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.

<table>
<thead>
<tr>
<th>Communication</th>
<th>Proportional Event Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2020 Communication</td>
<td>5.2%</td>
</tr>
<tr>
<td>May 2021 Communication</td>
<td>7.9%</td>
</tr>
<tr>
<td>December 2021 Communication</td>
<td>8.4%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th># of Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delay to restart (did restart) at implant</td>
<td>2</td>
</tr>
<tr>
<td>Failures at implant</td>
<td>5</td>
</tr>
<tr>
<td>Delay to restart (did restart) post-implant</td>
<td>9</td>
</tr>
<tr>
<td>Failure to restart post-implant</td>
<td>25</td>
</tr>
<tr>
<td><strong>Total # of Events</strong></td>
<td><strong>41</strong></td>
</tr>
</tbody>
</table>

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.

A 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.

**Table 1: Subgroup 1: Pump Exchange/Death Events**

<table>
<thead>
<tr>
<th>Year</th>
<th>Rate</th>
<th>Lower CI</th>
<th>Upper CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>2</td>
<td>0.8%</td>
<td>0.2%</td>
<td>3.2%</td>
</tr>
<tr>
<td>3</td>
<td>1.2%</td>
<td>0.4%</td>
<td>3.8%</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Year</th>
<th>Rate</th>
<th>Lower CI</th>
<th>Upper CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12.1%</td>
<td>7.5%</td>
<td>19.4%</td>
</tr>
<tr>
<td>2</td>
<td>17.2%</td>
<td>11.7%</td>
<td>25.5%</td>
</tr>
</tbody>
</table>

**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.
o Do NOT exchange the controller unless explicitly directed by a High Priority alarm condition or a VAD team member.
o 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.
o 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:
  o Whether the patient is a candidate for a pump exchange if the pump does not restart.
  o Patients with a Do Not Resuscitate (DNR) order and co-morbidities.
  o 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.
  o Distance/time it will take for the patient to reach the hospital/clinic for support.
  o 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:
  o 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.
  o 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.

Sincerely,
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
Urgent Field Safety Notice
HeartWare™ Ventricular Assist Device (HVAD™) System, Model 1104
Patient Management Recommendations

May 2021

Medtronic reference: FA944

Dear Physician or Healthcare Professional,

Medtronic is providing this letter as a follow-up to our December 2020 communication titled “Urgent Field Safety Notice” (attached). The December 2020 communication described an issue with implanted Medtronic HeartWare™ Ventricular Assist Device (HVAD™) Systems, where an identified subset of pumps may experience a delay to restart or failure to restart. This follow-up communication is being sent to clinicians that have patients with pumps in the sub-population that are currently implanted.

As of April 22, 2021, Medtronic has identified additional events related to the delay/failure to restart issue within the identified subset: four (4) new deaths (total 6) and six (6) new cases of critical harm (such as cardiac arrest or reoperation for pump exchange) (for a total of 15), two (2) new cases of major harm (such as hospitalization or prolonged implant procedure due to interoperative pump exchange) (for a total of 9), and two (2) new cases of patients who had a life-threatening event (pump delay to restart) but recovered without long term effects (for a total of 10).

In Medtronic’s December 2020 communication, we provided a number of patient management recommendations, provided on page 2 below. The purpose of this communication is to reinforce the same patient management recommendations and provide an update with the following information to assist in clinical decision making considering a controller exchange:

- In addition to the December recommendation, 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. Patient considerations to take into account include but are not limited to:
  - Is the patient a candidate for a pump exchange if the pump does not restart? Examples include, but are not limited to: Patient with a Do Not Resuscitate (DNR) order, 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.

- In addition to the December recommendation, BE ADVISED: The pump will not stop due to a Medium Priority alarm alone. A Medium Priority alarm can be temporarily muted pursuant to the IFU to allow time to bring the patient into a clinic to determine 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.

Please note, as stated in the previous communication, that if a pump has successfully restarted after a pump stop event, a delay to restart or failure to restart could be experienced in the future. If a delay to restart or failure to restart is experienced, please notify your Medtronic representative.

The following patient management recommendations were included in the original letter. Updates below are in (BOLD).

Patient Management Recommendations
In consultation with our Independent Practitioner Quality Panel, Medtronic continues to recommend the following actions for the subset of devices that exhibit the higher rate of failure (the identified subset of pumps from three (3) specific lots):

Reinforcing IFU
- Reinforce to patients and staff the following points from the current Instructions for Use (IFU) to avoid 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 by 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.

Informing Patients
- 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.

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 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 words [Change Controller] or [Connect Driveline] in the Controller Display. Once power and driveline connections are reestablished, if the pump does not restart:
    - Consider power cycling 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 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 prior to receiving guidance from their clinician.
  - In addition to the December recommendation, 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. Patient considerations to take into account include but are not limited to:
    - Is the patient a candidate for a pump exchange if the pump does not restart? Examples include, but are not limited to: Patient with a Do Not Resuscitate (DNR) order, 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
  - In addition to the December recommendation, BE ADVISED: The pump will not stop due to a Medium Priority alarm alone. A Medium Priority alarm can be temporarily muted pursuant to the IFU to allow time to bring the patient in to a clinic to determine 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.

Your Actions
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.

The Competent Authority of your country has been notified of this action. We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients. If you have questions, please contact your Medtronic Field Representative at <XXXXX>.

