Medtronic HVAD PAL™ System

Patient Manual

Medtronic

Quick Reference Guide for Alarms

When an alarm occurs, text displays on the controller screen. The text tells you what the alarm is and what to do. The chart below shows all potential alarms you may see on your controller.

Alarm Type: Critical			
Alarm Signal	**Controller Message**	**What it means**	**What action to take**
Flashing RED back light  **Flashing alert symbol** **Loud audio signal and vibration** **Unable to mute alarm**	**[Change Controller]** 	• Controller failure. • Controller component failed. • Pump failure. • Pump unable to start in 5 attempts.	• Change the controller immediately. • Contact your clinician.
	[Connect Pump Cable] 	• Pump cable (driveline) disconnection. • Pump cable (driveline) fracture. • Connector is malfunctioning or broken. • Pump electrical failure.	• Connect the pump cable (driveline) to the controller Coiled Cable. • If not resolved, change the controller. • Contact your clinician.
	[Plug in Power Cord] 	• Disconnecting external battery without a power cord connected could risk pump stop. • The internal battery has limited time remaining, is unreliable, disconnected or has failed AND • The external battery has less than 15 minutes runtime remaining or is unreliable.	• Connect the power cord to the controller. • DO NOT disconnect the external battery before connecting the power cord. • Contact your clinician.
	[Connect Power] 	• The internal battery has limited time remaining or is unreliable.	• Change the external battery or connect the power cord. • Contact your clinician.

Quick Reference Guide for Alarms (continued)

Alarm Type: Noncritical			
Screen Display Color	**Controller Message**	**What it means**	**What action to take**
Solid YELLOW back light  **Flashing alert symbol** **Periodic beep with escalating volume and vibration** **Able to mute alarm**	**[Plug In Power Cord]** 	• Disconnecting external battery without a power cord connected could risk pump stop • The internal battery has limited time remaining, is unreliable, disconnected or has failed AND • The external battery has less than 30 minutes runtime remaining or is unreliable AND	• Connect the power cord to the controller. • DO NOT disconnect the external battery before connecting the AC or DC power adapter. • Contact your clinician. Mute option: Two 5-minute mutes, then cannot be muted
	[Keep Power Connected] 	• Disconnecting external power could risk pump stop. • The internal battery has limited time remaining, is unreliable, or has failed.	• DO NOT disconnect the external power. • If the external battery needs to be changed, connect the power cord first. • If the alarm has not resolved in one (1) hour, contact your clinician. Mute option: 5 minutes
	[Electrical] 	• A fault in the normal operation of the pump-to-controller electrical connection.	• DO NOT change the controller • Check the pump cable and the connections for obvious damage. • Contact your clinician. Mute option: 15 minutes
	[Technical] 	• Controller component or power source malfunction.	• Contact your clinician. Mute option: 15 minutes
	[High Power] 	• The pump power exceeds the alarm threshold setting.	• Contact your clinician. Mute option: 15 minutes
	[Low Flow] 	• The pump flow exceeds the alarm threshold setting.	• Contact your clinician. Mute option: 15 minutes

Quick Reference Guide for Alarms (continued)

Alarm Type: Noncritical			
Screen Display Color	**Controller Message**	**What it means**	**What action to take**
Solid YELLOW back light ⚠ **Flashing alert symbol** **Periodic beep with escalating volume and vibration** **Able to mute alarm**	**[Suction]** Suction 1-555-555-7777	• A potential obstruction to pump flow has been detected	• Contact your clinician. Mute option: 15 minutes
	[Connect Power] Connect Power	• No external power source is connected (for at least twenty (20) seconds).	• Connect the power cord or a charged external battery Mute option: Two 5-minute mutes, then cannot be muted
	[Temperature] Temperature 1-555-555-7777	• The controller's temperature is out of recommended range.	• Move the controller to a room temperature environment and wait for the controller to return to normal temperature. • If the alarm persists for one (1) hour, contact your clinician. Mute option: 15 minutes
	[Change Battery] Change Battery	• The external battery has fifteen (15) minutes or less time remaining.	• Change the external battery OR • Connect the AC or DC power adapter to the controller. Mute option: 15 minutes.
	[Connect Cap or Battery] Connect Cap or Battery	A PAL Cap or external battery is not connected to the controller.	• Attach the PAL Cap or an external battery to the controller to protect it from dust, dirt, fluids, or electrical interference. Mute option: 15 minutes

Contact Information

All problems should be promptly reported to your clinician. Before you leave the hospital, add names and contact information below. It is very important to keep this information available in case something happens to you or to your Medtronic HVAD PAL™ System.

CLINICIAN CONTACT

Name	Name
Office	Office
Pager	Pager
Mobile	Mobile

IMPLANTING HOSPITAL

Name
Address
Implanting Surgeon Name
Phone Number

AMBULANCE

Company	Phone Number

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1.0 Introduction

1.1 Why You Should Read this Manual

This manual is intended for patients and caregivers. It will tell you about your HVAD System and explain how it works. It also provides information about proper care of the HVAD System and what to do in case of an emergency.

Additionally, your clinician will provide you with instructions on operating the HVAD System and on necessary medical care prior to leaving the hospital. You will understand how the HVAD System works, how to care for the equipment and what to do in emergency situations. If you have any questions after reading this manual, ask your clinician.

Symbols found in this manual

			
Indicates there is more information available in the manual and will provide details as to where to find it.	Identifies the information as a Warning. A Warning is a statement about the possibility of injury, death or other serious adverse reaction associated with the use or misuse of the device.	Identifies the information as a Caution. A Caution is a statement or instruction designed to prevent device misuse, malfunction or damage.	Indicates there is an additional quick reference guide available from your clinician.

WARNING! Carefully read this entire manual before using the HeartWare™ HVAD™ System outside of the hospital. It is not safe to use the system away from trained professionals until you understand the information in this manual.

1.2 Potential Benefits

The HVAD System was designed to assist a failing heart. The potential benefit of having the HVAD System is the relief of the symptoms of advanced heart failure while you are waiting for a heart transplant. As a result of the relief of symptoms of heart failure you will feel stronger and have the ability to be more active. However, there is no guarantee of this and your symptoms may remain unchanged.

1.3 Potential Complications and Risks

A list of possible complications is included below. Talk to your clinician to understand your risks associated with both the implant surgery and using the HVAD System.

Table 1: Complications that may occur with the HVAD System

Complications	
Bleeding	Irregular heart beat
Blood clots	Kidney problems
Damage to the blood cells	Liver problems
Death	Lung problems
Failure of the right side of the heart	Pain
High blood pressure	Re-operation
HVAD System malfunction or failure	Stroke
Infection	

WARNING! Serious and life threatening adverse events, especially stroke, have been associated with use of this device. The risk of death as a result of stroke has been observed in randomized clinical trials to be higher with the HVAD than with alternative treatment options. The overall rate of stroke was shown in randomized clinical trials to be higher with the HVAD than with alternative treatment options; however, one of the trials suggested that closely following a blood pressure treatment plan as recommended by your physician may reduce your stroke risk. You must fully consider and discuss with your physician the risks of this device with that of other treatment modalities before deciding to proceed with device implantation.

1.4 Warnings and Cautions

This section explains safety-related information related to the proper handling of the HVAD System. Read this section carefully.

WARNINGS

A Warning is a statement about the possibility of injury, death or other serious adverse reaction associated with the use or misuse of the device.

1. **WARNING!** Serious and life threatening adverse events, especially stroke, have been associated with use of this device. The risk of death as a result of stroke has been observed in randomized clinical trials to be higher with the HVAD than with alternative treatment options. The overall rate of stroke was shown in randomized clinical trials to be higher with the HVAD than with alternative treatment options; however, one of the trials suggested that closely following a blood pressure treatment plan as recommended by your physician may reduce your stroke risk. You must fully consider and discuss with your physician the risks of this device with that of other treatment modalities before deciding to proceed with device implantation.
2. **WARNING!** Carefully read this entire manual before using the HeartWare™ HVAD™ System outside of the hospital. It is not safe to use the system away from trained professionals until you understand the information in this manual.
3. **WARNING!** DO NOT use any components other than those supplied by Medtronic with the HVAD System, as this may affect the HVAD System operation.
4. **WARNING!** ALWAYS connect an AC adapter to the controller before relaxing or sleeping. Power from an electrical outlet (AC adapter) provides power for an unlimited period of time.
5. **WARNING!** ALWAYS have an external power source connected to the primary controller to avoid unintentional pump stoppage, except when changing a power source. The internal battery is a backup power source and should only be relied on while changing external power sources.
6. **WARNING!** DO NOT attempt to repair, service, or modify any component of the HVAD System as this may damage the component. If the equipment malfunctions, contact your clinician.
7. **WARNING!** DO NOT take a bath or swim, as this may damage the system components and/or result in pump cable (driveline) exit site infection.
8. **WARNING!** DO NOT submerge any HVAD System component in water, as this may damage the component. If this happens, contact your clinician.
9. **WARNING!** DO NOT plug the controller into an AC electrical outlet during showers; to eliminate the possibility of a severe electrical shock, the controller should only be connected to an external battery.
10. **WARNING!** DO NOT allow water or other fluids to enter the controller, power cords, batteries, battery charger or connectors, as this may damage the HVAD System components. If equipment is damaged, contact your clinician.

1.4 Warnings and Cautions (continued)

WARNINGS (continued)

11. **WARNING!** If your hearing is impaired and/or you cannot hear the controller alarms without the use of a hearing aid, make sure your caregiver will be close by to hear alarms.
12. **WARNING!** DO NOT shower until your clinician tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare™ Shower Bag.
13. **WARNING!** DO NOT use damaged equipment as it could lead to patient harm. If equipment is damaged, contact your clinician.
14. **WARNING!** DO NOT disconnect the pump cable (driveline) from the controller or the pump will stop. If this happens, reconnect the pump cable to the controller IMMEDIATELY to restart the pump.
15. **WARNING!** ALWAYS check for a click when connecting the pump cable (driveline) to the controller. Failure to ensure a secure connection may lead to a pump stop.
16. **WARNING!** ALWAYS have a backup controller and fully-charged spare external batteries available at all times in case of an emergency.
17. **WARNING!** ALWAYS keep the backup controller and spare external batteries available and in a dry environment where the temperature is between -5°C and +40°C (+23°F to +104°F).
18. **WARNING!** NEVER disconnect the pump cable (driveline) from the controller when loading equipment into the PAL™ Sport Pack as this will lead to a pump stop and potential harm. Bag loading does not require pump cable (driveline) disconnection.
19. **WARNING!** ALWAYS check the controller display for information regarding an alarm when using loud machinery, or near loud noises, as the alarms may not be audible.
20. **WARNING!** IMMEDIATELY replace a controller that has a blank display and/or no audible alarms. It could indicate a controller failure.
21. **WARNING!** ALWAYS switch to the backup controller if there is a [Change Controller] alarm since the pump may not be running. Call your clinician.
22. **WARNING!** ALWAYS investigate, and if possible, correct the cause of any alarm. Muting a non-critical alarm does not resolve the alarm condition and may lead to suboptimal therapy.
23. **WARNING!** DO NOT become pregnant while you have the HVAD System. If you are a woman of childbearing age, use birth control if you are sexually active. Blood thinners (which most VAD patients receive) have been associated with birth defects. If you do become pregnant, tell your clinician immediately.
24. **WARNING!** DO NOT undergo a magnetic resonance imaging (MRI) procedure while implanted with the HVAD System. Doing so could harm you or cause the pump to stop.
25. **WARNING!** DO NOT undergo procedures requiring high power electrical treatment while the pump is implanted. High power electrical treatments are typically prescribed for joint conditions such as rheumatoid arthritis and osteoarthritis and use high frequency electrical current to produce deep heat inside the body intended to decrease inflammation and pain. Consult your clinician before having any deep tissue heating procedure.

1.4 Warnings and Cautions (continued)

WARNINGS (continued)

26. **WARNING!** AVOID exposure to therapeutic levels of ultrasound energy. Consult your clinician before having lithotripsy procedures to treat kidney stones or any treatments involving high intensity ultrasound. The implanted device may inadvertently concentrate the ultrasound field and cause harm.
27. **WARNING!** AVOID therapeutic ionizing radiation. Consult your clinician before having any nuclear medicine procedures or radiation therapy for cancer. Radiation may damage the device and may not be immediately detectable.
28. **WARNING!** AVOID devices and conditions that may induce strong static discharges (e.g., close vicinity to television or computer monitor screens) as electrostatic discharges can damage the electrical parts of the system and cause the pump to perform improperly or stop.
29. **WARNING!** The HeartWare HVAD System components should not be used adjacent to or stacked with equipment other specified in the Patient Manual. If adjacent to or stacked use is necessary, the HeartWare HVAD System and other equipment should be observed to verify normal operation.
30. **WARNING!** ALWAYS have a backup controller and fully-charged batteries available and, whenever possible, a caregiver nearby when changing power sources or controllers in case unusual alarms occur.
31. **WARNING!** DO NOT operate the controller in temperatures less than -5°C (+23°F) or greater than +40°C (+104°F) or the controller may fail.
32. **WARNING!** AVOID areas with high magnetic forces such as theft detection devices or airport security systems, as these may affect the HVAD System operation.
33. **WARNING!** DO NOT drop the controller or other equipment. Dropping the controller may cause sudden stoppage of the pump. Dropped equipment should be reported to your clinician.
34. **WARNING!** DO NOT disconnect the pump cable (driveline) from the controller while cleaning it or the pump will stop. If this happens, reconnect the pump cable (driveline) to the controller IMMEDIATELY to restart the pump.
35. **WARNING!** NEVER clean the battery charger when it is connected to an electrical outlet, as this may lead to an electrical shock.
36. **WARNING!** The HVAD Pump may cause interference with AICDs. If electromagnetic interference occurs, it may lead to inappropriate shocks, arrhythmia and possibly death. Contact your clinician if you suspect that your AICD is not properly functioning due to electromagnetic interference from the HVAD Pump.

1.4 Warnings and Cautions (continued)

CAUTIONS

A Caution is a statement that not following the instruction in the statement may lead to device misuse, malfunction or damage.

1. **CAUTION:** DO NOT reuse or share PAL Controllers on multiple patients to avoid risks associated with an inadvertent mismatch of controller pump speed settings.
2. **CAUTION:** Tell your clinician if you have sight or hearing problems. The controller uses words, lights and sounds to tell you how the system is operating and when to seek additional help.
3. **CAUTION:** ALWAYS keep the primary controller that is connected to a pump in a carrying case except when changing external batteries. Failure to keep equipment in a carrying case may lead to damage of the controller and external peripherals.
4. **CAUTION:** DO NOT pull, kink, or twist the pump cable (driveline) or the power cables, as these actions may damage the cables. Special care should be taken not to twist the pump cable (driveline) while sitting, getting out of bed, adjusting the controller or the power sources, or when using the HeartWare™ Shower Bag.
5. **CAUTION:** ALWAYS keep all connectors free of liquid, dust and dirt, or the HVAD System may not function as intended.
6. **CAUTION**: AVOID changing power sources in or near water (e.g., shower, rain, ocean, etc.), as this may damage the controller. If equipment is damaged, contact your clinician.
7. **CAUTION:** DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.
8. **CAUTION:** ALWAYS have an external battery or cap connected to the battery connector even while using an AC or DC adapter with the controller. An uncovered battery connector can lead to electrostatic discharge (ESD) events.
9. **CAUTION:** ALWAYS recharge depleted batteries within 24 hours to avoid permanent battery damage.
10. **CAUTION:** AVOID changing the external battery in a wet, dirty, or dusty location as this may damage your controller. If equipment is damaged, contact your clinician.
11. **CAUTION:** ALWAYS verify that the battery symbol is present on the PAL™ Controller screen to confirm that the external battery is properly locked on to the controller in order to maintain optimal therapy.
12. **CAUTION:** DO NOT attempt to charge the controller using the USB data port. The USB data port should be used only for data transfer and will not provide power to the controller.
13. **CAUTION:** AVOID placing the controller in the following conditions to prevent harm from excessive heat:
    - Between the legs when sleeping or sitting.
    - Under the body while sleeping or sitting.
    - Under covers in a warm room.
    - In a heated room (e.g., sauna, steam room, hot yoga class, etc.).
    - Under a thick or thermal (hypothermia) blanket.
    - Under a heat lamp.
    - In direct sunlight.

1.4 Warnings and Cautions (continued)

CAUTIONS (continued)

14. **CAUTION:** ONLY use the PAL™ Controller or PAL™ Battery Charger to charge PAL™ Batteries. Other battery chargers will not charge the external batteries and may lead to damage.
15. **CAUTION:** Use caution when moving equipment around in the carrying case to avoid tugging on the pump cable (driveline) exit site.
16. **CAUTION:** Mobile phones should only be placed in the phone pocket of the PAL™ Sport Pack. Placing a mobile phone too close to the controller may compromise normal operating conditions of the controller.
17. **CAUTION:** ALWAYS place the pump cable (driveline) connector inside the HeartWare™ Shower Bag when showering. Exposing the pump cable (driveline) connector to water may lead to electrical faults, unrepairable damage to equipment and disruption of therapy.
18. **CAUTION:** DO NOT play contact sports. You may start bleeding or could damage your equipment.
19. **CAUTION:** DO NOT expose the pump cable (driveline) to direct or indirect sunlight. ALWAYS keep the pump cable (driveline) completely covered when in the sun. DO NOT use tanning lights or black lights. The light from these sources may damage the outer covering of the pump cable (driveline).
20. **CAUTION:** ALWAYS keep extra pump cable (driveline) length placed under clothing or secured with an abdominal binder or dressing. Do not let any portion of pump cable (driveline) hang freely where it might get caught on external items such as doorknobs or the corners of furniture.
21. **CAUTION:** ALWAYS notify your clinician promptly if there is drainage, swelling or reddened skin around the pump cable (driveline) exit site. These may indicate an infection.
22. **CAUTION:** DO NOT use prophylactic topical antibiotic ointments such as silver sulfadiazine, povidone iodine (betadine), or polymyxin-neomycin-bacitracin ointment on your exit site. These ointments can injure the tissue next to your pump cable (driveline).
23. **CAUTION:** ALWAYS examine the pump cable (driveline) for evidence of tears, punctures or breakdown of any of the material during exit site dressing changes. Report any damage to your clinician.
24. **CAUTION:** ALWAYS notify your clinician promptly, if you notice blood or fluid in the pump cable (driveline). The section of the driveline inside your body may have been damaged during pump implantation or during another operation. The pump cable (driveline) has built-in features that minimize the effect of blood or fluid entering it, so the HVAD Pump should continue to operate normally. However, your clinician should examine the pump cable (driveline) to fully evaluate the situation.
25. **CAUTION:** DO NOT place batteries in water or any other liquid as this may damage them.
26. **CAUTION:** ALWAYS check to be sure the DC adapter works in your motor vehicle. The DC adapter is for use in motor vehicles only and may not fit all motor vehicles.

1.4 Warnings and Cautions (continued)

CAUTIONS (continued)

27. **CAUTION:** DO NOT expose external batteries to temperatures less than -5°C (+23°F) or greater than +40°C (+104°F) or the battery may run the pump for less time than usual. To preserve battery life, batteries should be stored at room temperature.
28. **CAUTION:** ALWAYS keep HVAD System components away from children and pets. Children and pets may cause damage to or be harmed by damaged components. If damage to equipment results, contact your clinician.
29. **CAUTION:** DO NOT disassemble, crush, or puncture a battery to avoid personal injury and battery damage.
30. **CAUTION:** DO NOT use damaged batteries as it may lead to interrupting VAD therapy. Dispose of batteries according to federal, regional, and local regulations.
31. **CAUTION:** DO NOT short circuit the external contacts on a battery as this may result in battery damage.
32. **CAUTION:** DO NOT touch the fluid if a battery pack is leaking 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 fifteen (15) minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention. Dispose of batteries according to federal, regional, and local regulations.
33. **CAUTION:** DO NOT expose external batteries to excessive shock or vibration as this may affect battery operation.
34. **CAUTION:** DO NOT dispose of batteries in fire or water. Dispose of batteries according to federal, state, and local regulations.
35. **CAUTION:** DO NOT use a machine for drying the carrying cases as it may accelerate the end of useful service. The carrying case should only be air dried.
36. **CAUTION:** Use only Medtronic-supplied power adapters with the HVAD System.
37. **CAUTION:** The driveline connector is made of nickel-coated brass which may cause a rash in patients with a nickel allergy.

Notes

2.0 HeartWare™ HVAD™ System Overview

WARNING! DO NOT use any components other than those supplied by Medtronic with the HVAD System, as this may affect the HVAD System operation.

2.1 Identifying the Components of the HeartWare™ HVAD™ System

The HeartWare™ HVAD™ System is made up of the following components:

- HeartWare™ HVAD™ Pump and Pump Cable (Driveline)
- PAL™ Controller
- PAL™ Controller Power Sources (AC adapter, DC adapter, PAL™ Batteries)
- PAL™ Battery Charger
- Carrying Cases and HeartWare™ Shower Bag

2.2 HeartWare™ HVAD™ Pump and Pump Cable

The HVAD Pump (**Figure 1**) is small and has one moving part, called an impeller **(Figure 2)**. As the impeller spins it moves blood from the heart to the body. The amount of blood flowing through your pump depends on the speed of the impeller and on your blood pressure. The pump cable (driveline) passes through your skin and connects the pump to the controller.

Figure 1: HVAD Pump

Figure 2: Impeller

2.3 PAL™ Controller

The PAL™ Controller **(Figure 3)** is a microprocessor unit that controls and manages the HVAD System operation. It sends power and operating signals to the pump. It also collects information from the pump and provides you with audible, visual, and vibratory alerts, system status information, and instructions.

Figure 3: PAL™ Controller

2.3 PAL™ Controller (continued)

For additional information on how the controller works, see Section *3.1.1.*

CAUTION: Tell your clinician if you have sight or hearing problems. The controller uses words, lights and sounds to tell you how the system is operating and when to seek additional help.

CAUTION: DO NOT reuse or share PAL Controllers on multiple patients to avoid risks associated with an inadvertent mismatch of controller pump speed settings.

