireless transmitter in the Controller will be automatically disabled when connected to the HeartAttendant®. Patient or caregiver will have to manually enable the wireless transmitter after connection to the HeartAttendant® is terminated.

Preparing the VAD for surgery

Use the following instructions to ensure that the HeartAssist 5® VAD is ready for surgery.

Figure 3-5. VAD Components



Do not drop the VAD. If the VAD falls, do not use the VAD.

Assembling the sterilized surgical accessories

Use the following instructions to prepare the contents of the HeartAssist 5® VAD blister package for surgery.

Prior to removing the contents from the sterile HeartAssist 5® VAD blister package, inspect the blister package for damage, broken seals, or loose debris. If the package contains any damage, broken seals, or loose debris, do not use the VAD.

1. Remove the contents from the inspected sterile HeartAssist 5® VAD blister package, and prepare to place the contents in the sterile field.
2. Place the sterilized surgical accessories (as described in the following list) in the sterile field.
   - HeartAssist 5® VAD
     - attached wedge
     - attached wedge nut
   - Surgical kit
     - sewing ring

  - cable cap
  - graft protector
- Coring blade handle
  - two plastic pieces
  - one metal piece
- Coring blade
  - one metal circular blade
  - one plastic tip
- Percutaneous introducer
  - metal handle
  - metal shaft
  - metal point
  - metal cover
- Anatomic fit VAD (regular and low BSA sizes)
- VAD test extension cable (gray, approximately 0.8 meters)

Priming the VAD

To expel the air from the VAD, perform the following tasks.

1. Place the VAD in a basin of sterile water with 5% dextrose (minimum of 10 cm deep).
2. Tip the submerged VAD to ensure that the inflow cannula is in a position to allow ***all*** of the air to escape.

   See Figure 3-5 for an example of the VAD.

Figure 3-4. VAD preparation

Testing the VAD

Perform the following steps to verify the integrity of the VAD.

During testing of the VAD, it is imperative to completely submerge the VAD during starting. Do not allow the inflow cannula to ingest air. A dry start will damage the VAD.

1. Connect the sterile VAD test extension cable to the percutaneous connector of the VAD.
2. Connect the backup Controller to an empty battery pocket.

   Have a charged battery ready to be inserted into the battery pocket.

Do not place a battery into the battery pocket until you reach step 6. Failure to follow these instructions can result in the VAD starting prematurely, causing damage to the VAD.

3. Give the circulating assistant the distal end of the sterile VAD test extension cable.
4. Connect the test cable to the Controller and the ***empty*** battery pocket.
5. Before starting the VAD, firmly hold the VAD in the bottom of the basin.

   Do not occlude the inflow cannula.
6. At the instruction of the sterile assistant, insert the battery into the battery pocket to start the VAD.
7. Allow the VAD to run for five minutes.

If squealing noises are present when you test the VAD before implant, remove the battery, and do not use the VAD. Prepare the backup VAD for implant. Return the damaged VAD to ReliantHeart.

Once the VAD has started, allow it to run for five minutes to ensure complete evacuation of air within the bearings.

If the VAD stops after powering up with the Controller, do not use the VAD under test in surgery. Prepare the backup VAD for implant. Return the damaged VAD to ReliantHeart.

Fluid flow exiting the VAD and the absence of an emergency alarm within five minutes signify that the VAD is operating properly.

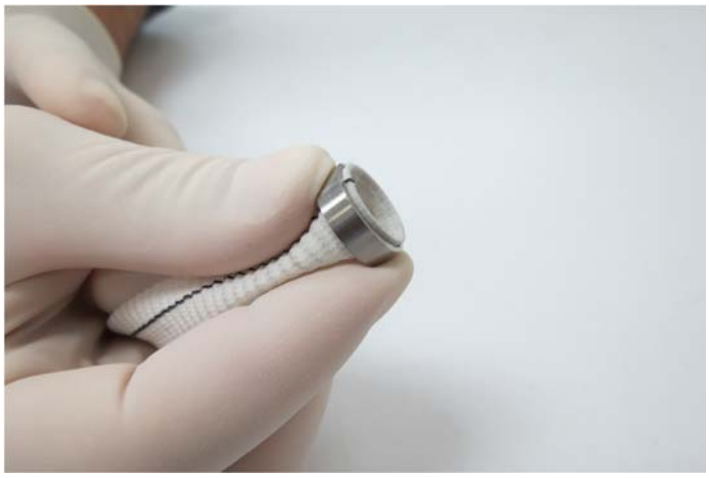
8. Disconnect the sterile VAD test extension cable from the percutaneous connector, and give it to the circulating assistant.
9. Disconnect the backup Controller from the battery pocket, and replace the Controller protective caps.
10. Set backup controller aside.
11. Remove the VAD from the basin.
12. Inspect the basin for loose debris, and then set it aside.

Attaching the graft to the VAD

Use the following instructions to attach the graft to the VAD and the flow probe.

1. Slide the wedge onto the graft, and seat the graft ring into the wedge, as shown in Figure 3-7.

Figure 3-7. Seating the ring into the wedge



2. Slide the end of the graft with the wedge onto the end of the VAD.

Figure 3-8. Attaching the graft with wedge to the VAD

3. Slide the nut over the graft and the wedge and tighten to a loose finger-tight fit.

Figure 3-9. Sliding the wedge nut over the wedge

4. Gently pull any pinched graft that occurs between the nut and the wedge.

   When the graft is installed correctly and not pinched, the wedge is visible when you gently pull the graft away from the nut.

Figure 3-10. Correct: graft free

Figure 3-11. Incorrect: graft pinched between the nut and the wedge

5. When you are sure that the graft is not pinched between the nut and the wedge, tighten the wedge nut with the wedge nut wrench.

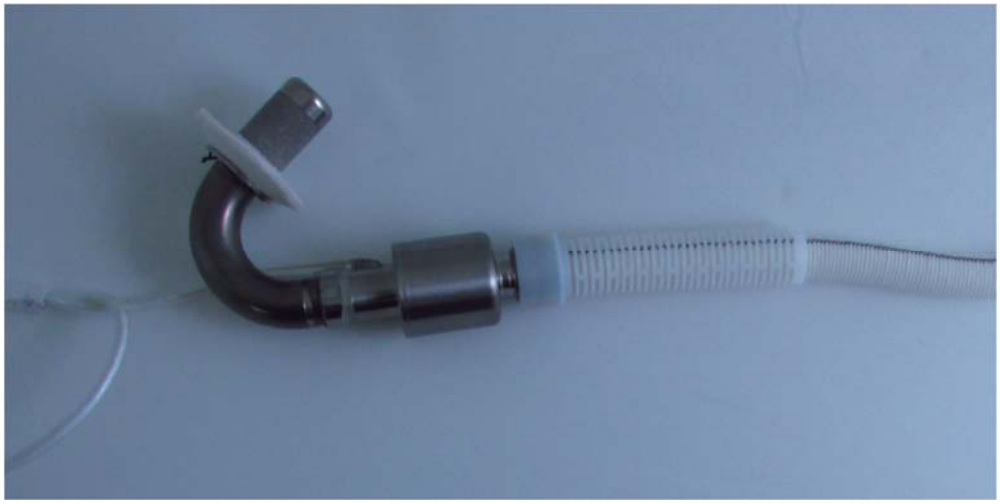
   Do **not** hold the inlet cannula or the wire strain relief when tightening the nut. Only hold the VAD housing as shown in Figure 3-12.

Figure 3-12. Tightening the wedge nut

Do not press on the power cable connection.

6. Slide on the graft protector until it snaps into place.

Figure 3-13. Attaching the graft protector



7. Slide the flow probe onto the graft, ensuring that the flow probe cable points in the direction of the VAD, parallel to the VAD motor wires.

Figure 3-14. Flow probe attachment to graft protector

Ensure that the graft protector prongs engage the flow probe when it is given to the surgeon for implantation.

8. Place the protective cap onto the percutaneous connector.
9. Inspect the basin for loose debris before placing the VAD back into the basin.
10. Place the VAD back into the clean, inspected basin until it is requested by the surgeon.

Surgical implantation

Use the following instructions as a guide for implantation of the VAD.

Preparing the VAD pocket (when necessary)

Use the following steps to prepare a pocket for the VAD if the surgeon determines that a pocket is required.

1. Make a median sternotomy incision extended to the xiphoid process.
2. Use either the regular or low BSA anatomic fit VAD provided to determine if a pocket is indicated.

   If indicated, form a pocket in the rectus sheath beneath the rectus muscle.
3. Using the appropriate anatomic fit VAD, size the pocket making it large enough to accommodate the HeartAssist 5® VAD.

   To minimize the potential for bleeding or infection, do not make the pocket too large.
4. Open the pericardium to access the left ventricular apex.

5. Divide the diaphragmatic attachment to the costal margin and extend both laterally beyond the apex.
6. Prior to placing the patient on cardiopulmonary bypass, assess the patient for the presence of a patent foramen ovale (PFO), and assess valve function using transesophageal echocardiography.
7. If a PFO or tricuspid insufficiency is present, correct the defect before proceeding with the VAD implant.

Applying the apical fixation ring

Use the following instructions to sew the apical fixation ring to the left ventricle.

1. Elevate the left ventricle so that the apex is exposed.
2. Select the insertion site for the inflow cannula.

   The coring site selected should be slightly anterior to the apex and 2–3 cm left of the anterior descending coronary artery.
3. Sew the apical fixation ring in place with 8–10 interrupted mattress sutures with large Teflon pledgets. The suture size and type should be appropriately determined by the Physician (ReliantHeart guidelines suggest double-armed 2-0 polypropylene mattress sutures with large Teflon pledgests).

Do not use absorbable sutures throughout the implantation of the entire HeartAssist 5® VAD system.

Do not enter the peritoneal cavity..

Use caution when applying the apical fixation ring or coring the ventricle in a patient who has sustained a recent myocardial infarction in this area of the heart.

Ensure that the VAD has the graft properly attached and has been tested prior to implant.

Inserting the inflow cannula

Perform the following steps to insert the inflow cannula into the left ventricle.

1. With the apex exposed, use an 11 blade to make a full thickness cruciate incision inside the apical ring.
2. Manually compress the ventricular apex to prevent bleeding if the ventricle is full or if the heart is beating.
3. Insert the coring device into the left ventricle and extract a core of the apex.
   - Core with the coring blade's orientation between the mitral valve and aortic valve inflows.

- Apply the cutting edge of the coring blade to the epicardium and maintain pressure while rotating the blade until the ventricular cavity is entered.

4. To confirm precise coring, examine apical tissue removed from the coring device.
5. Perform digital exploration to evaluate core position and ensure the absence of potential obstruction to the inflow inside the ventricle (for example, a thrombus or muscle remnant).
6. Clamp the outflow graft.
7. Insert the inflow cannula into the ventricle.
8. Tighten the two sets of purse strings on the apical fixation ring.
9. Using the previously placed polypropylene sutures, sew the sewing ring on the inflow cannula to the apical fixation ring.
10. With two running sutures (ReliantHeart guidelines suggest uninterrupted 2-0 polyproplene suture), tightly sew together the apical fixation ring and the sewing ring on the inflow cannula to prevent blood or air leakage.

    You can apply additional Teflon or felt strips to further prevent leakage.

De-airing the HeartAssist 5® VAD

Perform the following steps to fill the left ventricle with blood and remove all of the air from the VAD.

1. The perfusionist will fill the left ventricle completely from the bypass.
2. Elevate the VAD and outflow graft.
3. Allow the VAD and outflow graft to fill with blood from the ventricle by releasing the clamp.
4. Reapply the clamp on the outflow graft.
5. Check the apical insertion site for bleeding.

   Add reinforcing pledgeted sutures as needed (ReliantHeart guidelines suggest continuous 2-0 polypropylene suture with Teflon or felt strip).

Tunnelling the driveline

Use the following steps to create a passage through the abdomen for the driveline.

If preferred, the driveline can be tunneled before the insertion of the inflow cannula into the left ventricular apex.

1. Attach the handle, cover, and tip point to the percutaneous introducer.
2. Tunnel across the midline to exit through the skin in a convenient position above the right iliac crest.
3. The surgeon can slightly bend the percutaneous introducer to ease the passage across the abdomen.

Do not enter the peritoneal cavity.

4. Ensure that the bend radius as the cable leaves the VAD housing is not sharp. Provide a larger bend radius to prevent damage to the cable or wires.
5. Make a small incision where the percutaneous introducer tip will exit the abdomen.
6. Push the percutaneous introducer tip through the skin.
7. Remove the percutaneous introducer tip, and attach the handle to the distal end of the percutaneous introducer.
8. Attach the driveline to the proximal end of the percutaneous introducer.
9. Pull the driveline through the tunnel, exiting the skin.
10. After the driveline is pulled through the tunnel, attach the protector cap.

    The driveline will be passed off the table and connected to the Controller when the VAD is ready for use, and it is time for the second de-airing, prior to initialization of VAD support and weaning of cardiopulmonary bypass.

    If the driveline is not immediately attached to the Controller, attach the cap protector to the driveline.

Attaching the outflow graft to the aorta

Use the following steps to attach the outflow graft to the aorta.

1. Place the VAD into position, and measure the length of the outflow graft.
2. Trim the outflow graft at 45°angle and the appropriate length to ensure that the graft lies under the right sternal border without kinking or overstretching.
    - If the graft is not accurately trimmed, use the backup graft (supplied separately). If the graft is too long or too short, the graft might kink or stenose.
    - If the patient requires a VAD pocket, prevent kinking of the outflow graft protector by properly placing the VAD and by ensuring that the graft is the proper length.
    - A portion of the right diaphragmatic costal margin might require release to place the graft correctly without kinking.
3. Ensure that the flow probe placed on the outflow graft is immediately proximal to the graft protector.
4. Place the partial occlusion clamp on the ascending aorta.
5. Make a longitudinal arteriotomy, and sew the graft to the lateral ascending aorta using the suture size and type appropriately determined by the Physician (ReliantHeart guidelines suggest 5-0 polypropylene sutures).
6. Repair any bleeding site (for example, a needle hole or a tear in the graft) by suturing.

De-airing a second time

Perform the following steps to remove the air from the VAD again.

1. Place an 18-gauge needle in the outflow graft between the aortic anastomosis and graft clamp at the highest point.
2. Temporarily release the aortic partial occlusion clamp.

    This action fills the distal aortic graft with blood, and trapped air escapes through the needle.
3. Re-clamp the aorta; then un-clamp the outflow graft.

4. Intermittently start and stop the VAD.

   Ensure that the ventricle is full during the second de-airing process.

5. After all of the air is released, remove the 18-gauge needle.
6. Oversew the needle hole using the suture size and type appropriately determined by the Physician (ReliantHeart guidelines suggest 5-0 polypropylene sutures).

	**All entrapped air must be removed from the VAD blood pumping chamber and conduits to reduce the risk of air embolus.**
	Place the needle vent in the outflow graft in the highest point in the lumen (anterior side to optimize air removal).
	Optionally, flood the surgical field with sterile saline to further minimize the risk of air entry and possible embolization.

Connecting the percutaneous cable to the Controller

Use the following steps to connect the percutaneous cable to the Controller.

1. At the instruction of the sterile assistant or the surgeon, take the percutaneous cable (just tunnelled through the skin and below the sterile field), and inspect the connector for liquid and debris.

   If you find debris within the connector, rinse with deionized water and blow dry with a syringe or bulb.

2. Slide the white defibrillation cover onto the percutaneous cable, ensuring that the smaller diameter is on, facing toward the patient.
3. Connect the percutaneous cable to the primary Controller, and hang it off of the operating table.
4. Screw the defibrillation cover onto the connector of the Controller cable.
5. When the surgeon instructs, start and stop the VAD.

Managing VAD performance immediately after starting the VAD

Use the following steps after you start the VAD.

1. Report the VAD performance at the request of the surgeons.

   If the flow signal is noisy (tracing is not smooth), verify that the received voltages for either channel A or B are above 1 volt.

   Use the **PUMP** screen to check the voltages.

2. If necessary, request additional sterile saline at the graft probe site.
3. Set the VAD RPM conservatively slow (7500 – 9000 RPM).

Post implant

Perform the following procedures to complete the surgery after the VAD implantation is complete.

Finalizing the surgery

Perform the final surgical procedures.

1. Decrease cardiopulmonary bypass flows slowly to maintain a cardiac index of at least 2.0 L/min/m^2, being careful not to overload the right ventricle.
2. Maintain inotropic support for the right ventricle.
3. Ensure adequate preload to prevent ventricular collapse.
4. Use transesophageal echocardiography to assess the inflow cannula position.
5. If the inflow cannula position is acceptable, and when flows are adequate, wean the patient from bypass.
6. Reverse heparin with protamine if indicated.
7. Re-evaluate VAD flow and cannula position with the chest closed before placing sutures.
8. Consider covering the outflow graft and VAD/ventricular apex with an ePTFE pericardial membrane or similar product to facilitate re-entry upon transplant.
9. Place drains in the VAD pocket and mediastinum.
10. Secure the driveline in place with a single suture.

Transferring the patient out of the operating room

Use the following instructions when you are ready to transport the patient from the operating room to the intensive care unit and ready to transfer the HeartAssist 5® VAD System from wall power to battery power via the HeartAttendant®.

The following instructions assume that fully charged batteries are already in the battery pockets and mounted to the VADPAK Insert contained in the protective plastic bag. See “Setting up the primary Controller immediately before surgery” on page 3-7.

1. Ensure that the other Controller cable is connected to a fully charged battery.
2. Disconnect the HeartAttendant® from the Controller port for transfer.
3. Connect the second battery.
4. Reconnect the HeartAttendant® once the patient is settled in the intensive care unit.
5. At the bedside, secure the protective plastic bag containing the VADPAK Insert with the battery pockets, batteries, and Controller using one of the following methods:
   - Hang it from an intravenous IV pole.
   - Secure it to the bed with towel clamps.

Do not attach the protected VADPAK Insert to the bed rail. The motion of lowering and elevating the bed rail can damage cables.

Do not place the protected VADPAK Insert beneath blankets, sheets, or the patient's body. The Controller must be kept uncovered to allow proper cooling.

Because the VAD outputs are strongly affected by increases in load and decreases in preload, a portable blood pressure monitor can be used to gauge the effectiveness of support during transport. The HeartAttendant® and arterial pressure lines can be quickly re-attached upon reaching the ICU.

Setting VAD parameters

After surgery, use the following steps to make adjustments to VAD speed and alarm values.

1. Adjust the VAD pump speed on the **PUMP** screen using the HeartAttendant®.

   See “RPM INCREMENT buttons” on page 5-19.

2. Adjust the alarm values (flow and speed about 20% below the nominal values and excess current to 16 watts).
3. Check and record the performance of the flow probe by evaluating received amplitude on the **FLOW L/Min** waveform pane of the **PUMP** screen on the HeartAttendant®.

   See Figure 5-18 on page 5-18.

If you experience a device malfunction or have a complaint, contact ReliantHeart.

Patient management

This section presents an overview of the information required to maintain the patient following implantation with the HeartAssist 5® VAD. For detailed patient management, see the *HeartAssist 5® VAD System Patient User’s Manual*.

