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URGENT: MEDICAL DEVICE COMMUNICATION

HeartWare™ Ventricular Assist Device (HVAD™) System:

Communication update regarding failure/delay to restart pump events

24 August 2023 | 14:03 SGT

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Health Care Professional,

This letter is a follow-up to our 22 December 2020, 02 July 2021, 09 March 2022, and 14 October 2022 communications titled "Urgent Medical Device Communication," where Medtronic communicated that an identified subpopulation (defined as subgroups 1 and 2) 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. **Medtronic is providing this letter (1) to inform you about an additional subgroup population, subgroup 3, defined below; (2) to communicate current failure rates associated with a failure/delay to restart pump event and (3) to reiterate existing patient management recommendations.** Medtronic is sending this communication to all clinicians with patients currently on HVAD support. **It is important to note that this issue does not cause a running HVAD pump to stop; rather, the pump may fail to restart after a pump stop event.**

Summary Information:

1. Initially, the restart failure rate of pumps in **subgroup 3** was in line with that of the general HVAD population. However, as the duration of support has increased, the failure rate has risen and now resembles the higher rate observed in subgroup 1. See Appendix A for a detailed description of subgroups and patient events. See Appendix D for the list of serial numbers of devices in subgroup 3.

2. **Patient management recommendations previously communicated for subgroups 1 and 2 have not changed and also apply to subgroup 3. (See Appendix C).**

3. Table 1 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. See Appendix B for additional information on cumulative failure rates over time for each device population.

Table 1. Cumulative probabilities for each subgroup and general population at 3 years

Group	Patients on Support	Cumulative probability of experiencing a pump that results in a 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	38	2.7%	1.4%
Subgroup 2	17	31.0%	27.5%
Subgroup 3	~300	3.3%	3.0%
General Population Pumps	~2,000	0.5%	0.1%

Detailed Information:

Appendix A – Descriptions of subgroups 1-3 and event information

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

Appendix C – Patient management recommendations

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

Please discuss this new information with your patients as appropriate. Medtronic has provided a Patient Communication Template to facilitate your discussions with patients (attached).

Customer Actions:

- Complete the enclosed Customer Confirmation Form. Hand or scan then send back to your local Medtronic field representative once completed.
- Please share this notice with all those who need to be aware within your organization.

Additional Information:

Adverse reactions or quality problems experienced with this product should be reported to your local Medtronic field representative.

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

Sincerely,

DocuSigned by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 24 August 2023 | 14:02 SGT

90D0724C9B1C402A99B286449A1644B8

Quality and Regulatory Affairs Director
Mainland and Island Southeast Asia

Appendix A: Current Failure or Delay to Restart Rates

There have been two (2) suppliers (Supplier A and Supplier B) of the HVAD pump impeller component. A pump failure or delay to restart is linked to an interaction between the impeller and the top housing. Medtronic has identified three distinct subgroups from specific impeller manufacturing lots that have a higher occurrence rate than the general pump population. All affected impellers were produced by Supplier B. Previous communications have discussed subgroups 1 and 2. Current data analysis has identified a third subgroup (described below).

- **SUBGROUP 1** includes 316 distributed pumps manufactured from the first lot of impellers from supplier B, exhibiting 13 events of a delay or failure to restart, 4 of which involved a patient death. Our records indicate there are currently 38 patients on support with a pump from subgroup 1.
- **SUBGROUP 2** includes 174 distributed pumps manufactured from the 2 subsequent lots of impellers from supplier B, exhibiting 43 events of a delay or failure to restart, 14 of which involved a patient death. Our records indicate that there are currently 17 patients on support with a pump from subgroup 2.
- **SUBGROUP 3** includes 1,027 distributed pumps manufactured from the remaining 8 additional lots of impellers from supplier B, exhibiting 32 events of a delay or failure to restart, 9 of which involved a patient death. Our records indicate there are approximately 300 patients on support with a pump from subgroup 3. The failure rate in this population initially aligned with the general population; however, it has increased over time and is now similar to the rate of subgroup 1.
- **GENERAL POPULATION PUMPS.** Pumps in the general population are manufactured with impellers from supplier A. Our records indicate there are currently approximately 2,000 patients on support in the general population.

