The HeartAssist 5® VAD System

Patient User's Manual

Miniaturized ventricular assist technology co-developed with Dr. Michael E. DeBakey, Dr. George P. Noon and the National Aeronautics and Space Administration (NASA)

MicroMed Cardiovascular, Inc.
8965 Interchange Drive
Houston, TX 77054

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

The HeartAssist 5® Pediatric VAD is authorized by Federal law for use in providing temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients (5 – 16 years old, with BSA greater than or equal to 0.7 m^2 and less than 1.5 m^2) who are in NYHA Class IV end stage heart failure, are refractory to medical therapy and who are (listed) candidates for cardiac transplantation. The effectiveness of this device for this use has not been demonstrated.

L00088-01 Rev. M

Warning

Read this entire manual before handling the HeartAssist 5® VAD without supervision

Quick Reference - Support Team Phone Numbers

Title	Name	Phone Number
Emergency Assistance		
Cardiologist		
Cardiothoracic Surgeon		
Nurse		
Technical Assistance		

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

It is recommended that patients who have a limited ability to care for themselves or communicate clearly should have a trained companion available.

Conditions for calling for Emergency Assistance

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

- Loss of Consciousness
- Seizures or Convulsions
- Inability to Move or Speak
- Sudden Collapse

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

- Numbness, Tingling or Weakness
- Pain
- Redness, Swelling or Drainage at the Exit Site of the Percutaneous Cable
- Blurred Vision
- Speech Problems
- Shortness of Breath
- Dizziness
- Temperature Higher than 38° C (100.4° F)
- Unusual Bleeding
- Unusual Bruising
- Anytime you're feeling bad

Contents

General Warnings and Precautions xi

1.0 Overview 1

2.0 Introduction to the HeartAssist *5*® VAD 3
2.1 The Pump System 3
2.2 The Controller 4
2.3 The Clinical Data Acquisition System (CDAS) 4
2.4 The Patient Home Support System (PHSS) 4
2.5 The HeartAttendant® Console 4

3.0 Description of HeartAssist *5*® VAD System 5
3.1 The HeartAssist *5*® VAD System 5
3.2 The Pump 6
3.3 The Controller 8
3.4 Clinical Data Acquisition System (CDAS) 9
3.5 Patient Home Support System (PHSS) 10
3.6 The HeartAttendant® Console 12
3.7 VADPAK 13
3.8 VADPAK Shower Bag 14

4.0 Environmental Conditions 15
4.1 Temperature Conditions 15
4.2 Contact with Liquids 15
4.3 Electromagnetic Interference 15

5.0 Connecting Your Controller to the VADPAK, CDAS, PHSS, or HeartAttendant® 17
5.1 General Considerations 17
5.2 Clinical Data Acquisition System (CDAS) 18
5.3 HeartAttendant® Console 18
5.4 Controller 18
5.5 Batteries 19
5.5.1 Connecting a Battery Cable to the Battery Port 19
5.5.2 Battery Indicators on the Controller 20
5.5.3 Changing a Battery in the VADPAK 21
5.6 VADPAK 22
5.6.1 To Manage the VADPAK 23
5.7 Controller Replacement 26
5.8 Patient Home Support System (PHSS) 29
5.8.1 Connecting to the Power Source 29
5.8.2 Recharging Batteries 31

6.0 HeartAttendant® 33
6.1 Connecting to the Power Source 33
6.2 Using the HeartAttendant® as a Power Source 34
6.3 Description of Screens 34
6.3.1 Displays Common to All HeartAttendant® Screens 34
6.3.2 Patient Display Screens 36
6.3.3 Sleep Mode 38
6.4 Hazards 39
6.4.1 Grounding 39

7.0 The Controller: Front Panel Display, Alarms and Troubleshooting 41
7.1 Standard Messages (Seven Scrolled Information Screens) 42
7.2 Alarms 44
7.2.1 Emergency Alarms 44
7.2.2 Diagnostic Alarms 46
7.2.3 Fail-Safe Alarm 49
7.2.4 Controller Failure Alarm 49

8.0 Summary of Use 51
8.1 Quick Reference—Alarms from the Controller 51
8.2 Quick Reference—Alarms from the PHSS 55
8.3 Quick Reference—Alarms on HeartAttendant® 56
8.3.1 Emergency Alarm: Red Flashing Bar 56
8.3.2 Diagnostic Alarm: Yellow Flashing Bar 57

9.0 Daily Checks 59
9.1 Daily Checks using PHSS 59
9.1.1 Before You Go To Sleep 59
9.1.2 When You First Wake in the Morning 59
9.2 Daily Checks Using the HeartAttendant® 60
9.2.1 Before You Go To Sleep 60
9.2.2 When You First Wake in the Morning 60

10.0 Daily Operation 61
10.1 Tethered Operation 61
10.2 To Switch from Untethered to Tethered Operation 62
10.2.1 Be Sure that the CDAS, HeartAttendant®, or PHSS is ready to be used 62
10.2.2 Connect the CDAS, HeartAttendant®, or PHSS Interface Cable to the External Interface Port 62
10.3 Untethered Operation 63
10.4 To Switch from Tethered to Untethered Operation 63
10.4.1 Before Disconnecting From the CDAS, HeartAttendant®, or PHSS 63
10.4.2 Disconnecting the VADPAK From the CDAS, HeartAttendant®, or PHSS 64

10.5 When Away From the Residence 64
10.6 Bathing 64
10.7 Using the VADPAK and Shower Bag 65
10.8 Activity Restrictions 67
10.9 No Known Risk 67

11.0 Self-Care 69
11.1 Caring for the HeartAssist 5® VAD System While at Home 69
11.1.1 Exit Site 69
11.1.2 Percutaneous Cable Strain Relief 69
11.1.3 VADPAK 69
11.1.4 Medications 70

12.0 Equipment Care and Maintenance 71
12.1 Controller 71
12.2 CDAS 71
12.3 HeartAttendant® 71
12.4 PHSS 71
12.4.1 Changing Power Fuses on the Side of the PHSS 72
12.4.2 Changing the Controller Power Fuses on the Front of the PHSS 73
12.5 Warranty and Service 75
12.5.1 CDAS 75
12.5.2 PHSS and HeartAttendant® 75
12.6 Voltage Selector and Settings 75

13.0 Emergency Response and Troubleshooting 77
13.1 Emergency Response 77
13.2 Troubleshooting 78
13.2.1 Non Pump-Related Problems 78
13.2.2 VADPAK Problems 81
13.2.3 PHSS and HeartAttendant® Problems 82

14.0 The Pediatric Patient on HeartAssist 5® Pediatric VAD Support 83
14.1 Implant Surgery 83
14.2 Description 83
14.3 Environmental Conditions 83
14.3.1 Temperature 83
14.3.2 Contact with Liquids 84
14.3.3 Electromagnetic Interference 84
14.3.4 Electrostatic Discharge 85
14.4 Operating the HeartAssist 5® Pediatric VAD System 85
14.5 Daily Operation 86
14.5.1 Leaving your house 86
14.5.2 Return to School 86
14.5.3 Activities 87
14.5.4 Bedtime 87
14.5.5 Bathing 87
14.6 Emergencies 87

Figures

3.0: Description of HeartAssist 5® VAD System 5
Figure 3-1: The HeartAssist 5® VAD System 5
Figure 3-2: Assembled HeartAssist 5® VAD Pump 6
Figure 3-3: Assembled HeartAssist 5® Straight VAD Pump 7
Figure 3-4: The Controller 8
Figure 3-5: The CDAS with Laptop PC 9
Figure 3-6: The CDAS with Panel PC 9
Figure 3-7: The PHSS 10
Figure 3-8: The HeartAttendant® Console 12
Figure 3-9: The VADPAK System (with Controller and Batteries Installed) 13
Figure 3-10: The VADPAK Shower Bag 14

5.0: Connecting Your Controller to the VADPAK, CDAS, PHSS, or HeartAttendant® 17
Figure 5-1: Battery Charge Indicators 19
Figure 5-2: Connecting the VADPAK Battery Pocket Cable 20
Figure 5-3: The VADPAK 22
Figure 5-4: VADPAK Battery Bays 23
Figure 5-5: Battery Connector Cables 24
Figure 5-6: Battery Fastener 24
Figure 5-7: Closed VADPAK Cover 25
Figure 5-8: External Interface Port Connection 25
Figure 5-9: Description of Components 26
Figure 5-10: Internal Battery 27
Figure 5-11: Attaching the White Defibrillation Insulator 28
Figure 5-12: AC Power Setting 29
Figure 5-13: Connecting to AC Power Source 30
Figure 5-14: Battery Compartments 31
Figure 5-15: Inserting Batteries into PHSS Battery Slots 32

6.0: HeartAttendant® 33
Figure 6-1: AC Power Setting 33
Figure 6-2: Connecting the Controller to the HeartAttendant® as a Power Source 34
Figure 6-3: Alarm Status Bar 35
Figure 6-4: Status Display 35
Figure 6-5: Patient Display Screen 36
Figure 6-6: Alarm Status Bar with Sleep and Alarm History Buttons 36
Figure 6-7: Alarm Status Bar with Sleep and Alarm History Buttons and Alarms Detected 36
Figure 6-8: Alarm Status Bar with Sleep and Alarm History Buttons and Emergency Alarms Detected 36
Figure 6-9: Current Alarms and Alarm History Window 37
Figure 6-10: Acknowledge Controller Alarms button 38
Figure 6-11: Sleep Mode Display 39
Figure 6-12: "Mains" Input Socket on the Rear Panel of the HeartAttendant® 40
Figure 6-13: Fuse block in power inlet module 40

7.0: The Controller: Front Panel Display, Alarms and Troubleshooting 41
Figure 7-1: Controller Front Panel 41
Figure 7-2: Default Screen 1 42
Figure 7-3: Default Screen 2 42
Figure 7-4: Default Screen 3 42
Figure 7-5: Default Screen 4 43
Figure 7-6: Default Screen 5 43
Figure 7-7: Default Screen 6 43
Figure 7-8: Default Screen 7 44
Figure 7-9: Emergency Alarm 1 44
Figure 7-10: Emergency Alarm 2 45
Figure 7-11: Emergency Alarm 3 45
Figure 7-12: Diagnostic Alarm 1 46
Figure 7-13: Diagnostic Alarm 2 46
Figure 7-14: Diagnostic Alarm 3 46
Figure 7-15: Diagnostic Alarm 4 47
Figure 7-16: Diagnostic Alarm 5 47
Figure 7-17: Diagnostic Alarm 6 47
Figure 7-18: Diagnostic Alarm 7 47
Figure 7-19: Diagnostic Alarm 8 48
Figure 7-20: Diagnostic Alarm 9 48
Figure 7-21: Diagnostic Alarm 10 48
Figure 7-22: Diagnostic Alarm 11 48
Figure 7-23: Diagnostic Alarm 12 49
Figure 7-24: Fail-Safe Alarm 49
Figure 7-25: Controller Failure Alarm 49

10.0:Daily Operation 61
Figure 10-1: Using the VADPAK and Shower Bag - Step 2 65
Figure 10-2: Using the VADPAK and Shower Bag - Step 3 65
Figure 10-3: Using the VADPAK and Shower Bag - Step 4 66

12.0:Equipment Care and Maintenance 71
Figure 12-1: AC Power Input Module Latch 72
Figure 12-2: The Fuse Drawer 73
Figure 12-3: Controller Power Fuse on the Front of the PHSS 74

General Warnings and Precautions

Warnings

1. Do not undergo an MRI. Strong magnetic fields may affect device operation.
2. Do not use the PHSS or HeartAttendant® with ventricular assist devices other than the HeartAssist *5*® VAD System.
3. Do not disconnect both Batteries at the same time. The Pump will stop.
4. Do not disconnect the Pump from the Controller. The Pump will stop.
5. Disconnect the Controller from the PHSS or HeartAttendant® before unplugging the PHSS or HeartAttendant® from the power source.
6. Disconnect the power cord from the power source before changing fuses.
7. Use only Batteries supplied by MicroMed Cardiovascular, Inc.
8. Use only fuses supplied by MicroMed Cardiovascular, Inc. for the PHSS and HeartAttendant®.
9. Use only power cable(s) supplied by MicroMed Cardiovascular, Inc.
10. Do not open the back cover of any MicroMed Cardiovascular, Inc. device.
11. **Before external defibrillation**, the PHSS must be disconnected from the patient. The patient should be receiving power from the two Batteries in the VADPAK.
12. Before leaving the hospital, make sure the backup Controller has been preprogrammed to the same speed and alarm thresholds as the main Controller.
13. The PHSS or HeartAttendant® should not be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
14. Do not operate the CDAS, PHSS, or HeartAttendant® where temperatures are less than 10° C (50° F) or greater than 40° C (104° F).
15. Do not operate the Controller where temperatures are less than –10° C (14° F) or greater than 40° C (104° F).
16. Do not store the system in environments where temperatures are less than –20° C (–4° F) or greater than 55° C (131° F).
17. DO NOT attempt to wipe the liquid from the inside of the battery ports as the connector pins may become bent or otherwise damaged.

Cautions

1. Federal law restricts this device to sale or use by or on the order of a physician (or properly licensed practitioner).

2. Implantable parts of this system should not be reused.

3. Do not drop the PHSS, HeartAttendant®, or the Controller on any hard surface. Dropping it may damage internal components causing the device to malfunction.

4. Do not submerge the Controller in liquid. Submerging the Controller in liquid may damage internal components causing the device to malfunction. Do not expose the Controller to moisture.

5. Do not submerge Batteries in liquid or expose to heat. Submerging the Batteries in liquid or exposure to heat may cause them to malfunction. Do not expose the Batteries to moisture.

6. Do not expose the CDAS or HeartAttendant® to moisture.

7. The operator should not attempt to make any changes to system software or use the device as a laptop computer. Any modification of, or attempt to modify, the operating system software could result in rendering this device nonfunctional for its intended use.

8. The PHSS or HeartAttendant® should not be used near water, while bathing, or while showering due to the risk of electrical shock.

9. The Controller must always be placed in the Surgery Pouch (with battery) or the VADPAK to promote proper cooling of the Controller and eliminate potential harm to the patient.

10. The Percutaneous Cable from the patient to the Controller should be handled with care to prevent damage.

11. All connectors should be handled with care and kept free of liquid, dust or debris.

12. Take care not to trip over the power cord. Persons in the area should be instructed to take care to prevent tripping.

13. The CDAS, PHSS, or HeartAttendant® may be cleaned by wiping down with a damp cloth, followed by a wipe down with isopropanol to remove contaminants.

14. Do not invert the cabinet of the PHSS or HeartAttendant® while installing Batteries.

15. Avoid placing or operating the PHSS or HeartAttendant® in areas or near appliances that may expose it to temperatures outside its operating range of 10° C (50° F) to 40° C (104° F).

16. Batteries not in use with the VADPAK should be recharging in the PHSS or HeartAttendant® or other MicroMed Cardiovascular, Inc. charging system (i.e., the ChargePAK) at all times.

17. The PHSS may radiate radio frequency energy that may cause harmful interference with other devices in the vicinity if it is not installed and/or used according to instructions.

18. When the PHSS is not supplying power to the HeartAssist *5*® VAD or charging Batteries, the Batteries should be removed.

19. The Fail-Safe Dongle must be kept in the VADPAK.

20. The spare Controller, spare Battery Pocket, and Batteries must be accessible to the patient at all times.

21. Do not service this equipment yourself. Only qualified personnel can service this equipment. If service is required, contact your Support Team personnel.

22. Do not use the PHSS outside the hospital unless the following requirements can be met: 120 Volts, 60 Hz, 3 Amps, or 240 Volts, 50 Hz, 2 Amps.

23. Do not use the HeartAttendant® outside the hospital unless the following requirements are met: 115 Volts, 60 Hz, 3 Amps or 230 Volts, 50 Hz, 1.5 Amps.

24. When connecting the Controller to the PHSS or HeartAttendant®, ensure that MAINS (AC) power is available and/or fully charged Batteries are installed in the VADPAK battery pockets.

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

26. Damage can occur to the PHSS, HeartAttendant®, VADPAK cable, Controller ports, or VADPAK port if the connector is forced without proper alignment. DO NOT try to force a battery cable plug into the battery port on the Controller. Verify the correct VADPAK cable plug is being inserted in the correct battery port on Controller, and the red dots are aligned. When removing the cable, hold the connector and pull out. DO NOT twist the battery plug while inserting or removing after the connectors are aligned.

27. DO NOT obstruct the fans on the side of the PHSS OR close the flap of the PHSS cover when Batteries are charging. Doing so may prevent the Batteries from charging properly.

28. DO NOT obstruct the fans on the side of the HeartAttendant®. Doing so may prevent the Batteries from charging properly.

29. Do not shower with the VADPAK without it being properly encased in the provided Shower Bag.

Section
1

1.0 Overview

This manual gives you and your caregiver the information that you will need to use and care for the HeartAssist *5*® VAD System. It covers normal use and also explains how to handle emergencies. Please read the entire manual before using the HeartAssist *5*® VAD System without supervision. Unless otherwise specified, HeartAssist *5*® VAD refers to the curved inflow cannula, the straight inflow cannula (HeartAssist *5*® Straight VAD), and the pediatric VAD (HeartAssist *5*® Pediatric VAD) designs.

Following is a brief description of the kind of information you will find in each section. For more information, go to the appropriate section.

Preface **General Warnings and Precautions**

What are some general things that I should know about my device? When should I call for help?

Section 1. **Overview**

How is the manual arranged? What information is presented in each section?

Section 2. **Introduction to the HeartAssist 5® VAD**

Why do I need the HeartAssist *5*® VAD System? What does it do?

Section 3. **Description of HeartAssist 5® VAD System**

What are the names of the parts of the HeartAssist *5*® VAD System? What do they look like?

Section 4. **Environmental Conditions**

What kind of temperatures can I use it in? Are there conditions I should avoid while using my system?

Section 5. **Connecting Your Controller to the VADPAK, CDAS, PHSS, or HeartAttendant®**

How do I set up the HeartAssist *5*® VAD? Are there any special requirements?

Section 6. HeartAttendant®

How do I connect to, recharge, and use the HeartAttendant®?

Section 7. The Controller: Front Panel Display, Alarms and Troubleshooting

What do the different messages on the display mean? What do the alarms mean? What do I do if there is an alarm?

Section 8. Summary of Use

What should I do if something happens?

Section 9. Daily Checks

How do I check to see if the HeartAssist *5*® VAD is working properly? What do I need to do every day?

Section 10. Daily Operation

What will I be able to do while using this device? How often will I need to change Batteries and how will I tell? Are there some things I should not do while using the HeartAssist *5*® VAD?

Section 11. Self-Care

How do I take care of the area where the Pump Percutaneous Cable comes out of my body, i.e., exit site? When will I need to see my doctor?

Section 12. Equipment Care and Maintenance

How do I take care of the HeartAssist *5*® VAD and its components? Do I need to clean them? Is there someone I can speak with if I need advice?

Section 13. Emergency Response and Troubleshooting

How do I troubleshoot my system?

Section 14. The Pediatric Patient on HeartAssist 5® Pediatric VAD Support

Are there special considerations for children using the HeartAssist *5*® Pediatric VAD?

Section
2

2.0 Introduction to the HeartAssist *5*® VAD

You and your doctor have chosen to use the HeartAssist *5*® VAD to help support your body's circulation. Since your heart cannot pump well enough to adequately circulate the blood, theHeartAssist *5*® VAD will assist the pumping function of the left ventricle, the main pumping chamber of the heart.

This manual gives you and any caregiver information about the HeartAssist *5*® VAD, explaining how it works and how to care for the system. Your technical and clinical support staff have detailed manuals to supplement the Patient User's Manual.