2.4 Controller External Power Sources

There are four external power sources for the PAL™ Controller. The controller requires that at least one external power source be connected with a running internal battery for safe operation. The external power source can be either one Single Battery, one Dual Battery, an AC adapter or a DC adapter (**Figure 4**). When you are active, you will typically use battery power - either the Single or the Dual battery. While relaxing or sleeping, you should use power from an electrical outlet (AC adapter). You may also use the AC adapter or DC adapter to charge the external batteries through the controller.

WARNING! ALWAYS connect an AC adapter to the controller before relaxing or sleeping. Power from an electrical outlet (AC adapter) provides power for an unlimited period of time.

Figure 4: PAL™ Controller Power Sources

Single battery

Dual battery

AC adapter

DC adapter

2.4 Controller External Power Sources (continued)

The PAL™ Controller has four power configurations to operate under normal use conditions.

Table 2: Power Configurations

Configuration	Image
1. Controller with External Battery (Single)	
2. Controller with External Battery (Dual)	
3. Controller with Power Cord and Cap	
4. Controller with Power Cord and Battery	

WARNING! ALWAYS have an external power source connected to the primary controller to avoid unintentional pump stoppage, except when changing a power source. The internal battery is a backup power source and should only be relied on while changing external power sources.

For additional information on using an AC or DC adapter, see Section *3.3.3*.

For additional information on using the Batteries, see Section *3.3.4*.

2.5 Battery Charger

Figure 5: PAL™ Battery Charger

The PAL™ Battery Charger (**Figure 5**) is used to simultaneously recharge up to four batteries. It can take up to six (6) hours to fully charge a depleted battery. Each external battery slides into a bay and is connected to the battery charger. It is safe to leave the batteries in the charger.

For additional information about the battery charger, see Section *3.4*.

2.6 Carrying Cases and HeartWare™ Shower Bag

To ensure correct use of the PAL™ Sport Pack, you should be trained on how to use the Sport Pack prior to use.

A HeartWare™ Shower Bag is included to enable safe bathing with the Controller and the external battery.

Figure 6: PAL™ Accessories Bag

Figure 7: HeartWare™ Shower Bag

Figure 8: PAL™ Sport Pack

CAUTION: ALWAYS keep the primary controller that is connected to a pump in a carrying case except when changing external batteries. Failure to keep equipment in a carrying case may lead to damage of the controller and external peripherals.

2.6 Carrying Cases and HeartWare™ Shower Bag (continued)

WARNING! DO NOT attempt to repair, service, or modify any component of the HVAD System as this may damage the component. If the equipment malfunctions, contact your clinician.

WARNING! DO NOT use any components other than those supplied by Medtronic with the HVAD System, as this may affect the HVAD System operation.

WARNING! DO NOT take a bath or swim, as this may damage the system components and/or result in pump cable (driveline) exit site infection.

WARNING! DO NOT submerge any HVAD System component in water, as this may damage the component. If this happens, contact your clinician.

WARNING! DO NOT plug the controller into an AC electrical outlet during showers; to eliminate the possibility of a severe electrical shock, the controller should only be connected to an external battery.

WARNING! DO NOT allow water or other fluids to enter the controller, power cords, batteries, battery charger or connectors, as this may damage the HVAD System components. If equipment is damaged, contact your clinician.

WARNING! If your hearing is impaired and/or you cannot hear the controller alarms without the use of a hearing aid, make sure your caregiver will be close by to hear alarms.

WARNING! DO NOT shower until your clinician tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare™ Shower Bag.

WARNING! DO NOT use damaged equipment as it could lead to patient harm. If equipment is damaged, contact your clinician.

CAUTION: DO NOT pull, kink, or twist the pump cable (driveline) or the power cables, as these actions may damage the cables. Special care should be taken not to twist the pump cable (driveline) while sitting, getting out of bed, adjusting the controller or the power sources, or when using the HeartWare™ Shower Bag.

2.7 Data Security

Patients and their caregivers should keep control of primary and backup controllers to reduce the chance of tampering, and ensure data security. In the event of a suspected data security breach, contact your clinician.

The Controller USB port should only be connected to trusted HeartWare Monitors. This controller also features hardware for Bluetooth® wireless technology, but wireless capability is not currently supported.

Note: System settings cannot be changed via Bluetooth®.

3.0 Handling HeartWare™ HVAD™ System Components

3.1 PAL™ Controller

3.1.1 Controller Overview

The PAL™ Controller is worn by you, the patient, and it monitors and controls the operation of the HVAD System. The controller attaches to the pump driveline cable. The cable sends power and operating signals to the pump and collects information from the pump. The controller monitors the pump status and issues alerts to you. These alerts use vibratory, visual, and audible alarms. The controller also transmits alarm and pump operating information to the clinician's monitor. Pump status, battery capacity, battery time remaining, alarm conditions and troubleshooting tips are displayed on the controller screen. The controller utilizes power from an external power source: an external battery, an electrical outlet (using an AC adapter) or a car outlet (using a DC adapter). An internal, replaceable, rechargeable battery inside the controller is used to power the controller and pump during the time you are changing the external power sources.

Figure 9: Parts of the PAL™ Controller

1) Touchscreen display
2) Data port
3) Speaker
4) PAL™ Single Battery
5) Battery release button
6) Power connector port
7) Coiled Cable
8) Driveline cover
9) Coiled Cable connector

3.2 Controller Screens

3.2.1 Screen Overview

The controller face has a touchscreen display that uses icons and buttons to report the status of the pump and alert you when an alarm condition exists. Symbols on the display screen will also direct you to additional information.

Figure 10: PAL™ Controller touchscreen display

Figure 11: Example of navigation button (heart symbol) and display of controller system information

The background color of the screen indicates the overall status of the system.

Table 3: Background Screen Colors

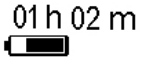
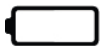
Background Color	Example of screen
BLUE Background When the Home screen has a solid blue backlight, the system is running normally.	 **BLUE (Normal)**
YELLOW Background When the Home screen has a solid yellow backlight, a non-critical alarm is active.	 **YELLOW (Non-critical alarm)**
RED Background A flashing red backlight indicates an active critical alarm condition that must be addressed immediately.	 **RED (Critical alarm)**

WARNING! IMMEDIATELY replace a controller that has a blank display and/or no audible alarms. It could indicate a controller failure.

Note: The background color will turn off after sixty (60) seconds of inactivity unless there is an active unmuted alarm. Touching the screen anywhere will reactivate the background color.

3.2.1 Screen Overview (continued)

Table 4: Guide to Controller Symbols

Symbol	Description	Symbol	Description
	The heart symbol displays on the Home screen when the controller is running a pump, e.g., the system is in the Running state. Press the symbol to view the VAD Status screen.		Press the information symbol to view the Controller Information screens. When there is important information related to the internal or external battery replacement, a flashing symbol will display on the Home screen, replacing the symbol for the controller operating state. Press the flashing symbol to display the pertinent information.
	The symbol displays on the Home screen when the system is in the Ready state. Press the symbol to view the VAD Status screen.		Press the home symbol to return to the Home screen. **Note:** The controller returns to the Home screen after sixty (60) seconds if there is no active alarm.
	The symbol displays indicating the remaining runtime charge for the external or internal battery.		The symbol displays when the external or internal battery is charging. When the lightning bolt disappears, the battery is fully charged.
	The external battery runtime remaining (hours and minutes) displays above the symbol.		The symbol displays when the external or internal battery no longer has a charge and is not charging.
	The symbol displays when the external or internal battery is not connected or is not found.		The symbol displays when the controller is powered by an AC or DC adapter.
	The symbol displays when one or more alarms is sounding. Pressing anywhere on the screen will temporarily mute a non-critical alarms.		The symbol displays when an alarm is muted.
	Press the symbol to view the active and resolved alarms in the Alarm History.		The symbol displays when one or more alarms are active. Active alarms must be investigated and resolved as soon as possible.

3.2.1 Screen Overview (continued)

Table 4: Guide to Controller Symbols (continued)

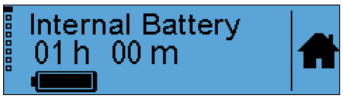
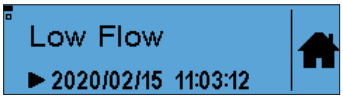
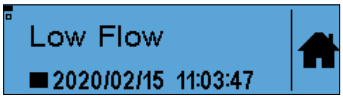
Symbol	Description	Symbol	Description
	The symbol displays next to the clinician's telephone number to indicate you must call your clinician.		The hourglass symbol displays while the controller is shutting down.
	Up to 10 small boxes display on the left side of the screen and indicate that there are multiple alarm messages to view. Press the center of the screen to cycle through the messages.		The symbol on the left side of the controller screen flashes to indicate that there are multiple active non-critical alarms currently active. Press the screen to mute the current alarm. Then press the screen again to cycle through the alarms. The highest priority alarm will display first. Press until all alarm messages have been viewed. **Note:** Non-critical alarms can be muted by pressing the screen.
	The symbol displays on the Alarm History screen next to the date and time that an alarm began.		The symbol displays on the Alarm History screen next to the date and time an alarm was resolved.
	The symbol displays on the Controller Information screens indicating that the setting is OFF.		The symbol displays on the Controller Information screens indicating that the setting is ON.

Table 5: Screen Definitions

Screen Definition	Example of Screen
Home screen – Shows the system state and the status of the connected power sources. **Note:** The controller returns to the Home screen after sixty (60) seconds of inactivity if there is no active alarm.	 **Figure 12: Home screen**
VAD Status screen – Shows the pump flow in liters per minute (L/min), the current pump speed in RPM, and the pump operating power in Watts.	 **Figure 13: VAD Status screen**
System screen – The symbols on the screen allow you to access the Controller Information screens, the Alarm History screens, and the Home screen.	 **Figure 14: System screen**

3.2.1 Screen Overview (continued)

Table 5: Screen Definitions (continued)

Screen Definition	Example of Screen
Controller Information screens – Shows the status of connected batteries, programmed controller settings, and pump performance information.	 Figure 15: Controller Information screen
Alarm History screen – Shows the active (unresolved) and the past (resolved) alarms. Each alarm page includes the alarm message, and time stamp related to onset and resolution status.	 Figure 16: Alarm onset  Figure 17: Alarm resolved
Alarm Notification screen – When the alarm condition is activated, the Controller Home screen is replaced by an Alarm Notification screen.	 Figure 18: Alarm Notification screen

3.2.2 Operating States

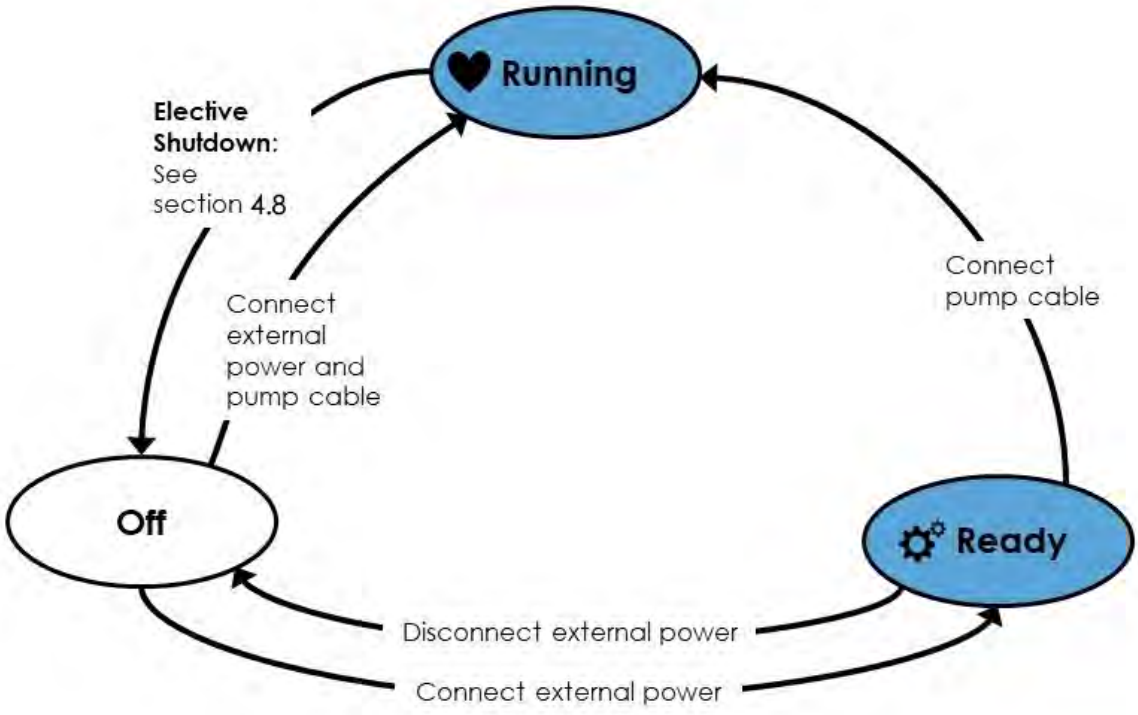


Figure 19: Diagram of the Operating States

3.2.2 Operating States (continued)

The Controller has the following patient-facing operating states:

Table 6: Operating State Definitions

Home Screen	What it represents:	What it means:
	**Off state**	The controller is off and will not power the pump when connected.
	**Ready state**	The controller is on but not connected to a pump. The pump will immediately start when the pump cable (driveline) is connected.
	**Running state**	The controller is on and powering a pump.

3.2.3 Screen Navigation

Refer to the graphic below to see the overall navigation for the Controller.

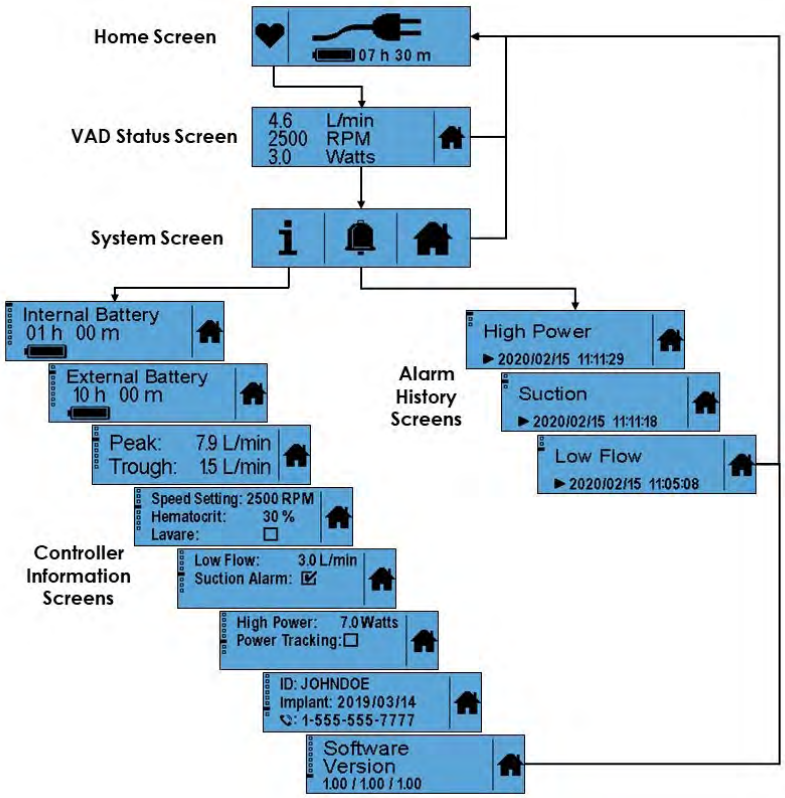


Figure 20: Controller Screen Navigation

- The controller will return to the Home screen automatically after sixty (60) seconds of inactivity.
- Press the symbol to manually return to the Home screen.
- To cycle through the Controller Information screens or the Alarm History screens, press the center of the current screen.

3.2.4 Screen Definitions

The Home screen displays the pump and the power source status, including battery runtime remaining, battery connection status, charge level, charging status, and power adapter connection status. When the Home screen is **BLUE**, the system is running normally.

> **Note:** The estimate of time remaining for an external battery may adjust for a few seconds after a power source change.

Table 7: Home Screen Variations

Home Screen	Meaning of Symbols on Screen
 Figure 21: Pump running	• ♥ - The pump is running. • - This symbol indicates the AC or DC adapter power is connected. • - This symbol shows the external battery is connected and its level of charge. • **08 h 30 m -** This is the time remaining until the external battery is depleted.
 Figure 22: Pump running; adapter ony	• ♥ - The pump is running. • - Only the AC or DC adapter power is connected (no external battery).
 Figure 23: Connected and charging	• ♥ - The pump is running. • - This symbol indicates the AC or DC adapter power is plugged in. • - These symbols indicate the external battery is connected and is charging. • **07 h 00 m -** This is the time remaining until the external battery is depleted.
 Figure 24: Pump running; external battery only	• ♥ - The pump is running. • **09 h 00 m** - This is the time remaining until the external battery is depleted. • - Only the external battery is connected (no AC or DC adapter power).
 Figure 25: Important information available	• When the ♥ symbol changes to a flashing **i** symbol, it indicates that there is important information available, related to the internal or external battery replacement.

3.2.4 Screen Definitions (continued)

Table 7: Home Screen Variations (continued)

Home Screen	Meaning of Symbols on Screen
 Figure 26: Pump running; no external power connected	• ♥ - The pump is running under normal operating conditions. • No external power is connected, or the external battery is fully depleted. • This screen displays for a twenty (20)-second period after all external power is removed. If power is not connected within twenty (20) seconds, the non-critical [**Connect Power**] alarm will activate. The non-critical alarm will escalate to a critical alarm after thirty (30) minutes or if the internal battery has fifteen (15) minutes or less time remaining, whichever comes first.
 Figure 27: Non-critical alarm occurring	• This is an example of a non-critical alarm occurring. • A non-critical alarms display with a yellow background. • For more information about specific alarms, see ***Section 4.0 Emergencies and Alarms***.

Pressing the ♥ symbol on the Home screen will display the VAD Status screen. After sixty (60) seconds of inactivity, the Home screen will appear.

Controller Information Screens

The Home screen, the VAD Status screen, and the Controller Information screens may all be used to view pump and controller information.

Table 8: Accessing the Controller Information Screens

Example of Screen	Description
	• Home screen is the default viewing screen. • Access the VAD Status screen by pressing the ♥ symbol or the ⚙ symbol.
	• Access the System screen from the VAD Status screen by pressing the left side of the screen.
	• Access the Controller Information screens from the System screen by pressing the ℹ symbol.

To navigate through the screens, press the center of the current screen (as shown in **Figure 28**).

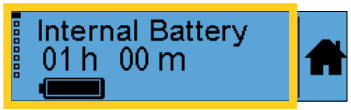


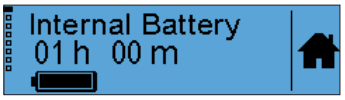
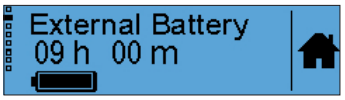
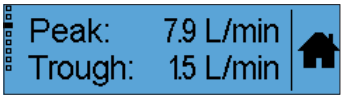
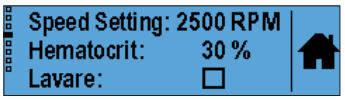
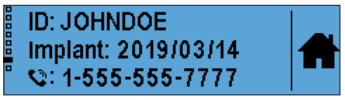
Figure 28: Press the center of the screen

3.2.4 Screen Definitions (continued)

The small boxes on the left side of the controller screen indicate there are more information screens available for viewing. After the last information screen, navigation will return to the first information screen. The controller will return to the Home screen automatically after sixty (60) seconds of inactivity, or you can press the ⌂ symbol to immediately return to the Home screen.

The Controller Information screens include the following pump and controller information (**Table 9**).

Table 9: Controller Information Screens

Example of Screen	Description
	• Internal battery connection status • Charge level • Runtime remaining • Charge status
	• External battery connection status • Charge level • Runtime remaining • Charge status
	• Pump peak flow • Pump trough flow
	• Pump speed setting • Hematocrit setting • Lavare™ setting
	• [Low Flow] alarm setting • [Suction] alarm setting
	• [High Power] alarm setting • Power Tracking setting
	• Patient Identification Number • Implant date (YYYY/MM/DD) • Clinician phone number
	• Software version

3.2.4 Screen Definitions (continued)

Controller Alarm History Screens

The Alarm History screens show the status of the ten (10) most recently occurring alarms. Both critical and non-critical alarms are recorded in the Alarm History, excluding the [Change Battery] alarm, [Connect Power] alarm and the [Connect Cap or Battery] alarm.

Table 10: Accessing the Alarm History Screens

	Screen Navigation Steps	Description
1.		The home screen is the default viewing screen. Press the ♥ symbol (or the ⚙ symbol) on the Home screen to access the VAD Status screen.
2.		Press the left side of the VAD Status screen to access the System screen.
3.		Press the 🔔 symbol in the center of the System screen to access the Alarm History screens.

To navigate through the screens, press the center of the current screen (as shown in the image below).

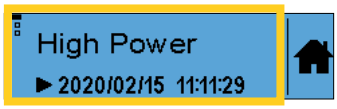
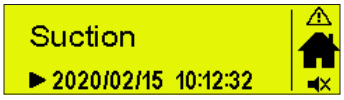
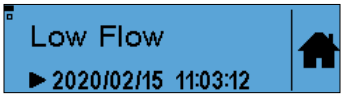
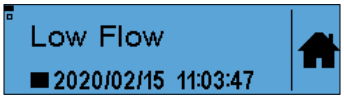


Figure 29: Example of an Alarm History screen

After the last Alarm History screen, navigation will return to the first Alarm History screen. The controller display will return to the Home screen automatically after sixty (60) seconds of inactivity. To exit the Alarm History screen manually, press the 🏠 symbol.

3.2.4 Screen Definitions (continued)

Table 11: Examples of Alarm History Screens (Active and Resolved)

Type of Alarm	Alarm History Screen Display
Active	 Figure 30: [Suction] alarm (onset)  Figure 31: Active [Suction] alarm
Resolved	 Figure 32: [Low Flow] alarm (onset)  Figure 33: [Low Flow] alarm (resolved)

Active alarms will display first, in order of priority. The small boxes down the left side of the screen indicate the number of alarms available for viewing. The black (filled) box in the display shows the position of the currently displayed alarm in the Alarm History.

Both the active and resolved alarms display two lines which can include the alarm name, time, and instruction.

Active Alarms: Alarms that are still active (e.g., with yellow background) display the alarm name followed by a triangle (onset) ▶ symbol with the time of alarm onset. It will alternate with your clinician's phone number.

