HeartWare®
Leading a small revolution

HeartWare® Ventricular Assist System

Instructions For Use

Table of Contents

Foreword

The HeartWare® Ventricular Assist System is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. Clinical users include physicians, registered nurses, perfusionists and biomedical engineers. Implant of the device must be performed by a qualified cardiac surgeon trained by HeartWare-authorized personnel. Clinical users of the HeartWare® System should attend HeartWare clinical operator training, should have a working knowledge of the principles of left ventricular assist devices (LVADs), and should be aware of the physical and psychological needs of patients undergoing LVAD support. Patients and caregivers should complete a user training program and demonstrate their ability to use the system. Clinicians should read the entire Instructions for Use before system operation. This manual may serve as a reference for detailed information including specific information on device function, system setup, implant and maintenance. This manual is not intended to replace comprehensive educational programs or to supersede acquired knowledge or proper medical judgment.

1.0 INTRODUCTION

WARNING: Carefully read this entire manual prior to implanting or operating the device.

The HeartWare® Ventricular Assist System (HeartWare® System) is designed to assist a weakened, poorly functioning left ventricle. The HeartWare® System utilizes a centrifugal blood pump, the HVAD® Pump (the "pump"), which is implanted in the pericardial space with left ventricular apex to ascending aortic cannulation for left ventricular support (Figure 1). The inflow conduit, which is partially sintered, is integrated with the pump and a 10mm gel impregnated outflow graft with a strain relief is attached to the pump. A percutaneous driveline connects the pump to an external controller. The controller, powered by two batteries or by one battery and electricity from the wall or car outlet, regulates pump function and monitors the system. The monitor is used to display system performance and to change controller operating parameters. A battery charger is also included.

All components of the HeartWare System were designed to be used only in conjunction with each other. They are not compatible or intended to be used with other manufacturer's devices.

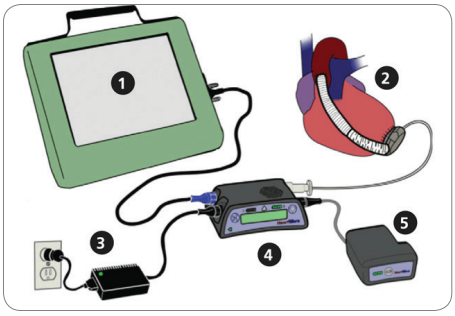


Figure 1: HeartWare® Ventricular Assist System
1. Monitor
2. HVAD Pump
3. AC Adapter
4. Controller
5. Battery

2.0 INDICATIONS AND CONTRAINDICATIONS FOR USE

- The HeartWare HVAD® System is intended for use in patients at risk of death from refractory end-stage heart failure. The HeartWare® System is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.
- The HeartWare® System is contraindicated:
  - In patients with a body surface area (BSA) less than 1.2 m^2
  - In patients who cannot tolerate anticoagulation therapy
  - During pregnancy

3.0 WARNINGS

1) **This Instruction for Use is intended to be used by physicians, nurses, and other clinical professionals. Setup and operation of this device should only be undertaken by personnel who have completed HeartWare's setup and operation training. A thorough understanding of technical principles, clinical applications and risks associated with the HeartWare® System is required before using this product. Failure to understand these principles, applications and risks may result in improper operation of the system and potential harm to the patient or to the user.**
2) **Carefully read this entire manual prior to implanting or operating the device.**
3) The HeartWare® System has only been evaluated in patients greater than or equal to 18 years of age. Consider other methods of mechanical circulatory support for patients younger than 18 years.
4) The HVAD® Pump should not be implanted in patients with a known nickel allergy.
5) Gel impregnated polyester vascular prostheses should not be implanted in patients who exhibit sensitivity to polyester or materials of bovine origin.
6) The HVAD® Pump may cause interference with AICDs. If electromagnetic interference occurs, it may lead to inappropriate shocks, arrhythmia and possibly death. The occurrence of electromagnetic interference with AICD sensing may require adjustment of lead sensitivity, proximal placement of new leads or replacement of an existing sensing lead.
7) Use only HeartWare-supplied components with the HeartWare® System.
8) Disconnecting both power sources (batteries and AC or DC adapter) at the same time will stop the pump. At least one power source must be connected at all times.
9) Keep a spare controller and fully charged batteries available at all times in case of an emergency.
10) Sterile components are intended for single use only. DO NOT use if package is damaged or opened. DO NOT re-sterilize or re-use.
11) During the Pre-Implant Test and prior to implantation: The HVAD® Pump must be completely submerged in fluid before being turned on. Never turn on the HVAD® Pump in air. DO NOT use an HVAD® Pump that was turned on without total submersion in fluid.
12) Rotate the graft clamp so that the clamp screw is located on the inner side of the outflow graft to avoid tissue irritation or damage.
13) DO NOT use excessive force when tightening the clamp screw because this could damage the graft clamp or graft clamp screw. Replace components if required.
14) DO NOT loosen the sewing ring's screw by turning the screw counterclockwise or it may fall off the sewing ring.
15) To remove the driveline cap from the driveline, unscrew the outer sleeve, then pull back on the grooved part of the connector. DO NOT grasp the driveline and pull because this may damage the driveline.
16) An audible click should be heard when connecting the driveline to the controller or driveline extension. Failure to ensure a secure connection may cause an electrical fault.
17) To remove the driveline from the controller, first pull back the driveline cover then grasp and pull the driveline connector. DO NOT grasp the driveline cable as this may damage the driveline.
18) All air must be removed from the HVAD® Pump and its conduits to reduce risk of air embolus.
19) In order to minimize the risk of air embolus during implant, keep both power supplies connected to the controller after setting up the primary controller. Disconnecting and then reconnecting both power supplies will result in the controller starting the pump as soon as the driveline is connected.
20) HVAD® Pump flow estimation may not be accurate during the de-airing procedure.
21) A controller with a blank display or no audible alarm should be replaced.
22) Silencing an alarm does not resolve the alarm condition. ALWAYS investigate, and if possible, correct the cause of any alarm.

23) When using loud machinery or in the vicinity of loud noises, the controller and battery alarms may not be audible. Under these conditions, periodically check the controller display for any information regarding an alarm.
24) DO NOT rely only on flow estimation to assess cardiac output. An average estimated flow on the monitor or controller display of less than 2 L/min or greater than 10 L/min may indicate an electrical fault, incorrect hematocrit entry or an occlusion due to thrombus or other materials (e.g., tissue fragments) in the device. Inaccurate assessment of HVAD® Pump flow may lead to less than optimal treatment.
25) DO NOT disconnect the driveline or power sources from the controller while cleaning it or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.
26) The alarm adapter silences the "No Power" alarm and should only be attached to a controller that has failed or malfunctioned and is no longer connected to the pump.
27) If there is a "Controller Failed" alarm, switch to the backup controller.
28) Do not turn the Lavare Cycle off while the cycle is occurring or certain alarms may become disabled.
29) The ventricular suction detection alarm must not be turned on while the patient is in a suction condition. The patient should be hemodynamically stable prior to enabling the ventricular suction detection alarm.
30) Manual changes to the speed will immediately disable the ventricular suction detection alarm. "Sx Off" will be displayed on the monitor screen below the "Fixed" mode display.
31) Whether or not the ventricular suction detection alarm is enabled ("Sx On") or is off ("Sx Off") can only be determined with the monitor; it cannot be determined from the controller.
32) At HVAD® Pump explant the percutaneous driveline is not sterile; therefore ensure that the driveline does not contaminate the sterile field.
33) DO NOT drop the controller or other equipment. Dropping the controller could cause sudden stoppage of the pump. Dropped equipment should be reported to HeartWare and inspected.
34) DO NOT allow water or other fluids to enter the controller, power adapters, batteries, battery charger or connectors. If this happens, contact HeartWare.
35) DO NOT submerge HeartWare® System components in water or other fluid.
36) DO NOT allow patients to take a bath or swim.
37) Patients may shower when they have received permission from their clinician to do so. Patients who shower must use the HeartWare® Shower Bag. Hearing impaired patients should not shower unless their caregiver is close by to hear alarms.
38) The controller should be connected to two batteries during showers; it should never be plugged into an AC wall outlet.
39) DO NOT operate the controller in temperatures less than -20ºC (-4ºF) or greater than 50ºC (122ºF) or the controller may fail.
40) DO NOT let the patient have a magnetic resonance imaging (MRI) procedure while implanted with the HVAD® Pump. Doing so could cause harm to the patient or could cause the pump to stop.
41) DO NOT apply high power electrical treatment (e.g. application of diathermy) directly to the patient.
42) Implanted components should not be exposed to therapeutic levels of ultrasound energy, as the device may inadvertently concentrate the ultrasound field and cause harm.
43) Therapeutic ionizing radiation may damage the device, which may not be immediately detectable.
44) Avoid devices and conditions that may induce strong static discharges (e.g., television or computer monitor screens) as electrostatic discharges can damage the electrical parts of the system and cause the LVAD to perform improperly or stop.
45) Always have a backup controller handy when changing power sources. Be watchful for unusual changes in power or flow alarms for a period of time following equipment changes.
46) Device recipients should avoid areas with high magnetic forces such as theft detection devices or airport security systems.
47) Keep cell phones a minimum of 0.5 meters (20 inches) away from the controller.

4.0 PRECAUTIONS

1) The HeartWare® Ventricular Assist System has had limited use in patients with mechanical valves and therefore the risks are currently unknown. Caution should be used in selecting patients with mechanical valves for HeartWare® System therapy.
2) Chest compressions may pose a risk due to pump location and position of the outflow graft on the aorta - use clinical judgment. If chest compressions have been administered, confirm function and positioning of HVAD® Pump.
3) During exit site dressing changes, examine the driveline for evidence of tears, punctures or breakdown of any of the material.
4) Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
5) Speeds below 2400 RPM or above 3200 RPM should be used with caution.
6) Optimal inflow cannula position is toward the mitral valve and parallel to the interventricular septum.
7) Position the sewing ring to permit access to its screw after cannulation.
8) Outflow graft attachment to the pump should be performed by a surgeon, physician's assistant or surgical assistant trained in the procedure.
9) If the outflow graft is too short or too long, it may kink. Prior to chest closure ensure that the graft is not kinked or compressed.
10) De-airing difficulty may be due to inadequate blood volume in the HVAD® Pump or leaks in the inflow/outflow connections.
11) DO NOT pull, kink or twist the driveline or the power cables, as these may damage the driveline. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting controller or power sources, or when using the shower bag.
12) During HVAD® Pump implantation and/or re-operation, be aware of the position of the driveline to avoid damage by surgical instruments and needles.
13) Position the driveline exit site so that the tunneler does not contact any vital organs or structures.
14) The HeartWare® Controller is designed for single patient use. DO NOT use the controller on more than one patient.
15) Prophylactic topical antibiotic ointments such as silver sulfadiazine, povidone iodine, or neomycin bacitracin ointment should not be used. These ointments can injure the tissue adjacent to the exit site.
16) When connecting cables, DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.
17) Confirm that the power cables are properly locked on the controller by gently pulling the cable near the controller power connector.
18) All connectors should be handled with care and kept free of liquid, dust and dirt.
19) Use only the HeartWare® Battery Charger to charge batteries. Other battery chargers may damage the batteries.
20) Recharge fully depleted batteries within 24 hours to avoid permanent battery damage.
21) ALWAYS wait until the "Ready" light turns on to disconnect the battery from the battery charger. If this is not followed over consecutive charging cycles, the Battery Capacity Display will not function properly and may convey misleading battery capacity.
22) DO NOT expose batteries to temperatures outside the storage and operational ranges or they may provide less support than usual. To preserve battery life, batteries should be stored at room temperature.
    Battery operating and storage temperatures:
    a. Operating: discharge (normal use with the HeartWare® System) and charge (while on battery charger): +5ºC to 40ºC (+41ºF to 104ºF). Operation at temperatures below 0ºC will **temporarily** reduce battery capacity but the battery will operate.
    b. Storage: -20º to 25ºC (-4º to 77ºF). Long-term storage outside of this range may **permanently** reduce the battery capacity. Best condition for storage is at room temperature.
23) Do not disassemble, crush, or puncture a battery.
24) Do not short the external contacts on a battery.

25) Do not dispose of a battery in fire or water. Dispose of batteries according to federal, regional, and local regulations.
26) Keep the battery away from children.
27) Avoid exposing the battery to excessive shock or vibration.
28) Do not use a damaged battery.
29) If a battery pack is leaking fluid, do not touch the fluid. Dispose of a leaking battery pack. In case of eye contact with fluid, do not rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention.
30) The DC adapter is for use in vehicles only and may not fit in some vehicles.
31) The "Set Defaults" button on monitor REF 1511 (no longer being placed on the market) will erase all patient VAD parameter information from the controller.
32) DO NOT allow patients to touch the monitor.
33) Never clean the monitor or battery charger with the power on. DO NOT use alcohol or detergent on the monitor display. Gently wipe the display with a soft, lint free cloth.
34) The monitor's internal battery should be fully charged prior to patient use.
35) Do not attempt to repair or service any components of the HeartWare® System. If HeartWare® System equipment malfunctions, contact HeartWare.

Precautions Related To The Vascutek® Gelweave™ Graft

1) DO NOT preclot. Gelweave prostheses are sealed grafts and must not be preclotted.
2) The Gelweave prostheses must be implanted within one month after removal from the foil pouch.
3) Clamping may damage any vascular prostheses. Atraumatic clamps, ideally with soft shod jaws, should be used with a minimum application of force.
4) Excessive tension or force should be avoided, as it will damage the polyester fibers and the gelatin impregnation.
5) Round body taper point needles should be used when implanting these prostheses to minimize fiber damage.
6) Use the smallest possible needle for de-airing, 19 gauge is normally sufficient. Hypodermic needles have a cutting point, which may result in blood leakage and may require repair by suturing.
7) Gelweave is based on a woven structure and may be cut with a cautery to minimize fraying. Note: Immersion of the Gelweave prosthesis in saline immediately prior to use will prevent focal burning, which may result during cauterization. Grafts should be immersed in saline for no longer than 5 minutes.
8) The foil pouch and outer tray are not sterile. Only the innermost tray may be introduced to the sterile field.

5.0 POTENTIAL COMPLICATIONS

Implantation of a Ventricular Assist Device (VAD) is an invasive procedure requiring general anesthesia, a median sternotomy, a ventilator and cardiopulmonary bypass. These surgical procedures are associated with numerous risks. All VAD patients face risks including, but not limited to:

- Air embolism
- Aortic insufficiency
- Arterial non CNS thromboembolism
- Battery related Injury
- Bleeding, perioperative or late
- Cardiac arrhythmias
- Death
- Device malfunction/failure
- Device thrombosis
- Driveline infection
- Driveline perforation
- Driveline wire damage
- Electrostatic Discharge (ESD) Damage to Controller
- Erosions and other tissue damage
- Gastrointestinal bleeding/ AV malformations
- Hemolysis
- Hepatic dysfunction
- Hypertension
- Injury from device exposure to therapeutic ionizing radiation
- Injury from device exposure to therapeutic levels of ultrasound energy
- Injury from high electrical power sources
- Interference with/from other devices
- Local infection
- Multi-organ failure
- Myocardial infarction
- Neurologic dysfunction
- Organ damage during driveline tunneling
- Pericardial effusion tamponade
- Platelet dysfunction
- Psychiatric episodes
- Renal dysfunction
- Re-operation
- Respiratory dysfunction
- Right heart failure
- Sensitivity to aspirin
- Sepsis/major infection
- Stroke
- Venous thromboembolism
- Worsening heart failure
- Wound dehiscence

Additional risks associated with a textured inflow cannula include:

- Embolization of sintered spheres
- Embolization of tissue adherent to inflow at time of pump removal

CAUTION: The HeartWare® Ventricular Assist System has had limited use in patients with mechanical valves and therefore the risks are currently unknown. Caution should be used in selecting patients with mechanical valves for HeartWare® Ventricular Assist System therapy.

6.0 SYSTEM COMPONENTS OVERVIEW

6.1 HeartWare® Ventricular Assist System

The HeartWare® System consists of a blood pump with integrated inflow cannula; a 10mm diameter gel impregnated polyester outflow graft with strain relief, and a percutaneous driveline. A strain relief is used on the outflow graft to prevent kinking. The driveline cable is wrapped with woven polyester fabric to encourage tissue in-growth at the skin exit site. The small, wearless pump has a displaced volume of 50cc and weighs 160 grams. The pump has one moving part, an impeller which spins blood to generate up to 10 L/min of flow. There are two motors in the pump housing with one motor providing redundancy. A short integrated inflow cannula, which may be smooth or partially sintered, is inserted into the left ventricle and the outflow graft connects the HVAD® Pump to the aorta. A sewing ring attaches to the myocardium and allows for pump orientation adjustments intraoperatively. The device size and short inflow cannula allow for pericardial placement, which eliminates the need for abdominal surgery and device pockets (Figure 2).

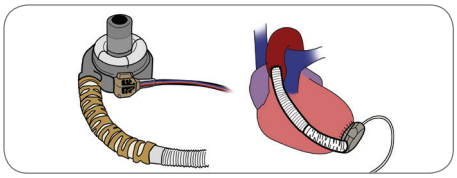


Figure 2: HVAD® Pump and left ventricular (LV) cannulation

6.2 HeartWare® Controller

The controller (Figure 3) is a microprocessor unit that controls and manages HeartWare® System operation. It sends power and operating signals to the blood pump and collects information from the pump. The percutaneous driveline is connected to the controller, which must always be connected to two power sources using an AC adapter or DC adapter and/or rechargeable batteries. The internal, non-replaceable rechargeable battery inside the controller is used to power an audible "No Power" alarm when both power sources are disconnected. The controller interfaces with the monitor through a data port.

CAUTION: The HeartWare® Controller is designed for single patient use. DO NOT use the controller on more than one patient.

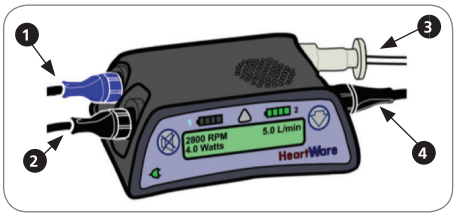


Figure 3: Controller
1. Monitor Connector
2. Power Connector
3. Driveline Connector
4. Power Connector

6.3 HeartWare® Monitor

The monitor (Figure 4) is a touch screen tablet PC computer that uses proprietary software to display system performance information and permits adjustment of selected controller parameters. When connected to a controller, the monitor receives continuous blood pump information from the controller and displays real-time and historical pump information. The monitor also displays alarm conditions.

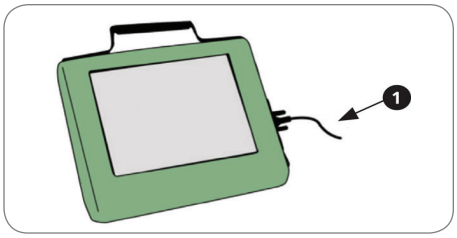


Figure 4: Monitor
1. Monitor/Controller Connection

6.4 HeartWare® Controller Power Sources

The controller requires two power sources for safe operation: either two batteries, or one battery (Figure 5) and an AC adapter (Figure 6) or DC adapter (Figure 7). While active, patients will typically use two batteries. While relaxing or sleeping, patients should use power from an electrical outlet (AC adapter) because it provides power for an unlimited period of time. The batteries should be exchanged when their charge falls below 25% capacity. Spare, fully charged batteries should always be available.

WARNING: Disconnecting both power sources (batteries and AC or DC adapter) at the same time will stop the pump. At least one power source must be connected at all times.

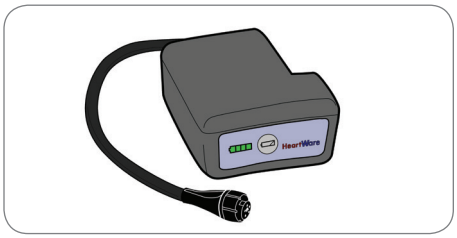


Figure 5: Battery

Figure 6: AC adapter

Figure 7: DC adapter

6.5 HeartWare® Battery Charger

The battery charger (Figure 8) is used to simultaneously recharge up to four batteries.