The HeartAssist *5*® VAD System potentially has two configurations: one configuration consisting four components: 1) the Pump System; 2) the VADPAK that contains the Controller and Batteries; 3) the Clinical Data Acquisition System (CDAS); and 4) the Patient Home Support System (PHSS) and one configuration consisting of three components: 1) the Pump System; 2) the VADPAK that contains the Controller and Batteries; and 3) the HeartAttendant®.

2.1 The Pump System

The Pump System is implanted and consists of the following components:

- Pump
- Inflow Cannula
- Flow Probe
- Outflow Graft
- Percutaneous Cable

The inflow cannula is inserted in the left ventricle of the heart and carries the blood to the Pump. The outflow graft is attached to the aorta and carries blood away from the Pump to the aorta.

A three-phase electric motor is integrated in the Pump and driven by the Controller. The Pump is connected to the Controller via a Percutaneous Cable that is passed through the skin. The Percutaneous Cable contains the three-phase Pump power cable and the flow probe cable.

2.2 The Controller

The Controller is a completely external module. It has audible and visual alarms, with messages and prompts displayed on the Liquid Crystal Display (LCD). The Controller displays flow rate, power consumption, percentage battery charge remaining, voltage, Pump speed and various diagnostic and emergency messages.

2.3 The Clinical Data Acquisition System (CDAS)

The Clinical Data Acquisition System (CDAS) consists of a computer, a signal conditioning and isolation module, a CDAS-to-Controller cable (CDAS/Controller Interface Cable), and an arterial pressure interface, all housed within one system module. The CDAS is connected to the Controller by the CDAS/Controller Interface Cable and stores Pump operating data, displays Pump and physiologic information, and can be used by your doctor or Support Team personnel to modify the Pump speed. It also serves as a primary and/or backup power source for the Pump when you are in the hospital.

2.4 The Patient Home Support System (PHSS)

The Patient Home Support System (PHSS) is portable and is designed to power the HeartAssist *5*® VAD while the patient is at home. The device eliminates the need for multiple battery changes while stationary for extended periods of time such as sleeping. The PHSS may be used as a power source for the HeartAssist *5*® VAD in or out of the hospital environment. The PHSS also serves as a battery charger. It has an alarm system that alerts when there is a power loss and automatically switches to battery power. With Batteries, the PHSS weighs approximately 7.7 kg (17 lbs).

2.5 The HeartAttendant® Console

The HeartAttendant® is a portable console that is designed to power the HeartAssist *5*® VAD while the patient is in the hospital and at home. The HeartAttendant® console provides power and communication for the HeartAssist *5*® VAD and transmits data from the patient-worn Controller. The HeartAttendant® software allows real-time visualization of the pump performance and its interaction with the native heart via a flow wave form. Also displayed are bar charts indicating power usage and mean flow. Other screens allow your doctor or support personnel to program pump operating parameters and alarm levels. Each patient is issued a HeartAttendant® upon implant and keeps the device for the duration of the implant.

Section
3

3.0 Description of HeartAssist 5® VAD System

3.1 The HeartAssist 5® VAD System

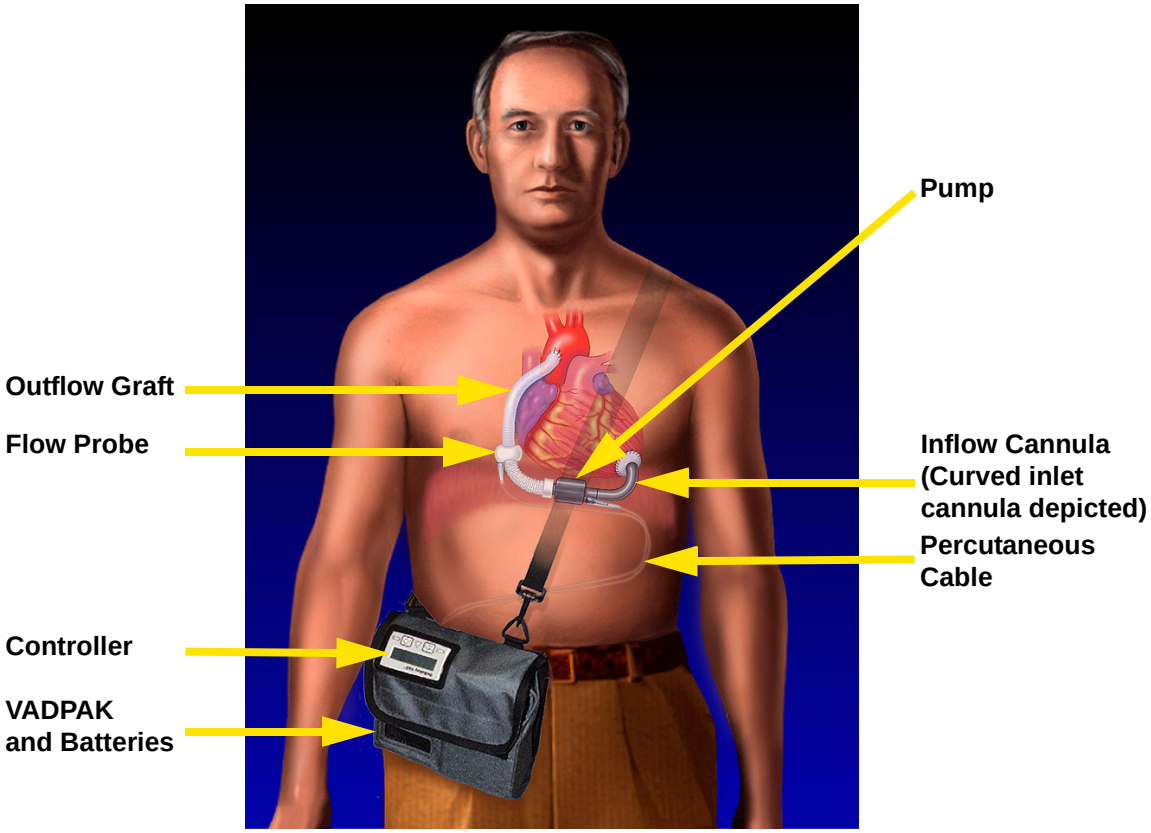


Figure 3-1 The HeartAssist 5® VAD System

You have the following components of this system:

- Pump (Implanted)
- Inflow Cannula (Implanted)
- Flow Probe (Implanted)
- Outflow Graft (Implanted)
- Percutaneous Cable (Partially Implanted)
- VADPAK and Batteries
- Controller

3.2 The Pump

The Pump is attached to a titanium inlet cannula that is placed in the left ventricle of the heart. A Dacron® graft is connected to the Pump outlet and attached to the aorta. A three-phase electric motor is integrated in the Pump and driven by the Controller. The Pump is connected to the Controller via a Percutaneous Cable that is passed through the skin. The Percutaneous Cable contains the Pump power cable and the flow probe cable.

The "exit site" is the area of your skin around which the Percutaneous Cable leaves your body.

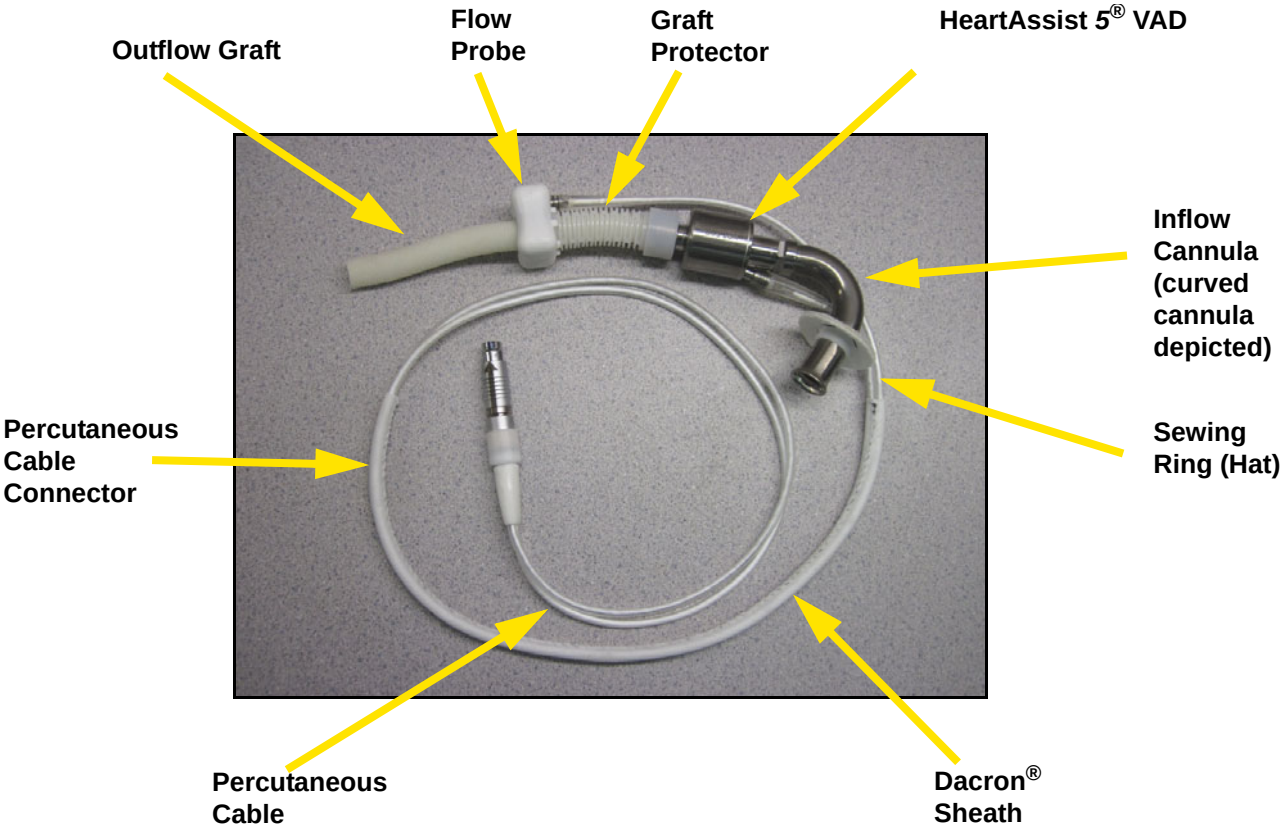


Figure 3-2 Assembled HeartAssist 5® VAD Pump

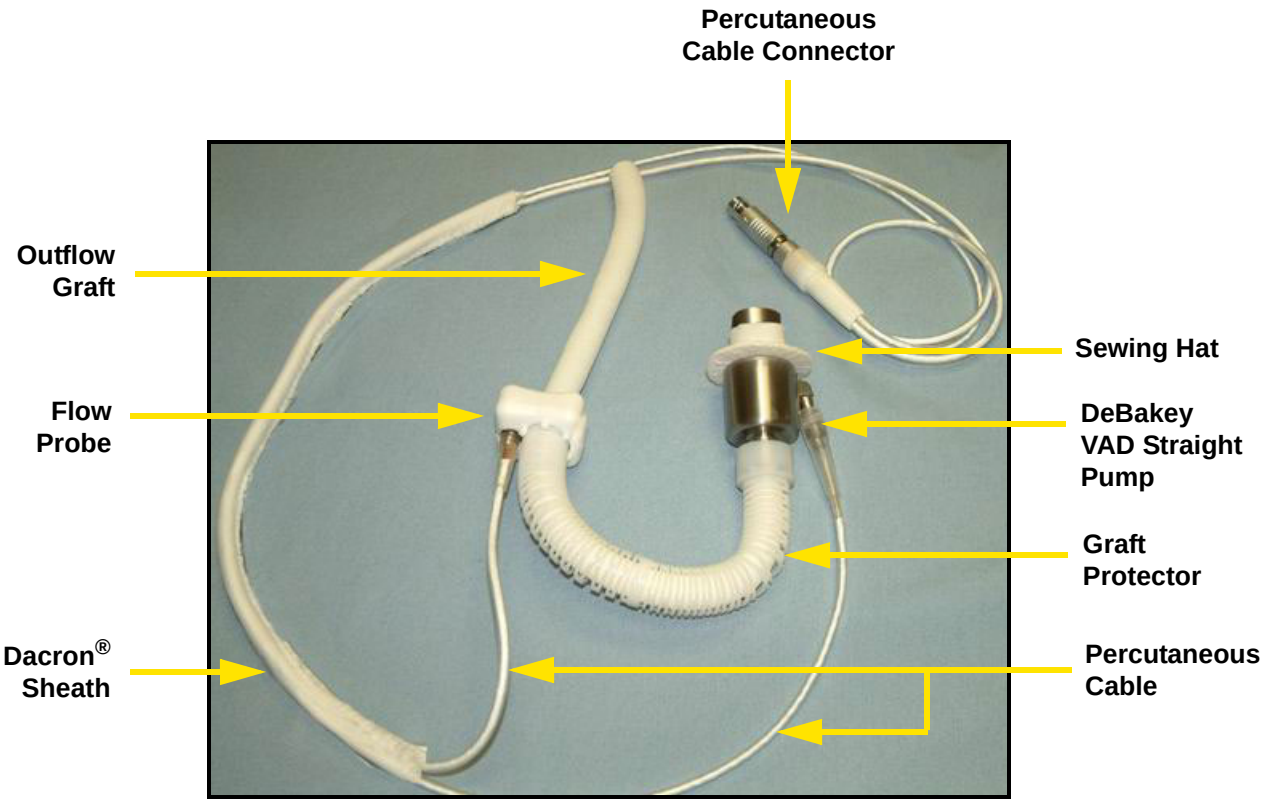


Figure 3-3 Assembled HeartAssist 5® Straight VAD Pump

3.3 The Controller

The Controller has two battery ports and one VAD port. The front display of the Controller contains the Liquid Crystal Display (LCD), two battery Light Emitting Diodes (LEDs), one fail-safe LED and two buttons; one to silence alarms and the other to scroll the display information.

The Controller is designed to be reliable and easy to operate. You can view the operational parameters of your VAD on the LCD as well as any emergency or diagnostic alarms that may occur. See Section 7.0, "The Controller: Front Panel Display, Alarms and Troubleshooting" for a description of front panel display and alarms.

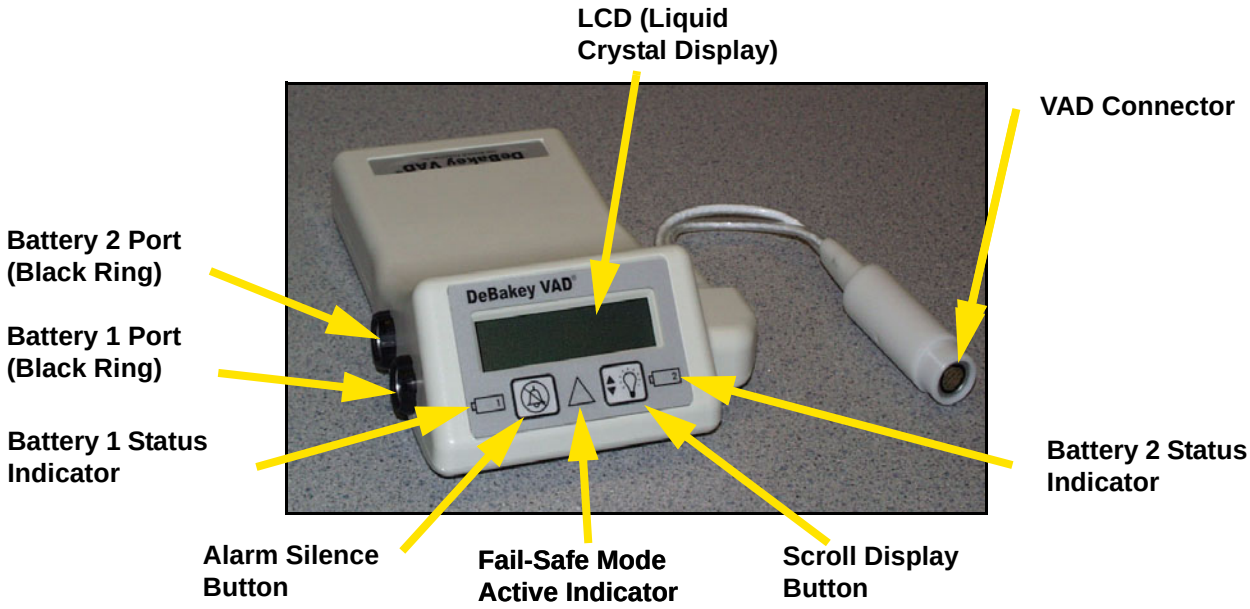


Figure 3-4 The Controller

3.4 Clinical Data Acquisition System (CDAS)

Figures 3-5 and 3-6 show the CDAS with Laptop PC and the CDAS with Panel PC. Both versions are in use and have the same functions. The description and operational instructions provided within this manual apply to both. Its primary purpose is to supply power and communicate with the Controller. The CDAS primary power is provided by an alternating current power source ("wall power") of 220VAC or 110VAC, depending on where you live. In addition to providing power to the Pump, the CDAS can change Pump speed and alarm thresholds. It also monitors and displays patient data and Pump operating parameters as well as captures alarm data. The CDAS is intended for in-hospital use only.

Figure 3-5 The CDAS with Laptop PC

Figure 3-6 The CDAS with Panel PC

3.5 Patient Home Support System (PHSS)

The Patient Home Support System (PHSS) is shown in Figure 3-7. It is designed to power the Controller by using 120 to 240 volts (50 to 60 hertz) AC power for extended use, eliminating the need for changing Batteries while stationary for extended periods. The PHSS also charges the Batteries to be used in the VAD system. Both of these operations can be performed simultaneously.

With Batteries, the PHSS weighs approximately 7.7 kg (17 lbs.). It is supplied in a durable cloth case that is both moisture and flame resistant.

Note: DO NOT obstruct the fans on the side of the PHSS <u>OR</u> close the flap of the PHSS cover when Batteries are charging. Doing so may prevent the batteries from charging properly.