Sincerely,

Local / BU Manager

Enclosure: December 2020, Urgent Field Safety Notice
Urgent Field Safety Notice
Medtronic HVAD® Pump Implant Kits
Retrieval of non-implanted HVAD® Pumps

December 2020

Medtronic reference: FA944

Dear Risk Manager,

Beginning 20 November 2020, Medtronic initiated an immediate quarantine request of a specific subset of nine (9) HVAD® Pump Implant Kits for engineering evaluation. You are receiving this letter because Medtronic records indicate your facility has one of the kits identified for retrieval. The affected serial number linked to your account is:

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Model Description</th>
<th>Serial Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1104</td>
<td>HVAD Pump Implant Kit</td>
<td>HWxxxxx</td>
</tr>
</tbody>
</table>

Medtronic internal processes identified a potential quality signal with a component in a subset of HVAD Implant Kits. To support investigation of the issue, Medtronic is voluntarily retrieving non-implanted product for further engineering evaluation.

Customer Actions:
Medtronic records indicate that your facility has received the above identified device. As a result, Medtronic requests that you take the following actions:

- Identify and quarantine this non-implanted identified device.
- Return the non-implanted identified product in your inventory to Medtronic. Your local Medtronic Representative can assist you in the return of this product and obtaining replacement product.
- Please share this notification with others in your organization as appropriate.

This letter serves as a notification for your records regarding the retrieval of the non-implanted product; no further actions are needed. The Competent Authority of your country has been notified of this action.

If you have questions regarding this material, please contact your Medtronic Field Representative at <XXXX>.

Sincerely,

Local / BU Manager
Urgent Field Safety Notice
HeartWare™ Ventricular Assist Device (HVAD™) System, Model 1104
Patient Management Recommendations

December 2020

Medtronic reference: FA944

Dear Physician or Healthcare Professional,

This letter is to inform you of a potential issue for the Medtronic HeartWare™ Ventricular Assist Device (HVAD™) System. Medtronic has identified a specific subset of HVADs that may experience a delay to restart or failure to restart. An internal pump component from three (3) specific lots puts the finished pumps at higher risk of delay to restart or failure to restart. The risk exists only when the pump is stopped, for example in a controller exchange when an attempt is made to restart the pump. A delay to restart or failure to restart could occur at any time after a pump stop, even if the pump initially started at the time of implant. If a pump has successfully restarted after a pump stop event, a delay to restart or failure to restart could be experienced in the future.

This issue does not impact the performance of a pump while it is running.

Medtronic records indicate you are following one or more patients implanted with an HVAD System from the identified subset, as noted in the enclosed serial number list.

Worldwide, 506 HVAD Systems were manufactured and distributed with the impacted components. This subset of pumps was manufactured between 2017-2019. Medtronic has received 26 complaints between March 1, 2017–November 16, 2020, associated with pumps in this identified subset failing to initially start, restart or experiencing a delay to restart.

Pumps in this subset have experienced a 5.2% rate of failing to initially start, restart or experiencing a delay to restart. As of November 16, 2020, Medtronic has identified two (2) deaths, nine (9) cases of critical harm (such as cardiac arrest or reoperation for pump exchange), seven (7) cases of major harm (such as hospitalization or prolonged implant procedure due to interoperative pump exchange), and eight (8) cases of negligible harm (such as a potentially life threatening event in which the patient recovered without long term effects, or a patient experienced a delay in implant). See table below.

<table>
<thead>
<tr>
<th>Category</th>
<th># of Complaints</th>
<th>Subset Rate of Occurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failures at implant</td>
<td>6</td>
<td>1.2%</td>
</tr>
<tr>
<td>Delay in restart (did restart)</td>
<td>7</td>
<td>1.4%</td>
</tr>
<tr>
<td>post-implant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Failure to restart post-implant</td>
<td>13</td>
<td>2.6%</td>
</tr>
</tbody>
</table>

In the general pump population, the observed rate of pumps failing to initially start, restart or experiencing a delay to restart is 0.087% for pumps operating in dual stator (normal operation with both stators driving the pump) and 0.4% for pumps operating in single stator (when continuity in the pump to controller electrical connection is interrupted) for example, due to accidental damage to the driveline cable during use.

**Patient Management Recommendations**

In consultation with our Independent Practitioner Quality Panel, Medtronic recommends the following actions for the subset of devices that exhibit the higher rate of failure (the 3 lots):

- Reinforce to patients and staff the following points from the current Instructions for Use (IFU) to avoid 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 by 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.

- 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.

- 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 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 words [Change Controller] or [Connect Driveline] in the Controller Display. Once power and driveline connections are reestablished, if the pump does not restart:
    - Consider power cycling 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 temporary hemodynamic support and pump 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.

Root cause investigation of the issue in the three (3) lots is ongoing and will notify you if there are changes in our recommendations. The Competent Authority of your country has been notified of this action.

**Your Actions**
- Please review the attached serial number list and confirm that your patient(s) is still on support
- This notice must be shared with all those who need to be aware within your organization or to any organization where potentially affected patients have been transferred

We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients. If you have questions regarding this material, please contact your Medtronic Field Representative at <XXXX>.

Sincerely,

Local / BU Manager

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**Attachment A: Affected Serial Number List**