EMERGENCY GUIDE

2020-2021

International Consortium of Circulatory Assist Clinicians

This guide was created in 2008 by the innovation of VAD Coordinators from some of the largest and most successful VAD implantation hospitals in the United States. ICCAC has ensured that this document continues to be a current resource for not only emergency medical services but to all healthcare workers providing care to the mechanical circulatory support patient population. The purpose is to be a quick emergency guide and should not replace the manufacturers' Instructions For Use as the primary source of information for each device listed in this guide.

Questions and Answers
MECHANICAL CIRCULATORY SUPPORT

Mechanical Circulatory Support Devices (MCS) are heart pumps that move blood from the heart to the body. They are temporary or permanent devices that either supplement or replace the action of a failing heart. MCS devices implanted are assisting the left ventricle (LVAD), the right ventricle (RVAD), or both ventricles (BiVAD) and the total heart (Total Artificial Heart – TAH). They consist of two major categories: Pulse generating (pulsatile) and pulseless devices (non-pulsatile/continuous flow). Patient management varies greatly between the two device categories.

Pulsatile or Non-pulsatile

Pulse generating devices have a chamber that fills with blood and ejects the blood similar to the rhythmic action of the human heart. These devices replace the majority of the heart and move the full amount of blood the patient needs. The Total Artificial Heart pump is a pulse generating device. Non-pulsatile or continuous flow devices use a motor at a fixed speed leading to a constant ejection of blood to the body. This is the reason patients with continuous flow VADs often lack a pulse upon palpation. The most common VADs are non-pulsatile/continuous flow devices.

What is a VAD?

A ventricular Assist Device (VAD) is an implantable mechanical heart pump that helps to pump blood from the lower chambers of the heart to the rest of the body in patients with advanced heart failure. The device helps move partial or full amount of blood meeting the patient needs. These devices can be attached to the Left (LVAD) or Right (RVAD) ventricles of the heart. Most patients have an LVAD and less common are RVADs and BiVADs (both left and right or Biventricular support).

What are the parts of a VAD?

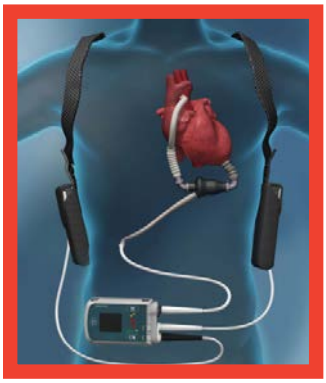
All VADs have at least 4 components. (1) A heart pump unit consisting of a short tube placed inside the ventricle pulling blood thru the pump and out a tube, delivering blood to the body's great vessel; (2) A power cord called a driveline that exits the abdomen and connects to a controller and power source; (3) A controller that displays information; (4) A power source.

What does the controller do?

The controller is a computer that operates the heart pump. It provides messages and audible alarms to help monitor the pump. It gives information about pump performance such as blood flow through the pump (L/min), pump speed (RPM) and the amount of power consumed (Watts). It also gives warnings and alarms if there is an alert/problem with the pump or with the power source, such as low battery or low flow.

What is the power source?

All VADs can be powered by two power sources: rechargeable batteries or AC (electricity) power. Batteries are used when patients are active throughout the day and often are kept in a holster, vest or belt for safety. AC power is recommended when the patient is planning to remain stationary. AC power should NOT be used when transporting the patient.



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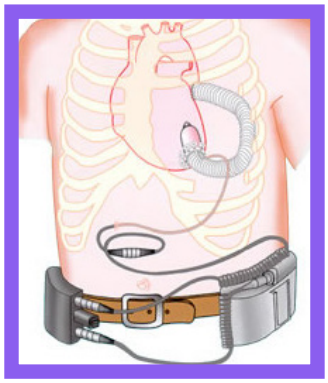

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What is a TAH?

A Total Artificial Heart (TAH) is a mechanical device that replaces the two lower ventricles of the heart. Tubes connect the TAH to a power source that is outside the body. The TAH then pumps blood through the heart's major artery to the lungs and the rest of the body. This is used for people who have inadequate function of both ventricles (biventricular failure).