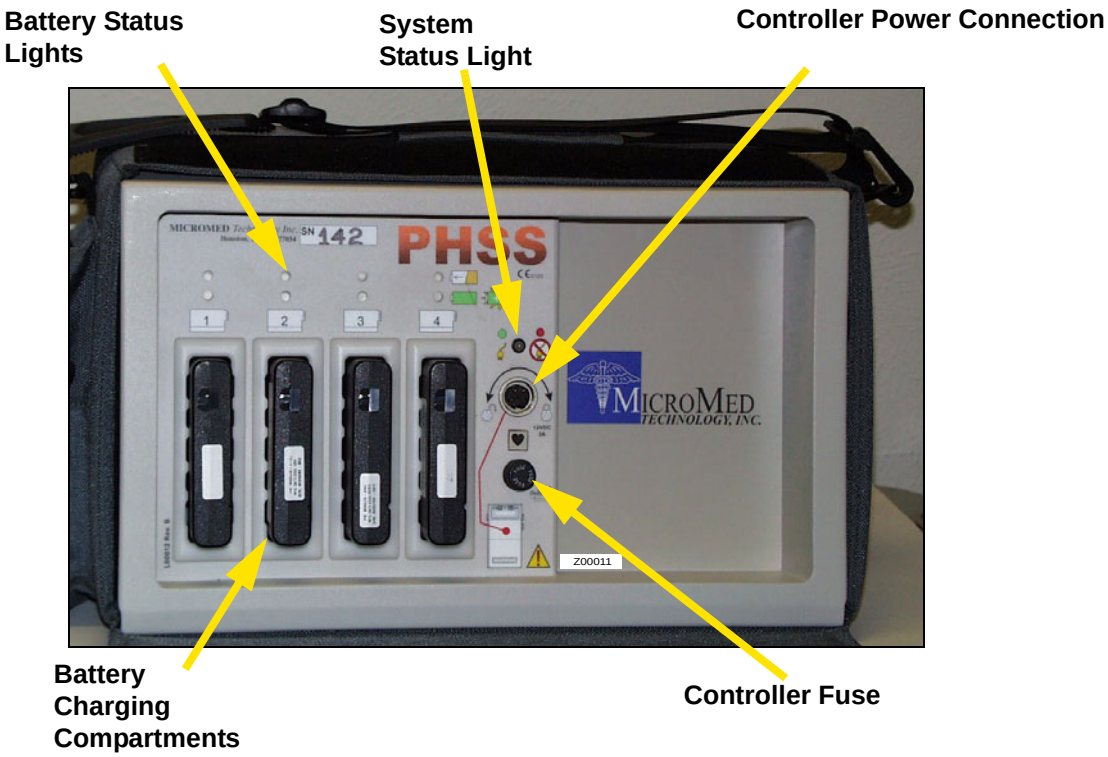


Figure 3-7 The PHSS

The symbols indicated on the PHSS labeled Z00011 are defined below:

Attention: Refer to Manual for Additional Information

Yellow Light: Battery is charging or awaiting charge

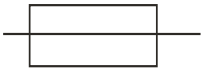
Green Light: Battery is charged

Flashing Green Light: Battery with the highest charge

Schematic of Battery Insertion

Type CF in accordance with EN 60601-1:1990

Danger: Risk of Electric Shock



Fuse

Locked

Unlocked

AC Mains Connected

AC Mains Not Connected

Controller

3.6 The HeartAttendant® Console

The HeartAttendant® is shown in Figure 3-8. The HeartAttendant® combines the functions of the CDAS and the PHSS units. It is designed to power the HeartAssist 5® VAD and Controller. The HeartAttendant® has a 7.5" touch screen for patient viewing of the Patient status screens and for physician or support staff viewing of the Patient, Holter, Pump, Setup, and Data status screens using a password.

Housed in the bottom left corner is a connector used with the Patient Interface Cable to connect to the Controller. Components inside the unit include a computer, patient isolation board, power supply, and toroid isolation transformer.

Figure 3-8 The HeartAttendant® Console

3.7 VADPAK

After implantation of the HeartAssist 5® VAD, you will be able to carry the Controller and Batteries using the VADPAK, an ergonomically designed wearable system that enables the patient to be mobile. The system is comprised of four integrated components:

- A plastic housing which provides structural form, protection, and secures all of the other components.
- A smart battery interface board which allows for the quick connection and disconnection of power and control devices via an external interface connector. This unit provides automatic switching from battery 1 of the Controller to an approved power supply or control device when the power supply or control device is connected via the External Interface Port.
- The External Interface Port (see Figure 3-9) allows connection to an approved external power source or control device without the need to disconnect the Battery cables within the VADPAK.
- A protective pouch with padded shoulder and waist support straps.

Figure 3-9 The VADPAK System (with Controller and Batteries Installed)

3.8 VADPAK Shower Bag

The VADPAK Shower Bag (see Figure 3-10) is designed to allow the patient to perform normal hygienic tasks such as showering while protecting the VADPAK, Controller, and Batteries from moisture.

Figure 3-10 The VADPAK Shower Bag

Section
4

4.0 Environmental Conditions

The HeartAssist *5*® VAD System is made of tough, durable materials, but it does require some basic care as described below. In addition, Support Team personnel should perform periodic safety and function checks of your HeartAssist *5*® VAD System equipment.

4.1 Temperature Conditions

- Do not operate the Controller where temperatures are less than -10° C (14° F) or greater than 40° C (104° F).
- Do not operate the CDAS, PHSS, or HeartAttendant® where temperatures are less than 10° C (50° F) or greater than 40° C (104° F).
- Do not store the system in environments where temperatures are less than -20° C (-4° F) or greater than 55° C (131° F).
- The Batteries should not be exposed to moisture or heat.
- The Controller, VADPAK, PHSS, and HeartAttendant® should not be exposed to moisture.
- The VADPAK carry bag is flame retardant but care should be exercised when used near open flame or embers. Any hot item that falls onto or within the bag should be removed as quickly as possible to prevent scorching or marring of the materials.

4.2 Contact with Liquids

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

4.3 Electromagnetic Interference

Laboratory testing suggests that there is little risk from most devices that may produce electromagnetic interference (such as metal detectors, microwave ovens, and cellular phones). The HeartAssist *5*® VAD has been shown to be safe from electromagnetic interference but the

system has not been tested with each possible brand of such devices, and the possibility of electromagnetic interference may exist.

Caution: **If you experience unexpected changes in the speed of the HeartAssist *5*® VAD, see if there is a potential source of electromagnetic interference (such as cellular phones, radio transmitters, microwave ovens) within a few feet. If there is, move away from the potential source and see if the HeartAssist *5*® VAD operation returns to normal. If it does not return to normal, contact your Support Team.**

Warning: **Do not undergo an MRI. The strong magnetic field may affect device operation causing injury to you.**

Section
5

5.0 Connecting Your Controller to the VADPAK, CDAS, PHSS, or HeartAttendant®

You should practice connecting the HeartAssist 5® VAD System with your Support Team personnel before connecting it on your own. This lets you become familiar with each part of your system, how they connect, and what they do. If you have any questions during the system connection, please contact your Support Team personnel for more information.

5.1 General Considerations

This equipment has alarm sounds and light indicators to let you know about important system conditions. The Controller has a display to tell you about these conditions.

Protect the power cords and equipment cables. **Do not** put them where people walk. **Do not** allow anything heavy to rest on top of or roll over the cables. Avoid pinching cables in doors, drawers, etc. To avoid the possibility of electric shock, replace frayed or damaged cords and plugs by contacting your Support Team personnel.

Use **only** the power cord(s) supplied with this system. **Do not** use an extension cord or adapters with this system.

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

Caution: **Plug this equipment into grounded outlets only. This reduces the risk of shock.**

Note: If the power outlets are not grounded, an electrician will need to install grounded outlets before you can use this equipment outside of the hospital.

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

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

5.2 Clinical Data Acquisition System (CDAS)

The CDAS is an integral part of the HeartAssist *5*® VAD. It is the means of setting the HeartAssist *5*® VAD Pump operating parameters, communicating with the Controller and is the primary source of power during implant and recovery. The CDAS has also been designed to acquire and store real-time performance data as well as historical performance data (Holter).

Each HeartAssist *5*® VAD CDAS will support several patients, but only one at a time.

Your Support Team personnel are responsible for setting up the CDAS.

5.3 HeartAttendant® Console

The HeartAttendant® console functions as the CDAS and the PHSS units combined as one unit. The HeartAttendant® is designed to set Pump operating parameters, communicate with the Controller, and is the primary source of power for the duration of the implant.

5.4 Controller

The Controller is designed to be very reliable and easy to operate. A Liquid Crystal Display (LCD) is integrated into the Controller to display the operational parameters of the VAD as well as any emergency or diagnostic alarms that may occur.

The Controller emits three distinct audible sounds:

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

The Controller contains two memory banks called Holter memories. These memories record the performance of the Controller and the Pump.

Note: Your Support Team personnel are responsible for programming the Controller.

5.5 Batteries

The Batteries that power the HeartAssist 5® VAD are nickel metal hydride, type DR36 "smart" Batteries. Each Battery will power the VAD for approximately 2.5 to 4 hours (with flow sensor disabled) giving a combined Battery time of approximately 5 to 8 hours. Each Battery contains an integrated charge indicator consisting of four green LEDs representing 25% charge increments (see Figure 5-1). To activate the Battery indicator, press the circular "button" below the LEDs.

Four LEDs

representing 25% charge increments

Figure 5-1 Battery Charge Indicators

Note: Battery time may vary from patient to patient depending on set Pump speed.

Warning: Only use Batteries supplied by MicroMed Cardiovascular, Inc.

5.5.1 Connecting a Battery Cable to the Battery Port

The two Battery ports for the Controller are color coded black and keyed so that only the CDAS, the HeartAttendant®, the PHSS, the VADPAK Battery plugs, the backup Battery Pocket or the Fail-Safe Dongle can be inserted. To insert the Battery cable into the Controller follow the steps below:

1. Locate the red dot on the Controller port.
2. Locate the slot on the VADPAK Battery Pocket Cable plug.
3. Visually align the slot on the VADPAK Battery Pocket Cable plug with the red dot on the Controller port.
4. Once the slot and red dot are aligned, firmly push the plug **straight** in the Controller port. A slight "click" will be heard and felt as the connector becomes fully seated.

Alternately, if the slot and red dot cannot be aligned visually, the plug can be gently inserted 2 mm (1/16 of an inch) with **very little** pressure applied, rotated until it mates with the port and no longer rotates freely. At this point, the connector is firmly pushed **straight** in the port until it is fully seated.

Caution: Damage can occur to the HeartAttendant®, PHSS, or VADPAK cable, Controller ports, or VADPAK port if the connector is forced without proper alignment. DO NOT try to force a Battery cable plug into the Battery port on the Controller. Verify the correct VADPAK cable plug is being inserted into the correct battery port on Controller, and the red dots are aligned. When removing the cable, hold the connector and pull out. DO NOT twist the battery plug while inserting or removing after the connectors are aligned.

5. The Controller will sound three audible beeps and display a 3-second solid green light for that VADPAK Battery Pocket to indicate a correct insertion.

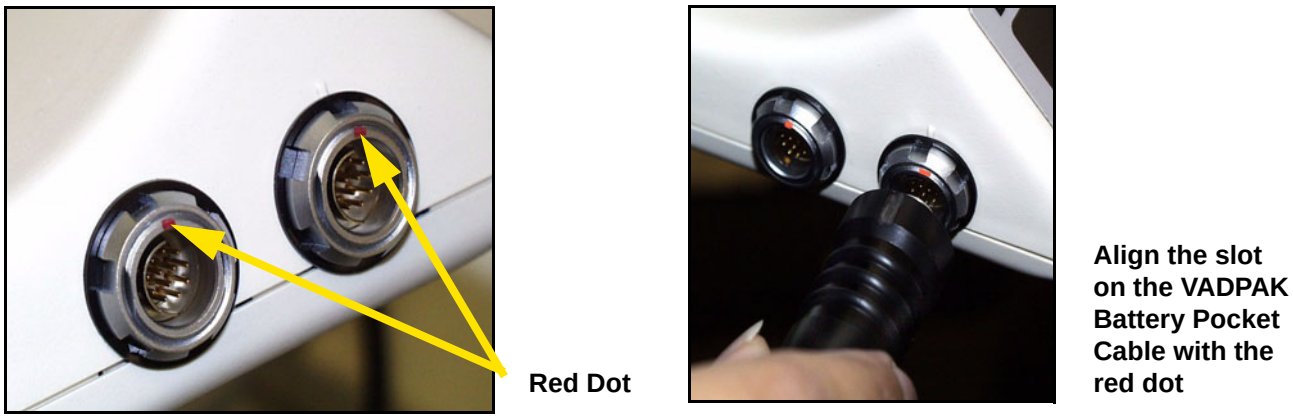


Figure 5-2 Connecting the VADPAK Battery Pocket Cable

Note: Both of the Controller's battery ports are identical and the Controller will automatically switch to take power from the appropriate Battery port.

5.5.2 Battery Indicators on the Controller

The battery port indicators on either side of the front display indicate four different conditions for each battery.

Battery Indicator	Condition
Green	Controller is using this Battery to run the Pump.
Blinking Amber	Battery is discharged, disconnected or expired.
Off	Battery is connected, charged but not currently being used to run the Pump.
Solid Green	3 seconds. Occurs immediately following a Battery insertion into a VADPAK Battery Pocket or when a spare Battery Pocket Cable plug (with charged battery) is inserted into a Battery port.

Note: The Controller always uses the Battery with the lower charge down to 25% thus preserving the Battery with the highest charge.

Note: You must periodically (every 2 to 3 hours) visually inspect the front panel of the Controller to verify Battery status in case the diagnostic audible alarm fails.

5.5.3 Changing a Battery in the VADPAK

1. Verify the replacement Battery is fully charged by pressing the charge status indicator on the Battery (see Figure 5-1). All four green LEDs on the Battery should illuminate indicating a charge between 75 to 100%.

2. Open the VADPAK.

3. Press the scroll display button on the front panel of the Controller to the screen displaying the battery status.

4. Check the remaining Battery charge level for each Battery.

5. Determine which Battery is to be changed by selecting the Battery with the lower charge ensuring the remaining Battery indicates adequate charge on the Controller LCD display

6. Open the VADPAK battery pocket cover (secure by hook and loop fastener) (see Figure 5-6).

7. Slide the Battery from the pocket. VADPAK Battery Pocket 1 is the pocket that resides furthest away from your body when carrying the VADPAK. It is also designated by the number 1 triangle located on the top of the VADPAK plastic housing which points toward the appropriate Battery slot. VADPAK Battery Pocket 2 is the pocket that is closest to your body when carrying the VADPAK. It is also designated by the number 2 triangle located on the top of the VADPAK plastic housing which points toward the appropriate Battery slot. The battery indicator for that Battery on the Controller front panel will be blinking amber and the indicator for the other Battery will be green (if that battery is above 25%, otherwise it will be solid green and blinking amber simultaneously).

8. Align the long groove in the Battery with the pocket and insert the charged Battery into the pocket until a slight "click" is felt. At this time, three beeps will be heard from the Controller and the LED indicator for this new Battery will light green for three seconds.

9. Press the Alarm Silence Button on the Controller. The LED for the new Battery:

   Turns from amber to green if the replaced Battery is a lower charge than the other connected Battery

   or

   Turns from amber to off if the replaced Battery is a higher charge than the other connected Battery.

10. Close the VADPAK battery pocket cover ensuring the pocket is well sealed (see Figure 5-7). Verify the percent charge of the replaced Battery on the Controller LCD display.

WARNING: **Only remove one Battery at a time from the VADPAK. Never remove both Batteries simultaneously.**

Caution: **Even when connected to an external power supply (PHSS, HeartAttendant®, or CDAS), the Batteries located inside the VADPAK will drain and lose capacity over time. The user should ensure that these two Batteries are always as close to fully charged as possible. The capacity of these Batteries can be determined in the following ways:**

1. **The Controller display will show the percentage capacity of Battery 2 when connected to the PHSS. Battery 1 can safely be removed from the VADPAK Battery Pocket and the capacity can be checked via the Battery charge indicator LEDs.**

2. **When connected to the CDAS or HeartAttendant®, the percent capacity of Battery 2 will be shown on the patient display screen. Battery 1 capacity can be checked as detailed above.**

5.6 VADPAK

The VADPAK is an ergonomically designed wearable pouch that will enable you to be completely mobile (see Figure 5-3).

Figure 5-3 The VADPAK

5.6.1 To Manage the VADPAK

1. Insert two (2) fully charged Batteries into the VADPAK Battery bays, one Battery in each bay (see Figure 5-4).

Note: There should always be two (2) Batteries in the VADPAK Battery bays, one in each bay, except when changing batteries.

Figure 5-4 VADPAK Battery Bays

2. To ensure that the Battery is securely inserted into the Battery bay, press down on the Battery until you feel it "click".

3. Insert Controller into the larger pocket. Connect battery cables (P1 and P2) to Controller (see Figure 5-5).

4. Verify the Battery capacity by pressing the scroll display button on the front panel of the Controller. Each battery connector is labeled to help you identify which corresponds to the Battery charge shown on the Controller display (see Figure 5-5).

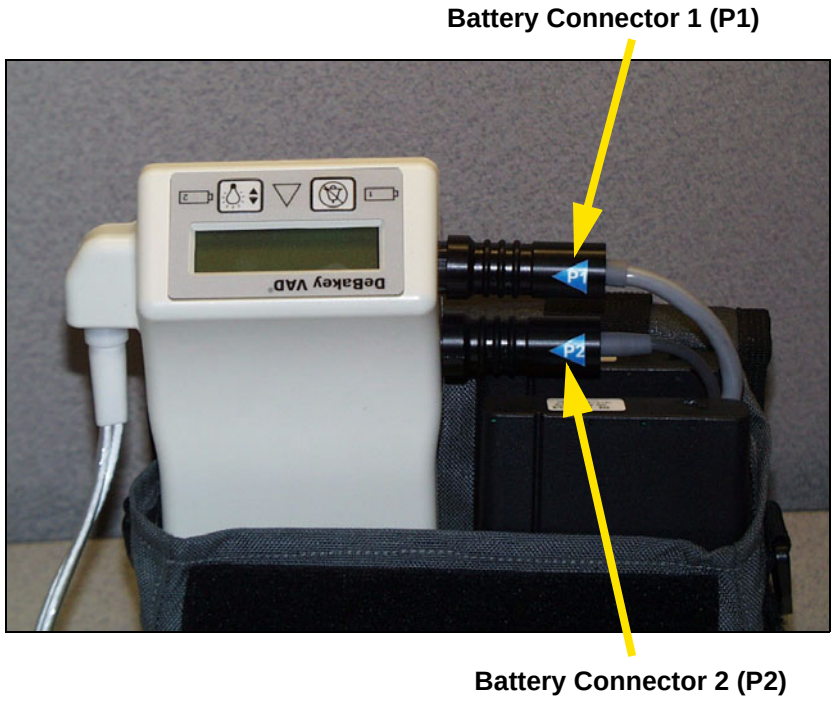


Figure 5-5 Battery Connector Cables

5. Secure the Batteries with the narrow hook and loop strap (see Figure 5-6).

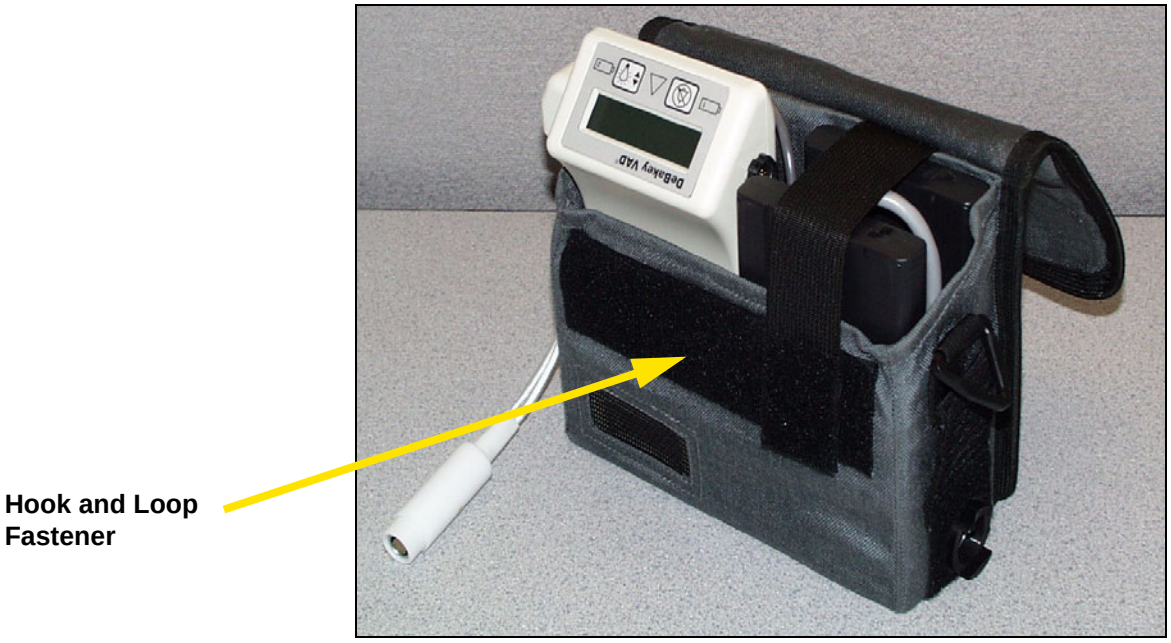


Figure 5-6 Battery Fastener

6. Close the cover of the VADPAK (see Figure 5-7).

Note: Secure the top cover of the VADPAK carry bag using the hook and loop strip.

