Medtronic HeartWare

Urgent Field Safety Notice

HeartWare™ Ventricular Assist Device (HVAD™) System, Model 1104

Update to failure rates and recommendations

December 2021

Medtronic reference: FA944

Dear Healthcare Professional:

Medtronic is providing this letter as a follow-up to our December 2020 and May 2021 communications titled "Urgent Field Safety Notice" (attached), where an identified subset of HeartWare™ Ventricular Assist Device (HVAD™) Systems may experience a delay to restart or failure to restart at a higher rate than the overall population of HVAD Systems. This is an update on the failure rates in this subset, as well as additional data to assist in clinical decision-making. **There are no new HVAD devices identified as part of this communication**. This communication is sent to clinicians with patients in this subset.

Updated Failure Rates

Since the May 2021 communication, Medtronic has identified two (2) new events of failure to restart within the subset, for a total of 41 events involving 36 devices. The two (2) new events both involved a patient death. In addition to the new events, two patients with failure to restart events reported in the previous communication have subsequently died, resulting in a total of 10 patient deaths.

Communication	Proportional Event Rate
December 2020 Communication	5.2%
May 2021 Communication	7.9%
December 2021 Communication	8.4%

Category	# of Events
Delay to restart (did restart) at implant	2
Failures at implant	5
Delay to restart (did restart) post-implant	9
Failure to restart post-implant	25
Total # of Events	**41**

Medtronic has identified two distinct subgroups within the initial subset of affected devices from specific component manufacturing lots that have exhibited differing failure rates. These two subgroups are referred to as “Subgroup 1” and “Subgroup 2”.

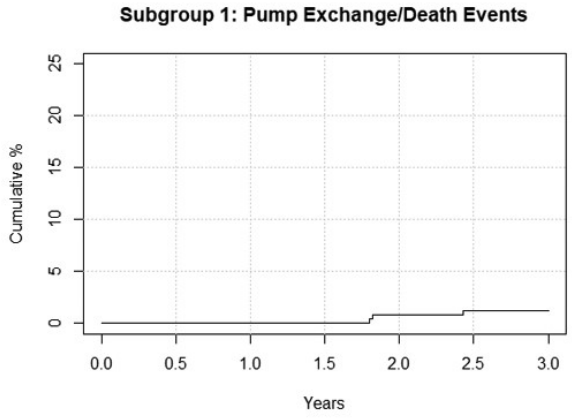
- Subgroup 1 includes 316 distributed pumps manufactured from a single supplier lot of components, exhibiting 9 events of a delay or failure to restart, 2 of which involved a patient death. Our records indicate there are currently 97 patients on support with a pump from Subgroup 1.
- Subgroup 2 includes 174 distributed pumps manufactured from the 2 subsequent supplier lots of components, exhibiting 32 events of a delay or failure to restart, 8 of which involved a patient death. Our records indicate there are currently 48 patients on support with a pump from Subgroup 2.

See Appendix A for the model and serial numbers of devices included in these subgroups. Please discuss this new information with your patients as appropriate, especially patients in Subgroup 2. A Patient Communication Template is being provided to facilitate discussions with patients.

1A delay or failure to restart is only observed after a pump has been stopped (e.g., double power disconnect, driveline disconnection, controller exchange, etc.) and the probability of a pump stop increases with time on support.

A competing risk analysis was performed to estimate the cumulative incidence of experiencing a pump stop with delay/failure to restart leading to a pump exchange or death. The competing risk analysis accounts for variability in the length of time patients are on support and unrelated events that may lead to device exchange or death. Only including events where the pump did not restart leading to an explant/pump exchange or death provides visibility to the events most relevant for making patient management decisions. Based upon the implant duration for each subgroup, Subgroup 1 was able to be analyzed to 3 years and Subgroup 2 was analyzed to 2 years.

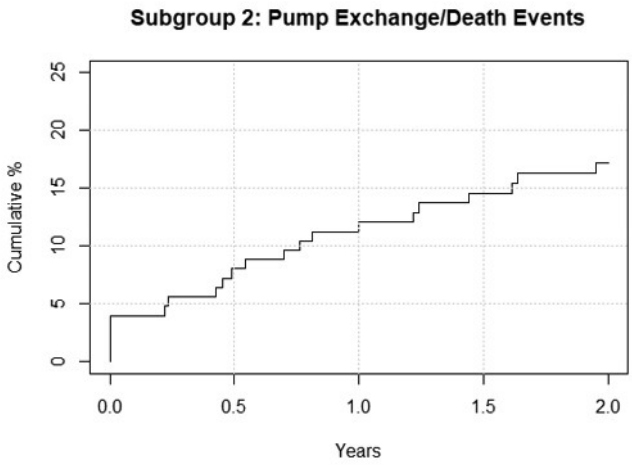
Subgroup 1: Pump Exchange/Death Events



Year	Rate	Lower CI	Upper CI
1	0	NA	NA
2	0.8%	0.2%	3.2%
3	1.2%	0.4%	3.8%

Figure 1: Cumulative incidence of experiencing a pump stop with delay/failure to restart leading to a pump exchange or death in Subgroup 1