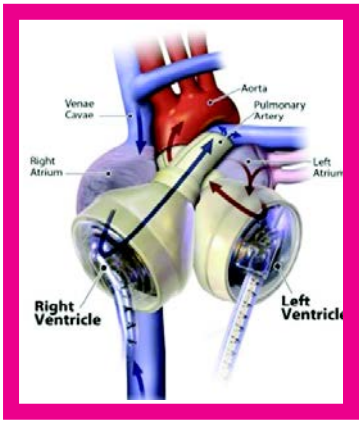
What are the parts of TAH?

The TAH has 3 components. (1) A pump assembly consisting of 2 short tubes attached to the top of the heart and 2 chambers that fill and empty using air that pushes and pulls a membrane back and forth; (2) Air tubes that exit the body and attach to a console; (3) A power source.

What is the power source?

The TAH uses a mobile console called a Freedom Driver when patients are ambulatory. The console is powered by two batteries or AC (electricity) power. The batteries must be well charged before moving the patient and the AC plug should be brought when transporting.

The devices in this MCS Emergency Guide are color coded for quick identification. Patients may have a color matching tag or identifier on their equipment or equipment bag. Patients will also have their primary VAD team contact information for an important resource.



TOTAL ARTIFICIAL HEART (TAH) Page 25

Patient Management For VADs

1. Treat the patient and follow your protocols. Do not focus only on the device. Most patients do not have a primary pump malfunction. Common MCS patient problems that arise are stroke, bleeding disorders (GI, nose bleeds), arrhythmias, dehydration and right heart failure.

2. Assess the patients airway and intervene per your protocol.

3. Auscultate heart sounds to determine if the device is functioning. If it is continuous flow device, you should hear a "humming sound".

4. Assess vital signs. Non-pulsatile or continuous flow devices provide continuous blood flow from the heart to the aorta. This continuous flow results in a narrow arterial pulse pressure. This means it may be difficult to obtain a pulse or blood pressure reading which may be a normal state for a continuous flow device patients. To obtain a blood pressure an automated cuff or doppler method can be used. If unable to obtain with automated cuff use the mean BP with a doppler (first sound you hear – MAP). Rely on other methods to assess perfusion e.g. mental status, skin color, capillary refill. The device flow shown on the controller display reflects the patient's cardiac output.

5. Start IV if indicated.

6. Assess the device for device information and alarms located on the controller display.

7. Intervene appropriately based on the type of alarm. See specific device alarm guides on the pages that follow.

8. Refer to the patient's medication list. They are typically, but not always, on anticoagulation and antiplatelet therapy.

9. Call the VAD Center's 24 hour emergency number on the patient's contact list, controller/equipment, or emergency bag for assistance in the management of the patient and transportation determination and location.

10. **Bring all of the patients equipment.**

11. **Bring the significant other if possible to act as a expert on the device in the absence of consciousness in the patient.**

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 device information and alarms located on the driver.

4. Intervene appropriately based on the type of alarm. See specific device alarm guide on the pages that follow.

5. Assess Vital Signs. REMEMBER THERE IS NO ECG. THE PATIENT IS ASYSTOLIC.

6. Start IV if indicated.

7. You should be able to get a systolic and diastolic blood pressure.

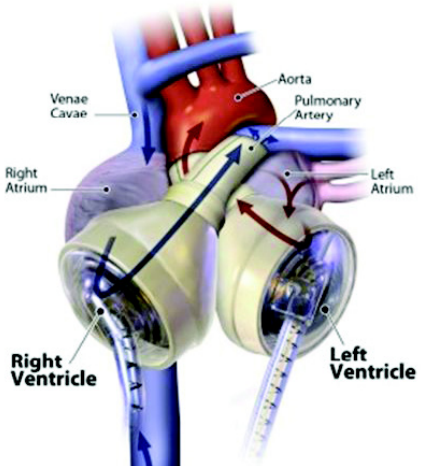
8. Call the VAD Center's 24 hour emergency number on the patient's contact list, controller/equipment, or emergency bag for assistance in the management of the patient and transportation determination and location.

