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URGENT: MEDICAL DEVICE COMMUNICATION

HeartWare™ Ventricular Assist Device (HVAD™) System:

Update regarding HVAD power source management and Autologs feature

April 03, 2024

Dear Health Care Professional,

As a follow-up to prior communications[†], Medtronic is providing this letter to **(1)** communicate updates to patient management recommendations around power source management and **(2)** inform you about new information included in Autologs and HVADlogs reports. Updated rates relating to failure or delay to restart events are similar to what have been previously communicated (see Appendix C). Medtronic is sending this communication to all clinicians with patients currently on HVAD support.

Given the potential for adverse events resulting from inappropriate power source management, we are taking the opportunity to emphasize and reiterate the importance of following appropriate power source management and controller alarm response by patients. Therefore, a letter reinforcing this information will be sent to patients directly on May 08, 2024.

Overview:

1. **Patient power source management recommendations:** Controller exchanges should be performed in a clinical setting unless directed by a high priority alarm or your VAD clinical team. It is recommended that a controller AC adapter be attached to any controller (standard controllers and controllers with the unapproved algorithm) being used to restart a stopped pump. **If a controller AC adapter is unavailable, connect two fully or partially charged batteries to the controller as soon as possible during any pump restart attempt.**

   During a pump restart, high power consumption will occur with use of the unapproved software algorithm controller or during repeated restart attempts due to a hard to start pump with a standard controller. Operating on a single battery during these attempts may cause the controller to enter a reset cycle rendering it unable to restart the pump or sound alarms. Connecting a second battery or AC/DC adapter will terminate the reset cycle. The reset condition has been observed in 11.8% of the delay or failure to restart events. In these cases, the reset cycle was resolved, and restart attempts resumed.

During normal operation, ALWAYS ensure two power sources are connected to the controller (standard controllers and controllers with the unapproved algorithm). NEVER disconnect both power sources (batteries and AC or DC adapter) from the controller at the same time. It is recommended that sites reinforce education of their patients regarding device management and alarm troubleshooting at regular intervals. Patient management recommendations in Appendix A have been reorganized and updated and it is imperative that they be reviewed in full.

2. **Autologs and HVADlogs: Medtronic recommends taking advantage of our complimentary HVADlogs and Autologs service by uploading controller logfiles with each patient visit.** New information regarding motor start events is now available in HVADlogs and will be included in Autologs reports starting April 08, 2024. While this additional logfile information detailed below may indicate that a pump may experience difficulty restarting when stopped, there are known limitations of this data. Clinical conditions, including but not limited to thrombus, hematocrit variation, and suction, affecting patient hemodynamics during motor start events may impact these parameters.
   - HVAD controllers record "motor start" events and their associated pump start parameters (e.g., starting power, voltage and current).
   - Higher pump start parameters indicate that the HVAD pump was more difficult to start.
   - Pump starts with parameters outside the typical range will contain additional notes in Autologs reports (see Figure 1 below - data highlighted in red box).
   - If an Autologs report includes this additional note, Medtronic requests clinicians to take the action of submitting the logfiles to HVADlogs for further review by the Medtronic Technical Services Team.
   - Your Medtronic Representative will then reach out to discuss the motor start events and how those events may be useful in the management of your patient.

   These motor start events are just one additional piece of data to consider when managing your patients, for example when creating individual patient management plans for controller exchanges.

