

CALIFORNIA EMERGENCY MEDICAL SERVICES (EMS) MECHANICAL CIRCULATORY SUPPORT (MCS) DEVICES BEST PRACTICES GUIDELINE

Purpose: To provide information and direction regarding the care of patients who have a Ventricular Assist Device (VAD) or a Total Artificial Heart (TAH), collectively known as Mechanical Circulatory Support (MCS) devices.

Overview of VADs and Total Artificial Hearts:

- MCS covers a range of devices that include VAD's and TAH's.
- The VAD assists the native ventricle pumping action and provides the cardiac output needed to survive.
 - These devices are either pulsatile or continuous flow (non-pulsatile).
 - They are further divided into Left Ventricular Assist Devices (LVAD), Right Ventricular Assist Devices (RVAD), or both ventricles (BiVAD).
 - The more common device is a continuous flow pump located in the patient's thorax or upper abdomen and attached to the patients' left ventricle and aorta (LVAD).
 - The assessment of patients with these devices will not be instinctual, as many of the "normal" assessment parameters will not be available or their results will be seemingly contradictory (see Patient Assessment below).
 - A Left Ventricular Assist Device does not preclude the patient from getting right sided heart failure, e.g., Right Ventricular Infarction. Treat per your local protocols.
 - Patients with continuous flow devices (HeartMate II VAD or HeartWare VAD) may not have a pulse.
- The Syncardia Total Artificial Heart (TAH) includes the actual removal of the heart itself. The device is pulsatile and is driven with compressed air. Patients with this device will not have an ECG but will have a pulse.

Pre-Arrival/ On Scene Cues:

- Information regarding the type of device, the implantation hospital, and/or the VAD/ MCS Coordinator contact telephone number may be available in your Computer Aided Dispatch (CAD) System.
- There may be a tag on the device, on the refrigerator, or on a medical alert bracelet with the name of the device and contact information for the VAD/ MCS Coordinator at the center that implanted the VAD or TAH. This tag or bracelet may be color coded to correspond with the devices listed in Appendix A (*Mechanical Circulatory Support Organization EMS Guide, January 2014*).
- Assess for the presence of a DNR, POLST or Advance Directive.

Initial Assessment

- First **ASSESS THE PATIENT**, not the device.
 - The reason for the call may or may not be a problem with the VAD/ TAH. VAD/ TAH patients can and frequently do have other medical conditions besides a weak heart.
 - Patients with a continuous flow VAD “typically” have **no discernible pulse or blood pressure**.
 - Families or caregivers of VAD patients may be able to use a Doppler device to obtain a Mean Arterial Pressure (MAP). This is described in more detail below.
 - Because there is no pulse, utilize other parameters for patient assessment (level of consciousness, skin signs, capillary refill, etc.)
 - Also, because of the lack of a palpable pulse, pulse oximetry will be either absent or unreliable.
 - Patients with a TAH **will** have a pulse and a blood pressure (systole/ diastole).
 - Utilize the American Heart Association’s C-A-B recommendations, with one addition:
 - C = Circulation/ **Connections (device)**
 - A = Airway
 - B = Breathing
- Second, asses to see if the device is working.
 - If the patient has a continuous flow VAD (non-pulsatile), you will be able to auscultate the let upper quadrant of the patient’s abdomen for the “hum” of the VAD, which can help direct the appropriate actions.
 - A pulsatile VAD will make an audible sound without auscultation
 - Pulsatile VADs are usually older devices which pump blood via pulsatile mechanism, generating a peripheral pulse.
 - A TAH patient will have a pulse and a blood pressure. Furthermore, the device is audible without a stethoscope.
 - Determine if the device has power.
 - If the device has power, it does not necessarily mean that it is working, so the previous step is very important.
 - If the device has power:
 - HeartMate II: You will see a green light
 - HeartWare: The display will clearly tell you the Liters per Minute (LPM) of blood flow.
 - TAH: You will hear an audible “gallop” indicating that the device is pumping.
 - A TAH will have a driver called the Freedom Driver, and an output can be seen in the driver screen when the bottom is depressed.

- If you are unsure what type of device it is, look for the tag which may be color coded to be in accordance with the MCSO EMS Guide – see Appendix A) on the controller, in the patient’s wallet, or on a medical alert bracelet. The patient and/ or family/ caregiver can also tell you what device the patient has.
- Check the VAD/ TAH for secure connections and that the batteries are charged and functional.
- **Remain patient-centric. Check the VAD/ TAH as directed, but remain aware of how your patient is doing clinically. Deliver routine medical care as required.**
 - If the pump is pumping then the problem is with the patient, not the device.
 - Do ABC’s in conjunction with your VAD/ TAH assessment.
- Sidestream or mainstream end tidal capnography **will** read accurately. This will be useful in assessment of these patients.

