Background Information
The Medtronic HeartWare™ HVAD™ System (Ventricular Assist Device) is designed with visual and auditory alarms that inform clinicians and patients about the status of the pump, controller, connections, and power supplies (batteries, AC adapter, DC adapter). A quick reference guide for all alarms can be found in both the Clinician Manual and the Patient Manual. When an alarm occurs, two lines of text appear in the Controller Display. The first line describes the alarm and the second line tells the patient what to do. See excerpt from the Clinician Instructions for Use (IFU), Figure 1.

Figure 1. HVAD Controller; Alarm Text Display (excerpt from Clinician IFU)

The HVAD System, as designed, can produce both High Priority (RED) or Medium Priority (YELLOW) alarms related to the operation of the controller. A Controller Fault Alarm (a Medium Priority alarm) is unrelated to pump stop – refer to excerpt from the Clinician IFU, Figure 2. Controller Fault alarms are an anticipated behavior of the HVAD System and signal a change in the status of the HVAD System and may include detection of internal wear on the controller or its components that can happen as part of normal progression as the controller ages.
Potential for More Frequent Controller Fault Alarms After Two Years of Useful Life

Medtronic has received an increase in inquiries from clinicians about patients who have encountered a Controller Fault Alarm, particularly on their primary controller, as the controller and its internal components age. An enhancement was added to Controller 2.0, which included monitoring of the controller internal battery as one of its reliability-focused updates. Engineering analysis of returned controllers with Controller Fault complaints, revealed the HVAD system was working as designed and appropriately detected a fault condition and subsequently issued a Controller Fault alarm with instruction on Line 2 of the Controller display indicating to [Call]. As a reminder, the controller is designed and tested to function for two (2) years. See excerpt from the Clinician IFU in Figure 3 below.

As of 09 September 2020, the rate of Controller Fault Alarms related to the primary controller’s internal battery is within predicted estimates. Controller performance will continue to be monitored per routine processes.

Continue to Follow Controller Fault Alarm Guidance as Indicated in the IFU – Recognize Alarms May Occur More Frequently After 2 Years of Useful Life
Controller Fault Alarms are an anticipated behavior of the HVAD system and can occur at any point throughout the life of the controller. Clinicians should remind patients that a Controller Fault Alarm is a Medium Priority alarm and may be a signal that the controller, or some of its internal components (e.g. internal battery), are reaching the end of their useful life. If a Controller Fault Alarm occurs, consider the following:

- A Controller Fault Alarm is a Medium Priority Alarm and should be managed as directed in the IFU for “Medium Priority Alarms.”
- There are a number of potential causes for a Controller Fault alarm – refer to excerpt from the Clinician IFU, Figure 2.
- A controller exchange may be necessary if the Controller Fault Alarm cannot be resolved. This exchange may be to a back-up controller, or to a new primary controller.

It is important to recognize, per the Patient Manual, the patient’s back-up controller is intended to be used for emergent situations. Patients should be advised to contact their clinician to obtain a new controller should a controller alarm require a controller exchange – see excerpts from the Patient Manual below.

Handling an Emergency
Emergencies may occur with your HeartWare™ HVAD™ System, with or without an alarm. A back-up controller and charged batteries must be available at all times. The controller should be exchanged if it fails.

**WARNING!** ALWAYS have a back-up controller handy and, whenever possible, a caregiver nearby when changing power sources or controllers. Be watchful for unusual changes in power or flow alarms for a period of time following equipment changes.

**CAUTION:** ALWAYS call your clinician for appropriate action if there is a [Controller Fault] alarm. The controller may need to be replaced with the back-up controller.