7. When relaxing or before sleeping, connect the PHSS/Controller Interface Cable or the HeartAttendant®/Controller Interface Cable into the External Interface Port (see Figure 5-8). Make sure the VADPAK material does not inhibit the connector from being fully seated in the External Interface Port.

8. Verify the PHSS or HeartAttendant® is supplying power to the Controller by checking that the green LED on the Controller is lit.

Figure 5-7 Closed VADPAK Cover

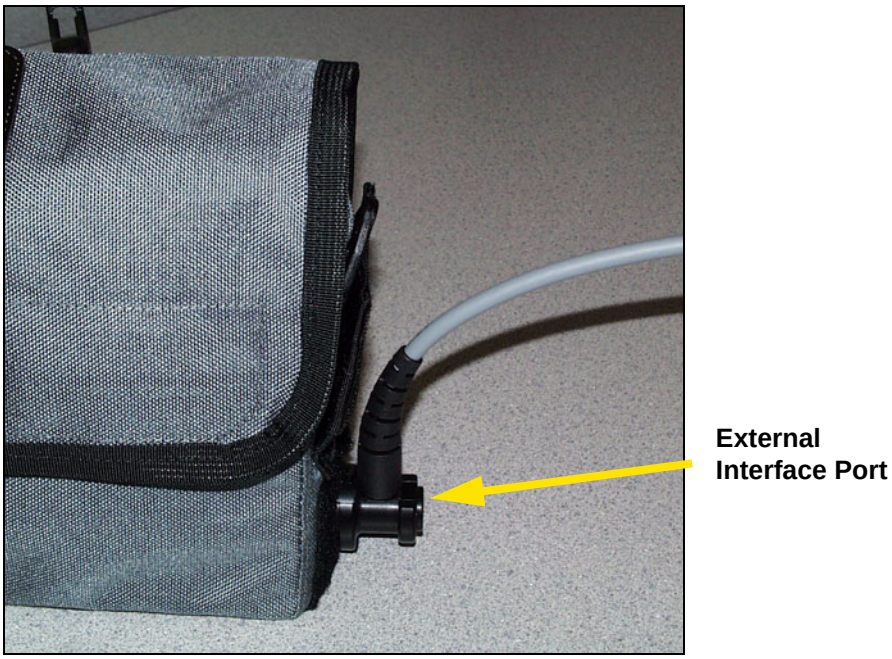


Figure 5-8 External Interface Port Connection

Note: All of the MicroMed Cardiovascular, Inc. external power and control devices (i.e., CDAS, PHSS, HeartAttendant®, or Fail-Safe Dongle) should only be connected via the External Interface Port. The battery cables connected to the Controller should never be removed unless the Controller or VADPAK needs to be changed.

Note: The hook and loop flap and the interface port cap on the side of the VADPAK carry bag should be closed over the External Interface Port whenever it is not in use.

5.7 Controller Replacement

In the event that the Controller needs to be changed, have a caregiver assist (if possible) in the following steps:

1. Sit or recline for this procedure.

Note: It is normal for the Controller to alarm during this process.

2. Ensure that both Batteries in the VADPAK are charged.

3. Unscrew the White Defibrillation Insulator from the Right Angle Extension Cable (RAEC) (see Figure 5-9 for component descriptions).

4. Disconnect the connector for VADPAK Battery Pocket 1 from the Controller currently in the VADPAK. Connect this cable to the top connector of the new (replacement) Controller. Ensure the replacement Controller has power. Leave Battery properly seated in pocket.

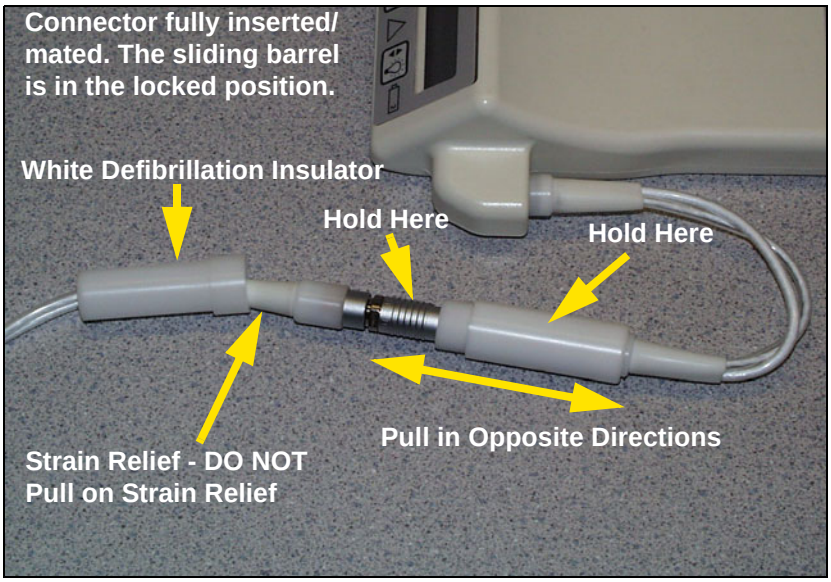


Figure 5-9 Description of Components

5. Disconnect the Percutaneous Cable from the old Controller (see Figure 5-9) and **immediately** connect it to the replacement Controller.

Note: The old Controller has an internal 9 volt battery that will cause the Controller alarm to sound. Ignore this alarm at this time or you may muffle the sound from the old Controller using a towel.

6. Press the Alarm Silence Button on the replacement Controller several times to silence alarms. (If alarm silences, the pump is running.)

7. Verify the connector is pressed in completely.

8. While holding the barrel of the connector, pull the Strain Relief Nut on the connector to engage the locking mechanism.

9. Disconnect the connector for VADPAK Battery Pocket 2 from the Controller currently in the VADPAK. Connect this cable into the bottom connector of the new (replacement) Controller. Leave Battery properly seated in pocket.

10. Remove the old Controller from its slot in the VADPAK.

11. Remove the 9 volt battery from the old Controller and install it in the replacement Controller. Press the Alarm Silence Button twice to silence the alarm (see Figure 5-10).

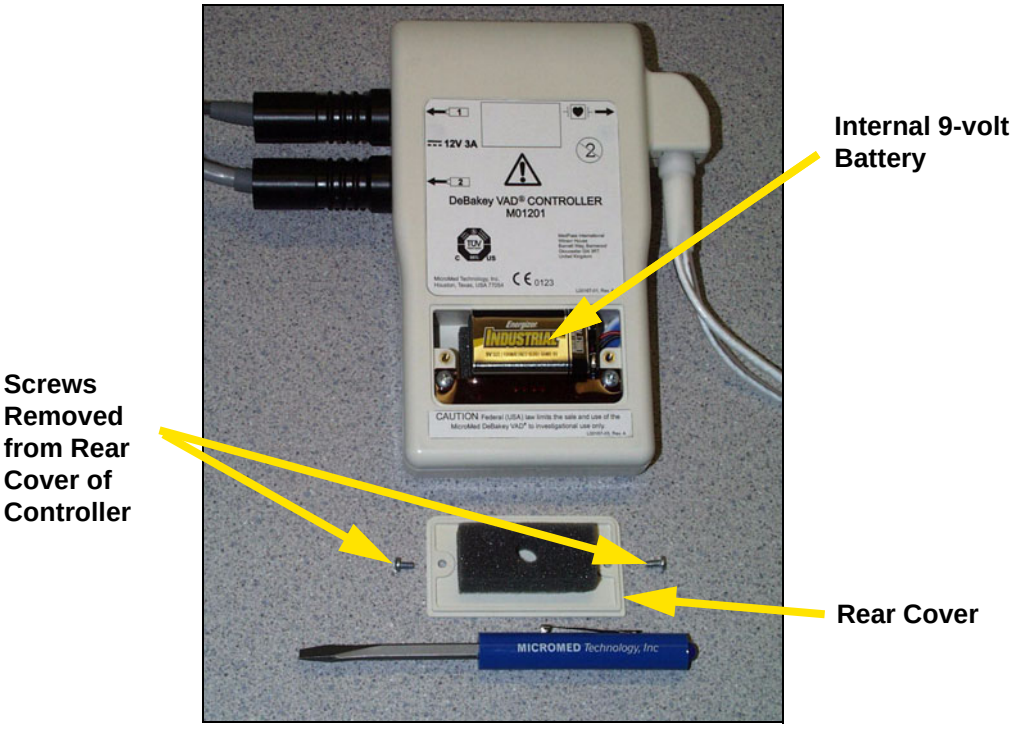
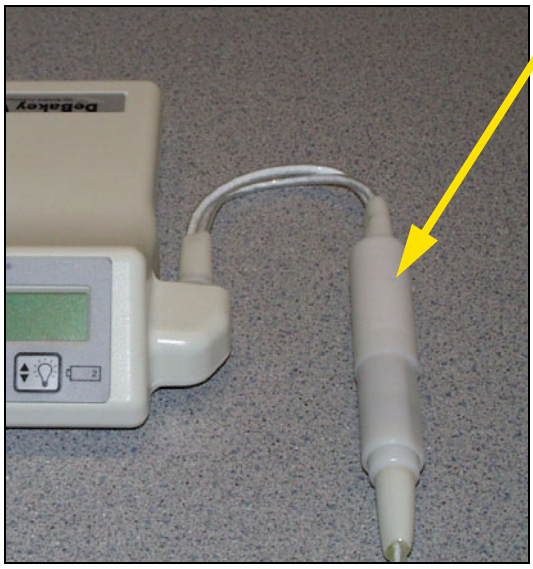


Figure 5-10 Internal Battery

12. Insert the new (replacement) Controller into the Controller slot in the VADPAK.

13. Screw the White Defibrillation Insulator onto the RAEC with finger-tight pressure only (see Figure 5-11).



White Defibrillation Insulator screwed onto RAEC Percutaneous Cable Connector. This protects the connector and the locking mechanism.

Figure 5-11 Attaching the White Defibrillation Insulator

14. Close and secure bag cover.

15. Contact your Support Team to ensure that the Pump speed and alarm settings do not need to be adjusted.

Note: In the unlikely event that the VADPAK is damaged, the PHSS, CDAS or a single Battery Pocket with a fully charged Battery should be connected to a battery port on the Controller.

5.8 Patient Home Support System (PHSS)

5.8.1 Connecting to the Power Source

The AC power setting appropriate to the country of use has been preset for either North America 120VAC, or Europe 240VAC.

1. Check the AC power input on the side of the PHSS to make sure that the power setting is appropriate (see Figure 5-12).

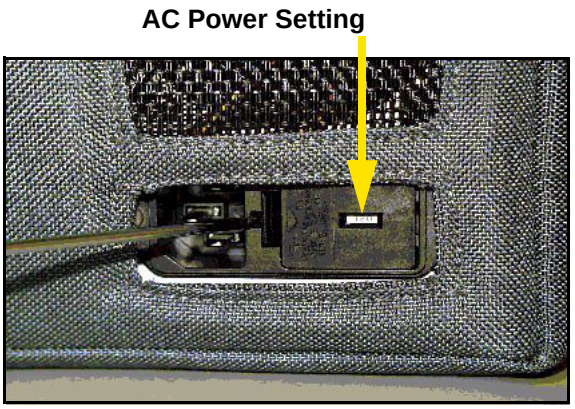


Figure 5-12 AC Power Setting

2. Plug the main power cord into the AC power input.

3. Connect the plug to the AC power source. The System Status Light (see Figure 5-14) will glow steady green when the PHSS is functioning on main power, indicating that the PHSS has passed the self-test and is ready for use.

Note: If the PHSS does not pass the self-test, ensure charged Batteries are installed in the VADPAK. Remove the Batteries from the PHSS and power cord from the wall outlet. Change the fuse on the side of the PHSS. (See Section 12.4.1, "Changing Power Fuses on the Side of the PHSS.") Plug in the AC power cord and insert the batteries. If it still does not pass the self-test, contact MicroMed Cardiovascular, Inc. immediately.

4. Insert the Batteries into the battery compartments of the PHSS.

5. To use the PHSS as the power source for the Controller:

   - Connect one end of the PHSS/Controller Interface Cable to the socket on the front of the PHSS.
   - Twist the outside threaded collar nut tightly, after securely seated (see Figure 5-13).
   - Connect the other end to the External Interface Port of the VADPAK.

Figure 5-13 Connecting to AC Power Source

5.8.2 Recharging Batteries

It is recommended that Batteries not being used in the VADPAK should be charging in the PHSS at all times (see Figure 5-14). Approximate charge time for a fully depleted Battery is two hours.

1. To recharge Batteries, open the front cloth cover of the PHSS.

Caution: Leave this cover open while the PHSS is connected to AC power.

2. Inspect the connector end of each Battery to ensure it is clean.

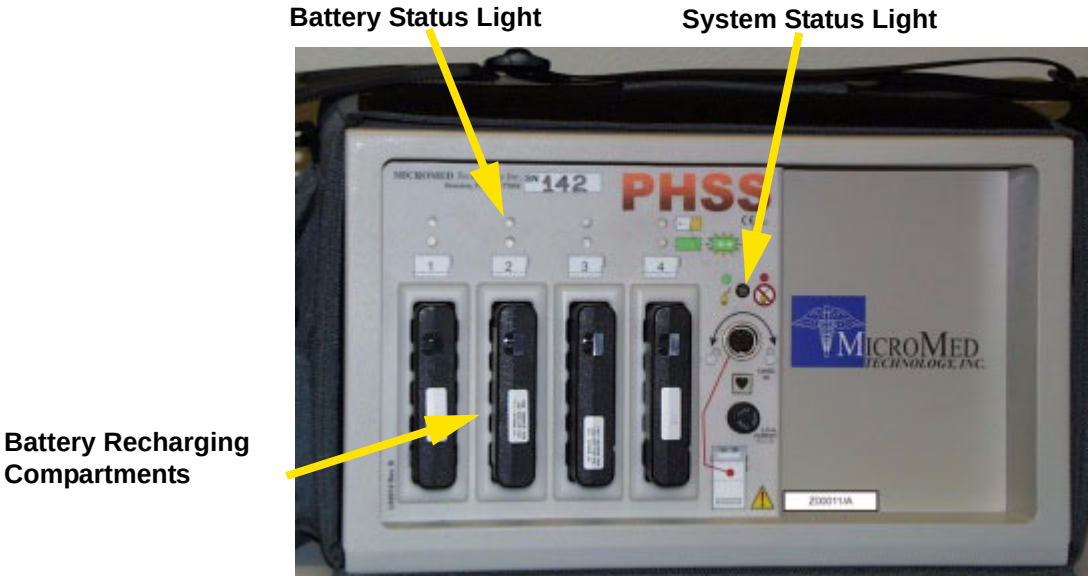


Figure 5-14 Battery Compartments

3. Insert one or more Batteries (connector side up) in the battery compartments on the front of the PHSS (see Figure 5-15), making certain each Battery is fully seated by hearing or feeling a "click" and by a lit Battery Status Light (see Figure 5-14).

Figure 5-15 Inserting Batteries into PHSS Battery Slots

4. Allow 5 to 10 seconds for the PHSS to recognize the Battery. If the Battery Status Lights above the Battery compartment show a steady yellow color, recharging is underway. If the Battery Status Lights do not light up, the Battery has not been recognized.

5. Check to make sure that it has not been put in backwards and reinsert. If the Battery Status Lights still do not light up, this Battery may not be functional. A Battery is charged when a steady green Battery Status Light appears.

Note: Always check Batteries by pushing the charge level button on the Battery to verify charge level when removing from the PHSS (see Figure 5-1 on page 19).

Section
6

6.0 HeartAttendant®

The HeartAttendant® is a portable console that is designed to power the HeartAssist 5® VAD while the patient is in the hospital and at home. The HeartAttendant® console provides power and communication for the HeartAssist 5® VAD and transmitts data to the patient-worn Controller. The HeartAttendant® software allows real-time visualization of the pump performance and its interaction with the native heart via a flow wave form. Also displayed are bar charts indicating power usage and mean flow. Other screens allow your doctor or support personnel to program pump operating parameters and alarm levels. Each patient is issued a HeartAttendant® upon implant and keeps the device for the duration of the implant.

6.1 Connecting to the Power Source

The AC power setting appropriate to the country of use has been preset for either North America 115VAC or Europe 230VAC.

1. Check the AC power input on the side of the HeartAttendant® to make sure that the power setting is appropriate. (See Figure 6-1.) If the setting is not appropriate, contact your support team.

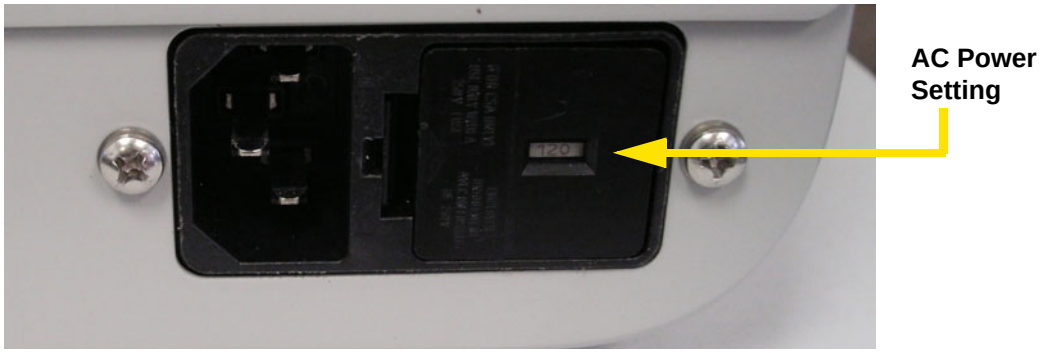


Figure 6-1 AC Power Setting

2. Plug the main power cord into the AC power input.

3. Connect the plug to the AC power source. The HeartAttendant® screen should boot up to the Patient Display Screen within 40 seconds.

6.2 Using the HeartAttendant® as a Power Source

Follow the steps below to use the HeartAttendant® as a power source for the Controller.

1. Connect one end of the HeartAttendant®/Controller Interface Cable to the socket on the front of the HeartAttendant®.
2. Connect the other end of the cable to the External Interface Port of the VADPAK. (See Figure 5-8 on page 25.)

Figure 6-2 Connecting the Controller to the HeartAttendant® as a Power Source

6.3 Description of Screens

The HeartAttendant® uses six screens to display and configure the systems. The patient has access to only two of these screens.

6.3.1 Displays Common to All HeartAttendant® Screens

Each of the six screens shares a common "Alarm Status" bar across the top that indicates if an alarm has been detected and allows you to navigate to the "Alarm History" screen or "Silence" an alarm on the Controller. Each of the six screens also

shares a common bar across the bottom; the "Status Display" and the "Display Select Buttons" sections.

Figure 6-3 Alarm Status Bar

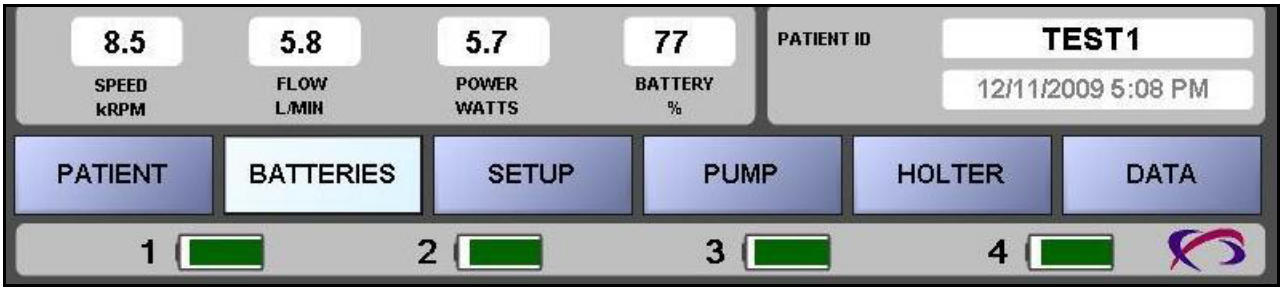


Figure 6-4 Status Display

Status Display – Shows the real-time values for speed, flow, and power as well as the patient's ID number, the date and time (Figure 6-4).