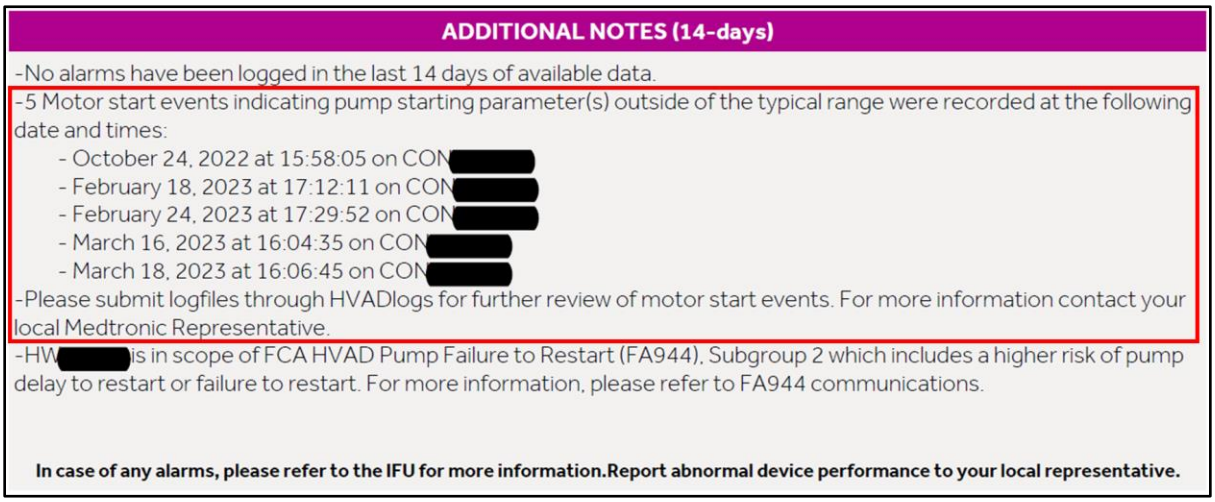


Figure 1. Example of Autologs report with notification of motor start events outside of typical range

Customer Actions:

- Complete the enclosed Customer Confirmation Form. When complete please return the form to rs.cfqfca@medtronic.com.
- Please share this notice with all those who need to be aware within your organization.
- Please discuss this new information with your patients as appropriate.
- Medtronic has provided a Patient Communication Template to facilitate your discussions with patients (attached).

Additional Information:

Adverse reactions or quality problems experienced with this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form from www.fda.gov/medwatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

We appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Field Representative.

Sincerely,

Gail Schroeder
Vice President, Quality and Regulatory
Medtronic Mechanical Circulatory Support

†Prior communications: December 2020, May 2021, December 2021, October 2022, August 2023, and December 2023

Detailed Information:

Appendix A – Patient management recommendations

Appendix B – Descriptions of event information, including clinical experience with unapproved controller software algorithm in all populations.

Appendix C – Competing risks analysis: cumulative failure rates over time for each device population

Appendix D – Model and serial numbers of active devices included in the existing subgroups. Device serial numbers for pumps that are confirmed to no longer be in use are not included in the Appendix D list.

APPENDICES

Appendix A: Patient Management Recommendations

Medtronic recommends that treatment decisions for all patients should be determined on an individual case-by-case basis, and that healthcare providers have prepared an individualized patient management plan for each subgroup patient, especially patients in subgroup 2. Controller exchanges should be performed in a clinical setting unless directed by a high priority alarm or your VAD clinical team.

It is recommended that healthcare providers speak with their patients to emphasize avoidance of unnecessary pump stops and reinforce education regarding device management and alarm troubleshooting on a regular basis. It is important to note that this issue does not cause a running pump to stop; rather, a failure to restart may follow a pump stop event.

A controller AC adapter should be attached to any controller (standard controllers and controllers with the unapproved algorithm) being used to restart a stopped pump. Using an AC adapter will provide consistent power and allow for the most efficient troubleshooting and restart attempts. If a controller AC adapter is unavailable, connect two fully or partially charged batteries to the controller as soon as possible during any pump restart attempt.

During a pump restart, high-power consumption will occur with use of the unapproved algorithm controller or during repeated start attempts due to a hard to start pump with a standard controller. Operating on a single battery during these attempts may cause the controller to enter a reset cycle rendering it unable to restart the pump or sound alarms. To break the reset cycle, connect a second power source.

Additionally, during sustained periods of high-power consumption with repeated start attempts while on battery power only, the batteries may be temporarily unable to provide power. This is a safety design of the batteries. Using an AC adapter will avoid this issue and provide consistent power.

Reinforce the HVAD system patient manual (PM) and instructions for use (IFU)

Since failure to restart events are based on a pump stop event, reinforce directions within the PM and IFU to patients and staff to prevent unnecessary pump stops:

- Do NOT disconnect the driveline from the controller.
- ALWAYS ensure two power sources are connected to the controller (standard controllers and controllers with the unapproved algorithm).
- 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.

When Considering a Controller Exchange

- 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 status and/or therapeutic recovery potential.
  - Distance and time it will take for the patient to reach the hospital/clinic for support.
  - Patient and caregiver understanding and compliance with alarm response protocols and power source management to prevent unnecessary pump stops.
- 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.
- 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 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 by the VAD team using a HeartWare monitor; however, clinicians should consider the associated risks before doing so.