Required and optional patient equipment

Refer to Table 3-1 for information on required primary and backup equipment and optional equipment for HeartAssist 5® VAD patients.

Table 3-1. HeartAssist 5® VAD System patient equipment

Component	Primary (required)	Backup (required)	Optional	Notes
Implanted HeartAssist 5® VAD[a]	1	1		
Controller[a]	1	1		
Rechargeable batteries	4		2	Four batteries are required; two optional, additional units are available if patient is discharged.
LVAD Battery Charger	1	1		
HeartAttendant®[a]	1	1		Available in the hospital
VADPAK	1			

Component	Primary (required)	Backup (required)	Optional	Notes
HeartAttendant® connector cable[a]	1	1		Required for patient discharge
Shower bag	1			Available in the hospital
Battery pockets	2			Two primary battery pockets
Independent Power Supply	1			

a ReliantHeart requires each active site to maintain one backup VAD for every three patients on VAD support. Every patient must have a backup Controller and a backup HeartAttendant® connector cable immediately available. Each active site must have at least one HeartAttendant® available for every three patients on the device. LVAD Battery Charger devices must be available to charge batteries. The number of HeartAttendant® devices varies with respect to the number of patients on the device, whether or not they are in an intensive care unit, and whether or not they are taking out-of-hospital excursions. For implant, a hospital must have at least two LVAD Battery Charger devices to allow for charging of the batteries to transport the patient from the operating room.

Adjusting the VAD speed

Stabilize the patient before beginning these steps.

1. Adjust the VAD speed to a level that provides the desired forward flow without signs of regurgitant flow or ventricular collapse.
2. Maintain the VAD speed level.

   Employ mixed venous oxygen saturation to adjust VAD speed and flow, maintaining mixed venous oxygen saturation between 60 – 70%.

Managing the batteries

Hospital staff must initially supervise battery management, and then, as appropriate, transfer management to the patient. Batteries last 4.5 – 7.5 hours, depending on power requirements.

Once the second battery alarm indicates that the battery has discharged to 25%, change the batteries immediately. However, ReliantHeart recommends changing the first battery immediately after it alarms at 25% discharge.

Managing general treatment issues

Flow across the VAD is, in large part, determined by the pressure gradient across the VAD (from outflow to inflow). Therefore, VAD output is dependent upon changes in left ventricular filling (preload) and systemic vascular resistance (afterload).

Although physician judgment and experience varies, proper care of a patient supported by the VAD requires a thorough understanding of system operation, the patient's condition, and the unique physiologic support provided by axial flow rotary devices.

The following treatment issues are critical to the achievement of the best outcomes in patients supported by the VAD.

Preload and afterload

Close surveillance for physiologic, pathophysiologic, or iatrogenic changes in left ventricular filling (preload) and systemic vascular resistance (afterload) is required following implantation. Small increases in afterload or small decreases in preload can result in diminished VAD flow, a reduction that can manifest in a clinically relevant

decrease in perfusion. If inadequate ventricular filling occurs, increasing VAD speed does not increase flow.

Perfusion

Standard methods for achieving adequate perfusion might not be helpful under all physiologic conditions. As described above, if preload or afterload changes, perform an immediate patient assessment that includes physical examination to confirm the adequacy of peripheral perfusion.

In shock states, physical examination might not provide adequate evidence of perfusion restoration. Right heart catheterization under conditions of hemodynamic instability is highly recommended. Mixed-venous O^2 saturation measured intermittently or continuously provides the most sensitive guide to perfusion in post-implantation shock states. If right heart catheterization is not possible, substitute a mixed-venous O^2 saturation from a right atrial catheter.

Blood pressure

Under stable physiologic conditions, automated blood pressure monitoring devices (oscillatory blood pressure) might not yield accurate blood pressure data. Use manual auscultation of an extremity to gauge blood pressure. However, in circumstances where the flow has minimal pulsatility (vasodilatory states), manual blood pressures can be difficult to obtain. Doppler stethoscope technologies have been effectively employed to obtain manual blood pressures when pulseless flow prevents palpation of pulses.

Right heart function

Maintain inotropes during the immediate post-operative period at pre-operative levels to protect right heart function.

Right heart failure can occur at any time following implantation. Follow-up closely and intervene with nitric oxide, vasodilators, diuretics, inotropic drugs, or right ventricular assist as indicated.

Rehabilitation

The following measures help assure the patient's success on VAD support.

Encourage early ambulation and resumption of dietary intake.

Encourage social and family support during rehabilitation.

Recommend exercise physiotherapy post-implantation.

Discourage excessive weight gain, which can produce a decline in device performance.

Managing fluids, inotropes, and vasoactive medications

Use the following guidelines to maintain flow, pressure, and volume.

Administer fluids to maintain a cardiac index of greater than 2.0 L/min/m^2 while central venous pressure and left atrial pressure are maintained less than 20 mm Hg.

Take all measures to maintain left ventricular filling. These measures include aggressive replacement of volume lost and close vigilance of right heart function and pulmonary vascular resistance.

Initially treat sudden decreases in pump flow with restoration of volume. If volume replacement does not augment flow, rule out potential sources of bleeding. If these measures do not restore adequate flow, evaluate right heart function, and institute inotropic support as indicated.

Immediately evaluate the patient and system upon any complaints of dizziness.

The attending physician has the discretion to treat post-implantation hypertension. Although ACE inhibitors are recommended, any therapy that consistently maintains mean arterial blood pressure less than 90 mm Hg is adequate.

Controlling infection

To prevent infection, administer a broad spectrum antibiotic during the first 48 hours following implant following procedures similar to any open heart surgery. Then, organism-specific antibiotics can be administered as needed based upon positive culture results. Early extubation, early ambulation, and removal of patient monitoring lines help prevent infection. To reduce the potential for infection, use nursing measures such as frequent hand washing, and use aseptic technique when contacting invasive lines and when changing the exit site dressing.

Use parenteral treatment with antibiotics and surgical drainage if evidence of pump pocket infection exists. Fungal infection resulting from organisms such as Candida species has been associated with vegetative growth on other VADs. Persistent systemic fungal infection that is refractory to antimicrobial treatment might require VAD replacement.

Treating the exit site

Perform daily exit site care using a persistent antiseptic cleansing agent such as chlorhexidine-containing scrub solutions. Dry the site following aseptic cleansing to avoid tissue maceration. Adhere to aseptic technique whenever the exit site is inspected, dressed, or otherwise handled.

Keep the exit site clean and dry, and apply a sterile bandage daily.

Prophylactic topical agents, such as silver sulfadiazine or polymixinneomycin-bacitracin, are not typically used as these ointments applied to the exit site can macerate the tissues and degrade the exterior cable.

Movement of the percutaneous cable should be minimized at the exit site.

Controlling patient bleeding

Bleeding is a common complication of VAD implantations in general. Carefully monitor chest tube output. Perform routine measurement of partial thromboplastin time, prothrombin time, INR, fibrinogen, and platelet count. Administer blood products as needed to correct hematologic abnormalities. Consider surgical re-exploration if chest tube bleeding exceeds 100 ml/hour after restoring coagulation factors.

Initiating anticoagulation therapy

Initiate anticoagulation therapy in VAD patients after chest tube bleeding stops (usually 48-72 hours after implantation). Optionally, start intravenous heparin or low molecular weight heparin at this time, and continue the therapy until warfarin reaches therapeutic levels. Start warfarin as soon as the patient can tolerate oral medications. Titrate warfarin to maintain an INR between 2.0 and 3.0. Administer a platelet inhibitor, such as aspirin or dipyridamole, in conjunction with warfarin therapy.

Identifying and correcting VAD stoppage

Identify and correct the cause of a VAD stoppage as soon as possible. Rectify mechanical or electrical causes of a VAD stoppage by applying the backup Controller. Make all attempts to restart the VAD immediately. VAD stoppages that are a result of thrombus might be preceded by increases in current and power with concurrent decreases in flow.

If the VAD stops for more than three minutes, blood inside the VAD can become stagnant. (This condition depends on the patient's coagulation status.) If the blood inside the VAD becomes stagnant, restarting the device presents a risk of stroke or thromboembolism.

Correcting regurgitant flow

Regurgitant flow can occur if the VAD stops or slows to less than 7,500 RPM. If speed cannot be increased, or if regurgitant flow associated with a VAD stoppage results in exacerbation of heart failure, the VAD might need to be exchanged. The VAD can also be removed completely or left in place if the physician ligates the outflow graft.

If the VAD stops operating, the patient must seek immediate medical attention to treat the potential physiologic consequences of regurgitant flow. Treatment measures might include heparinization, standard interventions for acutely decompensated congestive heart failure, or surgical exploration.

Treating right heart failure

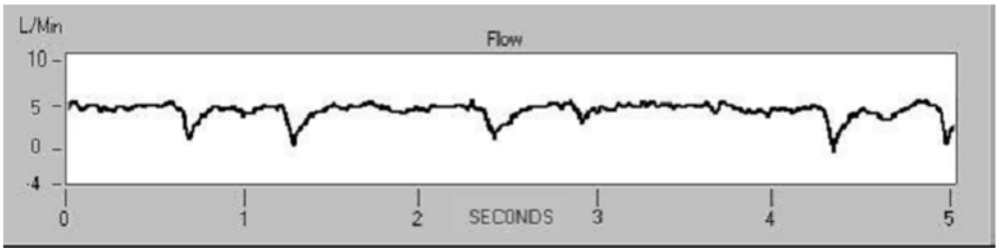
Patients can suddenly develop right ventricular (RV) failure during or after device implantation. The onset of RV dysfunction in these patients is often accompanied by the inability of the left ventricle to fill and by drastically reduced flows across the VAD. Limited filling is further exacerbated in the presence of right heart failure with an elevated trans-pulmonary pressure gradient or high pulmonary vascular resistance.

Treatment for patients in right heart failure includes the administration of inotropes to augment RV contractility, fluid management, hyperventilation, and pharmacologic modulation of pulmonary vascular resistance. If these measures are not effective, consider employing a right ventricular assist device.

Diagnosing ventricular collapse

When left ventricular filling is compromised by right ventricular failure, bleeding, or hypovolemia, the ventricular chamber might collapse around the inflow cannula of the VAD, further limiting flow. Recognize ventricular collapse by sudden flow reductions in the presence of any of the above conditions and from the flow waveform displayed on the HeartAttendant®. Figure 3-15 illustrates the characteristics of the flow waveform during ventricular collapse.

Figure 3-15. Flow waveform during ventricular collapse



Ambulating patients

Once recovered from surgery, ambulate patients as much as possible. Instruct patients on how to wear the VADPAK with Controller and batteries correctly. Whenever ambulating away from the hospital room or home, the patient must carry a backup Controller and at least two extra batteries. Once recovered, patients should be able to perform exercise, although contact sports and swimming must be avoided.

Sleeping

Because patients can sleep through a battery alarm, patients must sleep tethered to the HeartAttendant® or the Independent Power Supply. Do not adjust VAD operation to accommodate for normal physiologic changes that occur with sleeping. Decreases in flow and waveform patterns indicative of sucking (ventricular collapse) can occur overnight or during the early morning if the patient becomes hypovolemic. If this situation occurs, the patient must drink a glass of water prior to going to sleep.

Showering

Only showering is allowed, and showering may start after the clinician approves wound site readiness. During showering, the Controller, batteries, and cables must be attached to the VADPAK Insert. The VADPAK Insert must then be encased in the shower bag.

Avoiding static electric discharge

VAD patients must avoid static electric discharge. See Appendix D, “Manufacturer guidance for environmental conditions” for more information on static electric discharge.

Avoid direct contact with devices with high voltage such as television or computer screens since direct contact can damage the electrical components of the HeartAssist 5® VAD System and can cause the VAD to stop.

Do not handle batteries by the connector pins because a strong static discharge can cause a temporary loss of the charge status indicator. If you experience a loss in charge status, place the battery in a ReliantHeart-supplied charger and recondition the battery.

Patient discharge

Patients discharged to home or a lower care facility must master concepts presented in the *HeartAssist 5® VAD System Patient User's Manual*. A trained companion is recommended for patients going home with the HeartAssist 5® VAD System.

A device malfunction or other complication might necessitate emergency treatment; therefore, arrangements with local physicians and emergency systems should be established prior to patient release. Patients who live at distances away from the implanting hospital that might prevent timely return for surgical intervention when necessary might not be suitable for discharge.

Service

The HeartAssist 5® VAD System contains no user serviceable parts except for the HeartAttendant® fuses. Return any component requiring repair to ReliantHeart for service.

Explanting the VAD

Use the following steps to remove the VAD.

1. Expose the VAD, and dissect it free.
2. Place the patient on cardiopulmonary bypass, and establish flow.
3. Stop the VAD.
4. Dissect the percutaneous cable free, and cut the cable close to the VAD.
5. Pull the percutaneous cable at the exterior exit site to remove it.
6. Culture the cable as indicated.
7. Place the cable in the container for return to the manufacturer.
8. Cut the sutures between the sewing rings, and remove the inflow cannula from the ventricle.
9. Ligate and cut the outflow graft close to the aorta.
10. Remove the entire device and cannula as a unit.
11. Culture the VAD as indicated.
12. Place the entire device in 10% formalin in the jar provided in the explant kit.
13. After 24 hours, replace the formalin with saline and ship the device back to ReliantHeart.

It is a violation of law to ship formalin or formalin-containing jars. Ensure that formalin is removed prior to shipment.

Chapter 4
Controller, Batteries and VADPAK

In this chapter

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.

Users cannot adjust VAD operating parameters with the Controller. Use the HeartAttendant® to adjust these parameters. 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.)

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 or on the HeartAttendant® **PUMP** screen. 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. The flow sensor can be disabled on the **SETUP** screen of the HeartAttendant®.

It is uncommon to disable the flow sensor feature during the normal use of the HeartAssist *5*® VAD System.

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 ReliantHeart 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 (Figure 4-3):
   - 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 ReliantHeart 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.

Testing with the batteries

Test the safety of the Controller using the batteries.

1. Verify that all three connections to the Controller are secure and undamaged.
2. Disconnect the HeartAttendant® or 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.

Testing with the HeartAttendant®

Test the safety of the Controller using the HeartAttendant®.

1. Connect the HeartAttendant® to the external port of the VADPAK.

   See “Connecting the Controller to the HeartAttendant®” on page 5-4.

2. Perform the following tests from the **SETUP** screen and record any anomalies:
   - Test LCD Messages
   - Test LED Annunciators
   - Test Audible Annunciator
   - Test LCD Display and Backlight

   See “Running Controller tests” on page 5-14.

3. Store a screen shot from the **DATA** screen, entering the patient’s current, flow, speed, and power values into the comment box.

   See “Obtaining screenshots” on page 5-26.

4. From the **SETUP** screen, sync the HeartAttendant® time. See “SYNC TIME button” on page 5-16.

5. Press the **ALARM HISTORY** button to review a log of previous alarms.

   See “ALARM HISTORY button and Alarm window” on page 5-10.

6. Verify that the alarm parameters are appropriate for the patient.

7. If the Controller has displayed a **PUMP STOPPED** alarm since the last Controller check, download both the **First Event** and **Last Event** from the **EVENTS** screen.

   See “Retrieving data segments” on page 5-21.

If the Controller is functioning improperly during the safety check, replace the Controller using the procedure defined in “Controller replacement” on page 4-6, repeat the steps in “Controller safety check,” and contact ReliantHeart 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.

Patients 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 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 4-3 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.

The patient 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 charge level indicator 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 or the HeartAttendant®), 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 ReliantHeart 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 ReliantHeart.

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 chargers can only charge or recondition one battery at a time. This is denoted by the recondition arrow solely indicating the left bay as the recondition slot. Please verify the proper model before following the steps for charging or conditioning 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 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 recondition 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 ReliantHeart.
	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.

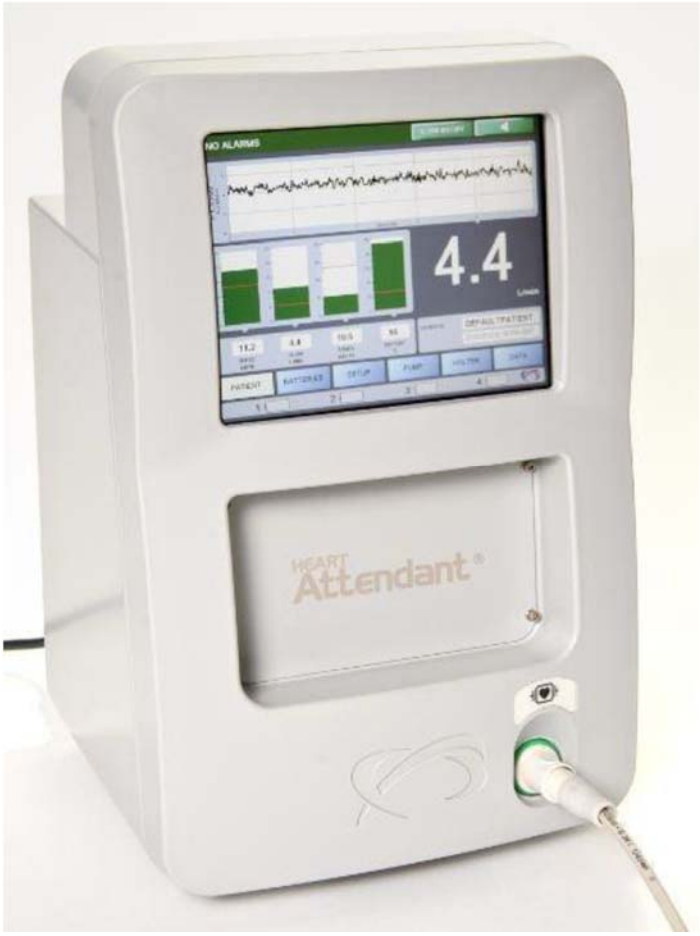
Chapter 5

In this chapter

Overview

The HeartAttendant® powers the VAD and the Controller. It is the means of setting the VAD operating parameters and communicating with the Controller, and it acts as the primary source of power during implant. The HeartAttendant® also acquires and stores real-time performance and historical performance data (event memory).

Figure 5-1. The HeartAttendant® console



Powering on the HeartAttendant®

Use the following steps to power on the HeartAttendant®.

1. Verify the setting of the power inlet module to the correct AC power setting for the specific country.
2. Verify or plug the appropriate power cord into the back of the HeartAttendant®.
3. Plug the power cord into the wall power source.

   After the HeartAttendant® is plugged in to the wall power source, it is ready to power the VAD, even though the boot process might still be underway.

When the HeartAttendant® receives a command, it makes several attempts to communicate with the Controller. If the Controller is disconnected from the HeartAttendant® when the HeartAttendant® receives commands the HeartAttendant® buffers the commands for up to one minute before the it ceases its attempts to execute the commands, and then it displays the word DISCONNECTED on the HeartAttendant® SETUP screen in the Controller box.

Initiating HeartAttendant® commands immediately prior to connecting a Controller can produce unexpected results.