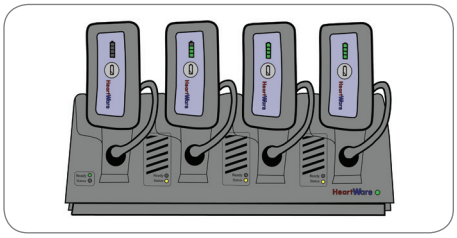


Figure 8: Battery charger

6.6 Equipment for Implant

Figure 9 shows the HeartWare® System components used at implant (provided ETO sterilized).

1. **HVAD® Pump**
2. **Outflow graft** – a 10mm diameter gel impregnated graft
3. **Sewing ring** (made of titanium and polyester) – to secure the HVAD® Pump to the LV
4. **Driveline cap** – to protect the driveline connector when tunneling
5. **Strain relief** – to prevent outflow graft kinking
6. **Inflow cap** – to cover the pump inflow cannula after the wet test and prior to implantation
7. **Driveline extension cable** – used only during the pre-implant wet test to keep the non-sterile controller isolated from the sterile field. The driveline extension cable is not intended to be used after the pump is implanted in the patient

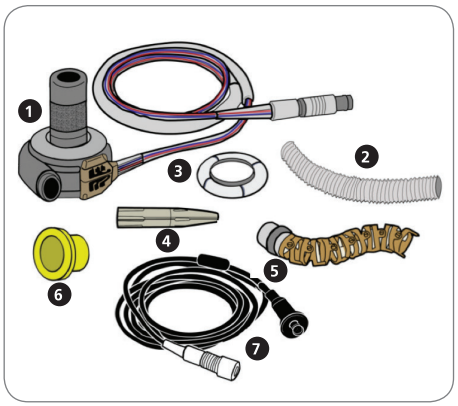


Figure 9: Components used at implant

A set of surgical tools (provided ETO sterilized) is also required for implantation of the device (Figure 10):

1. **Tunneler handle and rod** – to tunnel the pump's percutaneous driveline through the skin to the exit site
2. **Sewing ring wrench** – to tighten the screw on the sewing ring
3. **Driveline cover** – to cover the driveline connection to the controller
4. **Apical coring tool** – to core the LV apex
5. **Hex driver** – to secure the strain relief and outflow graft to the HVAD® Pump

All the tools and accessories used during implantation are for single-use only. A Patient Pack (carrying case) is available to hold the controller and two batteries.

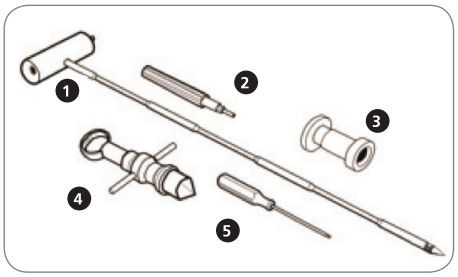


Figure 10: Surgical tools

7.0 PRINCIPLES OF OPERATION

7.1 Background

Continuous flow pumps contain a rotating impeller that adds energy to the blood by converting the rotational kinetic energy into mechanical energy (Figure 11). Impeller blades push the fluid through the pump using hydrodynamic and centrifugal forces. The net effect is to build up the fluid pressure, sometimes referred to as pump head (i.e., related to the differential pressure across the device) or just head, such that the fluid is moved from the inlet to the outlet of the pump. Pump head is the difference between the afterload and the preload. Energy to rotate the impeller is provided through electromagnetic coupling between permanent magnets (rotor magnet) attached or enclosed within the impeller and the motor stators. The motor stators consist of coils of wire that are sequentially charged by electrical current, turning the coils into electromagnets. These electromagnets have the effect of dragging the rotor magnets around an axis of rotation. The HVAD® Pump is efficient at pumping moderate quantities of blood against moderate amounts of resistance.

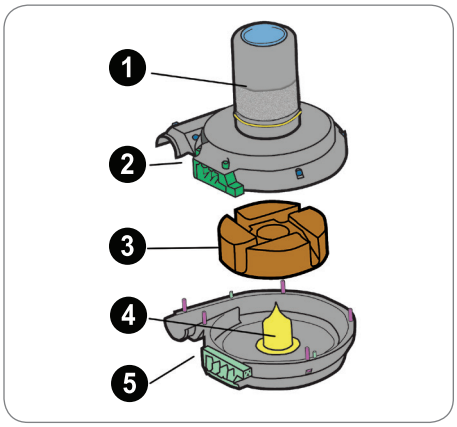


Figure 11: Exploded view of HVAD® Pump

1. Inflow Cannula
2. Front Housing Assembly
3. Impeller
4. Center Post
5. Rear Housing Assembly

7.2 Blood Flow Characteristics

The amount of flow a rotary pump can generate is dependent upon the diameter of the impeller, the geometry of the impeller blades, housing design, motor capacity, rotational speed, and pressure differential that exists across the pump. This allows for in-vitro pump characterization for a specific pump and is the basis for blood flow estimation.

The HeartWare System estimates blood flow rate using HVAD pump characteristics (electrical current, impeller speed) and blood viscosity. Viscosity is calculated from the patient's hematocrit. To obtain the most accurate estimate of blood flow, the patient's hematocrit must be entered into the HeartWare monitor. Flow estimation should be used as a trending tool only, as it cannot adapt to changing fluid conditions (see Section 7.3.1 "Flow Estimation").

The volume of flow generated by the HVAD® Pump is determined by the rotation speed of the impeller and by the pressure differential across the pump. The pressure that the HVAD® Pump must work against is similar to the mean arterial pressure. If the pump speed (RPM) is set too low then the device may not generate enough forward pressure. This can lead to retrograde flow (flow from the aorta back through the device and into the left ventricle).

The maximum rotational speed is determined by how much flow is available from the right heart. If the speed is set too high and the pump attempts to pump more blood than is available, ventricular suction may occur.

The controller operates in "Fixed" mode, which maintains a constant motor speed. The motor speed range is between 1800 and 4000 RPM. The appropriate speed should be determined based on the patient condition.

CAUTION: Speeds below 2400 RPM or above 3200 RPM should be used with caution.

7.3 Physiological Control Algorithms

The "Fixed" mode is used for HVAD® Pump operation, which means the clinician sets the pump speed (RPM). In addition, the HVAD® Pump control algorithms provide clinicians information about device performance and HVAD® Pump blood flow estimation.

7.3.1 Flow Estimation

Estimated HVAD® Pump blood flow is calculated using VAD power, speed parameters, and hematocrit based on a blood sample from the patient. The default hematocrit setting is 30%, but for accurate flow estimation, the patient's hematocrit should be entered into the monitor. Adjustments to the hematocrit setting on the monitor should be made for hematocrit changes 5% or greater.

NOTE: HeartWare recommends that hematocrit be updated in the monitor whenever hematocrit changes by 5% or more.

The valid range of estimated blood flow is -2 to 10 L/min. The table below shows monitor and controller display messages and what they mean.

Monitor and Controller Display	Estimated Flow Range
"----"	Invalid
"< -2 L/min"	less than -2 L/min
"-2 L/min" up to "10 L/min"	-2 to 10 L/min
"> 10 L/min"	greater than 10 L/min

Average Flow Range	Error*
less than 0 L/min	out of range
0 to 5 L/min	1 L/min
5 to 10 L/min	20%
greater than 10 L/min	out of range

* The error is the maximum of either 1 L/min or 20%, whichever is greater.

Out of range values on the low side (less than -2 L/min), are invalid in terms of estimated flow but could indicate an incorrect hematocrit value used in the flow calculation. Out of range values on the high side (greater than 10 L/min), may suggest thrombus formation in the HVAD® Pump or could also be indicative of an incorrect hematocrit value used in the flow calculation.

NOTE: Flow estimation should only be used as a trending tool. Actual flow may differ from readout due to variability of patient's hematocrit.

WARNING

- DO NOT rely only on flow estimation to assess cardiac output. An average estimated flow on the monitor or controller display of less than 2 L/min, or greater than 10 L/min may indicate an electrical fault, incorrect hematocrit entry or an occlusion due to thrombus or other materials (e.g., tissue fragments) in the device. Inaccurate assessment of HVAD® Pump flow may lead to less than optimal treatment.

7.3.2 Ventricular Suction Detection Alarm

A suction condition may occur due to ventricular collapse or inflow occlusion. Ventricular collapse occurs when a continuous flow VAD attempts to pump more blood from the left ventricle than is available, resulting in considerable reduction in ventricular volume. Left ventricular collapse can be the result of clinical events affecting left ventricular preload including hypovolemia (bleeding), right heart failure, arrhythmia or pulmonary embolus. An inflow occlusion occurs when an inflow cannula is obstructed by the interventricular septum, also causing a suction condition. Temporary inflow obstruction can occur as a result of surgical positioning, patient position or during straining (Valsalva).

The ventricular suction detection alarm functions by monitoring the estimated flow for sudden decreases in flow rate. A flow baseline is established by continuously tracking the minimum flow values. A trigger value is established at 40% below the estimated flow baseline. An indication of suction is obtained when the minimum flow falls below this trigger level. The alarm will be triggered if this condition is maintained for 10 seconds.

The flow minimum that triggers the suction alarm is also used to define the suction clear limit. The estimated flow baseline is continuously compared to this limit. The suction alarm will be cleared if the flow baseline is maintained above the trigger level for 20 seconds. This is an indication that the suction condition has cleared.

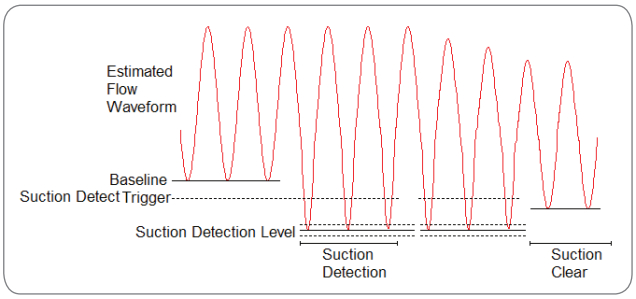


Figure 12: Suction Detection Alarm

The ventricular suction detection alarm can only be activated from the System Screen of the monitor. Therefore, only the clinician has access to control the state of this alarm. The default setting for Suction Response is off. In this mode, there will be no alarm during a ventricular suction condition. An "Sx Off" message will be displayed on the lower left-hand corner of the monitor screen below the "Fixed" mode display. When Suction Response is enabled on the "Setup: VAD" tab, the "Sx On" message will be displayed on the lower left-hand corner of the monitor screen below the "Fixed" mode display.

WARNING: Whether or not the ventricular suction detection alarm is enabled ("Sx On") or is off ("Sx Off") can only be determined with the monitor; it cannot be determined from the controller.

The Suction Response "Alarm" mode must not be turned on if the patient is in a suction condition. If the mode is turned on during a suction condition, the "Sx On" message will be displayed on the monitor and the ventricular suction detection alarm will be enabled but will be inaccurate due to the fact that normal baseline parameters could not be established during a suction condition. The algorithm attempts to establish a baseline detection level to distinguish abnormal conditions. This is not possible if the patient is experiencing ventricular suction when the algorithm is initiated. Once the suction condition clears, an accurate baseline will be obtained automatically and the suction detection will proceed.

NOTE: Ventricular suction detection should be activated once the patient's intravascular volume and pump flow have been stabilized.

If a ventricular suction detection alarm is triggered, the clinician should evaluate whether the alarm was triggered by a transient, reversible condition which corrects itself or whether the alarm is more serious and requires intervention. Transient alarms often occur at certain times during the day and/or under particular circumstances such as bending over or lying on one side. They usually resolve quickly without problems. If the ventricular suction detection alarm is persistent and there are clinical symptoms of decreased blood flow such as dizziness or hypotension or if a "Low Flow" alarm is active then the patient should be evaluated. This can be accomplished by checking the pump flow waveform on the monitor for evidence of suction or if necessary by visualizing the left ventricle with echocardiography. Next, the clinician should attempt to identify and treat the underlying cause of the suction event. If the cause for the suction event cannot be determined or if the cause is refractory to treatment, then the clinician should manually adjust the speed to resolve the suction condition under echocardiographic guidance. Manual changes to the speed will immediately disable the ventricular suction detection alarm. "Sx Off" will be displayed on the monitor screen below the "Fixed" Mode display. The clinician will have to reactivate the alarm after adjusting the speed.

WARNING

- Manual changes to the speed will immediately disable the ventricular suction detection alarm. "Sx Off" will be displayed on the monitor screen below the "Fixed" mode display.
- The ventricular suction detection alarm must not be turned on while the patient is in a suction condition. The patient should be hemodynamically stable prior to enabling the ventricular suction detection alarm.

The ventricular suction detection function will temporarily deactivate if:

- The estimated flow value becomes invalid - the flow is estimated to be outside of the range from -2 L/min to 11 L/min. Once the flow estimation is within valid range then the ventricular suction detection will resume.
- The baseline flow value is less than 1.8 L/min – the algorithm loses sensitivity if the baseline and, therefore, the suction detection level get too low. Once the baseline value is above 1.8 L/min then the ventricular suction detection will resume.
- The clinician changes the hematocrit input – the algorithm recognizes that a change in the fluid viscosity will cause a change in the estimated flow. The ventricular suction detection reactivates once a new baseline is established.
- Lavare Cycle is active – the Lavare Cycle has a direct impact on the Suction Alarm tracking parameters, so the algorithm is temporally disabled. The ventricular suction detection re-activates with the previous baseline once the Lavare Cycle is completed.

7.3.3 Lavare Cycle

The Lavare Cycle is a controlled variation in speed that takes place periodically when enabled (Figure 13). The Lavare Cycle consists of a decrease in speed of 200 RPM below set speed for two seconds followed by an equal increase in speed of 200 RPM above set speed for one second and then a return of the speed to the set speed. Lavare Cycle is limited by pump speed range of 1800-4000 RPM during the low and high speed portions of the cycles. This cycle is repeated periodically every 60 seconds. The Lavare Cycle is depicted in the figure below.

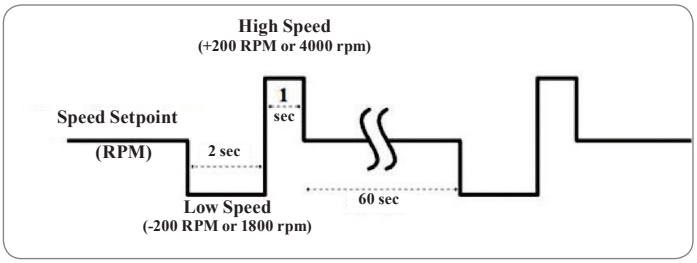


Figure 13: Lavare Cycle

The Lavare Cycle can be enabled or disabled by the clinician via the HeartWare® Monitor. It is recommended that the Lavare Cycle be initiated once the patient is hemodynamically stable. If thrombus is suspected within the device the Lavare Cycle should be turned "Off" until the thrombus is resolved.

NOTE: If thrombus is suspected within the device the Lavare Cycle should be turned "Off" until the thrombus is resolved.

8.0 USING THE HEARTWARE® MONITOR

To turn the monitor ON, press and hold the power button until the monitor software starts up (Figure 14). The power button is located on either:

1. the top right side (monitor REF 1511 (no longer being placed on the market)) or
2. the left side, top (monitor REF 1521).

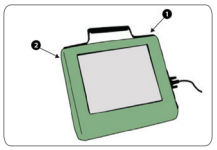


Figure 14: The Monitor Power Buttons (1 & 2)

8.1 Selecting a Language for the Monitor

The monitor is designed to provide a user-friendly way to monitor and control the HeartWare® System. The monitor displays information selected by the user. To choose a language for the monitor, go to the System Screen. The System Screen is accessed by pressing the HVAD® Pump Icon (Figure 15). The System Screen is password protected. HeartWare will provide the clinician with a password. The password dialog box shown in (Figure 16) is used to enter the numeric password. Following 11 minutes of non-use, the user is automatically logged out.

Figure 15: Icon to Access System Screen

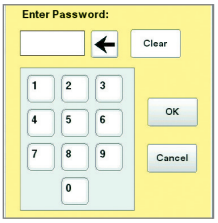


Figure 16: Password Entry

Once you have access to the System Screen, press the Setup tab and then the Monitor tab as shown in (Figure 17).

Next, press the Language button and the Monitor Language Selection Screen will appear (Figure 18).

Select the monitor language desired by pressing the appropriate button and then press OK. The language is selected and user is returned to the Monitor Setup Screen (Figure 17).

Should the Touchscreen require recalibration, press the Touchscreen Calibration button.

NOTE: Monitor Touchscreen calibration instructions will appear in English only—no matter what Monitor Language is selected. Call HeartWare if additional information is needed for recalibrating the Touchscreen.

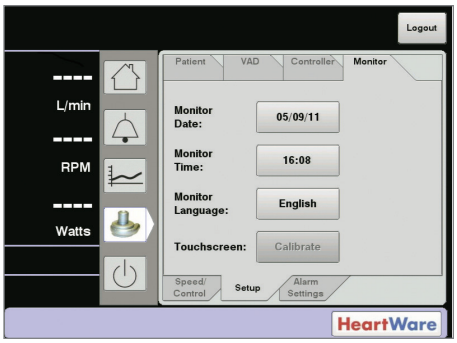


Figure 17: Monitor Setup Screen

8.2 Monitor Overview

The monitor is designed to provide a user-friendly way to monitor and control the HeartWare® System. The monitor:

- Displays pump information
- Allows users to adjust pump parameters
- Monitors and reports system errors and alarm conditions

The monitor is designed to use AC power from a wall outlet. The monitor can also use its internal battery during patient transportation. Keep the monitor's battery charged by connecting the monitor AC adapter to an electrical outlet at all times—even while in storage. It takes approximately 4 hours to charge a depleted monitor battery. If the monitor is going to be stored for a long period, removing the battery and leaving the monitor unplugged is also an option.

NOTE: The monitor should always use AC power except during patient transport.

CAUTION

- The monitor's internal battery should be fully charged prior to patient use.
- DO NOT allow patients to touch the monitor.

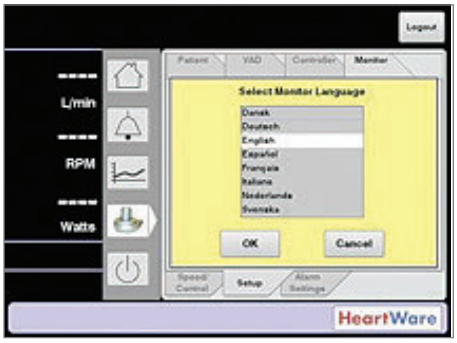


Figure 18: Monitor Language Selection Screen

There are 5 icons (Figure 19) on the monitor to access system information and to manage pump operation. The icons are displayed on all screens. When an icon is selected, it points to the screen.

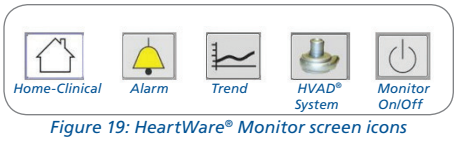


Figure 19: HeartWare® Monitor screen icons

The current state of the pump is displayed along the left-hand side of all monitor screens. Parameters displayed include average pump blood flow (L/min), speed (RPM) and power (Watts) (Figure 20). The top of the monitor screen displays alarm messages for active controller alarms. The alarm messages are identical to those displayed by the controller. During active alarms the Alarm Mute icon appears on the top right of the monitor screen. Pressing this icon silences the alarm for 5 minutes. This area of the monitor screen is also used for status messages.

The bottom of each screen includes the controller data download status icon, patient identification, time, postoperative day (POD) and power supply status. Either the "1" or "2" will light to indicate which source is powering the controller. The illuminated "2" in Figure 21 indicates that an AC or DC adapter is connected to power supply connector 2 and is operating the controller. The remaining battery capacity is also displayed for battery power. If one of the power sources is disconnected, the corresponding icon disappears.

