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Hayward, C.; Adachi, I.; Baudart, S.; Davis, E.; Feller, E.D.; Kinugawa, K.; ... ; VanderPluym, C.

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Christopher Hayward, MD, MBBS,[a] Iki Adachi, MD,[b] Sylvie Baudart, RN, BSN, MS, CCRN,[c] Erin Davis, BSN, RN,[d] Erika D. Feller, MD,[e] Koichiro Kinugawa, MD, PhD,[f] Liviu Klein, MD, MS,[g] Song Li, MD,[h] Angela Lorts, MD, MBA,[i] Claudius Mahr, DO,[h] Jacob Mathew, MBBS,[j] Michiel Morshuis, MD,[k] Marcus Müller, MD,[l] Minoru Ono, MD, PhD,[m] Francis D. Pagani, MD, PhD,[n] Federico Pappalardo, MD,[o] Jonathan Rich, MD,[p] Desiree Robson, RN, BSc(Hons),[q] David N. Rosenthal, MD,[r] Diyar Saeed, MD, PhD,[s] Christopher Salerno, MD,[t] Andrew J. Sauer, MD,[u] Thomas Schlöglhofer, MSc,[v] Laurens Tops, MD, PhD,[w] and Christina VanderPluym, MD[x]

ABSTRACT

Objectives: Six months after withdrawal of the HeartWare HVAD System (HVAD; Medtronic) from sale, approximately 4000 patients continue ongoing support with this device. In light of the diminishing experience, this global consensus document summarizes key management recommendations.

Methods: International experts with experience in the management of patients with ongoing HVAD support were invited to summarize key aspects of patient and pump management and highlight differences in the current HeartMate 3 (Abbott Laboratories) ventricular assist device. Clinicians from high-implanting HVAD sites reviewed current literature and reported experience to generate a consensus statement.

Results: Specific guidelines to assist in the management of ongoing HVAD patients are developed. Key management protocols and helpful techniques developed from experienced clinicians are combined into a short guideline document. As experience with HeartMate 3 increases, key differences in approach to management are highlighted, where appropriate.

Conclusions: With decreasing worldwide experience in the ongoing management of HVAD-supported patients, this consensus guideline provides a summary of best practice techniques from international centers. Differences in HeartMate 3 management are highlighted. (J Thorac Cardiovasc Surg 2022;164:1120-37)

Key aspects of the HVAD System (Medtronic) management: blood pressure and anticoagulation.

CENTRAL MESSAGE

After withdrawal of the HeartWare HVAD System (Medtronic), approximately 4000 patients continue on active support. In light of the diminishing experience, this global consensus document summarizes key management recommendations.

PERSPECTIVE

After withdrawal of the HeartWare HVAD System (Medtronic) from the market, there were significant concerns about ongoing management for patients still receiving active support. This global consensus provides best practice recommendations specific to HeartWare HVAD System patients, as well as significant differences in the HeartMate 3 pump (Abbott Laboratories).

See Commentary on page 1138.

From the [a]Heart Failure and Transplant Unit, [q]Heart Transplant Program, St Vincent's Hospital, Sydney, Australia; [b]Congenital Heart Surgery, Texas Children's Hospital, Baylor College of Medicine, Houston, Tex; [c]Department of Mechanical Circulatory Support, [g]Division of Cardiology, Department of Medicine, University of California San Francisco Medical Center, San Francisco, Calif; [d]University of Utah Health Transplant Service Line, Salt Lake City, Utah; [e]MedStar Health and Vascular Institute, Baltimore, Md; [f]Second Department of Internal Medicine, University of Toyama, Toyama, Japan; [h]Division of Cardiology, University of Washington, Seattle, Wash; [i]Division of Pediatric Cardiology, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio; [j]Department of Cardiology, The Royal Children's Hospital, Melbourne, Australia; [k]Department of Cardiothoracic Surgery, Heart and Diabetes Center, NRW, Bad Oeynhausen, Germany; [l]Department of Cardiothoracic and

Abbreviations and Acronyms

BP = blood pressure
CT = computed tomography
DLI = driveline infection
ECMO = extracorporeal membrane oxygenation
GIB = gastrointestinal bleeding
HF = heart failure
HQ = pump head flow
HVAD = Medtronic HeartWare HVAD System
INR = international normalized ratio
Intermacs = Interagency Registry for Mechanically Assisted Circulatory Support
ISHLT = International Society for Heart and Lung Transplantation
LV = left ventricular
LVAD = left ventricular assist device
MAP = mean arterial pressure
RPM = revolutions per minute
RV = right ventricular
RVF = right ventricular failure
STS = Society of Thoracic Surgeons
VAD = ventricular assist device

Scanning this QR code will take you to the table of contents to access supplementary information.

In the past decade, >18,000 patients with end-stage heart failure (HF) have received the Medtronic HeartWare HVAD System (HVAD) left ventricular (LV) assist device (LVAD), either as bridge-to-transplantation or as destination therapy. On June 3, 2021, Medtronic stopped global production and distribution of the HVAD.[1] This decision was made because of a higher frequency of neurologic events and all-cause mortality with the HVAD compared with the HeartMate 3 LVAD (Abbott Laboratories), and a number of failures of pump restart for which a root cause could not be consistently identified. In a recent report of the Society of Thoracic Surgeons (STS) Interagency Registry for Mechanically Assisted Circulatory Support (Intermacs), the 12-month survival of patients supported with the HVAD was 81%[2] and in the latest clinical trial with the HVAD, the 2-year freedom from disabling stroke was 95.0%.[3] At the end of 2021, it is estimated that approximately 4000 patients worldwide continue ongoing support with the HVAD.[4]

Several challenges have emerged after the removal of the HVAD for clinical use.[4] Preemptive replacement of the HVAD might remove the (small) risk of technical pump failure during use, however, a recent STS Intermacs analysis showed a lack of survival benefit if the HVAD is preemptively replaced by a HeartMate 3 LVAD, compared with continued HVAD support.[5] Although general guidelines are available for the management of LVAD patients,[6,7] there is a clear need for practical guidance on the optimal treatment of HVAD patients specifically. This document consolidates global clinical expertise in the technical and clinical management of patients supported with the HVAD to optimize patient outcomes throughout the duration of support.

PATIENT MANAGEMENT

Blood Pressure Management

Blood pressure (BP) management is of paramount importance in reducing the risk of adverse events in LVAD patients including strokes, thromboembolic events, right ventricular (RV) failure, and progressive aortic valve regurgitation.[8-10] Neurological events remain the number one cause of death in LVAD patients, significantly reducing quality of life, and might render patients ineligible for heart transplantation.[11] The best evidence for BP control in HVAD patients comes from the ENDURANCE Supplemental Trial in which an intensive BP control strategy targeting a mean arterial pressure (MAP) of ≤85 mm Hg

Vascular Surgery, German Heart Center Berlin, Berlin, Germany; [m]Department of Cardiac Surgery, University of Tokyo, Tokyo, Japan; [n]Department of Cardiac Surgery, University of Michigan, Ann Arbor, Mich; [o]Department CardioThoracic and Vascular Anesthesia and Intensive Care, AO SS Antonio e Biagio e Cesare Arrigo, Alessandria, Italy; [p]Division of Cardiology, Department of Medicine, Northwestern University, Feinberg School of Medicine, Chicago, Ill; [r]Department of Pediatrics, Stanford University and Lucille Packard Children's Hospital, Palo Alto, Calif; [s]University Department for Cardiac Surgery, Leipzig Heart Center, Leipzig, Germany; [t]Department of Surgery, University of Chicago Medicine, Chicago, Ill; [u]Department of Cardiovascular Medicine, University of Kansas School of Medicine, Kansas City, Kan; [v]Department of Cardiac Surgery, Medical University of Vienna, Vienna, Austria; [w]Heart and Lung Center, Leiden University Medical Center, Leiden, The Netherlands; and [x]Heart Center, Boston Children's Hospital, Harvard School of Medicine, Boston, Mass.

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Address for reprints: Christopher Hayward, MD, MBBS, Heart Failure and Transplant Unit, St Vincent's Hospital, Sydney, Victoria St, Darlinghgurst, New South Wales 2010, Australia (E-mail: cshayward@stvincents.com.au).

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reduced stroke incidence by 24.2% and hemorrhagic cerebrovascular accident by 50.5% compared with the HVAD-supported patients in the ENDURANCE trial.[12] The International Society for Heart and Lung Transplantation (ISHLT) guidelines also recommend a goal MAP of <80 mm Hg for continuous-flow LVADs.[6]

In addition to adverse events, BP is also a major determinant of LVAD pump output. The HVAD has a flatter pump head flow (HQ) curve than the previous HeartMate II (Abbott; axial flow) LVADs. At a fixed pump speed, aortic pressure, which directly correlates with pump head pressure gradient (ΔP [pressure gradient difference] = aortic pressure − LV pressure), has a significant effect on pump flow. Clinically, patients with uncontrolled hypertension might experience low cardiac output, residual HF symptoms, and ventricular arrhythmias. Because of the flatter HVAD HQ curve, low BP might cause excess LV unloading with subsequent RV volume overload, and might result in LV suction events especially in the case of small LV end-diastolic dimensions.

