

EMS Guide

Complete Document



This guide is produced by ICCAC – The International Consortium of Circulatory Assist Clinicians. The ICCAC is the professional society for MCS Clinicians throughout the world. It has been vetted by experts in MCS, Air Medical Transport, and Emergency Services. It should not replace the device operating manual as a primary source of information.

Questions and Answers Ventricular Assist Device

What is a Ventricular Assist Device (VAD)?

A ventricular assist device (VAD) is a mechanical pump that's used to support heart function and blood flow in people who have weakened hearts.

How does a VAD work?

The device takes blood from a lower chamber of the heart and helps pump it to the body and vital organs, just as a healthy heart would.

What are the parts of a VAD?

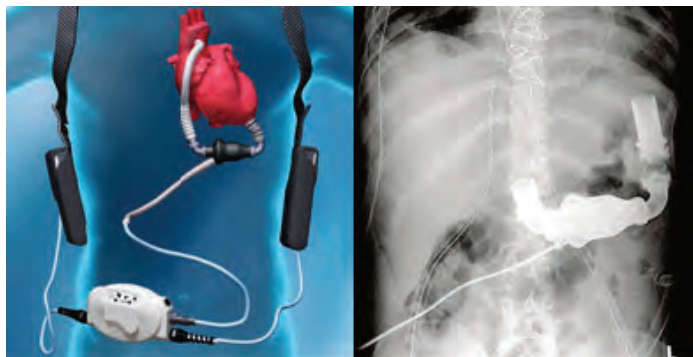
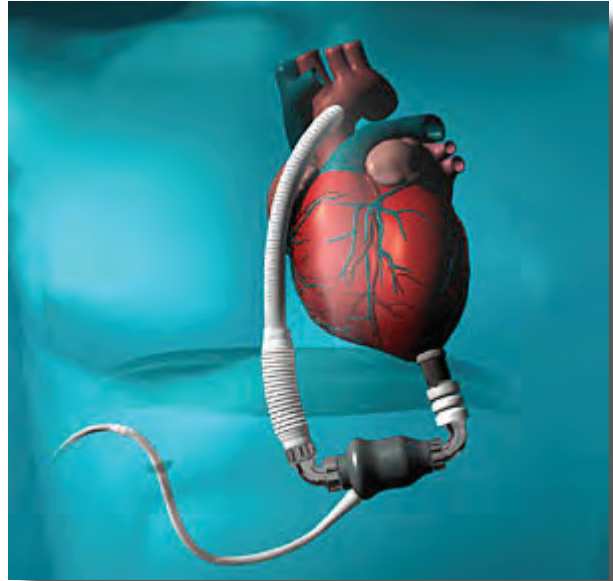
The basic parts of a VAD include: a small tube that carries blood out of your heart into a pump; another tube that carries blood from the pump to your blood vessels, which deliver the blood to your body; and a power source.

What is the power source?

The power source is either batteries or AC power. The power source is connected to a control unit that monitors the VAD's functions. The batteries are carried in a case usually located in a holster in a vest wrapped around the patients shoulders.

What does the control unit or controller do?

The control unit gives warnings, or alarms, if the power is low or if it senses that the device isn't working right. It is a computer.



The portability of the HeartMate II enables patients to resume many of their normal daily activities.

Color Coding System

MOST patients have a tag located on the controller around their waist that says what type of device it is, what institution put it in and a number to call. Most importantly is the color of the tag – it matches this EMS Field Guide and allows you to quickly locate the device you are caring for.

HEARTMATE III

HEARTMATE II

HEARTWARE

JARVIK 2000

FREEDOM DRIVER
Total Artificial Heart

Patient Management For VADs



1. **Assess the patients airway and intervene per your protocol.**
2. **Auscultate Heart Sounds to determine if the device is functioning and what type of device it is. If it is continuous flow device, you should hear a “whirling sound”.**
3. **Assess the device for any alarms.**
4. **Look on controller usually found around the waist of the patient and to see what color tag and device it is.**
5. **Match the color on the device tag to the EMS Guide.**
6. **Intervene appropriately based on the type of alarm, tag (device) and EMS Guide.**
7. **Start Large Bore IV.**
8. **Assess vital signs – Use Mean BP with Doppler – with the first sound you hear is the Mean Arterial Pressure (MAP).**
9. **If no Doppler, use the Mean on the non invasive blood pressure machine.**
10. **Transport to closest VAD center. Call the number on the device to get advice.**
11. **Bring all of the patients equipment.**
12. **Bring the significant other if possible to act as a expert on the device in the absence of consciousness in the patient.**

HeartMate III[®] with Pocket Controllers

- 1. Can I do external CPR?**
Only if absolutely necessary
- 2. If not, is there a “hand pump” or external device to use?**
No.
- 3. If the device slows down (low flow state), what alarms will go off?**
A red heart alarm light indicator and steady audio alarm will sound if less than 2.5 lpm. Can give a bolus of normal saline and transport to an LVAD center.
- 4. How can I speed up the rate of the device?**
No, it is a fixed speed.
- 5. Do I need to heparinize the patient if it slows down?**
Usually no, but you will need to check with implanting center.
- 6. Can the patient be defibrillated while connected to the device?**
Yes.
- 7. If the patient can be defibrillated, is there anything I have to disconnect before defibrillating?**
No.
- 8. Does the patient have a pulse with this device?**
Likely they will not because it is a continuous flow device, however some patients may have a pulse as this pump was designed with an “artificial pulse.”
- 9. What are acceptable vital sign parameters?**
MAP 70 - 90 mm Hg with a narrow pulse pressure.
- 10. Can this patient be externally paced?**
Yes.

FAQs

- Pump has “artificial pulse” created by speeding up & slowing down of pump. This can be heard when auscultating the heart and differs from other continuous flow devices.
- May not be able to obtain cuff pressure (continuous flow pump).
- Pump connected to electric line exiting patient’s abdominal area and is attached to computer which runs the pump.
- Pump does not affect EKG.
- All ACLS drugs may be given.
- A set of batteries last 14 – 16 hours
- Any emergency mode of transportation is ok. These patients are permitted to fly.
- Be sure to bring **ALL** of the patient’s equipment with them.

Trouble Shooting HeartMate III[®] with Pocket Controllers When the Pump Has Stopped

- Be sure to bring ALL of the patient’s equipment with them.
- Fix any loose connection(s) to restart the pump.
- If the pump does not restart and the patient is connected to batteries replace the current batteries with a new, fully-charged pair. (*see Changing Batteries section on next page*)
- If pump does not restart, change controllers. (*see Changing Controllers section on next page*)

Alarms: Emergency Procedures



Yellow or Red Battery Alarm: Need to Change Batteries. See changing batteries section on next page.



Red Heart Flashing Alarm: This may indicate a Low Flow Hazard. Check patient--the flow may be too low. If patient is hypovolemic, give volume. If patient is in right heart failure-- treat per protocol. If the pump has stopped check connections, batteries and controllers as instructed in the section above.



Trouble Shooting HeartMate III®

Changing Batteries

WARNING: At least one power lead must be connected to a power source **AT ALL TIMES**. Do not remove both batteries at the same time or the pump will stop.

- Obtain two charged batteries from patient's accessory bag or battery charger. The charge level of each gray battery can be assessed by pressing the battery button on the battery. (Figures 1 and 2)
- Remove only **ONE** battery from the clip by pressing the button on the grey clip to unlock the battery. (Figure 3)
- Controller will start beeping and flashing yellow signals and will read **POWER DISCONNECT** on the front screen. (Figure 4)
- Replace with new battery by lining up **RED** arrows on battery and clip. Gently tug on battery to ensure connection. If battery is properly secured, the beeping and yellow flashing will stop. (Figure 5)
- Slide a new, fully-charged battery (Figure 4) into the empty battery clip by aligning the **RED** arrows. The battery will click into the clip. Gently tug at battery to ensure connection. If battery is properly secured, the beeping and green flashing will stop.
- Repeat previous steps with the second battery and battery clip.

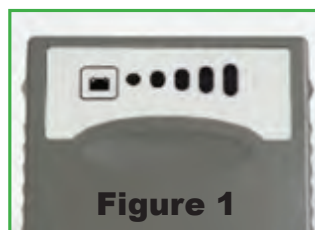


Figure 1

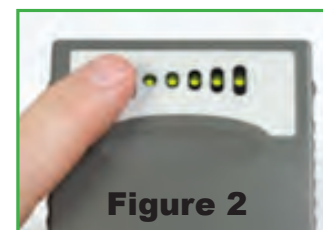


Figure 2

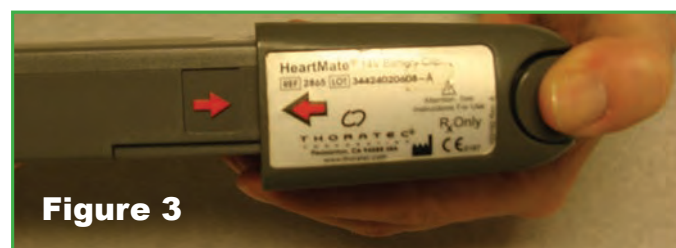


Figure 3



Figure 4

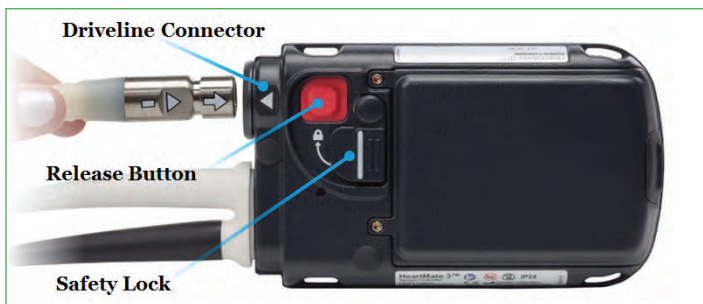


Figure 5

Trouble Shooting HeartMate III[®] with Pocket Controllers

Changing Controllers

- Place the replacement Controller within easy reach, along with the batteries/battery clips. The spare Controller is usually found in the patient's travel case.
- Make sure patient is sitting or lying down since the pump will momentarily stop during this procedure.
- Attach the battery clips to the spare controller by lining up the half moons and gently pushing together and attach the batteries to the spare controller by aligning the **RED** arrows.
- On the back of the replacement controller, rotate down the perc lock so the red tab is fully visible. Repeat this step on the original controller until the red tab is fully visible.



