

ATTACHMENT B

HVAD System with Controller 2.0 - Identifying Unexpected Power Source Switching Behaviors

The information below provides guidance on monitoring for power source switching behaviors and how to identify unexpected power source switching that requires further investigation. Refer to the HVAD Instructions for Use for a full list of precautions, warnings and potential complications as well as for normal power source switching behaviors.

Table 1: Unexpected behaviors include, but are not limited to:		
Description of unexpected behavior	Controller Display	Actions
A controller that changes to the second battery when the first battery has greater than (>) 25% capacity (2 or more LEDs) remaining.		Replace the first battery and remove from service.
There is a sudden change in charge capacity on a battery (for example, a sudden change from 3 LEDs to 0 LEDs, or from 3 LEDs to 1 LED).		Replace the abnormally behaving battery and remove from service.
"Beeping" and the controller rapidly switches back and forth between batteries.		Replace the battery with more lit LEDs first, then replace the battery with fewer lit LEDs. Remove the battery with more lit LEDs as it may be a faulty battery.

A power source that persistently exhibits any of these unexpected behaviors should be taken out of service and replaced. Consider replacing power sources before replacing the controller.

Important! If any unexpected power source switching behavior is observed, do NOT try to force the controller to go back to power source "1" by manually disconnecting the port 2 battery/AC.

Reporting a problem:

For patients reporting this issue, remind them to bring all power sources (AC and DC adapters and batteries) into the clinic. Inspect batteries and obtain logfiles from the patient's controller and send the files to Medtronic for analysis.