Speed – The displayed VAD speed may vary due to pulsatility.

Flow – Average flow through the VAD is in liters per minute. Instantaneous flow is shown graphically in the moving flow window.

Power – Power (in Watts) used by the Pump and Controller together (excludes CPU and flow sensor power requirements).

Display Select Buttons – These buttons are used to navigate between the six HeartAttendant® screens. Select the desired button to move to that screen. A password is required to change from the "Patient Display" screen to other screens.

6.3.2 Patient Display Screens

The following screens are for the benefit and use of patients.

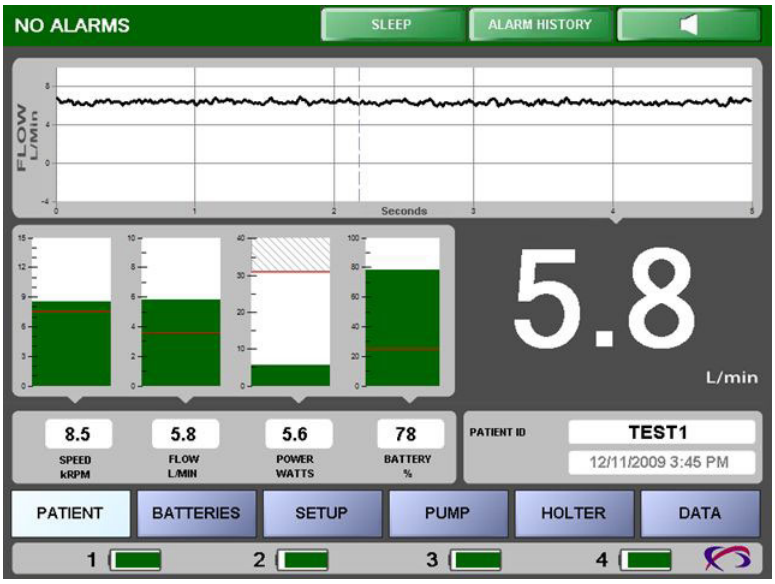


Figure 6-5 Patient Display Screen

Graphic Flow Display - Plots VAD Pump flow in real time. The time scale scrolls from left to right and covers a five-second time span.

6.3.2.1 Alarm Status Bar and Screens

The following screens show the Alarm Status Bar with varying states of alarm status as well as the Current Alarms and Alarm History window.

Figure 6-6 Alarm Status Bar with Sleep and Alarm History Buttons

Figure 6-7 Alarm Status Bar with Sleep and Alarm History Buttons and Alarms Detected

Figure 6-8 Alarm Status Bar with Sleep and Alarm History Buttons and Emergency Alarms Detected

Alarm Status Bar – The bar across the top of the all screens. This bar is green when conditions are normal (Figure 6-6), it will flash yellow when a diagnostic alarm occurs (Figure 6-7), and it will flash red when an emergency alarm occurs (Figure 6-8).

Alarm History Button – Opens a pop-up window that allows review of alarm messages that are stored on the HeartAttendant® for the patient (Figure 6-9).

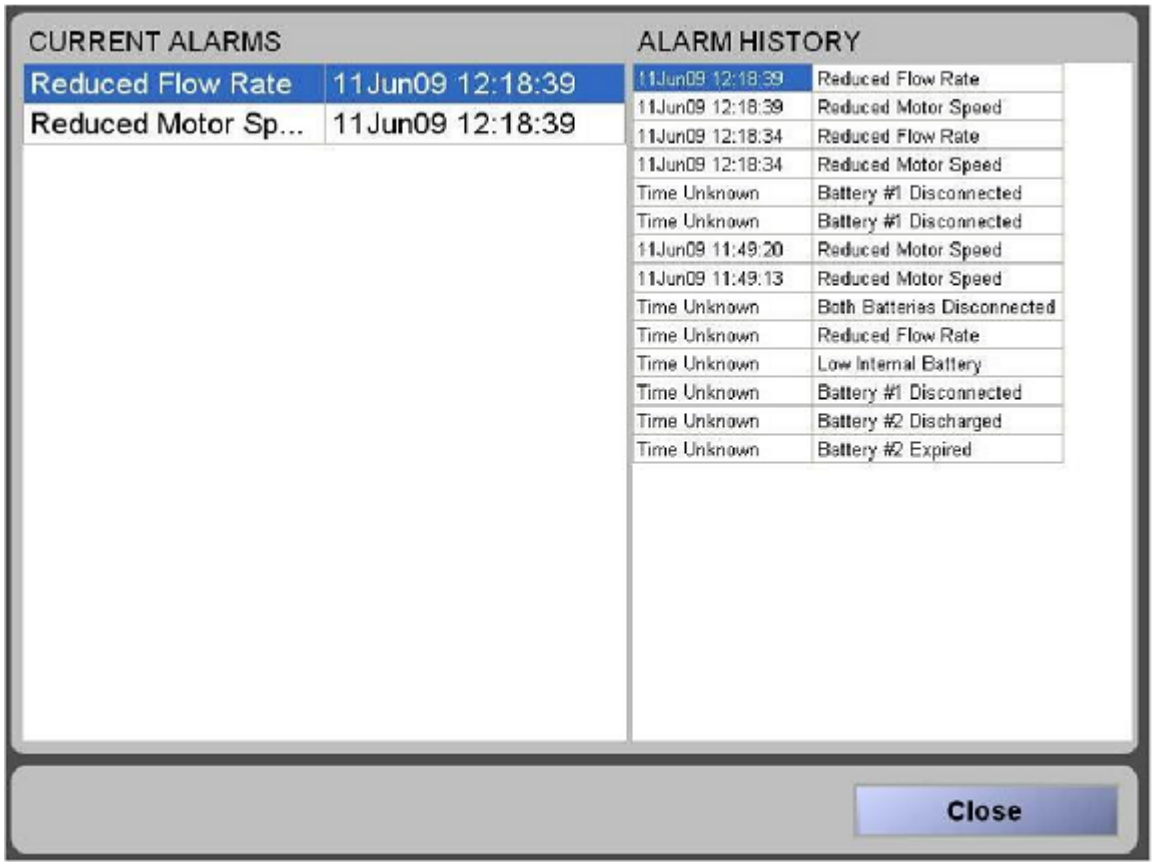


Figure 6-9 Current Alarms and Alarm History Window

Current Alarms – This window lists alarms as they occur while the HeartAttendant® is connected to the Controller. Alarms also cause the Alarm Status bar to flash. Alarm conditions should be cleared as soon as practical after they occur in order to detect a recurrence of the same alarm.

Alarm History – Alarms are listed in this window as they occur while the HeartAttendant® is connected to the Controller.

Possible Emergency Alarms

- Pump Stopped
- Both Batteries Disconnected
- VAD Disconnected

Possible Diagnostic Alarms

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

Acknowledge Alarms – As alarms occur in the Controller, they are transmitted to the HeartAttendant®. To clear the alarms from the status window and silence the Controller alarm, press the "Acknowledge Controller Alarms" button.

Figure 6-10 Acknowledge Controller Alarms button

Note: This action only "silences" the Controller audible signal; the Controller alarm silence/clear button must also be pressed to "clear" the alarm from the Controller's LCD and/or LEDs.

Note: The alarm messages continue to alternately display on the Controller LCD display until the Controller Alarm Silence Button on the Controller is pressed or the alarms clear automatically.

6.3.3 Sleep Mode

The HeartAttendant® has a Sleep Mode for times when the patient is resting sleeping and might not want to see the Patient screen. Select **Sleep** in the display bar at the top of the screen, and the screen will darken, showing only flow, date, and time. (See Figure 6-11.) To exit sleep mode, simply touch the display screen.

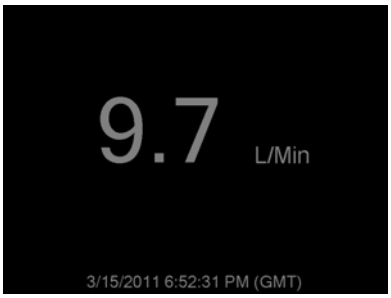


Figure 6-11 Sleep Mode Display

Note: The time on the display screen is shown in Greenwich Mean Time (GMT).

6.4 Hazards

Be aware of the following hazards associated with the HeartAttendant®.

6.4.1 Grounding

Before any connection to the Controller input is made, the HeartAttendant® must be connected to a protective earth ground via the three-core mains cable supplied. The mains plug should be inserted only into a socket outlet provided with a protective earth contact.

6.4.1.1 Mains Voltage Cord, Mains Voltage Range and Fuses

Before plugging the HeartAttendant® into an electrical outlet, make sure that the HeartAttendant® is configured for local mains voltage. The following are warnings typical to medical electrical equipment, which also apply to the HeartAttendant®. These warnings appear on HeartAttendant® labeling.

1. The HeartAttendant® should be disconnected from all voltage sources when a fuse is to be replaced.

2. The nominal mains voltage and frequency is 115VAC-60Hz or 230VAC-50Hz.

3. A fuse holder is located on the rear panel of the HeartAttendant® in the mains input socket. When the mains fuse needs replacing, proceed as follows (Figure 6-12):

    1) Disconnect the HeartAttendant® from the mains (line).

    2) Remove the cover of the fuse holder using a small screwdriver.

Figure 6-12 "Mains" Input Socket on the Rear Panel of the HeartAttendant®

3) Fit a new fuse of the correct rating according to the rear label of the DAS box (Figure 6-13) and reinsert the fuse holder into the power entry module.

Figure 6-13 Fuse block in power inlet module

4) Power on the HeartAttendant® and check functionality by watching for normal boot up.

Caution: **Make sure that only fuses with the required current rating and of the specified type as listed on the rear panel of the HeartAttendant® are used for replacement. The use of makeshift fuses or short circuiting of the fuse holder is prohibited.**

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

Section
7

7.0 The Controller: Front Panel Display, Alarms and Troubleshooting

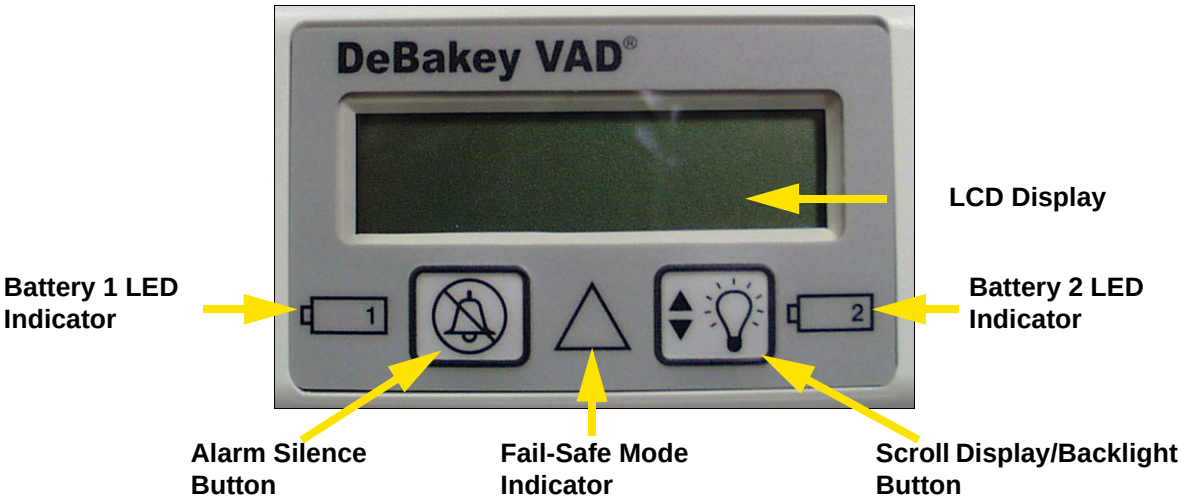


Figure 7-1 Controller Front Panel

The battery indicators on either side of the front display of the Controller indicate four different conditions for each Battery:

Battery Indicator	Condition
Green	Controller is using this Battery to run the Pump.
Blinking Amber	Battery is discharged, disconnected or expired.
Off	Battery is connected, charged but not currently being used to run the Pump.
Solid Green	3 seconds. Occurs immediately following a Battery insertion into a VADPAK Battery Pocket or when a Battery Pocket Cable plug (with a charged battery) is inserted into a battery port.