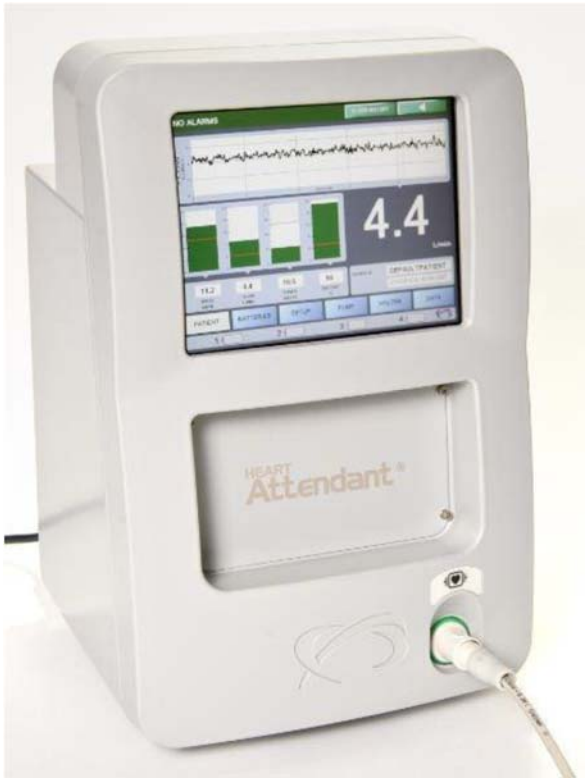
When connecting the Controller to the HeartAttendant®, ensure that AC power is available or that the battery pockets contain charged batteries.

Connecting the Controller to the HeartAttendant®

After the HeartAttendant® is powered on, use the following instructions to connect the Controller to the HeartAttendant® using the battery pocket's external power receptacle. Perform these steps while the Controller is in the VADPAK Insert. (See "Setting up the VADPAK Insert" on page 4-16.)

1. Connect the HeartAttendant® connector cable to the port on the HeartAttendant®.

Figure 5-2. Connecting the HeartAttendant® connector cable to the port on the HeartAttendant®



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

Figure 5-3. Exposing the battery pocket external power connector

3. Visually align the arrow on the HeartAttendant® connecter with the square on the battery pocket external power connector.

Figure 5-4. Aligning the arrow on the HeartAttendant® connector with the square on the battery pocket external power connector

4. After you align the arrow and the square, firmly push the HeartAttendant® connector straight into the battery pocket external power connector. A slight click sounds, and the connectors snap into place and becomes fully seated.
5. Verify the external power connection with the following indications:
   - 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 as the battery percentage for the connected battery pocket.

6. Route both cables to the opening below the end of the zipper in the VADPAK.

Figure 5-5. Routing the driveline and connector cables 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.

   The HeartAttendant® is now connected to the Controller, and the VADPAK is ready to carry using the handle or the shoulder strap.

Disconnect the Controller from the HeartAttendant® before unplugging the HeartAttendant® from the AC power source.

Description of screens

The HeartAttendant® has six screens that are used to display VAD parameter information and to configure the system. Patients and caregivers only have access to the **PATIENT** screen and the **BATTERIES** screen.

The panes shown in Figures 5-6 and 5-7 are common to all HeartAttendant® screens.

Each of the six HeartAttendant® screens share a common Alarm Status bar (shown in Figure 5-6) across the top of the screen that indicates any detected alarms and enables access to the Alarm History window and the Alarm Silence function.

Figure 5-6. Alarm Status bar

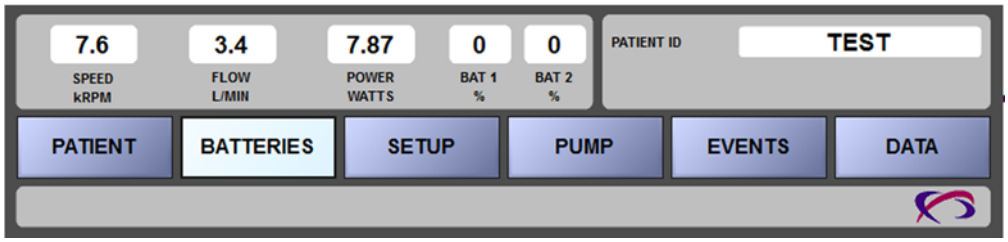
Each of the six screens also shares a common section across the bottom of the screen that contains three panes (shown in Figure 5-7):

- Status Display pane
- Display Select buttons pane
- Battery Status indicators pane

Status Display pane

The Status Display pane shows the real-time values for speed, flow, and power; the percent charge of the battery connected to battery port 2; and the patient's ID. (See the **PATIENT ID** pane on the top, right of Figure 5-7.)

Figure 5-7. Status Display, Display Select, and Battery Status indicators panes



Display Select buttons pane

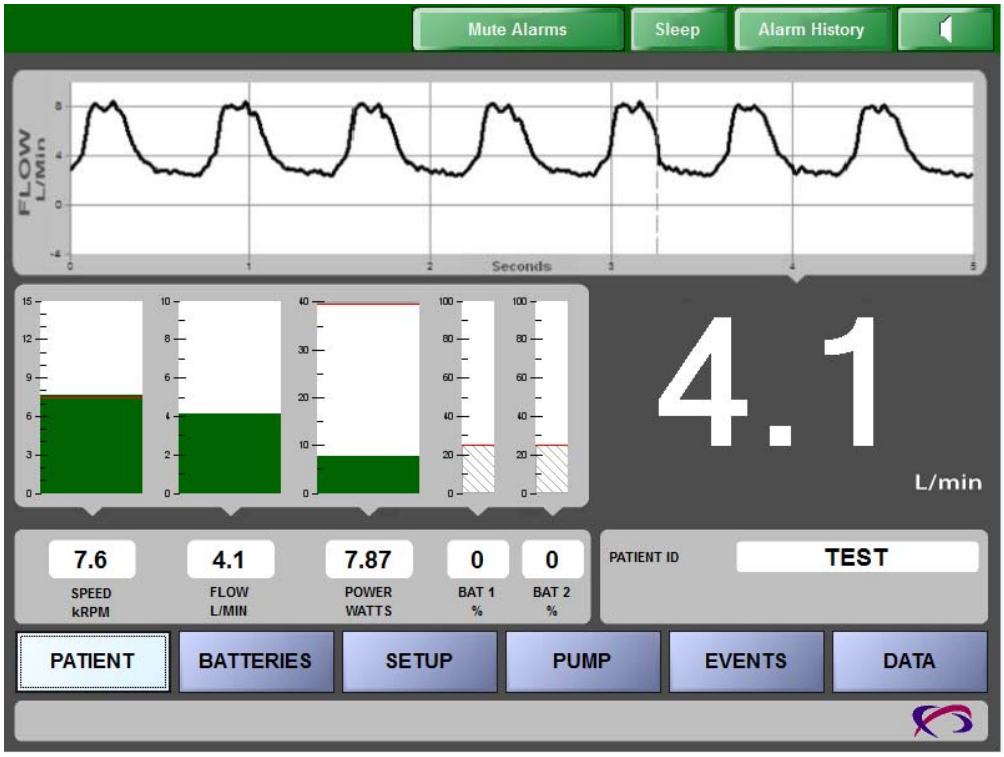
Use the Display Select buttons to navigate between the six HeartAttendant® screens. Select the desired button to open the corresponding screen. All users can access the **PATIENT** and **BATTERIES** screens. The clinician and support staff use the password-protected **SETUP**, **PUMP**, **EVENTS**, and **DATA** screens to change VAD settings and to download event or VAD performance data.

After the clinician or staff enters the password, the system enters tech mode, and all screens activate until the user exits tech mode on the **SETUP** screen. (See the Setup Action pane of Figure 5-16 on page 5-14.)

PATIENT screen

The following sections describe the **PATIENT** screen panes. The **PATIENT** screen is available to all users, including patients and caregivers.

Figure 5-8. PATIENT screen



Managing alarms and accessing sleep mode

The following sections describe the Alarm Status bar states, buttons on the bar, and the corresponding screens associated with each button.

> The Alarm Status bar appears on all HeartAttendant® screens.

Alarm Status bar

The Alarm Status bar resides in the thin, horizontal pane across the top of all screens.

- The bar remains solid green when conditions are normal (Figure 5-9).
- The bar flashes alternating green and yellow when the HeartAttendant® detects a diagnostic alarm (Figure 5-10).
- The bar flashes alternating green and red when the HeartAttendant® detects an emergency alarm (Figure 5-11).

The Alarm Status bar displays the **ALARM HISTORY** and Alarm Silence button on all HeartAttendant® screens. On the **PATIENT** screen, the Alarm Status bar also displays the **SLEEP** button. (See Figure 5-8 for an example of the Alarm Status bar with the **SLEEP** button.)

Figure 5-9. Green Alarm Status bar with ALARM HISTORY and Alarm Silence buttons, indicating normal conditions

Figure 5-10. Yellow Alarm Status bar with ALARM HISTORY and Alarm Silence buttons, indicating diagnostic alarms

Figure 5-11. Red Alarm Status bar with ALARM HISTORY and Alarm Silence buttons, indicating emergency alarms

SLEEP button

When the patient is sleeping, the operator can press the **SLEEP** button on the Alarm Status bar to place the HeartAttendant® into sleep mode, which darkens the display and only shows minimal information to lessen the light emitted from the HeartAttendant®.

Use the following steps to activate and deactivate sleep mode.

1. Press the **SLEEP** button on the Alarm Status bar (shown in Figures 5-8 and 5-12).

   This button is only visible from the **PATIENT** screen when the system is **not** in tech mode.

   Figure 5-12. SLEEP button on the Alarm Status bar

2. Press the Sleep touch screen (shown in Figure 5-13) to return to the **PATIENT** screen from sleep mode.

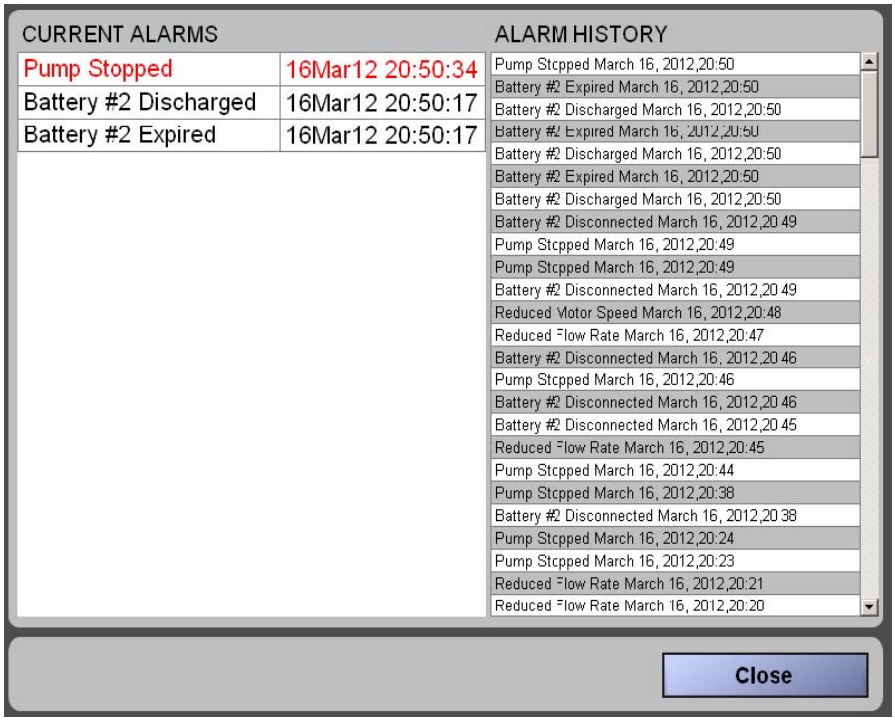
   Figure 5-13. Sleep screen

ALARM HISTORY button and Alarm window

Press the **ALARM HISTORY** button on the Alarm Status bar to open the Alarm window to review alarm messages that are stored in the HeartAttendant®.

Figure 5-14. Alarm window



CURRENT ALARMS pane

The **CURRENT ALARMS** pane (on the left side of Figure 5-14) lists existing alarms as they occur while the HeartAttendant® is connected to the Controller, until the alarm condition resolves and the operator presses the Alarm Silence button. The HeartAttendant® must be connected to the Controller for the **CURRENT ALARMS** pane to display current alarms.

Current alarms also cause the Alarm Status bar to flash. Clear alarm conditions using the Controller's Alarm Silence button as soon as practical after they occur to detect a recurrence of the same alarm.

ALARM HISTORY pane

The **ALARM HISTORY** pane (on the right side of Figure 5-14) lists *previous* alarms in chronological order as they occurred.

The HeartAttendant® must be connected to the Controller for the **ALARM HISTORY** pane to display alarm history. The **ALARM HISTORY** pane lists alarms that occurred both while the HeartAttendant® was connected and while it was disconnected from the Controller.

Possible emergency alarms

The following list contains possible emergency alarms that can display in the Alarm window and trigger a red Alarm Status bar.

- Pump Stopped

- Both Batteries Disconnected
- VAD Disconnected

For more information about emergency alarms, see “Emergency alarms” on page B-4.

Possible diagnostic alarms

The following list contains possible diagnostic alarms that can display in the Alarm window and trigger a yellow Alarm Status bar.

- Controller Failure
- Excess Current
- Reduced Flow Rate
- Reduced Motor Speed
- Pump Restarted
- Battery # 1 Disconnected
- Battery #1 Discharged
- Battery #1 Expired
- Battery #2 Disconnected
- Battery #2 Discharged
- Battery #2 Expired

For more information about diagnostic alarms, see “Diagnostic alarms” on page B-6.

Alarm Silence button

The Controller transmits alarms to the HeartAttendant® as the alarms occur. To clear the alarms from the Alarm Status bar and the **CURRENT ALARMS** pane in the Alarm window and to silence the Controller alarm, press the green Alarm Silence button on the Alarm Status bar (shown in Figure 5-15).

Figure 5-15. Alarm Silence button

Acknowledging the Controller alarms only silences the Controller audible signal; you must also press the Controller Alarm Silence button to clear the alarm from the Controller's LCD and LEDs. Clear alarms as soon as possible after they occur in order to detect new alarms or a recurrence of the same alarm.

The alarm messages continue to alternately display on the Controller LCD display until you press the Alarm Silence button on the Controller or until the alarms clear automatically.

Emergency alarms continue to sound and display until you resolve the source of the alarm. Pressing the Alarm Silence button on the Controller or HeartAttendant® does **not** silence the alarm until you resolve the underlying condition.

When the condition causing the emergency alarm no longer exists, the alarm silences and automatically clears from the **CURRENT ALARMS** pane in the Alarm window.

Viewing VAD flow in real time

The flow waveform graph in the **FLOW L\Min** flow waveform pane plots VAD flow in liters per minute in real time. The time scale scrolls from left to right and covers a five-second time span. See Figure 5-8 on page 5-8 for an example of this graph.

Viewing VAD status

The Status Display pane is near the bottom of the **PATIENT** screen on the left, just above the Display Select buttons pane. This pane contains four indicator boxes that display VAD statuses, including speed, flow, power, and battery percent, described in the following subsections.

The Graphical Display pane is just above the Status Display pane and contains four bar graphs that correspond with each indicator box in the Status Display pane. These bar graphs also display alarm thresholds. See “Setting alarm parameter thresholds” on page 5-16 for more information on alarm thresholds.

See Figure 5-8 on page 5-8 for an example of the indicators and graphs discussed in the following subsections.

The Status Display pane appears on all HeartAttendant® screens.

SPEED kRPM indicator

The **SPEED kRPM** indicator in the Status Display pane displays VAD speed in thousands of RPM (kRPM). Set VAD speed between the allowed settings of 7.5 kRPM (7,500 RPM) and 12.5 kRPM (12,500 RPM). The displayed VAD speed can vary due to pulsatility.

SPEED kRPM graph

The **SPEED kRPM** graph is directly above the **SPEED kRPM** indicator. This graph displays the current VAD speed in a green bar graph and also displays the **REDUCED MOTOR SPEED** alarm threshold in a red line.

FLOW L/MIN indicator and large flow display

The **FLOW L/MIN** indicator in the Status Display pane displays the average flow through the VAD, which is measured in liters per minute. (The flow waveform pane shows a graphical display of instantaneous flow.)

FLOW L/MIN graph

The **FLOW L/MIN** graph is directly above the **FLOW L/MIN** indicator. This graph displays the current VAD flow in a green bar graph and also displays the **REDUCED FLOW ALARM** threshold in a red line.

POWER WATTS indicator

The **POWER WATTS** indicator in the Status Display pane displays the watts used by the VAD and motor controller together. (This data excludes CPU and flow sensor power requirements.)

POWER WATTS graph

The **POWER WATTS** graph is directly above the **POWER WATTS** indicator. This graph displays the current VAD power consumption in a green bar graph and also displays the **EXCESS CURRENT** alarm threshold in a red line.

BATTERY % indicator

The **BATTERY %** indicator in the Status Display pane displays the battery charge level as a percent of full capacity for the battery connected to battery port 2.

BATTERY % graph

The **BATTERY %** graph is directly above the **BATTERY %** indicator. This graph displays the battery charge level in a green bar graph and also displays the **BATTERY DISCHARGED** alarm threshold as a red line.

L/min large flow display

The large **L/min** flow display in the center, right of the screen displays the average flow through the VAD in liters per minute in a larger format.