- Disconnect the drive-line from the original controller by pressing down on the red tab and gently pulling on the metal end. The pump will stop and an alarm will sound. **Note:** The alarm will continue until the original controller is put to sleep. You can silence the alarm by pressing the silence button.



Getting the replacement controller connected and pump restarted is the first priority.

- Connect the replacement Controller by aligning the **BLACK ARROWS** on the driveline and replacement Controller and gently pushing



the driveline into the replacement Controller. The pump should restart, if not complete the following steps:

- Step 1.** Firmly press the Silence Alarm or Test Select Button to restart the pump.
 - Step 2.** Check the power source to assure that power is going to the controller.
 - Step 3.** Assure the perc lead is fully inserted into the socket by gently tugging on the metal end. **DO NOT** pull the lead.
- After the pump restarts, rotate up the perc lock on the new controller so the red tab is fully covered. If unable to engage perc lock to a fully locked position, gently push the driveline into the controller to assure proper connection. Retry to engage perc lock.
 - Disconnect power from the original Controller. The original Controller will stop alarming once power is removed.
 - Hold down battery symbol for 5 full seconds for complete shutdown of old controller.



Adapted from Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport in ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010 in press.

CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use.

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January 2019

Trouble Shooting HeartMate III[®] with Pocket Controllers

Modular Cable

The HeartMate 3 has a modular cable connection near the exit site of the driveline (Figure 1). This allows a damaged driveline to be quickly replaced (if damage is external).

- When disconnecting a driveline, **NEVER** use the modular cable connection.
- If this section of the driveline requires replacement, this must be performed at and by the implanting center. Patients are not given a back-up modular cable.
- If the connection is loose, there will be a yellow/green line at the connection showing (Figure 2). If the line is visible, it can be retightened by turning with the arrow in the locked direction. It will ratchet and stop turning once tight.



Figure 1



Figure 2



HeartMate II®

- 1. Can I do external CPR?**
Only if absolutely necessary
- 2. If not, is there a “hand pump” or external device to use?**
No.
- 3. If the device slows down (low flow state), what alarms will go off?**
A red heart alarm light indicator and steady audio alarm will sound if less than 2.5 lmp. Can give a bolus of normal saline and transport to an LVAD center.
- 4. How can I speed up the rate of the device?**
No, it is a fixed speed.
- 5. Do I need to heparinize the patient if it slows down?**
Usually no, but you will need to check with implanting center.
- 6. Can the patient be defibrillated while connected to the device?**
Yes.
- 7. If the patient can be defibrillated, is there anything I have to disconnect before defibrillating?**
No.
- 8. Does the patient have a pulse with this device?**
May have weak pulse or lack of palpable pulse.
- 9. What are acceptable vital sign parameters?**
MAP 70 - 90 mm Hg with a narrow pulse pressure
- 10. Can this patient be externally paced?**
Yes.

FAQs

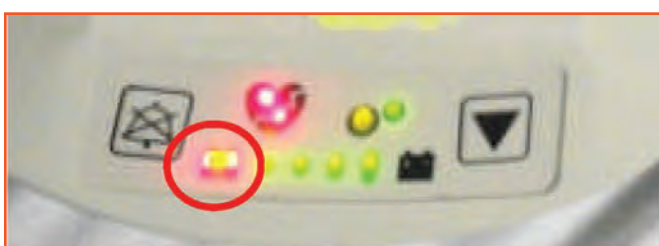
- May not be able to obtain cuff pressure (continuous flow pump).
- Pump connected to electric line exiting patient’s abdominal area and is attached to computer which runs the pump.
- Pump does not affect EKG
- All ACLS drugs may be given.
- No hand pump is available.
- A set of black batteries last approximately 3 hours, gray batteries last 8-10 hours.
- Any emergency mode of transportation is ok. These patients are permitted to fly.
- Be sure to bring **ALL** of the patient’s equipment with them.

Adapted from Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport in ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010 in press.

Trouble Shooting HeartMate II® When the Pump Has Stopped

- Be sure to bring ALL of the patient’s equipment with them.
- Fix any loose connection(s) to restart the pump.
- If the pump does not restart and the patient is connected to batteries replace the current batteries with a new, fully-charged pair. (see *changing batteries section on next page*)
- If pump does not restart, change controllers. (see *changing controllers section on next page*)

Alarms: Emergency Procedures



Yellow or Red Battery Alarm: Need to Change Batteries. See changing batteries section on next page.

Red Heart Flashing Alarm: This may indicate a Low Flow Hazard. Check patient--the flow may be too low. If patient is hypovolemic, give volume. If patient is in right heart failure-- treat per protocol. If the pump has stopped check connections, batteries and controllers as instructed in the section above.



Trouble Shooting HeartMate II®

Changing Batteries

WARNING: At least one power lead must be connected to a power source **AT ALL TIMES**. Do not remove both batteries at the same time or the pump will stop.

- Obtain two charged batteries from patient's accessory bag or battery charger. The charge level of each gray battery can be assessed by pressing the battery button on the battery. (Figures 3 and 4)
- Remove only **ONE** battery from the clip by pressing the button on the grey clip to unlock the battery. (Figure 1)
- Controller will start beeping and flashing green signals.
- Replace with new battery by lining up **RED** arrows on battery and clip. (Figure 2)
- Slide a new, fully-charged battery (Figure 4) into the empty battery clip by aligning the **RED** arrows. The battery will click into the clip. Gently tug at battery to ensure connection. If battery is properly secured, the beeping and green flashing will stop.
- Repeat previous steps with the second battery and battery clip.



Figure 1



Figure 2

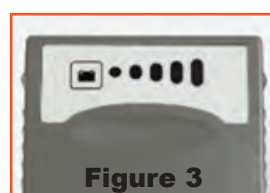


Figure 3

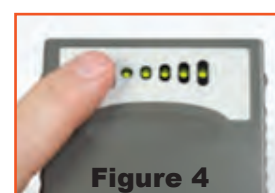


Figure 4

Changing Controllers

- Place the replacement Controller within easy reach, along with the batteries/battery clips. The spare Controller is usually found in the patient's travel case.

- Make sure patient is sitting or lying down since the pump will momentarily stop during this procedure.

- Attach the battery clips to the spare controller by lining up the half moons and gently pushing together and attach the batteries to the spare controller by aligning the **RED** arrows. **ALARMS WILL SOUND-THIS IS OK.**



Half-Moons

- Depress the silence alarm button (upside-down bell with circle) until the alarm is silenced on the new, replacement Controller.

- Rotate the perc lock on the replacement controller in the direction of the "unlocked" icon until the perc lock clicks into the fully-unlocked position. Repeat this same step for the original Controller until the perc lock clicks into the unlocked position.



Perc Lock

- Disconnect the perc lead/driveline from the original controller by pressing the metal release tab on the connector socket. The pump will stop and an alarm will sound.

Note: The alarm will continue until power is removed from the original Controller. **Getting the replacement Controller connected and the pump restarted is the first priority.**

- Connect the replacement Controller by aligning the **BLACK LINES** on the driveline and replacement Controller and gently pushing the driveline into the replacement Controller. The pump should restart, if not complete the following steps:

Step 1. Firmly press the Silence Alarm or Test Select Button to restart the pump.

Step 2. Check the powersource to assure that power is going to the controller.

Step 3. Assure the perc lead is fully inserted into the socket by gently tugging on the metal end. **DO NOT** pull the lead.



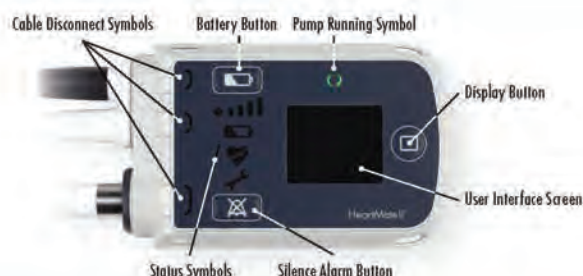
Tug gently on metal end in this direction

Perc Lead

- After the pump restarts, rotate the perc lock on the new controller in the direction of the "locked" icon until the perc lock clicks into the fully-locked position. If unable to engage perc lock to the locked position, gently push the driveline into the controller to assure a proper connection. Retry to engage perc lock.
- Disconnect power from the original Controller. The original Controller will stop alarming once power is removed.

HeartMate II® Controller Comparison Guide

POCKET CONTROLLER™



3 Modes: Run, Charge, Sleep

Run: Driveline + Power source connected.

Charge: Only power source connected.

Sleep: No driveline or power source connected; ready to use.

Backup Battery

An emergency backup battery is built into Pocket Controller, powering the pump for 15 minutes in the absence of an external power source. The backup battery is supplied NONSTERILE.

Event Logger

Pocket Controller includes date/time records in event history. Pocket Controller can store 240 events.

Green Pump Running Symbol

 Green "pump running" symbol signifies that the pump is on and running.

Controller Buttons


Display Button: Enables viewing of pump parameters and backup battery charge status.

Silence Alarm Button: Silences hazard alarms for 2 minutes and advisory alarms for 4 hours.


Display Button + Silence Alarm Button Together: Displays previous six alarms.

Battery Button: Displays the battery power gauge when pressed. Activates a self test when held for 5 seconds then released. Enters sleep mode when driveline and external power are disconnected and button is held for 5 seconds then released.

Self Test

 Press and hold the Battery Button for 5 seconds.

Low Power

 **Yellow Diamond Symbol:** Displayed when only 15 minutes of external power is remaining.

 **Red Battery Symbol:** Displayed when only 5 minutes of external power is remaining.

Backup Battery Mode: Entered after external power is depleted. Provides 15 minutes of internal emergency backup battery power.

Power Saver Mode: Entered when pump has run on backup battery for 15 minutes. Pump Speed is reduced to the set Low Speed Limit.