Measuring BP noninvasively in patients with an LVAD is challenging because most patients have diminished peripheral arterial pulse pressure. Traditional BP measurement methods such as auscultation of Korotkoff sounds and automated oscillometric BP cuffs[13] might fail to obtain a BP reading, and even when a reading is obtained, the accuracy is decreased.[13,14] Overall, the authors recommend the Doppler opening pressure method because of its wide availability, reliability, and validated accuracy as an estimate of MAP in all 3 US Food and Drug Administration-approved continuous-flow ventricular assist device (VAD) systems including the HVAD.[15,16] In patients only requiring partial support, in whom the aortic valve opens during systole, the opening pressure might be closer to the systolic pressure. In patients who are clinically suspected to have BP-related symptoms (dizziness, headache, very high or low VAD flow, etc), with Doppler opening pressure at goal (60-80 mm Hg), an arterial line study might be helpful to identify the rare patients in whom Doppler opening pressure does not correlate with MAP and to establish a new Doppler opening pressure goal.

Antiplatelet/Anticoagulation Therapy

The LVAD is a foreign metal object in left-sided circulation, and thus inherently thrombogenic. Nonpulsatile flow, platelet shear stress, regional stagnation of blood in the ventricle or pump, and endothelial activation continue to be important forces that contribute to the thrombogenicity of the LVAD system.[17] ISHLT guidelines recommend long-term aspirin therapy and vitamin K antagonism therapy to maintain an international normalized ratio (INR) of 2.0-3.0.[6] In the ENDURANCE Supplemental Trial with the HVAD device, an aspirin dose of 325 mg daily was used.[12] For patients intolerant to aspirin, clopidogrel 75 mg daily can be used.[18] When warfarin therapy has to be interrupted for surgery or other reasons, patients should be bridged with heparin. During treatment with intravenous heparin, anti-factor Xa monitoring is preferred because of often artificially prolonged activated partial thromboplastin time in LVAD patients.[19] For optimal outcomes, the HVAD device requires meticulous attention to anticoagulation. An INR of <2.0 should be bridged until in therapeutic range, to reduce the risk of stroke and device thrombosis with a weight and renal adjusted dose of enoxaparin as a daily dose. Direct thrombin inhibition (eg, dabigatran) is contraindicated.[20] Although factor Xa inhibitors have been used, there is insufficient evidence to support their recommendation.[21]

Medication Management

After LVAD implantation, many patients go from being essentially intolerant to neurohormonal therapy to requiring several medications to control their BP. In the immediate postoperative period, hydralazine is a renal-neutral agent. When renal function is stable and inotropic support weaned, renin-angiotensin-aldosterone system inhibition (including angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, and combination angiotensin receptor-neprilysin inhibitors) are useful. β-Blockers are reserved until patients are euvolemic and RV function permits initiating them. Analysis of the Intermacs registry has shown that continued use of neurohormonal agents is associated with improved symptomatic and survival outcomes in those who can tolerate them.[22] Many patients require long-term loop diuretic therapy to maintain euvolemia. Right heart catheterization at regular intervals to assess filling pressures and optimize hemodynamics might be helpful in patients awaiting transplant.[23] Serial echocardiography might also be useful in destination or bridge-to-decision patients.

Exercise

Patients post LVAD implantation have high satisfaction generally and much improved quality of life.[11] However, their objective exercise capacity remains limited as measured using cardiopulmonary exercise tests.[24] Current LVAD systems including the HVAD have a fixed speed that is often inadequate to support the increased metabolic demands of exercise. Additionally, exercise capacity is affected by the ability of the LVAD to unload the left ventricle, native heart contractility, chronotropic incompetence, respiratory function, and musculoskeletal function.[25] Cardiac rehabilitation is recommended in the ISHLT guidelines for LVAD patients and there have been multiple studies that have shown its safety and efficacy in this patient population.[6,26]

Key points for patient management
BP
• BP control is key to minimize adverse events
• Doppler opening pressure is the best estimate of MAP in patients in whom the aortic valve remains closed, but might overestimate MAP in patients with partial support in whom the aortic valve opens every beat
• Target MAP is <80 mm Hg, limited by patient symptoms
Antithrombotic therapies
• Antiplatelet therapy (aspirin 81-325 mg or clopidogrel 75 mg if aspirin not tolerated) and vitamin K antagonism are required (target INR 2-3).
• Dabigatran is contraindicated, Factor Xa inhibition requires further evidence before recommendation
• INR <2.0 might be bridged with weight- and renal function-adjusted short-term treatment with enoxaparin, or unfractionated heparin infusion
Medications
• Most patients will require BP medications post HVAD implantation
• HF therapies remain the mainstay of BP management
Exercise
• Structured exercise is helpful in enhancing outcomes
Comparison with HeartMate 3
• HVAD BP and anticoagulation might be more critical to ensure optimal outcomes

Device Management

Device settings. Controller settings available for adjustment include pump speed, hematocrit, alarm settings, and Lavare cycle activation and require the HVAD monitor. The HVAD flow estimation relies on 3 main inputs: pump speed, hematocrit (as a surrogate for fluid viscosity), and power consumption (watts).[27] As a result, an accurate hematocrit is required for accurate flow estimation, and defaults to 30% at implantation. It is suggested that this be updated when the hematocrit changes more than 5%. Some programs maintain constant hematocrit settings, however, to trend changes in flow as a marker for changes in hematocrit when the speed remains unchanged, especially in the outpatient setting. This is useful in the early diagnosis of gastrointestinal hemorrhage allowing investigation with bloodwork and endoscopy.

Pump speed. Pump speeds are usually set at a lower range, approximately 2400 revolutions per minute (RPM) coming out of surgery. This will typically provide adequate flow, without distortion of the intraventricular septum or right heart overload. Before hospital discharge, pump speed may be adjusted after echocardiography, examining intraventricular septal position and aortic valve opening as guides. Echocardiographic ramp studies are not mandated for HVAD management[28] because of the availability of information from the waveform (discussed in the next section). The global average pump speed for the HVAD is approximately 2655 RPM (Medtronic data on file).[28] Increasing pump speed >2800 RPM is rarely required, except in very large patients (body surface area >3 m^2). Pump speeds do not require frequent adjustment, even with long-term support, and management should be focused on patient BP, cardiac rhythm, and fluid balance.

The Lavare cycle is an automated pump speed option software which decreases speed by 200 RPM below the set speed for 2 seconds and then increases by 200 RPM

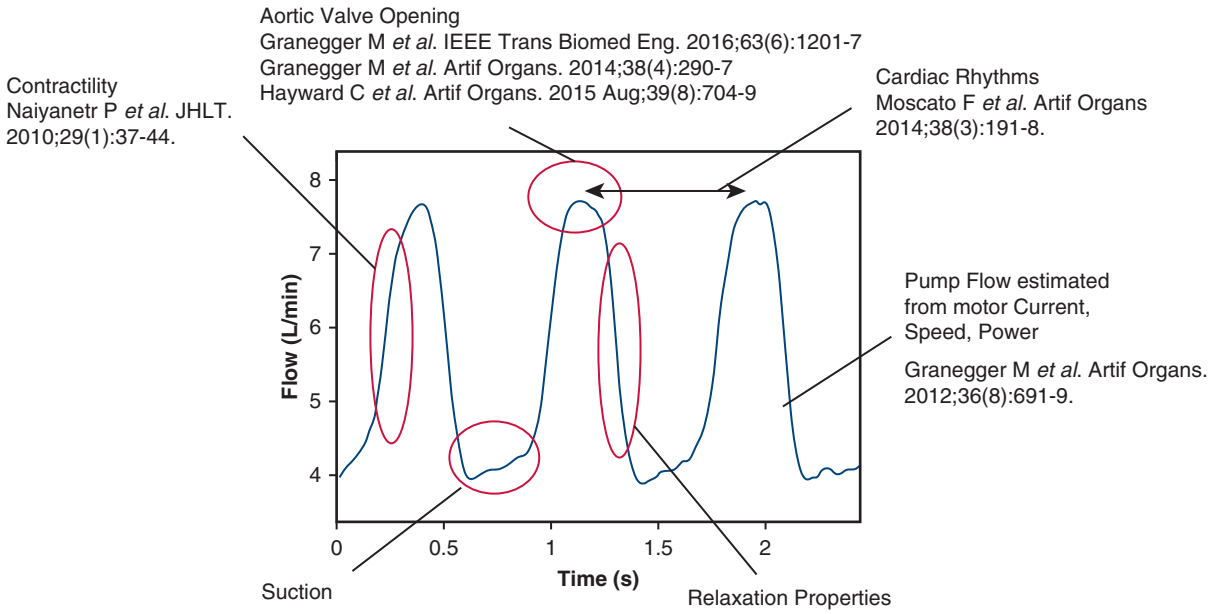

FIGURE 1. HeartWare HVAD System (Medtronic) waveform.

for 1 second above the set speed before returning to baseline, once per minute. There are significant benefits to apical washout in in vitro studies,[29] and 1 cohort study,[30] but no randomized studies confirming benefit in patients have been performed to date. Lavare is set to off by default. It should not be used at low pump speeds (baseline ≤2200 RPM), or if there is any evidence or suspicion of pump thrombosis.