When a Controller Exchange is Deemed Necessary

- Inform patients to contact their VAD coordinator prior to any controller exchange, and to coordinate performing an exchange of controllers in a clinical setting unless directed by a high priority alarm.
- **Controller exchanges for subgroup patients should be performed under clinician supervision in a controlled environment with the immediate ability to support the patient hemodynamically.**
- When performing a controller exchange:
  - Ensure a controller AC adapter is attached as one of the power sources.
  - If a controller AC adapter is unavailable, connect two charged batteries to the controller as soon as possible during any pump restart attempt.
  - If the pump does not restart after five (5) attempts on a standard controller and a [VAD Stopped] alarm is triggered, consider a controller exchange to a controller with the

unapproved algorithm, if available. Clinical experience using the controller with the unapproved algorithm is documented in Appendix B.

- Subsequently, if the pump does not restart after five (5) attempts and a [VAD Stopped] alarm is triggered, 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 start, proceed with hemodynamic support, and possible pump exchange.

Use of a Controller with Unapproved Algorithm

- Controllers with the unapproved algorithm should **only** be used when a controller exchange has been deemed necessary for a patient after a standard controller has been unable to restart the pump.
- As previously recommended, continue to avoid unnecessary pump stops. It is not known how effective the unapproved controller algorithm will be in restarting pumps.
- When possible, attach a controller AC adapter to the controller being used to restart a stopped pump. If a controller AC adapter is unavailable, connect two fully or partially charged batteries to the controller as soon as possible during any pump restart attempt.
- During normal operation, ALWAYS ensure two power sources are connected to the controller.
- Considerations should be made on an individual case-by-case basis when deciding whether to electively perform a controller exchange. If you determine in your medical judgment that potentially using a controller with the unapproved algorithm is the best option for your patient, consider waiting to perform an elective exchange until a controller with the unapproved algorithm has been provided to you.
- The availability of a controller with the unapproved algorithm should not influence your decision to perform an elective controller exchange.
- A controller exchange will stop the pump which can result in a pump failure to restart. The controller with the unapproved algorithm may not be successful in restarting pumps that do not restart with a standard controller.
- Medtronic will also provide you with a patient informed consent form (ICF) template that you may use, to be completed and signed by the patient prior to use of the unapproved controller algorithm. Prior to use Medtronic asks that you work with your institution's review processes (such as IRB or Risk Management Board). If you use one of the modified controllers in the future, we request that you please return the form to the Medtronic MCS Office of Medical affairs at: rs.mcsmedicalaffairs@medtronic.com.
- It is recommended that you discuss the unapproved controller algorithm with your patients in advance and obtain consent in the event that the unapproved controller algorithm is needed.

Requesting a controller with unapproved algorithm: To request a controller with the unapproved algorithm, please contact your local Medtronic Field representative to help determine next steps, including confirmation of the controller's availability in your country.

When Considering a Pump Exchange

- Routine prophylactic explant of the HVAD pump is not recommended, as risks associated with explantation may outweigh the potential benefits[1]. 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.

- Whether the patient is a candidate for an elective pump exchange depends on, but is not limited to:
  - whether the patient has a Do Not Resuscitate (DNR) order
  - co-morbidities
  - length of time the patient is expected to remain on therapy, whether the patient is bridge to transplant, or the patient is destination therapy.

[1] Salerno CT, Jorde UP, Molina E, Cantor R, Pagani FD, Kirklin J. Elective HeartWare HVAD to HeartMate 3 Pump Exchange: Risk Mitigation or Increasing Risk? Ann Thorac Surg. 2022 Dec 23:S0003-4975(22)01610-1. doi: 10.1016/j.athoracsur.2022.12.023. Epub ahead of print. PMID: 36572060.