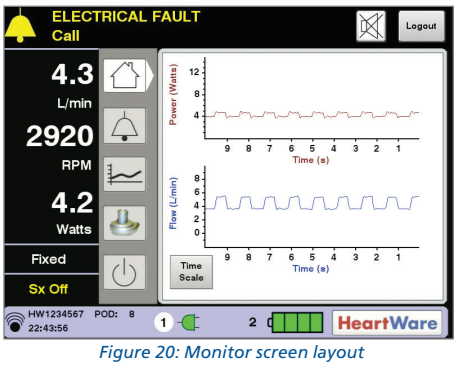


Figure 20: Monitor screen layout

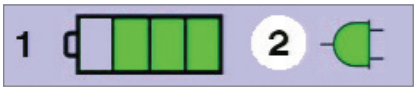


Figure 21: Power supply indicators

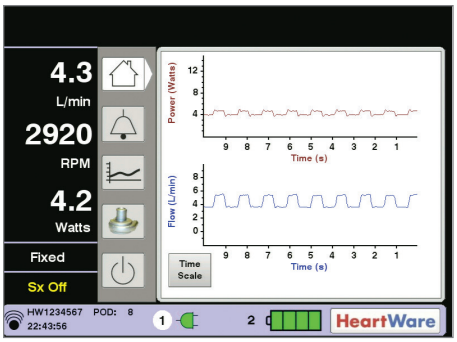


Figure 22: Clinical Screen

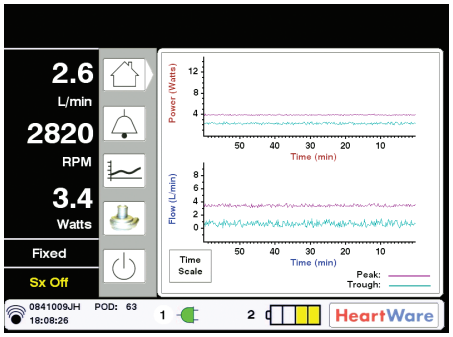


Figure 23: Clinical Screen with 60 Minute Time scale

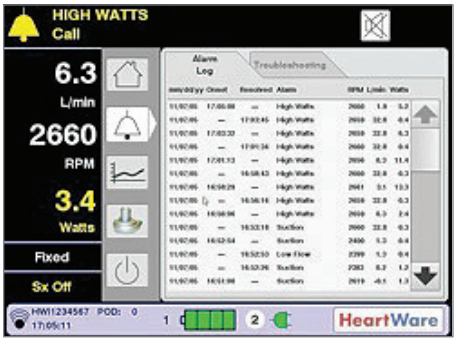


Figure 24: Alarm Log

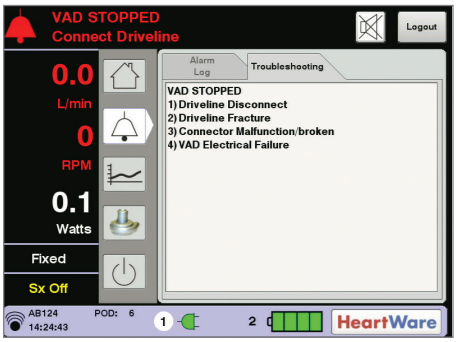


Figure 25: Troubleshooting tab

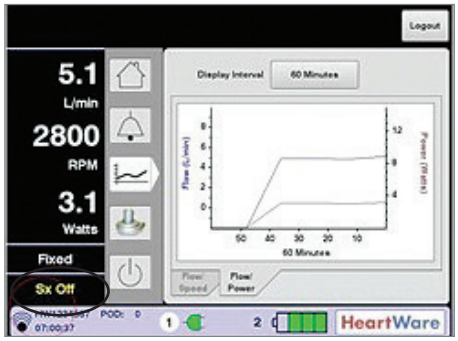


Figure 26: Trend Screen

8.3 Clinical (Home) Screen

Press the Home Icon to access the Clinical Screen.

The Clinical Screen (Figure 22) should be used when no pump adjustments or access to other screens is required. Unique parameters displayed on the Clinical Screen include a real-time power (Watts) waveform and a real-time estimated HVAD® Pump blood flow waveform (L/min). Waveform time scales may be selected for 10 seconds, 20 seconds or 60 minutes.

The waveform time scale may be changed by pressing the "Time Scale" button on the Clinical Screen. Available options are 10 seconds, 20 seconds or 60 minutes. When the 60 minute option is selected, peak and trough values are displayed in the lower right section of the screen (Figure 23).

8.4 Alarm Screen

The Alarm Screens (Figure 24 and 25) are accessed by pressing the Alarm Icon.

- A WHITE Alarm Icon is displayed for no alarms or for a low priority alarm.
- A YELLOW Alarm Icon indicates an active or resolved medium alarm.
- A RED Alarm Icon indicates an active or resolved high alarm condition.

If there are multiple alarms, the Alarm Icon will indicate the highest priority alarm. The Alarm Icon will not return to a white color until the icon is pressed after resolution of the alarm condition.

The Alarm Screen has two tabs (Alarm Log and Troubleshooting). The Alarm Log (Figure 24) provides access to the alarm information. The controller is designed to store 200 alarm entries on a first-in first-out basis. The Alarm Log displays the date and time when each high or medium alarm occurs and when the alarm resolves. Pump parameters are also displayed next to the alarm. The Troubleshooting tab displays active high and/or medium alarms and potential causes for each alarm (Figure 25). Low priority alarms are not displayed in the Troubleshooting tab.

8.5 Trend Screen

The Trend Screen (Figure 26) is accessed by pressing the Trend Screen Icon.

Waveform trend data is accessed on the Trend Screen by pressing the Flow/Speed tab or Flow/Power tab. Flow (L/min) and speed (RPM) or flow (L/min) and power (Watts) can be displayed. Use the Display Interval button to select between the following time intervals: 60 minutes, 4 hours, 24 hours, 14 days or 30 days.

Trend data is uploaded from the controller to the monitor by connecting the monitor data cable to the controller (see Section 8.6.2.1.1 "Downloading Controller Log Files").

8.6 System Screen

The System Screen is accessed by pressing the HVAD® Pump Icon.

The System Screen is password-protected. HeartWare will provide the clinician with a password. The dialog box (Figure 27) is used to enter the numeric password. User access is timed out after 11 minutes of non-use.

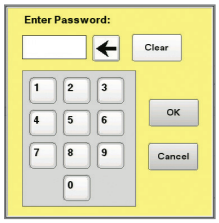


Figure 27: Password dialog box

8.6.1 Speed/Control Tab

Upon entering the System Screen, waveforms are available for displaying real-time flow (L/min) or real-time power (Watts). The preferred waveform is selected by pressing the Flow or Power tab (Figure 28).

The Speed/Control tab is used to adjust RPM and to turn the VAD on or off. The Set RPM button is used to adjust the pump speed (RPM) from 1800 to 4000, and the VAD button is used to turn the pump on and off. When the Set RPM button is pressed, a dialog box will appear with an up arrow and a down arrow. Pressing the up or down arrow will change the pump speed in increments of 20 RPM.

NOTE: Recommended minimum pump speed during patient support is 2400 RPM.

Confirm the speed adjustment by pressing the change button. The HVAD® Pump button is colored and labeled according to the running state of the HVAD® Pump:

- VAD: ON means the HVAD® Pump is pumping; the button is RED and labeled STOP. To stop VAD, press STOP.
- VAD: OFF means the HVAD® Pump is NOT pumping; the button is BLUE and labeled START. To start VAD, press START (Figure 29).
- A dialogue box will appear prompting the user to confirm each action.

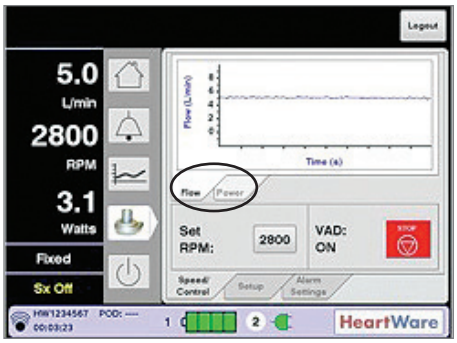


Figure 28: System screen

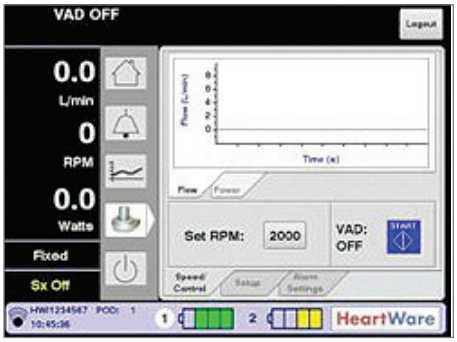


Figure 29: System Screen – VAD start

8.6.2 Setup Tab

When the Setup tab is pressed, four tabs are displayed and include: Patient, VAD, Controller and Monitor (Figure 30). The function of each is described below.

8.6.2.1 Patient Tab

The Patient tab is used to enter Patient ID, Implant Date and Hematocrit. Press the Patient ID to enter patient identification. The patient ID is entered by using the keypad (Figure 31). The A to Z and 0 to 9 tabs allow entry of numbers or letters.

NOTE: Patient ID must be entered for patient's alarms to be displayed in the monitor's alarm log.

Press the Implant Date button and enter the HVAD® Pump implant date using the keypad. Use the Enter button to confirm entry or the Cancel button to cancel entry (Figure 32).

The hematocrit can be changed using the Hematocrit (%) button. This method allows the clinician to manually input the patient's hematocrit using a measurement obtained from a blood sample. The default hematocrit value is 30%.

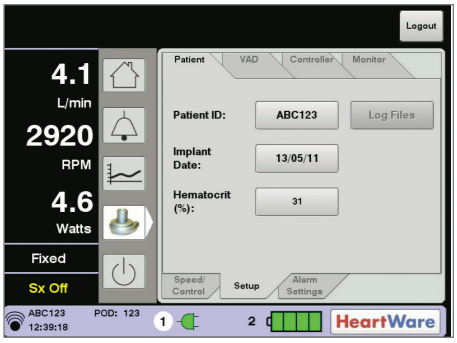


Figure 30: Setup patient tab

8.6.2.1.1 Downloading Controller Log Files

All logs are maintained in the controller in non-volatile flash memory. The Log Files button allows the clinician to obtain alarm and trend data from the controller and to transfer it from the patient's controller to a USB flash drive.

The process for downloading log files from the controller is as follows:

- Using the monitor data cable, connect the blue data port on the controller to the monitor.
- Check that the data download icon in the lower left hand corner of the monitor is flashing grey. The data download icon will become black when the download is complete. It may take up 10 minutes for all the data to transfer from the controller to the monitor.
- Press the Pump Icon to access the System Screen and enter the password.
- Press Setup tab.
- Press Patient tab.
- Wait until the data download icon stops flashing and turns black then disconnect the monitor data cable from the controller.

NOTE: DO NOT disconnect the controller from the monitor when the data transfer icon is flashing, as data is being transferred. If the message, "Log Transfer Not Complete!" appears, re-connect the monitor and controller to complete the data transfer.

Figure 31: Patient ID dialog box

- 5 seconds after disconnecting the data cable, the Log Files button will appear. Press this button and a list of the patient logs will be displayed.
- Place a HeartWare® Monitor compatible USB memory stick into the USB port on the left side of the monitor.
- Select the logs to be saved. Press the Save to USB button.
- A confirmation screen will appear to affirm selection. If correct, press YES button.
- A download complete message will appear when data download is complete. Press OK.
- Remove the USB stick and email the three files: data, alarm and events (3 separate files) to hvadlogsintl@heartware.com.

NOTE: The maximum storage for each controller is 3000 entries, which equates to approximately 31 patient days. A USB flash drive can be used intermittently to download data.

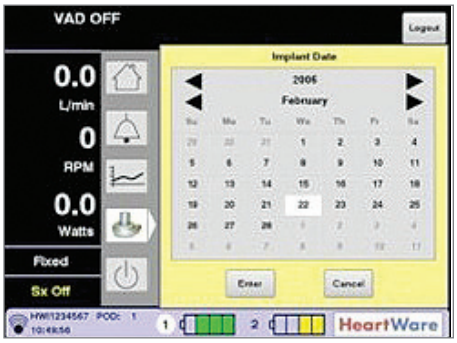


Figure 32: Implant Date screen

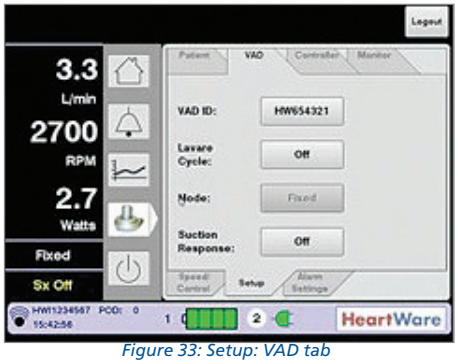


Figure 33: Setup: VAD tab

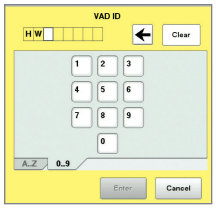


Figure 34: VAD ID dialog box

Figure 35: Lavare Cycle Button

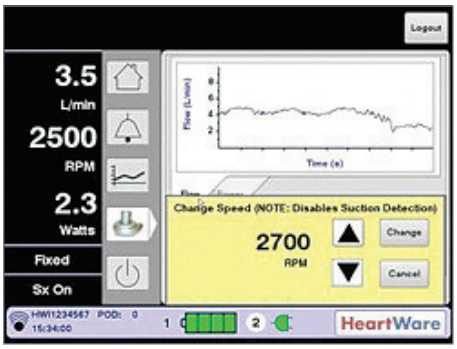


Figure 36: Dialog box for pump speed changes

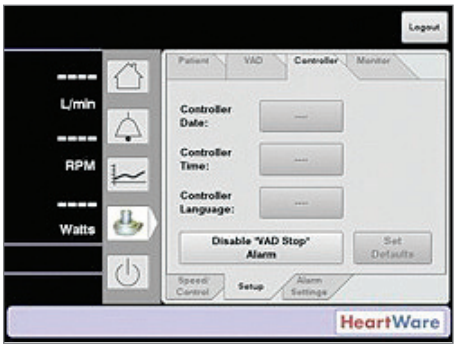


Figure 37: Controller tab ("Set Defaults" does not appear on monitor REF 1521)

Figure 38: Controller Language Selection

8.6.2.2 VAD Tab

The VAD tab (Figure 33) is used to enable or disable the Lavare Cycle and Suction Response and to enter the HVAD® Pump serial number. "Fixed" mode (manual entry of pump speed) is the only mode currently available, therefore this button is disabled.

Press the VAD ID button to enter the HVAD® Pump serial number from the Implant Kit package. After pressing the VAD ID button, a dialog box is displayed (Figure 34) and the serial number is entered by using the keypad to enter letters and numbers. The first two letters of the VAD ID are fixed with the letters "HW". After the information is entered, press the change button. If an incorrect number is entered press cancel and start again.

The "Lavare Cycle", when enabled, periodically slows and increases the RPM for a short period and returns the RPM to baseline. This algorithm is designed to provide a brief fluid pulse approximately once per minute through the VAD. See Section 7.3.3 "Lavare Cycle" for more information.

To turn the Lavare Cycle on, press the "Lavare Cycle" button. A dialog box displays, "Turn Lavare Cycle ON?" Press "Yes" (Figure 35).

To turn the Lavare Cycle off, care must be taken not to do so during the cycle or certain alarms may become disabled:

1) From the VAD tab, observe the speed display
2) Note when the Lavare cycle commences (a decrease in speed of approximately 200 RPM)
3) Wait 15 to 30 seconds and then press the "Lavare Cycle" button. A dialog box displays, "Turn Lavare Cycle OFF?"
4) Press "Yes" to turn the Lavare Cycle off.

WARNING: Do not turn the Lavare Cycle off while the cycle is occurring or certain alarms may become disabled.

To verify that alarms are enabled:

5) Press the "Alarm Settings" tab
6) Note the current "Low Flow Alarm Limit" setting and then raise the setting to a value 1.0 L/min above the current reported flow value
7) Verify that a Low Flow Alarm occurs
8) Return the Low Flow Alarm Limit to the previous setting

The Suction Response button includes two options for suction detection:

- Suction Response "Off." This is the default setting.
- Suction Response on with "Alarm." An alarm will sound if a suction event is detected.

See Section 7.3.2 "Ventricular Suction Detection Alarm" for more information on suction detection.

When the pump speed is changed by accessing the Speed/Control tab, the dialog box reminds users that this will disable the suction detection alarm (Figure 36).

8.6.2.3 Controller Tab

The Controller tab (Figure 37) allows the user to enter the controller date and time, select the controller language and activate the 'Disable "VAD Stop" Alarm' feature. Monitor REF 1511 (no longer being placed on the market) also allows the user to set controller default values.

Press the Controller Date and Controller Time buttons to enter the controller date and time, respectively.

Press the Controller Language button to select the language desired on the controller. After pressing, a pop up screen will appear as shown in Figure 38.

Set Defaults (Monitor REF 1511 only (no longer being placed on the market)): The Set Defaults (Figure 39) button sets the controller parameters to the original manufacturer settings listed below:

- Set Speed is 2500 RPM
- Low Flow Alarm threshold is 1.0 L/min
- High Power Alarm threshold is 16 Watts
- Suction Response is "Off"
- Lavare Cycle is "Off"
- Hematocrit is 30%

NOTE: A controller reset (removal of both power sources) is required following a "Set Defaults" command for the command to take effect.

The Set Defaults button should not be used when a controller is connected to a patient.

CAUTION: The "Set Defaults" button on monitor REF 1511 (no longer being placed on the market) will erase all patient VAD parameter information from the controller.

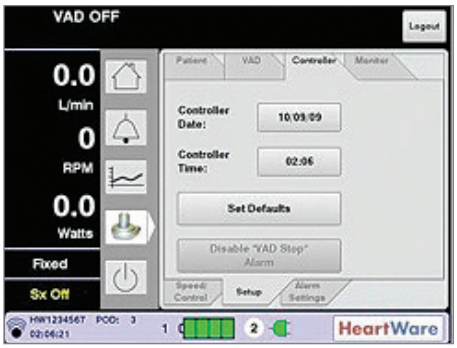


Figure 39: Default setting

Disable "VAD Stop" Alarm:

The purpose of this feature is to allow programming of a controller when it is not connected to a pump (or a motor fixture). After applying power to the controller, it will pause for ten seconds before detecting whether or not a pump is disconnected (a "VAD Stopped" condition). The Disable "VAD Stop" Alarm feature enables the user to send a command to the controller to tell it NOT to alarm when a pump is not attached. This allows the input of patient and controller information via the monitor without an audible alarm. This pending command will clear after 3 minutes.

Steps:

1) Press 'Disable "VAD Stop" Alarm' indicator on monitor (Figure 40)
2) Connect monitor to controller
3) Power up controller with 2 power sources
4) Enter patient and controller information via the monitor
5) Disconnect monitor from controller
6) Disable the "No Power" alarm. If a red alarm adapter is available, insert it into the blue connector on the controller. If no alarm adapter is available, press and hold the Alarm Mute and Scroll buttons simultaneously until a "beep" is heard, or for at least 5 seconds
7) Disconnect power from controller
8) The "VAD Stop" Alarm will be re-armed automatically after 3 minutes as long as the monitor is not connected to a controller (Figure 41)

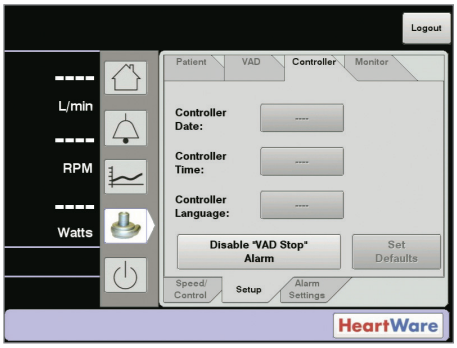


Figure 40: Disable "VAD Stop" Alarm ("Set Defaults" does not appear on monitor REF 1521)

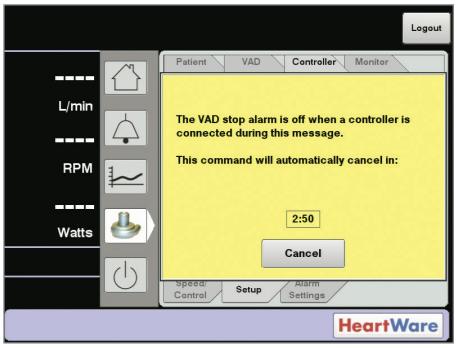


Figure 41: Pending VAD stop command

8.6.2.4 Monitor Tab

The Monitor tab is used to enter the date and time and to calibrate the monitor touch screen (Figure 42). This version of the HeartWare® System supports multiple languages.

