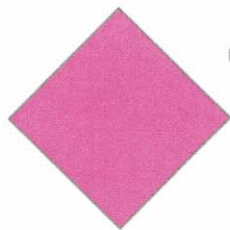


EMS Guide January 2015

M ECHANICAL
C IRCULATORY
S UPPORT
O RGANIZATION



Total Artificial Heart

This guide is produce by MCSO – The Mechanical Circulatory Support Organization. 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.

Questions and Answers for Total Artificial Heart

What Is A Total Artificial Heart?

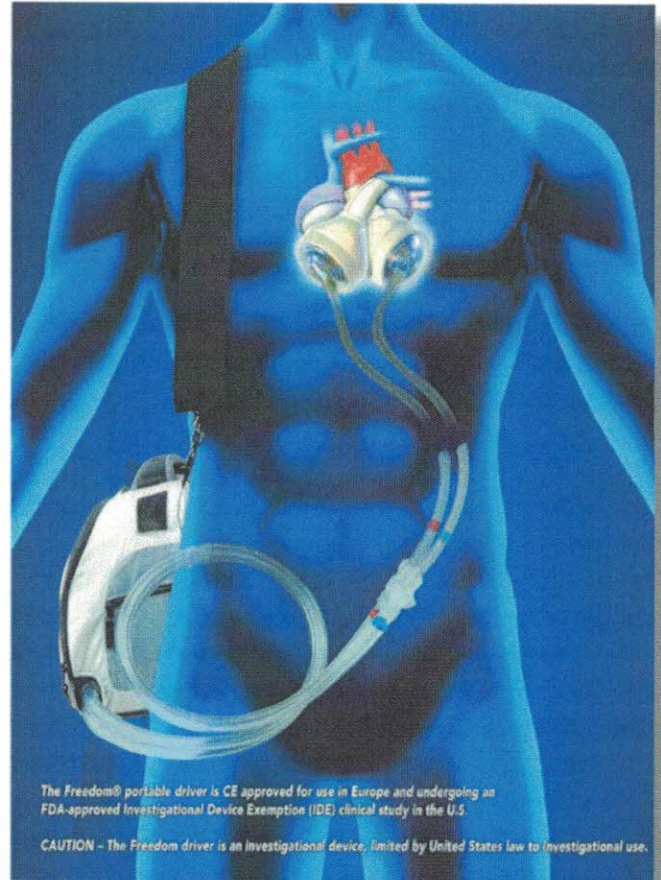
A total artificial heart (TAH) is a device that replaces the two lower chambers (ventricles) of the heart. You might benefit from a TAH if both of your ventricles don't work due to end-stage heart failure.

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.



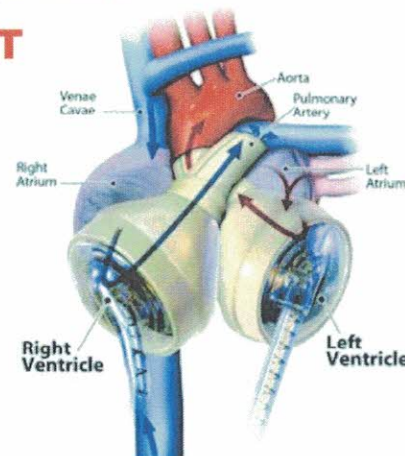
The portability of the Total Artificial Heart (TAH) enables patients to resume many of their normal daily activities.

Patient Management For TAHs

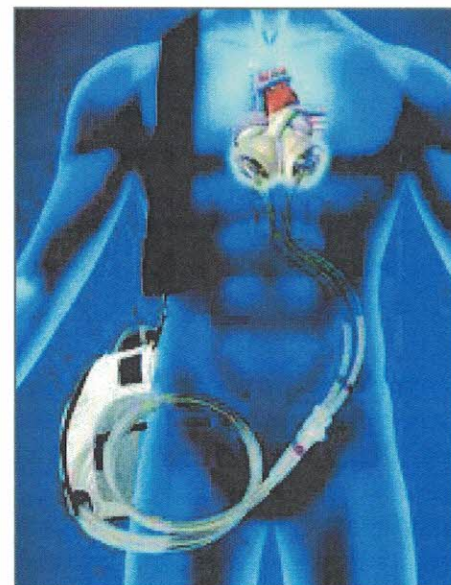
1. Assess the patients airway and intervene per your protocol.
2. Auscultate heart sounds but you can usually hear them without a stethoscope. Since this is pulsatile you should hear two sounds if properly functioning.
3. Assess the device for any alarms.
4. Look on controller usually found around the 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.

