

HEARTWARE™ HVAD™ SYSTEM ALARM TROUBLESHOOTING CLINICIAN GUIDE







Medtronic

HEARTWARE™ HVAD™ SYSTEM



ALARM TROUBLESHOOTING

CLINICIAN GUIDE



Alarm Type: High (Critical)

Alarm Symbol	Alarm Tone	LCD Display Line 1	LCD Display Line 2	Potential Causes	Potential Action
None 	Continuous loud-unable to mute 	(no message)	(no message)	<ul style="list-style-type: none"> No power to pump Pump has stopped 	<ul style="list-style-type: none"> Connect two new power sources Replace controller Contact Medtronic Clinical Support
Flashing Red 	Loud, Two-toned alarm-unable to mute 	VAD Stopped	Connect Driveline	<ul style="list-style-type: none"> Driveline disconnected Driveline fracture Connector malfunction/breakage VAD electrical failure 	<ul style="list-style-type: none"> Reconnect driveline Contact Medtronic Clinical Support Download/email patient log files
		VAD Stopped	Change Controller	<ul style="list-style-type: none"> Controller failure VAD failure VAD thrombus 	<ul style="list-style-type: none"> Exchange controller Contact Medtronic Clinical Support Download/email patient log files
		Controller Failed	Change Controller	<ul style="list-style-type: none"> Controller component failed 	<ul style="list-style-type: none"> Exchange controller Contact Medtronic Clinical Support
		Critical Battery	Replace Battery 1	<ul style="list-style-type: none"> Limited battery 1 or battery 2 time remaining Battery malfunction 	<ul style="list-style-type: none"> Replace critical battery with fully charged battery or the AC or DC adapter Change controller if new power sources
		Critical Battery	Replace Battery 2		

Alarm Type: Medium

Alarm Symbol	Alarm Tone	LCD Display Line 1	LCD Display Line 2	Potential Causes	Potential Actions
Flashing Yellow 	 <ul style="list-style-type: none"> Intermittent beep-gradual increase in alarm volume over time if not muted Able to mute alarm for 5 minutes or 1 hour Electrical Fault (audio) and Controller Fault (audio) can be permanently disabled Press the scroll button on the controller to clear resolved medium alarm messages 	Controller Fault	Call	<ul style="list-style-type: none"> Controller component malfunction but pump still working 	<ul style="list-style-type: none"> Confirm frequency and duration of alarm, concurrent alarms, and pump flow/speed/power Assess patient for complaints of shortness of breath, chest pain, palpitations, dizziness, etc. Isolated alarm should be monitored with download at next visit
		Controller Fault	Call: ALARMS OFF	<ul style="list-style-type: none"> Controller component malfunction Suction Detection disabled Low Flow alarm disabled VAD Connect alarm may be disabled High Power alarm may be disabled 	<ul style="list-style-type: none"> Multiple alarms within 24 hours without other issues will be assessed at non-emergent visit Multiple alarms within 1 hour with other alarms or symptoms replace controller and assess in emergent visit Download/email patient log files from original (alarming) controller and new controller Contact Medtronic Clinical Support
		High Watts	Call	<ul style="list-style-type: none"> HVAD™ Pump Watts have exceeded High Power alarm threshold Alarm threshold set too close to average power VAD thrombus High RPM High flow VAD electrical fault 	<ul style="list-style-type: none"> Confirm correct settings for High Power alarm and pump speed Consider checking blood coagulation labs Assess patient for hemolysis Download/email patient logs files Consider ECHO to confirm unloading of heart, check for aortic insufficiency, thrombus, etc. Contact Medtronic Clinical Support
		Electrical Fault	Call	<ul style="list-style-type: none"> Fault in continuity of pump-to-controller electrical connections Partial driveline fracture Connector malfunction Controller component failure VAD malfunction 	<ul style="list-style-type: none"> Check driveline cover and ensure driveline connector is engaged Inspect driveline for defects Download/email patient log files Contact Medtronic Clinical Support
		Low Flow	Call	<ul style="list-style-type: none"> Average flow below Low Flow alarm threshold Alarm threshold set too close to average flow Suction RPM too high or too low Poor VAD filling (right ventricular failure, hypovolemia, tamponade, arrhythmias, inflow cannula obstruction, etc.) High blood pressure Outflow graft kink 	<ul style="list-style-type: none"> Confirm VAD parameters If possible, confirm correct settings for Low Flow alarm limit and viscosity Confirm blood pressure (MAP < 85 mm Hg) Evaluate cause of poor left ventricle filling (include attaching patient to monitor to evaluate pump wave form) and consider volume resuscitation if indicated If no potential patient cause can be identified – download/email patient log files Consider ECHO Contact Medtronic Clinical Support
		Suction	Call	<ul style="list-style-type: none"> RPM too high Poor VAD filling (right ventricular failure, hypovolemia, tamponade, arrhythmias, inflow cannula obstruction, etc.) VAD thrombus 	<ul style="list-style-type: none"> Confirm pump flow trends to evaluate a decrease in mean flow Download/email patient log files Consider volume resuscitation and/or correct cause of poor left ventricle filling Consider decreasing pump speed Contact Medtronic Clinical Support Consider ECHO

Alarm Type: Low

Alarm Symbol	Alarm Tone	LCD Display Line 1	LCD Display Line 2	Potential Causes	Potential Actions
Solid Yellow 	 <ul style="list-style-type: none"> Intermittent beep-gradual increase in alarm volume if not muted Able to mute alarm for 5 minutes 	Low Battery 1	Replace Battery 1	<ul style="list-style-type: none"> Battery power is low 	<ul style="list-style-type: none"> Replace low battery
		Low Battery 2	Replace Battery 2		
		Power Disconnect	Reconnect Power 1	<ul style="list-style-type: none"> Power source is disconnected or malfunctioning 	<ul style="list-style-type: none"> Reconnect power source Replace power source Replace controller
		Power Disconnect	Reconnect Power 2		

Brief Statement: HVAD™ System

Indications: The HeartWare™ Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The HeartWare System is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.

Contraindications: The HeartWare System is contraindicated in patients who cannot tolerate anticoagulation therapy.

Warnings/Precautions: Proper usage and maintenance of the HVAD™ System is critical for the functioning of the device. Never disconnect from two power sources at the same time (batteries or power adapters) since this will stop the pump, which could lead to serious injury or death. At least one power source must be connected at all times. Always keep a spare controller and fully charged spare batteries available at all times in case of an emergency. Do not expose batteries to excessive shock or vibration since this may affect battery operation. Do not grasp the driveline cable as this may damage the driveline. Do not pull, kink or twist the driveline or the power cables, as these actions may damage the driveline. Special care should be taken not to twist the driveline including while sitting, getting out of bed, adjusting the controller

or power sources, or when using the shower bag. Do not disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

Potential complications: Implantation of a Ventricular Assist Device (VAD) is an invasive procedure requiring general anesthesia, a median sternotomy, a ventilator and cardiopulmonary bypass. There are numerous risks associated with this surgical procedure and the therapy including but not limited to, death, stroke, device malfunction, peripheral and device-related thromboembolic events, bleeding, infection, hemolysis and sepsis.

Refer to the "Instructions for Use" for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions and potential adverse events prior to using this device. The IFU can be found at www.heartware.com/clinicians/instructions-use.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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