- **Monitor Date and Monitor Time:** These buttons set the date and time on the monitor.
- **Language:** Use this button to select the monitor language. English is the default.
- **Touchscreen:** Use this button to initiate touch screen calibration for the monitor. The monitor will only initiate the calibration sequence if the controller is NOT connected to the monitor.

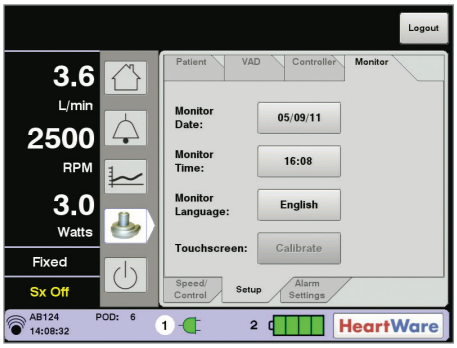


Figure 42: Monitor tab

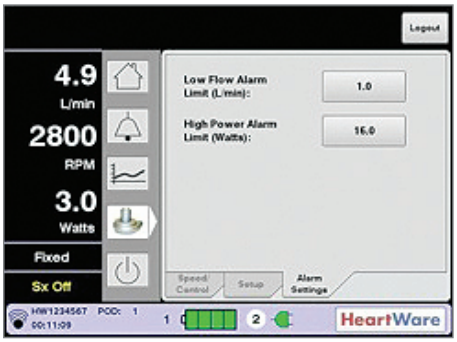


Figure 43: Alarm settings tab

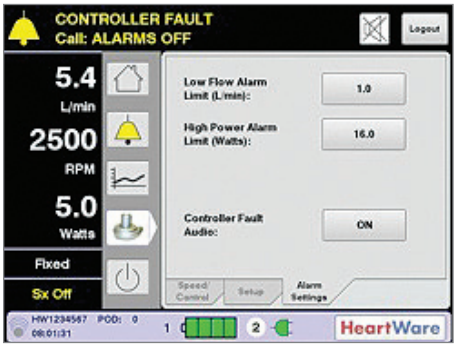


Figure 44: Controller fault audio

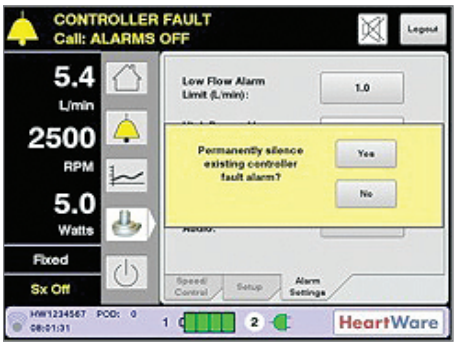


Figure 45: Permanently silence controller fault dialogue box

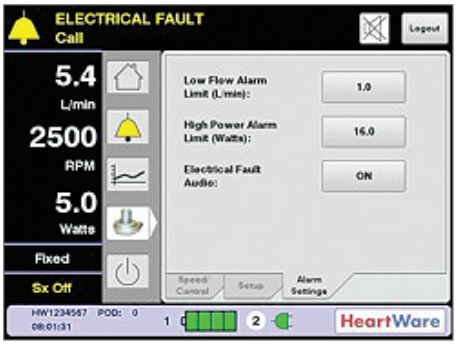


Figure 46: Electrical fault audio

8.6.3 Alarm Settings Tab

The Alarm Settings tab (Figure 43) is used to set the Low Flow Alarm and High Power Alarm thresholds. Both flow and power are time averaged values not instantaneous values. The Low Flow Alarm threshold may be set from 1 L/min to 9.9 L/min in 0.1 L/min increments. The Low Flow Alarm should be set at 2 L/min below the patient's average flow. Do not set the Low Flow Alarm below 2 L/min. The High Power Alarm may be set from 1.0 watts to 25.0 watts in increments of 0.5 watts. Default settings are 1 L/min for Low Flow and 16 watts for High Power. The High Power Alarm should be set 2 watts above the patient's current average power. If the flow drops below the low flow threshold (e.g. 1 L/min) or the power exceeds the high power threshold (e.g. 16 watts), an alarm is triggered. Clinicians should set the Low Flow and High Power Alarm thresholds close to the patient's flow and power values, respectively.

NOTE:

- The Low Flow Alarm should be set at 2 L/min below the patient's average flow. DO NOT set the Low Flow Alarm below 2 L/min.
- The High Power Alarm should be set 2 watts above the patient's current average power.

When certain alarm or fault conditions exist, the Alarm Settings tab may be used to access additional controls to silence the audio component of the alarm or fault for extended time periods.

The Controller Fault Audio button appears during a medium priority "Controller Fault" alarm (Figure 44). The Controller Fault Audio button can be used to permanently silence a controller fault alarm. However, the controller and monitor will continue to display the controller fault alarm until the condition resolves.

Permanently silencing the "Controller Fault" audible alarm is a two step process. Pressing the "Silence" button on the monitor touch screen will bring up a confirmation box (Figure 45). Pressing the "Yes" button will silence all current medium priority controller fault alarms. Subsequent controller faults will produce new audible alarms.

The Electrical Fault Audio button appears during a medium priority "Electrical Fault" alarm (Figure 46). The Electrical Fault Audio button can be used to permanently silence an electrical fault alarm. However, the controller and monitor will continue to display the electrical fault alarm until the condition resolves.

The user should always log off the password-protected System Screens after completing system adjustments. Press the Logout button and confirm by pressing the YES button to return to the Clinical Screen. If the System Screen is not used for 11 minutes, the user is automatically logged out and needs to enter the password to access these screens.

8.7 Monitor Shut Down

The Monitor On/Off Icon is used to shut down the monitor program.

NOTE: Always use the On/Off Icon to shut down the monitor or data may be lost.

A dialog box will appear after pressing the Monitor On/Off Icon asking you to confirm (Figure 47):

a. Press "Yes" to exit the program. When the "It is now safe to turn off power" prompt appears on the monitor, press the monitor power button. To completely power off, you must press AND HOLD the power button until the screen shuts off.

OR

b. Press "No" to return to the program.

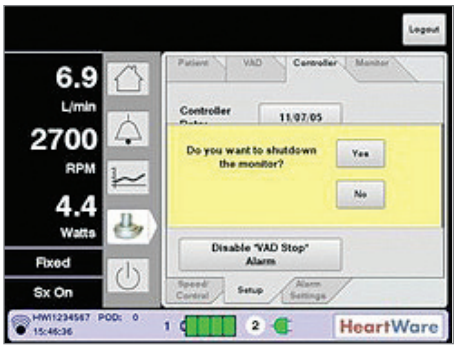


Figure 47: Confirming monitor shutdown

9.0 USING THE HEARTWARE® CONTROLLER

9.1 Connector Layout

There are four connectors, two on either side of the controller (Figure 48). The power supply connections are identical and are used to connect to any of the power sources (batteries, AC adapter or DC adapter). The controller should always be connected to two power sources for safety. If only connected to one power source, the controller will function but will sound an alarm after 20 seconds.

The driveline is connected to the silver connector (Figure 49). To connect the driveline to the controller, align the red markings on both connections and push together. The driveline cover should completely cover the controller's silver driveline connector to protect it and keep it clean. To disconnect the driveline, pull the driveline cover away from the silver controller connector, then pull the driveline connector from the silver controller connector.

WARNING

- To remove the driveline from the controller, first pull back the driveline cover then grasp and pull the driveline connector. DO NOT grasp the driveline cable as this may damage the driveline.

The monitor cable attaches to the blue data port connector on the controller. To connect, align the white arrow with the white dot and push the two halves until the connector locking mechanism latches. To disconnect, twist the connector counterclockwise and pull the two connectors apart.

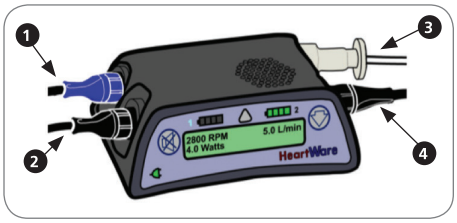


Figure 48: Controller

1. Monitor Connector
2. Power Connector
3. Driveline Connector
4. Power Connector

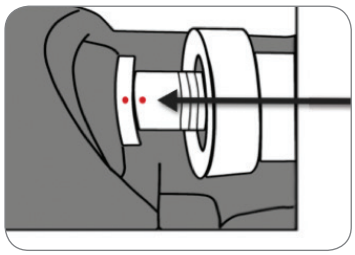


Figure 49: Driveline connection to controller

9.2 Controller Display and Operation

The controller face (Figure 50) incorporates a number of visual indicators and function buttons.

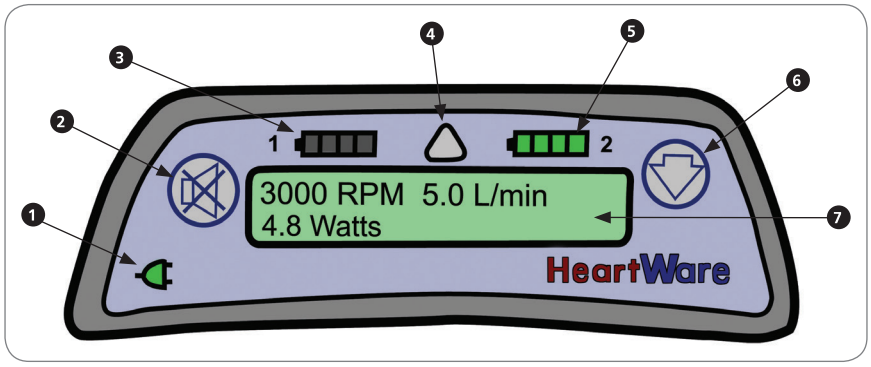


Figure 50: Controller display

1. AC/DC Indicator
2. Alarm Mute Button
3. Battery Indicator 1
4. Alarm Indicator
5. Battery Indicator 2
6. Scroll Button
7. Controller Display

Controller Display, Buttons, and Indicators			
	The **CONTROLLER DISPLAY** provides pump information, including impeller speed (RPM), power (Watts), and blood flow (L/min). When an alarm occurs, the pump information is replaced by two lines of text that tell you what the alarm is and what to do. Section 13.0 describes alarms in detail.		The two **BATTERY INDICATORS** located on the top of the controller are labeled "1" and "2." Either the "1" or "2" will be lit, depending upon which port is providing primary power. If an AC or DC adapter is connected, this will be the primary power source. Battery capacity is displayed on the Battery Indicators as follows: ◗ 75-100% battery capacity: 4 GREEN lights ◗ 50-74% battery capacity: 3 GREEN lights ◗ 25-49% battery capacity: 2 YELLOW lights ◗ ≤24% battery capacity: 1 RED light When the controller is attached to 2 batteries, it will switch power sources when the primary battery reaches 25% capacity, provided the secondary battery has >30% capacity. NOTE: If the AC adapter or DC adapter is connected to the controller, the corresponding Battery Indicator will not display lights but the corresponding "1" or "2" will be lit.
	The **ALARM INDICATOR** lights when one or more alarms occur. The Alarm Indicator changes color depending on the severity of the alarm and always displays the most severe alarm in the case of multiple alarms. The display for each alarm priority includes: ◗ **High Alarm:** Flashing Red ◗ **Medium Alarm:** Flashing Yellow ◗ **Low Alarm:** Solid Yellow		
	The **ALARM MUTE BUTTON** will silence (mute) a low or medium alarm for 5 minutes or until a new alarm occurs. A high priority alarm can only be silenced by resolving the alarm condition.		
	The **SCROLL BUTTON** on the right side of the controller is used to see all active alarms as well as pump information (RPM, L/min, Watts) on the Controller Display. The Scroll Button will also clear resolved medium alarms from the Controller Display and will brighten the Controller Display.		
	Simultaneously pressing and holding the **ALARM MUTE BUTTON** and the **SCROLL BUTTON** for 5 seconds will prevent the "No Power" alarm from sounding when power is removed during a controller exchange (see Section 9.3 "How to Change the Controller"). Use only on a controller not connected to a pump.		
	The **AC/DC INDICATOR** will be green if the AC adapter or DC adapter is used to power the controller.		

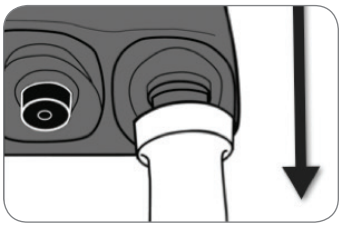


Figure 51: Remove white driveline cover

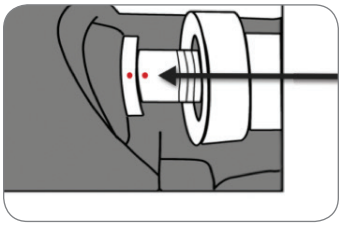


Figure 52: Connect driveline to New Controller (align the two red marks)

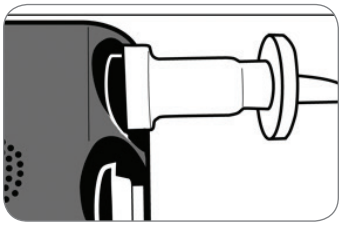


Figure 53: Replace driveline cover

9.3 How to Change the Controller

A backup controller and fully charged batteries must be available at all times for controller failures or malfunctions. The backup controller should be set with the same pump parameters and patient information as the primary controller.

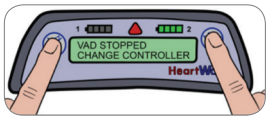
NOTE: Patients with a fused aortic valve, an aortic valve that has been sewn shut due to aortic valve regurgitation, or patients with very poor ventricular function should be educated in the importance of having a backup controller readily available at all times including when changing power sources.

A controller failure or high priority controller malfunction will generate a high priority or RED alarm and the controller display will tell you if you should "Change Controller."

To change the controller:

1) Have the patient sit or lie down.
2) Place the **new** controller within easy reach.
3) Connect backup power sources to the **new** controller.
   - Confirm that the power cables are properly locked onto the controller by gently pulling on the cable near the connector.
   - A "Power Disconnect" alarm will activate if a second power source is not connected to the new controller within 20 seconds of controller power up.
   - A "VAD Stopped" alarm will activate if the pump driveline is not connected to the new controller within 10 seconds. This alarm will resolve once the pump driveline is connected.
4) Pull back the white driveline cover from **original** controller's silver connector (Figure 51).
5) Disconnect the driveline from the original controller by pulling the silver connector away from the controller. Do not disconnect by pulling the driveline cable. A "VAD Stopped" alarm may activate.
6) Connect the driveline to the **new** controller (align the two red marks and push together) (Figure 52). If the "VAD Stopped" alarm was active on the new controller, it will now resolve.
   - The pump should restart. The RPM, L/min, and Watts numbers should show on the controller display.
7) To prevent the controller alarm from sounding after the power is removed, follow these instructions:

- **If a red alarm adapter is available,** insert it into the blue connector on the original controller.



- **If no alarm adapter is available:**
  - Press and hold the Alarm Mute and Scroll Buttons on the original controller until a "beep" is heard, or for at least 5 seconds.
  - Release the Alarm Mute and Scroll buttons.

8) Disconnect both power sources from the original controller. The controller will be turned off and all alarms silenced.
9) Slide the white driveline cover up to cover new controller's silver connector (Figure 53).
10) Contact HeartWare to obtain a new backup controller.

WARNING

- Keep a spare controller and spare fully charged batteries available at all times in case of an emergency.

10.0 USING THE HEARTWARE® BATTERIES

The batteries (Figure 54) contain lithium ion cells to power the HVAD® Pump for approximately 4 to 6 hours when fully charged. The capacity of each battery in hours is based on:

- Controller and HVAD® Pump operating power consumption
- Number of battery charge and discharge cycles

The batteries are expected to have a useful operating life of greater than 500 charge and discharge cycles. If a battery provides less than two hours of support duration, it should be replaced.

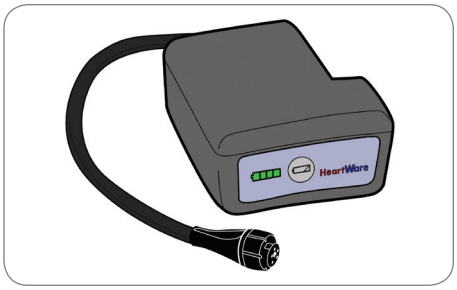


Figure 54: Battery

Battery Buttons and Indicators	
	Pressing the TEST BUTTON will light up the Battery Capacity Display.
	The BATTERY CAPACITY DISPLAY will tell you how much power remains in the battery.

The Battery Capacity Display on the battery is similar to the Battery Indicator on the controller (see Section 9.0 "Using the HeartWare® Controller") except that only green lights are used on the battery. For example, at 25-49% capacity, 2 green lights will be displayed on the battery while 2 yellow lights will be displayed on the controller (see chart below).

Battery Capacity	Battery Capacity Display on BATTERY	Battery Indicator on CONTROLLER
75-100%	4 GREEN lights	4 GREEN lights
50-74%	3 GREEN lights	3 GREEN lights
25-49%	2 GREEN lights	2 YELLOW lights
≤24%	1 GREEN light	1 RED light

NOTE: When one battery is depleted to <25%, the controller will automatically switch to the other battery. When this happens, an intermittent "beep" will sound, the Alarm Indicator on the controller will be yellow and a message will be displayed to replace the depleted battery (Figure 55).

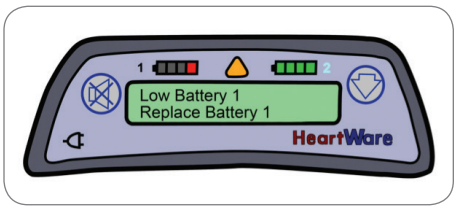


Figure 55: Replace depleted battery message on controller

If the battery is NOT changed within 5 minutes, the alarm volume will escalate until the battery is exchanged with a fully charged battery. When a depleted battery is not exchanged and there are only a few minutes of battery time remaining in both batteries, a high priority alarm will sound, the Alarm Indicator will flash RED and the message on the controller will display "Critical Battery 1" or "Critical Battery 2." If this occurs, there are only a few minutes of power remaining before the pump stops; therefore, the batteries must be replaced immediately.

CAUTION: Recharge fully depleted batteries within 24 hours to avoid permanent battery damage.

10.1 Changing a Battery

1) Make sure there is a fully charged battery available to replace the used or depleted battery.
2) Disconnect the depleted battery by turning the connector sleeve counterclockwise until it stops (follow arrow).
3) Pull the connector straight out from the controller.
4) Grasp the cable of the fully charged battery near the connector leaving the connector free to rotate.
5) Line up the solid white arrow on the connector with the white dot on the controller (Figure 56A).
6) Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place. A successful connection will result in an audible click.

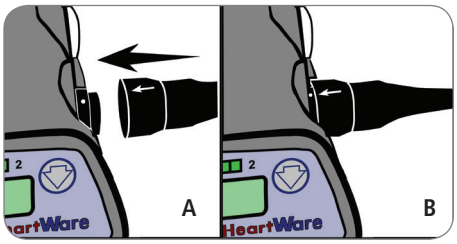


Figure 56: Connecting power to controller

NOTE: When pushing the connector onto the controller the white arrow will shift slightly. Correct locking position: White arrow aligned with white dot on controller.

7) Confirm that the battery cables are properly locked on the controller by gently pulling the cable near the controller power connector (Figure 56B).

CAUTION

- When connecting cables, DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.
- Confirm that the power cables are properly locked on the controller by gently pulling the cable near the controller power connector.

10.2 Care of Batteries

1) To preserve battery life, batteries should be stored at room temperature.
2) Protect batteries from extreme high and low temperatures. Avoid storage in direct sunlight.
3) Protect the battery connector from moisture, dirt and metal at all times.
4) Handle connectors so as to avoid touching the inside.
5) Do not drop the batteries or let them hit hard objects.
6) Do not let batteries get wet.
7) Do not twist or kink battery cables.
8) Do not force connection to the controller or battery charger.
9) Batteries should be stored in the battery charger. Store batteries fully charged.