Table 2 below summarizes the 88 patient events reported in Subgroups 1, 2 and 3:

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

Category	# of Events
Death	27
Reoperation with VAD exchange	22
Intraoperative Pump Exchange	6
Cardiac Arrest	1
Hospitalization	11
Worsening Heart Failure	1
Hypoperfusion	1

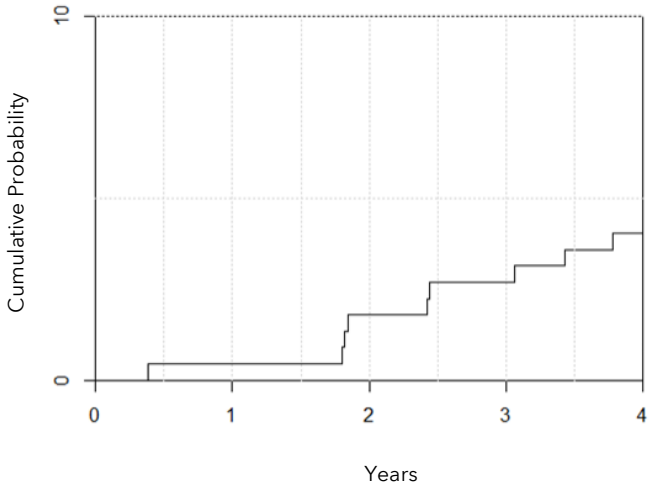
Asymptomatic VAD stop event	19
Total # of Events	**88**

Appendix B: Cumulative Failure Rates for each Device Population

Note: Figures on the left illustrate the rate of pumps failing/delaying to restart at each year on support. Figures on the right illustrate the rate of pumps failing to restart that resulted in death or device exchange at each year on support. Based upon the implant duration for each subgroup the occurrence rates were analyzed to include all available data.

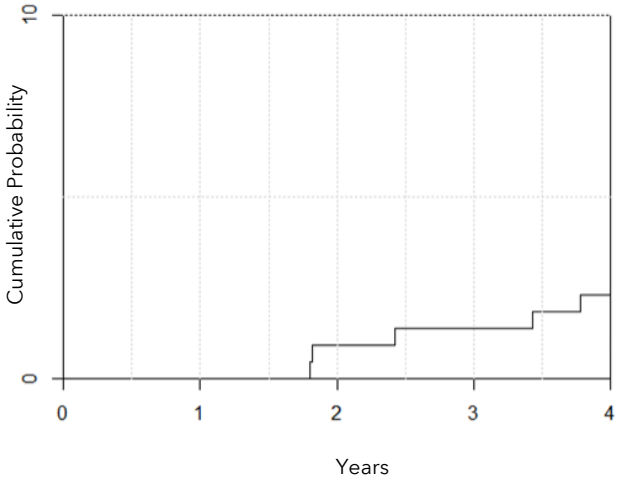
SUBGROUP 1

Probability of Experiencing a Pump Stop that Results in a Failure or Delay to Restart
Subgroup 1



Year	Probability of Failure (95% confidence interval)
1	0.4% (0.1%, 3.2%)
2	1.8% (0.7%, 4.7%)

Probability of Experiencing a Death or Device Exchange / Pump Decommission
Subgroup 1



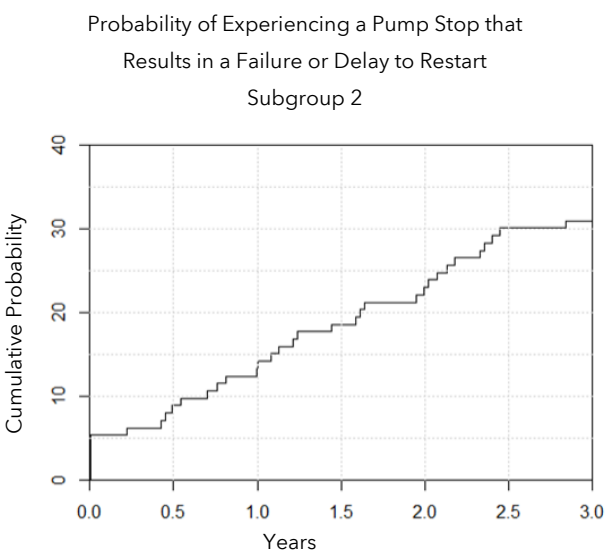
Year	Probability of Failure (95% confidence interval)
1	0%
2	0.9% (0.2%, 3.6%)