Total Artificial Heart Freedom™ Driver System

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



- 1. Can I do external CPR?**
No. Will need to rapidly exchange to the backup driver.
- 2. Is there a "hand pump" or external backup device to use?**
No.
- 3. 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.
- 4. Can I speed up the rate of the device?**
No. The device has a fixed rate between 120-140-BPM.
- 5. What is the primary emergency intervention for a TAH (Total Artificial Heart)?**
Nitroglycerin sublingual for symptomatic hypertension.
- 6. Can the patient be defibrillated or externally paced while connected to the device?**
No. There is no heart.
- 7. 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.
- 8. Does the patient have a pulse with this device?**
Yes. The device produces Pulsatile flow. The device is pneumatically driven and is normally loud.



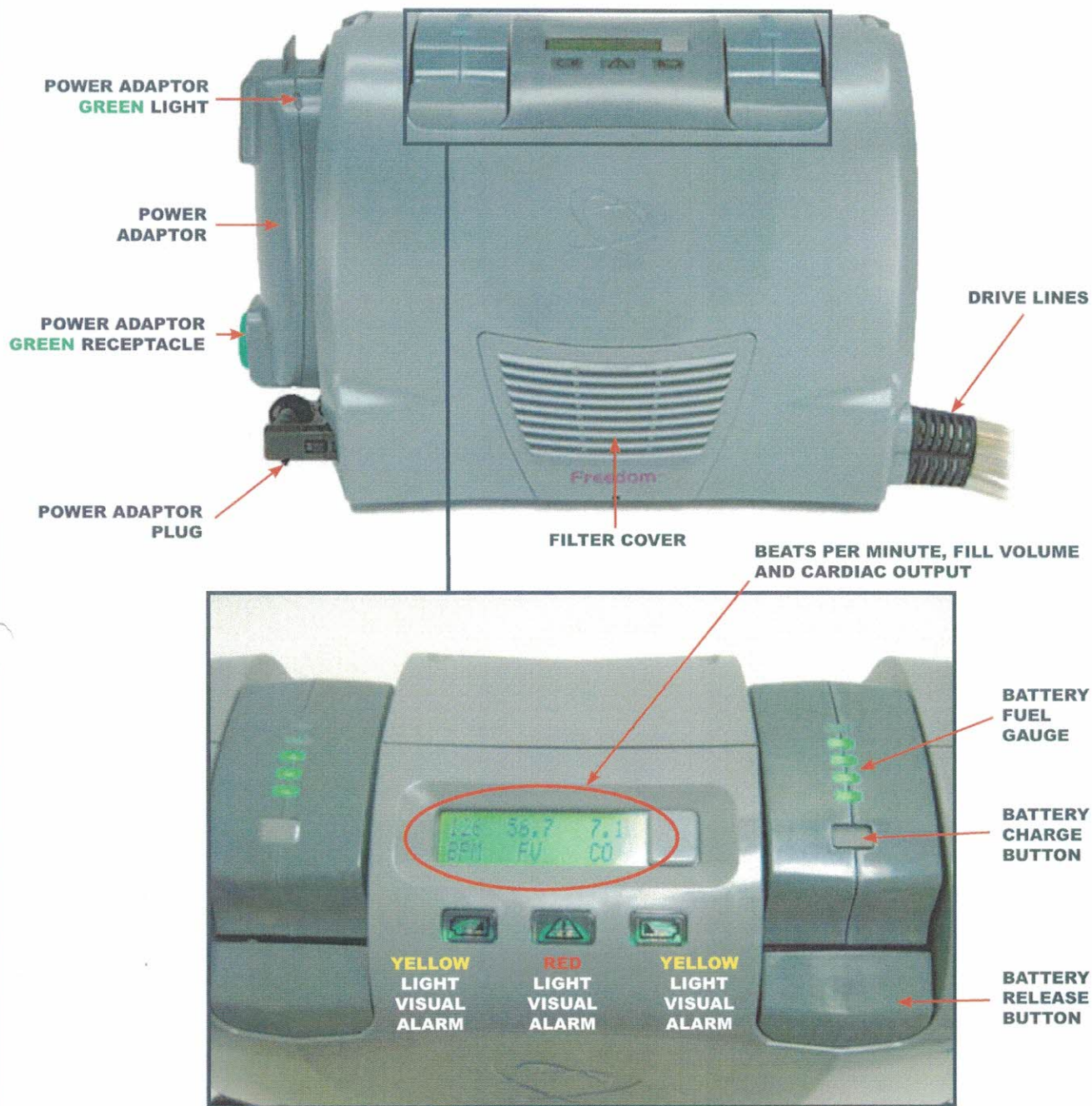
"Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport .ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010"