CAUTION

- DO NOT expose batteries to temperatures outside the storage and operational ranges or they may provide less support than usual. To preserve battery life, batteries should be stored at room temperature.

Battery operating and storage temperatures:

- **Operating:** (normal use with the HeartWare® System) and charge (while on battery charger): +5°C to 40°C (+41°F to 104°F). Operation at temperatures below 0°C will **temporarily** reduce battery capacity but the battery will operate.
- **Storage:** -20° to 25°C (-4 to 77°F). Long term storage outside of this range may **permanently** reduce the battery capacity. Best condition for storage is at room temperature
- Keep batteries away from children.
- Do not disassemble, crush, or puncture a battery.
- Do not use a damaged battery.
- Do not short the external contacts on a battery.
- If a battery pack is leaking fluid, do not touch the fluid. Dispose of a leaking battery pack. In case of eye contact with fluid, do not rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention.
- Avoid exposing the battery to excessive shock or vibration.
- Do not dispose of a battery in fire or water. Dispose of batteries according to federal, regional, and local regulations.

11.0 USING THE HEARTWARE® BATTERY CHARGER

Figure 57: Battery charger, its AC adapter and power cord.

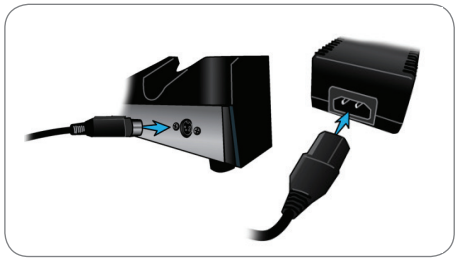


Figure 58: Connecting the battery charger AC adapter

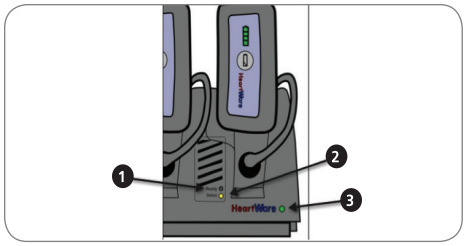


Figure 59: Battery charger – battery charge status indicators

1. Ready
2. Status
3. AC Power

The battery charger (Figure 57) can charge up to 4 batteries at a time. It takes approximately 4 to 5 hours to fully charge a depleted battery. Prior to charging batteries, connect the AC adapter to the back of the battery charger, connect the AC power cord to the AC adapter and then plug into an electrical outlet. The AC power indicator is green when the battery charger is properly connected to electrical power. Slide the battery into a bay and then connect the battery cable connector to the battery charger. It is safe to leave the batteries in the charger and the charger plugged into a wall outlet at all times.

The charger has two indicators for each charging bay. The indicators are "Ready" and "Status". The green light adjacent to the "Ready" indicates that the battery is fully charged (Figure 59).

Battery Charger "Status" Light	What it Means
No Light	Battery not connected or battery ready when green "Ready" light is on.
Yellow	Battery being charged; NOT ready for use.
Flashing Yellow	Battery not charging. Check battery connections. If connections are intact, switch to another battery slot. If problem persists, return battery to HeartWare.
Red	Battery too cold or too hot; waiting to charge.
Flashing Red	Defective battery. Do NOT use. Mark battery and return to HeartWare.

CAUTION

- Use only the HeartWare® Battery Charger to charge batteries. Other battery chargers may damage the batteries.
- ALWAYS wait until the "Ready" light turns on to disconnect the battery from the battery charger. If this is not followed over consecutive charging cycles, the Battery Capacity Display will not function properly and may convey misleading battery capacity.

11.1 Connecting the Battery to the Battery Charger

1) The battery connects to the battery charger the same way that it connects to the controller.
2) Grasp the cable of the battery near the connector leaving the connector free to rotate.
3) Line up the solid white arrow on the connector with the white dot on the battery charger.
4) Gently push the cable onto the battery charger until it locks in place.

11.2 Disconnecting the Battery from the Battery Charger

1) Disconnect the charged battery by turning the connector counterclockwise until it stops.
2) Pull the connector straight out from the battery charger.

CAUTION: ALWAYS wait until the "Ready" light turns on to disconnect the battery from the battery charger. If this is not followed over consecutive charging cycles, the Battery Capacity Display will not function properly and may convey misleading battery capacity.

12.0 USING THE HEARTWARE® CONTROLLER AC ADAPTER OR DC ADAPTER

The AC adapter (Figure 60) has cables that connect it to the controller and to an electrical outlet. Prior to connection to the controller, verify proper connection of the power cord to the adapter (Figure 61) and electrical outlet. If not properly connected, perform the following steps:

1) Using a Phillips screw driver, loosen the screw at the retainer clip to allow the retainer clip to open.
2) Insert the AC power cord completely and securely into the receptacle of the AC adapter.
3) Tighten the screw at the retainer clip closing the retainer clip.
4) Ensure that AC power cord is secure in the adapter receptacle and cannot be pulled out.

A green indicator light on the adapter will indicate proper connection.

The DC adapter (Figure 62) plugs into the power port located in most cars. When the DC adapter is properly connected to power, a green indicator light will be displayed.

CAUTION: The DC adapter is for use in vehicles only and may not fit in some vehicles.

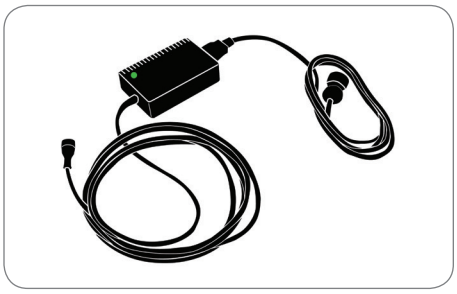


Figure 60: AC adapter

Figure 61: Power cord connection

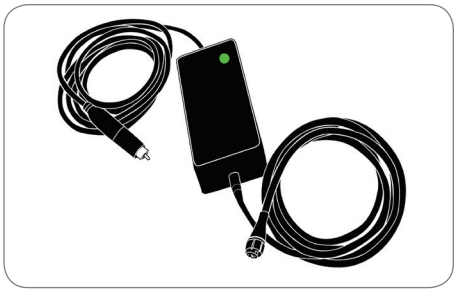


Figure 62: DC adapter

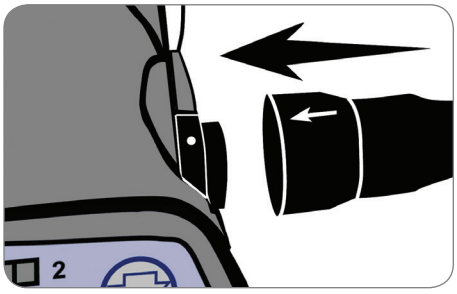


Figure 63: Correct adapter alignment

12.1 Operating the Power Adapters

Ensure that the power indicator on the power adapter turns green before plugging into the controller.

12.2 Connecting the AC Adapter or DC Adapter

1) Plug the AC adapter into an electrical outlet or the DC adapter into a power port located in most cars.
2) Disconnect the battery with the least remaining charge. The corresponding battery indicator will turn off.
3) Grasp the cable of the AC adapter or DC adapter near the connector, leaving the connector free to rotate.
4) Line up the solid white arrow on the connector with the white dot on the controller (Figure 63).

5) Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place. A successful connection will result in an audible click (Figure 64).

NOTE: When pushing the connector onto the controller, the white arrow will shift slightly. Correct locking position: White arrow aligned with white dot on controller.

6) Confirm that the power cables are properly locked on the controller by gently pulling the cable near the controller power connector.

CAUTION

- When connecting cables, DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.
- Confirm that the power cables are properly locked on the controller by gently pulling the cable near the controller power connector.

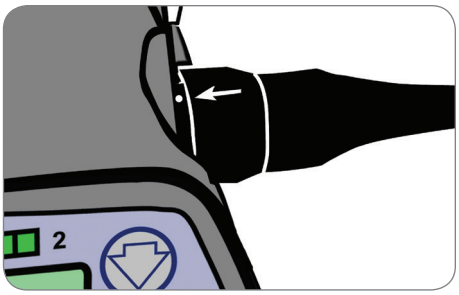


Figure 64: Correct locking position

7) Proper connection is also verified when the AC/DC Indicator on the controller turns green and the corresponding power supply indicator illuminates. If the AC/DC Indicator does not turn green, the controller is using battery power only and a "Power Disconnect" alarm will sound.

12.3 Disconnecting from the AC Adapter or DC Adapter

Before switching from AC or DC power to battery power, make sure that a fully charged battery is available. Connect the fully charged battery after disconnecting the AC or DC adapter. To disconnect power cables from the controller:

1) Turn the connector counterclockwise until it stops.
2) Pull the connector straight out from the controller.
3) Connect a fully charged battery to the controller power connector.
4) If a charged battery is not connected to the controller within 20 seconds, the "Power Disconnect" message will be displayed on the Controller Display and an alarm will sound.

13.0 ALARMS

Visual and auditory alarms tell clinicians and patients about the pump, controller, connections, and power supplies (batteries, AC adapter, DC adapter). A quick reference guide for alarms is located in Appendix A. Alarm conditions, are classified as high, medium or low. Each of these alarms has a 1) unique sound, 2) visual display (flashing RED, flashing YELLOW or YELLOW) and 3) message.

When an alarm occurs, two lines of text appear in the Controller Display. The first line describes the alarm and the second line tells you what to do. When an alarm is resolved, there is no longer an alarm sound or a light displayed in the Alarm Indicator.

WARNING: A controller with a blank display or no audible alarm should be replaced.

13.1 High Alarms

A high alarm is the highest priority and loudest alarm; the Alarm Indicator on the controller is flashing RED and the text message demands immediate action for VAD stoppage, controller malfunction or limited power to run the pump. The monitor will also display alarm information.

High Alarms on Controller – Immediate Action Required				
Message on Controller (line 1)	**Message on Controller (line 2)**	**Meaning**	**Alarm Indicator** ▲	**Alarm Sound**
(no message)*	(no message)*	Both power supplies removed - VAD stopped	None*	Continuous
VAD Stopped	Connect Driveline	Driveline disconnected or connector malfunction/broken	Flashing RED	Loud Unable to mute alarm
VAD Stopped	Change Controller	Controller failure		
Controller Failed	Change Controller	Controller failure		
Critical Battery 1	Replace Battery 1	Limited battery 1 and battery 2 time remaining		
Critical Battery 2	Replace Battery 2	Limited battery 2 and battery 1 time remaining		

The following are High-Priority Alarms:

***No Power** (no message): If both power sources are disconnected from the controller, a loud, continuous alarm will sound and there will be NO message on the Controller Display. The HVAD® Pump is NOT pumping and **power sources should be connected immediately**. If this action does not resolve the alarm condition replace the controller.

VAD Stopped: The HVAD® Pump will stop if the driveline is disconnected or if the controller fails. The text message indicates whether to connect the driveline or change the controller.

Controller Failed: Indicates a potential controller failure and the controller should be exchanged for a new controller. The HVAD® Pump may not be pumping.

WARNING: If there is a "Controller Failed" alarm, switch to the backup controller.

Critical Battery: Displayed when there are a few minutes of battery time remaining to power the HVAD® Pump or the battery has malfunctioned. Replace battery 1 or 2 with a fully charged battery or use the AC adapter or DC adapter.

If the controller has lost communication with a battery and the other power port is connected to either a battery with a remaining capacity of 25% or greater, or a valid power adapter, the controller shall generate a **Power Disconnect** alarm associated with the non-communicating battery. This alarm condition will clear or activate a different alarm if any of the following conditions occur:

1) Communication with battery is re-established.
2) The remaining capacity of other battery drops below 25% - in this case a critical battery alarm will be triggered.

When the controller has lost communication with a battery and the other power connector is NOT connected to a valid power supply or is connected to a battery with a remaining capacity of less than 25% the controller will generate a **Critical Battery** alarm. This alarm condition will clear when any of the following occur:

1) Communication with battery is re-established.
2) The non-communicating battery is disconnected.
3) The other power source is switched to a valid power adapter or to a battery having a remaining capacity of 25% or greater.

13.2 Medium Alarms

A medium alarm starts at a low volume and gets louder over the next minute, unless the Alarm Mute button is pressed. Pressing the Alarm Mute button will silence medium and low level alarms for 5 minutes or until an additional alarm occurs. If the Alarm Mute button is not pressed, after 5 minutes the alarm volume is elevated to the level used in high alarms. A medium alarm is indicated by a flashing YELLOW Alarm Indicator, and the text message tells the patient to call medical personnel for instructions to resolve the alarm condition.

Medium Alarms				
Message on Controller (line 1)	**Message on Controller (line 2)**	**Meaning**	**Alarm Indicator** ⚠	**Alarm Sound**
High Watts	Call	A change in the status of the HeartWare® System is detected	Flashing YELLOW	◗ Gradual increase in volume over the first minute if alarm not muted ◗ Alarm gets louder after 5 minutes if alarm not muted ◗ Able to mute alarm for 5 minutes or 1 hour ◗ Electrical Fault (audio) can be permanently disabled ◗ Controller Fault (audio) can be permanently disabled
Electrical Fault				
Low Flow				
Suction				
Controller Fault	Call	Controller malfunction		
Controller Fault	Call ALARMS OFF	◗ Controller malfunction ◗ Suction detection, low flow alarms disabled ◗ High power and VAD disconnected alarms may be disabled		

The following are Medium-Priority Alarms:

High Watts
This alarm warns of a high power condition in running the HVAD® Pump. The alarm is triggered when the Watts exceed the High Power Alarm threshold (see Section 8.6.3 "Alarm Settings Tab"). This could be an indication of thrombus forming within the pump.

Electrical Fault
A fault in the continuity of the pump to controller electrical connection triggers this alarm. The fault could be in the HVAD® Pump motor, driveline and connector or within the controller. The audio portion of this alarm can be permanently disabled via the monitor (see Section 8.6.3 "Alarm Settings Tab"). When this alarm condition occurs, the HVAD® Pump will be running on a single stator and will consume slightly more power.

Low Flow
The low flow alarm is triggered if average flow drops below the Low Flow Alarm threshold (see Section 8.6.3 "Alarm Settings Tab").

Suction
The ventricular suction detection alarm is triggered if the suction algorithm has identified a ventricular suction condition. This may self-clear if the suction is transient.

Controller Fault
The controller contains two microprocessors - one which controls pump function (PMC) and a second which controls user interface functions (UIC) such as Controller Display and buttons. The controller fault alarm indicates a possible controller malfunction may have occurred, but during this fault the UIC processor still receives a heartbeat message from the PMC indicating the PMC is still functioning and controlling the pump. The controller fault alarm will result in the word "Call" in the controller display, notifying the patient to call the Clinician. The Clinician should query the patient about the frequency and duration of alarm as well as any additional alarms and changes in pump flow, speed or power. The patient should also be asked about any clinical symptoms/changes including dizziness, shortness of breath, angina and/or palpitations. Based on the patient's responses, the following course of action should be taken:

- If there was a single, isolated controller fault alarm with no change in pump or clinical parameters, instruct the patient to report any additional alarms that may occur. Download the controller log files at the patient's next clinic visit and send to HeartWare for analysis.
- Instruct the patient to return to the center as soon as reasonable (not emergently) so the controller log file can be downloaded and sent to HeartWare for analysis if one of the following situations occurs:
  - If a controller fault alarm has occurred and been resolved multiple times over a 24-hour period, or
  - If a controller fault alarm has occurred in conjunction with other alarms even though it has not affected pump flow, power or speed and there are no concurrent clinical symptoms.

  The decision to change the controller or what other action is needed will be based on the log file analysis and the patient's clinical condition.
- The patient should be instructed to change the controller and return to the implanting center as soon as is reasonable (within 12-16 hours) if one of the following occurs:
  - The controller fault alarm is occurring frequently (more than 1 time per hour), with increasing frequency,
  - If the controller fault alarm has occurred and not resolved,
  - If the controller fault alarm has occurred in conjunction with other alarms, and is associated with a change in pump flow, speed or power or any adverse clinical symptom such as lightheadedness or shortness of breath.
  - Download the log files from the original controller and the current controller and send them to HeartWare for analysis.

When a medium alarm resolves, there is no audible alarm or light displayed in the Alarm Indicator located on the controller. However, the message on the Controller Display will remain until the message is cleared by pressing the Scroll Button. A new alarm will also clear a resolved medium alarm from the controller display. For instructions on how to silence (mute) an alarm, see Section 13.5.

The Controller Display and Alarm Indicator will continue to display all active alarms. Any new alarm condition will inactivate the 60-minute mute. The controller fault alarm audio can be permanently silenced but this cannot be done by the patient (requires the monitor, Section 8.6.3 "Alarm Settings Tab").

13.3 Low Alarms

A low alarm is indicated by a solid YELLOW Alarm Indicator. The message indicates whether to replace a low battery or reconnect a power source (battery, AC adapter or DC adapter). The alarm gets louder after 5 minutes and even louder after 10 minutes, if the alarm is not muted.

Low Alarms				
Message on Controller (line 1)	**Message on Controller (line 2)**	**Meaning**	**Alarm Indicator** 	**Alarm Sound**
Low Battery 1	Replace Battery 1	Battery 1 is low	YELLOW	Alarm gets louder after 5 minutes and even louder after 10 minutes, if alarm not muted. Able to mute alarm for 5 minutes. Press Alarm Mute Button.
Low Battery 2	Replace Battery 2	Battery 2 is low		
Power Disconnect	Reconnect Power 1	Power source 1 is disconnected or defective		
Power Disconnect	Reconnect Power 2	Power source 2 is disconnected or defective		

The following are Low-Priority Alarms:

Low Battery
This alarm is triggered if any batteries have a remaining capacity between 10% and 25%.

Power Disconnect
This alarm is triggered if a power source to the controller is disconnected or defective. The power supply should be replaced immediately because the patient will be without a backup power source.

WARNING: Disconnecting both power sources (batteries and AC or DC adapter) at the same time will stop the pump. At least one power source must be connected at all times.

13.4 Multiple Alarms

It is possible to have concurrent alarm conditions. For multiple alarms, the Alarm Indicator "△" will display the color of the most severe alarm and the alarm will sound the most severe alarm. An arrow is displayed on the right side of the alarm for multiple alarms (Figure 65). Use the Scroll Button to see all active alarms.

Alarm Indicator and Alarm Sound for Multiple Alarms		
Multiple Alarm Condition	**Alarm Indicator △**	**Alarm Sound**
More than 2 High Alarms	Flashing RED	Loud, continuous, unable to mute
High and Medium Alarms	Flashing RED	Loud, continuous, unable to mute
High and Low Alarms	Flashing RED	Loud, continuous, unable to mute
More than 2 Medium Alarms	Flashing YELLOW	Gradual increase in volume if alarm NOT muted
Medium and Low Alarms	Flashing YELLOW	Gradual increase in volume if alarm NOT muted
More than 2 Low Alarms	YELLOW	Gradual increase in volume if alarm NOT muted

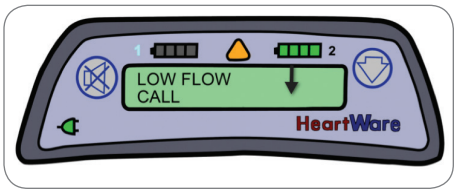


Figure 65: Arrow on right side of the alarm on controller display indicates two or more alarms. Use scroll button to see all alarms.

NOTE: If an arrow is displayed on the right side of the alarm message, there are multiple active alarms. Use the Scroll Button to see all alarm conditions. Press the Scroll Button to advance to the next alarm or to the pump parameters (flow, speed and power). If the Scroll Button is not touched for 1 minute the controller automatically displays the most severe alarm on the controller display. If a new alarm occurs, the controller display will show the new alarm.