Starting the Pump

>8000 RPM: Pump starts automatically.

<8000 RPM with Backup Battery: Start pump by pressing any button on Pocket Controller.

<8000 RPM with no Backup Battery: Pump can only be started via System Monitor.


System Monitor Event History Screen

PI Event:	10/04/13 07:20	4.8	9590	5.6	5.4	PI Event
System Information:	10/04/13 01:30	4.8	6900	5.7	6.6	* System Information

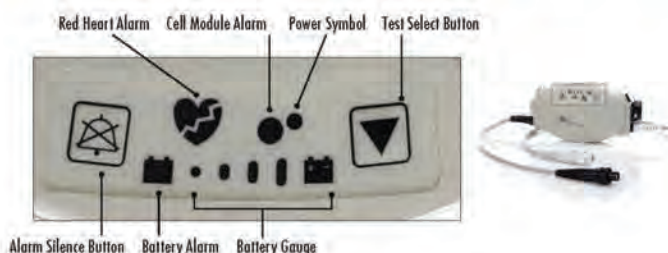
Compatibility

System Monitors I and II, Power Module, Power Module Patient Cable (14 Volt), 14 Volt Lithium-Ion Batteries and Battery Clips.

Alarms

 For a review of alarms and their meanings, reference HeartMate II Alarms for Clinicians, item 107526. Pocket Controller includes a yellow wrench icon to denote advisory alarms. Note that Pocket Controller includes drivelines fault detection.

EXTERNAL PERIPHERAL CONTROLLER (EPC)



2 Modes: On, Off

On: Driveline + Power source connected.

Off: No driveline or power source connected.


Cell Module Battery

No backup battery. The cell module battery powers an audible tone if EPC is removed from power while the driveline is connected. The cell module battery is supplied STERILE.

Event Logger

EPC does not include date/time records in event history. EPC can store 120 events.

Green Power Symbol

 Green light only means that the controller is receiving power. Listen over the pump pocket for confirmation that the pump is running.


Controller Buttons

Alarm Silence Button: Displays the battery fuel gauge. Also silences hazard alarms for 2 minutes and advisory alarms for 4 hours.


Test Select Button: Activates a self test when held for 3 seconds.


Note: EPC does not include a display button or user interface screen. The Display Module is used to view pump parameters and alarm events.

Self Test

 Press and hold the Test Select Button for 3 seconds.

Low Power

 **Yellow Battery Symbol:** Displayed when only 15 minutes of external power is remaining.

 **Red Battery Symbol:** Displayed when only 5 minutes of external power is remaining.

Power Saver Mode: Entered when the battery voltage falls to a critically low level. Pump Speed is reduced to 8000 RPM.

Starting the Pump

>8000 RPM: Pump starts automatically.

<8000 RPM: Start pump by pressing Alarm Silence Button or Test Select Button on EPC.

System Monitor Event History Screen

PI Event:	10/04/13 07:20	4.8	9590	5.6	5.4	PI Event
System Information:	10/04/13 01:30	4.8	6900	5.7	6.6	*

Compatibility

System Monitors I and II, Power Module, Power Base Unit (PBU), Power Module Patient Cable (12 Volt and 14 Volt), 14 Volt Lithium-Ion Batteries and Battery Clips, 12 Volt SLA and NiMH Batteries and Clips.

Alarms

For a review of alarms and their meanings, reference HeartMate II Alarms for Clinicians, item 103851. Note that EPC does not include driveline fault detection.

HeartMate II Controller Comparison Guide

DRIVELINE CONNECTION

Pocket Controller:

A safety tab is located on the back of the controller.



Unlocked

Locked

External Peripheral Controller (EPC):

A percutaneous lock is located on the side of the controller.



Unlocked

Locked

The Pocket Controller driveline connection and locking mechanism are different from the EPC. To insert and lock the driveline into Pocket Controller:



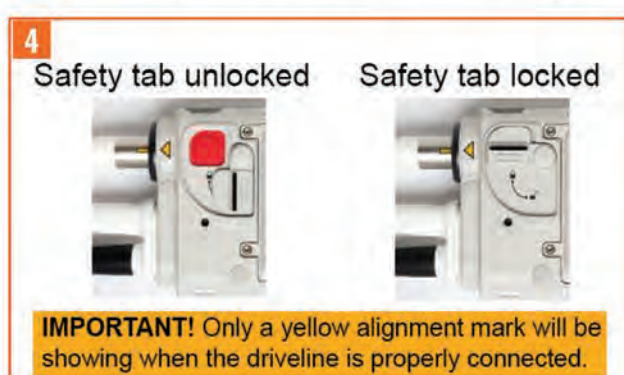
Slide the safety tab back to expose the red button.



Align the arrow on the driveline to the arrow on the Pocket Controller. Firmly insert the driveline until it snaps into place.



Tug gently on the metal portion of the driveline to ensure that it is fully engaged.



Slide the safety tab over the red button. Ensure the safety tab completely covers the red button.

HeartWare® Ventricular Assist System

1. Can I do external CPR?

Chest compressions may pose a risk of dislodgment – use clinical judgment. If chest compressions are administered, confirm function and positioning of the pump.

2. If not, is there a “hand pump” or external device to use?

No.

3. If the device slows down (low flow state), what alarms will go off?

The device runs at a fixed speed. If a low flow state occurs, an alarm will be heard, and the controller display will show a yellow triangle and “Low Flow – Call” message.



4. How can I speed up the rate of the device?

It is not possible to adjust the pump speed in the prehospital setting. Okay to give IV fluids.

5. Do I need to heparinize the patient if it slows down?

Call the accepting VAD facility for guidance.

6. Can the patient be defibrillated while connected to the device?

Yes.

7. If the patient can be defibrillated, is there anything I have to disconnect before defibrillating?

No, defibrillate per protocol.

8. Does the patient have a pulse with this device?

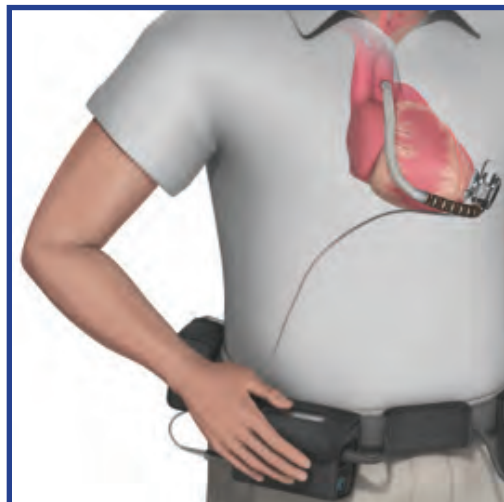
The patient may not have a palpable pulse. Depending on the patient's own heart function, you may be able to feel a thready pulse.

9. What are acceptable vital sign parameters?

Goal Mean Arterial Pressure (MAP) is <85 mmHg. Use a Doppler as the first option to assess blood pressure. If you are using a Doppler, place the blood pressure cuff on the patient arm. As you release the pressure in the blood pressure cuff, the first sound you hear with the Doppler is the MAP. If that is not available, use a non-invasive BP (NIBP).

10. Can this patient be externally paced?

Yes



FAQs

- May not be able to obtain cuff pressure (continuous flow pump)
- Pump connected to electric line (driveline) exiting patient's abdominal area and is attached to computer (controller) which runs the pump.
- Pump does not affect EKG, but patient may or may not be symptomatic even with ventricular arrhythmias.
- All ACLS drugs may be given.
- No hand pump is available. This is a rotary (continuous flow) pump with typical speed ranges of 2400 – 3200 RPMs. The patient should have back-up equipment.
- The controller draws power from one battery at a time. A fully charged battery will provide 4-6 hours of power. Both the battery and controller have status lights to indicate the amount of power remaining.
- Transport by ground to implanting facility if possible.
- Be sure to bring **ALL** of the patient's equipment with them.

HeartWare® Ventricular Assist System Emergency Operation



CONTROLLER



BATTERY

ALARM ADAPTER

- Used to silence the internal NO POWER ALARM.
- Should only be used on a controller that is NOT connected to a patient's pump.
- Must be inserted into the blue connector of the original controller after a controller exchange BUT before the power sources are disconnected or the NO Power alarm will sound for up to two hours.



DRIVELINE CONNECTION

To Connect to Controller:

- Align the two red marks and push together. An audible click will be heard confirming proper connection. (Figure A)
- The Driveline Cover must completely cover the Controller's silver driveline connector to protect against static discharge. (Figure B)
- NOTE: an audible click should be heard when connecting the Driveline or Driveline extension to the controller. Failure to use the Driveline Cover may cause an Electrical Fault Alarm.



Figure A



Figure B

CONNECTING POWER TO CONTROLLER

To Connect a Charged Battery:

- Grasp the cable of the charged battery at the back end of the connector (leaving front end of connector free to rotate)
- Line up the solid white arrow on the connector with the white dot on the Controller.
- Gently push (but DO NOT twist) the battery cable into the Controller until it naturally locks into place; you should hear an audible click.
- Confirm that the battery cable is properly locked on the controller by gently pulling the cable near the controller power connector.
- DO NOT force the battery cable into the controller connector without correct alignment as it may result in damaged connectors .



Controller

TO DISCONNECT A DEPLETED BATTERY

- Make sure there is a fully charged battery available to replace the depleted one.
- Disconnect the depleted battery by turning the connector counterclockwise until it stops.
- Pull the connector straight out from the controller.



HeartWare® Ventricular Assist System Emergency Operation

STEPS TO EXCHANGE THE CONTROLLER

Step 1: Have the patient sit or lie down.

Step 2: Place the new controller within easy reach.

Step 3: Connect back-up power sources (batteries or AC Power) to the new controller.

- Confirm that the power cables are properly locked on the controller by gently pulling on the cable near the connector.
- A “Power Disconnect” alarm will activate if a second power source is not connected to the new controller within 20 seconds of controller power up
- A “VAD Stopped” alarm will activate if the pump driveline is not connected to the new controller within 10 seconds - this alarm will resolve once the pump driveline is connected

Step 4: Pull back the white driveline cover from the original controller’s silver connector.