Contact/ Assistance:

- **Follow your local protocols or contact your base hospital for orders concerning patient care.**
- **If a caregiver is present, utilize his/ her knowledge. The patient and their caregiver are the experts on scene for all issues related to the VAD/ TAH.**
 - **Patients and their caregivers are taught to call 9-1-1 in an emergency and then page the on-call VAD/ MCS Coordinator immediately.**
 - **The VAD/ MCS Coordinator has experience and can make suggestions regarding the best course of action.**
- As early in the call as possible, contact the following:
 - Base Hospital – The nurse/ physician may wish to directly contact the VAD/ MCS Coordinator to coordinate the care of the patient with them.
 - Check the patient’s wallet card or labels on equipment for information on contact information for the VAD Coordinator.
 - **Only the base hospital is legally allowed to give orders regarding patient care.**
 - **Receiving hospital – an early “ring down” is critical to help the facility prepare for this highly specialized patient.**

If the VAD/ TAH is the problem:

- If any alarms are going off, or if the device appears not to have power:
 - Reconfirm that connections are secure and that the batteries are charged
 - Check that the driveline is connected to the controller. Exert great care not to dislodge the driveline.

- Utilize the caregiver or patient's knowledge to continue checking the VAD/ TAH.

Patient Assessment Points, VAD patients:

- MCS patients are of all ages, from infants through the elderly and all ages in between. Do not assume that because your patient is young they cannot have one of these devices.
 - Children and infants with an MCS may have a pulsatile device.
- Patients with a continuous flow VAD “typically” have ***no discernible pulse or blood pressure***.
- Pulse oximetry may not function or it may be inaccurate
- Automated blood pressure devices are not accurate, and manual blood pressures usually cannot be obtained in patients with a continuous flow VAD.
 - A Doppler device can be used to obtain a mean arterial blood pressure (MAP) in these patients. Having a Doppler device is not feasible in the prehospital area. However, the patient's caregiver may have one and be able to obtain a MAP.
 - The ideal range for this blood pressure is 70 – 85 mmHg.
- The 12-Lead ECG or heart monitor will show the patient's native heart rhythm and will not necessarily reflect the patient's circulatory function.
 - **Because of this, the patient may potentially be awake while in malignant rhythms such as ventricular fibrillation or ventricular tachycardia. Contact your base hospital for direction. Be able to discuss with the VAD/ MCS Coordinator, physician, and base hospital if the patient appears to be stable or unstable in this rhythm.**
 - Is the patient short of breath, have delayed capillary refill, poor skin signs, altered level of consciousness?
 - If defibrillation is necessary, consider pre-sedating the patient who is awake. Follow your local EMS protocols and/ or base hospital orders.
- The vast majority of VAD patients will also have an Implanted Cardioverter Defibrillator (ICD) or a Pacemaker/ ICD due to underlying ventricular dysrhythmias. Be sure to obtain this crucial data.
 - TAH patients will not have an ICD or a pacemaker/ ICD, since there is no heart muscle.
- The VAD is preload (filling volume) dependent. Dysrhythmias that would affect preload (e.g., supraventricular tachycardia, atrial fibrillation with rapid ventricular response, ventricular tachycardia, and ventricular fibrillation) need to be treated. VADs pump or work best with adequate patient volume.

Patient Assessment Points, TAH patients:

- Patients with a TAH will have a pulse and a blood pressure if the device is working correctly.
- A pulse oximeter can be used.
- An ECG in the TAH patient is nonfunctional as there are no ventricles generating an electrical signal.

Patient Treatment, VAD patients:

- All VAD patients should receive the following care:
 - Utilize the American Heart Association's C-A-B recommendations with one addition:
 - C = Circulation/ **Connections (device)**
 - A = Airway
 - B = Breathing
 - Standard airway management
 - Oxygen as clinically indicated.
 - Pulse oximetry will not measure or will not be accurate.
 - IV initiation – prepare for orders for fluid resuscitation (minimum amount initially delivered should be 250 – 500 mls, and then reassess the patient).
 - In a full arrest, consult your base hospital for orders.
 - Consult your local EMS protocols or base hospital regarding whether to perform chest compressions.
 - Morphine for chest pain management and trauma is appropriate.
 - The use of Nitroglycerin (NTG) can dangerously lower blood pressure and worsen their clinical condition due to the VAD's dependence upon preload (filling volume).