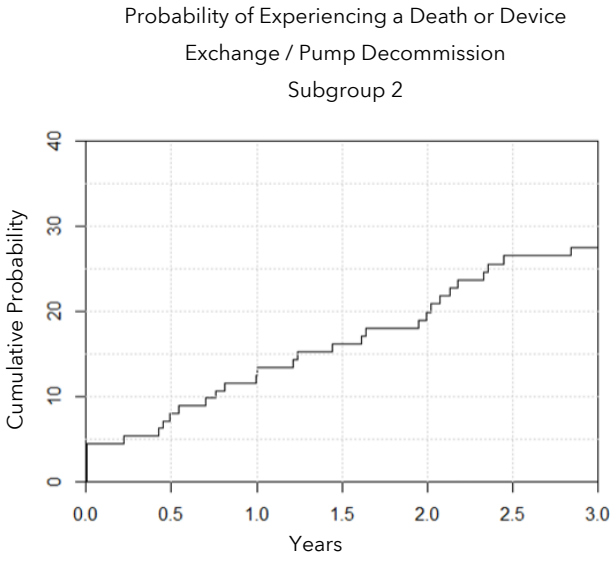
3	2.7% (1.2%, 5.9%)
4	4.0% (2.1%, 7.7%)

3	1.4% (0.4%, 4.2%)
4	2.3% (1.0%, 5.5%)

Figure 1: 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





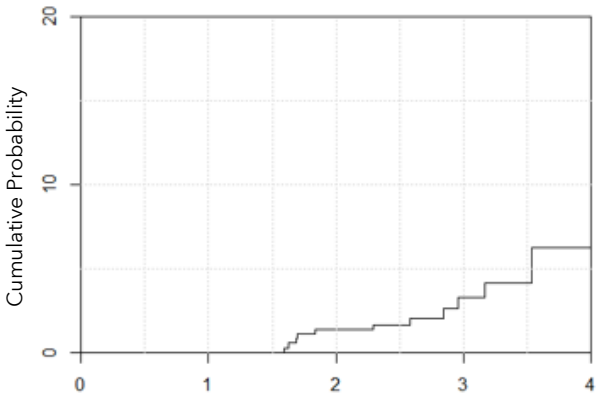
Year	Probability of Failure (95% confidence interval)
1	13.3% (8.3%, 21.3%)
2	23.0% (16.4%, 32.2%)
3	31.0% (23.5%, 40.8%)

Year	Probability of Failure (95% confidence interval)
1	12.5% (7.6%, 20.3%)
2	19.9% (13.7%, 29.0%)
3	27.5% (20.3%, 37.4%)

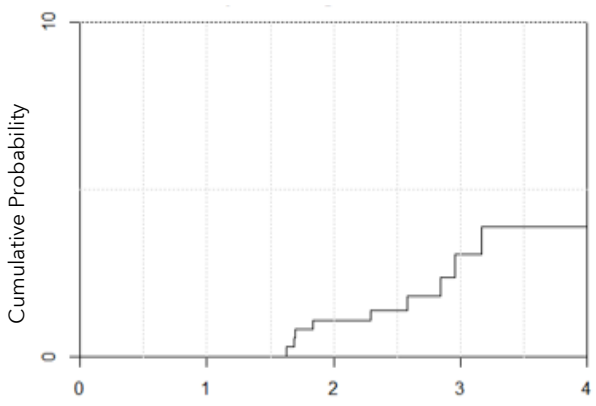
Figure 2: Cumulative incidence of experiencing a pump stop with delay/failure to restart (left) and the cumulative incidence of failures leading to a pump exchange or death (right) in Subgroup 2.

SUBGROUP 3

Probability of Experiencing a Pump Stop that Results in a Failure or Delay to Restart
Subgroup 3



Probability of Experiencing a Death or Device Exchange / Pump Decommission
Subgroup 3