Note: A flashing alarm alert ⚠ symbol indicates that the alarm condition has not yet been resolved.

Resolved Alarms: Alarms that have been resolved display the alarm name followed by a triangle (onset) ▶ symbol with the time of onset and alternates with a square (resolved) ■ symbol with the time of resolution.

3.3 Controller Connections

3.3.1 Connections Overview

There are four connection ports on the controller:

1. Data Cable Connection
   - Covered with a dust cover

2. Pump Cable (Driveline) Connection (see page 30)
   - Connects to the pump cable (driveline)
   - Must always be connected to the pump for continuous pump operation, unless performing a controller exchange
   - Must always be covered by the pump cable (driveline) cover

3. Power Cord Connection (see page 32)
   - Connects to the AC or DC power adapter
   - When not in use, must be covered with a dust cover

4. External Battery & Battery Cap Connection (see page 35)
   - Connects to the Single or Dual Battery
   - When not in use, it is covered with a PAL™ Cap

CAUTION: ALWAYS keep all connectors free of liquid, dust and dirt, or the HVAD System may not function as intended.

3.3.1 Connections Overview (continued)

CAUTION: AVOID changing power sources in or near water (e.g., shower, rain, ocean, etc.), as this may damage the controller. If equipment is damaged, contact your clinician.

3.3.2 Pump Cable (Driveline) Connection

WARNING! DO NOT disconnect the pump cable (driveline) from the controller or the pump will stop. If this happens, reconnect the pump cable to the controller IMMEDIATELY to restart the pump.

WARNING! ALWAYS check for a click when connecting the pump cable (driveline) to the controller. Failure to ensure a secure connection may lead to a pump stop.

Disconnecting the pump cable (driveline) from the Controller:

Instructions	Image
1. Slide the driveline cover towards the controller to reveal the whole silver connector.	 Figure 34: Slide the driveline cover
2. Grasp the pump cable below the connector with one hand, avoiding the grooved area, as shown in **Figure 35**.	 Figure 35: Grasp the pump cable
3. With the index finger and thumb of the same hand, pinch the grooved area of the pump cable connector (**Figure 36**).	 Figure 36: Pinch the grooved area of the pump cable connector

3.3.2 Pump Cable (Driveline) Connection (continued)

Instructions	Image
4. With the other hand, pinch the grooved area of the controller Coiled Cable connector (**Figure 37**).	 **Figure 37: Pinch the grooved area of the controller Coiled Cable connector**
5. Release the locking mechanism by pulling the controller Coiled Cable connector away from the pump cable connector (**Figure 38**). **Note**: Only pull on the grooved area of the connectors. If any other area of the cable or connector is pulled back, the cable will not release from the controller.	 **Figure 38: Release the locking mechanism**

Connecting the pump cable (driveline):

Instructions	Image
1. Align the red line on the controller Coiled Cable connector with the alignment marker on the pump cable connector.	 **Figure 39: Align the red line with the red dot/ black line**
2. Push the pump cable connector straight into the controller Coiled Cable port until there is a click. **Note:** To ensure proper connection, verify that the pump is running. If the pump is running, there will be a heart ♥ symbol displayed on the controller screen.	 **Figure 40: Push the connector into the port**
3. Slide the cover of the pump cable over the connectors until the cover is securely in place (**Figure 41**).	 **Figure 41: Slide the cover over connectors**

3.3.2 Pump Cable (Driveline) Connection (continued)

CAUTION: DO NOT pull, kink, or twist the pump cable (driveline) or the power cables, as these actions may damage the cables. Special care should be taken not to twist the pump cable (driveline) while sitting, getting out of bed, adjusting the controller or the power sources, or when using the HeartWare™ Shower Bag.

CAUTION: DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.

3.3.3 AC or DC Adapter Connection

AC or DC Power Adapter

The AC adapter (**Figure 42**) has cables that connect to the controller and an electrical outlet. Prior to connection to the controller, verify proper connection of the AC power cord to the power adapter (**Figure 43**) and to the electrical outlet. If the adapter connector is not properly connected, perform the following steps:

1. Make sure the AC adapter and the AC power cord are not connected to the controller or to an electrical outlet.
2. Insert the AC power cord completely and securely into the power adapter receptacle on the adapter brick.
3. Ensure that the AC power cord is secure in the power adapter receptacle.

When connected to an electrical outlet, a blue indicator light on the adapter will indicate proper connection. Ensure that the power indicator on the AC or DC power adapter turns blue before plugging the adapter into the controller. Since the AC Adapter does not contain a power switch, the AC power cord acts as the disconnection device from mains power. Position the AC adapter so the AC power cord can be easily disconnected from the electrical outlet or AC adapter if needed.

Figure 42: AC Adapter with AC Power Cord

Figure 43: AC power cord connection to AC Adapter Brick

Figure 44: DC adapter

The DC adapter (**Figure 44**) plugs into the power port located in most vehicles. When the DC adapter is properly connected to power, a blue indicator light will display on the adapter.

WARNING! ALWAYS connect an AC Adapter to the controller before relaxing or sleeping. Power from an electrical outlet (AC Adapter) provides power for an unlimited period of time.

Note: The DC adapter is for use in vehicles only and may not fit in some vehicles. The vehicle must have at least a 10-amp DC adapter fuse.

3.3.3 AC or DC Adapter Connection (continued)

Connecting an AC or DC Adapter:

Instructions	Image
1. Lift the power cord dust cover.	 Figure 45: Lift the dust cover
2. To connect an AC adapter or DC adapter, grasp the power cable near its connector.	 Figure 46: Grasp the cable near its connector
3. Align the solid yellow line on the cable connector with the solid yellow line on the controller power connector port (**Figure 47**).	 Figure 47: Align the cable connector to the controller power connector port
4. Gently push the cable into the controller power connector port. DO NOT twist the connector, but allow it to naturally slide into the power connector port.	 Figure 48: Allow the cable to slide into the power connector port

3.3.3 AC or DC Adapter Connection (continued)

Note: When correctly connected, the controller will vibrate and the controller screen will displays a power cord symbol.

Figure 49: Controller screen AC or DC power cord and charging symbols

WARNING! ALWAYS have an external power source connected to the primary controller to avoid unintentional pump stoppage, except when changing a power source. The internal battery is a backup power source and should only be relied on while changing external power sources.

CAUTION: ALWAYS have an external battery or cap connected to the battery connector even while using an AC or DC adapter with the controller. An uncovered battery connector can lead to electrostatic discharge (ESD) events.

CAUTION: DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.

Disconnecting an AC or DC Adapter:

Instructions	Image
1. Grasp the power cord and pull it straight out from the controller.	 **Figure 50: Pull the power cord out**
2. Cover the power cord port with the power cord dust cover.	 **Figure 51: Cover the port with the dust cover**

3.3.4 External Battery and PAL™ Cap Connection

External Batteries Overview

PAL™ External Batteries are available in two sizes: Single and Dual. The Single and Dual Batteries contain lithium ion cells to power the HVAD Pump for approximately six (6) hours and thirteen (13) hours, respectively. When connected to the controller, the battery will communicate battery capacity and other parameters to the controller. The capacity (hours of support) of each battery is based on:

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

Note: The amount of battery time may increase or decrease significantly depending on pump operating conditions.

Only fully-charged external batteries should be connected to the controller. There are three ways to know if the battery is fully charged and ready for use:

1. Battery Capacity Display on the battery
2. Battery Status Indicator on the controller display
3. Battery Status Indicator Light on the battery charger

On the battery to check its capacity, press the battery capacity button:

Figure 52: Battery Capacity button

The battery capacity display will light up showing how much power is in the battery. See **Table 12** for description of indicator lights.

Table 12: Battery Capacity Display

Battery Capacity	Battery Capacity Display
Full	4 GREEN lights
High	3 GREEN lights
Medium	2 GREEN lights
Low	1 GREEN light

Note: If no light displays at all, the battery is fully depleted. Connect the battery to a charger.

3.3.4 External Battery and PAL™ Cap Connection (continued)

CAUTION: ALWAYS recharge depleted batteries within 24 hours to avoid permanent battery damage.

The controller will provide three (3) indications for when to change an external battery:

1. The display background color will be yellow (**Figure 53**).
2. The display will show a non-critical [Change Battery] alarm (**Figure 53**).
3. The controller will vibrate then sound indicating a non-critical alarm (**Figure 53**).

Figure 53: Non-critical alarm [Change Battery]

The message is resolved when a charged battery is connected to the controller.

Note: If a depleted battery is not exchanged and the internal battery is used for thirty (30) minutes, a critical alarm will occur. The critical alarm will sound, the display background color will flash **RED** and the message on the controller display will read [Connect Power] (**Figure 54**). During the condition, a charged battery or adapter (AC or DC) should be attached immediately to the power port.

Figure 54: Critical alarm [Connect Power]

WARNING! ALWAYS have a backup controller and fully-charged spare external batteries available at all times in case of an emergency.

Connections to the External Battery and PAL™ Cap

The same mechanism is used to connect and disconnect the Single Battery, Dual Battery, and PAL™ Cap.

Disconnecting an External Battery

Make sure there is a fully-charged external battery available to replace the used or depleted battery.

Note: Change the external battery in a dry, clean and dust-free location.

CAUTION: AVOID changing the external battery in a wet, dirty, or dusty location as this may damage your controller. If equipment is damaged, contact your clinician.

3.3.4 External Battery and PAL™ Cap Connection (continued)

Disconnecting an External Battery (continued)

Instructions	Image
1. While holding the battery (so it does not drop), press the battery release button (**Figure 55**).	 **Figure 55: Press the battery release button**
3. Pivot the battery away from the battery latch to detach the battery tabs(**Figure 56**).	 **Figure 56: Detach the battery tabs**

WARNING! ALWAYS have a backup controller and fully-charged spare external batteries available at all times in case of an emergency.

WARNING! ALWAYS keep the backup controller and spare external batteries available and in a dry environment where the temperature is between -5°C and +40°C (+23°F to +104°F).

3.3.4 External Battery and PAL™ Cap Connection (continued)

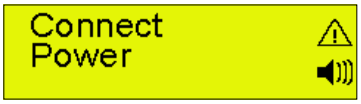
Connecting an External Battery

Instructions	Image
1. Insert the tabs of the fully-charged battery into the openings on the battery connector and pivot the battery to snap it into the controller (**Figure 57**). **Note:** DO NOT force the battery connection between the battery and the controller. Allow it to naturally lock into place. A successful connection will result in a vibration.	 **Figure 57: Insert tabs of the battery on the battery connector**
2. Look at the controller display. The hours and minutes of the time remaining for the battery will be displayed on a blue screen(**Figure 58**).	 **Figure 58: Estimation of remaining time for battery capacity**

The battery capacity will display estimated time remaining based off the following:

Estimated Time Remaining	Estimated Time Remaining Reporting Increments
>=6 hours	30 minutes
>=3.5 to 6 hours	15 minutes
>=1.5 to 3.5 hours	5 minutes
<1.5 hours	1 minute

Note: If an external power source is not connected within twenty (20) seconds, the [Connect Power] message will display on the controller screen and an alarm will sound.



The alarm will automatically clear when a power source is connected to the controller.

CAUTION: ALWAYS verify that the battery symbol is present on the PAL™ Controller screen to confirm that the external battery is properly locked on to the controller in order to maintain optimal therapy.

Charge External Batteries through the Controller

An external battery can be charged either by the primary or backup controller in temperatures between +10°C (+50°F) to +30°C (+86°F). It can take up to six (6) hours to fully charge a depleted battery.

3.3.4 External Battery and PAL™ Cap Connection (continued)

Instructions	Image
1. Make sure the external battery is properly connected to the controller.	 Figure 59: Battery connected
2. To connect an AC adapter or DC adapter, grasp the power cable near its connector.	 Figure 60: Grasp power cable
3. Align the solid yellow line on the cable connector with the solid yellow line on the controller.	 Figure 61: Align the yellow lines
4. Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally slide into the port.	 Figure 62: Push cable into controller
Note: When correctly connected, there will be a vibration and the controller screen will display a power cord symbol. 	

CAUTION: DO NOT attempt to charge the controller using the USB data port. The USB data port should be used only for data transfer and will not provide power to the controller.

3.4 Battery Charger

External batteries can be charged when inserted into the Battery Charger.

Charging the External Batteries through Battery Charger

Instructions	Image
1. Connect the AC power cord to the back of the battery charger.	 Figure 63: Connect the AC power cord
2. Plug the other end of the cable into an electrical outlet. **Note:** Since the Battery Charger does not contain a power switch, the AC power cord acts as the disconnection device from mains power. Position the Battery Charger so the AC power cord can be easily disconnected from the electrical outlet or Battery Charger if needed.	 Figure 64: Plug the cable into outlet
3. Once the battery charger is connected to power, the blue power light, located on the front center of the charger will turn on.	 Figure 65: Blue power light turns on
4. Place the battery into the charging bay, matching the curvature of the battery case to the curvature in the bay until it is seated in place. When it is properly seated, the battery charging status light will illuminate.	 Figure 66: Place battery into charging bay
5. Repeat step 4 for all batteries. The battery charger can hold up to four (4) batteries at one time.	 Figure 67: Holds up to 4 batteries

3.4 Battery Charger (continued)

Status of Batteries and Battery Charger

Each charging bay has an indicator light to show the battery charging status. A solid green light means the battery is fully charged. It can take up to (6) hours to fully charge a depleted battery. It is safe to leave the fully-charged batteries in the battery charger.

Figure 68: Green battery status indicator lights

Table 13: PAL™ Batteries Status Lights

Battery Status Light	What it Means
Off	Battery not charging
Solid Green	Battery fully charged
Flashing Green	Battery charging
Solid Red	Battery fault or incorrect placement Try removing and reconnecting the external battery. If the fault persists, replace the battery.
Flashing Red	Temporary battery fault (temperature) or a communications error

The Battery Charger has an indicator light to show the status of the charger.

Figure 69: Blue battery charger status indicator light

3.4 Battery Charger (continued)

Status of Batteries and Battery Charger (continued)

Table 14: Battery Charger Status Light

Charger Status Light	What it Means
Off	Charger off
Solid Blue	Charger operating normally
Solid Red	Charger fault Try disconnecting and reconnecting the battery charger power. If the fault persists, replace the battery charger.

WARNING! DO NOT use damaged equipment as it could lead to patient harm. If equipment is damaged, contact your clinician.

CAUTION: ONLY use the PAL™ Controller or PAL™ Battery Charger to charge PAL™ Batteries. Other battery chargers will not charge the external batteries and may lead to damage.

3.5 Internal Battery

The controller's internal battery contains lithium ion cells that power the Controller for at least thirty (30) minutes with a new internal battery when fully charged. Over time, the internal battery may provide shorter periods of backup power.

Intended Use

The controller internal battery is intended to provide power while changing from one external power source to another (external batteries, AC adapter, or DC adapter). The internal battery in the Controller is a backup power source and should never be used as the only source of power for the controller for extended periods of time. The internal battery is designed to provide safe and continuous pump operation during the exchange of external power sources.

WARNING! ALWAYS have an external power source connected to the primary controller to avoid unintentional pump stoppage, except when changing a power source. The internal battery is a backup power source and should only be relied on while changing external power sources.

3.5 Internal Battery (continued)

When no external power sources are active, the controller internal battery will automatically begin to provide power to the pump. Whenever the pump is running on the internal battery alone, the [Connect Power] message will appear on the controller display.

- If external power is not connected within twenty (20) seconds, the message will escalate to a non-critical alarm with vibration and sound. This alarm may be muted by pressing on the center of the controller screen. Note that after ten (10) minutes (e.g., two 5-minute mutes), the alarm cannot be muted.

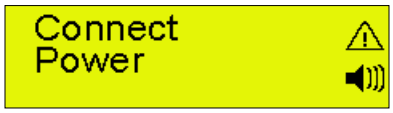


Figure 70: Non-critical [Connect Power] alarm

- If external power is not connected within thirty (30) minutes of running on the controller internal battery—or when the internal battery has only fifteen (15) minutes of power remaining—a critical [Connect Power] alarm will sound.

Figure 71: Critical [Connect Power] alarm

The [Connect Power] alarm will stop as soon as an external power source (charged external battery, AC adapter, or DC adapter) is connected.

Charging the Internal Battery

The controller internal battery is recharged whenever there is an external power source attached to the controller. The amount of time the internal battery has remaining is displayed in the Controller Information screens. It takes approximately ninety (90) minutes to charge the internal battery.

CAUTION: AVOID placing the controller in the following conditions to prevent harm from excessive heat:

- Between the legs when sleeping or sitting.
- Under the body while sleeping or sitting.
- Under covers in a warm room.
- In a heated room (e.g., sauna, steam room, hot yoga class, etc.).
- Under a thick or thermal (hypothermia) blanket.
- Under a heat lamp.
- In direct sunlight.

3.6 Carrying Cases

The Sport Pack, Accessories Bag, and the HeartWare™ Shower Bag are used to safely secure, store and carry the controller and external batteries. They can be used during normal daily activities.

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

Figure 72: PAL™ Sport Pack

WARNING! NEVER disconnect the pump cable (driveline) from the controller when loading equipment into the PAL™ Sport Pack as this will lead to a pump stop and potential harm. Bag loading does not require pump cable driveline disconnection.

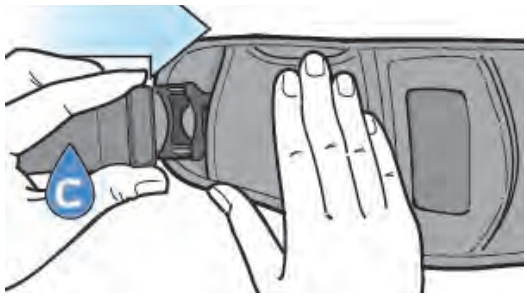
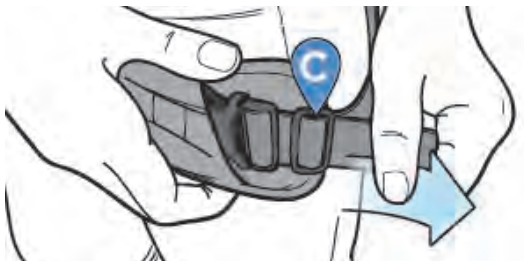
3.6.1 Sport Pack

Figure 73: PAL™ Sport Pack straps & belts

3.6.1 Sport Pack (continued)

Wearing the Sport Pack waist configuration

(*Refer to the Sport Pack images in Figure 73*)

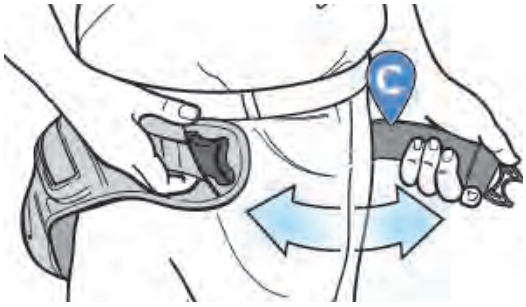
1. Place the Emergency Responder Guide and Patient ID Card into the back pocket of the pack.	
2. Connect one waist belt (**C**) buckle to the pack buckle and wrap the strap around the waist. Make sure that the zipper opening of the pack is facing up.	
3. Connect the remaining waist belt buckle (**C**) to the pack buckle.	
4. Adjust the length of the elastic strap to create a supportive and comfortable fit.	
5. Slide the loops along the strap to secure any unused extra length.	

Note: The Sport Pack waist configuration can be worn either in front, on the side, or at the back of the body.

CAUTION: Use caution when moving equipment around in the carrying case to avoid tugging on the pump cable (driveline) exit site.

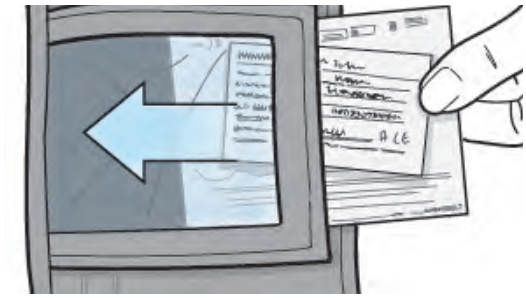
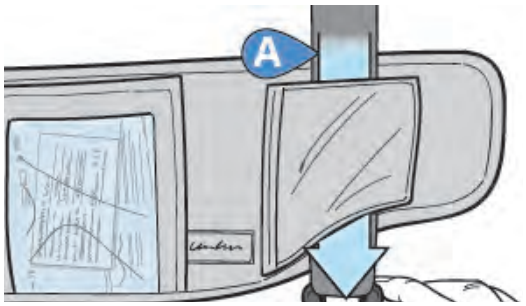
3.6.1 Sport Pack (continued)

Removing the Sport Pack waist configuration

1. Disconnect the waist belt buckle from the pack buckle.	
2. Remove the pack.	

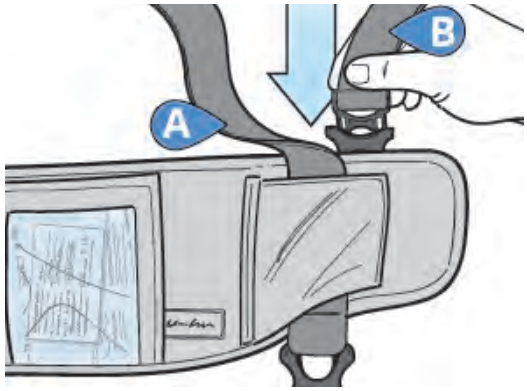
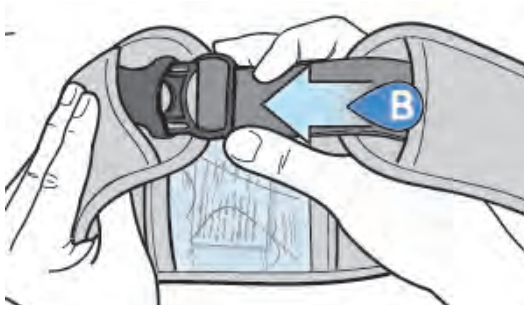
Wearing the Sport Pack shoulder configuration

The following buckle connection steps should be modified, depending on which shoulder is to be used.

1. Place the Emergency Responder Guide and Patient ID Card into the back pockets of the pack.	
2. With the pack face down, slide the shoulder belt (**A**) through the shoulder belt loop on which the bottom of the controller will be located.	