Viewing the patient ID

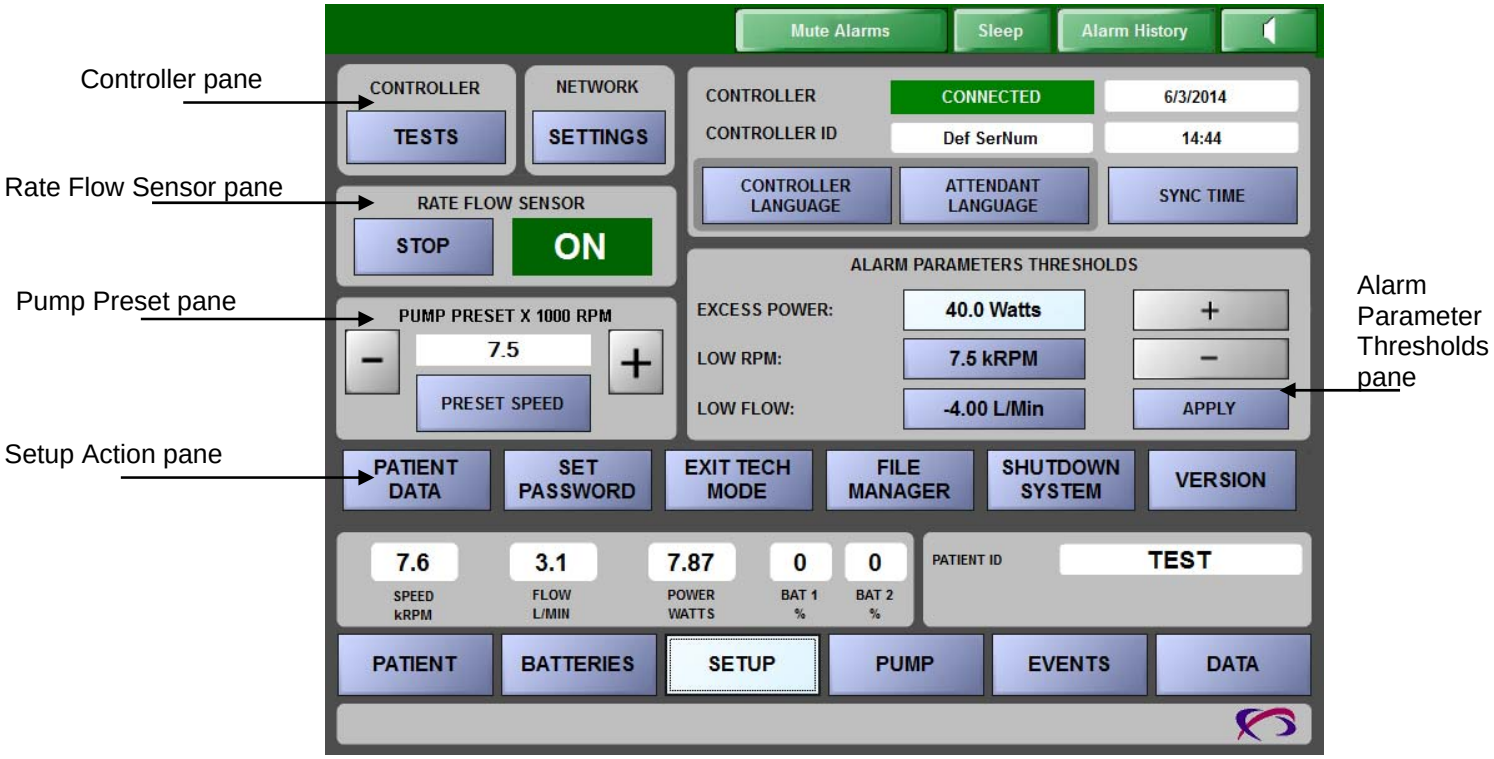
The **PATIENT ID** pane (shown in Figure 5-8 on page 5-8) displays the current patient directory folder name in the operating system.

To change the patient directory, see “Changing patient directories” on page 5-23.

SETUP screen

Use the **SETUP** screen to enter all operational data for the Controller. Configure the Controller before a patient is implanted. (See “Preparation for implant” on page 3-3.)

Figure 5-16. SETUP screen



Running Controller tests

Use the **TESTS** button in the top, left **CONTROLLER** pane to select the desired diagnostic test. View the results in the Test Results window. Some of the tests require monitoring the Controller.

> Only execute these tests prior to surgery or while the VAD and patient are stable. Some tests can take several seconds to complete.

Available tests include the following:

- Test Message/Parameter EEPROM
- Test LED Annunciators
- Test Audible Annunciators
- Test LCD Display

Viewing the Controller communication status and ID and setting the language, date, and time

The following controls display on the **CONTROLLER/CONTROLLER ID** pane on the **SETUP** screen.

Controller communication status

The first box on the **CONTROLLER** row of the **CONTROLLER/ CONTROLLER ID** pane is green and displays the word **CONNECTED** if the Controller is connected and communicating properly with the HeartAttendant®.

Date

The right box on **CONTROLLER** row displays the date for the connected Controller.

Controller ID (serial number)

The first box in the **CONTROLLER ID** row displays the serial number of the Controller connected to the HeartAttendant®.

Figure 5-17. Controller/Controller ID pane of the SETUP screen

Time

The right box on the **CONTROLLER ID** row displays the set time of the connected Controller.

CONTROLLER LANGUAGE button

Use the following instructions to set the language to display on the Controller screens.

1. Press the **CONTROLLER LANGUAGE** button in the **Controller/Controller ID** pane of the **SETUP** screen. A dialog box with a drop-down menu of languages opens.
2. Select and download the appropriate language.

   After you select and download your language, this language appears on the Controller display screens.

Set the Controller language before surgery begins. This action takes approximately one minute to complete. Do **not** disconnect the Controller from the HeartAttendant® for at least one minute after selecting the language. (See “Preparing the Controllers using the HeartAttendant®” in Chapter 3 on page 3-5 for instructions.)

ATTENDANT LANGUAGE button

Use the following instructions to set the language to display on the PATIENT screen.

1. Press the **ATTENDANT LANGUAGE** button. A dialog box opens.
2. Select the appropriate language to display on the **PATIENT** screen.

SYNC TIME button

The **SYNC TIME** button allows you to sync the HeartAttendant® date and time with the Controller. Use the following steps to reset the Controller date and time to correspond with the HeartAttendant®.

1. Connect the Controller to the HeartAttendant®.

   See “Connecting the Controller to the HeartAttendant®” on page 5-4.

2. Press the **SETTINGS** button and the **SYNC TIME** button.

Deactivating the flow sensor

Use the **STOP** button in the **RATE FLOW SENSOR** pane to deactivate the flow sensor function. You can disable the flow rate sensor circuit in the Controller to conserve energy or if its data become uninterpretable (for example, if the A and B received amplitude, which you can view on the **PUMP** screen, are both less than 1.0 volt). The **RATE FLOW SENSOR** pane indicates the current state of the flow rate sensor circuit.

Presetting VAD speed

Use the **PRESET SPEED** button to set a default VAD speed in the Controller.

1. Use the + and -buttons to increase or decrease the preset VAD speed that is displayed in the **PUMP PRESET** pane. See Figure 5-16 on page 5-14.
2. Press the **PRESET SPEED** button to save the new default VAD speed.
3. Wait 16 seconds before initiating any other HeartAttendant® commands.

The preset speed function on the **SETUP** screen is only available when a Controller is connected and the VAD is not running. If a Controller is connected and running a VAD, then you must change the speed on the **PUMP** screen of the HeartAttendant®.

See “Viewing the pump status and adjusting the VAD speed” on page 5-19 for instructions for changing the VAD speed on the **PUMP** screen.

Setting alarm parameter thresholds

The controls described in the following subsections allow you to set the upper and lower alarm parameter limits for power, flow, RPM, and battery level. The thresholds display as red bars on the **PATIENT** screen, are stored in the Controller, and control the audible alarms. See Figure 5-16 on page 5-14 for an example of these controls.

EXCESS CURRENT threshold

Use the + and – buttons to set excess current threshold to an appropriate number of watts for discharge.

1. In the **ALARM PARAMETERS THRESHOLDS** pane, press the blue Watts button to the right of **EXCESS CURRENT**.
2. Press the + button to increase or the – button to decrease the alarm threshold for the **EXCESS CURRENT** alarm. See Figure B-11 on page B-7 for an example of this alarm.
3. Press the **APPLY** button.

LOW RPM threshold

Use the + and – buttons to increase or decrease the RPM alarm threshold to a value between 7.5 kRPM (7,500 RPM) and 12.5 kRPM (12,500 RPM). Setting this alarm threshold to 7.5 inhibits this alarm on the Controller.

1. In the **ALARM PARAMETERS THRESHOLDS** pane, press the blue **kRPM** button to the right of **LOW RPM**.
2. Press the + button to increase or the – button to decrease the alarm threshold for RPMs.
3. Press the **APPLY** button.

LOW FLOW threshold

Use the + and – buttons to increase or decrease the flow alarm threshold in 0.2 L/min increments to a value between –4 L/min and 6 L/min.

1. In the **ALARM PARAMETERS THRESHOLDS** pane, press the blue **L/Min** button to the right of **LOW FLOW**.
2. Press the + button to increase or the – button to decrease the alarm threshold for flow.
3. Press the **APPLY** button.

Battery % threshold

The battery threshold is automatically set to alarm when a battery depletes to a 25% charge level.

Using the Setup Action buttons

See Figure 5-16, “SETUP screen,” on page 5-14 for an example of the buttons in the Setup Action pane.

The Setup Action buttons are password protected. The password is the same as the tech mode password. Knowledge of this password should be restricted to personnel responsible for maintaining patient data files for ReliantHeart.

PATIENT DATA button

Press the **PATIENT DATA** button to open a dialog box containing a patient data form. Use this form to modify the patient data stored in the Controller.

The operating system uses the data you enter in the **Patient ID** text box as the directory folder name. This directory cannot contain the following characters:

\ / : ? < > |*

Do **not** enter the above characters in the **Patient ID** text box.

SET PASSWORD button

Press the **SET PASSWORD** button to open a dialog box containing a form for changing the tech mode and Setup Action buttons password.

EXIT TECH MODE button

Press the **EXIT TECH MODE** button to return to the **PATIENT** screen. A member of the support team or hospital staff must re-enter the password to return to tech mode after exiting that mode.

FILE MANAGER button

The **FILE MANAGER** button starts the Windows Explorer file manager application. This feature is not designed to edit sored controller data, but allows the HeartAttendant user to locate and re-arrange controller data previously downloaded. Please operate the FILE MANAGER button only with the support of ReliantHeart.

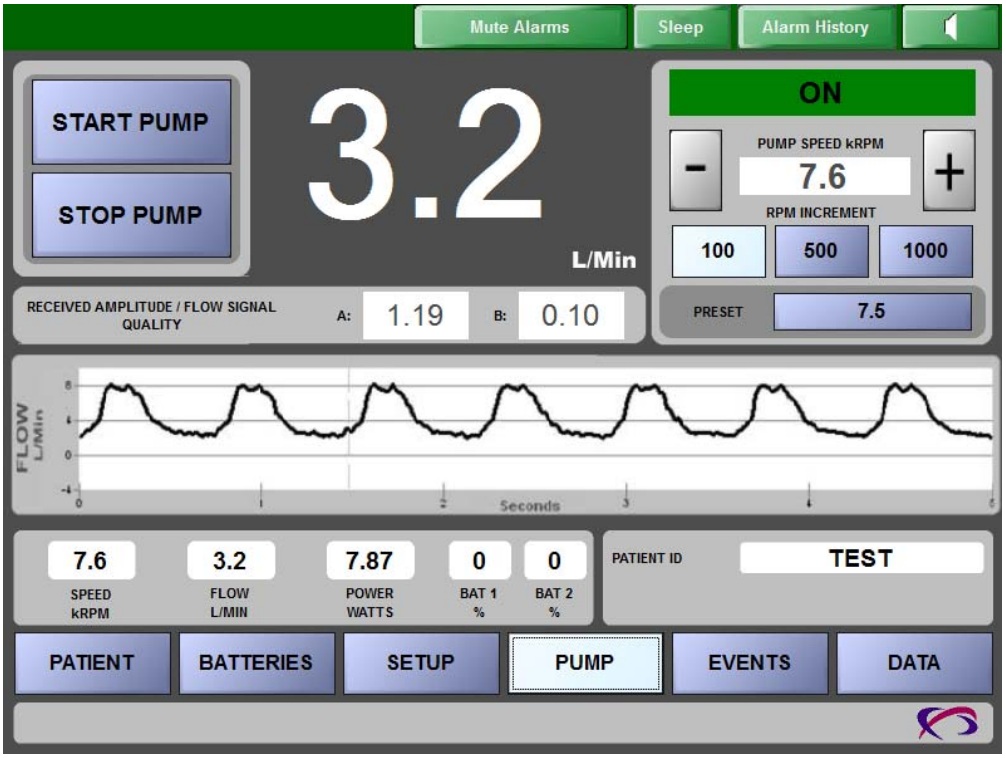
SHUTDOWN SYSTEM button

The **SHUTDOWN SYSTEM** button begins an orderly power-down of the HeartAttendant® system.

PUMP screen

Use the controls on the **PUMP** screen during implant, explant, and VAD control adjustment to increase or decrease the VAD speed and to start and stop the VAD.

Figure 5-18. PUMP screen



Starting and stopping the VAD

Use the **START PUMP** and **STOP PUMP** buttons to activate and deactivate the VAD.

START PUMP button

The **START PUMP** button starts the VAD.

> The **START PUMP** button has no effect if the VAD is already running.

STOP PUMP button

The **STOP PUMP** button stops the VAD and triggers a three-second audible emergency alarm.

Viewing the pump status and adjusting the VAD speed

The colored Pump Status box on the Pump Speed pane on the top, right of the PUMP screen displays the current state of the VAD.

Red Pump Status box

When the Pump Status box is red and displays **Pump OFF**, the VAD is not running.

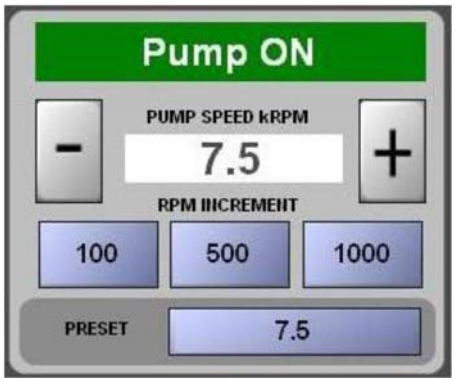
Green Pump Status box

When the Pump Status box is green and displays **Pump ON**, the VAD is running.

Yellow Pump Status box

When the Pump Status box is yellow and displays **PUMP CONDITION UNKNOWN**, the VAD could be on or off, but the HeartAttendant® cannot currently determine the state of the pump (possibly due to communication errors).

Figure 5-19. Pump Status box in the Pump Speed pane



PUMP SPEED kRPM indicator

View the current VAD speed in the **PUMP SPEED kRPM** indicator box under the Pump Status box.

RPM INCREMENT buttons

You can increase or decrease the speed using one of the three **RPM INCREMENT** buttons.

Use the following steps to increase or decrease the VAD speed by a specific increment.

1. Press an **RPM INCREMENT** button (with values of either 100, 500, or 1000) to increase or decrease the VAD speed by the value on that button.
2. Press the – button to decrease the speed, or press the + button to increase the speed.

VAD speed can only be adjusted (increased or decreased) when the VAD is running.

PRESET button

Use the **PRESET** button to change the VAD speed back to the default preset value specified on the **SETUP** screen. (See “Presetting VAD speed” on page 5-16.)

Use the following steps to change the VAD speed to the preset VAD speed value. If you have already specified a VAD speed preset on the **SETUP** screen, begin with step 3.

1. Press the **SETUP** button to access the **SETUP** screen.
2. Follow the instructions in “Presetting VAD speed” on page 5-16 to specify a default VAD speed.
3. Press the **PUMP** button to access the **PUMP** screen.

   The **PRESET** button on the **PUMP** screen displays the default VAD speed specified on the **SETUP** screen.
4. Press the **PRESET** button on the PUMP screen to change the VAD speed to the default value specified in step 2.

Viewing the flow waveform graph

The graph in the **FLOW L\Min** flow waveform pane (see Figure 5-18 on page 5-18) plots VAD pump flow in liters per minute in real time.

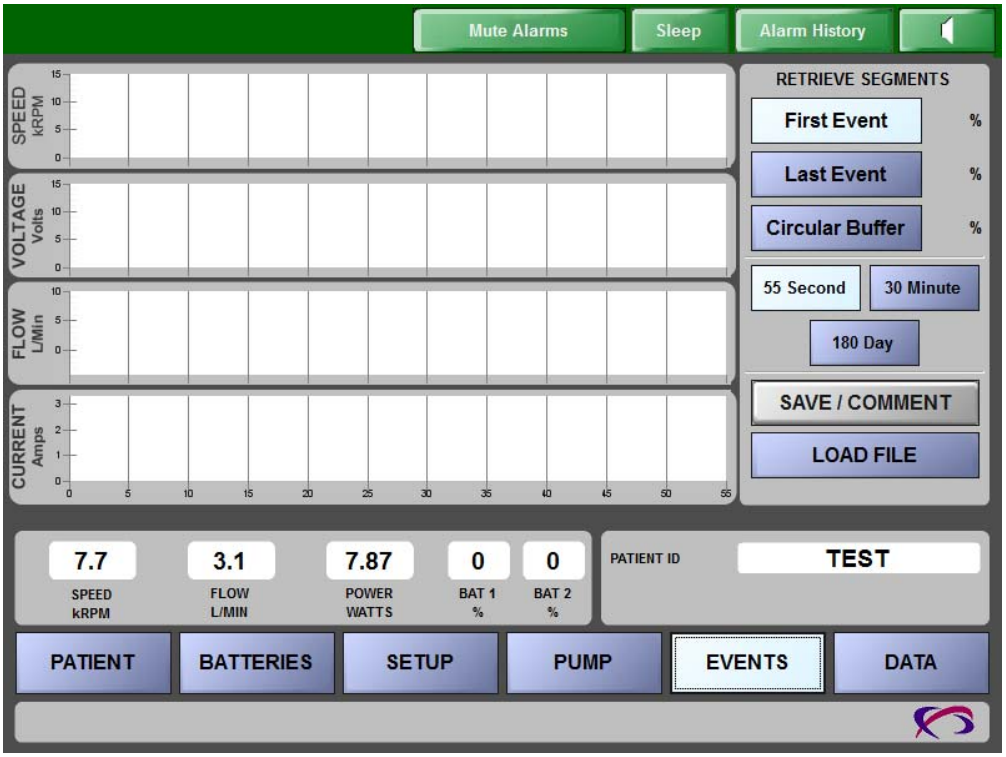
The time scale scrolls from left to right and covers a five-second time span. This pane is the same as the **FLOW L/MIN** flow waveform pane on the **PATIENT** screen.

EVENTS screen

Use this screen to retrieve and display selected data that is currently stored in the Controller event memory or to retrieve historic event memory data that is stored on the HeartAttendant® hard disk. A pump stoppage triggers and event to be captured within the controller memory and the pump parameters within a 55 second or 30 minutes time interval can be analyzed.

The 180 day button downloads a file that has stored flow, power and speed data every minute for up to 180 days.

Figure 5-20. EVENTS screen



Viewing event data

The four graphs in the Event Memory panes on the top, left of the **EVENTS** screen display data currently stored in the selected memory segments of the Controller:

- SPEED
  kRPM
- VOLTAGE
  Volts
- FLOW
  L/Min
- CURRENT
  Amps

Do not disconnect the HeartAttendant® from the Controller during an event memory download (approximately 60 seconds per segment). Wait for 10 seconds after the comment box closes. Disconnecting the HeartAttendant® before data downloading completes can cause loss of data.

Retrieving data segments

Use the buttons in the **RETRIEVE SEGMENTS** pane to view data stored in the selected segment in the Event Memory panes.

The circular buffer checks data every 60 seconds. When an event occurs, the **First Event** space stores that data. When a second event occurs, the **Last Event** space stores the data. If a subsequent event occurs, that data overwrites the existing data in the **Last Event** space. The **Last Event** space always contains the most recent event.

The First Event and Last Event can be analyzed with 3 individual time intervals: 55 second or 30 minute. The data retrieved for the first and last events display speed, voltage, flow, and current in the time period occurring before the event. For example, if the First Event were selected by choosing the 55 second button, the 55 seconds of recorded parameters prior to the event will be stored and displayed.

Viewing the first event

Use the 55 second or 30 minute button to designate the time interval.Use the **First Event** button to view the first event that occurred.

1. Press the **EVENTS** button to access the **EVENTS** screen.
2. Press the **First Event** button.
3. Press the **START DOWNLOAD** button.

   The first event data display in the Event Memory panes.

Viewing the last event

Use the 55 second or 30 minute button to designate the time interval.