Step 5: Disconnect the driveline from the original controller by pulling the silver connector away from the controller. Do not disconnect by pulling on the driveline cable. A “VAD Stopped” alarm may activate. Don’t panic. You can silence the alarm after restarting the pump, which is the priority.

Step 6: Connect the driveline to the new controller (align the two red marks and push together). If the “VAD Stopped” alarm was active on the new controller, it will now resolve.

Step 7: The pump should restart. Verify the pump is working (RPM, L/min, Watts).

Step 8: IF THE PUMP DOES NOT RESTART, CALL FOR MEDICAL ASSISTANCE IMMEDIATELY.

Step 9: Insert the Alarm Adapter into the blue connector on the original controller.

- Disconnect both power sources from the original controller.
- The controller will be turned off and all alarms silenced.

Step 10: Slide the white driveline cover up to cover new controller’s silver connector.

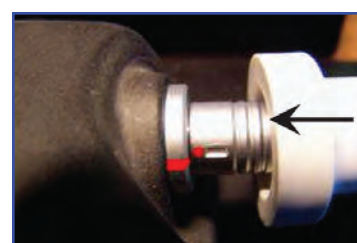
Step 11: Contact the VAD Center or Implanting hospital for a new backup controller.



Step 3



Step 4



Step 6



Step 9



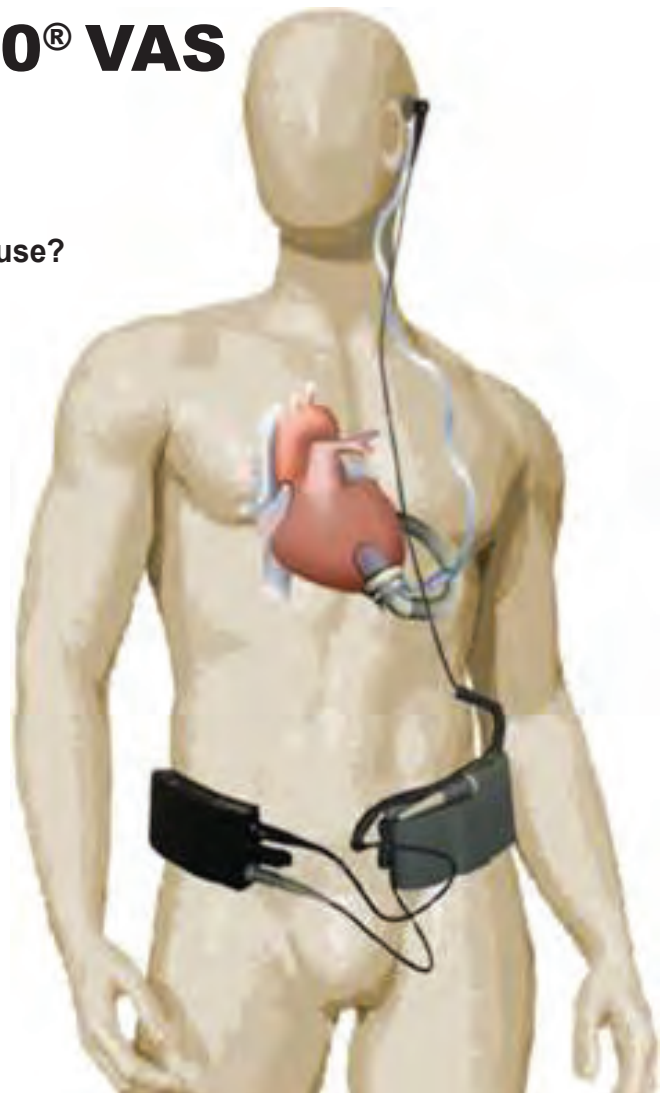
Step 10

HeartWare® Ventricular Assist System Troubleshooting

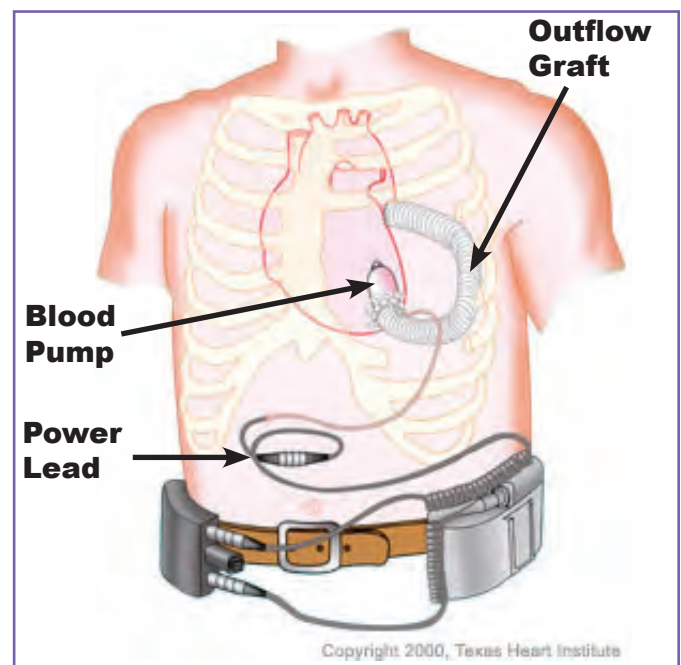
ALARM TYPE	ALARM DISPLAY (Line 1)	ACTION (Line 2)
High - Critical (FLASHING RED)	VAD STOPPED	CONNECT DRIVELINE
	VAD STOPPED	CHANGE CONTROLLER
	CRITICAL BATTERY 1	REPLACE BATTERY 1
	CRITICAL BATTERY 2	REPLACE BATTERY 2
	CONTROLLER FAILED	CHANGE CONTROLLER
MEDIUM (FLASHING YELLOW)	CONTROLLER FAULT	CALL ACCEPTING VAD HOSPITAL
	CONTROLLER FAULT	CALL: ALARMS OFF
	HIGH WATTS	CALL ACCEPTING VAD HOSPITAL
	ELECTRICAL FAULT	CALL ACCEPTING VAD HOSPITAL
	LOW FLOW	CALL ACCEPTING VAD HOSPITAL
	SUCTION	CALL ACCEPTING VAD HOSPITAL
LOW (SOLID YELLOW)	LOW BATTERY 1	REPLACE BATTERY 1
	LOW BATTERY 2	REPLACE BATTERY 2
	POWER DISCONNECT	RECONNECT POWER 1
	POWER DISCONNECT	RECONNECT POWER 2

Jarvik 2000® VAS

- 1. Can I do external CPR?**
Yes, only as a last resort.
- 2. If not, is there a “hand pump” or external device to use?**
No.
- 3. If the device slows down (low flow state), what alarms will go off?**
No alarm for low flow. If pump is off, the red “Pump Stop” symbol will light with a continuous alarm.
- 4. How can I speed up the rate of the device?**
There is a speed dial on the side of the controller (see picture on next page). Turning the dial in the direction of the arrow increases the speed. Each increment is 1,000 RPM. It is recommended not to change the speed without consulting the implanting center.
- 5. Do I need to heparinize the patient if it slows down?**
Typically yes, if the pump is stopped (red “Pump Stop” alarm). Check with the implanting center.
- 6. Can the patient be defibrillated while connected to the device?**
Yes.
- 7. If the patient can be defibrillated, is there anything I have to disconnect before defibrillating?**
No.
- 8. Does the patient have a pulse with this device?**
Most patients have a faint palpable pulse. If the controller is marked “ILS” (see below), the speed is automatically reduced every minute for 8 seconds & the patients pulse may increase during this time.
- 9. What are acceptable vital sign parameters?**
MAP 65 - 80mm Hg.
- 10. Can this patient be externally paced?**
Yes.



Jarvik 2000 with Post-Auricular exit site.



Jarvik 2000 with Abdominal exit site.

Adapted from Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport in ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010 in press. This guide does not supersede manufacturer instructions. Copy with permission only. March 2019 Jarvik 2000®

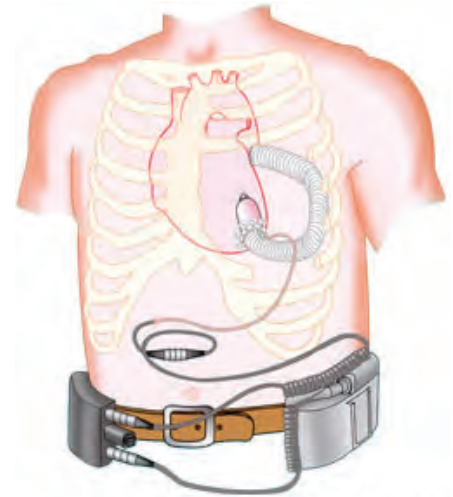
Jarvik 2000® VAS



**Jarvik 2000® VAS,
Post-Auricular Cable.**

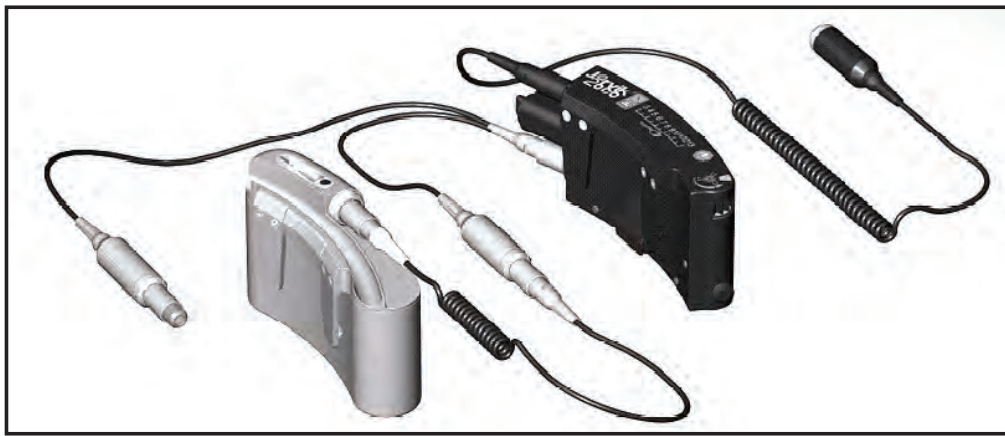


The Jarvik 2000® VAS is available in two models: the Jarvik 2000® VAS, Post-Auricular Cable (JHI-001) and the Jarvik 2000® VAS, Abdominal Cable (JHI-002). The main difference between the two models is the exit site of the drive cable. The drive cable of the Jarvik 2000® VAS, Abdominal Cable exits the abdomen and the drive cable of the Jarvik 2000® VAS, Post-Auricular Cable exits at a Pedestal surgically attached to the skull behind the ear.