Waveforms. A unique feature of the HVAD is clinical waveform availability.[31] Although the pump-patient

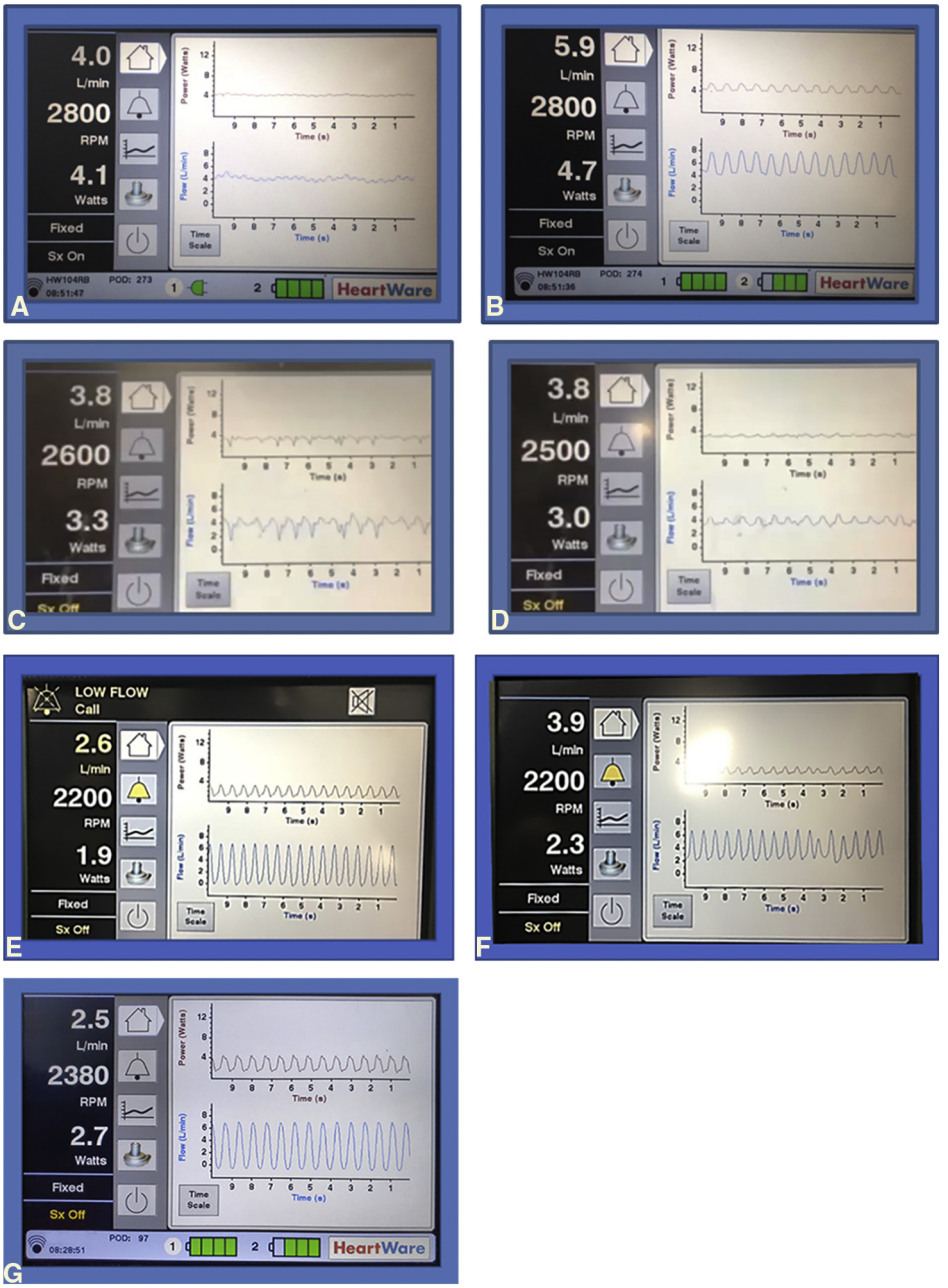

FIGURE 2. Effects of changes in management on HeartWare HVAD System (Medtronic) flow waveforms. A, Ventricular tachycardia; (B) postcardioversion. Note improved flow pulsatility evident in waveforms and mean flow (4.0 L/min improved to 5.9 L/min) postcardioversion. C, Suction waveforms; (D) post speed reduction with immediate restoration of normal pump flow waveforms. Note low flow pulsatility in the setting of right heart failure, predisposing to suction at relatively normal speeds in this patient. E, Acute hypertension immediately postoperatively (mean arterial pressure 89 mm Hg), (F) treated with intravenous nitrates with restoration of normal flow waveform (mean arterial pressure 72 mm Hg). The mean pump flow increased from 2.6 L/min to 3.9 L/min with reduction in afterload. G, Characteristic flow and power waveforms seen in the HeartWare HVAD System recovery. Wide flow pulsatility and features of aortic valve opening with "notching" of the power waveform are seen.

interaction is similar between pumps, the HVAD pump demonstrates that interaction through the flow waveform displayed on the monitor.[32] From the engineering perspective, this is defined by the HQ curve, at different pump speeds. The usefulness of the displayed waveform is in understanding the physiology of the patient-pump interaction including loading conditions (preload and afterload), ventricular function, heart rate, and valvular abnormalities. As shown in Figure 1, different portions of the flow waveform can be examined to assess each of these aspects of cardiac and vascular function.[33]

The importance of changes in physiological conditions contributing dynamic changes in the pump flow waveform can be in response to position,[31] and physiological intervention such as straining, or Valsalva maneuver.[34,35] Three immediately useful waveform characteristics to recognize are flow pulsatility (peak flow minus trough flow), evidence of ventricular suction, and changes associated with systemic hypertension because each of these can rapidly direct therapy (Figure 2).

Low flow pulsatility is due to more complete emptying of the LV chamber cavity than available preload. This might be due to relatively higher pump speeds or even normal pump speeds with very poor LV contraction, as is seen very early postoperatively. Scenarios with impaired LV filling (such as RV impairment, tamponade, severe mitral regurgitation, severe tricuspid regurgitation) are also associated with low flow pulsatility. Acute arrhythmias, including ventricular tachycardia or ventricular fibrillation, often result in low flow pulsatility, in the absence of syncope due to maintained mean pump flow (Figure 2, *A* and *B*). High mean pump flow with low flow pulsatility is seen in the setting of significant aortic regurgitation.

Suction waveforms are characterized by rapid downstroke in the diastolic portion.[36] This may be due to overpumping with a small ventricular cavity, and sharp decreases in flow related to transient obstruction of the inflow cannula (Figure 2, *C*). Suction events are more common at higher pump speeds, and may be managed by decreasing pump speed (Figure 2, *D*), as well as ensuring adequate hydration (by increasing oral intake or decreasing diuretics).

Hypertension is usually associated with increased flow pulsatility, with a very different waveform shape compared with suction (Figure 2, *E*).[37] Hypertension itself decreases the likelihood of suction, because the LV chamber empties less effectively in the setting of elevated afterload. A similar high flow pulsatility waveform (Figure 2, *G*) can be demonstrated if there has been significant LV recovery, and an echocardiogram might be required to distinguish if there is clinical ambiguity. In that setting, it would be expected that the aortic valve is fully open every beat, again able to be detected by waveform review.[38]

Key points for device management
Pump management settings available
• Pump speed, hematocrit setting, suction alarm, and Lavare activation
Displayed flow estimate
• A function of pump speed, hematocrit, and watts
• Overestimated during pump thrombosis
• Underestimated during decreased hematocrit (as with gastrointestinal bleeding [GIB])
Waveform
• Demonstrates pump-patient interaction
• Can identify cardiac arrhythmia, aortic valve opening, suction events, contractility, and relaxation
• Absence of waveform might occur due to arrhythmia (ventricular tachycardia or ventricular fibrillation), pump dysfunction due to inflow occlusion, or pump thrombosis
Flow pulsatility
• Low pulsatility is related to more complete LV emptying due to low preload/high pump speed or poor contractility
• Low pulsatility can reflect RV impairment, tamponade, severe mitral regurgitation, severe tricuspid regurgitation, or acute arrhythmia
• High flow pulsatility can be seen in hypertension and myocardial recovery
Suction events
• Characterized by rapid downstroke in the diastolic portion of the flow waveform
• Managed by increased fluid intake and decreased pump speed setting
Comparison with HeartMate 3 (Table E1)
• Flow waveform not available in HeartMate 3

Device Complications

Alarms and settings. Alarms and alarm priority outcomes are outlined in the HVAD Instructions for Use[18] and are important o prevent or diagnose complications early. Alarms cannot be disabled, except the suction alarm, and only low priority and medium priority alarms can be muted temporarily. The most frequent alarm is low battery, alerting the patient to change power source. The next most common alarms are suction alarms, low-flow, and less commonly, high watts alarms.

Suction alarms. The suction alarm is disabled by default as well as after any adjustment of pump speed and needs to be manually turned back on if required. If the suction response is turned on, a suction alarm will be triggered every time the estimated flow decreases 40% or more below the flow baseline for 10 or more seconds.[18] If suction alarms are triggered, the patient should be assessed for potential causes and their reversibility. It is important to obtain logfiles and interview patients to determine whether these suction alarms self-resolve quickly and/or occur periodically with certain activities (bending over, lying on one side) or if they indicate a more serious condition that requires clinical intervention. If the former, it might be reasonable to turn off the suction response if they do not indicate a clinical issue or

malfunction.[39] If the alarms do indicate true suction events and sustained decrease in flows this usually indicates underfilling of the left ventricle and the patient should be assessed for potential causes: dehydration, bleeding, arrhythmia, RV failure (RVF), etc. The logfiles can be particularly useful for differential diagnoses (Figure 3). Regardless of the etiology, if a patient presents with suction alarms representing true suction events, the priority management would be to get the patient out of suction by decreasing the RPM until the waveform regains some normal flow pulsatility. When the suction is resolved, the cause should be addressed rapidly.

Low flow alarms. Low flow alarms cannot be disabled, but the HVAD system allows the clinician to set a low flow alarm limit. This should be set at 2 L/min below the average pump flow, but no lower than 2 L/min. The minimum low flow alarm allowed by the system is 1 L/min. Frequency of low flow alarms are related to body size and, when very frequent, have been shown to have prognostic significance.[39] If a patient experiences recurrent low flow alarms, it is important to determine the cause. The waveform and logfile analyses can be particularly useful in that case. For instance, a low flow alarm with low pulsatility indicates underfilling of the left ventricle (caused by bleeding, overdiuresis, RVF) whereas a low flow alarm with a large flow pulsatility and low troughs indicates high systemic vascular resistance (eg, hypertension; Figure 3).