13.5 How to Silence (Mute) Alarms

High alarms CANNOT be silenced. However, medium and low alarms may be silenced for 5 minutes by pressing the Alarm Mute Button. Clinicians can also mute medium alarms for one hour by pressing and holding the Alarm Mute Button, then pressing and holding the Scroll Button, followed by releasing the Alarm Mute Button, and finally releasing the Scroll Button. The alarm will sound again if a new alarm condition occurs during the mute interval. The medium priority "Electrical Fault" alarm and "Controller Fault" alarm can be permanently disabled by accessing the Alarm Settings in the monitor's System Screen (see Section 8.6.3 "Alarm Settings Tab").

WARNING: Silencing an alarm does not resolve the alarm condition. ALWAYS investigate, and if possible, correct the cause of any alarm.

13.6 Status Message Display

The monitor may display a status message where alarms are typically displayed. The following are potential status messages:

Message	Potential Causes
VAD Off	Driveline connected to controller and HVAD® Pump manually stopped
Data @ Limit	Patient data cannot be stored due to maximum number of patients or lack of storage space

NOTE: The monitor will overwrite files at its data limit, which is based on the amount of hard disk space used. The USB flash drive can be used to transfer log files.

14.0 SURGICAL IMPLANT PROCEDURE

NOTE: In order to optimize patient outcomes HeartWare suggests that the following techniques be considered at the time of HVAD® Pump implant:

- **TEE**
  - Inspect LA and LV for thrombus - thoroughly remove any thrombus present.
  - Check for PFO - PFO should be surgically repaired prior to HVAD® Pump implant.
- **Coring**
  - After coring, make sure margins of the core are clean and smooth.
  - Perform visual inspection of cored area and remove any loose tissue and/or clots.
- **De-Airing**
  - After placement of HVAD® Pump in the LV, passively fill the LV and pump.
  - Elevate the apex of the heart and shake gently to remove any entrapped air in the heart/HVAD® Pump.
  - Clamp the distal outflow graft. After anastomosis of the outflow graft to the ascending aorta, complete the de-airing process using standard technique.
- **Pump Speed (RPM)**
  - Prior to starting the HVAD® Pump, the LV should be full. The pump must always start at 1800 RPM.
  - Speed should be increased by no more than 100 RPM at a time.
  - Increase the HVAD® Pump speed slowly to avoid suction events. Suction events can lead to the ingestion of tissue/clot from inside the LV, and may also lead to episodes of ectopy.

14.1 HeartWare® Ventricular Assist System Setup

Battery Charger

1) Connect the battery charger AC adapter to the battery charger and then plug its power cord into an electrical outlet. Verify the power indicator is lit next to "HeartWare."
2) Verify availability of four fully charged batteries. If batteries are not fully charged, start charging depleted batteries at least 4 hours before the HVAD® Pump implant procedure.

Monitor

1) Connect the monitor AC adapter to the monitor and then plug its power cord into an electrical outlet.
2) Turn the monitor on. The monitor program will appear in a few minutes.
3) Connect the monitor data cable to the serial port on the monitor and to the blue connector on the controller.
4) Press the HVAD® Pump Icon to access the System Screen and enter the password (see Section 8.6 "System Screen" for more detail).
5) Press Setup tab to display Patient, VAD, Controller and Monitor tabs (see Section 8.6.2 "Setup Tab").
6) Press the Monitor tab and enter monitor date and time.
7) The monitor battery should be charged a minimum of 4 hours before starting the implant procedure.

Backup Controller

1) Press the Controller tab on the Setup Screen, and then press the 'Disable "VAD Stop" Alarm' button.
2) Connect the monitor data cable to the blue data port on the controller.
3) Plug the AC adapter into an electrical outlet.
4) Connect the controller to the AC Adapter.
5) Connect a fully charged battery to the controller.

NOTE: Once powered, the controller performs a self-test and will display a temporary message regarding the status of the self-test. If the controller fails the self-test, a controller fault alarm message will appear. In that case replace the controller with the second controller.

6) Press Speed/Control tab and reduce the set speed to 1800 RPM.
7) Press Setup tab to display Patient, VAD, Controller and Monitor tabs (see Section 8.6.2 "Setup Tab").
8) Press the Patient tab and enter the Patient ID and Implant Date.
9) Ensure the Hematocrit setting is 30%.
10) Press VAD tab and enter HVAD® Pump serial number and verify that Lavare Cycle and Suction Response are "Off".
11) Press Controller tab and enter controller date and time.
12) Press the Alarm Settings tab to set the Low Flow Alarm limit and High Power Alarm limits. Default settings are 1 L/min for low flow and 16 watts for high power.
13) Remove data cable.
14) To prevent the controller alarm from sounding after the power is removed, follow these instructions:
    - If a red alarm adapter is available: Insert it into the blue connector on the controller.
    - If no alarm adapter is available: Press and hold the Alarm Mute and Scroll Buttons on the controller until a "beep" is heard, or for at least 5 seconds.
15) Disconnect both power sources from controller.
16) Set the backup controller aside for use during the Pre-Implant Test.

NOTE: A backup controller should always be available and programmed identical to the primary controller.

Programming Initial Settings for the Primary Controller

1) Press the Controller tab on the Monitor Setup Screen, and then press the 'Disable "VAD Stop" Alarm' button.
2) Connect the monitor data cable to the blue data port on the controller.
3) Plug the AC adapter into an electrical outlet.
4) Connect the primary Controller to the AC Adapter.
5) Connect a fully charged battery to the controller.
6) Press Speed/Control tab and reduce the set speed to 1800 RPM.
7) Press Setup tab to display Patient, VAD, Controller and Monitor tabs (see Section 8.6.2 "Setup Tab").
8) Press the Patient tab and enter the patient's ID and Implant Date.
9) Ensure the Hematocrit setting is 30%.
10) Press VAD tab and enter HVAD® Pump serial number and verify that Lavare Cycle and Suction Response are "Off".
11) Press Controller tab and enter controller date and time.
12) Press the Alarm Settings tab to set the Low Flow Alarm limit and High Power Alarm limits. Default settings are 1 L/min for low flow and 16 watts for high power.
13) Press the Logout button and return to the Clinical (Home) Screen.
14) After setting up the primary controller, keep both power supplies connected to the controller so that the pump does not stop, then restart automatically when power is restored. During implant the HVAD should be started only by pushing the password protected "Start" button.
15) Place the controller in the Patient Pack (carry bag) and position the bag close to the head of the OR table so the driveline can be connected to the controller after tunneling.

WARNING: In order to minimize the risk of air embolus during implant, keep both power supplies connected to the controller after setting up the primary controller. Disconnecting and then reconnecting both power supplies will result in the controller starting the pump as soon as the driveline is connected.

NOTE: Any changes to the primary controller should also be made to the backup controller.

14.2 HVAD® Pump Pre-implant Test

1) Examine the HVAD® Pump implant kit package and other component packaging. They must be unopened and without any visible damage including abrasion, delamination or punctures.

WARNING: Sterile components are intended for single use only. DO NOT use if package is damaged or opened. DO NOT re-sterilize or re-use.

2) Set up a sterile back table to prepare and test the HVAD® Pump.
3) Open the driveline extension cable first. Pass it onto the sterile field, wipe it off with a damp sponge and set on sterile back table. Dispose of sponge and change gloves.

NOTE: The driveline extension cable should only be used during the pre-implant test. It should not be connected when the VAD is running.

4) Grasp the Tyvek lid of the HVAD® Pump implant kit package at the point indicated and peel back, taking care not to contaminate the inner sterile tray.
5) Pass the HVAD® Pump tray and other components aseptically onto the sterile field. Examine all components, including the surgical tools, for damage, corrosion or any abnormalities that might affect the safety or functionality of the tools. If any abnormalities are noted please use the appropriate backup supplies.
6) Cover the HVAD® Pump with a sterile towel. With the driveline extended on the back table, remove the Tyvek sleeve (peel off by hand) covering the polyester covered portion of the driveline (see Figure 66). Wipe the driveline with a lap sponge moistened with antibiotic irrigation and discard the sponge.
7) On the sterile field, fill a basin with 2 liters of 5% dextrose.
8) Attach the sterile driveline extension cable to the HVAD® Pump and pass the distal portion of the cable (labeled "Controller") to the non-sterile assistant.

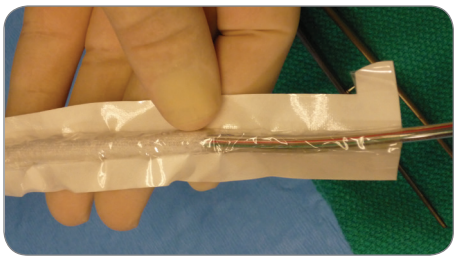


Figure 66: Tyvek sleeve covering polyester on driveline

WARNING: An audible click should be heard when connecting the driveline to the controller or driveline extension. Failure to ensure a secure connection may cause an electrical fault.

9) Clamp the sterile portion of the extension cable to the sterile field on the table to prevent cable movement.
10) The non-sterile assistant should have the backup controller and a charged battery ready for use. Completely submerge the HVAD® Pump in the dextrose solution. Fill the pump with dextrose and gently rotate it with the inflow cannula facing up in the dextrose to allow any trapped air to escape.
11) At least 4 inches (10.2cm) of dextrose solution must be above the VAD inflow and outflow conduits.
12) When the HVAD® Pump is completely submerged in the sterile basin and is de-aired, point the inflow cannula towards the wall of the basin and position your hand over the VAD outflow.
13) The non-sterile assistant should connect the driveline extension cable to the silver connection of the backup controller and then connect the battery to the controller. Ensure that the driveline cover on the driveline extension cable is pushed fully forward to cover the exposed metal driveline connector and the mating connector on the controller.
14) The pump will start at 1800 RPM.

WARNING: During the Pre-Implant Test and prior to implantation: The HVAD® Pump must be completely submerged in fluid before being turned on. Never turn on the HVAD® Pump in air. DO NOT use an HVAD® Pump that was turned on without total submersion in fluid.

NOTE: During the HVAD® Pump Pre-Implant Test, a low priority alarm will sound since one of the controller power ports is empty.

15) Run the pump for 30-60 seconds. **If, at any time during this test, the power exceeds 3 Watts, do not use the pump - set it aside and repeat this process using the backup HVAD® Pump.**
16) After the test is complete, disable the "no power" alarm. If a red alarm adapter is available, insert it into the blue connector on the backup controller. If no alarm adapter is available, press and hold the Alarm Mute and Scroll Buttons until a "beep" is heard, or for at least 5 seconds. Remove the battery from the controller. This will power down the controller and will stop the pump.
17) Wearing clean, dry, gloves, disconnect the driveline extension cable from the controller and the pump.
18) Connect the driveline cap to the driveline by pushing both connectors together until you feel a "click" (Figure 67). Protect the connector from exposure to fluids.
19) Cover the inflow cannula of the HVAD® Pump with the yellow inflow cap.

Figure 67: Driveline cap connection

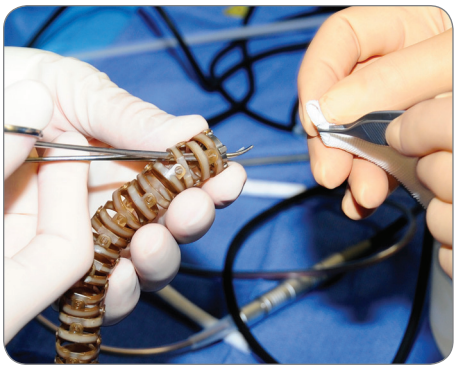


Figure 68: Strain relief over outflow graft

Figure 69: Stretch outflow graft over pump outflow conduit

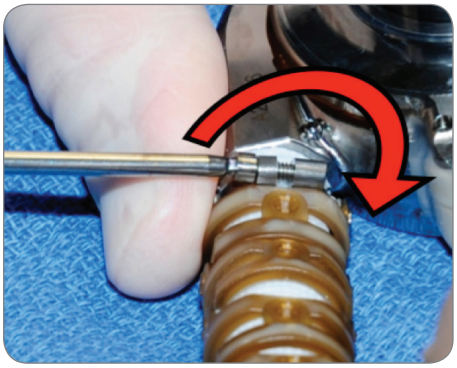


Figure 70: Rotate clamp screw to inner side of outflow conduit

14.3 Outflow Graft Attachment

1) Examine the outflow graft package. It must be unopened and without visible damage.

WARNING: Gel impregnated polyester vascular prostheses should not be implanted in patients who exhibit sensitivity to polyester or materials of bovine origin.

2) Open the package aseptically, talking care not to contaminate the sterile graft.
3) Pass the outflow graft onto the sterile field.

CAUTION:

- The foil pouch and outer tray are not sterile. Only the innermost tray may be introduced to the sterile field.
- DO NOT preclot. Gelweave prostheses are sealed grafts and must not be preclotted.
- The Gelweave prostheses must be implanted within one month after removal from the foil pouch.

CAUTION: Outflow graft attachment to the pump should be performed by a surgeon, physician's assistant or surgical assistant trained in the procedure.

4) Slide the strain relief over the outflow graft (Figure 68). Next, stretch the outflow graft over the HVAD® Pump outflow conduit (Figure 69). Hemostats can be used to assist with the procedure. Verify that the outflow graft is not kinked or twisted. If necessary reattach graft if kinking or twisting occurs.

CAUTION: Excessive tension or force should be avoided as it will damage the polyester fibers and the gelatin impregnation.

5) Loosen the graft clamp screw and place the graft clamp over the lip of the HVAD® Pump outflow conduit. Verify that the clamp screw is on the outflow conduit and attached to the graft clamp.
6) Tighten the clamp screw slightly with the hex driver, then rotate the strain relief so that clamp screw is located on the inner side of the outflow conduit (Figure 70). Finish tightening the clamp screw until resistance is met.

WARNING

- Rotate the strain relief so that the clamp screw is located on the inner side of the outflow conduit to avoid tissue irritation or damage.
- DO NOT use excessive force when tightening the clamp screw because this could damage the graft clamp or the graft clamp screw. Replace components if required.

7) Gently pull on the outflow graft to verify secure placement of the graft clamp to the outflow conduit.
8) Inspect the outflow graft and strain relief for any kinks or twisting. Reattach the outflow graft if necessary.
9) Clamp the HVAD® Pump outflow graft with a vascular clamp and wrap it all in a clean towel.

14.4 Pump Implantation Preparation

1) Make a standard median sternotomy incision.
2) Open the pericardium to expose and access the LV apex.
3) Consider a transesophageal echocardiography (TEE) prior to placing the patient on cardiopulmonary bypass to assess for a patent foramen ovale (PFO). If present, correct the defect prior to HVAD® Pump implantation.
4) Consider flooding the field with CO_2 when appropriate to reduce residual intracardiac air during surgery.

14.5 Left Ventricle (LV) Apex Cannulation

1) Elevate the LV apex.
2) Select the insertion site for the HVAD® Pump inflow cannula. It should be anterior to the LV apex with the inflow cannula pointing to the mitral valve and parallel to the interventricular septum. Evaluate where the HVAD® Pump will sit when implanted. If it appears it will directly contact adjacent rigid structures such as the chest wall consider placing the pump on the diaphragmatic surface, opening the left pleural space, or wrapping it in a sheet of PTFE.

CAUTION: Optimal inflow cannula position is toward the mitral valve and parallel to the interventricular septum.

3) Attach the sewing ring to the myocardium using 8-12 pledgeted, double-armed polypropylene sutures. Use felt strips or a felt ring for reinforcement if necessary.

CAUTION: Position the sewing ring to permit access to its screw after cannulation.

4) Perform a full-thickness cruciate incision inside the sewing ring using an 11-blade scalpel.
5) Using the apical coring tool (Figure 71), create and remove the apical core. To use the apical coring tool:
   - Insert the thumb in the thumb ring and wrap the first two fingers around the handle. Push the ring forward with your thumb, extending the cutting head.
   - After the cutting head is completely extended, place the cutting head through the myocardium. Release tension.
   - Grasp the tool with one hand and use the other to rotate the cutting head as it retracts.
   - Cored tissue is captured within the cutting head.
6) Perform a visual inspection of the left ventricle and remove any thrombus or potential obstruction to the inflow cannula.
7) Place a clamp on the HVAD® Pump outflow graft.
8) Remove the inflow cap from the HVAD® Pump inflow cannula and keep the HVAD® Pump outflow graft cross-clamped.
9) Insert the inflow cannula into the ventricle. Ensure that the HVAD® Pump housing is flush with the sewing ring housing.
10) Use the sewing ring wrench (Figure 72) to tighten the sewing ring's screw around the HVAD® Pump inflow conduit. Use the wrench to tighten the screw until an audible "click" is heard.

Figure 71: Apical coring tool

WARNING: DO NOT loosen the sewing ring's screw by turning the screw counter-clockwise or it may fall off the sewing ring.

11) Verify no blood or air leakage around the sewing ring. Add reinforced pledgeted sutures as needed.

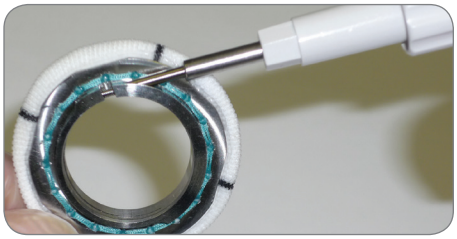


Figure 72: Sewing ring wrench

14.6 Outflow Graft Anastomosis

1) Gently stretch the outflow graft, measure and cut to length. The outflow graft should lie without kinking or overstretching.
2) Place a partial occlusion clamp on the portion of the ascending aorta where the outflow graft will be placed.
3) Make a longitudinal arteriotomy and sew the outflow graft to the aorta with 4-0 or 5-0 polypropylene suture.
4) Remove the partial occlusion clamp from the aorta and ensure an intact anastomosis without bleeding, while keeping the HVAD® Pump outflow graft clamped.

CAUTION:

- If the outflow graft is too short or too long, it may kink. Prior to chest closure ensure that the graft is not kinked or compressed.
- Gelweave is based on a woven structure and may be cut with a cautery to minimize fraying. Note: Immersion of the Gelweave prosthesis in saline immediately prior to use will prevent focal burning, which may result during cauterization. Grafts should be immersed in saline for no longer than 5 minutes.
- Round body taper point needles should be used when implanting Gelweave prostheses to minimize fiber damage.

14.7 Driveline Placement

Select the location where the driveline will exit the skin. Consider the position of major organs and structures when determining the path of the tunneler. Massage antibiotic solution into the external surface of the driveline's woven polyester velour.

The tunneler (Figure 73) is designed so that the handle can be attached and detached. To attach the handle to the tunneling rod, depress the locking pin, insert the tunneling rod into the handle until it bottoms out, release the locking pin and rotate the handle until the locking pops out. Using the tunneler, tunnel the driveline lead to the point of exit. Adjust distance of exit site from costal margin to fit body habitus and prevent rubbing against the costal margin.

Figure 73: Tunneler

Once the tunneling path has been made, screw the driveline cap on to the tunneling rod tip, as shown (Figure 74). Ensure that the two-piece driveline cap has not separated and remains tightly fastened. Pull the driveline through the tunneling path once it is secured to the tunneling tool.

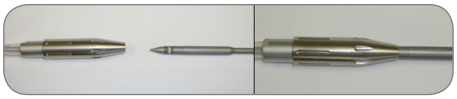


Figure 74: Driveline cap attachment to tunneler

Disconnect the tunneling rod from the driveline cap. Do not remove the driveline cap until it is time to connect the driveline to the controller. Make sure to protect the driveline connector from contamination during this time. Prior to removing the driveline cap, put on clean, dry gloves. To remove the driveline cap, unscrew the outer sleeve, and pull back on the grooved part of the connector. Next, place the white, rubber driveline cover over the driveline connector. Verify that the connector is dry and clean before attaching to the controller. If the driveline connector contains any fluid, tissue or foreign material, thoroughly clean it with isopropyl alcohol and dry it with a clean cloth. Attach the driveline to the controller and slide the driveline cover forward to completely cover the controller's silver driveline connector. After the driveline is connected to the controller, the driveline cover is on, and the pump has started, immobilize the driveline at the exit site with retaining sutures.

WARNING: To remove the driveline cap from the driveline, unscrew the outer sleeve, then pull back on the grooved part of the connector. DO NOT grasp the driveline and pull because this may damage the driveline.

CAUTION: During HVAD® Pump implantation and re-operation, be aware of the position of the driveline to avoid damage by surgical instruments and needles.