Patient Treatment, TAH patients:

- All TAH patients should receive the following care:
 - Utilize the American Heart Association's C-A-B recommendations with one addition:
 - C = Circulation/ **Connections (device)**
 - TAH patients will have a pulse
 - A = Airway
 - B = Breathing
 - Standard airway management
 - Oxygen as clinically indicated.
 - Pulse oximetry will measure accurately.

- IV initiation – prepare for orders for fluid resuscitation (minimum amount initially delivered should be 250 – 500 mls, and then reassess the patient).
 - In a full arrest, consult your base hospital for orders.
 - Compressions, cardioversion, and defibrillation are contraindicated on TAH patients since there is no native heart.
- A hypertensive crisis in a patient with a TAH (systolic blood pressure > 140 mmHg) should be treated with SL NTG.

Trauma patients:

- Assess **all** unconscious trauma patients for the presence of a VAD or TAH. Be sure that you do not cut the driveline, as this cuts off all connections with the computers driving these devices.
- Spinal immobilization and/ or splinting may need to be modified to protect the integrity of the VAD/ TAH equipment. Be careful not to pull or cut the driveline. Make sure all equipment is safely secured.
- Trauma patients with a VAD or TAH are trauma patients **first**, rather than a VAD or TAH patient with a trauma. Let the base hospital know that the patient has a VAD/ TAH and may be on anticoagulants.

VAD Complications:

- VAD patients experience a higher percentage of the following conditions:
 - Altered level of consciousness/ unconscious and apneic
 - The patient needs to have ACLS instituted immediately per protocol.
 - Check airway, institute breathing, then:
 - Immediately check the connections and listen for the “hum” of the VAD.
 - Troubleshoot using the MCSO EMS Guide, if available.
 - Contact the base hospital, who should be in contact with the VAD/ MCS Coordinator. Be prepared for the base hospital to give you directions for restarting the pump and possibly changing out the system controller.
 - **Medical direction must always come from the base hospital.**
 - Hemorrhage
 - Active bleeding/ hemorrhage is to be treated following standard protocol and the patient transported to the closest appropriate receiving facility.
 - Patients meeting Trauma criteria are to be taken to the closest Trauma Center and treated as trauma patients according to local protocols.

- Stroke
 - Stroke patients need to be transported as usual per local protocol.
 - Please note that these patients have a magnet in the device and many times an ICD. They cannot undergo an MRI study, but may undergo a CT scan. Pass this information to the base hospital and to the receiving hospital, if different from the Base hospital.
- Sepsis/ Septic Shock
 - If you feel that these patients have an infection or are in septic shock, they need fluid resuscitation and prompt transportation to the closest most appropriate receiving center.
- Dysrhythmias
 - **Dysrhythmias need to be managed according to standard ACLS protocols. Where there is conflict, follow the LEMSA's protocols.**
 - If defibrillation or cardioversion becomes necessary, follow the appropriate treatment protocol as there are no contraindications. The pump is insulated and will not be damaged.
 - Most of these patients will have an ICD.
 - If defibrillation is necessary, move the controller to the patient's right side, so it is as far away from the electrical therapy as possible.
 - **DO NOT** disconnect the system controller from the percutaneous lead (driveline) or stop the pump prior to delivering the shock.
 - Dysrhythmias may affect the device and a red heart alarm may sound if the patient is in a low-flow state (less than 2.5 LPM of blood flow, or inadequate to meet the patient's clinical condition).
 - Contact the base hospital as early in the call as possible. They can then contact the VAD/ MCS Coordinator for further directions regarding the device.

TAH Complications:

- TAH patients experience a higher percentage of the following conditions:
 - Altered Level of Consciousness/ Unconscious and apneic
 - The patient needs to have ACLS instituted immediately per protocol. However, **NO COMPRESSIONS, DEFIBRILLATION, OR CARDIOVERSION** should be performed on TAH patients.
 - Check airway, institute breathing, then:
 - Immediately check the connections and listen for a "galloping" sound. This is an indicator that the Freedom Driver is pumping. This sound is audible without a stethoscope.