7.1 Standard Messages (Seven Scrolled Information Screens)

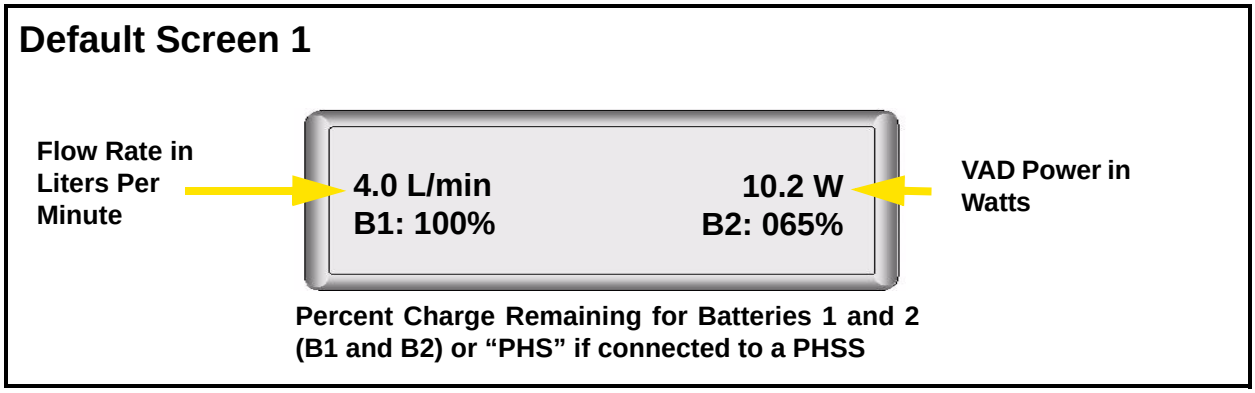


Figure 7-2 Default Screen 1

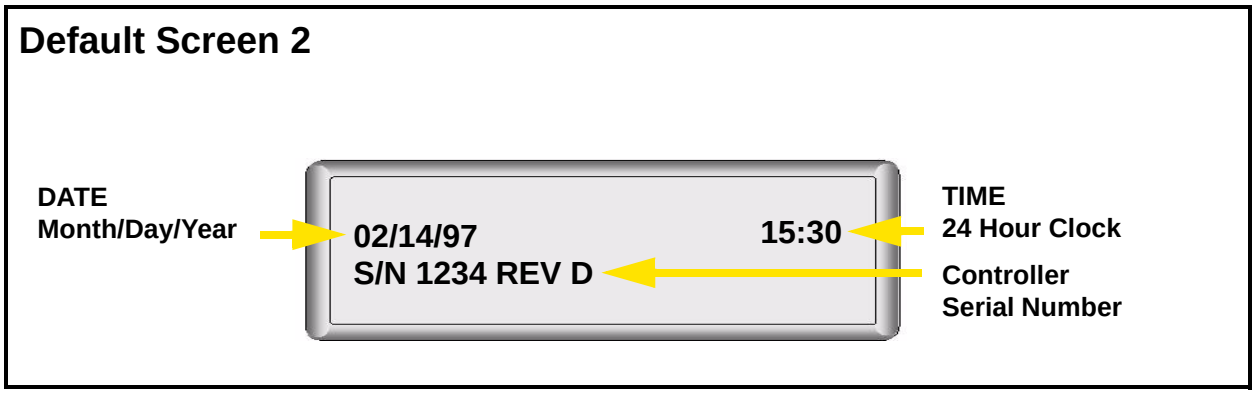


Figure 7-3 Default Screen 2

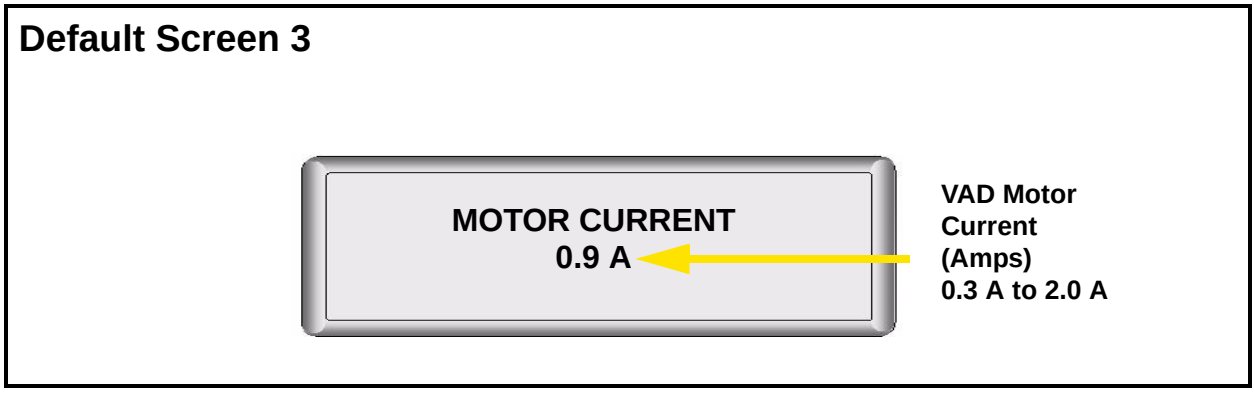


Figure 7-4 Default Screen 3

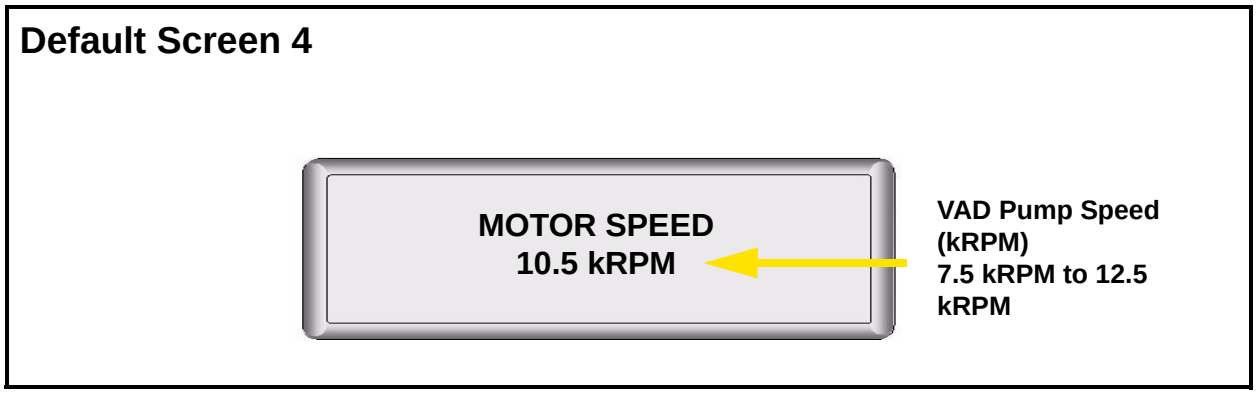


Figure 7-5 Default Screen 4

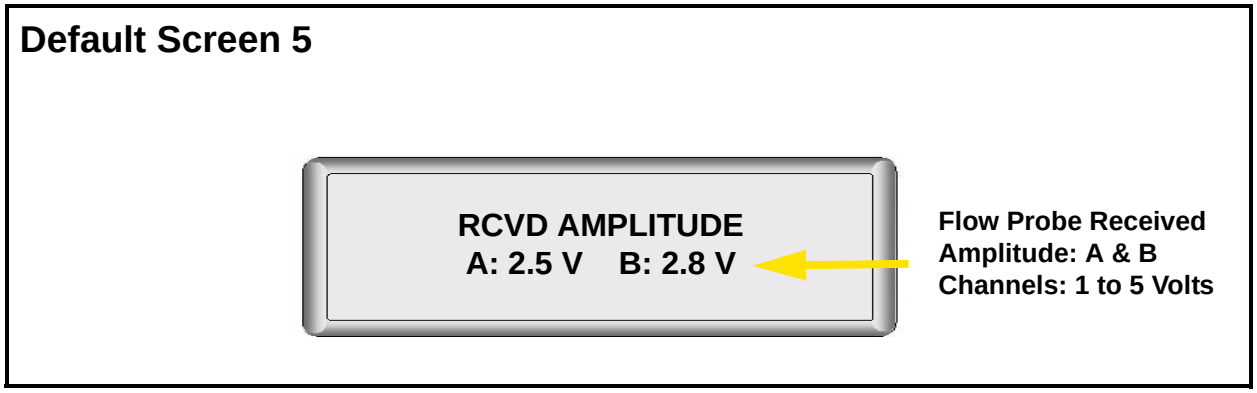


Figure 7-6 Default Screen 5

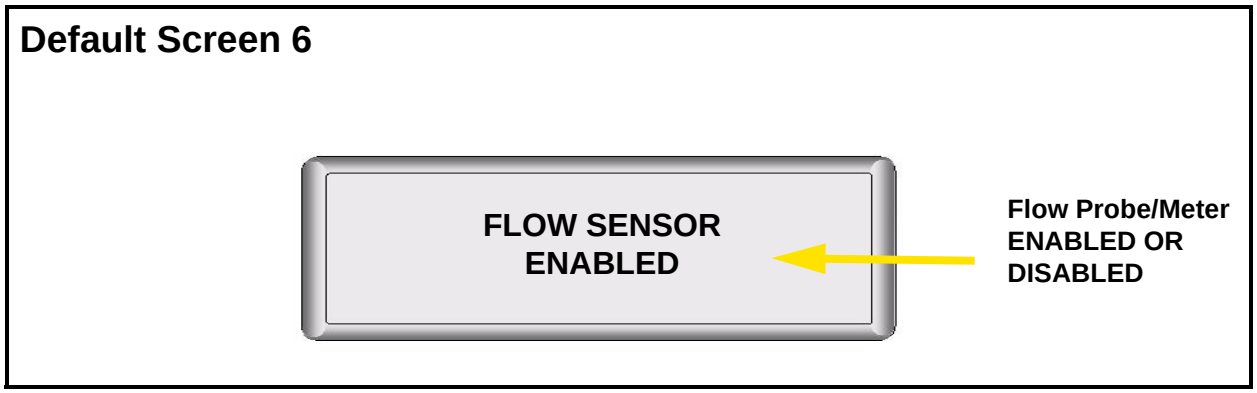
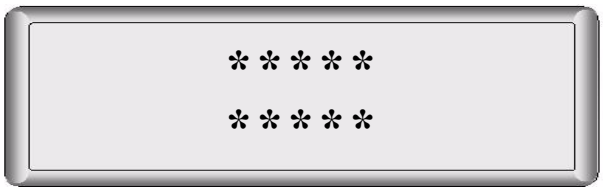


Figure 7-7 Default Screen 6

Default Screen 7



(Not Used)

Figure 7-8 Default Screen 7

7.2 Alarms

The Controller has two distinctive audible sounds to help you determine the type of alarm.

- The diagnostic alarm is a slower beeping sound.
- The emergency alarm is a faster, loud-ringing 2-tone sound.

7.2.1 Emergency Alarms

Emergency Alarm 1

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

Figure 7-9 Emergency Alarm 1

Note: If the pump successfully restarts, the emergency alarm will automatically clear.

ACTION TO BE TAKEN

- Contact the Support Team immediately.
- If pump does not start and message does not clear when Alarm Silence Button of the Controller is pressed, replace the Controller with backup Controller.

Note: The impeller and motor may occasionally lose synchronization (stop, then restart). When this occurs, the LCD displays PUMP STOPPED then PUMP RESTARTED then clears these alarms and returns to the default display (assuming no other alarms are present). The audible emergency alarm is not sounded for this event, but the Holter memory is captured and the CDAS alarm history is triggered. The resynchronization event typically allows the Pump to be stopped approximately 2 seconds.

Emergency Alarm 2

Figure 7-10 Emergency Alarm 2

ACTION TO BE TAKEN

- Plug a recharged Battery into the VADPAK or a battery pocket.
- Verify VADPAK battery pocket cables are plugged into the Controller.
- If pump does not start and message does not clear when Alarm Silence Button of the Controller is pressed, or the alarm does not clear automatically, replace the Controller with backup Controller.

Emergency Alarm 3

The VAD Pump is disconnected from the Controller.

Figure 7-11 Emergency Alarm 3

ACTION TO BE TAKEN

- Unscrew the White Defibrillation Insulator from the RAEC.
- Remove the Pump Percutaneous Cable plug from the RAEC. Plug the Pump Percutaneous Cable plug back into the RAEC making sure it is fully seated in the RAEC mating connector.
- Verify the Pump has restarted successfully.
- If pump does not start and message does not clear when Alarm Silence Button of the Controller is pressed, or the alarm does not clear automatically replace the Controller with backup Controller.
- Screw the White Defibrillation insulator onto the RAEC mating connector.
- If Pump does not start and message does not clear when the Alarm Silence Button is pressed, replace the Controller with backup Controller.
- Contact the Support Team immediately.

7.2.2 Diagnostic Alarms

Diagnostic Alarm 1

The VAD Pump is drawing current (power) in excess of the programmed alarm value.

Note: This alarm does not silence or clear automatically. The Controller Alarm Silence Button must be pressed to silence and clear this alarm.

Figure 7-12 Diagnostic Alarm 1

ACTION TO BE TAKEN

- Contact the Support Team immediately.
- Patient must return to the hospital for one or more Excess Current Alarms which cannot be cleared in 10 minutes or for multiple Excess Current Alarms over a period of more than 10 minutes but less than 24 hours.

Diagnostic Alarm 2

The flow rate measured by the implanted flow probe of the VAD Pump has dropped below the programmed alarm value.

Note: This alarm does not silence or clear automatically. The Controller Alarm Silence Button must be pressed to silence and clear this alarm.

Figure 7-13 Diagnostic Alarm 2

ACTION TO BE TAKEN

- Contact the Support Team immediately.

Diagnostic Alarm 3

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

ACTION TO BE TAKEN

- Contact the Support Team immediately.

Figure 7-14 Diagnostic Alarm 3

Diagnostic Alarm 4

The internal battery of the Controller is low on power.

Figure 7-15 Diagnostic Alarm 4

ACTION TO BE TAKEN

- For changing this battery, contact the Support Team immediately.

Diagnostic Alarm 5

The VAD Pump has stopped and is attempting to restart. This text displays briefly during restart attempt alternating with the PUMPED STOPPED message.

Figure 7-16 Diagnostic Alarm 5

ACTION TO BE TAKEN

- Every 2 to 3 seconds, press the Alarm Silence Button of the Controller and verify the flow rate, RPMs and current are normal. The alarm silencing will indicate a successful Pump restart.
- Contact the Support Team immediately.

Diagnostic Alarm 6

Battery 1 has been disconnected.

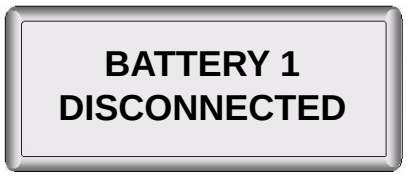


Figure 7-17 Diagnostic Alarm 6

ACTION TO BE TAKEN

- Verify the Battery is firmly seated into the VADPAK battery pocket.
- Verify the VADPAK battery pocket connector is firmly inserted into the Battery #1 Port on the Controller.
- This alarm will clear automatically when a Battery is connected.
- If alarm does not clear, contact the Support Team.

Diagnostic Alarm 7

The Battery plugged in VADPAK battery pocket #1 is discharged.

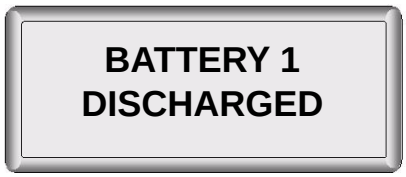


Figure 7-18 Diagnostic Alarm 7

ACTION TO BE TAKEN

- Replace Battery #1 with a charged Battery.
- This alarm will clear automatically when the discharged Battery is replaced with a charged Battery.

Diagnostic Alarm 8

The battery plugged in VADPAK battery pocket #1 has discharged below 15% or it's voltage is too low.

ACTION TO BE TAKEN

- Replace Battery #1 with charged Battery.
- Recharge expired battery.
- This alarm will clear automatically when the discharged Battery is replaced with a charged Battery.

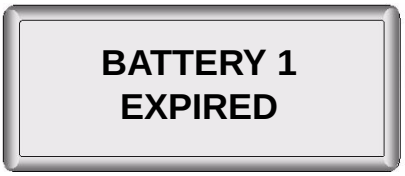


Figure 7-19 Diagnostic Alarm 8

Diagnostic Alarm 9

The Battery plugged in VADPAK battery pocket #2 has been disconnected.

ACTION TO BE TAKEN

- Verify the battery is firmly seated in the VADPAK battery pocket.
- Verify the VADPAK battery pocket connector is firmly inserted into Battery #2 Port on the Controller.
- Press the Alarm Silence Button of the Controller.
- This alarm will clear automatically when a Battery is connected.

Figure 7-20 Diagnostic Alarm 9

Diagnostic Alarm 10

The Battery plugged in VADPAK battery port #2 is discharged.

ACTION TO BE TAKEN

- Replace Battery #2 with a charged Battery.
- This alarm will clear automatically when the discharged Battery is replaced with a charged Battery.

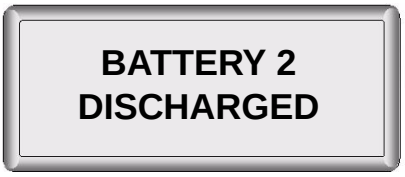


Figure 7-21 Diagnostic Alarm 10

Diagnostic Alarm 11

The Battery plugged in VADPAK battery pocket #2 has discharged below 15%, or it's voltage is too low.

ACTION TO BE TAKEN

- Replace Battery #2 with a charged Battery.
- This alarm will clear automatically when the discharged Battery is replaced with a charged Battery.

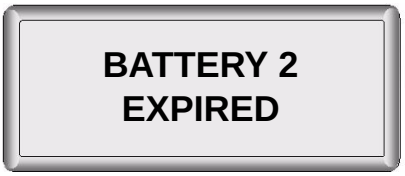


Figure 7-22 Diagnostic Alarm 11

Diagnostic Alarm 12

The Controller failed the memory test at power up.

ACTION TO BE TAKEN

- Disconnect all power and power up a second time.
- If alarm occurs at second power up: Replace Controller with backup. Notify MicroMed Cardiovascular, Inc., and request a replacement Controller.

Figure 7-23 Diagnostic Alarm 12

7.2.3 Fail-Safe Alarm

Fail-Safe Alarm

Fail-Safe LED is lit, high-pitch continuous alarm is heard, LCD display is frozen, battery LEDs are lit. The Pump is running at 8500 RPM.

ACTION TO BE TAKEN

- Replace the Controller with the backup Controller.

Figure 7-24 Fail-Safe Alarm

7.2.4 Controller Failure Alarm

Controller Failure Alarm

The LCD is off, the LEDs are off, and a high-pitch continuous emergency alarm is heard (not a beeping alarm). The Controller has failed internally. **The Pump has stopped.** Due to potential process failure, there will be no display associated with the alarm.

Figure 7-25 Controller Failure Alarm

ACTION TO BE TAKEN

- Replace the Controller immediately with the backup Controller.
- Contact the Support Team immediately to request a Controller replacement.

Section
8

8.0 Summary of Use

8.1 Quick Reference—Alarms from the Controller

Alarm	What Happened?	What Do I Do?	Who Do I Call?
BATTERY 1 OR 2 DISCONNECTED	Battery 1 or 2 is disconnected from the Controller.	See that the Battery is firmly seated in the VADPAK battery pocket.	Support Team
BATTERY 1 OR 2 EXPIRED	There is no power left in Battery 1 or 2.	1. Replace the Battery with a charged Battery. 2. Press the Alarm Silence Button of the Controller.	Support Team
BATTERY 1 OR 2 DISCHARGED	There is not enough power left in Battery 1 or 2.	1. Replace the Battery with a charged Battery. 2. Press the Alarm Silence Button of the Controller.	Support Team
BOTH BATTERIES DISCONNECTED	Both Batteries are disconnected.	1. See that the Batteries are fully seated in the VADPAK battery pockets. 2. See that the VADPAK battery pocket cable connectors are correctly inserted into the Controller ports. 3. See that the VADPAK battery pocket cables are not cut or damaged. 4. See that at least one of the Batteries is charged.	Support Team
EXCESS CURRENT	The VAD Pump current is above the alarm value.	Patient must return to the hospital for one or more Excess Current Alarms which cannot be cleared in 10 minutes or for multiple Excess Current Alarms over a period of more than 10 minutes but less than 24 hours.	Support Team
LOW INTERNAL BATTERY	The internal battery of the Controller is low on power.	Contact the Support Team.	Support Team

Alarm	What Happened?	What Do I Do?	Who Do I Call?
BATTERY TOGGLING BETWEEN BATTERIES 1 AND 2 ACCOMPANIED BY NUMEROUS SHORT AUDIBLE BEEPS	A Battery has experienced a prematurely low voltage.	1. IF POSSIBLE—connect to either the PHSS, HeartAttendant®, or CDAS. 2. Remove one Battery at a time from the VADPAK and replace with a charged Battery until both Batteries are replaced (**DO NOT REMOVE BOTH BATTERIES AT THE SAME TIME**). 3. Place the toggling Batteries aside to return to the Support Team. 4. Contact the Support Team for replacement batteries.	Support Team
PUMP RESTARTED	The Controller has attempted to restart the VAD Pump.	This alarm is displayed every time the Controller tries to restart the Pump. 1. Contact the Support Team immediately. 2. If no current is shown on the Controller and the Pump has stopped, change to the backup Controller. 3. If this does not start the Pump, (current, flow registered) seek emergency help immediately.	Support Team

Alarm	What Happened?	What Do I Do?	Who Do I Call?
PUMP STOPPED	The VAD Pump has stopped.	1. First, check for other alarms flashing which may show why the Pump has stopped. For example, VAD DISCONNECTED or BOTH BATTERIES DISCONNECTED. 2. Be sure that the Percutaneous Cable has not been cut or damaged. 3. See if an unknown electrical disturbance is affecting the Controller or Pump. Do this by physically moving to a different location if possible. 4. You can force the VAD to restart by removing both batteries and re-inserting one charged battery in VADPAK while not tethered to wall power. Once pump restart is successful, insert a second charged battery. If the Pump successfully restarts, press the Alarm Silence Button on the Controller. If the Controller doesn't restart the Pump, the alarm will continue even after the Alarm Silence Button is pressed. **If the Pump does not start, call for emergency medical assistance immediately.**	Support Team
REDUCED FLOW RATE	Flow rate from the Pump is reduced below the alarm value.	Contact the Support Team.	Support Team
REDUCED MOTOR SPEED	The VAD Pump speed is reduced below alarm value.	If you don't have any symptoms, contact the Support Team. If you experience dizziness, lightheadedness or other symptoms, seek medical assistance.	Support Team

Alarm	What Happened?	What Do I Do?	Who Do I Call?
VAD DISCONNECTED	The VAD Pump is disconnected from the Controller.	1. See that the VAD Percutaneous Cable is not cut or damaged. 2. Unscrew the White Defibrillation Insulator from the RAEC. 3. Remove VAD Percutaneous Cable connector from the RAEC. 4. Plug the VAD Percutaneous Cable back into the RAEC making sure the plug is fully seated (connected) in the RAEC mating connector. 5. Screw the White Defibrillation Insulator onto the RAEC connector. If the problem persists, replace the Controller with the backup Controller. **If the Pump does not start, call for emergency medical assistance immediately.**	Support Team
FAIL-SAFE LED	Controller malfunction.	Replace Controller.	Support Team
CONTINUOUS AUDIBLE ALARM	Controller malfunction.	Replace Controller.	Support Team

8.2 Quick Reference—Alarms from the PHSS

Alarm	What Happened?	What Do I Do?	Who Do I Call?
AUDIBLE TEN-SECOND ALARM	Main power has been lost. The Batteries inserted into the PHSS are powering the Controller.	1. Check that the power cord is still plugged into the PHSS and into the wall outlet. 2. Check the wall outlet power.	Support Team
AUDIBLE ONE-SECOND ALARM EVERY TEN SECONDS	Main power is still off and the PHSS Batteries still power the Controller.	Check the fuse on the side of the PHSS.	Support Team
SYSTEM STATUS LIGHT:			
Not Illuminated	AC power is off or the side fuse of the PHSS is blown; the Controller is not powered by the PHSS.	1. Check that the Batteries are installed properly in the PHSS. 2. Check the wall outlet power. 3. Change the fuse on the side of the PHSS.	
Steady Green	AC power is on; the system is operating properly.		
Flashing Red	AC power is off; the Controller is powered by the PHSS batteries.	1. Check that the power cord is still plugged into the PHSS and into the wall outlet. 2. Check the wall outlet power. 3. Change the fuse on the side of the PHSS.	
BATTERY STATUS LIGHTS:			
Flashing Green	Battery with the highest charge.		
Steady Green (Yellow Off)	Battery is charged.		
Steady Yellow Only	Battery is charging or awaiting charge.		
Flashing Green and Steady Yellow	Battery with the highest charge but is still recharging		

Alarm	What Happened?	What Do I Do?	Who Do I Call?
CONTROLLER ALARM: Battery Disconnect (3 beeps from Controller)	PHSS is disconnected from the Controller.	1. Ensure that the PHSS/Controller Interface Cable is securely connected to the PHSS and to the Controller. 2. Replace with spare PHSS/Controller Interface Cable. 3. Disconnect from PHSS and change the front panel fuse.	Support Team
PHSS DOES NOT SUPPLY POWER TO CONTROLLER (BATTERY #1 GREEN LED IS LIT AND "B1%: ----" DISPLAYS FOR NORMAL OPERATION)	Blown Controller power fuse (on front of PHSS). PHSS to Controller connection is not intact.	1. Replace Controller power fuse. 2. Check PHSS/Controller Interface Cable and connectors. 3. Replace PHSS/Controller Interface Cable. 4. Plug PHSS/Controller Interface Cable directly into Controller.	Support Team

8.3 Quick Reference—Alarms on HeartAttendant®

Note: The HeartAttendant® does not have any audible alarms. All audible alarms are only given from the Controller.

When connected to the HeartAttendant®, a flashing bar at the top of the screen denotes that one of the following two types of alarms has occurred.

8.3.1 Emergency Alarm: Red Flashing Bar

A red flashing bar signals an emergency alarm given by the Controller as described in Section 7.2.1, "Emergency Alarms" on page 44 and shown in Figure 6-8 on page 36.

- **VADPAK Connected to the HeartAttendant®**

When the VADPAK is connected to the HeartAttendant®, the emergency Controller alarm can only be silenced for a few seconds by pressing the speaker icon at the top right portion of the screen. The alarm repeats if the reason for the alarm remains. The alarm cannot be silenced by pressing the silence button on the Controller. When the reason for the alarm has been resolved, the audible alarm from the Controller will stop but the red flashing bar will continue to flash until the speaker icon is pressed.