14.8 De-airing Procedure

1) Start ventilation.
2) Be sure that all IV catheters and pressure monitoring lines are closed to the atmosphere to reduce the possibility of air entering the heart and pump.
3) Reduce cardiopulmonary bypass flow to allow filling of the left ventricle and pump.
4) Place a sterile 19-gauge (or smaller) needle into the outflow graft between the HVAD® Pump and the outflow graft clamp.

CAUTION: Use the smallest possible needle for de-airing; 19 gauge is normally sufficient. Hypodermic needles have a cutting point which may result in blood leakage and may require repair by suturing.

5) Start HVAD® Pump at 1800 RPM by pressing the blue button labeled "START" on the monitor.

WARNING: HVAD® Pump flow estimation may not be accurate during the de-airing procedure.

6) With the HVAD® Pump at 1800 RPM, use TEE to assess air in the left ventricle and aorta.
7) After all air is removed, remove the 19-gauge needle and oversew the needle hole with pledgeted sutures.
8) Release the outflow graft cross clamp.
9) Gradually increase HVAD® Pump speed to achieve the desired flow and wean from cardiopulmonary bypass as tolerated.

NOTE: Increase HVAD® Pump speed in increments of 100 RPM with a 20-second interval between speed changes to gradually increase flow and to help prevent ventricular collapse.

WARNING: All air must be removed from the HVAD® Pump and its conduits to reduce risk of air embolus.

14.9 Programming the Backup Controller to Match the Primary Controller

A backup controller should always be available and programmed identical to the primary controller. The backup controller should be programmed before the implant procedure, prior to patient transfer from the operating room, when the primary controller is replaced, and upon any parameter change to the primary controller.

Parameters include:

1) Pump speed
2) Hematocrit setting
3) VAD ID/Pump serial number
4) Lavare Cycle setting
5) Suction Response setting
6) Controller date and time
7) Low Flow Alarm limit
8) High Power Alarm limit
9) Patient ID

See Section 14.1 for instructions on programming the controller and removing power from the backup controller.

15.0 HVAD® PUMP EXPLANT

15.1 At Transplant

1) Surgically expose the HVAD® Pump and sewing ring.
2) Place patient on cardiopulmonary bypass according to institutional guidelines.
3) Connect the controller to the monitor and turn off the HVAD® Pump.
4) Cross-clamp two (2) sections of the outflow graft.
5) Cut outflow graft between two (2) clamps.
6) Cut and remove the percutaneous driveline.
7) Remove the HVAD® Pump with the heart.

15.2 Myocardial Recovery/Pump Exchange

1) Surgically expose the HVAD® Pump and sewing ring.
2) Place patient on cardiopulmonary bypass according to institutional guidelines.
3) Connect the controller to the monitor and turn off the HVAD® Pump.
4) Cross-clamp two (2) sections of the outflow graft.
5) Cut outflow graft between two (2) clamps.
6) Cut and remove the percutaneous driveline.

WARNING: At HVAD® Pump explant the percutaneous driveline is not sterile; therefore ensure that the driveline does not contaminate the sterile field.

7) Excise the remaining outflow graft from the aorta and repair the anastomosis site.
8) Use the sewing ring wrench to loosen the sewing ring screw.
9) Remove the HVAD® Pump.

NOTE: During HVAD® Pump removal for recovery or exchange it may be difficult to withdraw the pump from the left ventricle due to tissue ingrowth on the sintered portion of the inflow cannula. It may be necessary to excise tissue adjacent to the sintering potentially resulting in bleeding and/or air emboli.

10) For pump exchange, refer to section 14.5 (beginning with step #6). For myocardial recovery, follow the steps below.
11) Repair the hole in the LV.

12) Close sternum and skin incision per routine.
13) Once HVAD® Pump is explanted rinse gently with NaCL.
14) Place HVAD® Pump in 5% Formaldehyde for at least 2 days.
15) Allow the HVAD® Pump to thoroughly dry.
16) Follow the packaging instructions provided in the Explant Kit (provided by HeartWare) and return the HVAD® Pump in the Explant Kit.

HeartWare, Inc.
Product Quality Department
14400 NW 60th Avenue,
Miami Lakes, FL 33014 USA

16.0 PATIENT MANAGEMENT

16.1 Postoperative Management

After implantation, the patient is returned to the intensive care unit. Fluids are given to maintain pump flow index (pump flow ÷ BSA) at greater than 2.0 L/min/m^2 with central venous pressure and left atrial pressure less than 20 mm Hg. Some vasopressor and/or vasodilatory pharmacologic assistance can be used as required to adjust vasomotor tone. Patients may require inotropic assistance of right ventricular function.

To mitigate the risk of stroke, please adhere to the following patient management guidelines:

- Maintain MAP at <85 mm Hg, as tolerated. The HVAD® Pump is sensitive to both preload and afterload.
- Ramp speed and flows more slowly during the first few weeks (e.g., 30 days) post-implant to avoid excessive hemodynamic forces that may damage fragile blood vessels that have undergone remodeling secondary to the lower pressures and reduced flow associated with medically-treated heart failure. There is no apparent need to exceed a cardiac index of 2.6 L/min/m^2 until patients have fully recovered from the implant surgery and physical performance improves. A cardiac index of 2.6 L/min/m^2 is the lower limit of normal for a healthy adult.
- Maintain anticoagulation within the recommended INR range of 2.0-3.0.
- Check for ASA resistance with a reliable test (e.g., VerifyNow®) and adjust ASA mono-therapy accordingly or consider combination therapy such as ASA 81 mg plus Aggrenox® (ASA plus extended-release dipyridamole) or daily ASA 81 mg plus Plavix® 75 mg. In general, mono-therapy with ASA is not encouraged in the absence of testing for resistance.

16.2 Emergency Management

In the event of an emergency, such as a cardiac arrest, patients with the HeartWare® System may be defibrillated with either an internal or external defibrillator. The HeartWare® System can be left on, nothing needs to be turned off or disconnected. If chest compressions are performed, confirm function and positioning of HVAD® Pump once the patient is stable.

CAUTION: Chest compressions may pose a risk due to pump location and position of the outflow graft on the aorta—use clinical judgment. If chest compressions have been administered, confirm function and positioning of HVAD® Pump.

16.3 Anticoagulation

Prior to HVAD® Pump implantation, many patients with refractory heart failure have abnormal coagulation due to abnormal liver function and chronic use of anticoagulation. Prolonged INR can be associated with significant postoperative bleeding. The INR, PTT, and platelet count should be performed prior to HVAD® Pump implantation. The return of each of these parameters to a normal range prior to HVAD® Pump implantation is an important goal.

Anticoagulation should be individualized for each patient. In general, begin low-dose heparin at 10 units/kg/hr on postoperative day one to a target PTT of 40-50 seconds. Prior to initiation of anticoagulation, chest tube drainage should be less than 40 ml/hr for approximately three hours, the HCT should be stable without the need for transfusion of blood products, and coagulation factors approaching normal. Gradually increase the heparin dosage to maintain the a PTT in a range of 50-60 seconds.

The recommended long term oral anticoagulation regimen for the HVAD® Pump is a combination of warfarin and aspirin. In general, aspirin should be started at a dose such as 325 mg/day within 24 hours after implant if there are no postoperative bleeding complications. However, if ASA alone is the medication chosen for anti-platelet therapy, a check for ASA resistance with a reliable test (e.g., VerifyNow®) is recommended to establish the dose or to select an alternative medication. Multi-drug options include:

- ASA 81 mg plus Aggrenox® (ASA (25 mg) plus extended-release dipyridamole (200 mg)).
- ASA 81 mg plus clopidogrel 75 mg daily

For patients who are aspirin sensitive or otherwise intolerant, clopidogrel at doses of 75-150 mg/day is a viable alternative. A clopidogrel loading dose of 300 mg followed by 75 mg/day is recommended to reduce the lag time in reaching full therapeutic benefit (typically a 3-4 day lag). Warfarin should be started within 4 days post-op and titrated to maintain an INR of 2.0 to 3.0.

16.4 Infection Control Guidelines*

For prevention of infection, remove unnecessary IV lines and replace old IV lines before HVAD® Pump implantation. Administer antimicrobial prophylaxis based on the hospital's nosocomial and microbial sensitivity profile with sufficient coverage for staph aureus, staph epidermidis and enterococcus. Use pre-operative scrub with antiseptic the night before and again the morning of the operation. After HVAD® Pump implantation, continue systemic antimicrobials prophylaxis for 48 to 72 hours. Remove mediastinal and pleural drains as soon as appropriate. Early extubation, removal of monitoring lines, and patient ambulation are encouraged. Rapid restoration of oral nutrition should be attempted using tube feeding if necessary. Turning the patient side to side can start once the patient is clinically stable. Physical therapy and active range of motion can begin on the first postoperative day. The patient can be moved to a chair and can/should use an exercise bicycle or treadmill as soon as possible. Nursing measures to decrease infection include frequent hand washing and strict aseptic technique during contact with invasive lines and during HVAD® Pump dressing changes.

* Infection Control Guidelines and Driveline Care based on recommendations from "Multicenter Experience: Prevention and Management of Left Ventricular Assist Device Infections". Chinn et al. ASAIO Journal 2005; 51:461-470

16.5 Driveline Care*

To minimize the risk of infection, driveline exit site dressings should be changed daily. Routine driveline/exit site care is the responsibility of the patient and the primary caregiver. For proper HVAD® Pump driveline and exit site care, please ensure the following:

1) Use good hand-washing technique before and after dressing changes
2) Always use aseptic technique
3) Change dressings per institutional protocol/guidelines:
   a. Change once or twice daily 24-48 hours after implant (or sooner if saturated)
   b. Change BID for drainage, trauma or infection
   c. Change daily when all drainage has stopped, the site has good tissue ingrowth and there is no evidence of infection or trauma
   d. If present, remove sutures used to retain the driveline 2-3 weeks post-op, when the driveline has good circumferential tissue growth
4) Once the exit site dressing is removed, the driveline should be visually inspected for kinks, tears or other damage. If blood is seen within the lumen of the driveline, the implanting center should be notified immediately.

CAUTION: During exit site dressing changes, examine the driveline for evidence of tears, punctures or breakdown of any of the material.

5) Perform daily exit site care using an antiseptic cleansing agent, such as a diluted chlorhexidine scrub solution. Following aseptic cleansing, rinse and dry the site to avoid tissue injury. Aseptic technique should be followed anytime the dressing is removed and the exit site is exposed, inspected, dressed or handled. When performing exit site care, be sure to wear a cap, mask and sterile gloves.

CAUTION: Prophylactic topical antibiotic ointments such as silver sulfadiazine, povidone iodine, or neomycin bacitracin ointment should not be used. These ointments can injure the tissue adjacent to the exit site.

6) Immobilize the percutaneous lead with occlusive dressing and if necessary, a Hollister clip, Montgomery strap, or a custom-made percutaneous lead immobilization binder or belt. Keep the extra external length of the driveline under a binder or clothing.
7) Complicated, non-routine driveline dressing changes that involve exit site infections may require assistance/supervision from a health care professional.
8) For wounds/incisions other than the driveline exit site that require dressing changes and/or other care, the ability of the patient and caregiver to provide that care will be evaluated by the implanting center. Treatment plans will be dependent upon this evaluation.

16.6 Arrhythmias

The HVAD® Pump functions most effectively when adequate and stable amounts of preload are available. A stable supraventricular rhythm helps to optimize right heart performance and provide the HVAD® Pump with preload. Many heart failure patients will have permanent pacemakers and internal defibrillators in place by the time an LVAD is implanted. These devices are often needed in the early postoperative period.

16.7 Right Heart Failure

Right heart failure is common in patients receiving LVADs. Right heart failure usually develops within the first 24 hours after LVAD implant. Warning signs include increasing right atrial pressure (RAP) with concurrent decreases in the pulmonary capillary wedge pressure (PCWP) and LVAD flow. Systemic hypotension, tachycardia and a decrease in urine output soon follow. Volume should be given to increase the RAP to 15-18 mm Hg. This can be accomplished quickly and easily in the operating room while the patient is on cardiopulmonary bypass. Increasing the RAP to >20 mm Hg is usually ineffective. After optimizing intravascular volume, increasing inotropic drug support in conjunction with pulmonary vasodilators such as nitric oxide is usually effective. If volume and pharmacological therapy fail then a right ventricular assist device (RVAD) should be considered. Late right heart failure (weeks to months) post LVAD implant is unusual but would manifest itself with similar but less acute symptoms. The etiology of late right heart failure may be a progression of chronic heart disease such as coronary artery disease and/or right ventricular infarction. The cause of the right heart dysfunction should be identified and treated appropriately.

16.8 Blood Pressure Maintenance

The restoration of normal perfusion may lead to systemic hypertension in susceptible patients. Since the HVAD® Pump provides continuous flow, resulting in narrow arterial systolic/diastolic pulse pressures, it is best to monitor the mean arterial pressure (MAP). MAP should be monitored and maintained at <85 mm Hg. The blood pressure should be manually auscultated; however, it may be necessary to use a Doppler probe. If unable to manually auscultate a blood pressure or use a Doppler probe or if hypotension precludes either method, consider placing an arterial line.

16.9 Physical Rehabilitation

Physical Rehabilitation begins as soon as the patient admitted to the intensive care unit is stable. Early extubation, removal of monitoring lines, and patient ambulation are encouraged. Turning the patient from side to side should start once the patient is clinically stable. Physical therapy and active range of motion may begin on the first postoperative day. The patient may be moved to a chair and should use a bed bike, exercise bicycle or treadmill as soon as possible. Within a few days of LVAD implant, the patient should be ambulating in the halls and performing mild exercise under the supervision of a physical therapist. The nursing, physical therapy, and occupational therapy staff will work together to prepare the patient for hospital discharge - whether to home or a rehabilitation facility. If discharged to home, at the clinician's discretion, the patient may attend a structured outpatient cardiac rehabilitation program.

16.10 Patient Education

Patient training is critical to ensure safe and successful outcomes. The patient must be able to demonstrate proficiency in operating the HeartWare® System and in responding to emergencies. In order to ensure their understanding and ability, patients should be trained using hands-on demonstrations. At the end of the training, the patient should be able to do the following:

- Identify the AC adapter and successfully connect it to the controller and an electrical outlet
- Identify the power ports on the controller and be able to successfully replace batteries as indicated
- Successfully recharge batteries with the battery charger
- Monitor the remaining battery time on each battery using the LED light displays.
- Identify audible and text alarm messages on the controller

- Understand the meaning of alarms and demonstrate appropriate responses to alarm conditions
- Successfully switch from one controller to another controller
- Understand the importance of not pulling, twisting or kinking the driveline or power cables, especially while sitting, getting out of bed, adjusting controller or power sources, or when using the shower bag.
- Patients should be educated in the importance of having a backup controller readily available at all times including when changing power sources. Clinicians should emphasize this education in patients who may be at risk of catastrophic cardiovascular collapse if a pump shutdown occurrs. Patients at risk include those with a fused aortic valve, an aortic valve that has been sewn shut due to aortic valve regurgitation, or patients with very poor ventricular function.

Following hospital discharge, the patient's understanding of the HeartWare® System's operation and alarms should be re-evaluated during routine follow-up visits. This training should include reinforcement of the procedure for switching to a backup controller in the case of an emergency.

16.11 External Accessories

16.11.1 Patient Pack

The patient pack is used to safely secure, store and carry the controller and batteries. It can be used in or out of the hospital, when resting, sleeping or ambulating. One controller and two batteries fit into the patient pack.

16.11.2 HeartWare® Shower Bag

A shower bag is available for use in conjunction with the HeartWare® System. To ensure safe and appropriate use of the shower bag, all patients and caregivers should be trained on shower bag operation prior to use.

WARNING

- Patients may shower when they have received permission from their clinician to do so. Patients who shower must use the HeartWare® Shower Bag.
- The controller should be connected to two batteries during showers; it should never be plugged into an AC wall outlet.
- DO NOT kink or twist the driveline or the power cables.
- DO NOT allow water or other fluids to enter the controller, power adapters, batteries, battery charger or connectors. If this happens, contact HeartWare.
- DO NOT submerge HeartWare® System components in water or other fluid.
- DO NOT allow patients to take a bath or swim.
- Hearing-impaired patients should not shower unless their caregiver is close by to hear alarms.

16.12 Recommended Equipment for Use at Home

The minimum recommended amount of HeartWare-supplied equipment needed for use at home after discharge from the hospital is:

- 2 Controllers with AC power adapters
- 1 Battery charger with battery charger AC power adapter
- 4 Batteries
- 1 Patient Pack
- 1 Driveline cover
- 1 DC adapter
- 2 Alarm adapters
- 1 Shower bag

Whenever patients with the HVAD® Pump leave the hospital or their house on an excursion they must always have the following equipment with them:

- 2 Controllers
- 4 Charged batteries
- 1 Patient Pack
- 1 Shower bag
- 1 AC power adapter
- 1 Driveline cover
- Emergency contact information

NOTE: The monitor is not recommended for use at home.

WARNING

- Device recipients should avoid areas with high magnetic forces such as theft detection devices or airport security systems.
- Keep cell phones a minimum of 0.5 meters (20 inches) away from the controller.

16.13 Electrostatic Discharge (ESD)

Static electricity is widely present and more so in certain conditions such as in drier environments and in the vicinity of certain materials and fabrics such as silk clothing and carpeting. Discharge of static electricity, commonly referred to as electrostatic discharge (ESD), may interfere with electronic equipment. The HeartWare® Controller, as a piece of electronic equipment, is susceptible to ESD.

The controller may alarm in certain situations as a result of ESD. These alarms include a "Controller Failed" or a high priority audible alarm without accompanying alarm text on the controller screen. If either of these alarms occurs, the controller should be switched to the backup controller.

In the event of a "Controller Fault" alarm, it should be treated as directed in the IFU ("Medium Alarms, Controller Fault" section), since there are a number of potential causes for this alarm. In the case of a "Controller Fault" alarm and the alarm will not clear, a controller exchange should be performed.

Be aware of Electrostatic Discharge (ESD) and its potential to cause disruptive and possibly fatal faults in susceptible patients.

WARNING

- Avoid devices and conditions that may induce strong static discharges (e.g., television or computer monitor screens) as electrostatic discharges can damage the electrical parts of the system and cause the LVAD to perform improperly or stop.
- Always have a backup controller handy when changing power sources. Be watchful for unusual changes in power or flow alarms for a period of time following equipment changes.

In order to avoid or minimize the potential for ESD occurrence, follow good power/battery connection techniques as described in the IFU and patient manual. Do not touch the controller connector pins or let foreign objects or material come near a disconnected controller power port. Always utilize 2 power sources and do not leave the controller power port unconnected for extended periods when changing power sources.

When changing batteries, have the new battery within arm's reach before disconnecting the depleted battery.

Ensure that the driveline cover is in place and firmly positioned against the controller. Be careful around materials (e.g. carpeted floors, silk clothing, etc.) and electronic devices (TV screens, microwaves when in operation, and laptop or computer screens) prone to static electricity and avoid changing power sources in these areas. Avoid vacuuming and removing clothes from the dryer and always use anti-static dryer sheets and fabric softener and consider using a humidifier in the house.

In patients who may be at risk of catastrophic cardiovascular collapse associated with a pump shutdown (fused aortic valve, aortic valve that has been sewn shut due to aortic valve regurgitation, or patients with very poor endogenous ventricular function) ESD education is extremely important and controller exchanges should be performed in a controlled clinical setting whenever possible.

17.0 EQUIPMENT INSPECTION, CLEANING AND MAINTENANCE

17.1 General Care

The HeartWare® System is made of durable materials that will need occasional cleaning. The following steps should be used to clean the equipment:

1) Use a clean, soft cloth when cleaning the system.
2) Gently clean the equipment. Avoid hard rubbing.