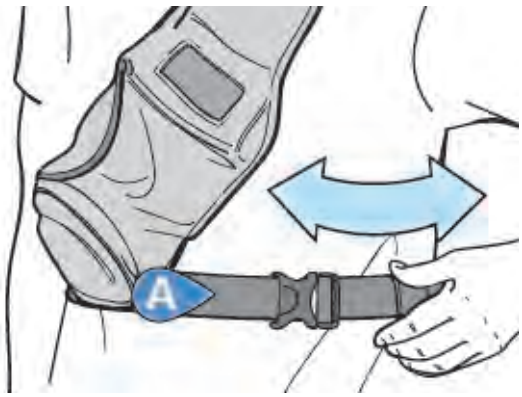
3.6.1 Sport Pack (continued)

Wearing the Sport Pack shoulder configuration (continued)

3. Connect one shoulder strap (**B**) buckle to the shoulder strap sliding buckle that is on the same side of the shoulder belt (**A**).	
4. Connect the other shoulder strap (**B**) buckle to the waist belt buckle on the opposite side of the pack.	
5. Place the shoulder strap (**B**) over the shoulder and adjust the length using the adjustable slides.	
6. Adjust the position of the shoulder padding for a supportive and comfortable fit.	

3.6.1 Sport Pack (continued)

Wearing the Sport Pack shoulder configuration (continued)

7. Connect the shoulder belt (**A**) buckles to the Sport Pack and adjust the length.	
8. Slide the loops along the strap to secure any unused extra length of shoulder belt.	

Note: The Sport Pack shoulder configuration can be worn either in front, on the side, or at the back of the body.

CAUTION: Use caution when moving equipment around in the carrying case to avoid tugging on the pump cable (driveline) exit site.

Removing the Sport Pack shoulder configuration

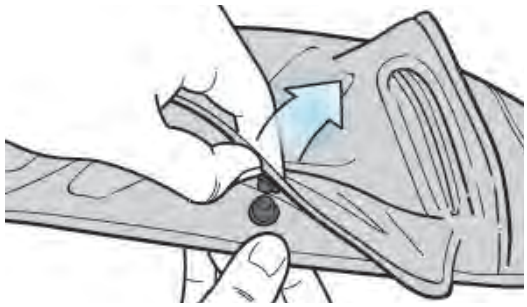
1. Disconnect the shoulder belt (**A**) buckles.	

3.6.1 Sport Pack (continued)

Removing the Sport Pack shoulder configuration (continued)

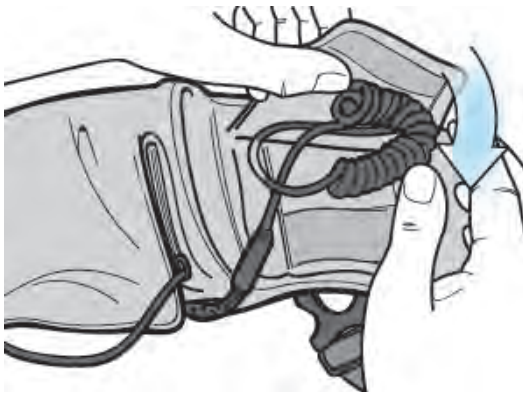
2. Remove the Sport Pack off the shoulder.	

Loading the Sport Pack

1. Place the Emergency Responder Guide and Patient ID Card into the back pockets of the pack.	
2. Unbutton the top snap and the Velcro® of the pouch flap.	
3. Grasp the middle of the zipper bar and pull it away from the snap button to open the pouch. **Note:** Individual zippers may need minor adjustments.	

3.6.1 Sport Pack (continued)

Loading the Sport Pack (continued)

4. Place the controller in the pack pouch. **Note:** The speakers of the controller must face away from your body. However, the controller can face left or right to allow for easier screen visibility.	
5. Grasp the middle of the zipper bar and pull it towards the snap button until the zipper is completely secure.	
6. Button the top snap and secure the Velcro® of the pouch flap. Be careful not to damage the pump cable.	
7. Open the preferred cable pocket (left or right side) and position the extra pump cable (either as a loop or carefully folded, depending on the length of cable) in the appropriate area. Secure the flap over the pump cable by pressing on the Velcro® portion.	

3.6.1 Sport Pack (continued)

Loading the Sport Pack (continued)

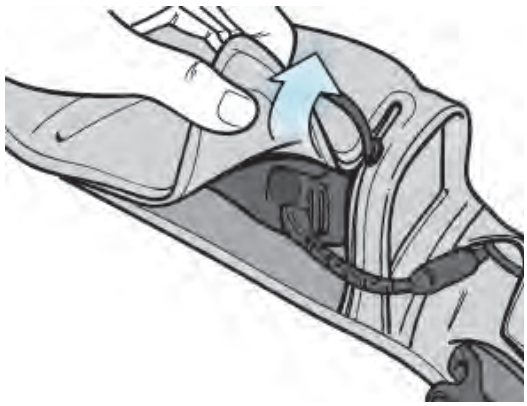
8. **Optional:** A mobile phone may be placed in the phone pocket.	

CAUTION: Mobile phones should only be placed in the phone pocket of the PAL™ Sport Pack. Placing a mobile phone too close to the controller may compromise normal operating conditions of the controller.

Connecting the Controller in the Sport Pack to an AC or DC Adapter

WARNING! NEVER disconnect the pump cable (driveline) from the controller when loading equipment into the PAL™ Sport Pack as this will lead to a pump stop and potential harm. Bag loading does not require pump cable (driveline) disconnection.

If the power cord connection is facing upward:

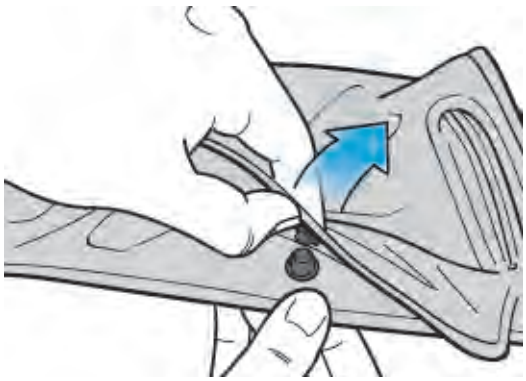
1. Detach the Velcro® corner of the pouch flap nearest to the power cord connection. 2. Slightly unzip the flap nearest to the power cord connection until dust cover can be seen.	

3.6.1 Sport Pack (continued)

Connecting the Controller in the Sport Pack to an AC or DC Adapter (continued)

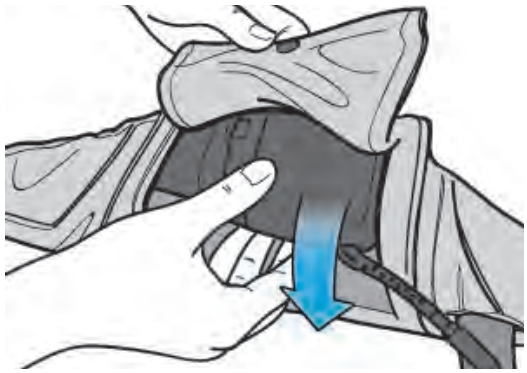
3. Remove the dust cover from the port.	
4. Attach the adapter to the controller.	

Unloading the Sport Pack

1. Unbutton the snap and detach the Velcro® of the pouch flap.	

3.6.1 Sport Pack (continued)

Unloading the Sport Pack to an AC or DC Adapter (continued)

2. Grab the middle of the zipper bar and pull away from the top of the case to open the pouch.	
3. Remove the controller from the pack.	

CAUTION: DO NOT pull, kink, or twist the pump cable (driveline) or the power cables, as these actions may damage the cables. Special care should be taken not to twist the pump cable (driveline) while sitting, getting out of bed, adjusting the controller or the power sources, or when using the HeartWare™ Shower Bag.

3.6.2 Accessories Bag

Make sure you have the following equipment in the Accessories Bag so that it is readily available at all times:

- 1 Backup Controller with attached PAL™ Cap
- 2 Single or Dual Batteries
- 1 AC or DC Adapter
- 1 Patient ID Card
- 1 Emergency Responder Guide

Figure 74: PAL™ Accessories Bag

3.6.2 Accessory Bag (continued)

Loading the Accessories Bag

1. Unzip the Accessories Bag.
2. Place the Emergency Responder Guide and Patient ID Card into the internal pocket of the Accessories Bag.
3. Place the backup equipment in compartments as shown in the picture (**Figure 75**).

   Backup equipment includes:

   - 1 Backup Controller
   - 1 AC Adapter or DC Adapter
   - 2 Batteries
4. Use the zipper to close the Accessories Bag.

Figure 75: Compartments of PAL™ Accessories Bag

Note: Do not place objects on top of the Accessories Bag.

Unloading the Accessories Bag

1. Unzip the Accessories Bag.
2. Remove the contents from the bag.

CAUTION: DO NOT pull, kink, or twist the pump cable (driveline) or the power cables, as these actions may damage the cables. Special care should be taken not to twist the pump cable (driveline) while sitting, getting out of bed, adjusting the controller or the power sources, or when using the HeartWare™ Shower Bag.

3.6.3 HeartWare™ Shower Bag

The cover of the HeartWare™ Shower Bag has a zipper closure that allows the pump cable (driveline) to exit the bag without being damaged by the zipper. An adjustable shoulder strap is used to wear the bag while showering.

Recommendations for Showering:

- Keep the pump cable (driveline) exit site covered and as dry as possible while showering.
- Try not to pull or move the pump cable. Pulling or moving the cable could injure an already healed exit site. DO NOT kink or bend the pump cable.
- Be careful not to catch the pump cable in the zipper when closing the shower bag.
- Prior to showering, make sure the battery is completely charged.
- If you are hearing impaired, make certain someone is always close by to hear alarms. If any alarm sounds during showering, the shower should be turned off and the alarm condition immediately addressed.
- The shower floor should be made of a non-slip surface or have a textured rubber mat.
- The shower stall should have a handrail and shower chair.

WARNING! DO NOT shower until your clinician tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare™ Shower Bag.

WARNING! If your hearing is impaired and/or you cannot hear the controller alarms without the use of a hearing aid, make sure your caregiver will be close by to hear alarms.

WARNING! DO NOT plug the controller into an AC electrical outlet during showers; to eliminate the possibility of a severe electrical shock, the controller should only be connected to an external battery.

WARNING! DO NOT take a bath or swim, as this may damage the system components and/or result in pump cable (driveline) exit site infection.

WARNING! DO NOT submerge any HVAD System component in water, as this may damage the component. If this happens, contact your clinician.

Getting Ready to Shower

1. Unzip and inspect the shower bag for rips or tears. Make sure the inside of the bag is dry.
   - If the bag has any rips, tears or is wet, do not use the bag and do not proceed to shower.
   - Contact your clinician to get a replacement HeartWare™ Shower Bag, if needed.

Figure 76: Unzip and inspect

3.6.3 HeartWare™ Shower Bag (continued)

2. Place the controller attached to an external battery inside the inner pouch of the HeartWare™ Shower Bag. It can be put in separately or left inside the Sport Pack. Always tuck the driveline connector inside the HeartWare™ Shower Bag.
   - The controller should be facing upward so the display is seen easily if an alarm occurs.
   - The controller can be in or out of the Sport Pack.

3. Pull the drawstring to close the inner pouch of the HeartWare™ Shower Bag.

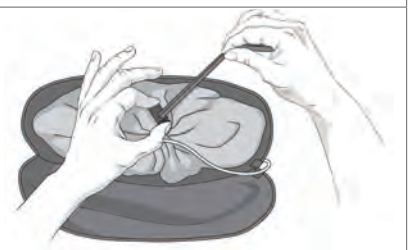


Figure 77: Pull the drawstring

4. With the shower bag opening facing away from you, position the pump cable (driveline) toward the farthest right corner of the zipper.
   - This part of the zipper is covered to prevent the pump cable from being damaged when zipping the bag.

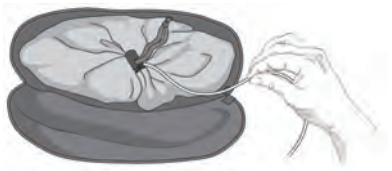


Figure 78: Position the pump cable toward the farthest right corner of the zipper

5. Use the zipper to close the HeartWare™ Shower Bag and fold the top flap down over the zipper.
   - Avoid catching the pump cable in the zipper; this could damage it.

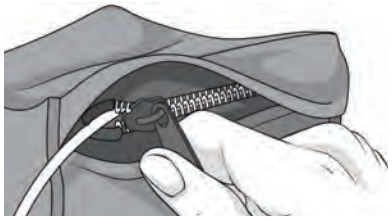


Figure 79: Zip to close bag

6. Guide the portion of the pump cable that exits the bag between the two Velcro® strips on the side of the bag.

Figure 80: Guide the pump cable between Velcro® strips

7. Firmly fasten the two Velcro® strips around the pump cable.
   - The pump cable will form a “U” shape as it exits the bag. This helps prevent water draining from the cable into the bag.

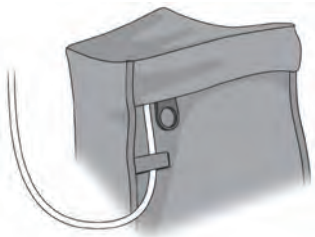


Figure 81: Fasten Velcro® strips around the pump cable

3.6.3 HeartWare™ Shower Bag (continued)

Getting Ready to Shower (continued)

8. Place the shower bag strap over your head and across your shoulder so it is hanging at your side.
   - Adjust the strap so the bag does not pull on the pump cable while showering.
   - There should be some slack in the pump cable so that the flap is completely folded over the zipper.

Figure 82: Bag should be hanging at your side

CAUTION: ALWAYS place the pump cable (driveline) connector inside the HeartWare™ Shower Bag when showering. Exposing the pump cable (driveline) connector to water may lead to electrical faults, unrepairable damage to equipment and disruption of therapy.

After Showering

1. Set the HeartWare™ Shower Bag on a flat, stable surface and dry the bag, the controller, and the battery, using a clean towel.
2. Transfer the controller and external battery to the carrying case.
3. Change the exit site dressing using the normal procedure. If the area around the exit site is wet, dry it off with a sterile gauze bandage before applying the new dressing.
4. Allow the HeartWare™ Shower Bag to air dry before using it again. Make sure the shower bag is dry before the next use.

3.6.3 HeartWare™ Shower Bag (continued)

WARNING! DO NOT shower until your clinician tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare™ Shower Bag.

WARNING! If your hearing is impaired and/or you cannot hear the controller alarms without the use of a hearing aid, make sure your caregiver will be close by to hear alarms.

WARNING! DO NOT plug the controller into an AC electrical outlet during showers; to eliminate the possibility of a severe electrical shock, the controller should only be connected to an external battery.

WARNING! DO NOT take a bath or swim, as this may damage the system components and/or result in pump cable (driveline) exit site infection.

WARNING! DO NOT submerge any HVAD System component in water, as this may damage the component. If this happens, contact your clinician.

WARNING! DO NOT allow water or other fluids to enter the controller, power cords, batteries, battery charger or connectors, as this may damage the HVAD System components. If equipment is damaged, contact your clinician.

CAUTION: DO NOT pull, kink, or twist the pump cable (driveline) or the power cables, as these actions may damage the cables. Special care should be taken not to twist the pump cable (driveline) while sitting, getting out of bed, adjusting the controller or the power sources, or when using the HeartWare™ Shower Bag.

4.0 Emergencies and Alarms

4.1 Handling an Emergency

Emergencies may occur with your HVAD System, with or without an alarm. A backup controller and charged batteries must be available at all times. The controller should be exchanged if it fails.

For information on how to change the controller, see Section *4.7*.

Call your clinician immediately if you notice a sudden change in how your pump works, feels or sounds (even if there is no alarm). Emergencies may also be related to how you feel. If there is an emergency such as an urgent or life-threatening problem, call your local emergency medical services and then your clinician, if possible. In the event of an emergency, such as a cardiac arrest, patients with the HVAD System may be defibrillated with either an internal or external defibrillator. The HVAD System can be left on; nothing needs to be turned off or disconnected.

Contact your clinician for any of the following conditions:

- Numbness, tingling or weakness in any limb
- Blurred vision or speech problems
- Shortness of breath or dizziness
- Any pain, including chest pain or unrelieved headache
- Fever (take your temperature daily)
- Any redness, swelling, drainage, odor or pain around the pump cable (driveline) exit site
- Unusual bleeding or bruising
- Unusually dark urine
- Any condition where you feel “unwell”
- Critical controller alarms

Call Emergency Medical Services (EMS) for any of the following conditions:

- Seizure or convulsion
- Loss of consciousness
- Awake but unresponsive
- Sudden fall or collapse
- Inability to talk or move body parts
- Heart stops
- VAD stops
- In case of emergency, it is safe for you to be transported by ground or air to your implanting hospital or the nearest hospital.

WARNING! IMMEDIATELY replace a controller that has a blank display and/or no audible alarms. It could indicate a controller failure.

4.2 Overview of Alarms

Alarms provide information and alerts about your pump, the controller, the connections, and the power sources (external batteries, AC adapter, DC adapter).

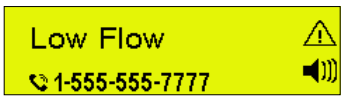
An Emergency Responder Guide for controller alarms is available from your clinician.

Alarm conditions are classified as either critical (red) or non-critical (yellow).

Each of these alarms has

- a unique sound
- a visual display
- vibration
- a displayed message

Table 15: Alarm Conditions: Critical and Non-critical

	Critical	Non-critical
Controller Display	Flashing Red back light with message and symbols	Yellow back light with message and symbols
Controller Vibration	Controller vibrates and displays the alarm message	Controller vibrates and displays the alarm message
Controller Audio	Loud periodic beep	Periodic beep that becomes louder after five (5) minutes
Controller Muting	Cannot be muted by pressing screen	May be muted for five (5) minutes or fifteen (15) minutes depending on the alarm type, by pressing the screen
Controller Message	 Critical Alarm displays the action to be performed	 Non-critical alarm displays the phone number to be called

When a non-critical alarm occurs, the controller vibrates and displays the alarm on the controller screen before producing an audible alarm. If the alarm is muted during the vibratory phase for non-critical alarms, the audible alarm will not sound. Critical alarms cannot be muted.

Estimated HVAD Pump blood flow is calculated using pump power, speed parameters, and hematocrit, which is based on a blood sample from the patient. The [Low Flow] alarm involves this calculation and the preset Low Flow Alarm Limit.

Power Tracking™ is an algorithm which drives the [High Power] alarm in place of the [High Power] alarm limit. The algorithm functions by comparing the current operating power to the historical baseline.

The [Suction] alarm functions by monitoring the estimated flow and searches for a sudden decrease in flow rate. A flow baseline is established by continuously tracking the minimum flow values. The alarm is triggered when flow is 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 ten (10) seconds.

Note: For critical alarms, the controller screen will only display the action required for resolution of the condition.

4.2 Overview of Alarms (continued)

WARNING! ALWAYS check the controller display for information regarding an alarm when using loud machinery, or near loud noises, as the alarms may not be audible.

4.3 Critical Alarms

A critical alarm condition is the highest priority and loudest alarm; the controller vibrates, the screen flashes **RED**, the display message indicates immediate action needs to be taken, and the loudest audible alarm is sounded. Critical alarms cannot be muted and the alarm condition must be resolved as soon as possible. Critical alarms sound when the pump has stopped, the controller has failed, or when the system is in danger of stopping due to limited power.

After the condition is resolved, the audible alarm stops, the alarm message clears from the controller display, returning it to the default Home screen, and the alarm condition is logged in the Alarm History screen. See the table below for critical alarm messages and their possible meaning(s).

Table 16: Critical Alarms

Alarm Type: Critical			
Alarm Signal	**Controller Message**	**What it Means**	**What action to take**
Flashing RED back light  **Flashing alert symbol** **Loud audio signal and vibration** **Unable to mute alarm**	**[Change Controller]** 	• Controller failure. • Controller component failed. • Pump failure. • Pump unable to start in 5 attempts.	• Change the controller immediately. • Contact your clinician.
	[Connect Pump Cable] 	• Pump cable (driveline) disconnection. • Pump cable (driveline) fracture. • Connector is malfunctioning or broken. • Pump electrical failure.	• Connect the pump cable (driveline) to the controller. • If not resolved, change the controller. • Contact your clinician.
	[Plug In Power Cord] 	• Disconnecting external battery without a power cord connected could risk pump stop. • The internal battery has limited time remaining, is unreliable, disconnected or has failed AND • The external battery has less than 15 minutes runtime remaining or is unreliable.	• Connect the power cord to the controller • DO NOT disconnect the external battery before connecting the power cord • Contact your clinician

4.3 Critical Alarms (continued)

Alarm Type: Critical			
Alarm Signal	**Controller Message**	**What it Means**	**What action to take**
	[Connect Power] 	• The internal battery has limited time remaining or is unreliable.	• Change the external battery or connect the power cord • Contact your clinician

WARNING! IMMEDIATELY replace a controller that has a blank display and/or no audible alarms. It could indicate a controller failure.

WARNING! ALWAYS switch to the backup controller if there is a [Change Controller] alarm since the pump may not be running. Call your clinician.

For information on how to change the controller, see Section *4.7*.

4.4 Non-critical Alarms

When an alarm occurs that is not immediately critical to pump function, it is considered a non-critical alarm.

Non-critical alarms display on the controller screen with a **YELLOW** background, and the controller vibrates for ten (10) seconds prior to the first audible alarm. Pressing the touchscreen will prevent or mute audio alarms for a brief period or until an additional alarm occurs.

When experiencing a non-critical alarm, follow the instructions on the screen which may be to call your clinician. A non-critical alarm may resolve on its own without intervention.

When an alarm condition is resolved, it no longer displays on the controller screen but is stored in Alarm History. Up to ten (10) alarms, starting with the highest priority active alarms followed by the most recent resolved alarms, are stored in Alarm History at any given time. Alarms typical to normal use, such as [Connect Power], [Change Battery], and [Connect Cap or Battery] are not stored in Alarm History.

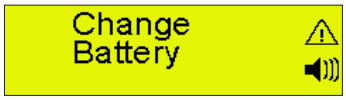
The controller screen instructs you to complete an action and/or to call a clinician for instructions. **Table 17** describes non-critical alarms and their meaning.