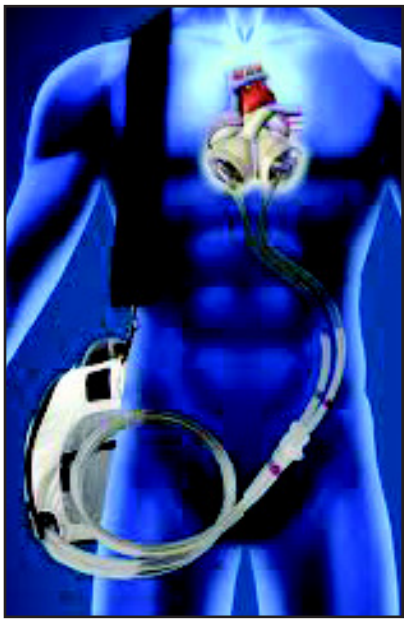
9. **Bring all of the patients equipment.**

10. **Bring the significant other if possible to act as a expert on the device in the absence of consciousness in the patient.**

Total Artificial Heart Freedom™ Driver System

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



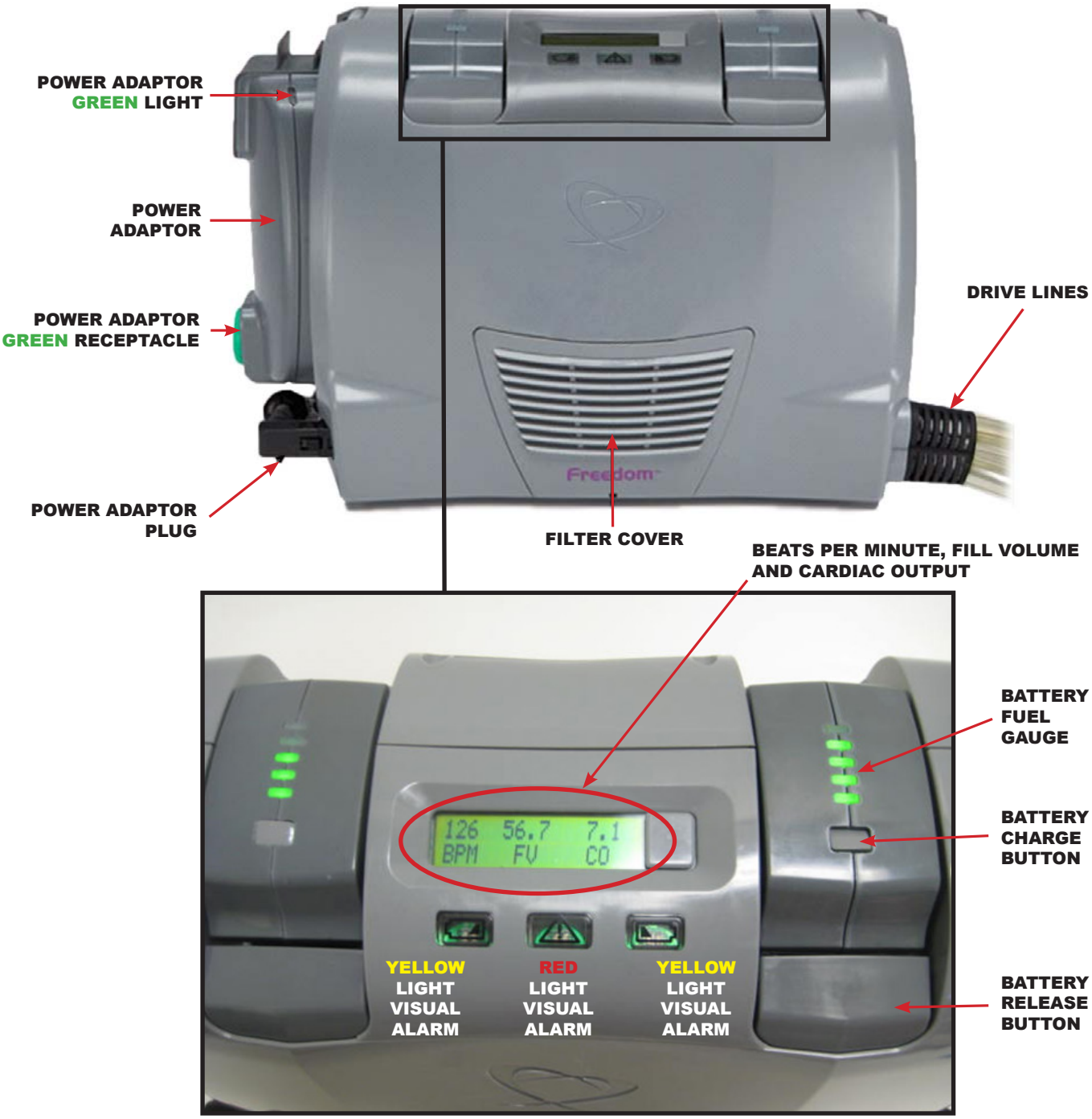


1. **Can I do CPR?**
   No. Will need to rapidly exchange to the backup driver.
2. **Can the patient be defibrillated or externally paced?**
   No, there is no native heart rhythm.
3. **Does the patient have a pulse with this device?**
   Yes. The device produces pulsatile flow. The device is pneumatically driven and is normally loud.
4. **What are acceptable vital sign parameters?**
   The BP will vary. Normal range 100-130 systolic and 60-90 diastolic.
5. **What kind of cardiac rhythm will be displayed on a monitor?**
   Asystole.
6. **Is there a "hand pump".**
   No. The priority is to secure connections to the Freedom Driver to ensure gas delivery.
7. **Can I give vasopressor IV drugs like epinephrine, dopamine or dobutamine?**
   Never give vasopressor drugs, especially epinephrine. Most IV vasopressor drugs can be fatal to a TAH patient. IV fluids are usually not required and may be unhelpful if the patient is already fluid overloaded. These patients primarily have symptomatic hypertension and rarely have symptoms of hypotension.