WARNING

- Use only HeartWare-supplied components with the HeartWare® System.
- DO NOT disconnect the driveline or power sources from the controller while cleaning it, or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

CAUTION

- DO NOT kink or twist the driveline or power cables.
- All connectors should be handled with care and kept free of liquid, dust and dirt.
- Never clean the monitor or battery charger with the power on. DO NOT use alcohol or detergent on the monitor display. Gently wipe the display with a soft, lint-free cloth.
- Do not attempt to repair or service any components of the HeartWare® System. If HeartWare® System equipment malfunctions, contact HeartWare.
- DO NOT drop the controller or other equipment. Dropping the controller could cause sudden stoppage of the pump. Dropped equipment should be reported and inspected.

17.2 Controller

Once a week: Instruct the patient to inspect the controller power connections and connector pins for dirt. This inspection can be done while the patient is changing batteries or when changing from batteries to the AC adapter. Check the power connections on the controller one at a time. DO NOT disconnect both power sources to examine the connections. DO NOT disconnect the pump to examine the percutaneous lead/controller connection. This connector should be inspected only during a controller exchange. The patient should not attempt to clean the controller connectors, but should be instructed to contact their VAD coordinator if they notice the connectors are dirty.

17.3 Batteries

Once a week: Inspect batteries for physical damage, including the battery cable and connectors for damage. DO NOT use batteries that appear damaged. Damaged batteries must be replaced.

Periodically or as needed:

- If the battery lasts for less than 2 hours after being fully charged, it should be replaced
- Exterior surfaces of the batteries should be cleaned using a clean cloth. DO NOT use water or liquid soap to clean batteries. DO NOT place batteries in water or liquid.

17.4 Battery Charger

Once a week:

- Inspect the battery charger for signs of physical damage, such as dents, chips, or cracks. DO NOT use the charger if it shows signs of damage. Contact HeartWare for a replacement.
- Inspect the AC adapter and power cord. Make sure the cord is not kinked, split, cut, cracked, or frayed. Do not use the adapter if it shows signs of damage. Contact HeartWare for a replacement.

Periodically or as needed: Unplug the battery charger AC adapter from the wall outlet, remove the batteries, and clean the exterior surface of the charger using a clean, dry cloth. DO NOT place the charger in water or liquid.

17.5 HeartWare® Monitor

Once a month: If not in use, check to be sure the monitor is plugged into an AC outlet. This will keep the internal monitor battery charged. If the monitor battery fails to hold a charge, or lasts less than one hour, please contact HeartWare for a replacement. Also, check the monitor AC adapter and power cord for wear or damage and confirm they are working correctly. Turn off the monitor prior to cleaning. Clean the monitor screen with a soft, lint-free cloth. Use care to avoid scratching or damaging the screen.

17.6 Expected Useful Life of HeartWare® System Components

The HeartWare® System components were designed and tested to function without failing for the following periods:

- HVAD® Pump at least two years.
- The controller is expected to function for at least one year.
- The battery charger is expected to function for at least one year.
- The battery is expected to function through a minimum of 500 charge and discharge cycles; this will provide patient support for at least one year.

17.7 Product Disposal

Specific product disposal considerations for certain HeartWare-supplied equipment appears below. Otherwise, dispose of all expired or damaged equipment according to applicable local, regional, and federal laws and regulations. For additional product disposal support and information, contact HeartWare.

Batteries

HeartWare Li-Ion battery cells DO NOT contain lead. Dispose of/recycle HeartWare batteries in compliance with all applicable local, regional, and federal laws and regulations. DO NOT incinerate.

Monitor

The HeartWare® Monitor contains a lithium battery (replaceable). Dispose of/recycle the monitor's internal battery in compliance with all applicable local, regional, and federal laws and regulations. DO NOT incinerate discarded monitor batteries.

Medical Waste Disposal

The explanted HVAD® Pump and associated implantable components must be disposed of in compliance with all applicable local, state, and federal laws and regulations concerning medical waste.

APPENDIX A: QUICK REFERENCE GUIDE FOR ALARMS

Alarm Symbol	Alarm Tone	LCD Display Line 1	LCD Display Line 2	Potential Causes	Potential Actions
Alarm Type: High (Critical)					
None 	**Continuous loud** - unable to mute 	***(no message)***	***(no message)***	• No power to pump • Pump has stopped	• Connect two new power sources • Replace controller • Contact HeartWare Clinical Support
Flashing Red 	**Loud, Two-toned alarm**-unable to mute 	**VAD Stopped**	**Connect Driveline**	• Driveline disconnected • Driveline fracture • Connector malfunction/ breakage • VAD electrical failure	• Reconnect driveline • Contact HeartWare Clinical Support • Download/email patient log files
		VAD Stopped	**Change Controller**	• Controller failure • VAD failure • Thrombus or other materials (e.g., tissue fragments) in the device	• Exchange controller • Contact HeartWare Clinical Support • Download/email patient log files
		Controller Failed	**Change Controller**	• Controller component failed	• Exchange controller • Contact HeartWare Clinical Support
		Critical Battery 1	**Replace Battery 1**	• Limited battery 1 or battery 2 time remaining • Battery malfunction	• Replace critical battery with fully charged battery or the AC or DC adapter • Change controller if new power sources do not correct alarm
		Critical Battery 2	**Replace Battery 2**		

APPENDIX A: QUICK REFERENCE GUIDE FOR ALARMS - cont'd

Alarm Symbol	Alarm Tone	LCD Display Line 1	LCD Display Line 2	Potential Causes	Potential Actions
Alarm Type: Medium					
Flashing Yellow 	 • **Intermittent beep** – gradual increase in alarm volume over time if not muted • Able to mute alarm for 5 minutes or 1 hour • Electrical Fault (audio) and Controller Fault (audio) can be permanently disabled • **Press the scroll button on the controller to clear resolved medium alarm messages**	**Controller Fault**	**Call**	• Controller component malfunction but pump still working	• Confirm frequency and duration of alarm, concurrent alarms, and pump flow/speed/ power • Assess patient for complaints of shortness of breath, chest pain, palpitations, dizziness, etc. • Isolated alarm should be monitored with download at next visit
		Controller Fault	**Call: ALARMS OFF**	• Controller component malfunction • Suction Detection disabled • Low Flow alarm disabled • VAD Connect alarm may be disabled • High Power alarm may be disabled	• Multiple alarms within 24 hours without other issues should be assessed at non-emergent visit • Multiple alarms within 1 hour with other alarms or symptoms, replace controller and assess in emergent visit • Download/email patient log files from original (alarming) controller and new controller • Contact HeartWare Clinical Support
		High Watts	**Call**	• HVAD® Pump Watts have exceeded High Power alarm threshold • Alarm threshold set too close to average power • Thrombus or other materials (e.g., tissue fragments) in the device • High RPM • High flow • VAD electrical fault	• Confirm correct settings for High Power alarm and pump speed • Consider checking blood coagulation labs • Assess patient for hemolysis • Download/email patient logs files • Check for aortic insufficiency, thrombus, etc. • Contact HeartWare Clinical Support
Flashing Yellow 		**Electric Fault**	**Call**	• Fault in continuity of pump-to-controller electrical connections • Partial driveline fracture • Connector malfunction • Controller component failure • VAD malfunction	• Check driveline cover and ensure driveline connector is engaged • Inspect driveline for defects • Download/email patient log files • Contact HeartWare Clinical Support
		Low Flow	**Call**	• Average flow below Low Flow alarm threshold • Alarm threshold set too close to average flow • Suction • RPM too high or too low • Poor VAD filling (right ventricular failure, hypovolemia, tamponade, arrhythmias, inflow cannula obstruction, etc. • High blood pressure • Outflow graft kink	• Confirm VAD parameters • If possible, confirm correct settings for Low Flow alarm limit and viscosity • Confirm blood pressure (MAP < 85 mmHg) • Evaluate cause of poor left ventricle filling (include attaching patient to monitor to evaluate pump wave form) and consider volume resuscitation if indicated • If no potential patient cause can be identified– download/email patient log files • Consider ECHO • Contact HeartWare Clinical Support
		Suction	**Call**	• RPM too high • Poor VAD filling (right ventricular failure, hypovolemia, tamponade, arrhythmias, inflow cannula obstruction, etc.) • Thrombus or other materials (e.g., tissue fragments) in the device	• Confirm pump flow trends to evaluate a decrease in mean flow • Download/email patient log files • Consider volume resuscitation and/or correct cause of poor left ventricular filling • Consider decreasing pump speed • Contact HeartWare Clinical Support • Consider ECHO

APPENDIX A: QUICK REFERENCE GUIDE FOR ALARMS - cont'd

Alarm Symbol	Alarm Tone	LCD Display Line 1	LCD Display Line 2	Potential Causes	Potential Actions
Alarm Type: Low					
Solid Yellow △	• **Intermittent beep** - gradual increase in alarm volume over time if not muted • Able to mute alarm for 5 minutes	**Low Battery 1**	**Replace Battery 1**	• Battery power is low	• Replace low battery
		Low Battery 2	**Replace Battery 2**		
		Power Disconnect	**Reconnect Power 1**	• Power source is disconnected or malfunctioning	• Reconnect power source • Replace power source • Replace controller
		Power Disconnect	**Reconnect Power 2**		

APPENDIX B: SYSTEM COMPONENTS

Pump
1 HVAD® Pump: Supplied Sterile – ETO
Outflow Graft
1 10mm gel impregnated polyester graft: Supplied Sterile – ETO
Surgical Tools and Accessories
(Supplied ETO sterilized)
1 Tunneler Rod and Handle
1 Sewing Ring Torque Wrench
1 Coring Tool
1 Driveline Extension Cable
1 Driveline Cap
1 Hex Driver
1 Strain Relief
1 Sewing Ring
1 Inflow Cap
Driveline Cover
Instructions for Use

All Externals are Supplied Non-Sterile

Controller
1 Controller
1 Controller AC Adapter / Power Cord
1 Alarm Adapter
Controller AC Adapter
Controller DC Adapter
Patient Pack (carrying case)
Shower Bag

Monitor
1 Monitor
1 Monitor AC Adapter / Power Cord
1 Data Cable
1 Display Case
Monitor AC Adapter
Battery Charger
1 Battery Charger
1 Battery Charger AC Adapter / Power Cord
Battery Charger AC Adapter
Battery
USB Flash Drive
Data Cable
Explant Kit

APPENDIX C: PRODUCT SPECIFICATIONS

Physical Pump
Mass (or weight) 160 g
Volume 50 cc
Materials Titanium, Titanium Nitride, PEEK® and ceramic

Outflow Graft Gel impregnated polyester graft
Length 60 cm
Diameter (or size) 10 mm
Materials Gelatin sealed polyester

Strain Relief
Material PEEK®, titanium

Driveline
Length 119 cm
Diameter 4.8 mm
Materials ETFE (Ethylene tetrafluoroethylene) PTFE-coated MP35N DFT wire in a silicone inner sleeve with a polyurethane outer sleeve along with a polyester sleeve

Sewing Ring
Materials Titanium, polyester

Controller
Weight 0.5 kg
Dimensions 13.4 x 10.5 x 5.1 cm
Material Plastic (ABS)

Battery
Type Li Ion, rechargeable
Weight 0.5 kg
Dimensions 9.9 x 8.9 x 4.6 cm
Indicators Battery level LEDs
Ratings 14.8V, 51.8Wh or 14.4V, 63.4Wh see battery label

Battery Charger
Capacity 4 batteries
Recharge Time 5 hours, fully depleted
Weight 1.3 kg
Dimensions 28.6 x 13.4 x 10.2 cm
Electrical Ratings 19 VDC, 4 A input; 16.8 VDC, 4 A output

Battery Charger AC Adapter
Weight 0.7 kg
Dimensions 12.1 x 7.5 x 5.1 cm
Electrical Ratings 100-240 V, 50-60 Hz, 190 VA input; 19 V, 4.2 A output

Controller AC Adapter
Weight 0.7 kg
Dimensions 12.1 x 7.5 x 5.1 cm
Electrical Ratings 100-240 V, 50-60 Hz, 140 VA input; 15 V, 3.3 A output

Controller DC Adapter
Weight 0.7 kg
Dimensions 12.1 x 7.5 x 5.1 cm
Electrical Ratings 12-15.6 VDC, 7 A Input; 15 V, 2 A output

Monitor	**REF1511 (no longer being placed on the market)**	**REF1521**
Operating System	QNX	QNX
Weight	2.5 kg	3.0 kg
Dimensions	29.9 x 23.5 x 4.5 cm	28.5 x 21.0 x 4.1 cm (without case) 29.9 x 29.9 x 6.4 cm (with case)
Electrical Ratings	19 V, 3 A maximum input	19 V, 3.4 A maximum input

Monitor AC Adapter
Weight 0.7 kg
Dimensions 16.6 x 9.6 x 5.6 cm
Electrical Ratings 100-240 V, 50-60 Hz, 215 VA input; 19 V, 4.7 A output

Software Parameters, Ranges & Factory Default Settings			
Parameter	**Range**	**Resolution**	**Factory Default**
Pump Speed	1,800 to 4,000 RPM	20 RPM	2,500 RPM
Low Flow Alarm	1.0 to 9.9 L/min	0.1 L/min	1.0 L/min
High Power Alarm Limit	1.0 to 25 Watts	0.5 Watts	16.0 Watts
Suction Detection	OFF, Alarm	N/A	Off
Hematocrit	20-50%	1%	30%

Notes: All dimensions are given as length x width x height.
PEEK is a registered trademark of Victrex plc.

IEC 60601-1 Classifications:
Type of protection against electric shock:
- Controller AC adapter – Class II
- Controller DC adapter – Class II
- Controller – Class II, Internally Powered
- Battery charger AC adapter – Class II
- Monitor AC adapter – Class I

Degree of protection against electric shock:
- Type CF Defibrillation-Proof Applied Parts

Degree of protection against the ingress of water:
- IP27 (controller, battery pack)
- IP65 (driveline extension cable)
- IP22 (controller AC adapter, controller DC adapter, monitor AC adapter, data cable)
- IP21 (battery charger, battery charger AC adapter, monitor)

CAUTION: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Recommended environmental conditions for general use:
Temperature range/humidity for:
- Monitor REF1511 (no longer being placed on the market): 0°C to +50°C, 0% to 95% humidity
- Monitor AC Adapter: 0°C to +40°C, 15% to 95% humidity
- Driveline Extension Cable: 0°C to +40°C, 10% to 90% humidity
- Battery Charger and Charger AC adapter: +10°C to +40°C, 15% to 95% humidity
- All other components (including monitor REF1521): +5°C to +40°C (+41°F to +104°F). Relative humidity range within 15% to 95% (non-condensing).
- Atmospheric pressure range within 700 to 1060 hPa (20.70 to 31.30 in Hg). Altitude less than 3,000 Meters.

Environmental conditions for transport and storage:
- Temperature range within -40°C to 70°C (-40°F to 158°F) for monitor, data cable, battery charger, driveline extension cable, and power adapters.
- Temperature range within -20°C to 50°C (-4°F to 122°F) for controller, battery (transport only).
- Temperature range within -20°C to 25°C (-4°F to 77°F) for battery (storage only).
- Driveline Extension Cable, Monitor and Monitor AC adapter: Relative humidity range within 10% to 90%. All other components: Relative humidity range within 10% to 93%.
- Atmospheric pressure range within 500 to 1060 hPa (14.76 to 31.30 in Hg).

The box label details conditions for transport and storage.

APPENDIX D: EMC MANUAL REQUIREMENTS GUIDANCE DOCUMENT

Electromagnetic Compatibility

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this user manual.

Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The HVAD® Pump is intended for use in the electromagnetic environments specified below. The customer or the user of the HVAD® Pump should assure it is used in such an environment.		
Emissions Test	**Compliance**	**Guidance**
RF Emissions CISPR 11	Group 1	The HVAD® Pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The HVAD® Pump is 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	Complies	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	
Radiated Emissions Avionics RTCA/DO-160G Section 21	Category M	The HeartWare® System with 2 battery packs or one battery pack and controller AC adapter is compliant with all related FAA safety requirements and will not interfere with aviation electronics, per Section 21, Category M of the RTCA document number RTCA/D0-160G, as specified in "Use of Portable Electronic Devices Aboard Aircraft" AC number 91.21-1B, Section 8A.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The HVAD® Pump is intended for use in the electromagnetic environments specified below. The customer or the user of the HVAD® Pump should assure it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Guidance**
Electrostatic Discharge IEC 61000- 4-2	◗ ± 6 kV Contact ◗ ± 8 kV Air	◗ ± 6 kV Contact ◗ ± 8 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
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 to line ◗ ± 2 kV Line to earth	◗ ± 1 kV Line to line ◗ ± 2 kV Line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interrupts, & Variations on power Supply Lines IEC 61000-4-11	◗ < 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 s)	◗ < 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 s)	Mains power quality should be that of a typical commercial or hospital environment. The HVAD® Pump will always have a battery backup power supply connected.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Guidance**
Power Frequency Magnetic Fields IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms (150 kHz to 80 MHz outside ISM bands[a]) 10 Vrms (150 kHz to 80 MHz inside ISM bands[a]) 10 Vrms (80 MHz to 2.5 GHz	3 Vrms 10 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the HVAD® Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2√P (outside ISM bands) d=1.2√P (within ISM bands) d=1.2√P (80 MHz to 800 MHz) d=2.3√P (800 MHz to 2.5 GHz) 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 may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 – At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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; 26.957 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.

c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HVAD® Pump is used exceeds the applicable RF compliance level above, the HVAD® Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HVAD® Pump.

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

Recommended separation distances between portable and mobile RF communications equipment and the HVAD® Pump

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands d=1.2√P	150 kHz to 80 MHz within ISM bands d=1.2√P	80 MHz to 800 MHz d=1.2√P	800 MHz to 2.5 GHz d=2.3√P
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

NOTE 1 – At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 – 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.

NOTE 3 – An additional factor of 10/3 is 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/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

APPENDIX E: SYMBOL DEFINITIONS

	Caution
	Consult Accompanying Documents
LOT	Batch code
REF	Catalog number
SN	Serial number
	Class II equipment
IPX1	Protected against vertically falling water drops
IPX2	Protected against dripping water
IPX5	Protected against water jets
IPX7	Protected against the effects of water immersion
IP2X	Protected against ingress of foreign objects with diameter 12.5 mm and bigger
	Temperature range
	Humidity range
106 kPa 50	Atmospheric pressure range

	Diameter
LATEX	Latex free
	Date of manufacture
	Manufacturer
STERILE EO	Sterilized with ethylene oxide gas
NON STERILE	Non sterile
	Single use only, do not reuse
	Do not use if damaged
	Properly dispose battery
	Use by YYYY-MM-DD or YYYY-MM
	Direct current power connection
	Monitor connection
	Pump connection

	Input power required
	Output power delivered
CE	CE Mark
EC REP	Authorized representative in the European Community
	Usable length
MH47972	The UL mark, product safety certification
4ICP11/34/50-2	41 CP11/34/SD-2 pin settings
	Defibrillation proof type CF applied part
CLASSIFIED c UL us 3MPM	UL Classification Mark. General medical equipment as to electrical shock, fire and mechanical hazards only in accordance with UL60601-1, CAN/CSA C22.2 no. 601.1, ANSI/AAMI ES60601-1 (2005, 3rd ed.), and CAN/CSA-C22.2 no. 60601-1 (2008). Note: UL Classification does not include evaluation of the implantable pump.
	Non-Pyrogenic
Segurança INMETRO	The INMETRO mark, product safety certification

24-Hour Clinical Support
Austria: 0800-296-574
Denmark: 808-865-69
France: 0800-91-6817
Germany: 0800-181-8743
Israel: 180-931-5751
Italy: 800-875-063
Norway: 800-16825
Poland: 00800-141-0046
Sweden: 020-790855
Switzerland: 0800-838-762
United Kingdom: 0808-234-9223

Commercial Operations Support
Europe: +31 13 547 9323
Email: cseurope@heartware.com
Australia: (02) 8078 6164

Web Site
heartware.com

HeartWare, Inc.
14400 NW 60th Avenue
Miami Lakes, FL 33014 USA
(305) 364-2500

HeartWare Pty Limited
68 Pitt Street
Level 10
Sydney NSW 2000
Australia

EC REP
MedPass International Limited
Windsor House, Bretforton,
Evesham, Worcs. WR11 7JJ
United Kingdom

HeartWare®

CE 0086
AUTHORIZED 2009

IFU00308 Rev 01 09/14 EN