4.4 Non-critical Alarms (continued)

Table 17: Non-critical Alarms

Screen Display Color	Controller Message	What it Means	What action to take
Solid YELLOW back light **Flashing alert symbol** **Periodic beep with escalating volume and vibration** **Able to mute alarm**	**[Plug In Power Cord]** 	• Disconnecting external battery without a power cord connected could risk pump stop • The internal battery has limited time remaining, is unreliable, disconnected or has failed AND • The external battery has less than 30 minutes runtime remaining or Is unreliable	• Connect the power cord to the controller. • DO NOT disconnect the external battery before connecting the AC or DC power adapter. • Contact your clinician. Mute option: Two 5-minute mutes, then cannot be muted
	[Keep Power Connected] 	• Disconnecting external power could risk pump stop. • The internal battery has limited time remaining, is unreliable, or has failed.	• DO NOT disconnect the external power. • If the external battery needs to be changed, connect the power cord first. • If the alarm has not resolved in one (1) hour, contact your clinician. Mute option: 5 minutes
	[Electrical] 	• A fault in the normal operation of the pump-to-controller electrical connection.	• DO NOT change the controller • Check the pump cable and the connections for obvious damage. • Contact your clinician. Mute option: 15 minutes
	[Technical] 	• Controller component or power source malfunction.	• Contact your clinician. Mute option: 15 minutes
	[High Power] 	• The pump power exceeds the alarm threshold setting.	• Contact your clinician. Mute option: 15 minutes
	[Low Flow] 	• The pump flow exceeds the alarm threshold setting.	• Contact your clinician. Mute option: 15 minutes

4.4 Non-critical Alarms (continued)

Screen Display Color	Controller Message	What it Means	What action to take
Solid YELLOW back light  Flashing alert symbol Periodic beep with escalating volume and vibration Able to mute alarm	[Suction] 	• A potential obstruction to pump flow has been detected	• Contact your clinician. Mute option: 15 minutes
	[Connect Power] 	• No external power source is connected (for at least twenty (20) seconds).	• Connect the power cord or a charged external battery Mute option: Two 5-minute mutes, then cannot be muted
	[Termperature] 	• The controller's temperature is out of recommended range.	• Move the controller to a room temperature environment and wait for the controller to return to normal temperature. • If the alarm persists for one (1) hour, contact your clinician. Mute option: 15 minutes
	[Change Battery] 	• External battery has fifteen (15) minutes or less time remaining.	• Change the external battery OR • Connect the AC or DC power adapter to the controller. Mute option: 15 minutes.
	[Connect Cap or Battery] 	A PAL™ Cap or external battery is not connected to the controller.	• Attach the PAL™ Cap or an external battery to the controller to protect it from dust, dirt, fluids, or electrical interference. Mute option: 15 minutes

4.5 Multiple Alarms

It is possible to have simultaneous alarm conditions. For multiple alarms, the screen will display the color and sound of the most severe alarm. A down arrow ↓ symbol is displayed on the left side of the controller screen to indicate there are multiple active alarms. Press the center of the screen to cycle through the non-critical alarms.

Figure 83: Controller screen displaying multiple alarms

Table 18: Multiple Alarms

Alarm Indicator and Alarm Sound for Multiple Alarms		
Multiple Alarm Condition	**Controller Screen**	**Alarm Sound**
Multiple alarms with at least one (1) critical alarms	**Flashing RED**	Loud, continuous, unable to mute
Multiple non-critical alarms	**YELLOW**	Gradual increase in volume if alarm NOT muted

Note: When an alarm of higher importance is resolved, the audible and vibratory signal pattern for any active alarms of lower priority will restart.

4.6 How to Mute Alarms

Critical alarms CANNOT be muted. However, non-critical alarms can be muted for five (5) or fifteen (15) minute intervals by pressing anywhere on the controller screen. The vibration precedes the audio of the alarm for a few seconds allowing you to mute the alarm before the audio begins. Muting an alarm pauses the audio and vibration.

The alarm will sound again if a new alarm condition occurs during the mute interval. Again, the vibration will precede the audio of the alarm.

For additional information about the mute duration of non-critical alarms, see *Table 17: Non-critical Alarms* in Section *4.4*.

WARNING! ALWAYS investigate, and if possible, correct the cause of any alarm. Muting a non-critical alarm does not resolve the alarm condition and may lead to suboptimal therapy.

4.7 Changing to the Backup Controller

Steps to changing the Controller

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

WARNING! ALWAYS have a backup controller and fully-charged spare external batteries available at all times in case of an emergency.

WARNING! IMMEDIATELY replace a controller that has a blank display and/or no audible alarms. It could indicate a controller failure

A controller failure or serious controller malfunction will generate a critical alarm and [Change Controller] will display on the screen.

When doing a controller exchange, the priority is to restart the pump quickly. It may be helpful to remember the following:

POWER... Connect a power source to the backup controller.

PUMP..... Restart the pump by connecting the pump cable (driveline) to the new controller.

Steps to changing the Controller:

1. Sit or lie down and place the new (backup) controller within easy reach.	  Figure 84: Sit or lie down
2. Remove the PAL™ Cap on the backup controller by pressing the battery release button on the controller.	 Figure 85: Press button to remove the cap
3. Insert the tabs of the charged battery into the opening on the battery connector. Pivot the battery to snap it into the backup controller.	 Figure 86: Insert tabs

4.7 Changing to the Backup Controller (continued)

Changing to the Backup Controller: (continued)

4. Disconnect the pump cable from the original controller and connect the pump cable to the new controller. This will restart the pump.

   Note: It is normal and expected that the original controller will have a new critical [Connect Pump Cable] alarm displayed if it did not already have a critical alarm.

Figure 87: Disconnect the pump cable

Disconnecting the pump cable (driveline) from the Controller:

1. Slide the cover of the pump cable towards the controller to reveal the whole silver connector.

Figure 88: Slide the cover of the pump cable

2. Grasp the pump cable below the connector with one hand, avoiding the grooved area as shown in **Figure 89**.

Figure 89: Grasp the pump cable

3. With the index finger and thumb of the same hand, pinch the grooved area of the pump cable connector.

Figure 90: Pinch the grooved area of the pump cable connector

4. With the other hand, pinch the grooved area of the controller Coiled Cable connector.

Figure 91: Pinch the grooved area of the controller Coiled Cable connector

4.7 Changing to the Backup Controller (continued)

Disconnecting the pump cable (driveline) from the Controller: (continued)

5. Release the locking mechanism by pulling the controller Coiled Cable connector away from the pump cable connector.

   Note: Only pull on the grooved area of the connectors. If any other area of the cable or connector is pulled back, the cable will not release from the controller.

Figure 92: Release the locking mechanism

Connecting the pump cable (driveline):

1. Align the red dot on the pump cable connector with the red line on the controller Coiled Cable connector.

Figure 93: Align the red line with the red dot

2. Push the pump cable connector straight into the port until there is a click.

   Note: To ensure proper connection, verify that the pump is running. If the pump is running, there will be a heart ♥ symbol displayed on the controller screen.

Figure 94: Push the connector into the port

3. Slide the cover of the pump cable over the connectors until the cover is securely in place.

Figure 95: Slide the cover over connectors

4. Use the Elective Shutdown procedures in **Section 4.8** to shut down the original controller.

WARNING! ALWAYS check for a click when connecting the pump cable (driveline) to the controller. Failure to ensure a secure connection may lead to a pump stop.

WARNING! DO NOT attempt to repair, service, or modify any component of the HVAD System as this may damage the component. If the equipment malfunctions, contact your clinician

4.7 Changing to the Backup Controller (continued)

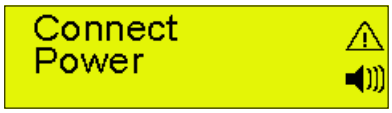
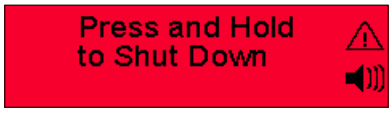
CAUTION: DO NOT pull, kink, or twist the pump cable (driveline) or the power cables, as these actions may damage the cables. Special care should be taken not to twist the pump cable (driveline) while sitting, getting out of bed, adjusting the controller or the power sources, or when using the HeartWare™ Shower Bag.

CAUTION: DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.

For additional information on alarms, see Tables in Section *4.3* and Section *4.4*.
For additional information on making good connections, see Section 3.3.

4.8 Elective Shutdown

Perform an elective shutdown to turn the controller off using the following procedures.

Follow these procedures:	When you see these screen alarm messages:
1. Disconnect all external power sources from the controller. **Note:** A [Connect Power] message will appear, which will progress to an audible non-critical [Connect Power] alarm after twenty (20) seconds.	 
2. Disconnect the pump cable (driveline). **Note:** A critical [Connect Pump Cable] alarm will appear.	
3. Wait ten (10) seconds for the Elective Shutdown screen to appear	
4. Press and hold the screen for five (5) seconds. The bar at the bottom of the screen will shrink until the display shuts off.	
5. An hourglass briefly displays while the controller shuts down.	

Note: If any of these steps are not executed, the controller will continue alarming until the process is complete. To exit the shutdown, reconnect the pump and/or the power.

5.0 Preparing for Discharge

Before going home, your clinician will make sure you understand how to handle and care for your HVAD System, care for your exit site and know what to do in an emergency. They will also schedule follow up appointments for you.

5.1 Equipment Needed to Go Home

At the time of discharge from the hospital, be certain that all of the following equipment and accessories are available and have been checked for proper function.

- 1 Patient Manual
- 2 PAL™ Controllers (1 active, 1 backup)
- 2 PAL™ Controller AC Adapters (1 set is for the backup controller)
- 1 PAL™ Controller DC Adapter
- At least 4 PAL™ Batteries (combination of Single and Dual batteries)
- 2 PAL™ Caps
- 1 PAL™ Battery Charger
- 1 PAL™ Sport Pack
- 1 PAL™ Accessories Bag
- 1 HeartWare™ Shower Bag
- 2 Emergency Responder Guides
- 2 Patient ID Cards

5.2 Discharge Instructions

At the time of discharge from the hospital, be certain to follow the instructions below.

Daily Care

1. Change your VAD exit site dressing as directed by your clinician following the sterile technique taught to you while in the hospital. During dressing changes look for signs of infection, such as redness, swelling, drainage, odor, or pain. Call your clinician if you notice any of these symptoms.
2. Call your clinician if your VAD flow falls to less than ____ L/min, the power goes above _____ Watts or the speed changes by more than 100 RPM.
3. Call your clinician if your temperature is above ____ degrees.
4. Check your weight each morning and record it on your flow sheet. Call your clinician if you gain more than ____ pounds in one week.
5. Take and record your blood pressure as your clinician team instructed. Reducing blood pressure has been shown to reduce the risk of stroke. Your clinician will teach you how to check your blood pressure. Call your clinician if it is higher than _____.

Continued on next page

5.2 Discharge Instructions (continued)

6. Call your clinician if you notice any swelling in your ankles or changes in your girth. This may be a sign of water retention.
7. Notify your clinician if there is a change in how the VAD sounds or feels.
8. Record your VAD speed (RPM), power (Watts) and flow (L/min) as directed by your clinician.

Care of Equipment

1. Do NOT twist or kink your pump cable (driveline).
2. Keep all your VAD equipment in a dry, room temperature (around +72°F) environment. Store all unused equipment in your house. Be sure the equipment is stable if stored in closets or shelves. Dropping VAD components may lead to damage.
3. When not in use keep batteries plugged into the charger – the charger should always be plugged into an AC outlet.
4. If you have any questions about operating, cleaning or storing your VAD equipment, ask your clinician.
5. Do not try to repair or modify any of your VAD equipment.

Pain

By the time you are ready to go home, you should not be having much pain. You may be sent home with pain medication which should be taken as prescribed. If you experience an increase in pain or pain where you never had pain before, call your clinician.

Diet

1. Follow the diet suggested by the dietitian.
2. If you have diabetes, be aware that your diabetes medications may need to be adjusted after VAD implantation. Talk to your clinician about any changes that are needed.

Tobacco Products

If you smoke, you must quit smoking.

NOTE: Avoid second-hand smoke as it has negative effects on your blood vessels.

Alcohol

Alcohol can interfere or interact with certain medications and leads to dehydration. Alcohol can impair your ability to understand and react to system alarms.

Continued on next page

5.2 Discharge Instructions (continued)

Weather

1. Avoid activity in very hot or very cold temperatures.
2. If you go outdoors during very hot or humid weather, be sure to drink plenty of water or non-alcoholic beverages.
3. Protect your equipment against moisture during rainy conditions.

Limitations

1. Do NOT take baths, get in a hot tub, or go swimming while implanted with your VAD. After the VAD implant, while still in the hospital, you will receive instructions on the method and equipment needed for daily hygiene.
2. Do NOT drive a car or operate heavy machinery unless your clinician gives you permission.
3. Do NOT play contact sports or engage in any activity that may lead to stitches, trauma or broken bones while implanted with the VAD.

Miscellaneous

1. You are responsible for making sure that your surroundings continue to be safe. If you have any questions or concerns about your home environment, call your clinician.
2. Be familiar with the warnings and cautions associated with having a VAD and for safe HVAD System operation.

5.3 Patient and Caregiver Training

1. Match the definition to the picture:

Fill in your answers below:

____ Single Battery

____ Dual Battery

____ Controller

____ AC and DC Adapters

____ Battery Charger

2. Match the four connections of the PAL™ Controller:

Fill in your answers below:

____ External Battery Connection

____ AC/DC Power Cord Connection

____ Pump Cable (Driveline) Connection

____ Data Cable Connection

3. What are the different power configuration options under normal use conditions? Check all that apply.

☐ No external battery, PAL™ Cap, or AC/DC adapter connected

☐ External battery connected only

☐ PAL™ Cap connected only

☐ External battery and AC/DC adapter connected

☐ PAL™ Cap and AC/DC adapter connected

5.3 Patient and Caregiver Training (continued)

4. Identify the Controller State:

Fill in your answers below:

____ Ready State - The controller is on but not running a pump.

____ Running State - The controller is on and running a pump.

____ Off State - The controller is off and will not power the pump when connected.

a

b

c

5. Match the controller's power-related symbol description:

Fill in your answers below:

____ External or internal battery is fully charged

____ External or internal battery is not connected or is not found

____ External or internal battery is charging

____ External or internal battery no longer has a charge

____ Controller is connected to an AC or DC adapter

a. 

b. 

c. 

d. 

e. 

6. Match the controller's button symbol descriptions:

Fill in your answers below:

____ Button returns you to the Home screen

____ Button takes you to the Controller Information screens

____ Button takes you to the Alarm History screens

a. 

b. 

c. 

5.3 Patient and Caregiver Training (continued)

7. Match the controller's symbol descriptions:

Fill in your answers below:

____ Indicates that a setting is on

____ Indicates that a setting is off

____ Indicates multiple alarms are active

____ Indicates the date and time that an alarm began

____ Indicates the date and time an alarm was resolved

____ Indicates the clinician's phone number

____ Indicates that at least one alarm is active

____ Indicates that an alarm is sounding

____ Indicates that an alarm is muted

a. 

b. 

c. 

d. 

e. 

f. 

g. 

h. 

i. 

8. The VAD Status Screen gives pump information such as:

Match the definition of the items:

Fill in your answers below:

___ Pump operating power

___ Blood flow

___ Pump speed

a. RPM

b. Watts

c. L/min

9. How long can one Single Battery provide power for?

5.3 Patient and Caregiver Training (continued)

10. How long can one Dual Battery provide power for?

11. When looking at the battery capacity display, how much power is available in a battery if there are:

4 green lights _____

3 green lights _____

2 green lights _____

1 yellow light _____

12. On the battery charger there are several battery status light indicators. Check which status light you will see if the battery is charging.

- ☐ Solid Red
- ☐ Flashing Red
- ☐ Solid Green
- ☐ Flashing Green
- ☐ No lights

13. When an alarm occurs, <u>check all</u> the indicators that you should look for to determine the severity of the alarm.

- ☐ A unique sound
- ☐ Visual display (Solid Yellow or Flashing Red)
- ☐ Vibration
- ☐ A message

5.3 Patient and Caregiver Training (continued)

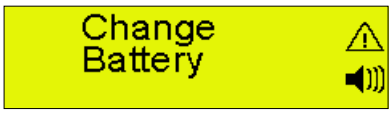
14. Circle True or False for the following:

1. Critical alarms can be muted	True	False
2. Muting an alarm resolves the alarm condition	True	False
3. These are all things that should be reported right away to your clinician:		
a. You have dropped and/or damaged any of your equipment.	True	False
b. Pressing a flashing **i** button on your Home screen leads you to an Internal Battery or External Battery screen with your clinician's phone number.	True	False
c. Any non-critical alarm that displays "Call Clinician" or the clinician contact phone number.	True	False
d. You just completed an emergency controller exchange.	True	False

15. How would you respond to a 

alarm on your controller display?

16. Your controller displays the following information; what is the correct immediate response?



- ☐ Do nothing, this is normal activity
- ☐ Change the external battery
- ☐ Change the controller
- ☐ Call your clinician

17. Your controller displays the following information; what is the correct immediate response?

- ☐ Do nothing, this is normal activity
- ☐ Change the external battery
- ☐ Change the controller
- ☐ Call your clinician

5.3 Patient and Caregiver Training (continued)

18. Check the activities that could cause the HVAD Pump to stop:

- ☐ Disconnecting an external battery during a 

alarm.
- ☐ Exchanging external batteries when no AC/DC adapter is connected and the controller is running normally.
- ☐ Disconnecting the pump cable (driveline) from the controller.
- ☐ Disconnecting all external power during a 

alarm.
- ☐ Disconnecting AC/DC power and then swapping the PAL™ Cap for an external battery while the controller is running normally

19. When preparing to go to bed at night, which of the following are acceptable power configurations?

- ☐ No external battery, PAL™ Cap, or AC/DC adapter connected
- ☐ External battery connected only
- ☐ PAL™ Cap connected only
- ☐ External battery and AC/DC adapter connected
- ☐ PAL™ Cap and AC/DC adapter connected

20. List six (6) items you should have with you when you leave your house:

21. Check the activities that are not allowed while on the HVAD Pump:

- ☐ Chest x-ray
- ☐ MRI xcan
- ☐ CT xcan
- ☐ Cardiac catheterization
- ☐ Swimming
- ☐ Walking

5.3 Patient and Caregiver Training (continued)

22. To minimize the risk of interference (electrostatic discharge) to your controller due to static electricity, which of the following should you avoid? Check all that apply.

- ☐ Putting your controller in a silk bag
- ☐ Using dryer sheets when doing laundry
- ☐ Using a humidifier in your home
- ☐ Touching the CRT TV screen while it is on
- ☐ Touching exposed metal pins of a connector or port
- ☐ Attaching the dust cover
- ☐ Ensuring that the pump cable (driveline) cover is securely positioned over the pump cable (driveline) connector
- ☐ Ignoring a 

alarm

23. List five (5) signs or symptoms of a pump cable (driveline) exit site infection:

24. Why do you take blood thinner medicine?

5.3 Patient and Caregiver Training (continued)

25. Circle True or False for the following:

1. A flashing red alarm requires immediate attention.	True	False
2. It is OK to have moisture, cracks, tears or punctures in your pump cable.	True	False
3. It is safe to take a tub bath or swim.	True	False
4. This flashing **i** symbol on the Home screen indicates pertinent information such as battery end of life.	True	False
5. Pushing the screen to mute an alarm resolves the alarm condition.	True	False
6. A connected controller with a blank display and no audible alarm should be replaced.	True	False
7. When an alarm occurs the Controller Display tells you which alarm is occurring and what to do.	True	False
8. This symbol  will indicate proper connection to an electrical outlet or a car power port.	True	False
9. When there is a  alarm, you should switch to the backup controller.	True	False
10. The PAL™ Sport Pack can be worn around the waist or torso.	True	False
11. It is safe to keep your PAL™ Controller under a thick or thermal (hypothermia) blanket at night.	True	False
12. It is never safe to disconnect your external battery during the following alarm. 	True	False

6.0 Living with the HeartWare™ HVAD™ System

6.0 Living with the HeartWare™ HVAD™ System

People who receive a VAD may notice an improvement in symptoms beginning in the hospital and will continue to get stronger in the weeks following surgery. However, adjusting to living with a VAD may take time. This manual provides some information about living with your HVAD System. Call your clinician if you have any questions about activities not included in this manual.

WARNING! DO NOT become pregnant while you have the HVAD System. If you are a woman of childbearing age, use birth control if you are sexually active. Blood thinners (which most VAD patients receive) have been associated with birth defects. If you do become pregnant, tell your clinician immediately.

WARNING! ALWAYS check the controller display for information regarding an alarm when using loud machinery, or near loud noises, as the alarms may not be audible.

WARNING! DO NOT undergo a magnetic resonance imaging (MRI) procedure while implanted with the HVAD System. Doing so could harm you or cause the pump to stop.

WARNING! DO NOT undergo procedures requiring high power electrical treatment while the pump is implanted. High power electrical treatments are typically prescribed for joint conditions such as rheumatoid arthritis and osteoarthritis and use high frequency electrical current to produce deep heat inside the body intended to decrease inflammation and pain. Consult your clinician before having any deep tissue heating procedure.

WARNING! AVOID exposure to therapeutic levels of ultrasound energy. Consult your clinician before having lithotripsy procedures to treat kidney stones or any treatments involving high intensity ultrasound. The implanted device may inadvertently concentrate the ultrasound field and cause harm.

WARNING! AVOID therapeutic ionizing radiation. Consult your clinician before having any nuclear medicine procedures or radiation therapy for cancer. Radiation may damage the device and may not be immediately detectable.

WARNING! ALWAYS connect an AC adapter to the controller before relaxing or sleeping. Power from an electrical outlet (AC adapter) provides power for an unlimited period of time.

CAUTION: DO NOT play contact sports. You may start bleeding or could damage your equipment.

CAUTION: DO NOT expose the pump cable (driveline) to direct or indirect sunlight. ALWAYS keep the pump cable (driveline) completely covered when in the sun. DO NOT use tanning lights or black lights. The light from these sources may damage the outer covering of the pump cable (driveline).