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**Jarvik 2000® VAS,
Abdominal Cable.**



External Equipment for Jarvik 2000® VAS, Abdominal Cable.



External Equipment for Jarvik 2000® VAS, Post-Auricular Cable.

NOTE: This Field Guide is NOT intended to replace the Operator Manual and Patient Handbook.

January 2019

Jarvik 2000® VAS



Li-ion Battery.



Reserve Battery/Charger.



FlowMaker® Controller.

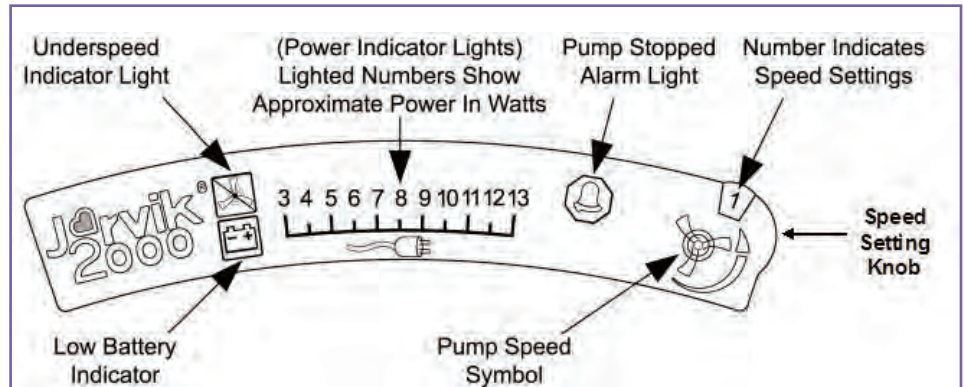


Diagram of FlowMaker® Controller Top Panel.

Dial Setting	Speed Rpm	Flow L/min	Power Watts
1	8,000	1-2	3-4
2	9,000	2-3	4-5
3	10,000	4-5	5-6-7
4	11,000	5-7	7-8-9
5	12,000	7-8.5	8-9-10

The FlowMaker Controller provides:

1. power to the implanted blood pump,
2. user settable speeds at which the pump runs, and
3. alarms and warnings.

The **FlowMaker®** Controller does not monitor the actual blood flow that the **Jarvik 2000® Ventricular Assist Device (VAD)** is pumping. In general, the higher the setting number the more blood the Jarvik 2000 VAD will pump. The tabulated flow estimates are based on research measurements in healthy animals. The actual blood flow may vary and will depend on several factors including blood pressure and the condition of the natural heart.

Jarvik 2000® VAS

Speed Setting, Alarms, and Warnings



Only one control adjustment to the **Jarvik 2000® VAD** can be made. The **Jarvik 2000® VAD speed** can be selected by turning the knob on the side of the **FlowMaker® Controller**. The setting number appears in the window on the top panel. The arrow indicates the direction to turn the knob to increase the speed.



Power Indicator Lights The numbers indicate the electrical power (Watts) that the VAD is using. One, two, or three numbers may be lit at any moment, and the lights may change rhythmically with the heartbeat of the natural heart. A power measure of 13 watts or more indicates malfunction. The High Power Indicator, number 13, will light yellow. This condition should receive prompt medical attention.



When the battery powering the **Jarvik 2000® VAD** is low, the **Low Battery Alarm** on the **FlowMaker® Controller lights yellow** and the alarm sound beeps. Remaining running time with the portable Li-ion Battery is about 5-10 minutes; with the Reserve Battery/Charger for approximately 15 minutes



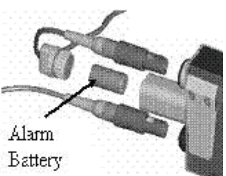
If the **Jarvik 2000® VAD** stops or if the VAD speed drops to below 5,000 RPM for any reason, a steady alarm sound is heard and the **Pump Stopped Alarm** on the **FlowMaker® Controller lights red**. The **Pump Stopped Alarm** will also sound if the intermittent low speed featured on the ILS FlowMaker® Controller fails to function for any reason. Immediate attention is required. **Follow the Pump Stopped Alarm procedure for the appropriate Jarvik 2000® VAS model (Post-Auricular Cable or Abdominal Cable) which is included in this Field Guide.**



The **Underspeed Indicator light will glow yellow** when the **Flowmaker® Controller** detects that the **Jarvik 2000® VAD** speed is slower than the dial setting selected. The most common reason is the battery voltage is too low.

In this case, corrective actions are to:

1 Select a lower speed setting on the **Flowmaker® Controller** and/or **2** Change the battery to a fully charged Li-ion Battery. If the underspeed indicator light is still lit, then the cause may be a fault in the system. Replace all external components; and if the underspeed light is still on after replacing all external components, treat the situation as an emergency and seek immediate medical attention. *See Patient Handbook and Operator Manual for more details.*



A non-rechargeable **Alarm Battery** is used to assure that the **FlowMaker Controller** has enough power for the alarms if the main battery fails, if the battery cable fails, or if the main battery becomes accidentally disconnected.

This **Alarm Battery** is located in a small housing on the end of the **FlowMaker® Controller** between the connectors for the cables. Be sure that the **Alarm Battery Cap** holding the Alarm Battery in place on the **FlowMaker® Controller** is screwed on finger tight whenever the **FlowMaker® Controller** is used. If the **Alarm Battery Cap** is not screwed finger tight in place, the backup power for the alarms will not function. Every time the **Alarm Battery Cap** is tightened, the Controller's back-up Alarm needs to be tested. With a caregiver present, briefly disconnect the main battery (Li-ion Battery or Reserve Battery/Charger) to be sure the Pump Stopped Alarm sounds. The disconnection should be brief and the main battery should be reconnected almost immediately. If the Pump Stopped Alarm does not sound, retighten the Alarm Battery Cap and repeat the test.

Contact the implant center immediately if the alarm does not sound during this test.



Jarvik 2000® VAS

Procedure to Resolve Pump Stopped Alarm Jarvik 2000® VAS, Post-Auricular Cable

The most likely reason for the Jarvik® 2000 VAD (pump) to stop is a completely **discharged battery** or a **disconnected** or **damaged cable**. If the cause of a component failure is clearly identifiable (i.e. low battery, physical damage, etc.) replace that cable or component **first**.

If the cause is unknown, follow these step-by-step instructions with the assistance of a support person. The patient should sit down or lie down. This procedure should be completed quickly. Back-up equipment must be immediately available.

1. Be sure the alarm is not an intermittent beeping which only indicates a low battery. If the alarm is beeping, change the battery as usual.
2. If the Jarvik 2000® VAD is stopped (steady alarm sounding, red light on):
 - a. **Disconnect the Pedestal Cable from the Pedestal at the skull, and set aside all the attached components.** Disconnect the Li-ion Battery Cable and also partially unscrew the Alarm Battery Cap on the FlowMaker® Controller to silence the alarm.
 - b. Plug in a backup Pedestal Cable into the Pedestal and into a backup FlowMaker® Controller. Make sure the FlowMaker® Controller is set at speed setting 1. Make sure to tighten the Alarm Battery Cap on the backup FlowMaker® Controller to activate the alarm.
 - c. Using the backup Li-ion Battery Cable, plug a fully charged Li-ion Battery into the FlowMaker® Controller.
 - d. If the Jarvik 2000® VAD now runs, and the patient is feeling well, red tag the original components that were set aside in step 2a.
 - e. Set the FlowMaker® Controller back at the speed the user was using prior to the alarm.
3. **If the Jarvik 2000 VAD (pump) is still stopped call the medical emergency number immediately.**
4. Red tag all components of the system that were set aside before changing to the backup components in step 2a. This should be done with the assistance of a medical support person if possible.
5. It is possible that one of the connectors is not fully plugged in and is not making contact. Recheck all connectors.
6. If the Jarvik 2000® VAD still has not started, the patient should lie down and the support person should double check batteries and connectors. Try changing batteries again. It is possible that a discharged battery was removed and the same discharged battery was accidentally plugged back into the system. It is possible that neither battery is charged. If no lights illuminate on either battery, use a third battery. It is also possible that one of the connectors is not fully plugged in and is not making contact. Recheck all connectors.
7. If all of the above steps have been followed and all cables and components have been replaced without successfully restarting the Jarvik 2000® VAD, **disconnect the power to the Jarvik 2000® VAD by unplugging the battery.** Also partially unscrew the Alarm Battery Cap on the FlowMaker® Controller. **(The alarm should stop sounding).** If the Li-ion Battery or Reserve Battery/Charger is not disconnected, the FlowMaker® Controller will apply power to the Jarvik 2000® VAD which could be harmful. Disconnecting the battery reduces the chance of a clot forming inside the Jarvik 2000® VAD by allowing the rotor to spin as blood flows across it.

Note: Return any failed or suspect component(s) to your Clinical Center for evaluation by Jarvik Heart, Inc.



Jarvik 2000® VAS

Procedure to Resolve Pump Stopped Alarm Jarvik 2000® VAS, Abdominal Cable

The most likely reason for the Jarvik 2000® VAD (pump) to stop is a completely **discharged battery** or a **disconnected** or **damaged cable**. If the cause of a component failure is clearly identifiable (i.e. low battery, physical damage, etc.) replace that cable or component **first**.

If the cause is unknown, follow these step-by-step instructions with the assistance of a support person. The patient should sit down or lie down. This procedure should be completed quickly. Back-up equipment must be immediately available.