Use the **Last Event** button to view the most recent event that occurred.

1. Press the **EVENTS** button to access the **EVENTS** screen.
2. Press the **Last Event** button.
3. Press the **START DOWNLOAD** button.

   The most recent event data display in the Event Memory panes.

If a **PUMP STOPPED** alarm has not occurred since the Controller powered up and prior to download, the Controller displays the default values of 0 in the first and last segments for **VOLTAGE**, **FLOW**, and **CURRENT**. The default value of **SPEED** is 12.5.

Inputting comments with event memory data

The **COMMENTS** button opens a dialog box that allows you to store comments with the event data. The comments dialog box is prepopulated with the patient ID and the date and time of the event. The HeartAttendant® automatically saves these comments with event data, which you can then recall and modify when you retrieve the event data. (See “Displaying and entering comments for currently displayed data” on page 5-25 for information on retrieving comments.)

After you save the comments in this dialog box, the HeartAttendant® instructs the Controller to clear the event memory segment. This process takes approximately six seconds.

Use the following instructions to save comments with event memory data.

1. Press the **EVENTS** button to access the **EVENTS** screen.
2. Press one of the following:
   - Press the **First Event** button to view the first event.
   - Press the **Last Event** button to view the most recent event.
3. Press the **START DOWNLOAD** button.

The **START DOWNLOAD** button now reads **CANCEL DOWNLOAD**.

Press this button if you want to stop the process.

The **EVENTS** screen displays the download progress in percent downloaded under the **CANCEL DOWNLOAD** button. When the percent downloaded reaches 100% Completed, the data display in the Event Memory panes.

4. Press the **COMMENTS** button after the data is 100% downloaded. The **HolterFile - Enter comments** dialog box opens.

Pressing the **COMMENTS** button only initiates an action after you save an event using steps 1 through 3.

5. Press the **EDIT** button on the **HolterFile - Enter comments** dialog box. The on-screen keyboard displays. The dialog box is prepopulated with the patient ID and the date and time of the event.
6. Type your comments in the dialog box.
7. Press the **SAVE** button on the **HolterFile - Enter comments** dialog box.

   The HeartAttendant® saves the comments with the event data.

Changing patient directories

The HeartAttendant® stores files in directories that correspond with the patient's ID. If a Controller is connected to the HeartAttendant®, the current directory defaults to the patient ID of the connected Controller.

Use the following instructions to change the patient directory (only for viewing a different patient's saved event files).

1. Press the **LOAD FILE** button.

   A drop-down menu opens that displays the files for all patients.
2. Select the patient file to display.

Loading previously saved event files

To view a previously downloaded and saved event memory file, press the **LOAD FILE** button; then select the file.

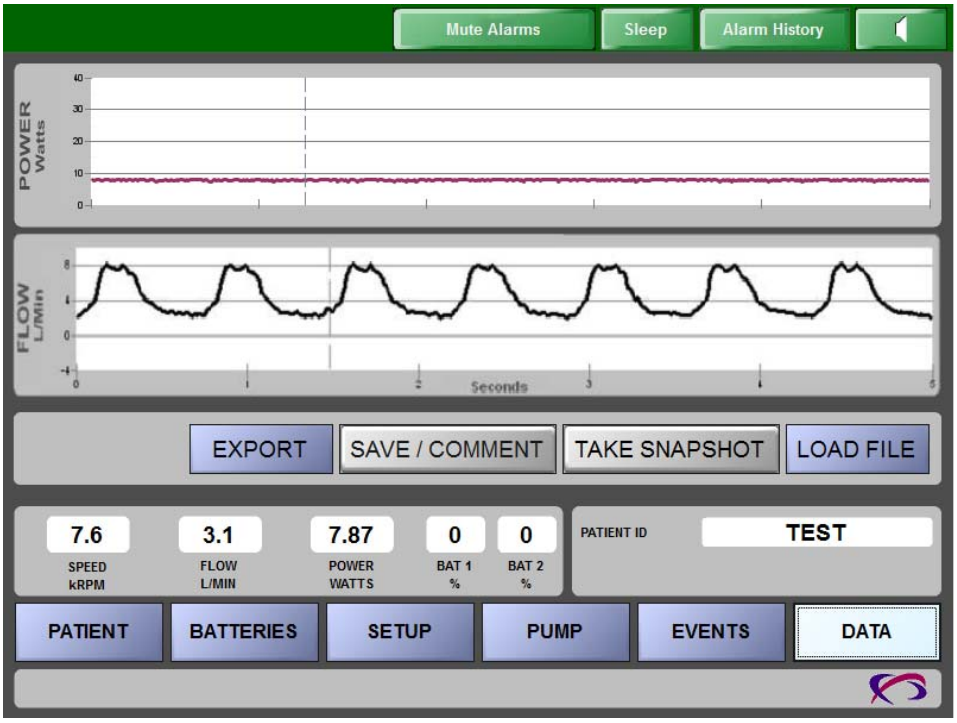
The HeartAttendant® stores the files in the format holxx-yymmdd_hhmmss.hol, where xx represents the saved segment in the file, yymmdd represents the date on which the file was saved, and hhmmss represents the time in which the file was saved (on a 24-hour clock).

For example, a file named hol01-120411_104033.hol is a last event segment saved on April 11, 2012 at 10:40:33 a.m.

DATA screen

The **DATA** screen allows real-time acquisition and storage of power and flow data. This screen allows you to export data, enter commands, and take and retrieve screenshots.

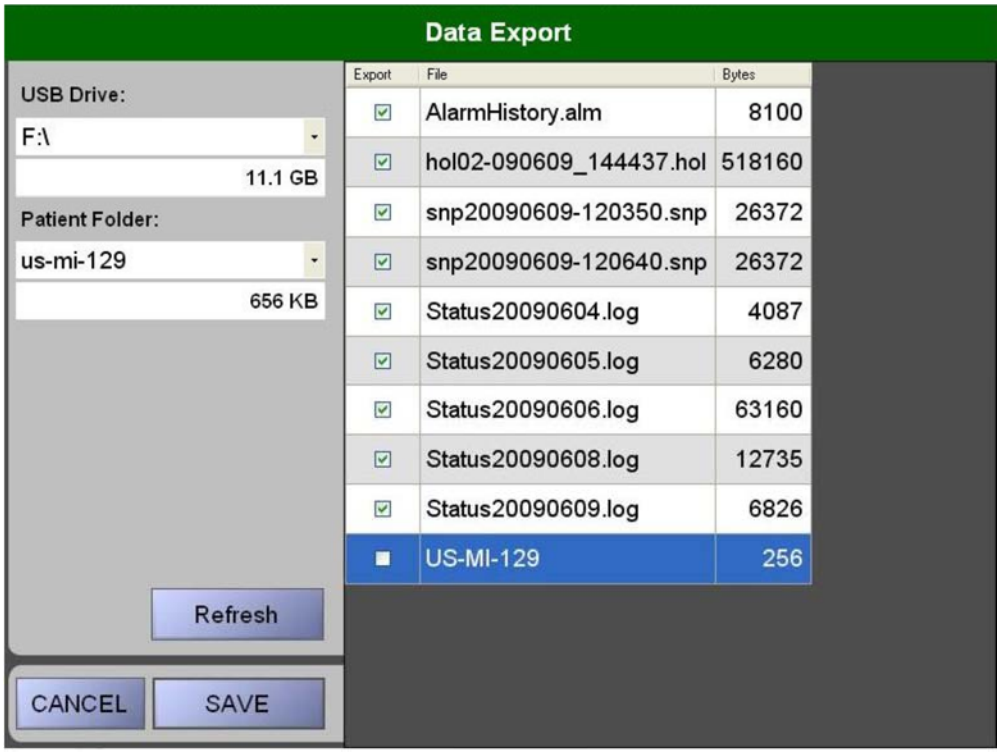
Figure 5-21. DATA screen



Exporting patient data

You can export patient data to a USB flash drive using the following instructions.

Figure 5-22. Data Export dialog box



1. Insert a USB drive into the USB slot on the HeartAttendant®.

2. Press the **PATIENT** button to navigate to the **PATIENT** screen.

   The **PATIENT** screen displays.

3. Record the patient ID in the **PATIENT ID** pane.

   See “Viewing the patient ID” on page 5-13.

4. Press the **DATA** button to navigate to the **DATA** screen.

5. Type the password if prompted.

   The **DATA** screen displays.

6. Press the **EXPORT** button.

   The **Data Export** dialog box opens.

7. In the **Patient Folder** drop-down menu, select the patient ID that you recorded in step 3.

8. In the **Export** column on the right pane, select the check boxes for the files that you want to copy to the USB drive.

   Table 5-1 lists the file extensions available for exporting.

   Table 5-1. File types available for exporting

File type	File description
Status*.log	Status log files, recorded automatically, one file per day, 110 Kb/day, one entry per minute
AlarmHistory.alm	Alarm history file, updated continuously as alarms are recorded
*.hol	Event memory files, downloaded from the Controller, 507 Kb/each
*.snp	Snapshot files from the **DATA** screen, 26 Kb/each

***Copy* files to the USB flash drive. Do not delete any files from the HeartAttendant®.**

9. Press the **SAVE** button.

10. Remove the USB drive from the HeartAttendant®.

11. Email all files to patientdata@reliantheart.com.

    Type the patient ID in the Subject field, and send each patient's data in a separate email message.

12. After you have successfully emailed the files, delete the confidential patient data from the USB drive.

Displaying and entering comments for currently displayed data

Use the **COMMENTS** button to display and type comments corresponding to the currently displayed data.

This button and its corresponding dialog box have the same functionality as the **COMMENTS** button on the **EVENTS** screen. See “Inputting comments with event memory data” on page 5-22 for detailed instructions for inputting comments.

Obtaining screenshots

Use the **TAKE SNAPSHOT** button to obtain and store a screenshot of five seconds of the current waveform on the screen.

To view the screenshot, see the next section, “Retrieving screenshots.”

Retrieving screenshots

Use the following steps to view a previously downloaded and saved screenshot in snap file format.

1. Press the **DATA** button.

   The **DATA** screen displays.

2. Press the **LOAD FILE** button.

   The current patient’s saved screenshots display.

3. Select the screenshot to display.
4. Highlight the screenshot that you want to view.
5. Press the **Select** button to view the highlighted file.

   The selected screenshot displays.

6. Press the **Show Live Data** button to return to the **DATA** screen.

Changing patient directories

The HeartAttendant® stores screenshots in snap file format in directories corresponding with the patient's ID. If a Controller is connected to the HeartAttendant®, the current directory defaults to the patient ID of the connected Controller.

To change this directory (only for viewing a different patient's screenshots), use the following steps.

1. Press the **DATA** button.

   The **DATA** screen displays.

2. Press the **LOAD FILE** button.

   The current patient’s saved screenshots display, and the **Patient Folder** dialog box opens with a drop-down menu that displays the directories for all patients.

3. Select the appropriate patient ID in the drop-down menu of the Patient Folder dialog box.

   The selected patient’s files display.

4. Highlight the screenshot that you want to display.
5. Press the **Select** button to view the highlighted file.
6. Press the **Show Live Data** button to return to the **DATA** screen.

Snap file format

The HeartAttendant® stores screenshots in snap files in snpyyyymmdd-hhmmss.snp format, where yyyymmdd represents the date on which the file was saved, and hhmmss represents the time in which the file was saved (on a 24 hour clock).

For example, the file named snp20120411-104033.snp is a screenshot saved on April 11, 2012 at 10:40:33 a.m.

Cleaning and maintenance

Use the following steps to maintain the cleanliness of the HeartAttendant®.

Cleaning the HeartAttendant®

Wipe the outer case of the HeartAttendant® with a slightly damp cloth, then wipe the case with isopropanol to remove contaminants. Do **not** allow liquid to spill into the HeartAttendant® components.

Always unplug the HeartAttendant® before cleaning it.

Maintaining the HeartAttendant®

The HeartAttendant® contains no user serviceable parts. Contact for service at the phone number listed on page iii. Replace the HeartAttendant® connector cable if the cable shows any signs of functional or visible damage.

Transporting the HeartAttendant®

You must place theHeartAttendant® on a secure surface. Use caution when moving it.

Do not allow the HeartAttendant® to tip at more than a 30° degree angle.

Transport the HeartAttendant® from location to location while it is powered off.

Dropping the HeartAttendant® while it is connected can cause injury. Disconnect the HeartAttendant® connector cable prior to moving the HeartAttendant®.

To carry the HeartAttendant®, grasp the top handle and the bottom handle near the front of the unit, and carry it close to your body for maximum support and comfort.

Contact before shipping the HeartAttendant® to another location. can provide a replacement shipping box with custom packing inserts for safe transport.

Hazards

Use the information in the following subsections to prevent damage and injury from electrical hazards.

Grounding the HeartAttendant®

Before you make any connection to the Controller input, you must connect the HeartAttendant® to a protective earth ground via the three-core mains cable supplied. Only insert the mains plug into a socket outlet provided with a protective earth contact.

Verifying local mains voltage

Before plugging the HeartAttendant® into an electrical outlet, ensure that the HeartAttendant® is configured for local mains voltage. See “Powering on the HeartAttendant®” on page 5-3 to verify the voltage configuration.

The following list contains warnings typical to medical electrical equipment, which also apply to the HeartAttendant®. These warnings appear on HeartAttendant® labeling.

- The HeartAttendant® must be disconnected from all voltage sources when a fuse is to be replaced.
- The nominal mains voltage and frequency is 120VAC-60Hz or 240VAC-50Hz.

Replacing fuses

The rear panel of the HeartAttendant® contains a fuse holder in the mains input socket. Use the following steps to replace the mains fuse.

See Figure 5-23 for an example. For information on obtaining replacement fuses, see “Connecter cables, power cords, and fuses” on page C-7.

1. Disconnect the HeartAttendant® AC power cord from the mains, and verify that the HeartAttendant® is disconnected from ***all*** other voltage sources.
2. Remove the cover of the fuse holder using a small screwdriver.

Figure 5-23. Mains input socket on the rear panel of the HeartAttendant®

3. Fit a new fuse of the correct rating according to the rear label of the HeartAttendant®.
4. Reinsert the fuse holder into the power inlet module.

Figure 5-24. Fuse block in power inlet module

5. Power on the HeartAttendant®, and verify that it boots up normally.

Only use fuses supplied by for the HeartAttendant®. When changing fuses, fully snap the fuse block back into place. Only use replacement fuses with the required current rating and of the specified type as listed on the rear panel of the HeartAttendant®. The use of makeshift fuses or short circuiting of the fuse holder is prohibited.

Any interruption of the protective conductor inside or outside the HeartAttendant® while the mains are connected is likely to make the device dangerous. Intentional interruption of the protective conductor is prohibited while the mains are connected.

Chapter 6
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.

System management

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

Contact ReliantHeart if any of the Controller alarms are not working.

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

Upon waking

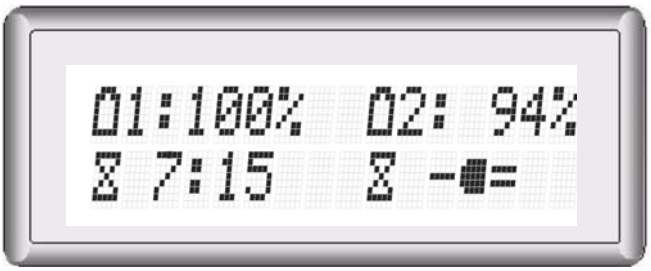
When the patient wakes in the morning, check the front panel display of the Controller for lighted symbols and messages. If the Controller is displaying alarm messages, see “Emergency alarms” on page B-4 and “Diagnostic alarms” on page B-6.

Before sleeping

Before the patient goes 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 6-1. 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 the patient is 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 the patient is relaxing or sleeping, use the HeartAttendant® or the Independent Power Supply in the tethered mode of operation (described in the following section).

When the patient is 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 or the HeartAttendant® during this time.

Tethered operation

During times of little activity, such as when the patient is sleeping or relaxing, you should use the HeartAttendant® or the Independent Power Supply. This method is called *tethered* operation. The HeartAttendant® is only used for monitoring the patient's condition while the patient is in the hospital.

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

When you use the Independent Power Supply, or the HeartAttendant®, 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 the patient to untethered mode. The Controller draws power from one battery until it reaches 25% before drawing power from the second battery. Once at 25% charge, the controller switches to the second battery until it reaches 25%. This design ensures that the second battery will have energy remaining when the first battery falls below a 25% charge level. If both batteries are at or below 25%, the controller switches back to the first battery and drains until 15% and switches to second battery. At this time, both batteries are at or below 15% charge and must be replaced to prevent pump stoppage.

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 the patient stays 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

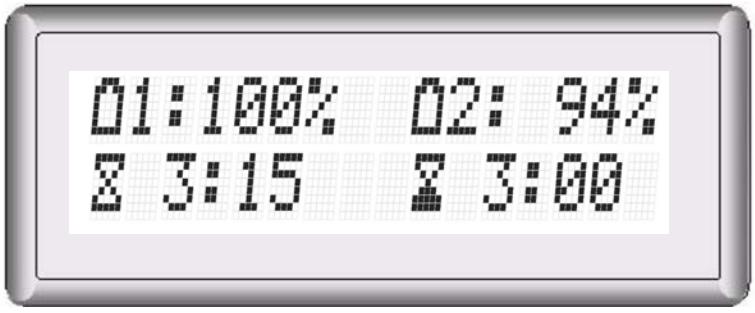
Use the following steps to change the power source from tethered to untethered operation.

Verifying battery charge

Use the following steps before disconnecting the patient from the Independent Power Supply or the HeartAttendant®.

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

Figure 6-2. 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 the patient is 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 or the HeartAttendant®

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

Disconnect the Independent Power Supply or the HeartAttendant® 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 not 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 HeartAttendant® or the Independent Power Supply connector from the battery pocket external power connector ***before*** removing power to or turning off the Independent Power Supply or the HeartAttendant®.

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 or the HeartAttendant® is ready to be used.

- Verify that the system status light of the Independent Power Supply is a steady green or the HeartAttendant® screen is illuminated.

Connecting to the battery pocket external power connector

Use the following general steps to connect the power source connector (Independent Power Supply connector or the HeartAttendant® 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.

Showering with the VADPAK Insert and shower bag

The patient's doctor will provide instructions for the exit site care before, during, and after showering.

Do not allow the patient to shower with the VAD connected to the Independent Power Supply or the HeartAttendant® (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, the patient 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, the patient 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 6-3. 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 6-4. 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 6-5. 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 ReliantHeart 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 allows the patient to 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 6-1 are ***always prohibited*** for the patient's safety and for the function of the device.

Table 6-1. 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 allowing the patient to engage in the activities described in Table 6-2.

Table 6-2. 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)	The patient and his or her doctor can determine whether participation in a certain sport could cause equipment damage or bodily harm.

The activities described in Table 6-3 have no known risks.

Table 6-3. Permitted activities

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

Caring for the exit site

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 the patient to carry the Controller, battery pockets, and batteries. If the patient is going for a walk, disconnect the Independent Power Supply or the HeartAttendant®.

Chapter 7
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 ReliantHeart.

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 7-1. 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, HeartAttendant® 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 ReliantHeart.