6.1 Medications

Talk with your clinician about your medications. Get an explanation of the purpose of each medication that your doctor prescribes for you. Write down the medication and how often you need to take it and ask your doctor to check the list to make sure it is correct. Talk with your clinician about what you should do if you accidentally forget to take your medicine. Discuss what to do for each medicine because it may be different for each one. You may also want to make a list of medications that you should not take. Some non-prescription medications and natural supplements may react with your prescribed medications.

You are probably taking blood thinner medication to thin your blood and reduce the risk of clot formation (anticoagulation) in your blood or pump. It is very important that you take this medication as prescribed and that you have your blood checked frequently to be sure that you are receiving a dose that is not too high (blood too thin) or too low (blood too thick).

You may notice bleeding as a result of your medication. If you are unsure whether the bleeding represents a problem, it is best to call your clinician.

Note: You should always remain on your anticoagulation dose schedule as written or as told to you by your clinician.

6.2 Electrostatic Discharge (ESD) Prevention

What is Electrostatic Discharge (ESD)?

Electrostatic discharge (ESD) is the sudden transfer of electricity from one object to another. It is most noticeable in dry environments and near certain materials such as silk and carpeting. A mild shock to your skin will not affect your controller. However, ESD to the controller or its connectors may cause your controller to function improperly.

WARNING! AVOID devices and conditions that may induce strong static discharges (e.g., close vicinity to television or computer monitor screens) as electrostatic discharges can damage the electrical parts of the system and cause the pump to perform improperly or stop.

WARNING! ALWAYS have a backup controller and fully-charged batteries available and, whenever possible, a caregiver nearby when changing power sources or controllers in case unusual alarms occur.

6.2 Electrostatic Discharge (ESD) Prevention (continued)

Electrostatic discharge (ESD) damage to the controller can cause:

1. A non-critical [Technical] alarm
2. An audible alarm without accompanying alarm text on the controller display

If any of these alarms occur, contact your clinician.

For additional information about alarms, see Section *4.0*.

Reducing the chance of ESD damage to the controller:

1. Make safe, secure connections when changing power sources
   - **Avoid Contacting Connectors** -- Do not touch the controller connector ports, or let foreign objects or materials come near a disconnected controller power port.
   - **Change Power Sources Quickly** -- Have new external battery within reach before disconnecting power source and when possible, have a caregiver nearby in case an alarm occurs.
   - **Do Not Expose Connectors** -- Only leave power source ports on the controller open for the time it takes to change the power sources.

Refer to making connections for additional information, see Section *3.3*.

2. Be careful near materials and electronic devices prone to static electricity, such as: carpeted floors, silk clothing, CRT TV screens, microwaves when in operation, and laptop or CRT computer screens.
   - Avoid changing power sources near the above materials and electronic devices.
   - Avoid vacuuming.
   - Avoid removing clothes from the dryer.
   - Use anti-static dryer sheets and fabric softener.
   - Recommend using a humidifier in your house.

6.3 Exit Site Care

Proper care of your skin around the pump cable (driveline) exit site is very important to prevent infection in this area. Prior to leaving the hospital, your clinician will explain and demonstrate proper care of the exit site. One of the most important measures you can take to prevent exit site infections is to protect the pump cable from excessive movement. Take care not to pull on the pump cable or get it caught on objects where the result may be sudden pulling or yanking.

The dressing around your exit site should be changed according to your clinician's instructions. Always thoroughly wash your hands with soap and water prior to any dressing change. Always use sterile technique with every dressing change. General guidelines include:

1. Obtain all necessary materials.
2. Wash your hands thoroughly.
3. Remove dressing.
4. Observe exit site for redness, swelling, drainage, odor, or pain.
5. Open new dressings.
6. Use sterile gloves.
7. Cleanse the exit site with saline solution or other agent (start close to the pump cable and then move away).
8. Apply sterile dressings.
9. Place any excess pump cable (driveline) length under an abdominal binder or dressing or keep it secured close to the body underneath clothing.

CAUTION: DO NOT pull, kink, or twist the pump cable (driveline) or the power cables, as these actions may damage the cables. Special care should be taken not to twist the pump cable (driveline) while sitting, getting out of bed, adjusting the controller or the power sources, or when using the HeartWare™ Shower Bag.

CAUTION: ALWAYS keep extra pump cable (driveline) length placed under clothing or secured with an abdominal binder or dressing. Do not let any portion of pump cable (driveline) hang freely where it might get caught on external items such as doorknobs or the corners of furniture.

CAUTION: ALWAYS notify your clinician promptly if there is drainage, swelling or reddened skin around the pump cable (driveline) exit site. These may indicate an infection.

CAUTION: DO NOT use prophylactic topical antibiotic ointments such as silver sulfadiazine, povidone iodine (betadine), or polymyxin-neomycin-bacitracin ointment on your exit site. These ointments can injure the tissue next to your pump cable (driveline).

CAUTION: ALWAYS examine the pump cable (driveline) for evidence of tears, punctures or breakdown of any of the material during exit site dressing changes. Report any damage to your clinician.

CAUTION: ALWAYS notify your clinician promptly, if you notice blood or fluid in the pump cable (driveline). The section of the driveline inside your body may have been damaged during pump implantation or during another operation. The pump cable (driveline) has built-in features that minimize the effect of blood or fluid entering it, so the HVAD Pump should continue to operate normally. However, your clinician should examine the pump cable (driveline) to fully evaluate the situation.

6.4 Washing and Showering

Your clinician will let you wash your incisions after your wounds have healed. When you wash, the controller, batteries and connectors must be protected from water and you should take care so that water does not run along the pump cable into the controller. The exit site should also be kept as dry as possible. Keeping the exit site dry helps avoid infections.

Your clinician will decide if it is safe for you to shower. If your clinician gives you permission to shower, you must use the HeartWare™ Shower Bag to protect the controller and batteries.

WARNING! DO NOT shower until your clinician tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare™ Shower Bag.

WARNING! If your hearing is impaired and/or you cannot hear the controller alarms without the use of a hearing aid, make sure your caregiver will be close by to hear alarms.

WARNING! DO NOT plug the controller into an AC electrical outlet during showers; to eliminate the possibility of a severe electrical shock, the controller should only be connected to an external battery.

WARNING! DO NOT take a bath or swim as this may damage the system components and/or result in pump cable (driveline) exit site infection.

WARNING! DO NOT submerge any HVAD System component in water, as this may damage the component. If this happens, contact your clinician.

WARNING! DO NOT allow water or other fluids to enter the controller, power cords, batteries, battery charger or connectors, as this may damage the HVAD System components. If equipment is damaged, contact your clinician.

CAUTION: DO NOT place batteries in water or any other liquid as this may damage them.

For instructions on shower bag use, see Section *3.6.3*.

The HVAD System steps to a successful dressing change reference is available from your clinician.

6.5 Leaving the House

During daily living, you may leave the house for extended periods of time. When you leave your house, make sure you have the following equipment with you:

- Backup controller
- Additional charged batteries
- AC adapter
- DC adapter (if traveling in vehicle)
- Emergency Responder Guide
- Patient ID Card

Whenever you leave your house on a short trip such as running errands, in addition to what you are currently using, you should bring the following equipment as backup:

- 1 backup PAL™ Controller
- 1 PAL™ Controller AC Adapter or DC Adapter
- 2 PAL™ Batteries (1 Single and 1 Dual)
- 1 PAL™ Accessories Bag
- 1 Emergency Responder Guide
- 1 Patient ID Card

Figure 96: Packed PAL™ Accessories Bag

WARNING! ALWAYS have a backup controller and fully-charged spare external batteries available at all times in case of an emergency.

WARNING! ALWAYS have a backup controller and fully-charged batteries available and, whenever possible, a caregiver nearby when changing power sources or controllers in case unusual alarms occur.

WARNING! DO NOT operate the controller in temperatures less than -5°C (+23°F) or greater than +40°C (+104°F) or the controller may fail.

CAUTION: ALWAYS check to be sure the DC adapter works in your motor vehicle. The DC adapter is for use in motor vehicles only and may not fit all motor vehicles.

6.6 Traveling and Transport

As you resume activities of daily living, you may wish to travel. Prior to making travel plans, talk with your clinician to make sure it is safe for you to travel. Once you are approved for travel, your clinician will work with you to ensure you are prepared for traveling safely. Always remember to take all prescribed medication with you and make sure you have your emergency contact information.

When you travel, make sure you have the following:

- Backup controller
- Fully-charged, additional batteries
- Battery charger
- AC adapter
- DC adapter

Equipment should be kept with you at all times for safety and security. If traveling by air, carry equipment with you on board the aircraft.

Note:

- Store and operate all equipment within the recommended temperature conditions listed in the WARNINGS and CAUTIONS section of this manual.
- Avoid passing through security screening equipment, as this may affect your VAD. Instead, request to be hand-screened with special care given to the pump cable exit site.
- If you are traveling on a long-haul flight, talk with your clinician about whether you should purchase extra batteries.
- If traveling internationally, talk with your clinician about purchasing international power adapters for use with your equipment.

WARNING! AVOID areas with high magnetic forces such as theft detection devices or airport security systems, as these may affect the HVAD System operation.

WARNING! DO NOT operate the controller in temperatures less than -5°C (+23°F) or greater than +40°C (+104°F) or the controller may fail.

WARNING! ALWAYS have a backup controller and fully-charged spare external batteries available at all times in case of an emergency.

CAUTION: ALWAYS check to be sure the DC adapter works in your motor vehicle. The DC adapter is for use in motor vehicles only and may not fit all motor vehicles.

CAUTION: DO NOT expose external batteries to temperatures less than -5°C (+23°F) or greater than +40°C (+104°F) or the battery may run the pump for less time than usual. To preserve battery life, batteries should be stored at room temperature.

7.0 Caring for HeartWare™ HVAD™ System Equipment

7.1 Recommended Storage and Operating Conditions

The following table shows the recommended storage and operating conditions for each of the PAL™ components.

Table 19: Recommended Storage and Operating Conditions

Component	Temperature Range	Relative Humidity	Atmospheric Pressure
PAL Controller (including Internal Battery)	Full Operating: +10 to +30°C (+50 to +86°F) *Extended Operating: -5 to +40°C (+23 to +104°F)	Operating: 15% to 95%	Operating: 700 to 1060 hPa
	Storage and Transport: -20 to +45°C (-4 to +113°F)	Storage and Transport: 10% to 95%	Storage and Transport: 500 to 1060 hPa
PAL Controller AC and DC Adapter	Operating: -5 to +40°C (+23 to +104°F)	Operating: 15% to 95%	Operating: 700 to 1060 hPa
	Storage and Transport: -40 to +70°C (-40 to +158°F)	Storage and Transport: 10% to 95%	Storage and Transport: 500 to 1060 hPa
PAL External Battery	Operating: -5 to +40°C (+23 to +104°F)	Operating: 15% to 95%	Operating: 700 to 1060 hPa
	Storage and Transport: -20 to +45°C (-4 to +113°F)	Storage and Transport: 10% to 95%	Storage and Transport: 500 to 1060 hPa
PAL Battery Charger	Operating: +5 to +40°C (+41 to +104°F)	Operating: 15% to 95%	Operating: 700 to 1060 hPa
	Storage and Transport: -40 to +70°C (-40 to +158°F)	Storage and Transport: 10% to 95%	Storage and Transport: 500 to 1060 hPa

Do not store Medtronic equipment in an area exposed to ultraviolet light.
The device label details the environmental condition limits under which the device should be operated.
*Full versus Extended Operating: Extended Operating does not support battery charging functionality and nominal battery runtime.

7.2 Equipment Care

CAUTION: AVOID placing the controller in the following conditions to prevent harm from excessive heat:

- Between the legs when sleeping or sitting.
- Under the body while sleeping or sitting.
- Under covers in a warm room.
- In a heated room (e.g., sauna, steam room, hot yoga class, etc.).
- Under a thick or thermal (hypothermia) blanket.
- Under a heat lamp.
- In direct sunlight.

CAUTION: ALWAYS keep all connectors free of liquid, dust and dirt, or the HVAD System may not function as intended.

CAUTION: DO NOT expose the pump cable (driveline) to direct or indirect sunlight. ALWAYS keep the pump cable (driveline) completely covered when in the sun. DO NOT use tanning lights or black lights. The light from these sources may damage the outer covering of the pump cable (driveline).

WARNING! DO NOT use any components other than those supplied by Medtronic with the HVAD System, as this may affect the HVAD System operation.

WARNING! DO NOT disconnect the pump cable (driveline) from the controller while cleaning it or the pump will stop. If this happens, reconnect the pump cable (driveline) to the controller IMMEDIATELY to restart the pump.

WARNING! DO NOT drop the controller or other equipment. Dropping the controller may cause sudden stoppage of the pump. Dropped equipment should be reported to your clinician.

WARNING! DO NOT use damaged equipment as it could lead to patient harm. If equipment is damaged, contact your clinician.

WARNING! DO NOT attempt to repair, service, or modify any component of the HVAD System as this may damage the component. If the equipment malfunctions, contact your clinician.

For information on electrostatic discharge (ESD), see Section *6.2*.

7.2.1 Controller Care

Inspecting Controller

Once a week:

Inspect your controller power connections and connector pins for dirt. This inspection can be done while you are changing batteries or using the AC adapter. DO NOT disconnect the pump to examine the percutaneous lead/controller connection. This connector should be inspected only during a supervised controller exchange. Do not attempt to clean the controller connectors; you should contact your clinician if you notice that the connectors are dirty.

Cleaning Controller

Periodically or as needed:

Exterior surfaces of the controller should be cleaned using a soft, clean cloth. A damp cloth may be used but a wet cloth should not be used. Clean the controller gently; avoid hard rubbing.

The controller may be cleaned with the following agents:

- Alcohol (Isopropyl 90% or Ethyl 70%).
- Hydrogen peroxide solution (1.4%).
- n-Alkyl Dimethyl Dibenzyl Ammonium Chloride combined with n-Alkyl Dimethyl Ethybenzyl Ammonium Chloride (active agent in some disinfecting wipes).
- UV-C disinfecting wand, one that radiates “short wave” UV-C band rays (100 to 280 nanometers) from a 4-watt bulb (or stronger).
- Diluted bleach solution (8.25% bleach solution diluted 1:10 with water, or equivalent, resulting in a 0.825% sodium hypochlorite concentration)

WARNING! DO NOT drop the controller or other equipment. Dropping the controller may cause sudden stoppage of the pump. Dropped equipment should be reported to your clinician.

WARNING! DO NOT disconnect the pump cable (driveline) from the controller while cleaning it or the pump will stop. If this happens, reconnect the pump cable (driveline) to the controller IMMEDIATELY to restart the pump.

7.2.1 Controller Care (continued)

Internal Battery Replacement Notification

When the Controller internal battery needs replacement, typically occurring after eighteen (18) months of use, the controller will notify you, via the internal battery status screen (see **Figure 98**), to call your clinician. The notification means the controller internal battery is nearing its end of life (EOL) and that it should be replaced. You should communicate to your clinician that the notification occurred. The internal battery has a limited lifespan of eighteen (18) months from the date of first use.

Figure 97: EOL Home screen

Figure 98: EOL internal battery status screen

The Controller will notify you via the flashing information **i** symbol on the Home screen (**Figure 97**). The Internal Battery Status screen will include the clinician's phone number (**Figure 98**) when it is time to replace the internal battery.

7.2.2 External Batteries Care

Your batteries include many features to make them safe and dependable. However, you must care for them properly. The following information will ensure that your external batteries are kept at optimal functionality:

- To preserve battery life, batteries should be stored at room temperature.
- Protect batteries from extreme high and low temperatures. Avoid storage in direct sunlight.
- Protect the battery connectors from moisture, dirt and metal at all times.
- AVOID touching the inside of the connectors.
- DO NOT drop the batteries or let them hit hard objects.
- DO NOT let batteries get wet.
- DO NOT force the battery connection to the controller or to the battery charger.
- Batteries should be stored in the battery charger. Store batteries fully charged.
- Rotating use of batteries will allow all batteries to age at a similar rate so no battery has significantly fewer charge cycles than the others.
- Bring all batteries to clinic visits.

WARNING! NEVER clean the battery charger when it is connected to an electrical outlet, as this may lead to an electrical shock.

7.2.2 External Batteries Care (continued)

CAUTION: DO NOT expose external batteries to temperatures less than -5°C (+23°F) or greater than +40°C (+104°F) or the battery may run the pump for less time than usual. To preserve battery life, batteries should be stored at room temperature.

CAUTION: ALWAYS keep HVAD System components away from children and pets. Children and pets may cause damage to or be harmed by damaged components. If damage to equipment results, contact your clinician.

CAUTION: DO NOT disassemble, crush, or puncture a battery to avoid personal injury and battery damage.

CAUTION: DO NOT use damaged batteries as it may lead to interrupting VAD therapy. Dispose of batteries according to federal, regional, and local regulations.

CAUTION: DO NOT short circuit the external contacts on a battery as this may result in battery damage.

CAUTION: DO NOT touch the fluid if a battery pack is leaking 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 fifteen (15) minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention. Dispose of batteries according to federal, regional, and local regulations.

CAUTION: DO NOT expose external batteries to excessive shock or vibration as this may affect battery operation.

CAUTION: DO NOT dispose of batteries in fire or water. Dispose of batteries according to federal, state, and local regulations.

Inspecting Batteries

Once a week: Inspect batteries and connectors for physical damage. DO NOT use batteries that appear damaged. Damaged batteries must be replaced. Bring all batteries to clinic visits.

Cleaning Batteries

Periodically or as needed:

Batteries may be cleaned periodically to remove dirt and debris. Use a soft, clean cotton cloth with a cleaning agent (see list below for options) in a circular motion for a minimum of twenty (20) seconds. Clean the battery gently; avoid hard rubbing.

The Batteries may be cleaned with the following agents:

- Alcohol (Isopropyl 90% or Ethyl 70%).
- Hydrogen peroxide solution (1.4%).
- n-Alkyl Dimethyl Dibenzyl Ammonium Chloride combined with n-Alkyl Dimethyl Ethybenzyl Ammonium Chloride (active agent in some disinfecting wipes).
- UV-C disinfecting wand, one that radiates “short wave” UV-C band rays (100 to 280 nanometers) from a 4-watt bulb (or stronger).
- Diluted bleach solution (8.25% bleach solution diluted 1:10 with water, or equivalent, resulting in a 0.825% sodium hypochlorite concentration)

7.2.2 External Batteries Care (continued)

Note: The Batteries are expected to have a useful operating service of 500 charge and discharge cycles in which the battery can reach at least 70% of full capacity; this should provide patient support for two years. Batteries that reach the end of life should be replaced.

CAUTION: DO NOT place batteries in water or any other liquid as this may damage them.

Replace an External Battery

When the external battery needs replacement, typically occurring after 500 charge and discharge cycles, the controller will notify you, via the external battery information screen, to call your clinician. The notification means the external battery has reached its end of life (EOL) and that the external battery should be replaced and removed from service immediately. You should call your clinician and let them know that the notification occurred and which battery needs replacement.

Figure 99: EOL Home screen

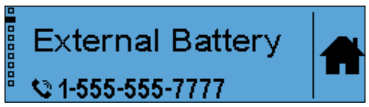


Figure 100: EOL external battery status screen

The Controller will notify you when it is time to replace the external battery via the flashing information **i** symbol on the Home screen (**Figure 99**). The External Battery Status information screen will include the clinician's phone number (**Figure 100**).

7.2.3 Battery Charger Care

Inspecting Battery Charger

Once a week:

- Inspect the battery charger for signs of physical damage, such as dents, chips, or cracks. DO NOT use the battery charger if it shows signs of damage. Contact your clinician for a replacement.
- Inspect the power cord used to connect the battery charger to an electrical outlet. Make sure the cord is not kinked, split, cut, cracked, or frayed. DO NOT use the cord if it shows signs of damage. Contact your clinician for a replacement.

Cleaning Battery Charger

Periodically or as needed:

To clean the battery charger, remove the batteries and unplug the battery charger from the electrical outlet. Clean the exterior surface of the battery charger to remove dirt and debris. Use a soft, clean cotton cloth with a cleaning agent (see list below for options) in a circular motion for a minimum of twenty (20) seconds. AVOID placing the battery charger in water or liquid. Clean the battery charger gently; avoid hard rubbing.

The Battery Charger may be cleaned with the following agents:

- Alcohol (Isopropyl 90% or Ethyl 70%).
- Hydrogen peroxide solution (1.4%).
- n-Alkyl Dimethyl Dibenzyl Ammonium Chloride combined with n-Alkyl Dimethyl Ethybenzyl Ammonium Chloride (active agent in some disinfecting wipes).
- UV-C disinfecting wand, one that radiates “short wave” UV-C band rays (100 to 280 nanometers) from a 4-watt bulb (or stronger).
- Diluted bleach solution (8.25% bleach solution diluted 1:10 with water, or equivalent, resulting in a 0.825% sodium hypochlorite concentration)

Note: Following cleaning it may be necessary to dry the battery charger. Use a dry cotton cloth on the exterior surfaces of the battery charger and ensure that the battery terminals in the bays of the battery charger are absent of visible fluid.

7.2.4 AC Adapter and DC Adapter Care

Cleaning the AC Adapter or DC Adapter

Periodically or as needed:

The adapters may be cleaned periodically to remove dirt and debris. Use a soft, clean cotton cloth with a cleaning agent (see list below for options) in a circular motion for a minimum of twenty (20) seconds. Clean the adapters gently; avoid hard rubbing.

The controller AC and DC adapters may be cleaned with the following agents:

- Alcohol (Isopropyl 90% or Ethyl 70%).
- Hydrogen peroxide solution (1.4%).
- n-Alkyl Dimethyl Dibenzyl Ammonium Chloride combined with n-Alkyl Dimethyl Ethybenzyl Ammonium Chloride (active agent in some disinfecting wipes).
- UV-C disinfecting wand, one that radiates “short wave” UV-C band rays (100 to 280 nanometers) from a 4-watt bulb (or stronger).

7.2.5 Carrying Cases Care

Cleaning the Sport Pack or Accessories Bag

Periodically or as needed:

The Sport Pack may be cleaned using a washing machine to remove dirt and debris, followed by air drying. Washing parameters include:

- Mild detergent
- Cold water
- Gentle laundry cycle

Note: The Sport Pack should be washed separate from other items. Ensure all Velcro®, zippers, and buttons on the Sport Pack are fastened together prior to washing to maintain durability.

Periodically or as needed: The Accessories Bag may be spot cleaned with a damp rag or towel to remove dirt and debris.