- **VADPAK Not Connected to the HeartAttendant®**

When the VADPAK is **not** connected to the HeartAttendant® and an emergency alarm occurs, it cannot be silenced by pressing the silence button on the Controller. When the

cause of the alarm has been resolved, the audible alarm will stop. When the VADPAK is then reconnected to the HeartAttendant® the same alarm that was previously resolved will not appear as a flashing red bar but will show in the alarm list as the alarm description followed by Time Unknown.

8.3.2 Diagnostic Alarm: Yellow Flashing Bar

A yellow flashing bar signals a diagnostic alarm given by the Controller previously described in Section 7.2.2, "Diagnostic Alarms" on page 46 and shown in Figure 6-7 on page 36.

- **VADPAK Connected to the HeartAttendant®**

When the VADPAK is connected to the HeartAttendant® and a diagnostic alarm occurs, the audible alarm from the Controller may be silenced by pressing the silence button on the Controller. Pressing the silence button on the Controller does not clear the flashing bar on the HeartAttendant®. The speaker icon must be pressed for the flashing yellow bar to return to the normal green display.

- **VADPAK Not Connected to the HeartAttendant®**

When the VADPAK is **not** connected to the HeartAttendant® and a diagnostic alarm occurs, it can be silenced by pressing the silence button on the Controller. When the VADPAK is then reconnected to the HeartAttendant®, the same alarm that was previously silenced will appear as a flashing yellow bar.

Section
9

9.0 Daily Checks

9.1 Daily Checks using PHSS

Check your Controller, your primary and reserve batteries, and your PHSS every day as described below.

Caution: **Contact your Support Team personnel if any of the Controller or PHSS alarms are not working.**

Every 2-3 hours when awake (whether attached to the PHSS or not), check the Battery status on the front panel of the Controller.

9.1.1 Before You Go To Sleep

Before you go to sleep, check the following things (see Figure 5-14 on page 31):

1. Verify that the System Status Light on the PHSS is green.
2. Verify that the Battery Status Lights are lit for all Batteries in the PHSS.
3. Verify that you have two fully charged Batteries in your VADPAK.
4. Verify that the PHSS is supplying power to the Controller by:

   - Checking that the Battery LED on your Controller's front panel is green for the battery port connected to the PHSS.
   - Pressing the Scroll Display Button on the front panel of your Controller to check that the Battery percentage is displaying '----' for the battery port connected to the PHSS.

9.1.2 When You First Wake in the Morning

When you first wake in the morning, check the front panel of the Controller for lighted symbols and messages. If there are alarm messages, see Section 6.0, "HeartAttendant®" of this manual to find out how to handle them. Check the System Status Light of the PHSS to see if it is green.

9.2 Daily Checks Using the HeartAttendant®

Check your Controller, your primary and reserve batteries, and your HeartAttendant® every day as described below.

Caution: Contact your Support Team personnel if any of the Controller alarms are not working.

Every 2-3 hours when awake, check the Battery status on the front panel of the Controller if not tethered to the HeartAttendant®. If tethered to HeartAttendant® check Battery 2 status on Patient Display screen on HeartAttendant®. Pull Battery 1 from VADPAK to check LEDs.

9.2.1 Before You Go To Sleep

Before you go to sleep, check the following things (see Figure 5-14 on page 31):

- Verify that you have two fully charged Batteries in your VADPAK.
- Verify that the HeartAttendant® is supplying power to the Controller by checking that the Battery LED on your Controller's front panel is green for the battery port connected to the HeartAttendant®. The Controller front panel will read DAS CONNECTED.

9.2.2 When You First Wake in the Morning

When you first wake in the morning, check the front panel of the Controller and HeartAttendant® Patient Display screen for lighted symbols and messages. If there are alarm messages, see Section 7.0, "The Controller: Front Panel Display, Alarms and Troubleshooting" of this manual to find out how to handle them.

Section
10

10.0 Daily Operation

Always connect the Controller to two power sources. It draws power from one source at a time. The second source serves as backup power. When you are using the two Batteries in the VADPAK as the two power sources, check the remaining charge in each Battery every hour.

While you are relaxing or sleeping, you should use the CDAS, HeartAttendant®, or PHSS in the tethered mode of operation.

Most of the time that you are active, you will use the Batteries in the VADPAK in the untethered mode of operation. You will not be connected to the CDAS, PHSS, or HeartAttendant®.

10.1 Tethered Operation

During times of little activity, such as when you are sleeping or relaxing, it is recommended that you use your CDAS, HeartAttendant®, or PHSS. This is called the "tethered" mode of operation. Your CDAS will only be used if you are in the hospital and your physician wishes to monitor your condition with the CDAS. You must be in tethered mode whenever you think you might fall asleep, or if you do not have charged batteries available for use in the VADPAK.

When you use the CDAS, HeartAttendant®, or PHSS, the Controller uses power from the grounded wall outlet. The Controller can also get power from the batteries in the VADPAK if the wall outlet fails.

Note: A fully charged Battery will provide adequate power to run the Pump for 2.5 to 4 hours. If your Pump speed is set high, it will reduce the amount of time the Battery can operate the Pump.

10.2 To Switch from Untethered to Tethered Operation

10.2.1 Be Sure that the CDAS, HeartAttendant®, or PHSS is ready to be used.

- The CDAS, HeartAttendant®, or PHSS should be powered up.
- The System Status Light of the PHSS should be a steady green.
- The CDAS/Controller Interface Cable should be plugged into the CDAS, the PHSS/Controller Interface Cable should be plugged into the PHSS, or the HeartAttendant®/Controller Interface Cable should be plugged into the HeartAttendant®.

Note: You can leave the CDAS/Controller Interface Cable plugged into the CDAS at all times; you can leave the PHSS/Controller Interface Cable plugged into the PHSS at all times; and you can leave the HeartAttendant®/Controller Interface Cable plugged into the HeartAttendant® at all times.

10.2.2 Connect the CDAS, HeartAttendant®, or PHSS Interface Cable to the External Interface Port

- Visually align the slot on the cable connector with the red dot on the External Interface Port of the VADPAK. The cable should be oriented so it is pointing upwards.
- Once the slot and red dot are aligned, firmly push the plug into the External Interface Port. A slight "click" will be heard and felt as the connector becomes fully seated.

Note: Damage can occur if the connector is forced without proper alignment. After the connectors are aligned, do not twist the connector plug while inserting.

- If all connections are tight and all the components are working properly, the Controller front panel will display either "DAS CONNECTED" if using the CDAS Cable/Controller Interface Cable or HeartAttendant®/Controller Cable or "B1:----" if using the PHSS Cable/Controller Interface Cable.

Note: In the event that a power failure occurs, the PHSS will begin to alarm loudly and the Power Status Light on the front panel of the PHSS will begin to blink red. Disconnect the PHSS/Controller Interface Cable from the VADPAK immediately.

Note: In the event that a power failure is expected to last for an extended period of time, it is recommended that the patient take the PHSS or HeartAttendant® and all Batteries to the nearest location with suitable mains power.

Caution: Batteries not being used in the VADPAK should always be charging in the PHSS while in the tethered mode of operation.

Caution: Batteries not being used in the VADPAK should always be charging in the HeartAttendant®.

10.3 Untethered Operation

You will probably want to use the Batteries in the VADPAK instead of the CDAS, HeartAttendant®, or PHSS while you are active. This is called "untethered" operation.

You must have two fully charged Batteries in the VADPAK before you switch to the untethered mode. The Controller will draw power from one Battery before drawing power from the second Battery. This design ensures that the second Battery will have energy remaining when the first Battery falls below 25% capacity.

Each fully charged Battery will power the HeartAssist *5*® VAD Pump for approximately 2.5 to 4 hours giving a combined Battery time of approximately 5 to 8 hours. Higher Pump speeds may reduce Battery time. The Controller front panel will tell you the percent capacity remaining for each Battery. Each Battery is expected to last at least 200 charge/discharge cycles.

Note: The amount of time that you stay in untethered operation depends on the set Pump speed.

Warning: Only use Batteries supplied by MicroMed Cardiovascular, Inc.

10.4 To Switch from Tethered to Untethered Operation

10.4.1 Before Disconnecting From the CDAS, HeartAttendant®, or PHSS

Check that the capacity of the two Batteries connected to the Controller is nearly full (>80%) on the Controller panel. If one or both are not, proceed as follows:

- Remove one or two fully charged Batteries from the PHSS or HeartAttendant®.
- Check the Batteries by pushing the charge level button on each Battery to verify charge level (see Figure 5-1 on page 19).
- Remove only one discharged Battery from the VADPAK battery pocket and insert the fully charged Battery. Remove the second discharged Battery from the VADPAK battery pocket and insert the fully charged Battery.

  Note: Never remove both Batteries from the VADPAK battery pocket at the same time.

- Check the capacity of the new Battery connected to the Controller on the Controller front panel.

10.4.2 Disconnecting the VADPAK From the CDAS, HeartAttendant®, or PHSS

Disconnect the CDAS or PHSS Interface Cable connector from the External Interface Port of the VADPAK as follows:

- With one hand, firmly hold the VADPAK casing.
- With the other hand, pull the connector from the External Interface Port. This connection may be tight and may take some force to pull it loose.

Note: Do not twist the connector while removing. Do not pull on the wire.

Note: During the untethered operation, check the battery capacity of both VADPAK Batteries every hour to be sure that enough power is available.

Note: Always ensure that the CDAS/Controller Interface Cable has been disconnected from the VADPAK BEFORE removing power to or turning off the CDAS or HeartAttendant®.

10.5 When Away From the Residence

Always travel with fully charged batteries, spare Controller, spare battery pocket, and carry extra Batteries as well as the PHSS or HeartAttendant®. You may need these components in an emergency.

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

Before going on extended trips, notify your Support Team personnel.

10.6 Bathing

Caution: Do not bathe or shower with the HeartAssist 5® VAD Pump connected to the CDAS, HeartAttendant®, or PHSS, i.e., while in tethered mode. Operating in untethered mode reduces the risk of shock.

Caution: Do not shower with the VADPAK without it being properly encased in the provided Shower Bag.

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

10.7 Using the VADPAK and Shower Bag

Step 1

Open the top cover of the Shower Bag.

Step 2

Insert the complete VADPAK unit, including shoulder strap, into the Shower Bag with the VAD Percutaneous Cable pointing towards the left (as viewed facing the Shower Bag).

Figure 10-1 Using the VADPAK and Shower Bag - Step 2

Step 3

Secure the VAD Percutaneous Cable to the side of the Shower Bag using the hook and loop strap attached to the left side of the Shower Bag.

Figure 10-2 Using the VADPAK and Shower Bag - Step 3

Step 4

Close the lid of the Shower Bag and carefully press the sides of the cover inward to secure the hook and loop fasteners located along each face of the Shower Bag.

Figure 10-3 Using the VADPAK and Shower Bag - Step 4

Step 5

When finished bathing, carefully dry off the outside of the Shower Bag, open the top cover of the Shower Bag and remove the VADPAK. If water has leaked into the Shower Bag, contact the hospital staff immediately.

Note: Limit the time (30 minutes) the VADPAK and Controller are used in the Shower Bag since the Controller requires air circulation for proper cooling.

10.8 Activity Restrictions

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

You should discuss with your doctor what activities you may do.

The following activities are **always prohibited** for your safety and for the function of the device:

Absolutely NO	Comments
Total Body Submersion (i.e., swimming)	Do not submerge the Controller or Batteries in water. Submerging them may cause the device to malfunction.
Steam Bath or Dry Saunas	Do not operate the system in environments where the temperature is less than 10° C or greater than 40° C.
Participation in Contact Sports	Hard physical contact with other people or objects could damage the external HeartAssist *5*® VAD System hardware, injure internal organs, or interfere with the tissue healing at the exit site.

You should consult your doctor before engaging in the following activities:

Consult Your Doctor Regarding	Comments
Bathing or Showering	Prior approval of your doctor and a Shower Bag are required.
Driving an Automobile	You must first get approval from your doctor. In addition, local laws may prohibit persons in your condition from operating motor vehicles.
Flying	You must first get approval from your doctor. In addition speak with the airlines about any special requirements that they may have.
Non-Contact Sports (i.e., golfing, jogging, tennis)	You and your doctor can determine whether participation in a certain sport may pose a danger either to yourself or to your HeartAssist *5*® VAD equipment.

10.9 No Known Risk

- Careful Sponge Baths
- Sexual Activity
- Housework
- Moderate Exercise (i.e., walking, gardening, cycling)
- Shopping

Section
11

11.0 Self-Care

11.1 Caring for the HeartAssist 5® VAD System While at Home

11.1.1 Exit Site

The tube (Percutaneous Cable) coming out of your skin contains wires that connect the HeartAssist 5® VAD Pump to the Controller and allow the Pump and Controller to communicate. The area where the VAD Percutaneous Cable comes out of your skin is called the "exit site." While in the hospital, the exit site was bandaged to prevent infection. Now, your "exit site" probably doesn't require bandaging but you still must prevent the skin around the "exit site" from breaking down. The skin grown around your Percutaneous Cable forms a barrier to infection.

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

- Redness
- Swelling
- Drainage
- Presence of an Open Sore or Ulcer
- Pain
- Warm to Touch

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

11.1.2 Percutaneous Cable Strain Relief

Discuss with your Support Team how to prevent pulling, tugging, or excessive movement of the VAD Percutaneous Cable.

11.1.3 VADPAK

The VADPAK is an ergonomic storage system designed to allow the patient to carry the Controller and Batteries. If you are going for a walk, disconnect the CDAS or HeartAttendant® if in the hospital, or disconnect the PHSS or HeartAttendant® while at home.

11.1.4 Medications

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

Please contact your doctor with questions about your medications.

Section
12

12.0 Equipment Care and Maintenance

12.1 Controller

The Controller should always be placed in the VADPAK to promote proper cooling of the Controller and eliminate potential harm to you.

Caution: **Do not drop the Controller on any hard surface. Dropping the Controller may damage internal components causing the device to malfunction.**

12.2 CDAS

Warning: **Replace the CDAS/Controller Interface Cable every 6 months or earlier if it shows signs of functional or visible damage.**

Use a slightly damp cloth with mild disinfecting detergent to clean all surfaces. **DO NOT** allow liquid to spill into the CDAS components.

12.3 HeartAttendant®

The HeartAttendant® does not require routine maintenance. Dust may be wiped off the surface of the device with a clean, dry, lint-free cloth and spills may be cleaned from the cover with a dampened cloth.

To safely change fuses, see Section 6.4.1.1, "Mains Voltage Cord, Mains Voltage Range and Fuses" on page 39.

12.4 PHSS

Other than periodic fuse changes (see instructions following), the PHSS does not require routine maintenance. Dust may be wiped off the surface of the device with a clean, dry, lint-free cloth and spills may be cleaned from the cloth cover with a dampened cloth.

It is recommended that the audible alarm be checked once a month. To check the alarm, disconnect the AC power cord while the PHSS contains at least 2 fully charged Batteries and is supplying power to the VADPAK. A loud alarm should be heard. Reconnect the AC power cord to stop the sound.

12.4.1 Changing Power Fuses on the Side of the PHSS

A blown fuse will be signaled by a blinking red System Status Light and an audible alarm from the PHSS, if the Controller is connected and the AC power source is functional.

1. To change a power fuse in the AC Power Input Module of the PHSS, first untether from the PHSS, remove Batteries, remove the AC power cord, then push the latch up in the center of the AC Power Input Module (see Figure 12-1). The fuse drawer will pop out.

2. Check the fuses. Remove the fuse(s) that has/have blown.

3. Put a new fuse(s) (Part #M00438-04 for Europe, #M00438-05 for North America) in the spring clip(s) in the fuse drawer (see Figure 12-2).

4. Reinsert the fuse drawer and snap it into place.

5. Reattach power cord.

6. Check to make sure that the System Status Light shows green after completion of the PHSS self-test.

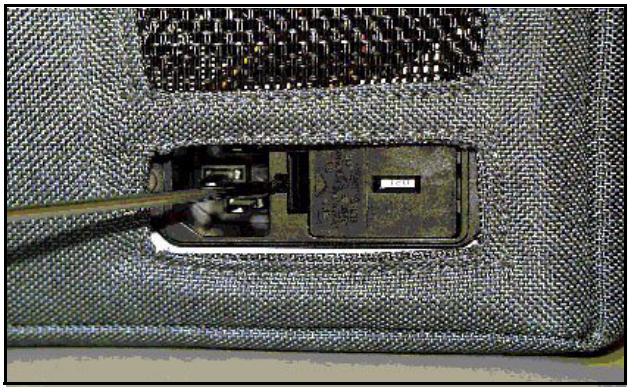


Figure 12-1 AC Power Input Module Latch

Figure 12-2 The Fuse Drawer

Note: The fuses for the mains are glass (clear) and the fuse for the Controller power is ceramic (opaque).

12.4.2 Changing the Controller Power Fuses on the Front of the PHSS

If the PHSS is operational but is not supplying power to the Controller (normal operation is green LED for Battery #1 and "B%: is ----" is displayed) the Controller power fuse may be blown.

1. Check that the capacity of both batteries in the VADPAK are above 75%.
2. Disconnect the PHSS tether from the VADPAK, and remove Batteries from the PHSS.
3. Disconnect the power cord from the wall outlet.
4. Release the fuse holder on the front panel by turning the fuse holder cap counter clockwise.
5. Pull the fuse holder completely out of the socket.
6. Remove the old fuse from the fuse holder.
7. Insert the new fuse (Part #M00413-03) into the fuse holder.
8. Align the tabs on the fuse holder with the slots in the fuse socket.
9. Insert the fuse holder into place.
10. Gently press the fuse holder cap and turn it clockwise until it is locked into position.

11. Plug the power cord into the wall outlet.

12. Reconnect the PHSS/Controller Interface Cable to VADPAK, and place Batteries back in charger.

Note: The Controller power fuse is ceramic (opaque) and the fuses for the mains are glass (clear).

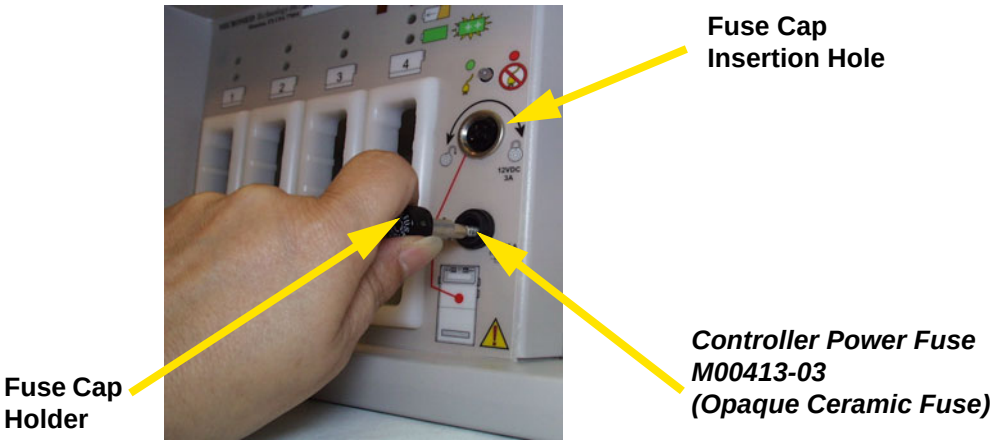


Figure 12-3 Controller Power Fuse on the Front of the PHSS

12.5 Warranty and Service

12.5.1 CDAS

There are no user serviceable parts in the CDAS. Contact MicroMed Cardiovascular, Inc. for service.