Appendix B: Current Failure or Delay to Restart Rates

Tables 1 and 2 summarize pump populations and current observed events of failure or delay to restart, and events in subgroups 1, 2 and 3:

Group	# of Pumps Distributed	Cumulative Event Total	Related Death Events
Subgroup 1	316	13	4
Subgroup 2	174	44	14
Subgroup 3	1,027	41	13
General Population	21,511	148	32
Totals	**23,028**	**246**	**63**

Table 1: Cumulative event data by pump population

Category	# of Events
Death	31
Reoperation with VAD exchange	21
Intraoperative Pump Exchange	7
Cardiac Arrest	1
Hospitalization	14
Worsening Heart Failure	1
Neurological	1
Hypoperfusion	1
Asymptomatic VAD stop event	21
Total # of Events	**98**

Table 2: Total number of events categorized for Subgroups 1, 2 and 3

Clinical experience using the controller with the unapproved algorithm through January 2024

To provide clinicians information on the use of the controller with the unapproved algorithm in order to make informed decisions, clinical experience information is as follows:

There have been 17 instances where a controller with the unapproved algorithm has been used in an attempt to restart an HVAD pump. The pump restarted in 15 of the 17 instances. Of the 15 restarts, two (2) were subgroup 2 patients, four (4) were subgroup 3 patients, and nine (9) were general population patients. No adverse events have been reported from use of the controller with the unapproved algorithm in the 15 successful use cases. For the two unsuccessful use cases, the clinical information is as follows:

- The first instance in which the controller with the unapproved algorithm was unsuccessful was for a patient who required a controller exchange in July 2022. This patient's pump was in the general population and the patient was not a candidate for a pump exchange. The patient's pump had been off for over 18 hours. After five failed restart attempts using a standard backup HVAD controller, the clinician exchanged to the HVAD controller with the unapproved algorithm. The pump did not restart after multiple attempts using the controller with unapproved algorithm. The patient was placed under hospice care.
- The second instance in which the controller with the unapproved algorithm was unsuccessful was for a general pump population patient who experienced an unexpected pump stop and [VAD

Stopped] alarm at home. The patient exchanged their controller to their backup standard controller, which failed to restart the pump. The patient was transferred to the hospital where the controller with the unapproved algorithm was attempted but was unsuccessful at restarting the pump. The pump remained off for an unknown amount of time and the next day the patient's pump was exchanged to another commercially available device.

It is not known if any of these results will be typical or representative.

Appendix C: Cumulative Failure Rates for each Device Population

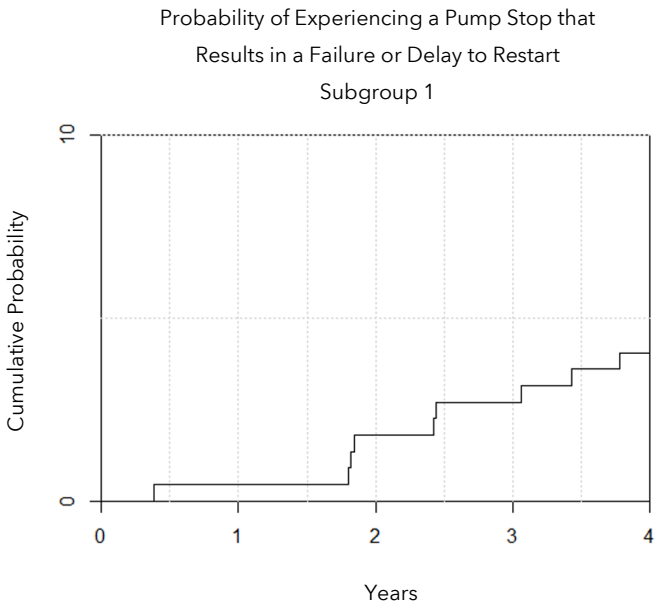
Table 3 below presents the cumulative probabilities of experiencing a pump stop resulting in either a failure or delay to restart, or a failure or delay to restart leading to a device exchange, decommission, or death after three (3) years. These probabilities are similar to what have been previously communicated.