High watts alarms. The HVAD system allows the clinician to set a high watts alarm. This should generally be set at 1-2 W above the patient's baseline to allow for normal increase in power accompanying increased activity or volume status. It is recommended by the manufacturer to be set at 2 W above usual power. More sensitive settings for the high watts alarm (eg, 0.5 W above circadian maximum power consumption) might provide earlier detection of pump thrombosis, enabling early detection and potentially allowing medical therapy to avoid pump exchange.[40] If a high power alarm is triggered, the patient should be carefully evaluated for potential pump thrombus formation. Hemolysis markers (lactate dehydrogenase, plasma free hemoglobin) should be obtained. Logfiles should be reviewed to assess for a sustained increasing trend in power and flows and a loss of circadian rhythm all of which would indicate intrapump thrombosis (Figure 3). A transthoracic echocardiogram should be obtained to rule out aortic insufficiency. If early pump thrombosis is suspected (slightly elevated pump powers, usually 15%-20% above patient's baseline, with mildly elevated hemolysis markers) early thrombolytic management should be initiated with heparin infusion or enoxaparin injections. If intrapump thrombosis appears advanced, treatment should be escalated as described in the Pump Thrombosis section.

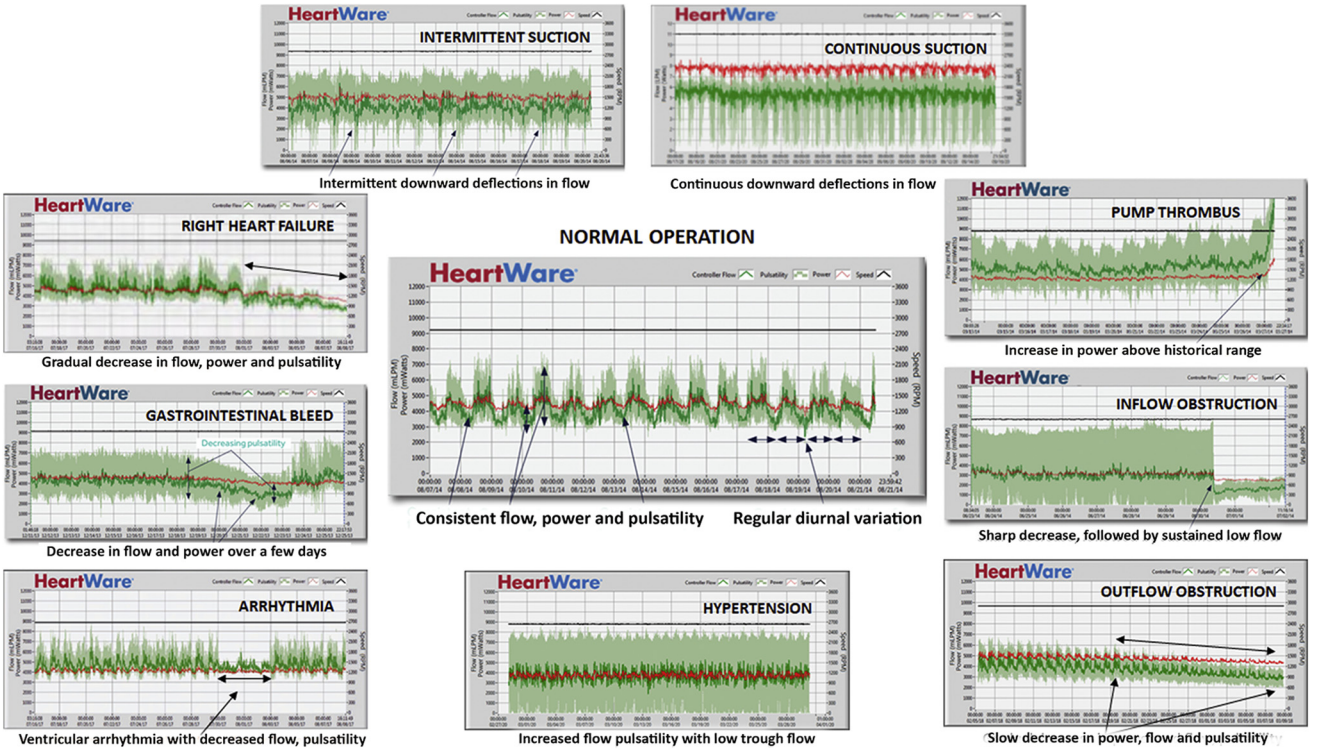

FIGURE 3. Pump performance trends from controller logfiles indicating differences in flow, power, and pulsatility during normal operation (*central*) versus suction, right heart failure, gastrointestinal bleed, arrhythmia, hypertension, pump thrombus, and inflow or outflow obstruction.

Pump Malfunction

Controller fault. The most common reason for controller fault is the expiration of the HVAD internal battery that powers an audible[18] alarm when both power sources are disconnected from the controller.[18] In this situation the controller will continue to function properly, but the audio alarm notification will cease to function. The manufacturer recommendation is to exchange the HVAD controller approximately every 2 years. It is very important to download and submit logfiles for analysis to assess the cause of the alarm before any interventions are performed. If the logfiles confirm that the cause is an expired internal battery, then a controller exchange is warranted to ensure that the alarm for complete power disconnect will be audible to the patient. This scenario does not represent a clinical emergency, but the patient should be brought into the clinical setting to perform the controller exchange safely with the capability to support the patient's hemodynamics should the pump fail to restart after the controller exchange.

Pump stop, failure to restart, or controller failure. The most common cause of pump stop is a double disconnect, where both power sources have been disconnected at the same time or do not have a secure electrical connection. During a power change, care must be taken in inserting power cables not to force them or twist the pins. If this occurs, a new controller must be used. Proper patient education can prevent this event. Although incidence of pump failure to restart is extremely low, this event can be catastrophic. If blood remains stagnant in the pump for a period of time, there is a risk of thrombus formation and embolization should the pump be restarted. For patients who are "pump dependent" with little residual cardiac function, sudden stoppage might result in immediate death. Every attempt should be immediately made to restart the pump by exchanging the controller. Although it is recognized that failure of pump restart is a major reason for the withdrawal of distribution of the HVAD,[1] recent STS Intermacs registry analysis does not suggest that routine pump exchange to HeartMate 3 in the setting of normal system function should be entertained.[5] Failure of pump restart or unresolved pump thrombosis (see Management of Pump Malfunction and Thrombosis section) might require exchange to HeartMate 3. In the event of pump exchange (HVAD to HeartMate 3) being planned, a recent best practice recommendation has been published.[41]

Controller exchange strategies. Controller failure is a critical alarm priority, and mandates immediate patient attention. In case of a controller failure or pump stop for unknown cause, a controller exchange should be attempted to restart the pump. Ideally the patient should be brought into the clinical setting to ensure patient's safety and adequate medical and surgical support should the pump fail to restart after the controller exchange. Certain emergency situations (VAD stopped, pump failure, controller failure) might require the controller exchange to be performed in the outpatient setting by the patient and the caregiver. Regardless of the setting, the patient should be lying down, have a correctly programmed back-up controller and back-up batteries available as well as the presence of a caregiver or clinician competent in controller exchange. The key important step in controller exchange is to first power-up the back-up controller. If the driveline is not connected immediately (within 10 seconds) the back-up controller will appropriately alarm until the driveline is inserted. A second power source is then connected and the primary controller can then be silenced with the alarm silencer plug.[18] The "4 P's" mnemonic is most helpful (Figure 4).

If the controller exchange fails to restart the pump despite multiple attempts and connection verification, connecting to the supplemental back-up controller should be attempted. In the event of failure of pump restart, the power cables should be disconnected, inspected, cleaned where appropriate, and reinserted. After a few attempts, the patient should be managed for the likely ensuing cardiogenic shock with inotropes, vasopressors, and temporary mechanical support (extracorporeal membrane oxygenation; ECMO) as necessary. The patient should be evaluated for expedited device exchange to HeartMate 3 depending on the urgency of their clinical situation and their eligibility for heart transplantation.

Pump thrombosis. Pump thrombosis can occur in 3 different areas of the HVAD system: inflow, intra-pump, or outflow graft[42] (Figure 3, *3 right panels*; Table 1). Analysis of HVAD waveforms and logfiles are key to defining the site of pump thrombosis and might allow early medical treatment of thrombosis, avoiding surgical intervention.[42,43] The clinical presentation of pump thrombosis can vary widely from noncardiac symptoms such as

1. POWER... Connect a power source to your back up controller.
2. PUMP... Restart the pump by connecting the driveline to the new controller.
3. PREVENT... Prevent the [No Power] alarm on the original controller with the red alarm adapter or pressing the "Scroll" and "Alarm Mute" buttons at the same time.
4. POWER... Connect a second power source to the new controller.

FIGURE 4. Controller exchange sequence—the "4Ps." All patients should be aware, but might not be able to complete it in an emergency and might need to be guided through it.

