

URGENT: Important Information for Patients

HeartWare™ Ventricular Assist Device (HVAD™) System Battery Performance

30 June 2022,

Dear HVAD Patient,

Medtronic is writing to inform you about important information related to the batteries used with your Medtronic HVAD™ System, the device that is helping your heart pump blood to your body. This information has recently been provided to your VAD Clinical team (surgeon, physician, and VAD coordinator).

Please review all the information below and reach out to your VAD Clinical team with any additional questions on this notice.

Batteries are provided with your HVAD System and are used to power your HVAD Controller. If there is an issue with your battery, the controller is designed to provide an alarm indicating when power is not reaching the controller. Electrical issues can cause the battery to stop providing power to your controller or may prevent the battery from properly recharging or holding a charge. If this happens, your HVAD System may malfunction or stop functioning, and this could rapidly lead to serious health consequences. To lower the risk of experiencing an issue with your HVAD system due to a battery problem, it is important to follow the actions recommended below.

What should you do?

Medtronic recommends you take the following actions to lower the risk of experiencing an issue with your HVAD system caused by a battery problem:

- **Attend all scheduled medical and device check appointments.**
- **Keep two sources of power connected to the controller and have at least two fully charged spare batteries available at all times.**
- **Stop using batteries and immediately notify your VAD Clinical team if:**
 - they cause alarms,
 - you notice that they have issues charging
 - they are not recognized when connected to your controller

- Follow the instructions in your Patient Manual for proper battery management.** When you connect a battery to the controller, make sure the battery capacity display lights up and the battery indicator lights on the controller light up. **Do not use the battery if the indicator lights do not light up.** When using the battery charger, if the status light flashes red or yellow (figure 1), please follow the troubleshooting steps outlined in section 3.6 your patient manual.

1. "Ready"
2. "Status"
3. AC Power

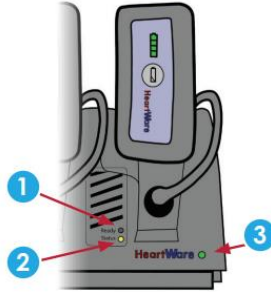


Figure 1. Battery Charger Indicators

- Be aware if your battery capacity or battery indicator lights do not decrease over time while in use.** This could be a sign of a battery electrical fault. When reading the battery capacity (see Figure 2) or battery indicator (see Figure 3), one light indicates approximately 25% of a battery charge. A full battery charge lasts between 4 to 7 hours. **If you observe that your indicator lights do not decrease over time, stop using the battery, and reach out to your VAD Clinical team.**



Figure 2. Battery Capacity Display on Battery

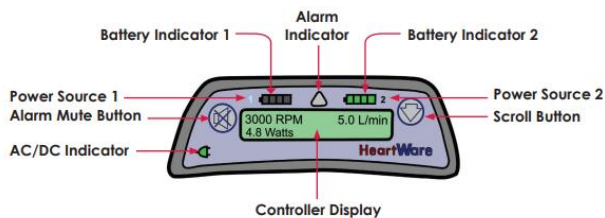


Figure 3. Battery Indicators on Controller

- **Report alarms to your VAD Clinical team.** If a [Power Disconnect] alarm occurs while a battery is physically connected to the controller. If this happens, you should **stop using that battery and contact your VAD Clinical team.** Below are the battery alarms from your patient manual:

Alarm (Line 1 on controller) Action (Line 2 on controller)	Meaning	Alarm Indicator	Alarm Sound
[Critical Battery] [Replace Battery 1]	Limited time remaining on battery connected to power source 1	Flashing Red	Loud Unable to mute alarm
[Critical Battery] [Replace Battery 2]	Limited time remaining on battery connected to power source 2		
[Low Battery 1] [Replace Battery 1]	Battery 1 is low	Yellow	Alarm gets louder after 5 minutes and even louder after 10 minutes if alarm is not muted. Able to mute alarm for 5 minutes by pressing Alarm Mute Button.
[Low Battery 2] [Replace Battery 2]	Battery 2 is low		
[Power Disconnect] [Reconnect Power 1]	Power Source 1 disconnected or defective		
[Power Disconnect] [Reconnect Power 2]	Power Source 2 disconnected or defective		

You may contact our office at _____ to speak with your VAD team about
(clinic phone number)
this issue or if you have any questions.

Physician's Name: _____

Signature: _____

Date: _____