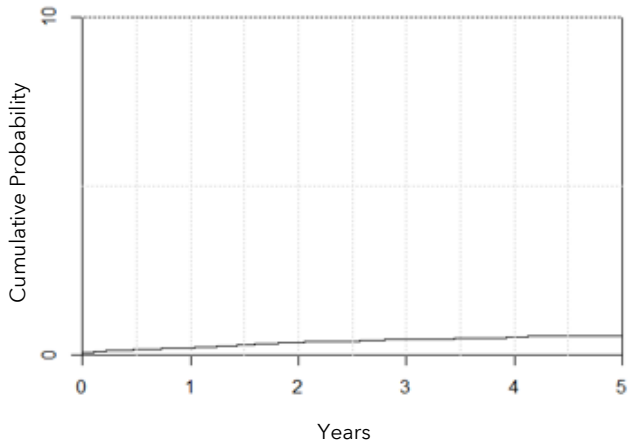
Year	Probability of Failure (95% confidence interval)
1	0%
2	1.3% (0.6%, 3.2%)
3	3.3% (1.7%, 6.6%)
4	6.2% (2.9%, 13.3%)

Year	Probability of Failure (95% confidence interval)
1	0%
2	1.1% (0.4%, 2.8%)
3	3.0% (1.5%, 6.3%)
4	3.9% (1.9%, 7.9%)

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 3.

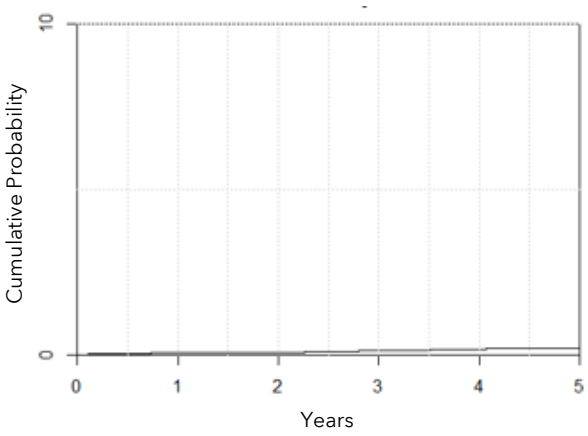
GENERAL POPULATION PUMPS

Probability of Experiencing a Pump Stop that Results in a Failure or Delay to Restart
General Population



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	0.5% (0.4%, 0.7%)

Probability of Experiencing a Death or Device Exchange / Pump Decommission
General Population



Year	Probability of Failure (95% confidence interval)
1	0.04% (0.01%, 0.1%)
2	0.05% (0.02%, 0.1%)
3	0.1% (0.07%, 0.2%)
4	0.2% (0.1%, 0.3%)
5	0.2% (0.1%, 0.3%)

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 the general population.

Appendix C: Patient Management Recommendations

It is recommended that management of patients in the new subgroup 3 follow the recommendations previously provided for subgroups 1 and 2 (see below) and to have prepared an individualized care plan for each subgroup patient, especially patients in subgroup 2. Described below are the patient management recommendations previously provided regarding the delay or failure to restart issue, including considerations for formulating individualized patient management plans.

All Patients on support

- It is recommended that all HVAD healthcare professionals and all HVAD patients, when possible, attach a Controller AC adapter to the controller being used to restart a stopped pump (e.g., during a controller exchange connect the AC adapter to the oncoming controller). Using an AC adapter will provide consistent power and allow for the most efficient troubleshooting and restart attempts. During a sustained period of high-power consumption (i.e., when the HVAD pump is attempting to restart repeatedly), the battery may be temporarily unable to provide power.

Patients in Subgroups 1, 2, and 3

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 subpopulation of devices (subgroup 1, subgroup 2 and subgroup 3) should be determined on an individual case-by-case basis, and that 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, a failure to restart may follow a pump stop event.

Reinforcing IFU

- Since failure to restart is predicated on a pump stop event, reinforce directions within the IFU to patients and staff 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 a pump in subgroup 1, 2 or 3 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 and/or 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 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 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, consider proceeding with hemodynamic support, and possible pump exchange.

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[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. 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 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 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. 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, HW31568, HW31613, HW31652, HW31765, HW31785, HW32284, HW32312, HW32362, HW32417, HW32425, HW32439, HW40169
Germany	1104	HW30769, HW30954, HW31235, HW31543, HW32260, HW32499
Kazakhstan	1104	HW31079
Lebanon	1104	HW31018, HW35021
Netherlands	1104	HW31096, HW31164, HW31173
Spain	1104	HW30797
Turkey	1104	HW30798
United Kingdom	1104	HW30803, HW30840