TABLE 1. Characteristics of pump thrombosis in the HeartWare HVAD System

	Thrombosis type		
	Intra-pump thrombosis	**Inflow obstruction**	**Outflow obstruction**
Pump parameters	• Elevated powers • Elevated flow	• Decreased powers • Decreased flow	• Decreased powers • Decreased flow
Logfiles	• Sudden or progressive increase in powers and flows • Sustained • Loss of flow pulsatility • Loss of circadian rhythm	• Sudden drop in power and flows • Might be intermittent • Loss of flow pulsatility	• Progressive decrease in powers and flows • Sustained
LDH, pfHgb	Marked elevation	Mild or marked elevation	Mild or no elevation
Diagnostic	• Logfiles • TTE	• Logfiles • TTE	• CT angiogram
Treatment options	• Heparin • TPA • Pump exchange • Transplant	• Heparin • TPA • Pump exchange • Transplant	• Heparin • Inotropes • Outflow stenting • Outflow sleeve excision • Pump exchange • Transplant

The HeartWare HVAD System is from Medtronic. *LDH*, Lactate dehydrogenase; *pfHgb*, plasma free hemoglobin; *TTE*, transthoracic echocardiogram; *CT*, computed tomography; *TPA*, tissue plasminogen activator.

hematuria, due to intravascular hemolysis, incidental recognition of elevated flow estimate, to worsening HF symptoms or advanced cardiogenic shock. Supportive therapies should be initiated immediately while diagnostics are initiated and escalated depending on patients' presentation until definitive treatment is implemented.[39,42] Bloodwork will usually reveal elevated hemolysis markers. Diagnostic tools include echocardiography (might reveal a poorly unloaded LV, worsening mitral regurgitation, an opening aortic valve, elevated pulmonary artery pressures).

Pump thrombosis supportive therapies include:

- Heparin infusion: initiated on presentation and dosed according to the center's policies to prevent embolic strokes (usually anti-Xa 0.3-0.5 U/mL)
- Inotropes: initiated on presentation to sustain a cardiac index >2 L/min/m^2
- Vasopressors: as needed to maintain MAP >60 mm Hg
- Venoarterial ECMO: initiated for worsening hemodynamics despite optimal medical therapy and/or worsening renal/liver function

Pulmonary artery catheter placement might be useful to assess patient's hemodynamics. Renal function should be carefully monitored, and urine pH should be maintained neutral to alkalotic to facilitate hemolysis byproduct excretion to prevent renal failure. Lactate should be measured routinely as a measure of worsening tissue perfusion and need for mechanical temporary support. The decision to modulate HVAD speed will depend on patient's presentation and degree of hemolysis, but speed increase is generally not advisable because it will not be sufficient to support the patient's cardiac output while simultaneously yielding increased hemolysis. If the patient's hemodynamic picture worsens despite optimal medical management and/or if the renal functions deteriorate, peripheral venoarterial ECMO support should be initiated to protect end organ function and retain good candidacy for device exchange or transplant. After ECMO initiation, the thrombosed HVAD might offer sufficient flow to allow LV venting. The goal of supportive therapies is to sustain the patient until the appropriate definitive treatment is implemented.

Inflow Obstruction

Inflow obstruction is usually caused by LV pannus and/or associated thrombus that occludes the inflow cannula. Patients experiencing inflow obstruction present with sudden decreased power and flows, often with accompanying low flow alarms (Figure 3). The low power and flows might be sustained or intermittent depending on the pannus configuration, position in relationship to the inflow cannula, and LV geometry. Supportive therapies outlined previously should include a heparin infusion ("high goal" of anti-Xa approximately 0.5-0.7 U/mL). Thrombolysis may be attempted to further eliminate any thrombi obstructing the inflow cannula. If these attempts fail, the patient should be considered for a pump exchange to HeartMate 3 or expedited transplant. Experienced centers have reported a noninvasive "wash-out" procedure with intermittent pump stop with direct carotid artery protection in a hybrid operating room.[42]

Intrapump Thrombosis

Intrapump thrombosis occurs when a thrombus is caught in the impeller, representing 70% of the cases of pump thrombosis.[42] Although the analysis of intrapump thrombosis in the HVAD suggests the initiating factor is a result of thrombus ingestion,[44] the hydrodynamic bearing of the HVAD pump with narrow flow paths might constitute a risk for thrombus adhesion and propagation within the pump. Pump parameters will include elevated powers and flows, with accompanying high-power alarms. On logfile analysis, the elevated pump parameters can be sudden or slowly progressing over days or weeks.[43]

Although intrapump thrombosis in the HeartMate II is usually treated surgically, there is extensive experience in medical/thrombolytic management for HVAD-associated thrombosis.[45] Rates of success vary between 33% and 94% for thrombolysis,[42,43,45,46] providing a potential alternative to pump exchange.[47] Early recognition is important, because the success rate might be better with earlier treatment.[42,48] Repeat thrombolysis has been used on occasion, although it is noted that recurrent pump thrombosis is a significant risk for future thrombosis.[46] Features that were associated with greater likelihood of successful thrombolytic therapy include lesser degree of power elevation on logfile (consistent with lower intrapump thrombosis burden), and somewhat paradoxically a more gradual increase in the power.[43] The thrombolysis regimen used varies with institutions, but systemic alteplase 50 mg infusion over 24 hours is commonly used, with continuation of intravenous heparin.[48] Other strategies might be administering 2 initial boluses of 10 mg alteplase, followed by an infusion of 50 to 70 mg alteplase over several hours. The frequency of intracranial hemorrhage complicating thrombolysis varies between 0% and 21%.[42,48] A review of the patient's history and prethrombolysis brain computed tomography (CT) scan is recommended to help predict hemorrhagic risk. It is recommended that the patients are managed in the intensive care unit for 24 hours after thrombolysis. For non–transplant-eligible HVAD patients with nonresolving thrombosis, pump exchange to HeartMate 3 is indicated.[42]

Outflow Obstruction

Outflow obstruction is rare and can be challenging to diagnose because its presentation can be subtle. Its causes include a distal thrombus in the outflow graft, kinking or, more commonly, external compression exerted on the outflow graft by fibrin and clots. During HVAD implantation the pump is de-aired by inserting a venting needle in the outflow graft. Material can subsequently leak between the outflow graft and the graft covering sleeve, leading to compression of the graft. In the setting of outflow obstruction, pump parameters demonstrate a progressive decrease in flow and power. Hemolysis markers might be normal or only slightly elevated. Patients might be asymptomatic or experience HF recurrence. If outflow graft obstruction is suspected, a chest CT angiogram with 3D reconstruction should be obtained to visualize the location and severity of the obstruction. Immediate treatment depends on the cause of the obstruction and can include heparin infusion, graft covering sleeve excision, or stent placement. If these attempts fail, the patient should be considered for a device exchange or expedited transplant.

Key points for device complications

Controller exchange strategy
- Controller failure is a critical alarm priority and warrants immediate attention
- Patients should be taught controller exchange for emergencies, but optimally should be performed with the patient supine in the hospital
- Key step in controller exchange is to first power up the back-up controller
- 4P's is important to remember—Power (backup), Pump, Prevent, Power

Pump stop or malfunction
- The most common cause of pump stop is double-disconnect of power sources
- Check connections to power sources first
- If unable to connect power sources (because of bent pins), immediate controller exchange
- If failure for pump restart occurs, immediate surgical back-up is required, with consideration of temporary alternative mechanical circulatory support
- Pump exchange to HeartMate 3 is not recommended in the absence of pump stop with failure to restart

Inflow or outflow obstruction
- Site of pump thrombosis in HVAD pumps might be inferred from the changes in pump flows and waveforms
- Changes in pump power trends are critical in diagnosing site of pump thrombosis
- Intrapump thrombosis is associated with increased power consumption (and flow estimate), whereas inflow obstruction and outflow obstruction are associated with decreased pump flow
- Actual pump flow might decrease during intrapump thrombosis, despite an apparent increase in estimated flow displayed on the HVAD monitor

Management of pump thrombosis
- Early intrapump thrombosis recognition is associated with better medical management (thrombolysis) outcomes
- Intracranial hemorrhage is a risk post thrombolysis; pre-thrombolysis brain CT imaging might help to define risk
- Surgical pump exchange to HeartMate 3 might be indicated in non–transplant-eligible patients

Comparison with HeartMate 3
- Pump thrombosis is more commonly seen than with HeartMate 3

Management of Pump Malfunction and Thrombosis: LVAD Exchange Versus Transplant

Directing care to pump exchange or transplant should be made by an interdisciplinary team including advanced HF specialists, cardiothoracic surgeons, social workers, VAD coordinators, and patient/family. Device exchange (HVAD to HeartMate 3) introduces surgical challenges: the coring and sewing ring diameters differ from HVAD to HeartMate 3, as does the outflow conduit.[41] If feasible, an expedited transplant would be the preferred option but patient factors such as comorbidities, obesity, social support, or substance use might complicate the transplant option.

ADVERSE EVENT PREVENTION AND MANAGEMENT

The most common adverse events reported during durable LVAD support include (driveline) infections, nonsurgical bleeding (mainly gastrointestinal), stroke, and RVF.[49] Because these adverse events negatively affect prognosis and quality of life in LVAD patients, all efforts should be done to avoid them. In the following paragraphs, measures for prevention of these adverse events and their management are discussed.

Right HF

This consensus document is intended to guide physicians to optimize care for patients continuing HVAD support, therefore acute RVF immediately after LVAD implantation is not discussed. Instead, late RVF during long-term HVAD support will be reviewed. As seen in the STS Intermacs Database report, rates of RVF are similar in patients with the HVAD compared with those with the HeartMate 3[2] and factors resulting in late RVF are common across the LVAD population. Late RVF is defined as a hospitalization that occurs 30 days after LVAD implantation and requires intravenous diuretics or inotropic support for at least 72 hours.[50] The prevention and (medical) management of late RVF is related to several factors, including intrinsic RV function (contractile state), RV preload and afterload, as well as clinical factors such as the presence of pulmonary, hepatic, and renal dysfunction.[51] Optimization of RV preload includes adequate volume management, in particular avoidance of venous congestion. In general, this can be achieved with the use of (oral or intravenous) loop diuretics. RV afterload can be optimized by ensuring sufficient LV unloading by the LVAD (eg, guided by echocardiography and right heart catheterization) and treatment of reversible components of increased pulmonary vascular resistance. Pulmonary vasodilators may be considered in case of persistent pulmonary hypertension after LVAD insertion.[52] Finally, RV contractility can be improved with the (temporary) use of inotropes. In case of severe late RVF that does not respond to medical management, invasive (temporary) mechanical RV support, a total artificial heart or heart transplantation can be considered in carefully selected patients.[51] Some centers considered off-label use of durable LVADs in these patients.[53] The implantation of a Berlin Heart EXCOR RV assist device in these patients might be another less attractive option for selected patients. If none of the previously mentioned options is possible, palliative therapy may be considered.