8. **How can symptomatic hypertension be treated?**
   Sublingual nitroglycerin.
9. **Can I speed up the rate of the device?**
   No. The device has a fixed rate between 120-140 BPM
10. **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 with alarming, the device will continue to pump. Confirm the drivelines are connected and are not damaged or kinked. If the patient is conscious and can participate, assist the patient to immediately change out the Freedom Driver.

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.

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.

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

BEATS PER MINUTE, FILL VOLUME AND CARDIAC OUTPUT

FIGURE 3

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Switching from Primary to Backup Freedom™ Driver

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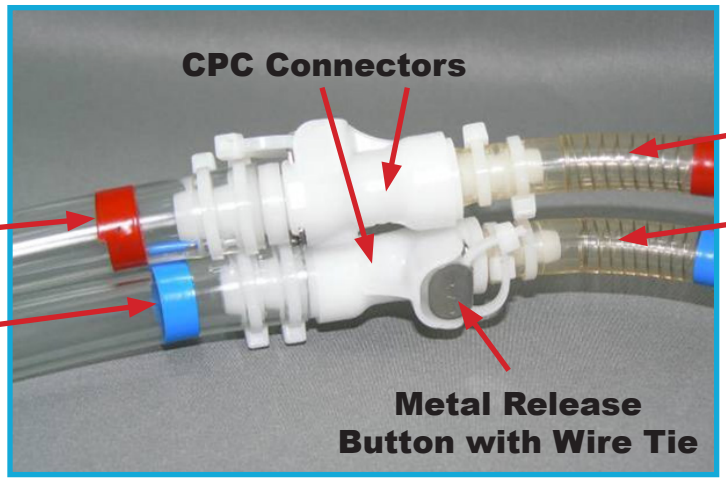

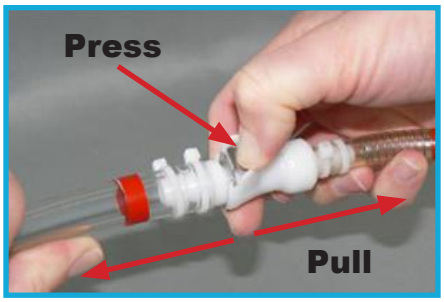

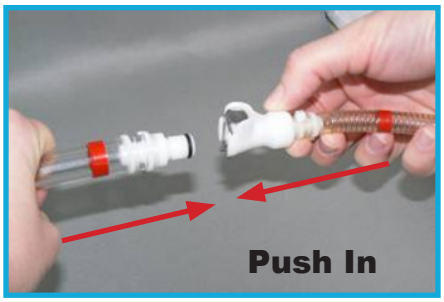

1. With the Wire Cutter Tool, cut the Wire Tie under the metal release button of the CPC Connector that secures the RED TAH-t Cannula to the RED Freedom Drive line. Gently pull to remove the Wire Tie and discard. DO NOT DISCONNECT THE CANNULA FROM THE DRIVE LINE YET.

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:
- Simultaneously 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.