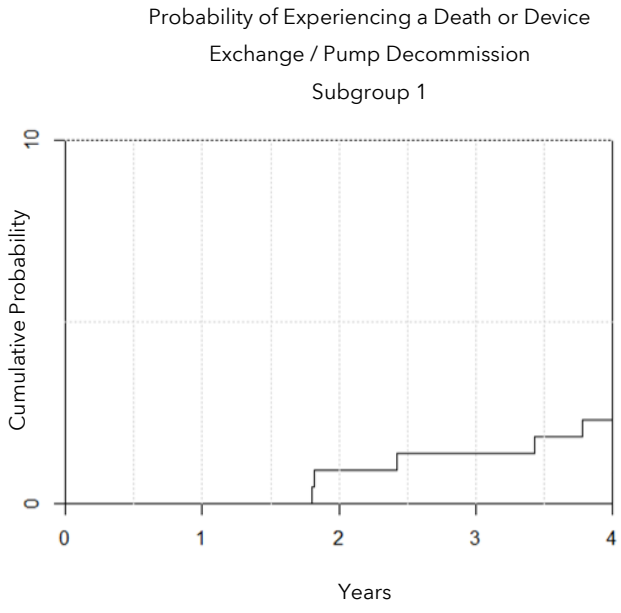
Group	**Patients on support globally**	**Cumulative probability of experiencing a pump stop resulting in failure or delay to restart (at 3 years)**	**Cumulative probability of device exchange, decommission, or death due to a failure or delay to restart pump event (at 3 years)**
Subgroup 1	31	2.7%	1.4%
Subgroup 2	13	30.2%	26.8%
Subgroup 3	~252	3.1%	2.3%
General Population	~1,754	0.5%	0.1%

Table 3. Cumulative probabilities for each subgroup and general population at 3 years

Note: Figures on the left below illustrate the rate of pumps failing or delaying to restart at each year on support. Figures on the right below illustrate the rate of pumps failing to restart that resulted in pump decommission, death or device exchange at each year on support.

SUBGROUP 1





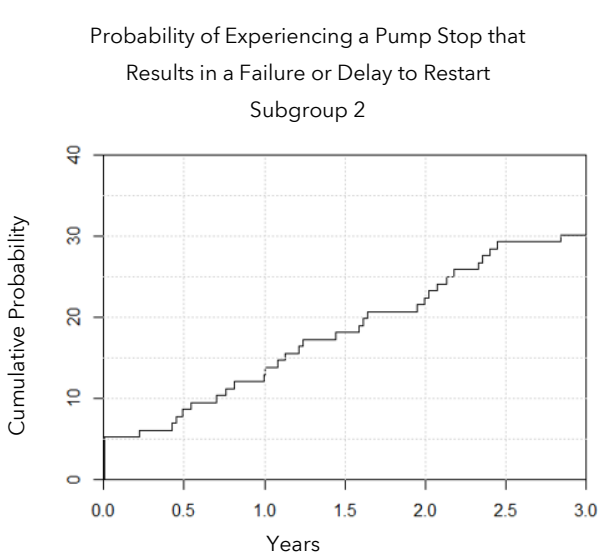
Year	**Probability of Failure (95% confidence interval)**
1	0.45% (0.1%, 3.2%)

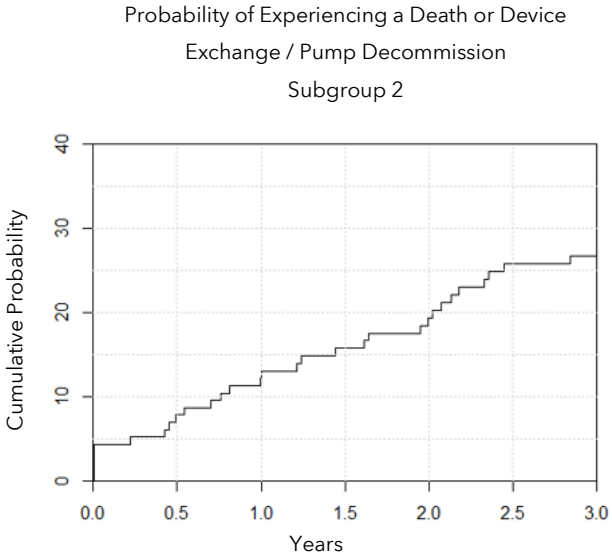
Year	**Probability of Failure (95% confidence interval)**
1	0%

2	1.8% (0.7%, 4.7%)	2	0.9% (0.2%, 3.6%)
3	2.7% (1.2%, 5.9%)	3	1.4% (0.4%, 4.2%)
4	4.0% (2.1%, 7.7%)	4	2.3% (1.0%, 5.5%)

Figure 2: Cumulative incidence of experiencing a pump stop with delay/failure to restart (left) and the cumulative incidence of failures leading to a pump exchange or death (right) in Subgroup 1.