Driveline Infection

Major infections contribute to significant morbidity and mortality in LVAD patients. In a recent report of STS Intermacs registry, up to 41% of the patients experienced a major infection within the first 12 months after LVAD implantation.[49] Infections can be classified as VAD-specific infections (eg, driveline infections [DLIs]); VAD-related infections (eg, endocarditis) and non-VAD infections (eg, pneumonia).[54] DLIs are the most common VAD-specific infections and are typically caused by Gram-positive bacteria (*Staphylococcus Aureus* or *S epidermidis*) or Gram-negative bacteria (*Pseudomonas aeruginosa*).

In the ENDURANCE trial, the rate of DLI was similar in the HVAD and the HeartMate II groups,[55] whereas in a recent single-center study with 3 contemporary continuous-flow LVADs, readmissions for DLI were more common in patients with a HeartMate 3 compared with the HVAD.[56] The driveline should be implanted with the entire velour portion of the driveline contained within the subcutaneous tunnel, resulting in a silicone-skin interface at the exit site.[57] Several patient-related factors have been identified as risk factors for DLI, including larger body mass index, diabetes, and prolonged duration of LVAD support.[54,58] Importantly, trauma to the driveline exit site (eg, accidental pulling) is also an important risk factor for the development of DLI. Therefore, the driveline should be carefully stabilized on the abdominal wall with the use of an anchor.

The exact protocol for dressing changes (including materials used) might vary per institution, but in general it is recommended to change the dressings 1 to 3 times per week at home using an aseptic technique.[54] All patients and caregivers should be well educated (preferably on a regular basis) on how to perform the driveline dressing changes. This includes instructions to contact the treating physician or VAD coordinator in case of driveline exit site changes such as erythema or tenderness, or fever. Documentation of the driveline exit site over time using photography or clinical scoring systems might be helpful to guide clinical decision-making. Different imaging modalities (ultrasound, CT, positron emission tomography) are available to provide additional information to guide clinical management.[59] For superficial DLI, oral or intravenous antibiotics might be sufficient, whereas for relapsing or more severe infection, surgical interventions might be needed.[54]

GIB

GIB is a major cause of readmissions in patients with continuous flow LVADs. Several conditions might predispose to this complication. It has recently been recognized that gastrointestinal arteriovenous malformations are seen in unsupported HF patients, representing a significant fixed risk for GIB.[60] LVAD-specific factors that contribute include shear-related loss of large von Willebrand factor multimers,[61] platelet dysfunction, and anticoagulation and antiplatelet therapy.[62] Rates of GIB were higher in the STS Database Report for HVAD compared with the HeartMate 3.[2] For all LVAD patients with GIB, the usual diagnostic workup includes an esophago-gastroduodenoscopy and/or colonoscopy. When these evaluations are unremarkable, a push enteroscopy and/or video-capsule endoscopy can be performed to evaluate the small bowel.[62] The treatment of LVAD patients with GIB depends on the location and severity of the bleeding. Medical therapy includes the start of proton pump inhibitors, management of anticoagulation, and fluid resuscitation or blood transfusion if needed. In a patient who presents with clinically significant GIB, anticoagulation and antiplatelet therapy should be discontinued temporarily. In case of a more severe bleeding, complete reversal of anticoagulation using titrated application of vitamin K and/or 4-factor prothrombin complex concentrates may be considered. These patients should be monitored closely, including HVAD parameters and markers of hemolysis, to detect signs of pump thrombosis. When vitamin K is given, INR levels should be monitored closely, and administration of intravenous heparin may be considered when deemed appropriate to prevent pump thrombosis.

Endoscopic treatment of arteriovenous malformations can be challenging because of high recurrence rates. In patients with recurrent GIB, permanent withdrawal of antiplatelet therapy and lowering of target INR should be considered. On the basis of a number of (small) observational studies, it has been suggested that thalidomide, danazol, and octreotide treatments may be considered in patients with recurrent GIB.[63] Carefully selected patients with recurrent GIB not responding to conventional treatment might be considered for heart transplantation because permanent reduction/discontinuation of anticoagulation in HVAD patients might expose them to a very high risk of stroke or pump thrombosis.

Stroke/Neurologic Events

Neurologic dysfunction is one of the most common adverse events after LVAD implantation. In the latest report from the STS Intermacs Registry, the reported incidence rate of neurologic dysfunction was 0.141 per patient-year, and up to 13% of the patients experienced a stroke within 12 months post implant.[49] Importantly, neurologic dysfunction is the third most common cause of death after LVAD implantation. (49). Neurologic events can be classified according to the presence of brain injury on neuroimaging and the correlation with neurologic symptoms.[50] The most reported neurologic events include ischemic stroke and intracranial hemorrhage.

Risk factors for neurologic events are related to the LVAD itself (eg, pump type and design, acquired coagulopathy), to the patient (eg, BP, infection), and to patient management (eg, anticoagulation control). In earlier studies, it was noted that stroke rates were higher in centrifugal flow LVADs compared with axial flow devices.[55,64] A recent report from the European Registry for Patients with Mechanical Circulatory Support (EUROMACS) using propensity matched cohorts showed that the cumulative incidence rate of neurologic events was higher in patients supported with the HVAD than with HeartMate 3,[65] similar to that reported with the STS Intermacs Database Report.[2] An important patient-related risk factor is elevated BP, which results in an increased afterload of the LVAD with subsequent reduced flow. This promotes blood stasis and increases the risk of pump thrombosis and stroke. In HVAD patients, poor anticoagulation control is associated with a higher incidence of stroke.[66] Regular INR check and applying INR self-management (for example with the use of CoaguChek; Roche Diagnostics) is recommended to maximize the time of therapeutic INR values in HVAD patients and decrease the risk of stroke.

If stroke is suspected, a neurologist should be consulted to perform neurologic assessment. Additional imaging (preferably CT angiography) should be performed to confirm the diagnosis and to assess the etiology (ischemic vs hemorrhagic vs hemorrhagic conversion, vascular abnormalities) and the extent of the neurologic injury. In addition, levels of anticoagulation and the HVAD parameters and logfiles should be assessed.

The treatment of neurologic events depends on the (imaging) diagnosis, and decisions should be made by a multidisciplinary team (including a VAD specialist, neurologist, and anticoagulation specialist). Intracranial hemorrhage should be treated with urgent reversal of anticoagulation, with administration of vitamin K and/or 4-factor prothrombin complex concentrates.[67,68] Current studies suggest the risk of pump thrombosis is not excessive, although randomized studies are not available.[69] It is recommended to obtain serial INR levels to ensure adequate reversal of anticoagulation. The decision if and when to resume vitamin K antagonists should again be made by a multidisciplinary team but appears to be safe after 14 days.[70] In LVAD patients who present with an ischemic stroke, intravenous thrombolysis is usually contraindicated because of the use of anticoagulation. In selected patients, reversal of anticoagulation before

Key points for adverse event prevention and management
RVF
• Late RVF is characterized by clinical signs of low cardiac output or signs of systemic venous congestion
• Echocardiography and right heart catheterization are key diagnostic elements
• RV pre- and afterload should be optimized to avoid RVF
• Medical management includes diuretics, pulmonary vasodilators, and inotropes
DLI
• DLIs are the most commonly experienced VAD-specific infection
• Driveline fixation and (continuous) patient education on driveline change of dressings are important measures to avoid DLI
• Treatment of DLI (medically or surgically) depends on location and severity of the infection
GIB
• Pathophysiology of GIB in LVAD patients is multifactorial
• The diagnostic workup should include esophagogastroduodenoscopy and/or colonoscopy
• For significant GIB, anticoagulation and antiplatelet therapy should be discontinued temporarily, or even withdrawn, in select cases
• For more severe bleeding, complete reversal of anticoagulation using vitamin K and/or 4-factor prothrombin complex concentrates must be considered
Stroke/neurologic events
• Adequate INR management and BP control are the most important measures to avoid neurologic events
• Neurologic events should be treated by a multidisciplinary team, including a VAD specialist, neurologist, and anticoagulation specialist
• Intracranial hemorrhage should be treated by urgent reversal of anticoagulation
Comparison with HeartMate 3
• Management of RVF, DLI, GIB, and stroke are similar for HVAD and HeartMate 3
• Withdrawal of anticoagulation might create increased risk of pump thrombosis compared with HeartMate 3

thrombolytic therapy may be considered. To avoid hemorrhagic transformation of the ischemic stroke, temporary withdrawal of anticoagulation/antiplatelet therapy can be considered by a multidisciplinary team. Selected patients with (repeat) minor stroke events need to be considered for heart transplantation.

Outpatient Monitoring and Management

Multidisciplinary approach to follow-up care. Successful long-term management of HVAD patients depends on comprehensive care by a multidisciplinary team[6,71] that includes cardiac surgeons, advanced HF cardiologists, dedicated VAD coordinators, and the patient and their family members/caregivers. The VAD coordinator is the central figure in the VAD team, interacting directly with all specialized disciplines who are involved in HVAD recipient care.[72] As a part of the multidisciplinary approach, Medtronic has established a Patient and Provider Support Program to help ensure the safety and well-being of patients supported by the HVAD, and to support the clinicians and caregivers involved in their care. This program includes ongoing product support with continued availability of the peripheral equipment, ongoing HVAD-trained clinical support teams, and ongoing training for clinicians and patients/caregivers throughout the duration of HVAD support.