Subgroup 2: Pump Exchange/Death Events



Year	Rate	Lower CI	Upper CI
1	12.1%	7.5%	19.4%
2	17.2%	11.7%	25.5%

Figure 2: Cumulative incidence of experiencing a pump stop with delay/failure to restart leading to a pump exchange or death in Subgroup 2

In addition to the events leading to a pump exchange or death depicted in the preceding charts, there have been 11 events out of the total 41 events with a delay to restart where the pump ultimately restarted. 6 events in Subgroup 1, and 5 events from Subgroup 2.

The following patient management recommendations are consistent with prior communication. Updates to the recommendations below are in (BOLD).

Patient Management Recommendations

In consultation with our Independent Practitioner Quality Panel, composed of cardiologists, surgeons and VAD coordinators, Medtronic recommends that treatment decisions for patients with a pump identified in the subset of devices **(Subgroup 1 and Subgroup 2) should be determined on an individual case-by-case basis and Healthcare providers speak with their patients with affected devices to emphasize avoidance of unnecessary pump stops. It is important to note that this issue does not *cause* a running VAD to stop; rather, an event of failure to restart follows a pump stop event.**

Reinforcing IFU

- **Since failure to restart is predicated on a pump stop event, reinforce directions to patients and staff within the IFU to *prevent unnecessary pump stops:***
    - Do NOT disconnect the driveline from the controller.
    - NEVER disconnect both power sources (batteries and AC or DC adapter) from the controller at the same time; one external power source should remain connected to the controller at all times.

- Do NOT exchange the controller unless explicitly directed by a High Priority alarm condition or a VAD team member.
- Reinforce the proper response to a [Controller Fault] alarm and [Electrical Fault] alarm. These are Medium Priority alarms unrelated to an immediate pump stop. These alarms will result in the word [Call] in the Controller Display, notifying the patient to call their clinician.
- Reinforce making good connections of power sources and the data cable in the controller ports.

Controller Exchange

- Inform patients implanted with one of these identified pumps to contact their VAD coordinator prior to any controller exchange, and to coordinate performing an exchange of controllers in a clinical setting.
- Factors that should be considered **for a controller exchange** include but are not limited to:
  - Whether the patient is a candidate for a pump exchange if the pump does not restart.
  - Patients with a Do Not Resuscitate (DNR) order and co-morbidities.
  - Length of time the patient is expected to remain on therapy. Examples include but are not limited to: bridge to transplant care, therapeutic recovery potential.
  - **Distance/time it will take for the patient to reach the hospital/clinic for support.**
  - **Patient and caregiver understanding/compliance to alarm response protocols and power source management to prevent unnecessary pump stops.**

When a Controller Exchange is Deemed Necessary

- If a controller exchange is deemed necessary for patients implanted with one of these identified pumps, consider the following:
  - Controller exchanges should be performed under clinician supervision in a controlled environment with the immediate ability to put the patient on hemodynamic support. Failure to restart can be fatal.
  - Upon a pump stop, a High Priority [VAD Stopped] alarm will result in the text [Change Controller] or [Connect Driveline] on the Controller Display. Once power and driveline connections are reestablished, if the pump does not restart:
    - Consider power cycling (disconnect both power sources and reconnect) of the current controller or consider a controller exchange. This will allow the restart algorithm to reset and start over. The controller automatically attempts to restart the pump a maximum of 30 times; the [VAD Stopped] alarm begins after five (5) attempts.
    - If the pump still does not restart, proceed with hemodynamic support, and possible pump exchange**.**

When Considering a Controller Exchange

- If a patient's controller is beyond two (2) years of service, consider proactively scheduling a controller exchange prior to the internal controller battery reaching end of life and triggering a [Controller Fault] alarm.

- Although a [Controller Fault] alarm is a Medium Priority alarm that is not related to a pump stop, proactively scheduling a controller exchange could help avoid a patient reacting to the alarm by exchanging a controller

outside of a clinical setting. Per the IFU, patients should call their clinician upon receiving a Medium Priority alarm and not take any action before receiving guidance from their clinician.

- BE ADVISED: The pump will not stop due to a Medium Priority alarm alone. A Medium Priority alarm can be temporarily muted according to the IFU to allow time to bring the patient into a clinic to determine the next steps while the pump is still functioning. A Medium Priority alarm can also be permanently silenced pursuant to the IFU; however, clinicians should consider this risk before doing so.
- BE ADVISED: Considerations should be made on an individual case-by-case basis when deciding whether or not to electively perform a controller exchange. Depending on a number of clinical factors that Medtronic does not have visibility to, clinicians should use their clinical judgment in proceeding with individual patient treatment decisions, as noted above.