Devices in Subgroup 2

Country	Model Number	Serial Number
United States	1103	HW35425, HW40054, HW40732, HW40762, HW40767
Belgium	1104	HW35503
Czech Republic	1104	HW35897
Cyprus	1104	HW35614
Finland	1104	HW35662
Germany	1104	HW35969, HW35996
Netherlands	1104	HW35823
Serbia	1104	HW35930
Turkey	1104	HW35228, HW35915, HW36106
United Kingdom	1104	HW35391

Devices in Subgroup 3

Country	Model Number	Serial Number
United States	1103	HW40857, HW40870, HW40875, HW40876, HW40902, HW40905, HW40916, HW40924, HW40925, HW41038, HW41054, HW41058, HW41060, HW41072, HW41073, HW41076, HW41077, HW41084, HW41097, 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
Australia	1104	HW36028, HW36033, HW36126, HW36749, HW36851, HW36904, HW37237
Austria	1104	HW35976, HW36258, HW36818, HW41894, HW41895, HW41897, HW41936, HW41994,
Belgium	1104	HW36872, HW36876, HW37349, HW41927
Canada	1104	HW31983, HW36058, HW36059, HW36061, HW36062, HW36114, HW36115, HW36122, HW36146, HW36157, HW36158, HW36221, HW37174, HW37175, HW37176, HW37220, HW37266, HW37268, HW37269, HW37270
Croatia	1104	HW36451, HW36735, HW37201
Czech Republic	1104	HW35933, HW36208, HW36984, HW37236
Denmark	1104	HW36188, HW36238, HW41953
Egypt	1104	HW36533, HW36761, HW36794
Finland	1104	HW36297, HW36539, HW36865, HW37202
France	1104	HW34292, HW35963, HW36084, HW36087, HW36129, HW36171, HW36172, HW36263, HW36264, HW36265, HW36415, HW36689, HW36707, HW36992, HW36993, HW36994, HW37159, HW37160, HW37183, HW37209, HW37252, HW37254, HW41961, HW41962, HW41964, HW41965, HW41966, HW41967, HW41968, HW41970, HW42003, HW42011, HW42017
Germany	1104	HW35749, HW35972, HW35988, HW35994, HW35995, HW35997, HW36006, HW36007, HW36009, HW36013, HW36018, HW36021, HW36069, HW36174, HW36176, HW36179, HW36180, HW36186, HW36193, HW36195, HW36197, HW36198, HW36225, HW36226, HW36229, HW36230, HW36231, HW36259, HW36303, HW36314, HW36317, HW36318, HW36321, HW36325, HW36397, HW36430, HW36500, HW36502, HW36503, HW36504, HW36506, HW36507, HW36509, HW36511, HW36513, HW36514, HW36530, HW36563, HW36670, HW36672, HW36680, HW36681, HW36683, HW36685, HW36704, HW36708, HW36711, HW36712, HW36718, HW36722, HW36723, HW36724, HW36725, HW36726, HW36727, HW36750, HW36752, HW36753, HW36754, HW36755, HW36786, HW36816, HW36817, HW36823, HW36827, HW36829, HW36830, HW36832, HW36833, HW36837, HW36839, HW36853, HW36855, HW36877, HW36881, HW36882, HW36891, HW36897, HW36900, HW36937, HW36940, HW36945, HW36964, HW36966, HW36982, HW36988, HW36996, HW36997, HW36999, HW37002, HW37005, HW37184, HW37185, HW37186, HW37187, HW37188, HW37189, HW37190, HW37193, HW37194, HW37195, HW37212, HW37213, HW37214, HW37216, HW37222, HW37223, HW37225, HW37226, HW37228, HW37230, HW37231, HW37233, HW37234, HW37242, HW37245, HW37246, HW37273, HW41901, HW41934, HW41937, HW41938, HW41939, HW41940, HW41972, HW41974, HW41975, HW41977, HW41993, HW41997, HW42001, HW42005, HW42009, HW42021, HW42022, HW42026
Greece	1104	HW36147, HW36206, HW36826, HW36905, HW41921
Hong Kong	1104	HW36165, HW36494, HW36970, HW37205
Hungary	1104	HW36742, HW36745, HW36871, HW37200, HW37204, HW37206