- Troubleshoot the device using the MCSO EMS Guide, if available.
- Contact the base hospital, who will contact the VAD/ MCS Coordinator. Be prepared for the base hospital to give you directions for restarting the pump and possibly changing out the system controller (Freedom Driver).
- ***Medical direction must always come from the base hospital.***
- Hemorrhage
 - Active bleeding/ hemorrhage is to be treated following standard protocol and the patient transported to the closest appropriate receiving facility.
 - Patients meeting Trauma criteria are to be taken to the closest Trauma Center and treated as trauma patients according to local protocols.
- Stroke
 - Stroke patients need to be transported as usual per local protocol
 - These patients do **not** have an ICD.
 - These patients cannot undergo an MRI study, but may undergo a CT scan. Pass this information to the base hospital and to the receiving hospital, if different from the base hospital.
- Sepsis/ Septic Shock
 - If you feel that these patients have an infection or are in septic shock, they need fluid resuscitation and prompt transportation to the closest most appropriate receiving center.
- Dysrhythmias
 - Patients with a TAH do not have dysrhythmias since there is no heart generating an electrical signal.

Transport

- When transporting these patients to the hospital, the VAD/TAH emergency bag, power module, power base unit, batteries, charger, and backup controller **must** all be brought to the hospital.

Transport to the closest appropriate prehospital receiving center, per local EMS protocols in the following circumstances:

- Patient appears to be in shock (poor skin signs, delayed capillary refill, and/ or altered level of consciousness);
- Patient's ECG (except TAH patients) shows a dysrhythmia that affects preload (such as ventricular tachycardia, ventricular fibrillation, supraventricular tachycardia, or atrial fibrillation with rapid ventricular response);
- Whenever possible, allow the caregiver to accompany the patient in the ambulance or EMS airship to help facilitate care.

Additional information:

- **Medical direction or destination decisions must be made by the Base hospital or local protocols/ policies.**
- Remember to always check your patient and treat the patient first rather than the equipment (the VAD or TAH).

There are multiple videos available from the device manufacturers on their websites, www.thoratecu.com, www.heartware.com, www.syncardia.com. There is also an EMS Guide to VADs and MCSs available at www.mylvad.com or in Appendix A of this document.

VAD and TAH differences

Ventricular Assist Device	Total Artificial Heart
Usually pulseless	Pulsatile
ECG shows native heart rhythm	ECG is meaningless since there is no heart
Pulse oximetry is inaccurate or absent	Pulse oximetry is accurate
Do not use NTG	Patients are ordered to use NTG for systolic blood pressure >140 mmHg
Consult your local EMS protocols or base hospital regarding whether to perform chest compressions on VAD patient	No compressions on TAH patients
You may cardiovert or defibrillate	Do NOT cardiovert or defibrillate
Must auscultate the left upper quadrant of the patient's abdomen for the "hum" of the VAD	The TAH's Freedom Driver is audible without a stethoscope, making a "galloping" type of sound
Usually have an ICD	Do not have an ICD
May be able to obtain a Mean Arterial Pressure (MAP) using a Doppler device only. Normal sphygmomanometer will not work. MAP should be from 70 – 85 mmHg.	Blood pressure is obtainable utilizing a normal sphygmomanometer.

Alarms – ALWAYS check your patient first

Thoratec HeartMate II	HeartWare	Syncardia Total Artificial Heart
<p>Red Heart Alarm: There will be a red heart warning light on the system controller and a steady audio tone</p> <ul style="list-style-type: none"> • Pump flow is less than 2.5 LPM (inadequate to meet the patient's condition) • Pump has stopped • Percutaneous lead (driveline) is disconnected • Pump is not working properly <p>What should you do?</p> <ul style="list-style-type: none"> • Check your patient • Make sure the system controller is connected to the percutaneous lead (driveline). Handle with great care • Treat any sources of low flow or shock (bleeding, hypovolemia, tamponade, etc.) • Contact your base hospital who should be in touch with the VAD/ MCS Coordinator. The base hospital may direct you to change the system controller to the backup controller 	<p>Flashing Red (High - Critical Alarm)</p> <ul style="list-style-type: none"> • VAD stopped • Critical Battery • Controller has failed <p>What should you do?</p> <ul style="list-style-type: none"> • First check your patient and treat as indicated • Connect the driveline, replace the batteries, or change the controller as directed by your base hospital <ul style="list-style-type: none"> ○ ALWAYS change batteries one at a time. At least one battery must be connected at all times 	<p>Battery Alarm: Beeping tone, audible alarm, and a blinking yellow light on the top of the Freedom Driver</p> <ul style="list-style-type: none"> • The illuminated blinking yellow light will indicate which battery needs to be replaced <p>What should you do?</p> <ul style="list-style-type: none"> • Replace the blinking battery with another fully charged battery <ul style="list-style-type: none"> ○ ALWAYS change batteries one at a time. At least one battery must be connected at all times. • If no fresh batteries are available, connect to an external power source such as AC power or DC power (car adapter) <ul style="list-style-type: none"> ○ The battery alarm will turn into a Fault Alarm if one or both batteries drop below 30% of remaining charge