SUBGROUP 2



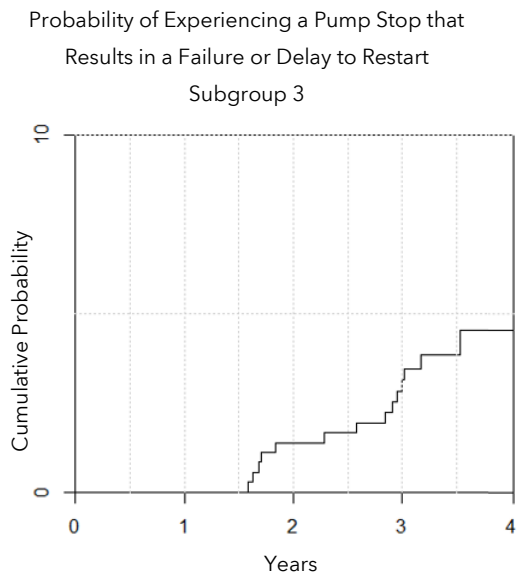


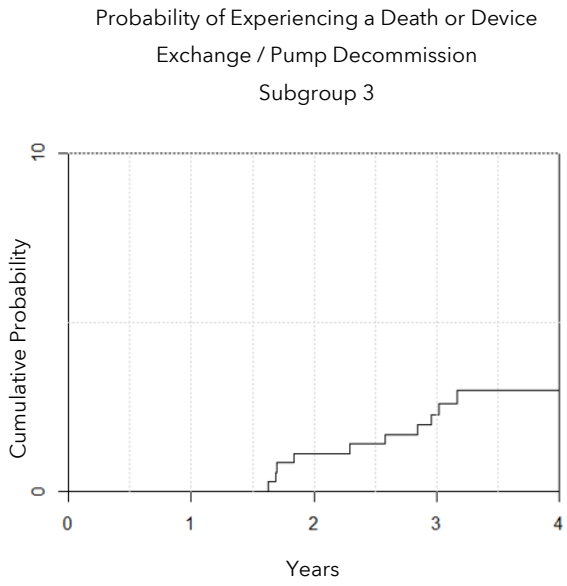
Year	Probability of Failure (95% confidence interval)
1	12.9% (8.1%, 20.7%)
2	22.4% (16.0%, 31.4%)
3	30.2% (22.9%, 40.0%)

Year	Probability of Failure (95% confidence interval)
1	12.1% (7.4%, 19.8%)
2	19.4% (13.3%, 28.2%)
3	26.8% (19.7%, 36.4%)

Figure 3: Cumulative incidence of experiencing a pump stop with delay/failure to restart (left) and the cumulative incidence of failures leading to a pump exchange or death (right) in Subgroup 2.