CAUTION: DO NOT use a machine for drying the carrying cases as it may accelerate the end of useful service. The carrying case should only be air dried.

7.2.6 Shower Bag Care

Keeping your shower bag clean will help ensure it works properly and lasts longer. It can be washed by hand using a mild detergent and cold water. Once the bag has been washed, allow it to air dry. Never heat the shower bag to dry it or place it in an electric or gas heated clothes dryer. Make sure your shower bag is completely dry before taking the next shower. Inspect your shower bag for damage or wear before each use. If you have problems or questions about your HeartWare™ Shower Bag, your clinician can assist you.

7.3 How Long HeartWare™ HVAD™ System Equipment Should Last

The PAL™ components were designed and tested to function for at least:

Table 20: Expected Useful Life

PAL Component	Expected Useful Life
HVAD Pump	at least 2 years
PAL™ Controller	at least 2 years
PAL™ Internal Battery	at least 1 year
PAL™ External Batteries (Single and Dual)	at least 2 years or 500 charge and discharge cycles
PAL™ Cap	at least 2 years
PAL™ Battery Charger	at least 2 years
PAL™ Controller AC Adapter or DC Adapter	at least 2 years
Carrying Cases (PAL™ Sport Pack, PAL™ Accessories Bag, and HeartWare™ Shower Bag)	at least 1 year

Note: Contact your clinician with any equipment questions or concerns.

WARNING! DO NOT drop the controller or other equipment. Dropping the controller could cause sudden stoppage of the pump. Dropped equipment should be reported to your clinician.

WARNING! DO NOT disconnect the pump cable (driveline) from the controller while cleaning it or the pump will stop. If this happens, reconnect the pump cable (driveline) to the controller IMMEDIATELY to restart the pump.

7.4 Product Disposal

Product disposal considerations for certain Medtronic-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 your clinician.

Medtronic Li-Ion battery cells DO NOT contain lead. Dispose of or recycle the Controller and Batteries in compliance with all applicable local, state, and federal laws and regulations. DO NOT incinerate.

Figure 101: Components containing Li-Ion batteries are marked with this symbol on the device label.

CAUTION: DO NOT dispose of batteries in fire or water. Dispose of batteries according to federal, state, and local regulations.

8.0 Appendix

8.1 Background Information

8.1.1 Heart Failure Overview and Considering VAD Therapy

If you have been diagnosed with heart failure, it does not mean your heart has stopped working; it means your heart is weak and as a result, cannot supply enough oxygen and nutrient-rich blood to your body's cells. Common symptoms of heart failure include fatigue and shortness of breath. Everyday activities like walking, climbing stairs, or carrying groceries can become very difficult. Heart failure also affects the kidneys' ability to dispose of waste and extra fluid. Fluid retained by the kidneys increases swelling. Heart failure is generally a chronic, progressive condition in which the heart weakens to the point in which it can no longer pump enough blood to meet the body's needs.

A Ventricular Assist Device (VAD) is a mechanical pump. When one of the heart's natural pumps (a ventricle) does not perform well, a VAD is used to increase the amount of blood that flows through the body.

Clinicians use VADs such as the HVAD System to treat patients with severe heart failure who have not improved despite using all other treatment methods available. The HVAD System can be used in patients both as a Bridge-to-Cardiac Transplantation and as Destination Therapy.

8.1.2 How to Decide if the HeartWare™ HVAD™ System is the Right Treatment for You

Only you, in consultation with your clinicians can decide if having the HVAD System is right for you. Your clinicians will talk with you about the potential benefits and risks of surgery and implantation of the HVAD System. Be sure to talk to your clinicians about any concerns or questions you may have. The HVAD System should not be used if you cannot take blood thinning medications.

WARNING! DO NOT become pregnant while you have the HVAD System. If you are a woman of childbearing age, use birth control if you are sexually active. Blood thinners (which most VAD patients receive) have been associated with birth defects. If you do become pregnant, tell your clinician immediately.

8.1.3 Indications for Use

The HVAD System is indicated for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a Bridge to Cardiac Transplantation (BTT), myocardial recovery, or as Destination Therapy (DT) in patients for whom subsequent transplantation is not planned.

8.1.4 Contraindications

The HVAD System is contraindicated in patients who cannot tolerate anticoagulation therapy.

CAUTION: Safety and effectiveness in persons less than 18 years of age and in persons with a BSA of less than 1.5 m2 have not been established.

CAUTION: The HVAD System has had limited use in patients with artificial mitral or aortic valves and therefore the risks are currently unknown. Caution should be used in selecting patients with artificial mitral or aortic valves for HVAD System therapy.

8.1.5 Summary of Clinical Study Information Using the HeartWare™ HVAD™ System

The HVAD System has been evaluated in patients with advanced heart failure in two clinical studies. The first clinical study was conducted in Europe and Australia. This study included 50 patients of which 90% successfully reached the study success point. The definition of success was:

- Being alive on the HVAD System for 180 days or
- Receiving a heart transplant within 180 days of having the HVAD Pump implanted or
- Having the HVAD Pump successfully removed after the patient's own heart recovered within 180 days of pump implant.

A second, larger bridge to heart transplantation study was performed in the United States. This study included 140 patients. Of the 140 patients who received the HVAD System as a bridge to heart transplantation in the United States, 91% reached the study success point. In both these studies, there were improvements in the patients' quality of life and their ability to better perform physical activities with at least 92% of the patients being able to return home after the HVAD System was placed inside the body.

The HVAD System was evaluated as a destination therapy in patients with advanced heart failure who are not on the list for a heart transplant in two additional clinical trials in the United States. These studies included over 900 patients; 2/3 of the patients received the HVAD System, and the other 1/3 received a different pump already approved for destination therapy. The primary endpoint for the first clinical trial was being alive at 2 years on support, without having experienced a severely disabling stroke or having to undergo urgent heart transplant or require surgery to change the heart pump for a new one due to problems with the original pump. A severely disabling stroke is a stroke that results in long-lasting, even permanent side effects that prevent you from being able to take care of yourself or perform everyday tasks without help. The first trial showed that in patients with advanced heart failure who were not on the list for a heart transplant, the HVAD System had similar primary outcomes as the other device available for destination therapy, and both devices resulted in similar improvements in the patients' quality of life and their ability to better perform physical activities. However, there were more overall strokes in patients who received the HVAD System, including more patients who also died as a result of a stroke. The second clinical study showed that managing patients' blood pressure may reduce the risk of these strokes.

Finally, a clinical study was performed to evaluate the use of a thoracotomy approach for implanting the HVAD System. The typical way the surgeon implants the pump is to open up your chest with a single long vertical incision along your sternum in order to access your heart. In the thoracotomy approach, the surgeon makes a short horizontal incision between the ribs on the left side of your chest and attaches the pump to your heart through that space. Sometimes this technique requires a second small incision on the upper right side of your chest in order to attach the tube that carries the blood from the pump to the aorta, which pushes the blood to the rest of your body. This study showed that implanting the HVAD System through a thoracotomy has similar outcomes as when the pump is implanted through the usual approach with a single long incision down your sternum.

The risks identified in the clinical trials are listed in Section *1.3*.

8.1.6 Understanding How the HeartWare™ HVAD™ System Works

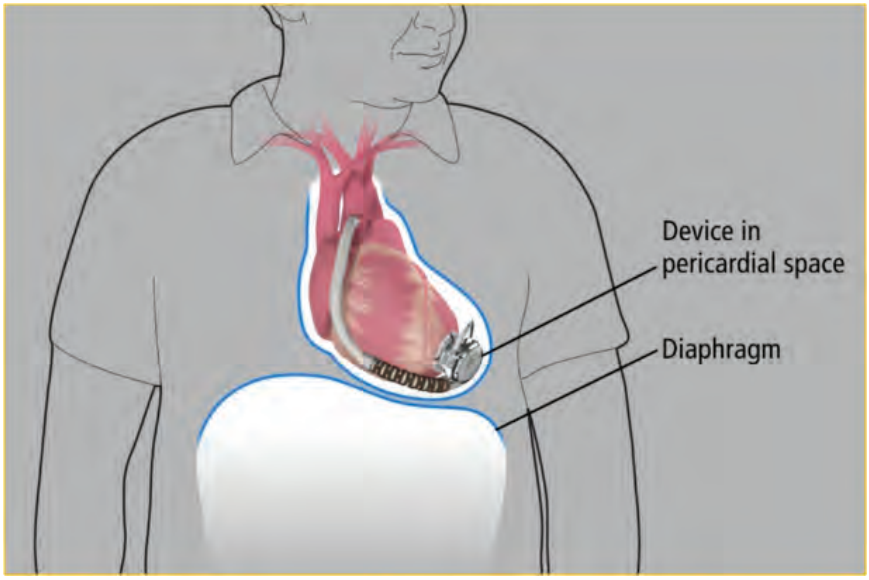


Figure 102: Illustration of an Implanted HVAD Pump

Placement of the HVAD System requires a major operation. An incision will be made on your chest, in a sac around the heart known as the pericardial space so the surgeons can gain access to your heart. Part of the pump will be inside the heart and part will sit in the chest cavity, right next to the heart. The HVAD Pump is connected directly to your heart at the bottom of the left ventricle, where it draws oxygen-rich blood through the pump and pushes it into your aorta (large blood vessel that carries blood from your heart to the rest of your body).

Your clinician will program the HVAD Pump so it delivers the right amount of flow for your body's needs. The pump cable (driveline) is already connected to the pump and will be tunneled under the skin and come out through a small incision in the skin just above the abdomen. The pump cable (driveline) is then connected to the controller. After the pump is in place and working, the incisions will be sutured closed.

Once the surgery is finished, you will be taken to the Intensive Care Unit where nurses and doctors will provide you with the level of care you need. You will likely be on a breathing machine for 12-24 hours and will have to spend some time in the Intensive Care Unit. You may also be connected to several intravenous lines and drainage tubes. During this time you will receive antibiotics to reduce the risk of infection and medications to help keep your heart beating regularly. You may also need to get some blood transfusions. None of these treatments are unusual; they are all intended to reduce the chances that a complication may occur. As you regain your strength, you will be taken off the breathing machine and the intravenous lines and tubes will be removed. You may also be moved from the Intensive Care Unit to a general hospital floor. While you are in the hospital, you will begin a rehabilitation program designed to help you return to a more active lifestyle. As part of this program, you and your caregiver will be given training on the HVAD System. You will be trained on how to handle and care for your HVAD System equipment, as well as how to respond to emergencies and alarms. Your hospital team will indicate if and when it is best to directly contact Medtronic or your Medtronic representative.

8.1.7 System Model Numbers

Medtronic HVAD PAL System Component	MODEL #
PAL Controller	MCS3101CO
PAL Single Battery	MCS3205SB
PAL Dual Battery	MCS3215DB
PAL AC Adapter	MCS3425AC
PAL DC Adapter	MCS3435DC
PAL Accessories Bag	MCS3335AB
PAL Sport Pack	MCS3315SP
HeartWare Shower Bag	2000US
PAL Battery Charger	MCS3255BC
PAL Cap	MCS3235CP
MCS Patient Power Cord	MCS2450PC

8.0 Appendix

8.1.8 Product Specifications

Essential Performance	
The HVAD Pump maintains flow.	
Critical Alarms.	
Pump	
Mass (or weight)	160 g
Volume	50 cc
Materials	Titanium, Titanium Nitride, PEEK® and ceramic
Pump 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 Nickel-coated brass connector
Controller	
Weight	0.7 kg
Dimensions	10.4 x 10.9 x 6 cm (not including connectors)
Display	Monochrome LCD with colored backlight
Messages	Status, 2 alarm priorities, information, instructions
Controls	Touchscreen
Audible Alarm Volume	Critical Alarms: 79-100 dBA SPL Noncritical Alarms: 58-70 dBA SPL
Internal Battery	
Type	Li ion, rechargeable
Weight	0.1 kg
Dimensions	7.6 x 3.8 x 2.2 cm
Ratings	7.2 Vdc, 15.1 Wh.
Charge Time	90 min [Note: 90 min nominal; 2.5 hrs. max]
External Battery	
Type	Li ion, rechargeable
Weight	Single: 0.3 kg; Dual: 0.5 kg
Dimensions	Single: 9.6 x 7.6 x 4.8 cm; Dual: 9.6 x 12.0 x 4.8 cm
Indicators	Battery level LED
Ratings	Single: 14.4 Vdc, 46.1 Wh.; Dual: 14.4 Vdc, 92.2 Wh.
Recharge time	Single Battery or Dual Battery: up to 6 hours (Charge times may increase at temperatures above +30°C)
Battery Charger	
Capacity	4 batteries
Weight	1.7 kg
Dimensions	36.5 x 20.1 x 8.3 cm
Indicators	1) Charger status LED 2) Four (4) battery status LEDs
Electrical Ratings	100-240 VAC, 50-60 Hz, 160 VA input, 135 VA output

8.1.8 Product Specifications (continued)

Controller AC Adapter	
Weight	0.5 kg
Dimensions	12.1 x 7.6 x 4.7 cm
Output cable length	2.8 m
Input cable length	2.5 m
Electrical Ratings	100-240 VAC, 50-60 Hz, 140 VA input, 18 Vdc, 3.3A output
Controller DC Adapter	
Weight	0.5 kg
Dimensions	12.1 x 7.6 x 4.7 cm
Output cable length	2.0 m
Input cable length	1.0 m
Electrical Ratings	12.0-15.6 V, 7 A input; 18 Vdc, 3.3 A output
Controller Coiled Cable	
Length (extended)	71.1 cm
Length (non-extended)	40.6 cm
Diameter	3.5 to 4.0 mm
Materials	main cable jacket is TPU (thermoplastic polyurethane) Nickel-coated brass connector

Software Parameters, Ranges & Factory Default Settings

Parameter	Factory Default
[Low Flow] alarm	1.0 L/min
[High Power] alarm limit	8.0 Watts
Power Tracking	Off
[Suction] alarm	Off

8.0 Appendix

8.1.8 Product Specifications (continued)

Safety Standards:

IEC 60601-1:2012 (Ed. 3.1)
IEC 60601-1/A2:1995
IEC 60601-1-11:2015
IEC 60601-1-8:2012
IEC 60601-1-6:2013 (IEC 62366)
IEC 62133:2012
IEC 60950-1:2001

EN 60601-1:2006/A1:2013
EN 60950-1:2006/A11:2009

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Ed. 3.1)

CAN/CSA C22.2 No. 601.1
CAN/CSA-C22.2 No. 60601-1:14 (Ed. 3.1)
CAN/CSA C22.2 No. 60950-1-07

UL 60601-1:2003
UL 60950-1:2007
UL 2054:2004
UL 1642:2012

UN/DOT Part III, subsection 38.3:2011

ISO 14708-5:2010

EMC Standards:

IEC 60601-1-2:2014
RTCA DO-160G
EN 50498:2010

ISO 7637-2:2011

ISO 16750-2:2012

Bluetooth® Standards:

EN 301489-17:2017

EN 300 328 v2.1.1

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

Applied Parts - HVAD Pump and driveline: Type CF Defibrillation-Proof

Battery charger – Class II

Essential performance for the HVAD controller and pump, as defined by IEC 60601-1, is:

- at speeds between 1800 RPM and 4000 RPM under normal conditions, flow shall be maintained within +/-10% of original set flow rate without excursions longer than 15 sec.
- critical audible alarms operate as intended.
- The other devices in the HVAD system do not have essential performance, as defined by IEC 60601-1.

Degrees of protection against the ingress of foreign objects and fluid:

IP20 (Controller alone)

IP54 (Controller connected to external battery or Cap)

IP22 (Controller AC & DC adapter)

IP54 (External battery)

IP21 (Battery charger)

8.1.8 Product Specifications (continued)

Wireless / RF Specifications

CAUTION: Modifying the device without the approval of Medtronic can void your authority to operate the radio equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

RF/Wireless allocations and technical parameters may be different outside of the United States, possibly affecting the functioning of the device. Contact your clinician if there are any concerns about using RF/ wireless capabilities of this device when outside of the Unites States.

Use of this device near other emitters such as microwaves or WiFi routers (in-band) may result in reduced or degraded log-file transmission quality. Move the device away from the interference and re-attempt any action.

Protocol	Bluetooth + Low Energy
Frequency of Operation	2402 - 2480 MHz
Output power	-3.2 dBm measured + 1.5 dB uncertainty = -1.7 dBm 0.676 mW EIRP
Modulation	Gaussian Frequency Shift Keying
Channelization	Number of channels: 40 Channel spacing: ≤ 2 MHz
Maximum Range	1 meter
Duty cycle	≤ 100%
Duplex/Simplex	Semi-Duplex
RF Exposure (SAR)	N/A – Maximum RF Output < 20 mW
Applied EU standards	EMC EN 301 489-1, -17 RF EN 300 328 Safety IEC/EN 60601-1 RF Exposure EN 62311
Antenna Information	Antenna Type: Monopole Manufacturer: Murata Model number: LBCA2HNZYZ Antenna Gain: -0.6 dBi Polarization: Linear
Model: MCS3101CO Major Market Certifications	FCC ID: LF5MCS3101CO IC ID: 3408D-MCS3101CO

8.1.9 Electromagnetic Compatibility (EMC) Guidance

Electromagnetic Compatibility

The HeartWare HVAD System 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 the HeartWare HVAD System.

WARNING! The HVAD Pump may cause interference with AICDs. If electromagnetic interference occurs, it may lead to inappropriate shocks, arrhythmia and possibly death. Contact your clinician if you suspect that your AICD is not properly functioning due to electromagnetic interference from the HVAD Pump.

Guidance - Electromagnetic Emissions

The HeartWare HVAD™ System is indicated for use in the electromagnetic environments specified below. The customer or the user of the HVAD System should assure it is used in such an environment.

Emissions	Compliance	Guidance
Radiated and Conducted RF Emissions CISPR 11	Group 1 Class B (all except Monitor) Class A (Monitor)	The HVAD System (except the monitor) 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 Current Emissions IEC 61000-3-2	Complies	
Voltage Changes, Voltage Fluctuations and Flicker IEC 61000-3-3	Complies	
Aircraft Radiated and Conducted Emissions RTCA/DO-160G Section 21	Category M	The HVAD System with battery pack and/or controller AC adapter is suitable for use on board aircraft.
Automotive Broadband and Narrowband Radiated Disturbances EN 50498:2010	Complies	The HVAD System with battery pack and/or controller DC adapter is suitable for use on board vehicles.
Automotive Conducted Transient Disturbances EN 50498:2010	Complies	The HVAD System with battery pack and/or controller DC adapter is suitable for use on board vehicles.

8.1.9 Electromagnetic Compatibility (EMC) Guidance (continued)

Guidance - Electromagnetic Immunity

The HVAD System is indicated for use in the electromagnetic environments specified below. The customer or the user of the HVAD System should assure it is used in such an environment.

CAUTION: If operation of the HVAD System is degraded, or if essential performance is not met due to suspected electro-magnetic interference (EMI), move to a suitable environment.

Immunity Test	Compliance Level	Guidance
Electrostatic Discharge IEC 61000- 4-2	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air	Refer to **Section 9.1** for guidance on minimizing the impact of ESD. The HVAD System is suitable for use in all establishments.
Electrical Fast Transient / Burst IEC 61000-4-4	± 2 kV on Power Supply Ports ± 1 kV on Signal Input/Output Ports	Mains power quality should be that of a typical hospital, clinic, or home environment.
Surge IEC 61000-4-5	± 1 kV on Power Supply Ports (for the Controller AC adapter) ± 2 kV on Power Supply Ports (for the Monitor AC adapter)	Mains power quality should be that of a typical hospital, clinic, or home environment.
Voltage Dips IEC 61000-4-11	0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles single phase: at 0°. 25/30 means 25 periods at 50Hz or 30 periods at 60Hz.	Mains power quality should be that of a typical hospital, clinic, or home environment. The HVAD System will always have a battery backup power supply connected.
Voltage Interruptions IEC 61000-4-11	0% U_T; 250/300 cycles 250/300 means 250 periods at 50Hz or 300 periods at 60Hz.	Mains power quality should be that of a typical hospital, clinic, or home environment. The HVAD System will always have a battery backup power supply connected.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.		
Power Frequency Magnetic Fields IEC 61000-4-8	30 A/m	The HVAD System is suitable for use in all establishments.

8.1.9 Electromagnetic Compatibility (EMC) Guidance (continued)

<table>
<tr><th>Immunity Test</th><th>Compliance Level</th><th>Guidance</th></tr>
<tr><td rowspan="2">Conducted Disturbances Induced by RF Fields

IEC 61000-4-6</td><td>3 Vrms from 0.15 MHz to 80 MHz
6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz
80% AM at 1 kHz</td><td>The HVAD System (except the Monitor) is suitable for use in all establishments.</td></tr>
<tr><td>3 Vrms from 0.15 MHz to 80 MHz
6 Vrms in ISM bands between 0.15 MHz and 80 MHz
80% AM at 1 kHz</td><td>The HVAD Monitor is suitable for use in professional healthcare facilities.</td></tr>
<tr><td rowspan="2">Radiated RF EM Fields

IEC 61000-4-3</td><td>10 V/m from 80 MHz to 2.7 GHz
80% AM at 1 kHz</td><td>The HVAD System (except the Monitor) is suitable for use in all establishments.</td></tr>
<tr><td>3 V/m from 80 MHz to 2.7 GHz
80% AM at 1 kHz</td><td>The HVAD Monitor is suitable for use in professional healthcare facilities</td></tr>
<tr><td>Proximity Fields from RF Wireless Communications Equipment

IEC 61000-4-3</td><td>Complies with 8.10 (Table 9) of IEC 60601-1-2:2014</td><td>The HVAD System is suitable for use in proximity to common RF wireless communications equipment.</td></tr>
<tr><td>Dipole Radiated RF Immunity

ISO 14117:2019</td><td>
<table>
<tr><th>Frequency (MHz)</th><th>Test Level (W rms)</th><th>Separation Distance (cm)</th></tr>
<tr><td>450, 600</td><td>0.2</td><td>1.5</td></tr>
<tr><td>680</td><td>0.2</td><td>2.0</td></tr>
<tr><td>745</td><td>0.2</td><td>1.5</td></tr>
<tr><td>800, 825, 850</td><td>2</td><td>1.5</td></tr>
<tr><td>875, 900, 930</td><td>8</td><td>1.5</td></tr>
<tr><td>1610</td><td>2</td><td>1.5</td></tr>
<tr><td>1750</td><td>4</td><td>1.5</td></tr>
<tr><td>1850, 1910</td><td>2</td><td>1.5</td></tr>
<tr><td>2310, 2450, 2600</td><td>0.2</td><td>1.5</td></tr>
<tr><td>3000</td><td>2</td><td>1.5</td></tr>
</table>
</td><td>The HVAD System is suitable for use in proximity to common RF wireless communications equipment.</td></tr>
<tr><td>Aircraft Radiated and Conducted Immunity

RTCA/DO-160G Section 20</td><td>Category R</td><td>The HVAD System with battery pack and/or controller AC adapter is suitable for use on board aircraft.</td></tr>
</table>

8.1.9 Electromagnetic Compatibility (EMC) Guidance (continued)

Immunity Test	Compliance Level	Guidance
Automotive Conducted Transient Immunity ISO 7637-2:2011	Severity Level 4	The HVAD System with battery pack and/or controller DC adapter is suitable for use on board vehicles.
Automotive Electrical Loads BS ISO 16750-2:2012	Sections 4.3, 4.4 (Severity Level 4), 4.5, 4.6, 4.7, 4.9, 4.10, 4.11, 4.12	The HVAD System with battery pack and/or controller DC adapter is suitable for use on board vehicles.