12.5.2 PHSS and HeartAttendant®

The PHSS and HeartAttendant® are under warranty for one year. If the PHSS or HeartAttendant® fail to operate in the described manner, contact your Support Team personnel for a replacement and return of the original for service.

Caution: Do not service this equipment yourself. Only qualified personnel can service this equipment. If service is required, contact your Support Team personnel.

Description	MicroMed Part Number
Fuse (European)	M00438-04
Fuse (North American)	M00438-05
Fuse (Controller Power)	M00413-03
PHSS/Controller Interface Cable	M01067
HeartAttendant®/Controller Interface Cable	M01507
VADPAK Battery	M00098 or M00527

Note: Use MicroMed Cardiovascular, Inc. replacement parts ONLY. For a mains power cord replacement, please contact MicroMed Cardiovascular, Inc.

12.6 Voltage Selector and Settings

Area	Voltage and Setting
North American	120V MAINS (AC)
European	240V MAINS (AC)

Section
13

13.0 Emergency Response and Troubleshooting

An emergency situation may be caused by conditions requiring medical care or by a mechanical problem that interferes with the pumping ability of the HeartAssist *5*® VAD. It is important to learn how to identify and respond to an emergency. The most important action is to restore power and function to the HeartAssist *5*® VAD.

13.1 Emergency Response

911 or local emergency number should be called when any of the following symptoms occur:

- Loss of Consciousness
- Seizures or Convulsions
- Inability to Move or Speak
- Sudden Collapse
- Conditions for Calling the Doctor

Warning: **BEFORE EXTERNAL DEFIBRILLATION, the PHSS must be disconnected from the patient. The patient should be receiving power from the two VADPAK Batteries in the VADPAK.**

If AC power is lost, ensure that fully charged batteries are installed in the VADPAK, remove the Controller connector from the PHSS or HeartAttendant® and travel to the nearest source of correct AC power with the PHSS or HeartAttendant®.

13.2 Troubleshooting

13.2.1 Non Pump-Related Problems

Situation	Action
The Controller LCD display is unreadable, the Battery LEDs respond to Battery changes and the Fail-Safe Mode LED is OFF. It is likely the Pump is still running normally.	Verify the functionality of the Battery LEDs by inserting and removing a fully charged Battery into one of the Battery ports while the other Battery port contains a charged Battery. If the LCD is not functional but the Battery and Fail-Safe Mode status indicators are still active **and** you feel no adverse affects, the Pump is probably still functioning correctly. The Controller should be replaced with the backup Controller.
The Controller LCD display is unreadable, the Battery LEDs respond to Battery changes and the Fail-Safe Mode LED is ON (Amber). It is likely that the Pump is still running but at the Fail-Safe Mode speed (8.5 kRPM). Because the motor Controller is separate circuitry from the Controller CPU, the Pump may continue to run in the event of a Controller failure; however, the "watchdog" circuitry that verifies the functionality of the CPU will detect a failure in the CPU and fix the motor Controller to the preset speed of 8,500 RPM.	The Controller should be replaced with the backup Controller.
The Controller LCD display is unreadable, the Battery LEDs do not respond to Battery changes. It cannot be determined if the Pump is operational or not.	The Controller should be immediately replaced with the backup Controller.
The Controller is splashed with liquid	Wipe the liquid from the case of the Controller. If one of the battery ports is open, tilt the Controller to allow the liquid to drain from the open port. **Warning: DO NOT attempt to wipe the liquid from the inside of the battery ports as the connector pins may become bent or otherwise damaged.** Contact the Support Team immediately.

Situation	Action
The Controller becomes soiled	The Controller can be wiped with a slightly damp cloth with mild detergent (for example, dishwasher soap). **<u>Caution:</u> NEVER spray water or detergent directly on to the Controller. Always apply water or detergent to a soft cloth, wring out until just slightly damp and wipe Controller.**
The Controller becomes submerged in liquid	Replace the Controller immediately, **and** Contact the Support Team immediately for an additional backup Controller.
A VADPAK battery pocket or VADPAK is submerged in liquid	Remove the Controller from the VADPAK immediately - **DO NOT** disconnect from the VADPAK yet! Locate a spare Battery Pocket and insert a fully charged battery into it. Locate PHSS/Controller Interface Cable or HeartAttendant®/Controller Interface Cable (verify that the PHSS or HeartAttendant® is powered up). Remove the **Battery 2** connection to the Controller and replace with the spare Battery Pocket connector. Verify connection of the Battery using the Controller display. Remove the **Battery 1** connection to the Controller and replace with the PHSS/Controller Interface Cable or HeartAttendant®/Controller Interface Cable. Verify connection of the PHSS or HeartAttendant® using the Controller Display. The Controller should no longer be connected to the VADPAK at this point. Drain the liquid from the VADPAK and contact the Support Team immediately for assistance. If spare Battery Pocket and the PHSS or HeartAttendant® are not available, <u>DO NOT</u> disconnect the Controller. Try to drain liquid and contact the Support Team immediately. **<u>REMEMBER</u>: Always carry extra Batteries, a spare Battery Pocket, and a spare Controller with you.**

Situation	Action
A battery or VADPAK is submerged in Liquid	If the Battery is in the VADPAK battery pocket, remove it immediately from the pocket. DO NOT attempt to use or recharge this battery. Contact the Support Team for a replacement Battery.

13.2.2 VADPAK Problems

Situation	Action
CDAS, HeartAttendant®, or PHSS is Connected to the External Interface Port of the VADPAK but is not indicated on the Controller display.	Verify that the CDAS/Controller, HeartAttendant®/ Controller, or PHSS/Controller Interface Cable is correctly inserted in the External Interface Port. Check the battery status for both VADPAK Batteries. • Press the Scroll Display Button until you see the default screen 1 with the battery percent values. • Determine which Battery the VAD Pump is receiving power from by looking at the battery LED indicator of the Controller. The Battery with a green indicator is providing power to the VAD Pump. Disconnect the connector of the backup Battery (Battery not in use in the VADPAK). The Battery with no indicator light lit is the Battery not being used. • Firmly hold the connector with one hand. • With the other hand, firmly hold the Controller. • Pull the connector from the Controller. This connection may be tight, and may take some force to pull it loose. • Press the Alarm Silence Button on the Controller front panel. **Note: If you do not press the Alarm Silence Button on the Controller front panel, the alarm will sound and tell you it is disconnected.** Connect the CDAS/Controller, HeartAttendant®/Controller, or PHSS/Controller Interface Cable to the Controller. • Visually align the slot on the cable connector with the red dot on the Controller port. • Once the slot and red dot are aligned, firmly push the plug straight into the Controller port. A slight "click" will be heard and felt as the connector becomes fully seated.
CDAS, HeartAttendant®, or PHSS is connected to the External Interface Port of the VADPAK but is not indicated on the Controller display.	**Caution: Damage can occur if the connector is forced without proper alignment. Do not twist the connector plug while inserting after the connectors are aligned.** • If all connections are tight and all components are working properly, the Controller front panel will display either "DAS CONNECTED" if using the CDAS or HeartAttendant® cable while in the hospital or "B1:----" if using the PHSS cable. Contact the Support Team for a VADPAK replacement.
CDAS	The Support Team personnel will be responsible for the CDAS.

13.2.3 PHSS and HeartAttendant® Problems

Situation	Reason	Action
Battery Status Light fails to light when Battery is inserted.	Installation of inappropriate Battery; Battery inappropriately seated; dirty Battery connector	Reseat battery. Call the Support Team.
System Status Light blinks red.	AC power out or blown side fuse of the PHSS or HeartAttendant®	Check power fuses. Call the Support Team.
System Status Light does not light when cord is plugged into main outlet.	No AC power is supplied to PHSS or HeartAttendant®; blown power fuse; microprocessor has not passed self-test	Check power fuses. Call the Support Team.
Batteries take a long time to charge, or do not charge.	Exposure to too low or too high a temperature; faulty Battery or faulty PHSS or HeartAttendant® charger	Call the Support Team.
Replacement fuse blows.	Installation of incorrect fuse	Check fuses and replace with correct ones. Call the Support Team.
Reduced fan sound, warm PHSS or HeartAttendant®, extended charging time for Batteries.	Fan malfunction	Call the Support Team.
Slow fans, power fuse blown.	Main input voltage inappropriate	Check voltage selector on Power Entry Module. Call the Support Team.
Blown fuse, System Status Light not illuminated.	Use of incorrect or too long an extension cord; power failure when unattached to Controller; dirty or broken cable connector or broken cable; failure of audible alarms with full discharge of Batteries	Replace power fuses. Call the Support Team.
PHSS does not pass self-test.	Microcomputer in PHSS not operational	Check power fuses. Call the Support Team.
Green LED on Controller does not indicate PHSS or HeartAttendant® is supplying power to Controller port #1.	Blown Controller fuse (on front panel of PHSS) or improperly seated connectors on PHSS/Controller Interface Cable or HeartAttendant®/Controller Interface Cable	Replace PHSS fuse. Verify connections to PHSS or HeartAttendant® and VADPAK are properly seated Call the Support Team.

Section
14

14.0 The Pediatric Patient on HeartAssist *5*® Pediatric VAD Support

All of the material previously presented in this Patient User's Manual is true for the pediatric patient. It is expected that pediatric patients between 12 and 16 years of age will encounter situations similar to the adult patient as described in this manual. This section provides guidance for situations that pediatric patients, especially younger children, might encounter and is aimed at the child's parents or caregiver. Parents or caregivers of pediatric patients of any age and children or adolescents with the appropriate skills should read this manual thoroughly before taking on care of the device. This section does not repeat all of the cautions and instructions contained elsewhere in this manual and it should not be substituted for reading the entire manual.

14.1 Implant Surgery

The HeartAssist *5*® Pediatric VAD will be placed in your child's chest with an operation. Your child's doctor will explain the surgery to both of you. When you and your child are ready after the operation to implant the device, the hospital staff will train you and your child, if he or she is old enough, on how to operate the HeartAssist *5*® Pediatric VAD.

14.2 Description

The Controller, VADPAK, SmartPak Batteries, PHSS, ChargePak, HeartAttendant®, and CDAS that the pediatric patient will use are the same as described in Section 2.0 and 3.0 of this manual. The pump your child will receive has been adjusted so it will fit better in a child's smaller chest. The pump operates exactly like the adult pump, Section 2.0 and 3.0 of this manual describe how the HeartAssist *5*® Pediatric VAD pump works.

14.3 Environmental Conditions

14.3.1 Temperature

HeartAssist *5*® Pediatric VAD system operation and storage is not recommended in certain environmental conditions:

Note: Do not operate the Controller where temperatures are less than -10° C (14° F) or greater than 40° C (104° F).

Your child must wear the Controller at all times or the child's pump will not run. Therefore, you should not allow your child to spend time in areas with temperatures outside this range or to place their Controller in locations where this temperature range may be exceeded, e.g., heaters, radiators, air conditioners.

Note: The SmartPak Batteries, Controller, and VADPAK should not be exposed to moisture or heat.

Whenever your child is mobile or operating in the un-tethered mode (i.e., child is operating pump on Batteries alone), he or she will have two Batteries and the Controller in the VADPAK. These Batteries and Controller must not get wet, so you should not allow your child to swim or play in water such that moisture may enter the VADPAK and come in contact with either the Batteries or Controller. On days with heavy rains, it might be helpful to make sure the child is wearing rain gear or the Shower Bag to protect the VADPAK, Controller, and Batteries as he or she goes outside.

The Batteries also should not be exposed to extreme heat. Care should be taken when the child is playing in very hot environments like at the beach. Young children should not stand in front of or come in contact with sources of heat such as fireplaces, space heaters, stoves, etc. As a reminder, your child's PHSS, HeartAttendant®, and ChargePak should never be placed close to these types of heat sources.

Note: The VADPAK carry bag is flame retardant but care should be exercised when used near open flame or embers. Any hot item that falls onto or within the bag should be removed as quickly as possible to prevent scorching or marring of the materials.

Special care should be taken if your child is around campfires or other sources of open flame. You should teach your child to stay a safe distance away from them.

14.3.2 Contact with Liquids

All forms of liquid should be kept away from the equipment in order to prevent accidental spills. For example, you may want your child to wear an apron or bib while eating so drinks don't spill on the VADPAK or its components. The equipment should never be submerged in any liquid. Young children may need to be watched carefully when near sources of water, such as the bathroom, as they may attempt to put their equipment in places like the toilet. Your child will not be able to swim or take a full bath while supported by the HeartAssist *5*® Pediatric VAD. Bathing while wearing the HeartAssist *5*® Pediatric VAD is covered later in Section 14.5, "Daily Operation."

14.3.3 Electromagnetic Interference

Testing has shown that there is little risk from electromagnetic interference, e.g., cellular phones, microwave ovens, etc., with the HeartAssist *5*® Pediatric VAD. However, not all brands of every type of device were tested. It is important to observe your child's pump

functions, e.g., flow and speed, closely anytime your child is in the presence of devices that may cause electromagnetic interference including toys that use wireless or radio controlled technology. If an unexpected change occurs, ask your child to move away from the potential source. If the pump function does not immediately return to normal when the source is removed, you should contact your Support Team.

14.3.4 Electrostatic Discharge

Testing has demonstrated that the function of the HeartAssist *5*® Pediatric VAD is not affected by electrostatic discharge. However, children often come in close contact with television screens or computer monitors. Although this should not effect the operation of the HeartAssist *5*® Pediatric VAD, you should consider teaching your children to stay a safe distance from television screens and other sources of electrostatic discharge as an added measure of safety.

14.4 Operating the HeartAssist *5*® Pediatric VAD System

Sections 5 and 6 of this manual tell you how to operate and manage your child's HeartAssist *5*® Pediatric VAD System. A few additional comments should be made specific to device management for the pediatric patient.

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

If the child is old enough to participate in his or her care and understand what to do, the child should be encouraged to be responsible for changing of Batteries. Since the duration of the Batteries will vary according to the pump speed, you will only be able to estimate the time interval between battery changes. If your child cannot change his or her Batteries, you will need to develop a system whereby you or a caregiver is with the child around the time a battery needs changing. If you cannot reasonably estimate the battery duration for your child, it is advisable to keep the child within hearing distance so you will be able to detect the battery discharged alarm. A rule must be made with your child that he or she will always have two Batteries in the VADPAK.

The VADPAK may be large for your child. Adjust the shoulder strap and waist belt so the VADPAK fits securely on your child. If the weight of the VADPAK pulls on your child's shoulder, additional padding may be placed beneath the shoulder strap to reduce the force. Your child should be taught to keep the VADPAK closed at all times, except for when changing a battery or checking the Controller. Active children should be cautioned against upside-down maneuvers on jungle gyms or other apparatus because the Batteries or Controller may come loose from the VADPAK if the Velcro flaps are dislodged. Your child will almost certainly get the VADPAK dirty. You may wipe the exterior of the bag with a slightly damp cloth to clean, taking care not to get water inside the VADPAK. If the child would like, you may apply stickers to the exterior of the

VADPAK, but nothing should be placed in the interior of the bag where equipment is placed. Because sand or dirt particles could easily get into the VADPAK and potentially interfere with connections, it may be desirable to keep your child from sitting and playing in sand or dirt. Your child's VADPAK should be exposed to ambient air to allow proper cooling and to prevent the alarms from being muffled. You should not allow your child to wear the VADPAK beneath clothing for extended periods of time.

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

14.5 Daily Operation

14.5.1 Leaving your house

Your child should have fully charged Batteries whenever he or she goes away from your house and you or your child should always carry a spare Controller, spare battery pocket and spare Batteries. If your child will be away from home for extended periods of time, a PHSS or HeartAttendant® should travel with your child so his or her Batteries may be charged and he or she will have backup wall power. If you do not accompany your child, it is very important to teach him or her to carry the required backup equipment. Your child should also have a card, letter, bracelet or other medical identification that shows that he or she has a HeartAssist *5*® Pediatric VAD left ventricular support device. This should also include the parent or caregiver's name and a method of contact, as well as the name and phone number of the child's physician.

14.5.2 Return to School

It is expected that some children will return to school while on HeartAssist *5*® Pediatric VAD support. Before the child returns to school, the school nurse and classroom teacher should receive training in the management of the child's device. It may be helpful to provide a copy of this manual to school staff. You and your child's teacher should evaluate playground and classroom areas to identify any situations that might cause harm to the child or his or her device. It may be useful to discuss your child's device with his or her classmates before he or she returns to school. Other children who play with your child should be cautioned not to pull the child's VADPAK, straps or percutaneous cable during play. Classmates and playmates should be reminded to seek adult help as soon as possible if your child doesn't feel well or passes out.

14.5.3 Activities

While on HeartAssist *5*® Pediatric VAD support, your child may not participate in swimming or contact sports activities. This is to protect the safety and function of your child's device. With your doctor's permission, your child may participate in moderate activities like jogging, golfing, walking, shopping, etc. with a low risk of harm to the device. You should consult your doctor about whether or not your child should travel by car or plane. If your child requires a car seat during travel, you should be sure to position the VADPAK so there is no pull on the cables or the child's shoulder. Seatbelts should not interfere with travel for older children in any case; however, they may be more comfortable riding on the right side of the vehicle where the belt buckles connect on the left because the percutaneous cable and VADPAK are located on the right side of the body.

14.5.4 Bedtime

When sleeping, your child should be tethered to the HeartAttendant® or PHSS (CDAS if in hospital) so there is a continuous power supply and the child does not have to be awakened to change Batteries. It will be important for you to arrange your child's room so that he or she can take the VADPAK off while sleeping, yet keep it close by so the percutaneous cable connection will not be stretched. You should put things the child may need at night in close reach because their connection to the VADPAK limits the distance they can safely move. Many children like a glass of water at their bedside; use of a non-spillable cup to prevent liquid from entering the VADPAK, Controller or Batteries is recommended.

14.5.5 Bathing

Children supported by the HeartAssist *5*® Pediatric VAD may not take a bath because the VADPAK, Controller and Batteries would be fully submerged in water. Careful sponge baths are suggested in children not yet old enough to shower. If your child showers with the device, the VADPAK must be fully enclosed in the Shower Bag as described in Section 9.0 of this manual.

14.6 Emergencies

An emergency situation may be caused by conditions requiring medical care or by a mechanical problem that interferes with the pumping ability of the HeartAssist *5*® Pediatric VAD. It is important to learn how to identify and respond to an emergency. The most important action is to restore power and function to your child's HeartAssist *5*® Pediatric VAD.

Local emergency services should be briefed about your child's heart pump and you should have a plan established with your family to activate these emergency services when needed. If your child must be defibrillated, the child must be disconnected from the PHSS. Cardiopulmonary resuscitation (CPR) may be performed for children with a HeartAssist *5*® Pediatric VAD. You may not be able to feel the child's pulse even if the pump is operating normally, so CPR and defibrillation should not be done if your child is awake and responsive, even if a pulse cannot be

felt. If you lose power to your home and you are not certain when it will be restored, you should move your child and his or her PHSS or HeartAttendant® with Batteries to a location that has power as soon as possible to prevent pump stoppage due to battery expiration.

Prevention is the key to handling emergencies with the child who has a HeartAssist *5*® Pediatric VAD, especially if that child is old enough to sometimes be without a parent or caregiver. The child should always carry identification as an assist device patient with contact information for the parent and physician. The child's teachers, coaches, classmates, friends and siblings should be educated about the HeartAssist *5*® Pediatric VAD and taught what to do in the case of emergency for your child. If your child is not with you, he or she should be accompanied by a responsible person such as a friend or sibling, so that someone is available to immediately seek help for your child in the case of an emergency. Children who are too young or unable to respond to device alarms, change Batteries or seek help should always be accompanied by a parent, caregiver or other individual knowledgeable in the operation of the HeartAssist *5*® Pediatric VAD.