Patient/caregiver education and documentation of device and vital parameters. Structured patient education and 24/7 on-call support from the VAD team are key components of successful ongoing outpatient care.[6,71] The patient and caregivers should be trained primarily to recognize HVAD alarms and troubleshoot emergencies. This training should be conducted with written materials and visual demonstrations, and emergency response skills. Because device-related malfunctions (eg, controller fault) are rare, patients and caregivers should receive regular retraining to maintain competency in emergency response.[6] Therefore, as highlighted in a survey of international VAD coordinators, 91.4% of international VAD centers retrain their HVAD patients during outpatient visits, and 54.3% additionally train patients' primary care physicians on HVAD use and patient management.[73] Further community outreach[6] should be performed by VAD implanting centers to inform the local health care providers, including emergency medical providers, referring cardiologists, and self-support groups about the concept of HVAD device therapy and the associated physiologic changes.

HVAD outpatients should be evaluated whenever significant changes in pump flow, power, or pulsatility occur or when a high watts or low flow alarm is triggered. Pump parameters should be recorded daily in a written log by the patient or caregivers to demonstrate trends. Other parameters that should be recorded regularly at home are weight, temperature, MAP, and the INR.[73] Most VAD centers ask their outpatients to measure their INR every 2 to 4 days up to weekly,[73] although it was recently shown that increased frequency of INR point-of-care testing was a key factor in reducing hemocompatibility-related adverse events.[74]

Driveline Exit Site Management and Infection Prevention

Education of patients and caregivers on care of the driveline exit site in strict adherence to institutional best practices, including aseptic technique during dressing changes, is crucial.[54] A mild antiseptic solution should be used for the cleaning the exit site. Wound photo documentation, including wound staging,[75] is recommended during follow-up. The driveline should be stabilized using a binder or anchoring device.[6,54,75] Most commonly, dressings are changed at the exit site of the driveline 1 to 3 times per week,[54,73] with changes occurring immediately after the

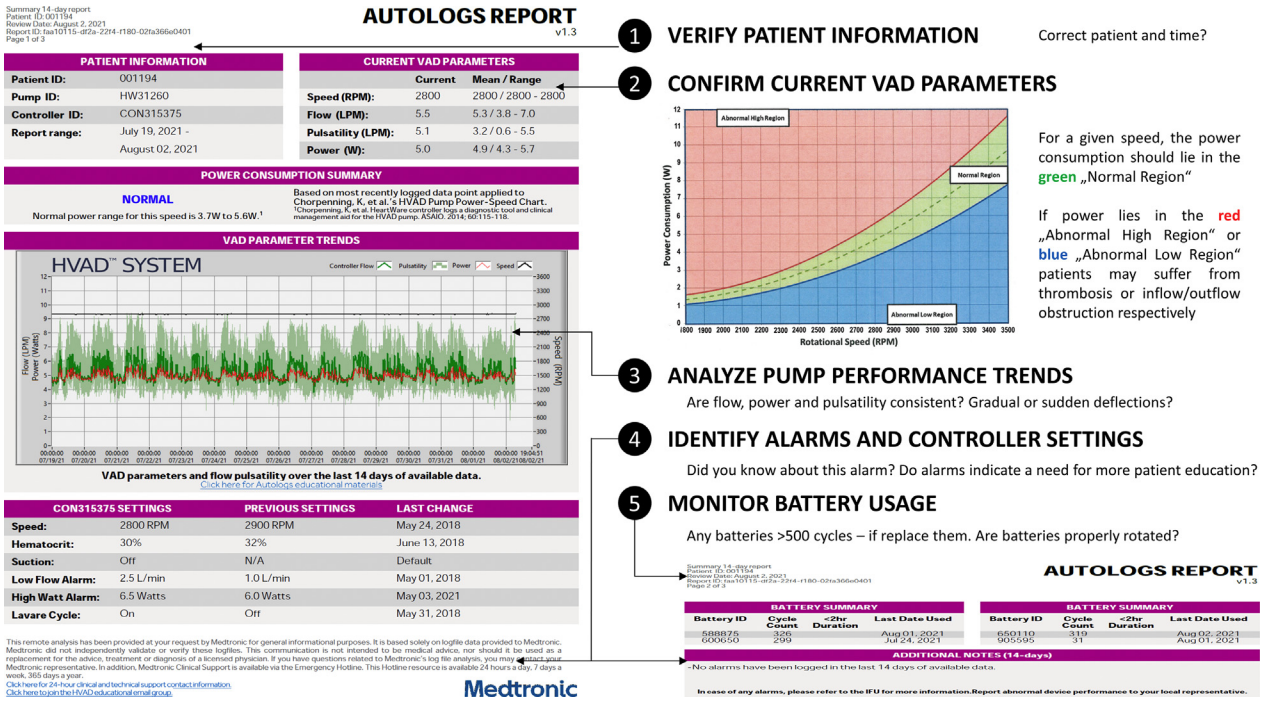

FIGURE 5. How to read an AutoLogs1.3 (Medtronic) report. Request AutoLogs report at https://autologs.medtronic.com. AutoLogs from Medtronic. *HVAD*, Medtronic HeartWare HVAD System; *VAD*, ventricular assist device.

patient showers. Nearly 85% of centers cover the exit site with temporary waterproof dressings during showering.[73]

Frequency of visits. Continuous outpatient follow-up is key to optimized patient management. The most common frequency of clinical visits[73] is initially weekly, but can be changed to as often as every 3 months[76] depending on patient status[6,71] and patient distance from the center.[71] Between routine visits, phone calls to the patient/caregiver are recommended to maintain ongoing communication with patients[6,71] and proactively identify emerging issues, and have been shown to improve outcomes for HVAD patients.[77]

Clinical Examinations During Follow-up

Laboratory testing must be obtained periodically to assess end organ function, hematology, anticoagulation, hemolysis, and infection status. Echocardiography[6,76] should be performed to ensure optimal HVAD speed setting and clinical outcomes,[78] and to evaluate signs of myocardial recovery or new symptoms of HF. Right heart catheterization should be performed after HVAD implantation in patients being evaluated for or listed for heart transplantation, usually 3 to 6 months post implant. Routinely assessed chest radiographs can be used to assess for complications related to HVAD inflow cannula malposition.[79] Body weight monitoring and consultation with dietitians should be ongoing to ensure that nutritional goals are met. Cardiopulmonary exercise testing and/or 6-minute walk tests performed at regular intervals might be helpful to objectively assess function capacity.[6] At each follow-up, an assessment of MAP and possible adjustment of HF therapy should be performed as standard. If available at the center, HVAD pump acoustic

TABLE 2. Possible contributing factors for observed changes in HeartWare HVAD System log file trends

	Decreased mean flow (power)	Increased mean flow (power)
Decreased pulsatility	• Hypovolemia • Right heart failure • (Gastrointestinal) bleeding, tamponade • Inflow/outflow graft obstruction • Ventricular/atrial fibrillation or ventricular tachycardia	• Hypotension (vasodilation) • Aortic valve insufficiency • Pump thrombus (falsely overestimated flow)
Increased pulsatility	• Hypertension • Low speed setting • Suction (continuous or intermittent downward deflections in flow and pulsatility)	• Hypervolemia • Possible recovery

The HeartWare HVAD System is from Medtronic.

spectrum analysis[80] can be used as a reliable method to detect pump thrombus.

Logfiles. Two unique aspects of the HVAD are the availability of flow and power waveforms and logfiles.[81] VAD coordinators should download and analyze logfiles at each follow-up. AutoLogs (Medtronic) reports (Figure 5) provide easy-to-understand information to give insight into patient status and pump performance. As described previously,[82] HVAD power consumption at a given speed should be within the normal power range; power in the red "abnormally high range" could indicate pump thrombus, whereas abnormally low power consumption might be due to inflow or outflow graft obstruction.[43,45] Table 2 shows a summary of contributing factors for observed changes in HVAD mean flow, power, and pulsatility, and accompanying deviation from normal operation device condition.

Figure 3 describes typical long-term trends in HVAD pump performance during normal operation compared with suction,[36] RVF, GIB, arrhythmia, hypertension, pump thrombus,[43,45] inflow or outflow graft obstruction.[42,83] Enhanced analysis of HVAD logfiles to detect changes in pump power might allow early medical therapy for pump thrombus[40,43,84,85] and potentially avoid pump replacement. Many HVAD patients experience circadian variations in flow and pulsatility during normal operation (Figure 3). Although this is not the case in all patients, VAD clinicians should pay attention to these fluctuations. It is unclear whether loss of a cardiovascular circadian rhythm is a cause or an effect of adverse events and occurs as a precursor to, for example, GIB or RVF, but there is evidence that its return is associated with better outcomes.[86]

Finally, VAD coordinators should regularly remind patients of the critical nature of backup equipment and emphasize proper use and safe maintenance of all wearable peripherals. The AutoLogs alarm, events, and controller settings (Figure 5) should be used to check for device malfunction and potential patient maloperation requiring retraining. Any batteries close to end-of-life (>500 cycles or <2 hours run time) should be replaced, taking care to rotate the batteries evenly to ensure maximum life.