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 8
Return and Disposal

In this chapter

Introduction

This chapter discusses the procedures necessary to return and dispose of the HeartAssist 5® VAD System components.

Return of components

If the patient is participating in a clinical trial, ReliantHeart requests the return of all components of the HeartAssist 5® VAD System to ReliantHeart when the device is explanted, as described in the following subsections.

HeartAssist 5® VAD

Explant the VAD according to the procedures in “Explanting the VAD” on page 3-26. Package and return the VAD using the supplied return container. Return the VAD components to ReliantHeart using an approved Returned Goods Authorization (RGA).

Return the following VAD components:

HeartAssist 5® VAD

Inflow cannula

Outflow graft

Graft protector

Flow probe

Intact sewing ring

Percutaneous cable

VAD accessories

Pack VAD accessories (devices that are used during the operation of the VAD system and that are in contact with the patient) in the original suitcase supplied, label them clearly with the patient ID number, and return them to ReliantHeart using an approved Returned Goods Authorization (RGA). Do not return the HeartAttendant®, 12-volt batteries, LVAD Battery Charger, or Independent Power Supply.

Return the following devices:

Controllers (primary and backup)

VADPAK

HeartAttendant®

The HeartAttendant® is retained by the center for use with additional patients. If the HeartAttendant® is no longer needed, contact customer support (see page iii) to arrange shipping for the unit to ReliantHeart.

LVAD Battery Charger

The LVAD Battery Charger is retained by the center for use with additional patients. If the LVAD Battery Charger is no longer needed, contact customer support (see page iii) to arrange shipping for the unit or units to ReliantHeart.

12-volt batteries

If batteries are part of an ongoing clinical trial, contact customer support (see page iii); otherwise, dispose of batteries in accordance with Disposal.

Disposal

Follow local governing ordinances and recycling plans regarding disposal or recycling of non-returnable device components.

Chapter 9

The HeartAssist 5® LBSA VAD and the Pediatric Patient

In this chapter

Overview

The HeartAssist 5® LBSA VAD is indicated for use to provide temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients (5-16 years old, with BSA greater than or equal to 0.7 m2 and less than 1.5 m^2) who are in NYHA Class IV end stage heart failure, are refractory to medical therapy and who are (listed) candidates for cardiac transplantation.

All of the information presented in the *HeartAssist 5® VAD System Operator's Manual* is true for the HeartAssist 5® LBSA VAD and the pediatric patient. This section reviews issues that are specific to the use of the HeartAssist 5® LBSA VAD in pediatric patients. This section is directed toward the physician-investigator and hospital staff caring for the HeartAssist 5® LBSA VAD patient.

Persons providing care to pediatric patients who receive this device should read this entire manual and Chapter 7 of the *HeartAssist 5® VAD System Patient Manual* before managing operation of the HeartAssist 5® LBSA VAD in children or adolescents. This section 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.

Description

The HeartAssist 5® LBSA VAD is essentially the same device as the adult HeartAssist 5® VAD with modifications to enhance fit in the child. The functionality of the HeartAssist 5® LBSA VAD and the HeartAssist 5® VAD are the same in providing adequate blood flow, so the HeartAssist 5® LBSA VAD is expected to provide clinical benefit in children with end-stage heart failure. The HeartAssist 5® LBSA VAD has all of the same attributes as the HeartAssist 5® VAD since the primary differences in the HeartAssist 5® LBSA VAD are to optimize fit of the device in children.

The following minor modifications have been incorporated into the adult VAD to make the HeartAssist 5® LBSA VAD:

- 140° inflow cannula angle

  The tighter inflow angle (140^{o} vs. the 115^{o} angle of the adult VAD) allows for better positioning of the VAD to facilitate the best fit in the pre-peritoneal or thoracic cavity of the smaller BSA patient.

- Shortened graft protector

  The function of the flexible graft protector is to assure a smooth bend radius of the outflow graft and prevent it from kinking. A shorter graft protector is necessary because the tighter inflow cannula angle positions the pump outflow somewhat closer to the aorta, thereby decreasing the distance between the pump outflow and the aorta in smaller-framed patients. The graft protector is shortened to a length that will facilitate a better fit in a smaller thoracic cavity while not affecting its function.

- Shortened inlet cannula

  The length of the inflow cannula is shortened by 1 cm to adapt to the smaller pediatric ventricle.

There are no changes to function or additional safety risks. All ancillary equipment and accessories for the HeartAssist 5® LBSA VAD are identical to those used in the adult HeartAssist 5® VAD System.

At locations where both the adult HeartAssist 5® VAD and the HeartAssist 5® LBSA VAD are being implanted, it is imperative to select the HeartAssist 5® LBSA VAD for children. The outer packaging for the HeartAssist 5® LBSA VAD is clearly labeled and indicates

that the VAD is a humanitarian use device. Moreover, the visibility of the pump in its blister pack allows identification of the tighter inflow cannula angle and the shortened graft protector.

Implant

The sequence of surgical steps to implant the HeartAssist 5® LBSA VAD is the same as performed with adult implants. The primary concern for implant in children is achieving the proper fit of the HeartAssist 5® LBSA VAD in the thoracic cavity. Assess the potential fit of the HeartAssist 5® LBSA VAD in pediatric patients prior to implant using methods such as chest x-ray, echocardiogram, or CAT scan. At the time of surgery, fit may be determined using the anatomical fit pump provided with the implant kit. Once implanted, the position of the inflow cannula in the ventricle can be evaluated with trans-esophageal echocardiography and the pump adjusted in the pocket to result in proper position.

Consider the nature of axial flow and each child's specific cardiac anatomy when implanting the HeartAssist 5® LBSA VAD. Septal shunts can reduce flow across the pump and can also be exacerbated by the continuous pumping action of the device. Certain cardiac anomalies might make it difficult to place the inflow cannula properly, and when it lies too close to the septum or free wall might result in ventricular collapse. The potential device-heart interaction for all variations of potential cardiac anomalies in children is beyond the scope of this discussion and is left to the surgeon's expertise.

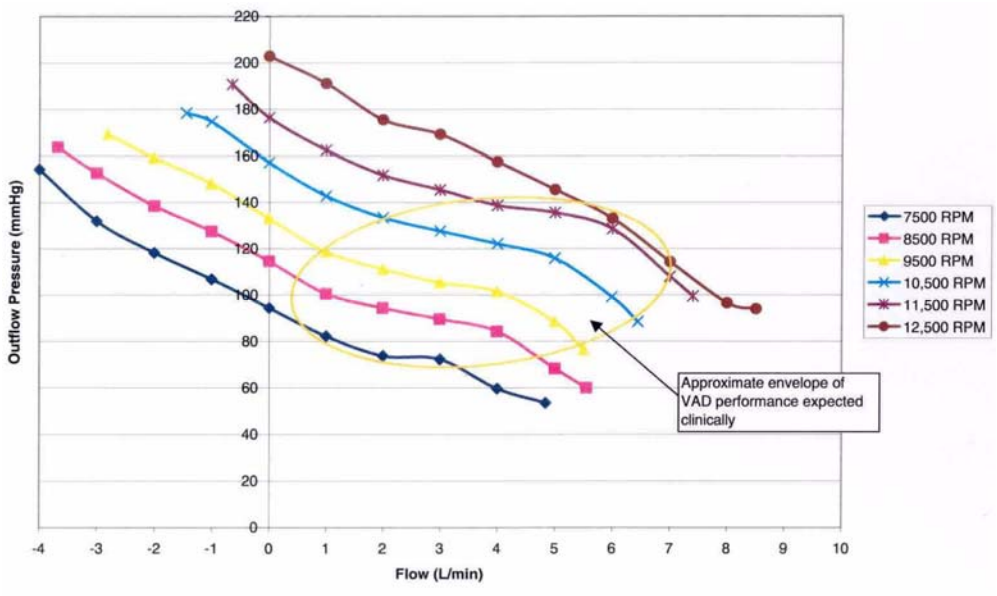
HeartAssist 5® LBSA VAD operation

The HeartAssist 5® LBSA VAD has a flow capacity equivalent to the adult pump that should be adequate to provide circulatory support in children. The pump can operate effectively at the range of flows expected for pediatric heart failure patients. When assessing the suitability of the small child's flow needs, Figure 6-3 shows the relationship between speed, flow, and outflow pressure that may be helpful in estimating flow and speed settings for the child. As with the adult HeartAssist 5® VAD, pump flows can be adjusted in the HeartAssist 5® LBSA VAD by controlling the pressure gradient across the pump with perturbations of preload and afterload.

Children are more reactive to neurovascular stimuli such as changes in cardiac output or the administration of vasoactive drugs. In particular, rapid changes in systemic vascular resistance (SVR) can be experienced with pediatric patients. Elevated SVR reduces pump flow by elevating the outflow pressure and increasing resistance across the pump. In such situations of low flow and increased SVR, treating the elevated SVR could be superior to altering the pump speed to attain more flow. If a child receives a low flow alarm, the SVR should be evaluated by checking the patient's blood pressure. When frequent low flow alarms occur, consider arranging for home monitoring of the child's blood pressure with a Doppler stethoscope if necessary.

The minimum pump speed for the HeartAssist 5® LBSA VAD is 7500 RPM; the VAD cannot run at a lower speed regardless of the patient's physiology. Figure 9-1 on page 9-4 depicting the relationship between outlet pressure, pump speed, and flow can be helpful in determining the speed to set the VAD to achieve the desired flow for a child.

Figure 9-1. Outlet pressure vs. flow



Initially, set the HeartAssist 5® LBSA VAD speed threshold alarm so that repeated **REDUCED MOTOR SPEED** alarms do not occur at the speed required to obtain the desired pump flow for a child. See “Setting alarm parameter thresholds” on page 5-16.

All ancillary equipment and accessories for the HeartAssist 5® LBSA VAD are identical to those used in the adult HeartAssist 5® VAD System. There is a slight, but unlikely, chance that toys that utilize wireless or radio controlled technology might cause electromagnetic interference with the Controller. Prior to patient discharge to the home, this possibility should be tested with toys the child frequently uses.

Smaller children might have difficulty changing batteries due to the size and weight of the batteries. In such cases, caregivers must change batteries for the child at appropriate intervals or the child should be carefully supervised during battery changes.

The VADPAK containing the Controller and two batteries might be large for the child and might be heavy for the child to wear. The shoulder strap and waist belt should be adjusted to fit the child well before the child is discharged to the home. If the weight of the VADPAK puts pressure on the child’s shoulder, extra padding can be placed beneath the shoulder strap. In the event that alternate means for wearing the Controller and batteries must be employed, ensure that the child’s percutaneous cable, Controller and batteries remain in close proximity to the exit site to avoid stretching or uncoupling of connections.

Alarms

Alarm functions for the HeartAssist 5® LBSA VAD are identical to those used in the adult HeartAssist 5® VAD System. The alarm threshold for flow might need to be reduced to avoid low flow alarms in smaller children who may have flows less than 2 L/min. If the child is old enough, he or she should be taught to react to alarms by seeking help from a

parent or caregiver. Adolescents can be taught how to resolve diagnostic alarms and respond to emergency alarms. Children who cannot recognize or respond to alarms properly should be within hearing distance of a responsible person knowledgeable in the operation of the HeartAssist 5® LBSA VAD at all times. The significance of emergency alarms, i.e., **PUMP STOPPED**, should be communicated to the child with a HeartAssist 5® LBSA VAD.

Patient teaching

Both children and their parents or caregivers should receive training in how to manage the HeartAssist 5® LBSA VAD system. Parents and caregivers can be trained in a manner similar to adult HeartAssist 5® VAD patients. Information in the *HeartAssist 5® VAD System Patient User's Manual* must be taught to children using age appropriate materials that match the child's attention and comprehension abilities. Information should be conveyed to children in multiple, short sessions and the child should be allowed to practice or interact with their device as much as possible. The focus of HeartAssist 5® LBSA VAD teaching in the pediatric patient should be on making the child an active participant in his or her care. Special emphasis should be placed on the ability to recognize and respond to alarms as well as procedures for the child to follow in case of emergency.

To ensure their safety, children should be taught to understand that the device is life supporting and that none of the components, especially the Controller, are objects with which to play. The child will need a sense of the criticality associated with the connection between the percutaneous cable and the Controller so that he or she will protect it. It is essential to teach the child and the caregiver how to care for the exit site and how to avoid situations that might cause the site to get dirty in order to prevent exit site or driveline infections. As a result of patient teaching efforts, children with the HeartAssist 5® LBSA VAD should become comfortable with the device and know its value to their life, while at the same time, have no fear of the device.

Children should not be discharged home with the HeartAssist 5® LBSA VAD unless the parent or caregiver and the child, to the extent possible, have successfully completed training in the device's management. Parents or caregivers should be advised to continue to reinforce teaching with the child while at home. Local emergency services personnel, the child's teacher and school nurse, and any other people who will assume a care-giving role with the child should be given training in the management of the device, alarms, and emergency procedures when the child is to be discharged.

Outside of the hospital

Before going outside of the hospital, pediatric patients and their parents or caregivers should be provided with the necessary backup equipment and instructed to carry it.

The *HeartAssist 5® VAD System Patient User's Manual* that accompanies The *HeartAssist 5® VAD System Operator's Manual* (this book) provides a discussion of issues that pediatric patients might face with the device during daily operation.

Individuals with a limited ability to care for themselves, including some children, must be accompanied by a companion knowledgeable in the management of the HeartAssist 5® VAD System at all times. Older children, who may not always be with a trained companion, must be well trained in the management of their HeartAssist 5® LBSA VAD system and able to change batteries as well as respond to alarms on their own. Frequent close supervision might be necessary for the parent or caregiver and child to ensure that anticoagulant and other cardiac medications are taken properly and that the exit site is cared for properly.

Infection

The small diameter and flexibility of the HeartAssist 5® LBSA VAD percutaneous cable reduces the potential for infection along the driveline or at the exit site. However, the driveline tunnel is shorter for children and the external cable is likely to be longer at the cable's exit from the body. Both of these factors can increase the impact of any infection in a child with the HeartAssist 5® LBSA VAD.

Because the cable exiting the child's body might be longer, it can be subject to increased movement or damage at the exit site, enhancing the potential for infection. For these reasons, ReliantHeart recommends that the percutaneous cable be stabilized at the exit site in children for the first two weeks after implant until good tissue in-growth has occurred. Tape can be used to secure the cable during this period. Thereafter, the exit need only to be covered when children are in an environment that has a high likelihood of getting the exit site dirty (e.g., a sandbox, playing with cars in the dirt, and so forth). Of course children, parents, and caregivers must be taught proper hygiene for the exit site, and this hygiene should be emphasized during the patient's clinic follow-up visits.

Nutrition and hydration

Nutritional needs vary between the adult and child. Physicians should be cognizant of the varied needs of children and appropriately provide dietary instruction and prescribe nutritional supplements. It should be kept in mind that as blood flow increases in the child as a result of VAD support, they may become more active, restore growth processes, and thus, have dynamic nutritional needs. As in all chronically ill patients, nutrition should achieve a positive nitrogen balance for the child. A positive nitrogen balance is an important factor for preventing infection.

Children become dehydrated more rapidly than adults. Dehydration may lead to reduced left ventricular filling in the child and result in ventricular suction due to the continuous pumping action of the HeartAssist 5® LBSA VAD. In the adult HeartAssist 5® VAD experience, hypovolemic perturbations of pump flow have been observed in the early morning upon awakening. If a child awakes with dizziness or has a flow waveform consistent with suction, the child should be hydrated during the night when feasible. Simply, having the child drink a glass of water if he or she wakes up at night might resolve his or her symptoms of hypovolemia. Parents and caregivers must be careful to prevent dehydration in children when children are active, particularly in hot environments. Children also may become critically dehydrated with various viral illnesses. It is very important to administer appropriate fluids to sick children with the HeartAssist 5® LBSA VAD early in the course of the virus to maintain proper left ventricular filling and pump output.

Anticoagulation

Children with the HeartAssist 5® LBSA VAD must be anticoagulated. Coumadin and aspirin have been used primarily for anticoagulation in the adult HeartAssist 5® VAD population. However, a child may metabolize drugs more rapidly, and might have a greater effect from an adult dosage. Anticoagulation experience with implantable VADs in children is limited. In general, physicians should determine the intensity of anticoagulation in light of their rapidly changing physiology and their propensity for activity and potential injury. The exact pharmacologic agents employed for anticoagulation in a child are left to the discretion of the physician, but in any case, the child should have adequate coverage for the coagulation cascades as well as for platelet activity.

Emergencies

An emergency situation can be caused by conditions requiring medical care or by a mechanical problem that interferes with the pumping ability of the HeartAssist 5® LBSA VAD. It is important to teach the parent or caregiver and the child how to identify and respond to an emergency. The most important action is to restore power and function to the HeartAssist 5® LBSA VAD. Prior to a pediatric patient leaving the hospital, the hospital staff should provide the child and the parent or caregiver with a card, letter, bracelet, or other form of medical identification that indicates the child has a left ventricular assist device. Contact information for the parent or caregiver and the child's physician should be included with the medical identification.

Both cardiopulmonary resuscitation (CPR) and cardiac defibrillation may be performed on the child with a HeartAssist 5® LBSA VAD system. As with the adult HeartAssist 5® VAD patient, a pulse for the child with a HeartAssist 5® LBSA VAD may not be palpable even when the pump is operating properly. Parents and caregivers should be instructed **not** to perform CPR or cardiac defibrillation if the child is awake and responsive, even if they cannot feel a pulse.

Children who are too young or unable to respond to device alarms, change batteries or seek help should always be accompanied by a parent, caregiver, or other individual knowledgeable in the operation of the HeartAssist 5® LBSA VAD.

Appendix A
Troubleshooting

In this appendix

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.	You can force the VAD to restart by removing both batteries and reinserting 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**. • Check for system damage. • Attempt to verify that an unknown electrical disturbance is not affecting the Controller by moving to another location. If the VAD has stopped and the Controller has finished trying to start nine times, one way to force a restart is as follows: 1. Connect the Controller to the HeartAttendant®. 2. Navigate to the **PUMP** screen. See page 5-18. 3. Wait three seconds, then press the Alarm Silence button. 4. Press **STOP PUMP**, then press **START PUMP**. See page 5-18 and page B-4. **Manual VAD restart** If a HeartAttendant® is not available, and 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 EMS and ReliantHeart. 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 and the HeartAttendant® alarm history triggers. 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-8. 2. Contact ReliantHeart.