When Considering a Pump Exchange

Routine prophylactic explant of the HVAD™ device is not recommended, as risks associated with explantation may outweigh the potential benefits. The decision regarding explant and exchange of the HVAD™ pump should be made by physicians on a case-by-case basis, considering the patient's clinical condition and surgical risks. If a physician determines that pump exchange is appropriate, we recommend exchanging to an alternative commercial LVAD.

Whether the patient is a candidate for an elective pump exchange depends on, but is not limited to

- **Whether patients have a Do Not Resuscitate (DNR) order**
- **Co-morbidities**
- **Length of time the patient is expected to remain on therapy, whether patient is bridged to transplant or the pump is destination therapy.**

For specific questions related to the data provided in this communication, please contact the Medtronic Office of Medical Affairs at rs.mcsmedicalaffairs@medtronic.com.

Your Actions

• Notify patients implanted with one of these identified pumps of this issue

• This notice must be shared with all those who need to be aware within your organization or to any organization where patients have been transferred

Medtronic has notified the Competent Authority of your country of this action.

Medtronic remains dedicated to patient safety and will continue to monitor device performance and provide updates as appropriate to ensure we meet your needs and those of your patients. We sincerely regret any difficulties this may cause you and your patients. If you have any questions, please contact your local Medtronic Representative at <**XXXXX**>.

Medtronic HeartWare

Sincerely,

Local / BU manager

Enclosure:

Appendix A: List of model and serial numbers of devices included in the subgroups

Appendix B: December 2020 FSN

Appendix C: March 2021 FSN

Appendix A: List of model and serial numbers of devices included in the subgroups

Devices in Subgroup 1

Country	Model Number	Serial Number
Austria	1104	HW31550
Belgium	1104	HW31075, HW31520, HW35574
Czech Republic	1104	HW31123
Finland	1104	HW30766, HW35559
France	1104	HW31077, HW31080, HW31095, HW31161, HW31348, HW31555, HW34006
Germany	1104	HW30768, HW30769, HW30809, HW30813, HW30954, HW30966, HW30967, HW30970, HW31076, HW31111, HW31114, HW31192, HW31219, HW31226, HW31228, HW31235, HW31242, HW31251, HW31254, HW31255, HW31261, HW31398, HW31402, HW31451, HW31454, HW31541, HW31543, HW31544, HW31549, HW31559, HW31571, HW31579, HW31731, HW32260, HW32468, HW32499, HW35669
Greece	1104	HW31146, HW31147, HW31162
Italy	1104	HW31580
Kazakhstan	1104	HW31079, HW31081, HW31168, HW35558
Kuwait	1104	HW31009, HW31014
Latvia	1104	HW30834
Lebanon	1104	HW31018, HW31063, HW31510, HW35021
Netherlands	1104	HW30984, HW31096, HW31164, HW31173
Poland	1104	HW31129, HW35837
Serbia	1104	HW31187
South Africa	1104	HW31554
Spain	1104	HW30797
Switzerland	1104	HW30771, HW31244
Turkey	1104	HW30848, HW30981, HW30982, HW31100, HW31110, HW31112, HW31137, HW31138, HW31430, HW31444, HW34954, HW30793, HW30794, HW30798, HW30800
United Kingdom	1104	HW29362, HW30738, HW30741, HW30803, HW30838, HW30840, HW30939, HW31515, HW32264, HW34932

Devices in Subgroup 2

Country	Model Number	Serial Number
Austria	1104	HW35581
Belgium	1104	HW35503, HW35797
Czech Republic	1104	HW35788, HW35897, HW35948
Egypt	1104	HW35328
Estonia	1104	HW35547
Finland	1104	HW35662
France	1104	HW35958, HW35965
Germany	1104	HW35305, HW35332, HW35334, HW35396, HW35584, HW35629, HW35674, HW35692, HW35696, HW35702, HW35707, HW35769, HW35806, HW35807, HW35814, HW35859, HW35875, HW35939, HW35969, HW35975, HW35978, HW35996, HW36175
Greece	1104	HW36210
Italy	1104	HW35336, HW35484, HW35885, HW35987
Kazakhstan	1104	HW35497, HW35575
Latvia	1104	HW35095, HW35351
Netherlands	1104	HW35158, HW35346, HW35382, HW35389, HW35401, HW35823, HW35961
North Macedonia	1104	HW35365, HW35418, HW35895
Norway	1104	HW35309, HW35756, HW35955

Poland	1104	HW35846, HW35954
Serbia	1104	HW35930, HW36242
Slovakia	1104	HW35398
South Africa	1104	HW35411
Spain	1104	HW35162, HW35590
Turkey	1104	HW35228, HW35278, HW35297, HW35298, HW35300, HW35303, HW35614, HW35746, HW35915, HW36103, HW36106
United Kingdom	1104	HW35314, HW35329, HW35338, HW35391, HW35408, HW35409, HW35795, HW35822, HW35949, HW35960, HW36030