Key points for outpatient monitoring and management

Documentation of vital parameters
- Patients and caregivers should be trained in alarms and emergency troubleshooting
- Regular training and retraining is recommended
- Patients should document flow, power, weight, MAP, and INR regularly

Driveline exit site management
- Patients and caregivers should be educated in driveline care
- Aseptic technique, and adherence to institutional best practice is required
- Wound photo documentation, including staging, might be helpful
- Driveline should be immobilized using anchor or binding device
- Exit site should be kept dry and covered during showering

Clinic follow-up
- Early postoperatively weekly visits are required, but that may stretch to 3 months according to patient status and distance from implanting center
- Communication/telehealth support remains vital at other times
- Flow waveforms should be reviewed at every clinic visit
- Echocardiography should be performed every 3 to 6 months
- Hemodynamics should be assessed between 3 and 6 months post implantation, and as clinically required

Logfiles
- Logfiles should be downloaded at each visit
- Analytics are available through online portal (https://autologs.medtronic.com)
- Logfiles show pump performance trends indicating differences in flow, power, and pulsatility (Figure 3)

Comparison with HeartMate 3
- HVAD outpatients should have waveform, and logfiles reviewed

Special Considerations: Explant for Recovery

From the STS Intermacs Registry, recovery may be expected to occur in at least 2% of all LVAD support patients,[2] and might occur more frequently in carefully selected cohorts.[87] It is important to continually assess patients for the possibility of recovery, even late post implantation.[88] LV cardiac recovery might initially be suggested by typical waveform changes seen on the HVAD monitor (Figure 2, *G*). The estimated flow waveform shows marked flow pulsatility with typically low mean flow (due to parallel ejection through the aortic valve). The flow waveform might show a broad systolic peak, although this is more apparent in the power waveform on the monitor, due to rapid aortic valve opening.[38] Recovery might be confirmed with a combination of echocardiography and hemodynamic studies under decreased pump support.[89] Hemodynamic assessment during exercise has also been shown to be a strong predictor of recovery success.[90]

Key points for explant for recovery
- Recovery should be sought because it possible even late in pump support
- Waveform changes of high pulsatility with low baseline flow and notched systolic wave might suggest recovery
- Recovery is confirmed with echocardiography, and hemodynamic changes under decreased support and with exercise
- Full device explantation is recommended in the setting of infection
- Decommissioning is less invasive and might be suitable with similar long-term outcomes
- Consider psychological evaluation and/or support because patients sometimes feel they are losing their "parachute"

Comparison with HeartMate 3
- Management and approaches are similar

Pump support withdrawal might be achieved by formal explant of the pump and all components or pump decommissioning (achieved by surgical division of driveline and ligation of outflow conduit).[91-93] Decommissioning has the advantage that the surgery may be performed off bypass and with the pump in situ. The sewing ring might be left in situ and an occlusive plug used in place of the pump for a less invasive procedure.[94] In the setting of infection, complete removal of all device components is recommended. Patients should continue neurohormonal therapies post pump removal.[93] Irrespective of the type of an explant procedure chosen, it is of critical importance to perform the operation with a focus on maintaining adequate cardiac protection throughout. Even with functional recovery, the heart might still be vulnerable to any additional stress from the explant procedure, which could negatively affect cardiac function.

CONCLUSIONS

This document combines best available evidence and consensus opinion to optimize ongoing HVAD patient management. These consensus guidelines should be read in combination with the Instructions for Use.[18] This does not replace the Instructions for Use, but provides a summary of international expert experience using the HVAD pump.

Conflict of Interest Statement

Christopher Hayward, MD, MBBS: honoraria/consultant from Abbott Inc and Medtronic; Iki Adachi, MD: consultant and proctor for Berlin Heart Inc, Medtronic, Jarvik Inc, BiVACOR Inc, and Sony-Olympus Medical Solutions Inc; Erin Davis, BSN, RN: consultant to Medtronic; Erika D. Feller, MD: advisor/consultant/advisory boards/honoraria—Medtronic; Koichiro Kinugawa, MD, PhD: advisor/consultant/advisory boards/honoraria—Medtronic; Liviu Klein, MD, MS: consultant for Medtronic and Abbott, Inc; Angela Lorts, MD, MBA: consultant/educational grant—Abbott Inc, Berlin Heart, Syncardia, Medtronic, and Abiomed; Claudius Mahr, DO: consultant and investigator for Abbott, Inc, Medtronic, Abiomed, Carmat, and Syncardia; Jacob Mathew, MBBS: consultant for Medtronic; Marcus Müller, MD: consultant and advisor for Medtronic; Minoru Ono, MD, PhD: consultant for Medtronic; Francis D. Pagani, MD, PhD: noncompensated scientific advisor for FineHeart, Inc, Member of the Data Safety Monitoring Board for Carmat and the National Heart, Lung, and Blood Institute PumpKIN Clinical Study; Jonathan Rich, MD: consultant for Abbott Inc, and Medtronic; Desiree Robson, RN, BSc(Hons): travel grants Abbott Inc and Medtronic; David N. Rosenthal, MD: no direct financial conflict of interest. Serves as co-Director of ACTION, which has received financial support from Berlin Heart, Medtronic, and Abbott, Inc, and consultant for the Department of Justice but this was not related in any manner to the publication; Diyar Saeed, MD, PhD: consultant for Abbott Inc, Medtronic, and Abiomed; Christopher Salerno, MD: consultant for Medtronic and Abbott Inc; Andrew J. Sauer, MD: speaking/consulting for Medtronic, Abbott, Boston Scientific, Edwards Life Sciences, and Impulse Dynamics; Thomas Schlöglhofer, MSc: consultant and advisor, and has received research grants from Medtronic and Abbott, Inc; Laurens Tops, MD, PhD: consultant for Medtronic. All other authors reported no conflicts of interest.

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Key Words: HeartWare HVAD, left ventricular assist device, blood pressure, anticoagulation, adverse events, management guidelines

TABLE E1. There are differences in the equipment and patient management for the HVAD System and HeartMate 3 LVAS; below is a simplified summary of key differences

	HeartWare HVAD System	HeartMate 3 LVAS
Equipment		
Pump size/outflow	Displaces 50 cc, inflow length 32.3 mm, outflow graft 10 mm	Displaces 80 cc, inflow length 22 mm, outflow graft 14 mm
Pump mechanics	Impeller suspended by magnetic and hydrodynamic forces: Lavare cycle (automatic decrease and increase in speed) 1 time per minute to washout the pump	Rotor suspended by Bearingless Full Maglev: artificial pulse is activated 30 beats per minute asynchronously to washout the pump
Main display on monitor	• Pump wave forms • Power • Flow • Speed	• PI • Power • Flow • Speed
Settings providers can change	• RPM • HCT • High and low flow alarms • Lavare on/off • Suction alarm on/off	• RPM (fixed speed) • HCT • Lower speed limit
Pump characteristics to prevent suction	Pump waveforms can be monitored in real time to determine if suction events occur. In addition, there is a suction alarm (triggered if flow goes 40% lower than baseline for >10 seconds)	The provider sets a lower speed limit on the pump. If the pump detects a 45% change in PI the pump will decrease RPM to the lower speed and automatically increase back to fixed speed
Batteries	• Each battery last 4-7 hours • Two batteries together will last 12-14 hours • One battery is drained at a time	• Each battery lasts 8-10 hours • Two batteries together will last up to 17 hours • Both batteries/clips are drained at the same time
Power sources required	**Must have either:** • 2 batteries connected • 1 battery and AC adaptor • 1 battery and DC adaptor	**Must have either:** • 2 batteries in clips connected • Connected to power module • Mobile power unit
Safety from pump stop	Pump will stop if both batteries are disconnected	Internal controller 11-V lithium battery will prevent pump stop if external batteries or power are disconnected. Internal battery lasts approximately 15 minutes
Backup controller	Must change the settings manually to match the primary controller	No need to change settings in the back-up controller; must be charged at least every 6 months to maintain internal battery
Driveline	Approximately 4.8 mm in diameter. If driveline is severely damaged the device must be changed, or Medtronic engineering support to repair	Approximately 6.2 mm in diameter. Modular driveline that is replaceable in case of significant damage
AC power	Requires the AC power adaptor to connect patient to wall power. Patient may be connected to the AC power adaptor and 1 battery to power the pump	Requires the power module or the mobile power unit to connect to AC power. Patient may be connected to either the batteries or the power module or the mobile power unit but not to both simultaneously

(Continued)

TABLE E1. Continued

	HeartWare HVAD System	HeartMate 3 LVAS
Pump monitoring and alarms		
Understanding patient and pump interactions	Pump wave forms display systolic (peak), diastolic (trough) flow and pulsatility. The waveforms can be interpreted by the providers and used to modify settings and patient management. Suction events will result in an alarm, if activated, and a change in waveforms	PI is displayed to give a sense of the pump/patient interaction but not able to see waveforms to assess flow dynamics. To understand patient status, providers must follow PI trend. PI events occur when the PI decreases or increases by >45%. PI events might be from suction or many other etiologies such as coughing or moving
Alarms classifications	Low (yellow) medium (flashing yellow) and high priority alarms (flashing red)	Advisory (yellow) and hazard (red) alarms
Suction alarm/PI events	There is an audible/flashing yellow suction alarm if suction detection is activated	There is no suction alarm. PI events can be seen on the monitor when downloading the events page
Low flow alarms	Low flow alarm is set at 1.0 L/min to 9.9 L/min. Setting below 2 L/min not recommended	Low flow alarm is set at 2.5 L/min (can be changed by Abbott Laboratories clinical support to 2 L/min)

HVAD, Medtronic HeartWare HVAD System; *LVAS*, Left Ventricular Assist System; *PI*, pulsatility index; *RPM*, revolutions per minute; *HCT*, hematocrit; *AC*, alternating current; *DC*, direct current.