SUBGROUP 3



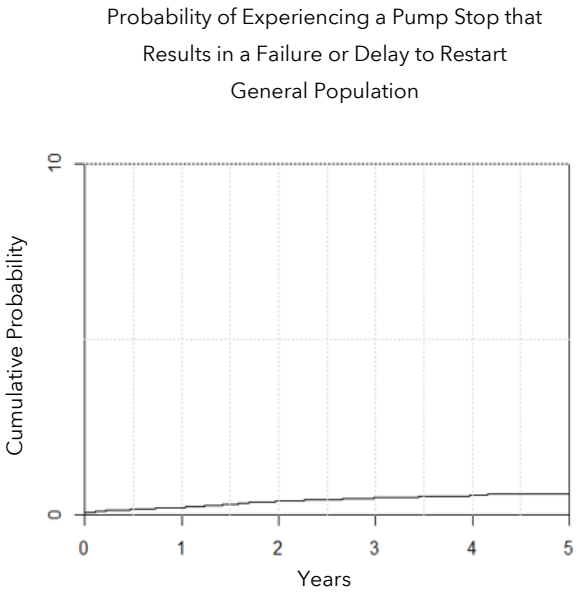


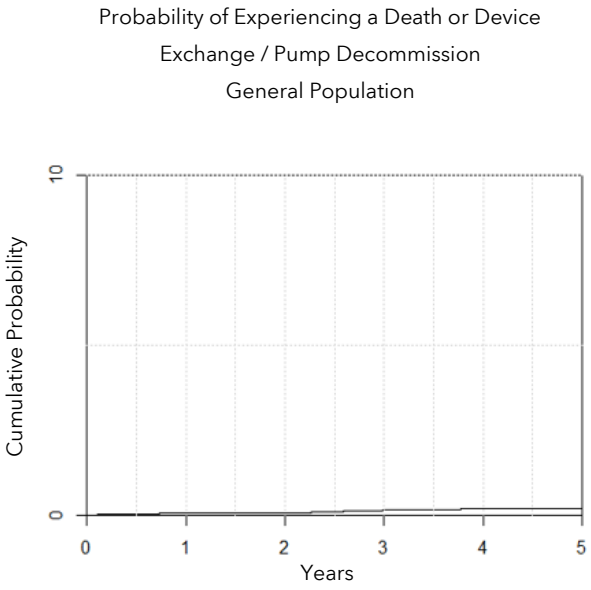
Year	Probability of Failure (95% confidence interval)
1	0%
2	1.4% (0.6%, 3.3%)
3	3.1% (1.7%, 5.6%)
4	4.5% (2.6%, 7.8%)

Year	Probability of Failure (95% confidence interval)
1	0%
2	1.1% (0.4%, 2.9%)
3	2.3% (1.1%, 4.5%)
4	3.0% (1.6%, 5.5%)

Figure 4: Cumulative incidence of experiencing a pump stop with delay/failure to restart (left) and the cumulative incidence of failures leading to a pump exchange or death (right) in Subgroup 3.

GENERAL POPULATION PUMPS





Year	Probability of Failure (95% confidence interval)
1	0.2% (0.1%, 0.3%)
2	0.4% (0.3%, 0.5%)
3	0.5% (0.3%, 0.6%)
4	0.5% (0.4%, 0.7%)
5	0.6% (0.4%, 0.7%)

Year	Probability of Failure (95% confidence interval)
1	0.04% (0.01%, 0.1%)
2	0.06% (0.03%, 0.1%)
3	0.1% (0.08%, 0.2%)
4	0.2% (0.1%, 0.3%)
5	0.2% (0.1%, 0.3%)

Figure 5: Cumulative incidence of experiencing a pump stop with delay/failure to restart (left) and the cumulative incidence of failures leading to a pump exchange or death (right) in the general population.

Appendix D: Serial numbers of delivered devices by country. ***

***Note: The below lists for each subgroup population only include devices that Medtronic has either confirmed to be active or has not confirmed to be inactive as of Nov 2023. The below lists do not include confirmed inactive pumps, and accordingly, are not all inclusive of all affected pumps ever sold/implanted.

Devices in Subgroup 1

Country	Model Number	Serial Number
United States	1103	HW30553, HW30942, HW31041, HW31043, HW31099, HW31181, HW31191, HW31212, HW31327, HW31344, HW31613, HW31785, HW32312, HW32362, HW32417, HW32425, HW32439, HW40169

Devices in Subgroup 2

Country	Model Number	Serial Number
United States	1103	HW35425, HW40054, HW40762, HW40767

Devices in Subgroup 3

Country	Model Number	Serial Number
United States	1103	HW40857, HW40870, HW40875, HW40876, HW40902, HW40916, HW40924, HW40925, HW41038, HW41044, HW41054, HW41058, HW41060, HW41072, HW41073, HW41076, HW41077, HW41084, HW41098, HW41100, HW41104, HW41111, HW41124, HW41137, HW41138, HW41154, HW41158, HW41167, HW41172, HW41207, HW41385, HW41388, HW41394, HW41400, HW41410, HW41412, HW41419, HW41421, HW41424, HW41425, HW41427, HW41431, HW41432, HW41435, HW41438, HW41441, HW41443, HW41444, HW41451, HW41453, HW41456, HW41459, HW41461, HW41463, HW41464, HW41468, HW41470, HW41478, HW41481, HW41492, HW41497, HW41517, HW41519, HW41524, HW41525, HW41526, HW41529, HW41541, HW41548, HW41551, HW41556, HW41577, HW41578, HW41588, HW41589, HW41603, HW41614, HW41616, HW41618, HW41626, HW41627, HW41630, HW41631, HW41650, HW41657, HW41659, HW41662, HW41664, HW41666, HW41668, HW41678, HW41679, HW41681, HW41688, HW41692, HW41702, HW41703, HW41712, HW41719, HW41731, HW41735, HW41748, HW41756, HW41787, HW41795, HW41797, HW41807, HW41812, HW41814, HW41816, HW41820, HW41821, HW41822, HW41823, HW41836, HW41841, HW41844, HW41861, HW41866, HW41867, HW41873, HW41880, HW41508