Note: The replaceable cables are the Controller AC adapter input power cable(2.5m long), Monitor AC adapter input power cable (2.5m long), and USB data cable (2.8m long); the replacement accessories are the AC power adapters for the controller and monitor and the DC power adapter for the controller.

WARNING! The HVAD System components should not be used adjacent to or stacked with equipment other than equipment specified in the IFU. If adjacent to or stacked use is necessary, the HVAD System and other equipment should be monitored regularly to verify normal operation.

WARNING! Use of accessories and cables other than those specified or provided by Medtronic for use with the HVAD System could result in increased electromagnetic emissions or decreased electromagnetic immunity of the HVAD System and result in improper operation.

8.2 Answers to Patient and Caregiver Training

1. Match the definition to the picture:

Fill in your answers below:

- **c** Single Battery
- **d** Dual Battery
- **b** Controller
- **e** AC and DC Adapters
- **a** Battery Charger

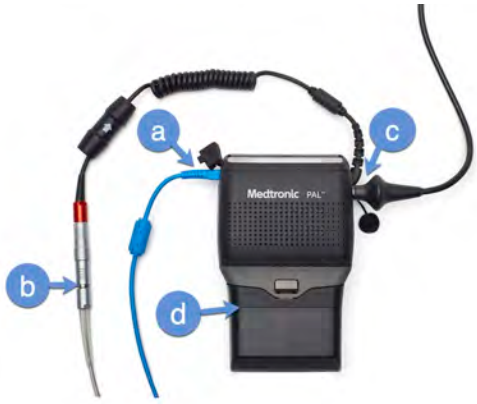
See Section 2.4 and Section 2.5 for more information.

2. Match the four connections of the PAL™ Controller:

Fill in your answers below:

- **d** External Battery Connection
- **c** AC/DC Power Cord Connection
- **b** Pump Cable (Driveline) Connection
- **a** Data Cable Connection

See Section 3.2 for more information.



3. What are the different power configuration options under normal use conditions? Check all that apply.

- ☐ No external battery, PAL™ Cap, or AC/DC adapter connected
- ☑ External battery connected only
- ☐ PAL™ Cap connected only
- ☑ External battery and AC/DC adapter connected
- ☑ PAL™ Cap and AC/DC adapter connected

See Table 2: Power Configurations in Section 2.4.

8.2 Answers to Patient and Caregiver Training (continued)

4. Identify the Controller State:

Fill in your answers below:

b Ready State - The controller is on but not running a pump.

c Running State - The controller is on and running a pump.

a Off State - The controller is off and will not power the pump when connected.

See Table 6: Operating State Definitions in Section 3.2 for more information.

a

b

c

5. Match the controller's power-related symbol description:

Fill in your answers below:

e External or internal battery is fully charged

d External or internal battery is not connected or is not found

b External or internal battery is charging

a External or internal battery no longer has a charge

c Controller is connected to an AC or DC adapter

See Table 4: Guide to Controller Symbols of Section 3.2 for more information.

a.

b.

c.

d.

e.

6. Match the controller's button symbol descriptions:

Fill in your answers below:

c Button returns you to the Home screen

b Button takes you to the Controller Information screens

a Button takes you to the Alarm History screens

See Table 4: Guide to Controller Symbols of Section 3.2 for more information.

a.

b.

c.

8.2 Answers to Patient and Caregiver Training (continued)

7. Match the controller symbol descriptions:

Fill in your answers below:

- **i** Indicates that a setting is on
- **h** Indicates that a setting is off
- **d** Indicates multiple alarms are active
- **c** Indicates the date and time that an alarm began
- **g** Indicates the date and time an alarm was resolved
- **f** Indicates the clinician's phone number
- **e** Indicates that at least one alarm is active
- **b** Indicates that an alarm is sounding
- **a** Indicates that an alarm is muted

See Table 4: Guide to Controller Symbols of Section 3.2 for more information.

a. 

b. 

c. 

d. 

e. 

f. 

g. 

h. 

i. 

8. The VAD Status Screen gives pump information such as:

Match the definition of the items:

Fill in your answers below:

- **b** Pump operating power
- **c** Blood flow
- **a** Pump speed

a. RPM

b. Watts

c. L/min

See Table 5: Screen Definitions of Section 3.2 for more information.

9. How long can one Single Battery provide power for?

Approximately 6 hours

See Section 3.3.4 for more information.

8.2 Answers to Patient and Caregiver Training (continued)

10. How long can one Dual Battery provide power for?

Approximately 13 hours

See Section 3.3.4 for more information.

11. When looking at the battery capacity display, how much power is available in a battery if there are:

4 green lights **Full**

3 green lights **High**

2 green lights **Medium**

1 yellow light **Low**

See Table 12: Battery Capacity Display in Section 3.3.4 for more information.

12. On the battery charger there are several battery status light indicators. Check which status light you will see if the battery is charging.

- ☐ Solid Red
- ☐ Flashing Red
- ☐ Solid Green
- ☑ Flashing Green
- ☐ No lights

See Table 13: PAL™ Batteries Status Lights in Section 3.4 for more information.

13. When an alarm occurs, check all the indicators that you should look for to determine the severity of the alarm.

- ☑ A unique sound
- ☑ Visual display (Solid Yellow or Flashing Red)
- ☑ Vibration
- ☑ A message

See Section 4.2 for more information.

8.2 Answers to Patient and Caregiver Training (continued)

14. Circle True or False for the following:

1. Critical alarms can be muted — True **False**
2. Muting an alarm resolves the alarm condition — True **False**
3. These are all things that should be reported right away to your clinician:
   a. You have dropped and/or damaged any of your equipment. — **True** False
   b. Pressing a flashing ℹ button on your Home screen leads you to an Internal Battery or External Battery screen with your clinician's phone number. — **True** False
   c. Any non-critical alarm that displays "Call Clinician" or the clinician contact phone number. — **True** False
   d. You just completed an emergency controller exchange. — **True** False

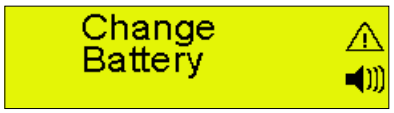
See Section 4.0 for more information.

15. How would you respond to a Connect Pump Cable ⚠ alarm on your controller display?

Connect pump cable (i.e., driveline)

See Table 16: Critical Alarms in Section 4.3 for more information.

16. Your controller displays the following information; what is the correct immediate response?



- ☐ Do nothing, this is normal activity
- ☑ Change the external battery
- ☐ Change the controller
- ☐ Call your clinician

See Table 17: Non-critical Alarms in Section 4.4 for more information.

17. Your controller displays the following information; what is the correct immediate response?

- ☐ Do nothing, this is normal activity
- ☐ Change the external battery
- ☑ Change the controller
- ☐ Call your clinician

See Table 16: Critical Alarms in Section 4.3 for more information.

8.2 Answers to Patient and Caregiver Training (continued)

18. Check the activities that could cause the HVAD Pump to stop:

- [x] Disconnecting an external battery during a 

alarm.
- [ ] Exchanging external batteries when no AC/DC adapter is connected and the controller is running normally.
- [x] Disconnecting the pump cable (driveline) from the controller.
- [x] Disconnecting all external power during a 

alarm.
- [ ] Disconnecting AC/DC power and then swapping the PAL™ Cap for an external battery while the controller is running normally

See Section 4.0 for more information.

19. When preparing to go to bed at night, which of the following are acceptable power configurations?

- [ ] No external battery, PAL™ Cap, or AC/DC adapter connected
- [ ] External battery connected only
- [ ] PAL™ Cap connected only
- [x] External battery and AC/DC adapter connected
- [x] PAL™ Cap and AC/DC adapter connected

See Section 4.2 for more information.

20. List six (6) items you should have with you when you leave your house:

Backup controller, additional charged external batteries, AC adapter, DC adapter (if in vehicle), Emergency Responder Guide, and Patient ID Card

See Section 6.5 for more information.

21. Check the activities that are not allowed while on the HVAD Pump:

- [ ] Chest x-ray
- [x] MRI scan
- [ ] CT scan
- [ ] Cardiac catheterization
- [x] Swimming
- [ ] Walking

See Section 6.0 for more information.

8.2 Answers to Patient and Caregiver Training (continued)

22. To minimize the risk of interference (electrostatic discharge) to your controller due to static electricity, which of the following should you avoid? Check all that apply.

- [x] Putting your controller in a silk bag
- [ ] Using dryer sheets when doing laundry
- [ ] Using a humidifier in your home
- [x] Touching the CRT TV screen while it is on
- [x] Touching exposed metal pins of a connector or port
- [ ] Attaching the dust cover
- [ ] Ensuring that the pump cable (driveline) cover is securely positioned over the pump cable (driveline) connector
- [x] Ignoring a 

alarm

See Section 6.2 for more information.

23. List five (5) signs or symptoms of a pump cable (driveline) exit site infection:

Redness, swelling, drainage, odor, or pain

See Section 6.3 for more information.

24. Why do you take blood thinner medicine?

To help keep blood from clotting

See Section 6.1 for more information.

8.2 Answers to Patient and Caregiver Training (continued)

25. Circle True or False for the following:

1. A flashing red alarm requires immediate attention.	**True**	False
2. It is OK to have moisture, cracks, tears or punctures in your driveline.	True	**False**
3. It is safe to take a tub bath or swim.	True	**False**
4. This flashing ℹ symbol on the Home screen indicates pertinent information such as battery end of life.	**True**	False
5. Pushing the screen to mute an alarm resolves the alarm condition.	True	**False**
6. A connected controller with a blank display and no audible alarm should be replaced.	**True**	False
7. When an alarm occurs the Controller Display tells you which alarm is occurring and what to do.	**True**	False
8. This symbol  will indicate proper connection to an electrical outlet or a car power port.	**True**	False
9. When there is a  alarm, you should switch to the backup controller.	**True**	False
10. The PAL™ Sport Pack can be worn around the waist or torso.	**True**	False
11. It is safe to keep your PAL™ Controller under a thick or thermal (hypothermia) blanket at night.	True	**False**
12. It is never safe to disconnect your external battery during the following alarm. 	**True**	False

See Section 6.1 for more information.

Notes

9.0 Glossary

9.1 Glossary of Terms

If you have any questions or need more information about the terms defined below, please ask your clinician.

A

AC Power Adapter (PAL™ AC Adapter): A box with wires that plugs into an electrical outlet and the controller. It powers the controller and the pump.

Accessories Bag (PAL™ Accessories Bag): A bag designed to hold the PAL™ accessories such as: the backup controller, the AC and/or the DC Power adapter, the extra batteries, etc.

Alarm: An audible and/or visual and/or vibratory notification, intended to alert the user to take the necessary action(s) to correct the situation(s). There are two types of alarms: critical and non-critical alarms. See "Critical Alarm" & "Non-critical Alarm" for descriptions.

Anticoagulants: Drugs that increase the time it takes blood to clot.

B

Battery (External Battery, PAL™ Single or Dual Battery): A rechargeable, portable power source that attaches to the bottom of the controller. The battery is available in two sizes – the small battery, Single, will run the pump for approximately 6 hours and the large battery, Dual, will run the pump for approximately 13 hours.

Battery Capacity Display: An indicator on the battery that when pressed, shows the amount of power left in the battery. Each green bar represents 25% of the power (time) left in the battery. Note that when the battery becomes old and needs to be replaced, the fourth bar will not light.

Battery Charger (PAL™ Battery Charger): The unit used to charge the PAL™ batteries. Up to four batteries may be charged at a time.

Battery Release Button: A button on the controller that when pushed, unlatches the battery or cap.

Continued on next page

9.1 Glossary of Terms (continued)

C

Caregiver: The Caregiver is generally a family member or close friend of the Patient (person who has the HVAD implanted) who is trained to be familiar with the HVAD System and thereby is equipped to assist the patient with their device.

Carry Case: A container designed to hold the controller with an attached battery. Its purpose is to keep the controller and battery safe and secure during the user's normal daily activities. The Carry Case is intended to be worn by the user, secured either around the waist or over the shoulder.

Clinician: The doctor or nurse who is called when the user has questions about the HVAD System.

Controller (Pal™ Controller): A small, externally worn computer that regulates pump function and watches over the system. If there is a problem, the controller alerts the user with graphics, text, lights, vibration, and sound.

Critical Alarm: The most serious, highest-priority alarm. This type of alarm sounds with the loudest audio and most compelling visual (flashing red display) in addition to vibration. This type of alarm requires immediate action. The controller screen provides graphic and/or written instructions to guide the user to resolve the alarm.

D

Data Port: The USB input on the controller that allows connection to the monitor (via USB cable). This connection is used by clinicians to transfer information from the controller to the monitor, and to send instructions from the monitor to the controller.

Driveline (Pump Cable): The cable that connects the implanted pump to the external Pal™ Controller. The driveline passes through the skin and provides a way to connect and disconnect the external Pal™ Controller from the implanted pump. The Driveline is also referred to as "Pump Cable".

Driveline Cover: A small enclosure, surrounding a portion of the driveline, which slides over the pump/controller Coiled Cable connectors to protect from: accidental disconnect, dirt, and moisture.

DC Power Adapter: A box with wires that plugs into a vehicle's electrical or accessory outlet and the controller. It powers the controller and the pump.

Driveline Connectors; Mating Connectors on the end of the controller Coiled Cable and pump driveline.

Continued on next page

9.1 Glossary of Terms (continued)

E

Emergency Responder (ER): An Emergency Responder is typically a medically-trained professional (e.g. Paramedic, EMT, etc.) who would be dispatched to the scene in emergency situations.

Emergency Responder Guide (ERG): The Emergency Responder Guide (ERG) is a document that provides emergency information and instructions on how to change the controller. It is intended to be a quick reference for laypersons who may not be familiar with the equipment as well as for patients and caregivers who should have some familiarity with the equipment. It is a multi-fold document that is generally kept in the top flap of the accessories bag and inside the carry case.

Exit Site: Location where the driveline passes through the patient's skin.

External Battery (PAL™ Single or Dual Battery): A rechargeable, portable power source that attaches to the bottom of the controller. The battery is available in two sizes – the small battery, Single, will run the pump for approximately 6 hours and the large battery, Dual, will run the pump for approximately 13 hours.

External Power Sources: Rechargeable, external batteries (Single and Dual); AC adapter and DC adapter.

F

Flow: The estimated volume of blood the HVAD pumps over time, measured in liters per minute (L/min).

H

HeartWare™ HVAD™ Pump: An implantable centrifugal blood pump designed to assist a weakened, poorly functioning left ventricle of the heart.

HeartWare™ HVAD™ System: The HeartWare™ Ventricular Assist System, which includes: the HVAD Pump, surgical tools, monitor, Pal™ Controller, and all peripheral support equipment like batteries, charger, and power adapters.

Hospital Team (HT): This group consists of clinical staff that may interact with the HVAD System or with VAD patients and have VAD training specific to their discipline or expertise, but are not as comprehensively trained as VAD Coordinators. This group may include staff nurses (ICU or step-down unit), nurse educators, physical therapists, or occupational therapists. "Hospital Team" is sometimes abbreviated as "HT".

HVAD: An implantable centrifugal blood pump designed to assist a weakened, poorly functioning left ventricle of the heart.

I

Internal Battery: A rechargeable, portable power source that is located inside the controller. The battery can run the pump for at least 30 minutes and should only be relied on while changing external power sources.

Impeller: The only moving part of the pump. As the impeller spins it moves blood from the heart to the rest of the body.

L

L/min: "Liters per minute" is a unit of measurement for flow (volume over time). In the VAD systems, this is the unit of measurement for blood flow, i.e., how much blood the pump is pumping through the body per minute. The flow rate is shown on the controller VAD Status screen and on the monitor.

Continued on next page

9.1 Glossary of Terms (continued)

M

Monitor: The monitor is a touchscreen, tablet computer used to communicate with and program the controller. Clinicians use the monitor during initial set-up, anytime a patient is in a hospital setting, and during clinical visits to retrieve data trends, alarm history, and event logs from the patient's controller.

Multiple Alarms: Condition in which there are two or more alarms occurring at the same time. The alarms can be either critical and/or non-critical alarms. The alarms are displayed in order of criticality, with the critical (higher priority) alarms displaying first.

N

Non-critical Alarm: A less serious, lower priority alarm. This type of alarm initially displays a visual alert (solid yellow back light) with vibration. If not addressed, it will progress to an audible alarm, but at a lower volume and different cadence than a critical alarm. The alarm message displayed on the controller screen identifies the type of alarm and provides instruction for resolving the issue and/or displays a telephone number to call for assistance.

P

Pal™ Cap: A plastic cover that should be attached to the controller whenever an external battery is not in use (e.g., when the controller is powered by AC or DC power). The cap's purpose is to protect the controller's power connections from dust, dirt, and fluid.

Pal™ Controller: A small, portable computer that controls and monitors the implanted pump. The Pal™ is the Controller for the HVAD Pump and is worn by the user.

Patient: The Patient is the HVAD System user who has the implanted pump and wears the Pal™ Controller.

Power: The amount of energy in Watts (W) that it takes to operate the HVAD Pump.

Power Adapter Connector: The "plug" on the end of the AC and DC Power Adapter that inserts into the Controller to deliver power.

Power Port: The female connector on the Pal™ Controller where AC and DC power adapters plug in.

Pump: Also known as the HVAD, the pump is a device that moves blood from the heart to other parts of the body. The pump is implanted at the base of the patient's heart during surgery.

Pump Cable: The cable that passes through the skin and connects the implanted pump to the external Pal™ Controller. Also referred to as the "driveline".

R

RPM (Revolutions Per Minute): RPM is the measure of the frequency of rotation and is used with respect to the VAD system to indicate pump speed (i.e. the number of times the impeller rotates in a minute). The RPM is shown on the PAL™ Controller status (parameters) screen and on the monitor.

Continued on next page

9.1 Glossary of Terms (continued)

S

Shower Bag (HeartWare™ Shower Bag): A water resistant bag designed to fit the PAL™ Controller and an external battery, for use during a shower. The shower bag provides an additional layer of water protection for the controller.

Sport Pack (PAL™ Sport Pack): A pack designed for patient mobility that is able to hold a controller and a dual or single battery securely. The Sport Pack comes in two configurations: around the waist or over the shoulder.

U

UI: User Interface. This is everything that allows the user to interact with an application or with a device. For instance, the controller's user interface is designed to allow users to interact with it via touchscreen, while it uses vibration, sound, lights, and color to alert the user to potential problems.

V

VAD: Ventricular Assist Device. This is a mechanical pump device that assists either the left (LVAD) or the right (RVAD) ventricle of the heart. The HVAD is a Medtronic HeartWare version of this device.

VAD Coordinator: The VAD coordinator is usually a VAD clinician (sometimes a bioengineer) that has specific advanced training in managing patients on mechanical circulatory support, troubleshooting equipment, and handling emergencies. They are usually the "super expert" when it comes to VAD equipment.

W

Watts: Measure of the amount of power used to run the pump. The Watts (W) are shown on the Controller status screen and on the monitor.

9.2 Glossary of Controller Device Label Symbols

	Attention, consult accompanying documents
	Operating Instructions
	Follow instructions for use
	Batch code
	Catalog number
	Serial number
	Class II equipment
	Protected against vertically falling water drops
	Protected against vertically falling water drops when enclosure tilted up to 15 degrees.
	Protected against dust; protected against splashing water in any direction for 5 minutes
	Protected against solid foreign objects of 12.5 mm diameter or greater; protected against vertically falling water drops
	Protected against solid foreign objects of 12.5 mm diameter or greater; protected against vertically falling water drops when enclosure tilted up to 15 degrees
	Temperature Range
	Humidity Range
	Atmospheric Pressure
	Date of manufacture

	Manufacturer
	Sterilized with ethylene oxide
	Do not reuse
	Do not use if package is damaged
	Separate collection of waste batteries
	Properly dispose of Li-ion battery
	Waste of electrical and electronic equipment
	Use by date
	Direct current
	Non-pyrogenic
	Pump connection
	Defibrillation proof type CF Applied Part
	Not made with natural rubber latex
	CE Mark
	Authorized representative in the European Community
	The UL Recognized Component certification mark
	UL Classification Mark
	MR unsafe

	Prescription only
	No battery
	TÜV SÜD Certification Mark
	Alternating currents
	Rechargeable battery
	Rechargeable Lithium Ion battery
	Diameter
	Monitor connection
	Usable length
	Clinician Contact
	Doctor or Health Care Center
	Medical Device
	Unique Device Identifier
	Consult IFU at this website
	Implant Date
	Patient Information Website

9.2 Glossary of Controller Device Label Symbols

	Package Contents
	PAL™ Controller for HeartWare™ HVAD™ Pump
	PAL™ Single Battery
	PAL™ Dual Battery
	PAL™ Cap
	PAL™ AC Adapter
	PAL™ DC Adapter
	PAL™ Battery Charger
	MCS Patient Power Cord
	PAL™ Sport Pack
	PAL™ Accessories Bag
	PAL™ Data Cable
	PAL™ Internal Battery Replacement Kit

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