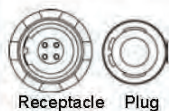
1. Be sure the alarm is not an intermittent beeping which only indicates a low battery. If the alarm is beeping, change the battery as usual.
2. If the Jarvik 2000® VAD is stopped (steady alarm sounding, red light on):
 - a. **Disconnect the Extension Cable from the drive cable at the abdomen, and set aside all the attached components.** Disconnect the Li-ion Battery Cable and also partially unscrew the Alarm Battery Cap on the FlowMaker® Controller to silence the alarm.
 - b. Plug the drive cable (the cable exiting the skin at the abdomen) directly into the backup FlowMaker® Controller (eliminating the Extension Cable). Make sure the FlowMaker® Controller is set at speed setting 1. Make sure to tighten the Alarm Battery Cap on the backup FlowMaker® Controller to activate the alarm.
 - c. Using the backup Li-ion Battery Cable, plug a fully charged Li-ion Battery into the FlowMaker® Controller.
 - d. If the Jarvik 2000® VAD now runs and the patient is feeling well, red tag the original components that were set aside in step 2a.
 - e. Set the FlowMaker® Controller back at the speed the user was using prior to the alarm.
3. **If the Jarvik 2000® VAD (pump) is still stopped call your medical emergency number immediately.**
4. Red tag all components of the system that were set aside before changing to the backup components in step 2a.
5. Be sure that all external cables and connectors have been changed and check to see if the connector at the end of the drive cable exiting the skin at the abdomen is broken. If it is broken and has come apart – try to put it back together where it is broken. If the Jarvik 2000® VAD does not run, take the connector apart again – rotate the parts 90° and put the connector back together again. Repeat three times. The Jarvik 2000 VAD may start. The connector may then be held together with tape while the patient is transported to the hospital for it to be repaired.
6. It is possible that one of the connectors is not fully plugged in and is not making contact. Recheck all connectors.
7. If the Jarvik 2000® VAD still has not started, the patient should lie down and the support person should double check batteries and connectors. Try changing batteries again. It is possible that a discharged battery was removed and the same discharged battery was accidentally plugged back into the system. It is possible that neither battery is charged. If no lights illuminate on either battery, use a third battery. It is also possible that one of the connectors is not fully plugged in and is not making contact. Recheck all connectors.
8. If all of the above steps have been followed and all cables and components have been replaced without successfully restarting the Jarvik 2000® VAD, **disconnect the power to the Jarvik 2000 VAD by unplugging the battery.** Also partially unscrew the Alarm Battery Cap on the FlowMaker® Controller. **(The alarm should stop sounding).** If the Li-ion Battery or Reserve Battery/Charger is not disconnected, the FlowMaker® Controller will apply power to the Jarvik 2000® VAD which could be harmful. Disconnecting the battery reduces the chance of a clot forming inside the Jarvik 2000® VAD by allowing the rotor to spin as blood flows across it.

Note: Return any failed or suspect component(s) to your Clinical Center for evaluation by Jarvik Heart, Inc.



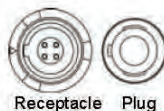
Jarvik® 2000

Jarvik 2000® Adult Ventricular Assist System—Quick Reference Guide



Receptacle Plug

Connection from Jarvik 2000 VAD to FlowMaker Controller: The black receptacle on the FlowMaker Controller is located above the housing for the small back-up Alarm Battery. The receptacle has double key slots for a black plug. The Extension Cable and the Pedestal Cable (depending on the model of the device used) also have double key slots.



Receptacle Plug

Connection from FlowMaker Controller to Y Cable or battery: The gray receptacle on the FlowMaker Controller is located below the housing for the small back-up Alarm Battery. This receptacle has a single key slot for the gray plug of the Y Cable, Li-ion Battery Cable, and Reserve Battery/Charger.



Note that the single and double keys on the plugs and receptacles are easily visible and must be placed in the proper rotational position, with the arrows on receptacle and plug lined up, for the connectors to go together. The connectors are attached and removed by a push-pull latch mechanism, not by a screw thread. Place the plug into the receptacle with slight pressure and gently rotate the plug until the key-way engages. Then push the connector together. The connector should click into place and should not come apart if the cable is tugged. To remove the plug, hold it close to the receptacle and pull.

- Never attempt to disconnect any connector by twisting.
- Do not attempt to pull the connector apart by the wire or by the strain relief.
- Never force a connector together. If the plug does not go into the receptacle easily, gently rotate it until it is aligned properly. When it is fully engaged, a soft click can be heard.
- If a connector is damaged or pins are bent, do not attempt to repair but replace the cable instead.

The **Y Cable** for the Jarvik 2000 VAS is used to allow battery changes without removing power from the Jarvik 2000 VAD. Before unplugging a discharged battery, a recharged battery should be plugged into the Y Cable. If the battery cable is unplugged prior to attaching a charged battery to the other end of the Y Cable, the Jarvik 2000 VAD stops, but the natural heart continues to beat. If this occurs, the beeping tone of the alarm will change to a steady tone, indicating that the Jarvik 2000 VAD is stopped. After the used battery is replaced with a fresh one, always remove the discharged battery from the Y Cable.



The portable **Li-ion Battery** will run the Jarvik 2000 VAS for 7-12 hours under usual conditions. The Li-ion Battery has an indicator with 5 lights that indicates how much power is remaining. Depress the black button to turn on the indicator lights:

Indicator	Approximate Remaining Time
All 5 LEDs lit	8-12 hours
4 LEDs lit	6-10 hours
3 LEDs lit	5-8 hours
2 LEDs lit	3-5 hours
1 LED lit	5 minutes - 2 hours

Li-ion Battery Charger

When the Li-ion Battery Charger is first connected to wall power, the green light next to the vertical green bar will turn on. The second light will simultaneously turn on green for approximately 1-3 seconds, followed by the startup sequence below.

- Flashing yellow for approximately 18-24 seconds
- Solid green for approximately 1-3 seconds
- Off

The Li-ion Battery Charger is not required to go through the startup sequence each time it is connected to a Li-ion Battery. It will only occur when wall power is first applied to the Li-ion Battery Charger.

Never connect the Li-ion Battery to the Li-ion Battery Charger while the second light is green. If a connection is made during this brief period of time, the Li-ion Battery will not charge.

When disconnecting the Li-ion Battery Charger from a fully charged Li-ion Battery, always wait for the second light to turn off before connecting another Li-ion Battery.

The **Reserve Battery/Charger** has both a battery and a charger built into a single unit; however, they are not electrically connected to each other.

Reserve Battery Use:

1. Unplug the gray cable from the battery charger and plug it into the gray connector of the Y cable or the FlowMaker Controller.
2. Unplug the black power cord from the Reserve Battery/Charger and the wall plug.
3. If the Reserve Battery/Charger is used for under 12 hours and then recharged, it will last for more than 1000 recharge cycles. If it is not recharged until it is fully discharged (>24 hrs capacity) and the low battery alarm sounds, it will last for fewer than 200 recharge cycles.
4. Use the Reserve Battery/Charger for less than 12 hours each night and recharge it each morning after switching to the Li-ion Battery.



Reserve Battery Use



Charging the Reserve Battery

Charging the Reserve Battery:

Disconnect the gray plug from the Y Cable or FlowMaker Controller and plug it into the gray receptacle on the Reserve Battery/Charger.

A yellow light next to the Charge label on the Reserve Battery/Charger will turn on to indicate charging. When the Reserve Battery/Charger is near fully charged, the yellow light will turn off and automatically start to safely slow charge the battery. Continue charging the battery after the yellow light goes out and whenever the battery is not in use.

The green light next to the Power label on the Reserve Battery only indicates that wall power is connected to the charger section of the unit. The green light does not indicate the Reserve Battery/Charger is fully charged.

The Reserve Battery/Charger is near fully charged only when the Charge light turns off and the gray cable is plugged into the gray receptacle on the unit.

If the gray cable is not plugged into the receptacle on the Reserve Battery/Charger while the unit is also plugged into the wall, the Reserve Battery/Charger will not charge.

It is not possible to run the Jarvik 2000 VAS from wall power even if the Reserve Battery/Charger is plugged into wall power. It is also not possible to charge the Reserve Battery/Charger while the same Reserve Battery/Charger is being used to run the Jarvik 2000 VAD. At all times, the Jarvik 2000 VAD is run only from battery power.

TOTAL ARTIFICIAL HEART EMS Guide

January 2019



International Consortium of Circulatory Assist Clinicians

It is produced by VAD Coordinators from some of the largest and most successful VAD implantation hospitals in the US. It has been vetted by experts on VADS in Air Medical Transport and EMS. It should not replace the operator manual as the primary source of information.

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Patient Management For TAHs

1. **Assess the patients airway and intervene per your protocol.**
2. **Auscultate heart sounds but you can usually hear them without a stethoscope. Since this is pulsatile you should hear two sounds if properly functioning.**
3. **Assess the device for any alarms.**
4. **Look on controller usually found around the waist of the patient and to see what color tag and device it is. The backpack or freedom driver should have a pink tag on it. It will have the type of device this is and contact information to the implantation center.**
5. **Match the color on the device tag to the EMS Guide. The tag on the backpack or freedom driver's colored tag should matches the ems guide. This will tell you how to manage any alarms.**
6. **Intervene appropriately based on the type of alarm, tag (device) and EMS Guide.**
7. **Start Large Bore IV.**
8. **Assess Vital Signs. REMEMBER THERE IS NO EKG. THE PATIENT IS ASYSTOLIC.**
9. **YOU SHOULD BE ABLE TO GET A SYSTOLIC AND DIASTOLIC BLOOD PRESSURE.**
10. **Transport to the closest center that can care for a TAH. Look on the PINK tag to find out this information.**
11. **Bring all of the patients equipment.**
12. **Bring the significant other if possible to act as a expert on the device in the absence of consciousness in the patient.**

Questions and Answers for Total Artificial Heart

What Is A Total Artificial Heart?