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.	This alarm does not automatically clear. You must press the Controller Alarm Silence button. 1. Verify that the VAD is running at the appropriate speed. See Figure B-2 on page B-2. 2. Attempt fluid consumption. 3. Verify that the flow sensor is enabled. See “Deactivating the flow sensor” on page 5-16. 4. Verify that the **RECEIVED AMPLITUDE** on the LCD display of the Controller or on the PUMP screen of the HeartAttendant® (Figure 5-18 on page 5-18) is greater than 1.0 volt for both channels A and B. See Figure B-4 on page B-3. 5. On the Controller or HeartAttendant®, verify that the VAD is not drawing excess current greater than 16 watts. See Figure B-2 on page B-2. 6. Contact ReliantHeart. Even if the VAD appears to be running normally, the patient must return to the hospital to have the situation diagnosed. The speed of the VAD must be increased or the flow alarm value decreased in order to avoid this alarm.
EXCESS CURRENT alarm	The VAD is drawing current in excess of the programmed alarm threshold.	This alarm does not automatically clear. You must press the Controller Alarm Silence button. 1. Verify that the VAD is still producing flow. See Figure B-1 on page B-2. 2. Verify that the VAD is running at or near the set VAD speed. See Figure B-2 on page B-2. 3. Contact ReliantHeart. The patient must return to the hospital for one or more **EXCESS CURRENT** alarms that cannot be cleared in 10 minutes, or for recurrent **EXCESS CURRENT** alarms. During a restart, the **EXCESS CURRENT** alarm can occasionally appear. This condition is normal because the VAD momentarily uses high power during a restart.
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 ReliantHeart.

Alarm or error	Associated event	Troubleshooting
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 ReliantHeart.
BOTH BATTERIES DISCONNECTED alarm	Both batteries are disconnected.	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. If the emergency alarm clears, the batteries are connected; disregard further steps. If the alarm does not silence, continue with step 5. 5. Replace the Controller with the backup Controller. 6. Contact ReliantHeart.
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 ReliantHeart.
Continuous audible alarm	The Controller is malfunctioning.	1. The patient must seek immediate medical assistance if the VAD has stopped. 2. Replace the Controller with the backup Controller. 3. Contact ReliantHeart.
REDUCED MOTOR SPEED alarm	The RPM of the VAD has fallen below the programmed alarm threshold.	1. If the patient experiences dizziness, light-headedness or other **MOTOR SPEED** below the programmed alarm symptoms, he or she must seek medical assistance. 2. Contact ReliantHeart.
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.

Alarm or error	Associated event	Troubleshooting
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 Controller. 3. If alarm does not clear, contact ReliantHeart.
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 ReliantHeart 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 ReliantHeart.
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 ReliantHeart.
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 ReliantHeart.
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 ReliantHeart.

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 ReliantHeart. If the backup battery pocket and the Independent Power Supply are not available, do **not** disconnect the Controller. Try to drain liquid, and contact ReliantHeart immediately.  **The patient 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 ReliantHeart 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 6-4. 4. Press the Alarm Silence button on the Controller front panel. If you do not press the Alarm Silence button on the Controller front panel, the alarm 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 ReliantHeart 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 ReliantHeart for a replacement IPS or APS.

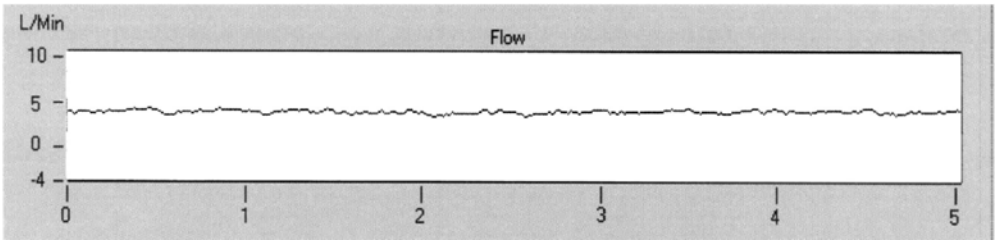
Interpreting suction in analog waveforms

The VAD generates a change in pressure. A gradient works to draw blood out of a filled ventricle by creating a low pressure in the VAD’s inflow cannula. Suction refers to a condition where the VAD cannot draw blood. This condition can be a result of inadequate filling of the ventricle or partial or complete obstruction of the inflow cannula by some portion of the myocardium. The result can be a collapse of the ventricular wall with further reduction in VAD flow. Suction is typically seen with hypovolemia, poor cannula placement, or poor flow of blood from the right side to the left side. Suction with ventricular collapse can occur at any time during a patient’s course.

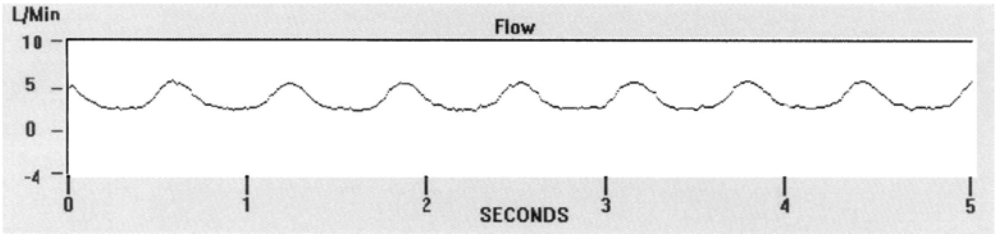
This problem is best resolved by increasing the filling of the left ventricle, by improving cannula placement, or by decreasing pump speed. As an interim measure, or if the cause of the suction cannot be identified, the VAD speed can be reduced to relieve the suction

and resultant ventricular collapse. Figure A-1 shows examples of waveforms without suction.

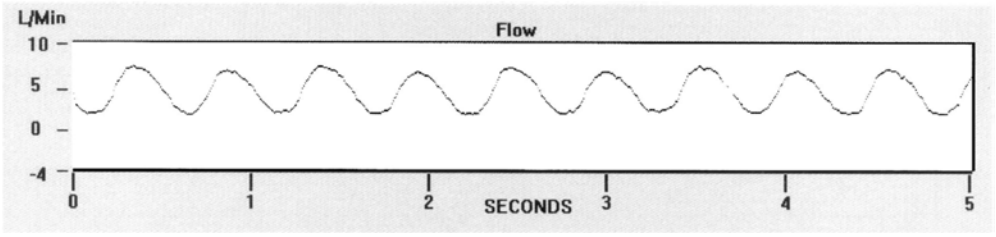
Figure A-1. Examples of normal flow with the HeartAssist 5® VAD



A. No pulsatility



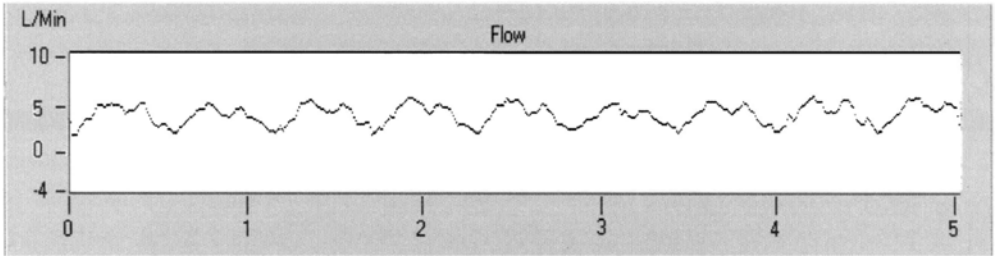
B. Pulsatility, low amplitude



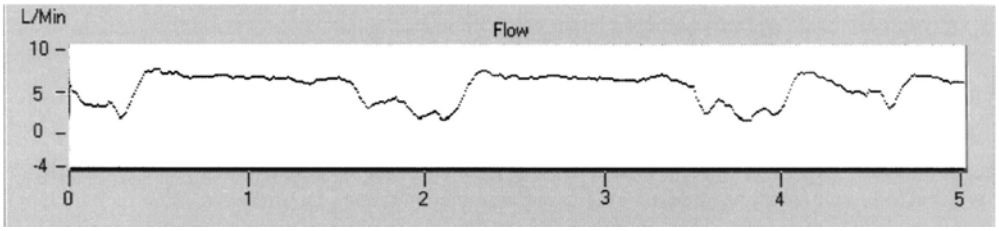
B. Pulsatility, high amplitude

As shown in Figure A-2, the presence of suction creates unique flow wave forms that can be identified by a “double hump” at the end of the systolic phase of the pulse or, in the case of the non-pulsatile ventricle, sharp, sudden downward slopes. The physician should be consulted when suction occurs to decide if the patient’s blood volume needs to be increased or some other therapy is necessary to provide more blood to the ventricle prior to changing speed. Only immediately decrease the speed in cases of severe suction.

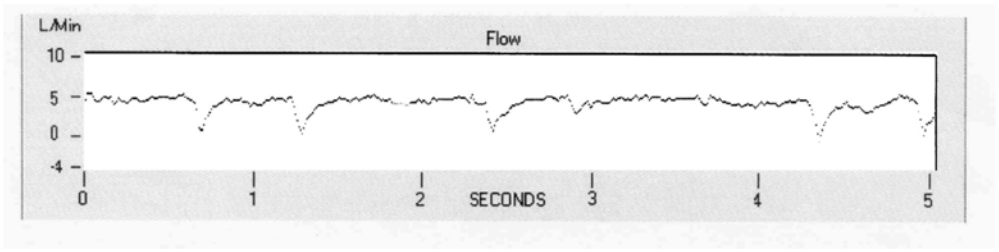
Figure A-2. Examples of excess suction with the HeartAssist 5® VAD



A. Suction with ventricular function – produces erratic wave form with multiple peaks



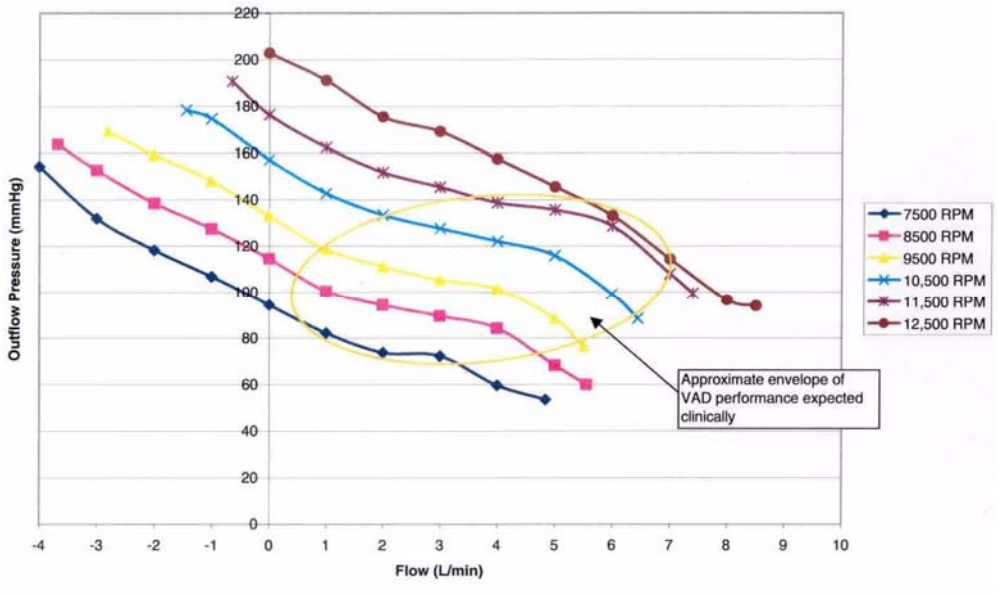
B. Suction with no native ventricular function



C. Suction with no native ventricular function - produces sharp downward gradients in flow

You can use Figure A-3 to estimate flow through the VAD.

Figure A-3. HeartAssist 5® VAD characterization outlet pressure vs. flow



The table in Figure A-3 was generated using a water and glycerin mix.

HeartAttendant® errors

Table A-3 contains HeartAttendant® troubleshooting information.

Table A-3. Troubleshooting guide for the HeartAttendant®

Event or Error	Troubleshooting
The HeartAttendant® will not turn on	1. Check the power connection at the wall. 2. Check the power cord connection on the back of the HeartAttendant®. 3. Check the fuse of the HeartAttendant®. (See “Verifying local mains voltage” on page 5-28.) 4. Call technical support.
The HeartAttendant® software “locks up” or becomes nonresponsive	1. Wait 45 seconds for the software to reset automatically. 2. If problem persists, disconnect the VADPAK from the HeartAttendant® first, then unplug and re-plug the HeartAttendant® power cord from the wall. 3. Call technical support.
Battery status icons fail to illuminate when a battery is placed in battery charging compartments.	1. Ensure that the battery is inserted correctly with the connector side facing up. 2. Check for and clear any dirt from the battery connector. 3. If the battery was exposed to cold temperatures, allow the battery to warm to room temperature before charging. 4. Call technical support.
The fan sound is reduced, and the HeartAttendant® is warm.	Call technical support.

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 through B-6 display the seven messages shown on the Controller.

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

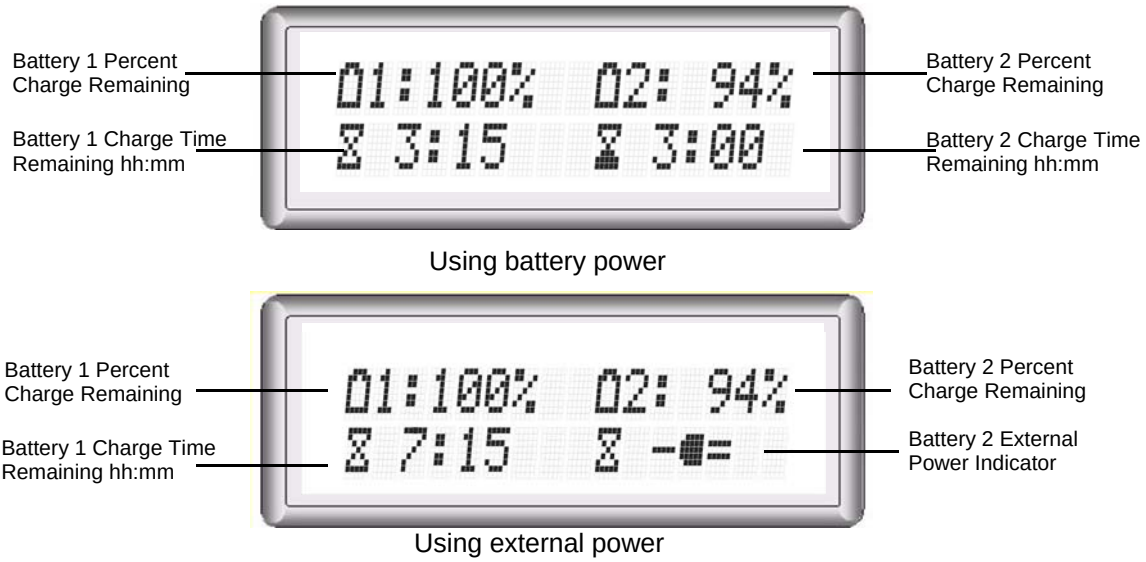


Figure B-2. Standard message screen 2: current VAD parameters

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

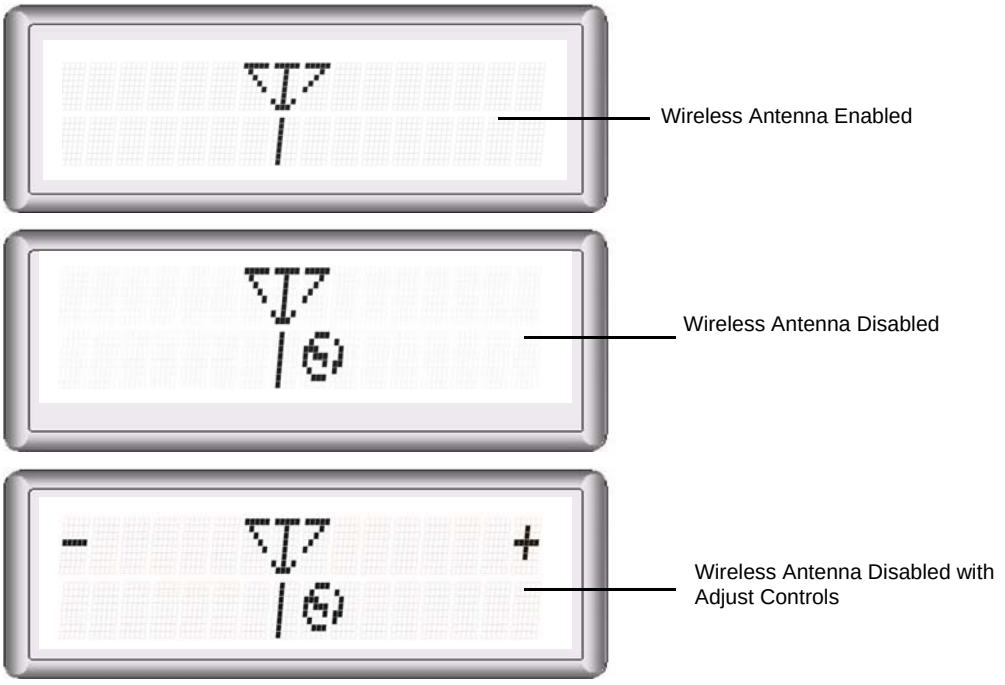


Figure B-4. Standard message screen 4: flow probe received amplitude

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

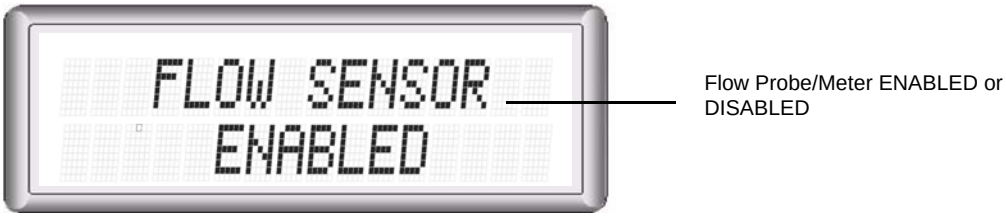


Figure B-6. Standard message screen 6: battery capacity

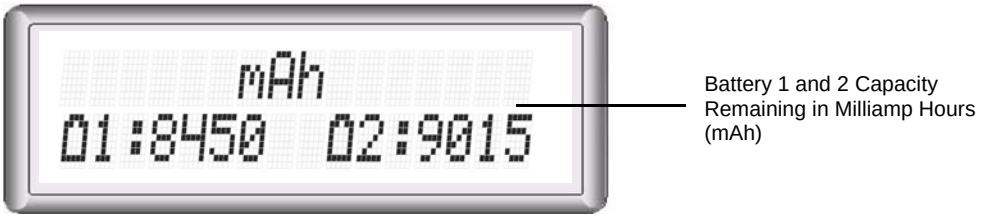
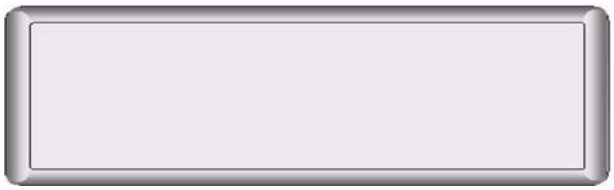


Figure B-7. Standard message screen 7: not used



Emergency alarms

The following subsections describe emergency alarms. See “Emergency alarms” on page 4-4 for an explanation of these 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 ReliantHeart immediately.

Emergency alarm 2: BOTH BATTERIES DISCONNECTED

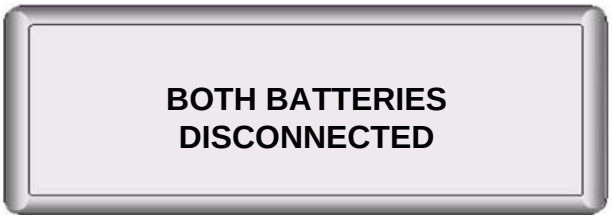
The Controller is not receiving power from either of the batteries.