- 9. What are acceptable vital sign parameters?**
The BP will vary.
Normal range 100-130 systolic and 60-90 diastolic.
- 10. What kind of Cardiac rhythm should be displayed?**
Asystole.



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"

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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"

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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



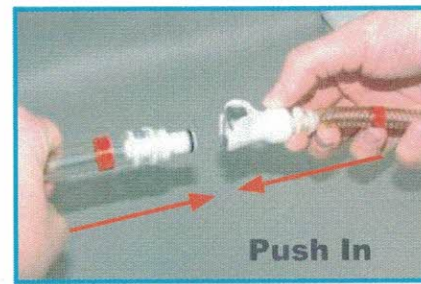
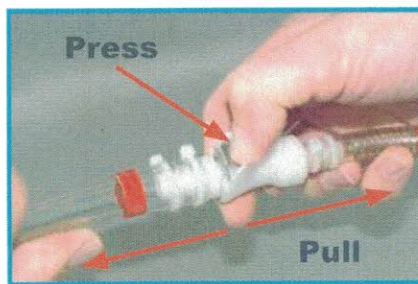
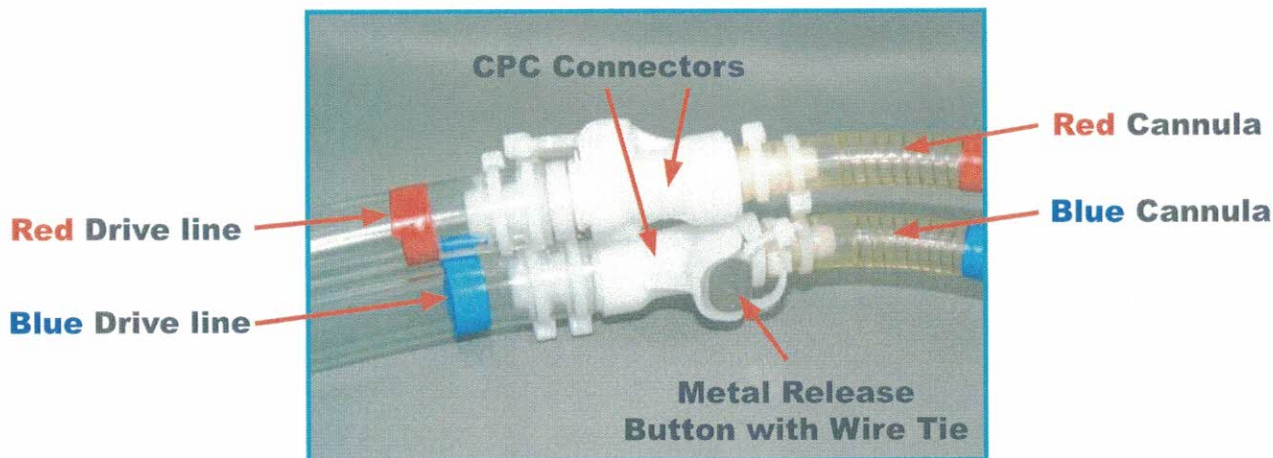
**BEATS PER MINUTE, FILL
VOLUME AND CARDIAC
OUTPUT**

FIGURE 3

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 Driver. 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.

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