Thoratec HeartMate II	HeartWare	Syncardia Total Artificial Heart
<p>Low Voltage Alarm (Red Battery Alarm): You will hear a continuous alarm</p> <ul style="list-style-type: none"> • There is less than 5 minutes of battery power remaining • Voltage is too low • The system controller is not getting enough power from the power module <p>What should you do?</p> <ul style="list-style-type: none"> • Immediately replace depleted batteries with a new, fully charged pair • ALWAYS change batteries one at a time. At least one battery must be connected at all times • If batteries are not available, switch to the power module • The controller must be connected to a power source at all times. Batteries or power must be changed one lead at a time to prevent the pump from stopping • Note: Pump speed will gradually decrease to “Power Saver Mode” until the condition is resolved and the alarm clears 	<p>Flashing Yellow (Medium Alarm):</p> <ul style="list-style-type: none"> • Controller fault • High watts • Electrical fault • Low flow • Suction type event <p>What should you do?</p> <ul style="list-style-type: none"> • Contact your base hospital to contact the VAD/ MCS Coordinator for advice. The base hospital can then pass this advice to the prehospital personnel 	<p>Temperature Alarm: Indicated by a beeping tone, audible alarm and a blinking red light visual alarm on top of the Freedom Driver</p> <p>What should you do?</p> <ul style="list-style-type: none"> • Replace each battery one at a time <ul style="list-style-type: none"> ○ ALWAYS change batteries one at a time. At least one battery must be connected at all times ○ Remove any objects blocking the Filter Cover/ Fan ○ Move the Freedom Driver into a cooler environment

Thoratec HeartMate II	HeartWare	Syncardia Total Artificial Heart
<p>No Power Alarm: You will hear a steady, audible tone, but will see no lights on the system controller.</p> <ul style="list-style-type: none"> System controller is not receiving power <p>What should you do?</p> <ul style="list-style-type: none"> Make sure the system controller is connected to 2 batteries or a single power source <ul style="list-style-type: none"> Batteries Power Module If alarm continues, switch to a different power source Contact your base hospital who should be in touch with the VAD/ MCS Coordinator. The base hospital may direct you to change the controller to the backup controller 	<p>Solid Yellow (Low Priority Alarm):</p> <ul style="list-style-type: none"> Low battery, power disconnected <p>What should you do?</p> <ul style="list-style-type: none"> Replace batteries, one at a time ALWAYS change batteries one at a time. At least one battery must be connected at all times Reconnect the power <ul style="list-style-type: none"> If the alarm stops once you have made the adjustment the equipment problem is solved. Check your patient 	<p>Fault Alarm: Indicated by a constant audible tone alarm and a solid red light visual alarm on the top of the Freedom Driver</p> <p>What should you do?</p> <ul style="list-style-type: none"> Check immediately that the drivelines are not kinked or disconnected. Undo kinks or reconnect drivelines Check battery charge. Change out batteries or connect to external power <ul style="list-style-type: none"> ALWAYS change batteries one at a time. At least one battery must be connected at all times The Fault Alarm will stop once the batteries are recharged above 35% Check patient's blood pressure and treat hypertension (systolic BP >140 mmHg). Patients should have SL NTG tabs with them If Fault Alarm continues, CONTACT YOUR BASE HOSPITAL TO CALL THE VAD/ MCS COORDINATOR FOR FURTHER DIRECTION

Thoratec HeartMate II	HeartWare	Syncardia Total Artificial Heart
<p>Low Voltage Advisory Alarm (Yellow Battery Alarm): You will see a yellow battery warning light and hear an audible tone of one beep every 4 seconds</p> <ul style="list-style-type: none"> • The voltage is too low • The system controller is not getting enough power from the power module or power base unit <p>What should you do?</p> <ul style="list-style-type: none"> • Immediately replace depleted batteries with a new, fully charged pair • ALWAYS change batteries one at a time. At least one battery must be connected at all times. • If batteries are not available, switch to power module 		

Appendix A: Mechanical Circulatory Support Organization EMS Guide, January 2014