Italy	1104	HW35999, HW36066, HW36086, HW36216, HW36219, HW36418, HW36516, HW36802, HW36820, HW36858, HW36859, HW36979, HW37272, HW41957, HW41959, HW41960, HW42023, HW42024
Japan	1104JP	HW40661, HW40953, HW40957, HW41047, HW41255, HW41544, HW41670, HW41672, HW41673, HW41674, HW41675, HW41696, HW41699, HW41700, HW41783, HW41791, HW41792, HW41803, HW41804, HW41828, HW41847
Kazakhstan	1104	HW36065, HW36078, HW36801, HW36822, HW36973, HW36985
Republic of Korea	1104	HW36160, HW36161, HW36163, HW36381, HW36385, HW36464, HW36470, HW36480, HW36482, HW36483, HW36484, HW36486, HW36487, HW36489, HW36492, HW36493, HW36495, HW36496, HW36497, HW36499, HW36519, HW36914, HW36915, HW36924, HW36926, HW36957, HW36958, HW36974, HW36976, HW36977, HW37255, HW37256, HW37257, HW37260, HW37261, HW37262, HW37329, HW37335, HW37342
Kuwait	1104	HW36346
Lebanon	1104	HW36043, HW36190, HW36191, HW36343, HW36907, HW36908, HW37250, HW37279
Macedonia	1104	HW36696
Netherlands	1104	HW36148, HW36674, HW36675, HW36676, HW36693, HW36863, HW36922, HW36923
New Zealand	1104	HW36527, HW36743, HW36771, HW36848
Norway	1104	HW37171, HW37173
Poland	1104	HW36143, HW36290, HW36453, HW36454, , HW36746, HW36797, HW41905, HW41910, HW41920, HW42019, HW36729, HW36737, HW36739, HW36741
Saudi Arabia	1104	HW36150, HW36744, HW36991
Serbia	1104	HW36202, HW36239, HW36731
Slovakia	1104	HW36046, HW36525, HW37249, HW41903, HW42018
South Africa	1104	HW36913, HW42006, HW42008
Spain	1104	HW36077, HW36524, HW41943, HW41944, HW41991, HW42002
Switzerland	1104	HW36508, HW36515, HW41932
Taiwan	1104	HW36456, HW36457, HW37177, HW37178
Turkey	1104	HW36001, HW36003, HW36035, HW36036, HW36039, HW36040, HW36048, HW36049, HW36054, HW36055, HW36088, HW36089, HW36094, HW36095, HW36096, HW36097, HW36101, HW36102, HW36170, HW36542, HW36757, HW36759, HW36760, HW36763, HW36764, HW36765, HW36766, HW36767, HW36768, HW36769, HW36775, HW36776, HW36777, HW36778, HW36779, HW36780, HW36781, HW36783, HW36791, HW36792, HW36805, HW36808, HW36809, HW36918, HW36946, HW36948, HW36950, HW36951, HW36952, HW36953, HW36954, HW36955, HW36956, HW36959, HW36960, HW36961, HW36962, HW37006, HW37007, HW37008, HW37010, HW37154, HW37155, HW37156, HW37157, HW37161, HW37164, HW37165, HW37166, HW37168, HW37169, HW41915, HW41916, HW41918, HW41919, HW41945, HW41946, HW41947, HW41948, HW41978, HW41979, HW41981, HW41982, HW41983, HW41984, HW41990
United Kingdom	1104	HW35950, HW36134, HW36440, HW36455, HW36520, HW36522, HW36846, HW36869, HW41924, HW42004, HW42007

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Customer Confirmation Form

Urgent Medical Device Communication

Medtronic HeartWare™ Ventricular Assist Device (HVAD) system

Communication update regarding failure/delay to restart pump events

For completion by Medtronic Customers Only – Please complete all fields below and return immediately

Medtronic is asking that you sign and date this form to acknowledge receipt of the enclosed letter.

Note: The addressee may continue to receive reminders of this notice until a response is received.

Customer Contact Details		Medtronic Contact Details
Distributor/Hospital/Clinic/Patient name:		**Name:**
		Contact:
Address:		**Email:**
Phone no:	**Email:**	

By signing this form, I confirm that I have read the Urgent Medical Device Communication Notification Letter, dated 24 August 2023 | 14:03 SGT **, from Medtronic regarding the HeartWare™ Ventricular Assist Device (HVAD) system listed above and will take appropriate action.**

Name (print): _____ Signature: _____ Stamp: _____ Date: dd Mmm yyyy

Please complete and sign the form as indicated below and hand or scan then email back to your local Medtronic field representative.

For questions, contact your local Medtronic field representative.