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.

   See “Controller replacement” on page 4-6.

   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.

   See “Connecting the percutaneous cable to the Controller” on page 3-18.
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.

   See “Controller replacement” on page 4-6.
5. Contact ReliantHeart immediately.

Diagnostic alarms

The following subsections describe diagnostic alarms. See “Diagnostic Alarms on page 4-4 for an explanation of these 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 ReliantHeart 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 ReliantHeart immediately.

Diagnostic alarm 3: REDUCED MOTOR SPEED

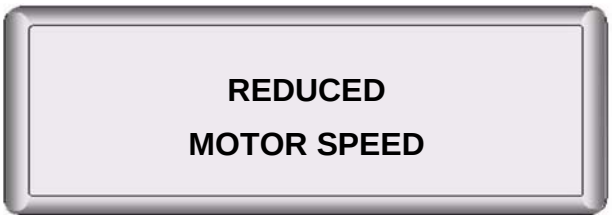
The speed (RPM) of the VAD has fallen below the programmed alarm threshold.

> 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 ReliantHeart 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 ReliantHeart 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.

   See “Charging a battery” on page 4-26

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.

   See “Connecting a battery pocket to the Controller” on page 4-24. This alarm clears automatically after you reconnect battery 1.

3. If alarm does not clear, contact ReliantHeart.

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.

   See “Charging a battery” on page 4-26.

2. Recharge the discharged battery.

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

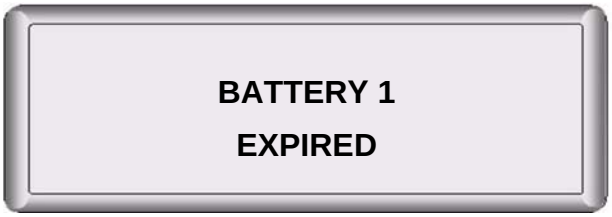
Diagnostic alarm 7: BATTERY 1 EXPIRED

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.

   See “Charging a battery” on page 4-26.

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.

   See “Charging a battery” on page 4-26.

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.

   See “Charging a battery” on page 4-26.

2. Recharge the discharged battery.

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

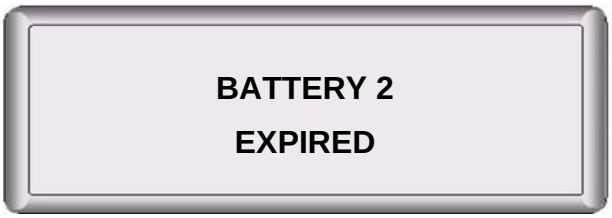
Diagnostic alarm 10: BATTERY 2 EXPIRED

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.

   See “Charging a battery” on page 4-26.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.

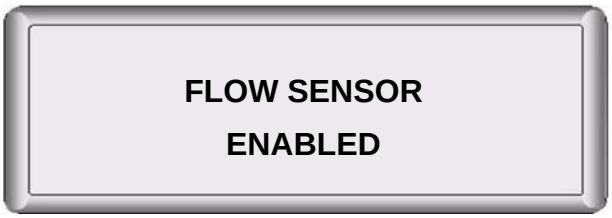
Controller failure alarm 1: fail-safe alarm

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.

   See “Controller replacement” on page 4-.6

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.
   See “Controller replacement” on page 4-6.
2. Notify ReliantHeart 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. See Figure 4-2, “Controller front panel,” on page 4-3 for an example of the Controller front panel interface.

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

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)
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

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

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. See “Replacing fuses” on page 5-28 for fuse replacement instructions.

Essential performance of the HeartAssist 5® VAD

The HeartAssist 5® VAD operates, without stoppage, at the preset speed. See “Presetting VAD speed” on page 5-16 for more information.

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 >

Heading	Heading	Heading
Immunity Test	**RTCA/DO 160F Test Level**	**Com[pliance**
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: CTL001

FCC ID: 2AB4ZCTL001.

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

Glossary

Anticoagulants

Non habit-forming medications that keep existing blood clots from growing larger as well as prevents the formation of new blood clots. Heparin is an example.

Aorta

The large arterial trunk that carries blood from the heart to be distributed by branch arteries through the body.

Aortic regurgitation (“leaky” aortic valve)

The diastolic flow of blood from the aorta into the left ventricle. Regurgitation is caused by incompetence of the aortic valve or any disturbance of the valvular apparatus (e.g., leaflets, annulus of the aorta) resulting in diastolic flow of blood into the left ventricular chamber.

Aortic valve

A valve with 3 cusps between the left ventricle and the aorta.

Apex

Blunt rounded end of the heart, directed downward, forward, and to the left.

Arrhythmias

Problems that affect the electrical system of the heart, producing abnormal heart rhythms. They can cause the heart to pump less effectively.

Arterial blood pressure

The pressure of the circulating blood on the arteries.

Arteries

The thick, muscular tubes that carry blood away from the heart.

Atrium

An upper chamber of the heart. Right atrium receives unoxygenated blood from the body. Left atrium receives oxygenated blood from the lungs.

Cannula

Tube that connects the heart and blood vessels to the pump.

Cardiopulmonary resuscitation (CPR)

An emergency first aid protocol for an unconscious person on whom neither breathing nor pulse can be detected.

Cardiovascular

Pertaining to the heart and blood vessels.

CE-mark

The approval of manufacturing and quality systems identified with the ISO 9001 certification. This label allows a medical device company to commercialize products in Europe.

Centrifugal pump technology

As blood is drawn into the pump, a paddle wheel like component (impeller) forces the blood toward the outside walls and expels it through an opening.

Class IV heart failure

End stage heart failure in which an individual is unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased. In order to determine the best course of therapy, physicians often assess the stage of heart failure according to the New York Heart Association (NYHA) functional classification system. This system relates symptoms to everyday activities and the patient's quality of life.

Coagulation

1. a. The process of becoming viscous, jellylike, or solid; especially the change from a liquid to a thickened curd-like state not by evaporation but by chemical reaction:
   - the spontaneous coagulation of freshly drawn blood
   - the coagulation of egg albumen by heat

   b. The process by which such change of state takes place consisting of the alteration of a soluble substance (as a protein) into an insoluble form or of the flocculation or separation of colloidal or suspended matter.
2. A substance or body formed by coagulation. There are three systems that are involved in the coagulation process:
   - platelets
   - pro-coagulant system
   - fibrinolytic system

In artificial heart or ventricular assist device implantation it is necessary to achieve a new equilibrium among these systems.

Connector

The end of a HeartAssist 5® VAD System component cable. Connectors join HeartAssist 5® VAD System component together. Connectors are universal across the HeartAssist 5® VAD System and join using the same method.

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 includes two battery cables and one driveline cable for the VAD connection.

Console

The part of a circulatory support system that drives the blood pumps, thus allowing the blood to flow through its normal cycle. The console is powered by electricity and has a back-up battery.

Coronary artery disease (CAD)

Conditions such as atherosclerosis which cause narrowing of the coronary arteries resulting in decreased blood flow to the heart muscle.

Coronary heart disease (CHD)

A disease in which plaque deposits containing cholesterol atherosclerosis and fat globules are deposited within the arteries.

Driveline

The driveline consists of a double cable that extends from the implanted LVAD, through the skin, to the external environment. After emerging from the body, the driveline is often referred to as the percutaneous cable, and the lead terminates at an electric connector that attaches to the Controller.

Echocardiography

One of the most important non-invasive techniques used in the diagnosis of heart disease. This technique allows for the visualization of abnormal valve function or contraction of the cardiac walls and can also be used to measure ejection fraction. Echocardiograms are obtained by reflecting high frequency sound waves (ultrasound) off various structures of the heart, then translating the reflected waves into one and two-dimensional images.

Embolization

The therapeutic introduction of various substances into the circulation to occlude vessels, either to arrest or prevent hemorrhaging, to devitalize a structure, tumor, or organ by occluding its blood supply, or to reduce blood flow to an arteriovenous malformation.

External power indicator

A plug symbol that display on the Controller screen when the HeartAssist 5® VAD System is connected to an external power source (such as the Independent Power Supply).

Extubated

To remove a tube from a hollow organ or passageway, often from the airway. The opposite of extubate is intubate.

Heart chambers

The four sections of the heart through which blood is pumped. The two upper chambers are called the left atrium and right atrium. The two lower chambers are the left and right ventricles. Oxygen-rich blood from the lungs enters the left atrium, while oxygen-depleted blood from the rest of the body flows into the right atrium. Both atria simultaneously pump blood into the ventricles. The ventricles then pump the blood to the lungs (from right ventricle) and to the rest of the body (from the left ventricle).

Heart failure

Almost always a chronic, long-term condition, although it can sometimes develop suddenly. This condition might affect the right side, the left side, or both sides of the heart. As the heart's pumping action is lost, blood might back up into other areas of the body, including: the liver, the gastrointestinal tract and extremities (right-sided heart failure), the lungs (left-sided heart failure). Class 4 heart failure is the condition when a patient is exhausted, short of breath or fatigued when just sitting still or lying down in bed.

Heart rate (HR)

The number of beats per minute (avg: 72 beats/min).

Hemoglobin

Protein in red blood cells that transports oxygen. The mean range is 14.5-15.5 g/dL.

Hemolysis

Defined as plasma-free hemoglobin of greater than 50 mg for more than 12 hours. Associated with systemic hypertension, this condition is usually resolved by reducing the driving pressure in combination with anti-hypertensive agents.

Hemorrhage

Bleeding; an escape of the blood through ruptured or unruptured vessel walls.

Hemostasis

The prevention of blood loss; a complex process that changes blood from a fluid to a solid state. Intact blood vessels are central to moderating blood's tendency to clot. The endothelial cells of intact vessels prevent thrombus formation by secreting tissue plasminogen activator (t-PA) and by inactivating thrombin and adenosine diphosphate (ADP). Injury to vessels overwhelms these protective mechanisms and hemostasis ensues. Hemostasis proceeds in two phases: primary and secondary hemostasis.

Heparin

A highly sulfated glycosaminoglycan widely used as an injectable anticoagulant. Heparin acts via binding to as an anti-thrombin thereby preventing consequent thrombus formation; it also enhances activity of lipoprotein lipases. It is also used to form an inner anticoagulant surface on various experimental and medical devices such as test tubes and renal dialysis machines. Pharmaceutical grade heparin is commonly derived from the tissue of slaughter house animals, e.g. porcine intestine or bovine lung.

Hepatic function or failure

Liver function. Fulminant hepatic failure (FHF) is usually defined as the severe impairment of hepatic functions in the absence of preexisting liver disease.

Impeller

A propulsion device that draws liquid in and forces it through an opening.

LVAD

Left ventricular assist device.

Left atrium

Receives oxygen enriched blood from the lungs and passes it on to the left ventricle.

Left ventricle

One of the two bottom chambers in the human heart. It receives oxygenated blood from the left atrium via the mitral valve, and pumps it into the aorta via the aortic valve. It forms a small part of the sternocostal surface and a considerable part of the diaphragmatic surface of the heart; it also forms the apex of the heart.

Left ventricular assist device (LVAD)

A mechanical pump that is surgically implanted and is used to aid the natural pumping action of the heart's left ventricle. This device is sometimes called a “bridge to transplant” because it buys time until a heart transplant can be performed.

Left ventricular assist system

A class of medical devices that helps the left side of the heart pump oxygen-rich blood through the body. Also called a Left Ventricular Assist Device.

Mains power

General-purpose alternating current (AC) electric power supply.

Mechanical circulatory support

A uni- or bi- ventricular device used to treat patients with advanced heart failure. A mechanical pump is surgically implanted to provide pulsatile or non-pulsatile flow of blood to supplement or replace the blood flow generated by the native heart. Types of circulatory support pumps include pneumatic and electromagnetic pumps. Rotary pumps are also available.

Mediastinal infections

Acute bacterial infection of the mediastinum. Such infections can evoke a devastating disease which, in its fulminating form, is often unresponsive to the best therapeutic efforts. However, if mediastinitis is diagnosed before it reaches the morbid pathological state, appropriate antibiotic therapy and well-planned surgical intervention might favorably alter the prognosis.

Mitral valve

Bicuspid valve, left atrioventricular valve: a valve in the heart located in the opening between the left atrium and the left ventricle, prevents the blood in the ventricle from returning to the atrium, and consists of two triangular flaps attached at their bases to the fibrous ring which surrounds the opening and connected at their margins with the ventricular walls by the chordae tendineae and papillary muscles.

Myocardial infarction

Damage or death of myocardial tissue (heart muscle) of blood flow to the area.

Myocardial revascularization

Restoring blood flow to the myocardium (heart muscle).

Myocarditis

Inflammation of the heart muscle brought on by a virus or bacteria, which might even result from allergic reaction.

Myocardium

The middle muscular layer of the heart wall. The myocardium is responsible for the heart's pumping action and contracts to pump blood out of the heart, and then relaxes as the heart refills with returning blood. The myocardium is the layer that has the largest oxygen need and is most affected by decreased blood flow (ischemia).

Occlusion

Venous or arterial occlusion is a state of being closed or shut.

Percutaneous

Passed through the skin.

Perfusion

Blood flow.

Perfusion pressure

The difference between the arterial and venous pressures through an organ or capillary bed.

Perfusion scan

A test to determine blood flow through the vessels to the heart.

Pericardial cavity

The potential space formed between the two layers of serous pericardium around the heart. Normally, it contains a small amount of serous fluid that acts to reduce surface tension and lubricate. Therefore, the cavity facilitates the free movement of the heart. The cavity surrounds the heart and is continuous with it at all but the points of entry and exit of great vessels.

Pericardium

The thin outer covering sac (membrane) that surrounds the heart and the roots of the great blood vessels.

Plasma

The liquid portion of the blood.

Pulmonary artery

The artery which carries blood away from the heart and extends from the right ventricle and branches into left and right pulmonary arteries. The left and right pulmonary arteries extend to the left lung and right lung, and deliver deoxygenated blood to the corresponding lung.

Pulmonary edema

A condition which involves fluid accumulation and swelling in the lungs. Pulmonary edema is usually caused by heart failure that results in increased pressure in the pulmonary (lung) veins. However, problems within the lungs themselves can also result in fluid accumulation. Pulmonary edema can be a complication of a heart attack, leaking or narrowed heart valves (mitral or aortic valves), or any disease of the heart that either results in weakening and/or stiffening of the heart muscle (cardiomyopathy). Pulmonary edema can also be caused by direct lung injury from toxins including heat and poisonous gas, severe infection, or an excess of body fluid as seen in kidney failure.

Pulmonary valve

Heart valve between right ventricle and pulmonary artery.

Pulse pressure

The difference between systolic and diastolic pressures.

Renal function or failure

An indication of the state of the kidney and its role in physiology. Renal failure is characterized by the loss of the ability of the kidneys to excrete wastes, concentrate urine, and conserve electrolytes.

Right atrium

Receives oxygen depleted blood from the body and passes it on to the right ventricle.

Right heart failure

Heart failure caused by damage to the heart's right-sided chambers. This usually occurs as a result of left-sided heart failure. When the left ventricle fails, increased fluid pressure is, in effect, transferred back through the lungs, ultimately damaging the heart's right side. When the right side loses pumping power, blood backs up in the body's veins. This usually causes swelling in the legs and ankles.

Right ventricle

One of the two bottom chambers in the human heart. The right ventricle receives de-oxygenated blood as the right atrium contracts. The pulmonary valve leading into the pulmonary artery is closed, allowing the ventricle to fill with blood. Once the ventricles are full, they contract. As the right ventricle contracts, the tricuspid valve closes and the pulmonary valve opens. The closure of the tricuspid valve prevents blood from backing into the right atrium and the opening of the pulmonary valve allows the blood to flow into the pulmonary artery toward the lungs.

RVAD

Right ventricular assist device.

Sepsis

A toxic condition resulting from the spread of bacteria or their products from a focus of infection. The immunological response that causes sepsis is a systemic inflammatory response causing widespread activation of inflammation and coagulation pathways. This

might progress to dysfunction of the circulatory system and, even under optimal treatment, might result in the multiple organ dysfunction syndrome and eventually death.

Stenosis.

A narrowing or constriction of the diameter of a bodily passage or orifice. Aortic stenosis is the narrowing or obstruction of the heart's aortic valve, which prevents it from opening properly and blocks the flow of blood from the left ventricle to the aorta.

Sternotomy

A type of incision in the center of the chest that separates the sternum (chest bone) to allow access to the heart.

Stroke

The sudden death of a portion of the brain cells due to a lack of oxygen. A stroke occurs when blood flow to the brain is damage resulting in abnormal function of brain. It is caused by blockage or rupture of an artery to the brain.

Thoracic cavity

The space within the walls of the chest, bounded below by the diaphragm and above by the neck, and containing the heart and the lungs.

Thromboembolism

Occurs when red blood cells, fibrin, platelets and leukocytes form a mass or thrombus within an intact cardiovascular system. An embolism occurs when a segment of a thrombus within the cardiovascular system detaches from the vessel, travels within the body and lodges within another, smaller vein or artery.

Thrombus

A blood clot in a blood vessel or within the heart.

Tricuspid valve (right atrioventricular valve)

A valve that is situated at the opening of the right atrium of the heart into the right ventricle and consists of three triangular membranous flaps.

VAD

HeartAssist 5® VAD. See also, ventricular assist device.

Valves

Flap-like structures in the heart that open and close to let the blood flow in only one direction. The four heart valves are: the tricuspid, the pulmonary or pulmonic (in the right side of the heart), the mitral and the aortic valve (in the left side).

Vascular graft

A tube created by using portions of another artery or vein from the patient's body or synthetic materials to reroute blood around a blockage.

Vasodilators

Agents that open vessels by relaxing their muscular walls. For example, nitroglycerin is a vasodilator.

Ventricular assist device (VAD)

Mechanical device that is used to partially or completely replace the function of a failing heart. The devices are generally designed to replace or assist cardiac function temporarily, but recently devices are becoming available that can be implanted permanently for so called “destination therapy.” Most patients using the devices, however, are awaiting heart transplant.

Ventricular septal defect (VSD)

A defect between the two lower chambers (the ventricles) of the heart.

Ventricular thrombus

A fibrinous clot formed in the ventricle of the heart.

Warfarin (Coumadin®)

An anticoagulant with the same actions as dicumarol; also used as a rodenticide; also available as the potassium salt, with the same actions and uses. An anticoagulant medicine that decreases the ability of blood to form clots. Blood clots can occur in the veins of the lower extremities, usually after periods of immobility. These clots can break off and become lodged in the blood vessels of the lung (pulmonary embolism), causing shortness of breath, chest pain, and even life-threatening shock. Blood clots can also occur in the atria of the heart during atrial fibrillation, and around artificial heart valves. One of these clots can also break off and obstruct a blood vessel in the brain, causing an embolic stroke with paralysis. Coumadin is important in preventing the formation of blood clots. It is also important to prevent extension of clots already formed, and to minimize the risk of blood clot embolization to other vital organs such as the lungs and brain.

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