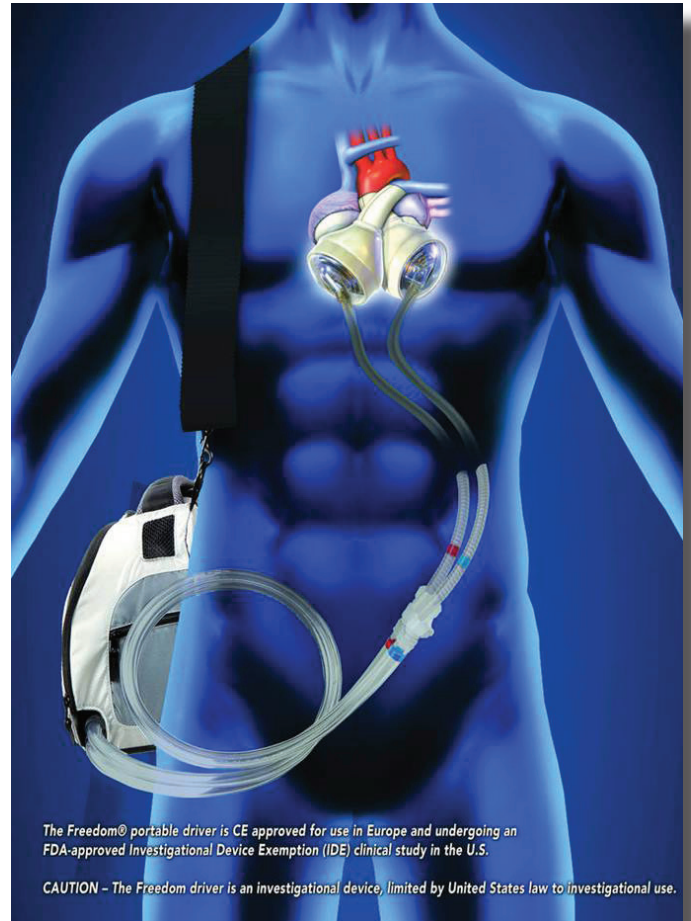
A total artificial heart (TAH) is a device that replaces the two lower chambers (ventricles) of the heart. You might benefit from a TAH if both of your ventricles don't work due to end-stage heart failure.

What are the parts of a TAH?

The SYNCARDIA has tubes that, through holes in the abdomen, run from inside the chest to an outside power source.

What is the power source?

Shortly after the TAD is implanted, the patient is switched to the Freedom driver. This is a mobile "driver" for patients to who are ambulatory. The patient considered discharge from the hospital while awaiting a transplant but ultimately received a heart transplant while still an inpatient. Higher rates of survival to transplant have already been proved with the TAH. Potential benefits for the portable Freedom driver include increased mobility, decreased cost, and improved quality of life.



The Freedom® portable driver is CE approved for use in Europe and undergoing an FDA-approved Investigational Device Exemption (IDE) clinical study in the U.S.

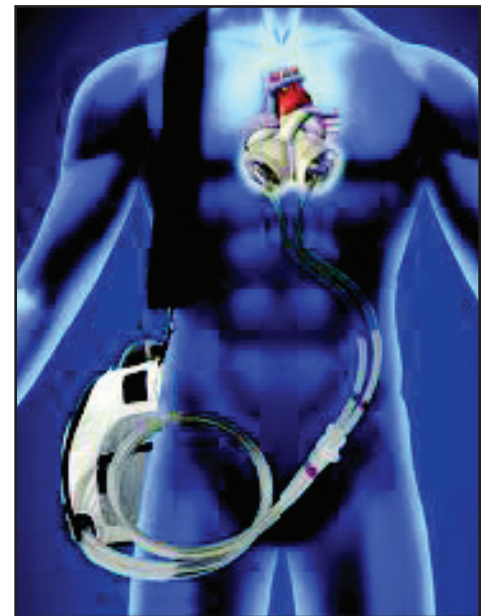
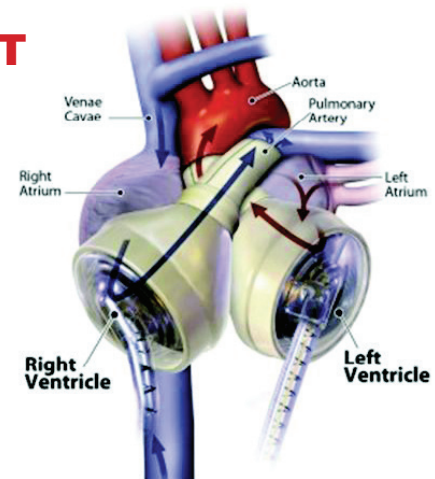
CAUTION - The Freedom driver is an investigational device, limited by United States law to investigational use.

The portability of the Total Artificial Heart (TAH) enables patients to resume many of their normal daily activities.

Total Artificial Heart Freedom™ Driver System

This Patient is on an ARTIFICIAL HEART (not a left ventricular assist device-LVAD)

- Can I do external CPR?**
No. Will need to rapidly exchange to the backup driver.
- Is there a “hand pump” or external backup device to use?**
No.
- Can I give vasopressive IV drugs like epinephrine, dopamine or dobutamine?**
Never give vasopressive drugs, especially epinephrine. These patients primarily have symptomatic hypertension and rarely have symptoms of hypotension. Most IV vasopressive drugs can be fatal to a TAH (Total Artificial Heart) patient.
- Can I speed up the rate of the device?**
No. The device has a fixed rate between 120-140-BPM.
- What is the primary emergency intervention for a TAH (Total Artificial Heart)?**
Nitroglycerin sublingual for symptomatic hypertension.
- Can the patient be defibrillated or externally paced while connected to the device?**
No. There is no heart.
- What if the patient is symptomatic and the Freedom Driver is alarming with a continuous alarm and the red light ?**
If the pump has failed or a line is disconnected or kinked, the patient may pass out within 30 seconds. Even when alarming, the device should continue to pump. When in doubt, immediately change out the Freedom™ Driver immediately. Then quickly check for loose or kinked connections.
- Does the patient have a pulse with this device?**
Yes. The device produces Pulsatile flow. The device is pneumatically driven and is normally loud.
- What are acceptable vital sign parameters?**
The BP will vary. Normal range 100-130 systolic and 60-90 diastolic.
- What kind of Cardiac rhythm should be displayed?**
Asystole.

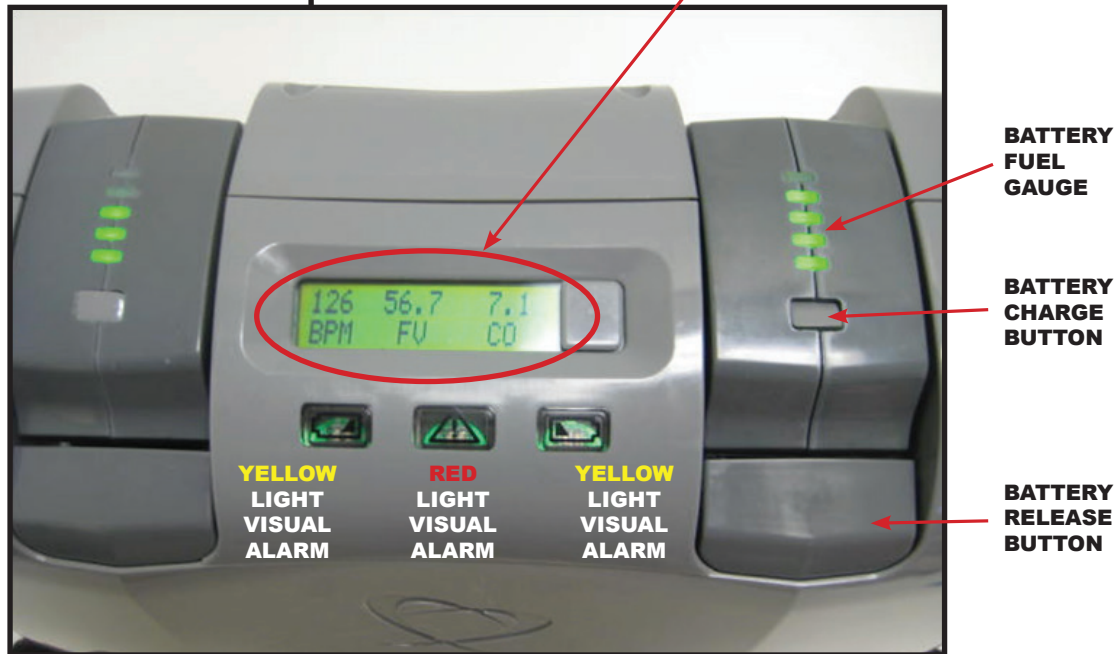
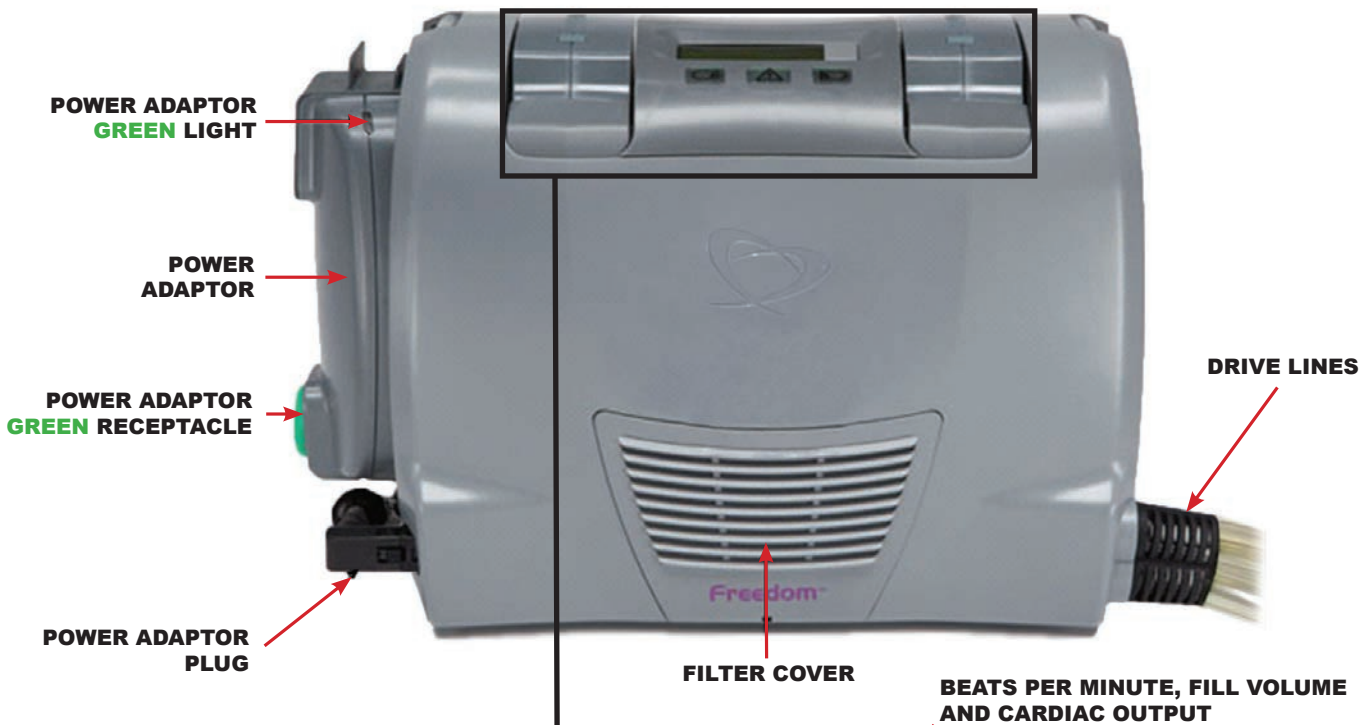


“Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport .ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010”



Trouble Shooting Freedom™ Driver System

**This Patient is on an ARTIFICIAL HEART
(not a left ventricular assist device -LVAD)**



Freedom™ Driver System

IN THE EVENT OF AN EMERGENCY

Immediately notify VAD coordinator listed on the medical alert bracelet or tag attached to the console - please identify the device as a total artificial heart.

"Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport .ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010"

HOW TO RESPOND TO FREEDOM™ DRIVER ALARMS

There is no way to mute an Alarm.

ALARM	HEAR	SEE	MEANING	WHAT YOU SHOULD DO
Battery Alarm	Loud Intermittent Tone	Yellow Battery LED Flashing	One or both of the Onboard Batteries have less than 35% remaining charge (only two green lights display on the Battery Fuel Gauge).	Replace each low Onboard Battery, one at a time, with a charged Onboard Battery or connect to external power (NOTE: Once the batteries are charged above 35% the Battery Alarm will stop).
			Onboard Battery is incorrectly installed.	Reinsert Onboard Battery until locked in place. If Battery Alarm continues, insert a new Onboard Battery.
			One Onboard Battery missing.	Insert charged Onboard Battery into Freedom™ Driver until locked in place.
Temperature Alarm	Loud Intermittent Tone	Red Alarm LED Flashing	The temperature of the Driver is too hot or too cold.	Remove any objects that are blocking the Filter Cover and/or Fan and check the filter.
			The internal temperature of the Driver is too hot.	Move the Freedom Driver to a cooler or warmer area.
Fault Alarm	Loud Continuous Tone	Red Alarm LED Solid	Valsalva Maneuver: Strenuous coughing or laughing, vomiting, straining during a bowel movement, or lifting a heavy weight.	Relax/interrupt Valsalva Maneuver.
			Kinked or disconnected drive lines.	Straighten or connect drive lines.
			Driver is connected to External Power without at least one correctly inserted Onboard Battery.	Insert a charged Onboard Battery into the Freedom™ Driver until locked into place.
			One or both of the Onboard Batteries have less than 30% remaining charge.	Replace each low Onboard Battery, one at a time, with a charged Onboard Battery or connect to external power. (NOTE: the Fault Alarm will continue and will change into a Battery Alarm as the Onboard Batteries recharge. Once the Onboard Batteries are charged above 35%, the Battery Alarm will stop.)
			Malfunction of the Driver	If the steps above do not stop the Fault Alarm, switch to Backup Freedom Driver. Return to implant hospital.
Temperature Alarm	Loud Intermittent Tone	Red Alarm LED Flashing	The internal temperature of the Driver is too hot.	Remove any objects that are blocking the Filter Cover and / or Fan and check filter.
			The temperature of the Onboard Batteries is too hot or too cold.	Move the Freedom Driver to a cooler or warmer area.

You must immediately address the issue that caused the Alarm.

"Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport .ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010"

JANUARY 2019

Switching from Primary to Backup Freedom™ Driver

CAUTION: It is recommended to have TWO people exchange the primary Freedom Driver for the backup Freedom Driver. Make sure all items and accessories are closely available before attempting to exchange Drivers.

Setting up the Backup Freedom™ Driver

1. Remove the drive line caps from the ends of the Drive lines.
2. Insert one charged Onboard Battery. The driver will immediately start pumping. (*Figure 1*)
3. Remove the Orange Dummy Battery. (*Figure 1*)
4. Insert the second charged Onboard Battery. (*Figure 2*)
5. If possible, connect the backup Driver into a wall power outlet.
6. Your Freedom™ Driver is now ready to connect to the patient.



FIGURE 1



FIGURE 2



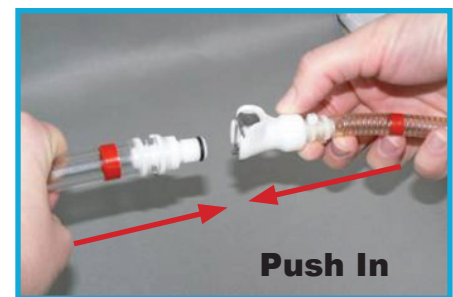
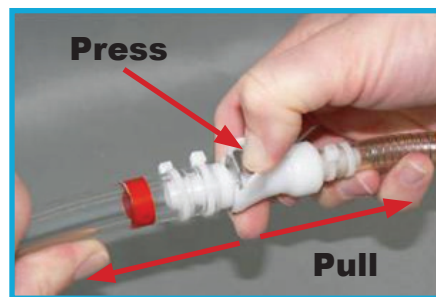
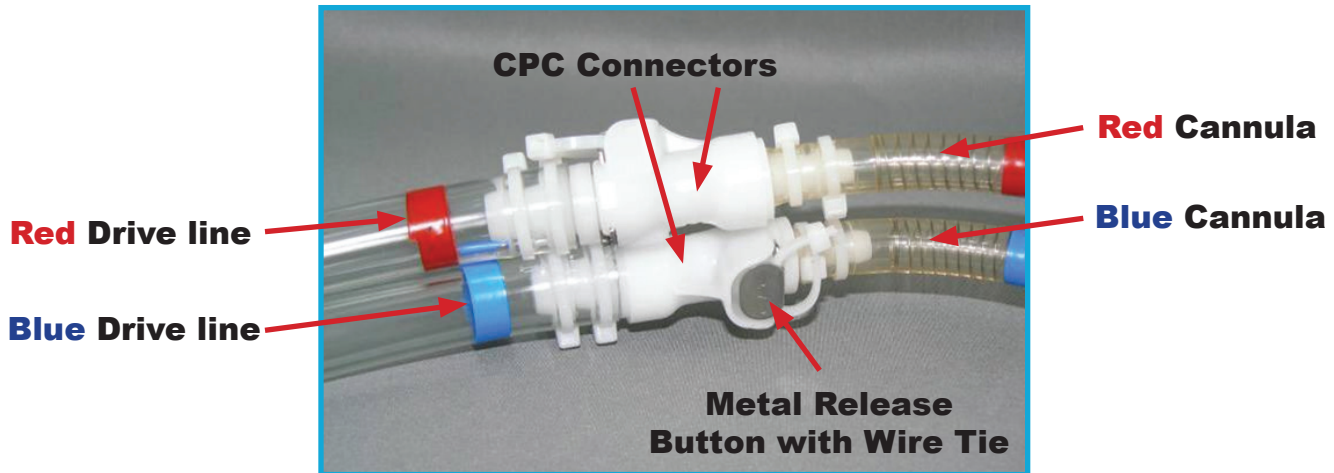
FIGURE 3

BEATS PER MINUTE, FILL VOLUME AND CARDIAC OUTPUT

Continued on next page.

Switching from Primary to Backup Freedom™ Driver

Continued on from previous page



1. With the Wire Cutter Tool, cut the Wire Tie under the metal release button of the CPC Connector that secures the **RED** TAH-t Cannula to the **RED** Freedom Drive line. Gently pull to remove the Wire Tie and discard. **DO NOT DISCONNECT THE CANNULA FROM THE DRIVE LINE YET.**
2. With the Wire Cutter Tool, cut the Wire Tie under the metal release button of the CPC Connector that secures the **BLUE** TAH-t Cannula to the **BLUE** Freedom Drive line. Gently pull to remove the Wire Tie and discard. **DO NOT DISCONNECT THE CANNULA FROM THE DRIVE LINE YET.**

CAUTION: Before disconnecting the Drive lines of the primary Freedom Driver, you must have the Drive lines of the backup Freedom Driver within reach. The backup Driver must be turned on. Perform steps 3 and 4 simultaneously.

3. Disconnect the **RED** Cannula from the **RED** Drive line of the primary Freedom Driver:
 - Press and hold down the metal release button. Pull the **RED** Cannula away from the **RED** Drive line.
 - Immediately insert the **RED** Cannula into the new **RED** Drive line from the backup Freedom Drive. Insert until a click is heard and lightly tug on the connection to make sure that it is secure.
4. Simultaneously disconnect the **BLUE** Cannula from the **BLUE** Drive line of the primary Freedom Driver:
 - Press and hold down the metal release button. Pull the **BLUE** Cannula away from the **BLUE** Drive line.
 - Immediately insert the **BLUE** Cannula into the new **BLUE** Drive line from the backup Freedom Driver.
 - Insert until a click is heard and lightly tug on the connection to make sure that it is secure.
5. Slide a Wire Tie under the metal release button of each CPC connector. Create a loose loop in the tie, taking care not to depress and disconnect the connectors. Cut off the excess length of both Wire Ties.
6. Patient must notify Hospital Contact Person of the switch.
7. The Hospital should notify SynCardia Systems that the Driver has been switched and return the faulty Driver.