Considerations for Left Ventricular Assist Device Patients Receiving Hyperbaric Oxygen Therapy

by

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Abstract

Hyperbaric Oxygen Therapy (HBOT) is a widely accepted treatment for patients suffering from conditions associated with low oxygen content or delivery. HBOT utilizes a pressurized environment (typically 2.4 to 2.8 atmospheres absolute) and high fraction of inspired oxygen to drive oxygen deep within the body's tissues to facilitate healing. Although a variety of patients may benefit from this therapy, many medical devices have not been tested in the hyperbaric environment, including ventricular assist devices (VADs). Such testing needs to consider the mechanical operation of VADs and the environmental changes that occur with HBOT. There are few published documents describing the ability of VADs to function during descent to a therapeutic depth and the return to surface pressure that occur with HBOT.

The main goal of this study was to determine if two common VADs (HeartMate II and HeartWare) and their components would properly function during HBOT. The specific hypothesis tested was that the LVADs and their components would maintain function throughout the duration of the testing without suffering any damage from a pressurized mono-place chamber. One parameter used to assess adequacy of VAD function was the ability of the VAD to maintain flow within 1 liters per minute (LPM) of the initial flow at pressures ranging up to 2.8 ATA in the mono-place hyperbaric chamber. Thoratec's HeartMate II Left Ventricular Assist System (HM II LVAS) was powered in the mono-place chamber using its mobile power unit (MPU). The MPU utilizes AC power, which met the requirements stated in the 2018 version of the *National Fire Protection Agency 99* guidelines for safe use of the medical device within a hyperbaric chamber. Medtronic's HeartWare Ventricular Assist System (HW VAS) was powered using its AC adapter. Again, the setup met the requirements stated in the 2018 version of the *National Fire Protection Agency 99* guidelines for safe use of the medical device within a hyperbaric chamber.

The HM II LVAS maintained flow within ±0.25 LPM of the VAD's initial flow during testing in the mono-place chamber. The HM II LVAS remained completely functional for the entirety of testing and no components suffered any damage from the pressurized environment. The HW VAS maintained flow within ±0.50 LPM of the VAD's initial flow during testing in the mono-place chamber. The HW VAS remained completely functional for the entirety of testing and no components suffered any damage from the pressurized environment. The results of this study indicate that the mechanical operation of the VADs will function appropriately at high pressures during HBOT. However, prior to utilizing HBOT for a VAD patient, extra safety precautions, such as N_2 purging of electrical components and the use of non-explosive/waterproof fittings for AC power cords, should be implemented and tested.

Acknowledgments

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Table of Contents

List of Figures

List of Tables

1. Introduction

A ventricular assist device (VAD) is a mechanical pump used to support heart function and blood flow in people who have weakened hearts. This mechanical pump is implanted with the goal of reducing the overall workload of the native heart by helping pump blood from the weakened ventricles, to the rest of the body [1, 2]. Often, VAD patients have multiple medical conditions that accompany their weakened heart. Many of these conditions may benefit from hyperbaric oxygen therapy (HBOT).

HBOT is defined as an intervention in which an individual breathes near 100% oxygen while inside a hyperbaric chamber that is pressurized to greater than sea level pressure (1 atmosphere absolute, or ATA) [3]. HBOT is a well-established treatment for decompression sickness, carbon monoxide poisoning, arterial gas embolism, and wounds that will not heal as a result of diabetes or radiation injury [3, 4, 5, 6]. HBOT benefits the patient by increasing oxygen carrying content of the blood through improved oxygen transfer across the lung tissues [3, 4, 7, 8]. The increased oxygen in the body greatly enhances the ability of white blood cells to kill bacteria, reduces swelling and allows new blood vessels to grow more rapidly in the affected areas [4, 8, 9, 10]. It is a simple, non-invasive, and painless treatment that many patients may benefit from. However, many medical devices, including VADs, have not been tested or approved for use in the hyperbaric environment, which limits the number of patients that can take advantage of HBOT.

In order to determine if VADs are safe to use in hyperbaric chambers, the first goal of this study was to identify and assess the mechanical concerns for a VAD patient receiving HBOT. The second goal was to develop a standard for treating VAD patients

with HBOT by addressing any required safety alterations to the VAD components for use at Aurora St. Luke's Medical Center in Milwaukee, WI. An additional goal was to complete an Electronic Device Approval Form for VADs in HBOT for Aurora St. Luke's Medical Center.

2. Background

2.1 Introduction to Ventricular Assist Devices (VADs)

A ventricular assist device (VAD) is a mechanical circulatory support (MCS) device used to support heart function in people with weakened hearts. They work by pulling blood from the ventricles, increasing the flow over what the native heart can do, and delivering the increased flow into either the pulmonary artery or the aorta. VADs have been shown to restore circulatory blood flow, functional cardiac status, and increase survival rates and quality of life in a broad range of advanced-stage heart failure patients [1, 2, 11, 12]. Specific uses of VADs are covered in Section 2.4.

There are two basic types of VADs, based on the ventricle they are aiding: a right ventricular assist device (RVAD) and a left ventricular assist device (LVAD). If both types are used at the same time, they may be called a biventricular assist device (BIVAD) [1]. Clinically, LVADs are implanted more often than RVADs and the number of LVADs implanted continues to increase. Figure 1 displays the increase in LVAD implants from 2006 to 2010 [11]. Clinically, the HM II LVAS is the most commonly used LVAD, with more than 20,000 implants as of 2013 [12, 13]. In 2012, the HW VAS

received FDA approval for bridge-to-transplant and since then, more than 13,000 HW VAS have been implanted worldwide [14]. Because of this, if VADs are going to be approved for use in hyperbaric chambers, initial testing should be performed on LVADS, particularly the common types. Therefore, this study focused on the Heartmate II Left Ventricular Assist System (HM II LVAS) and the HeartWare Ventricular Assist System (HW VAS).

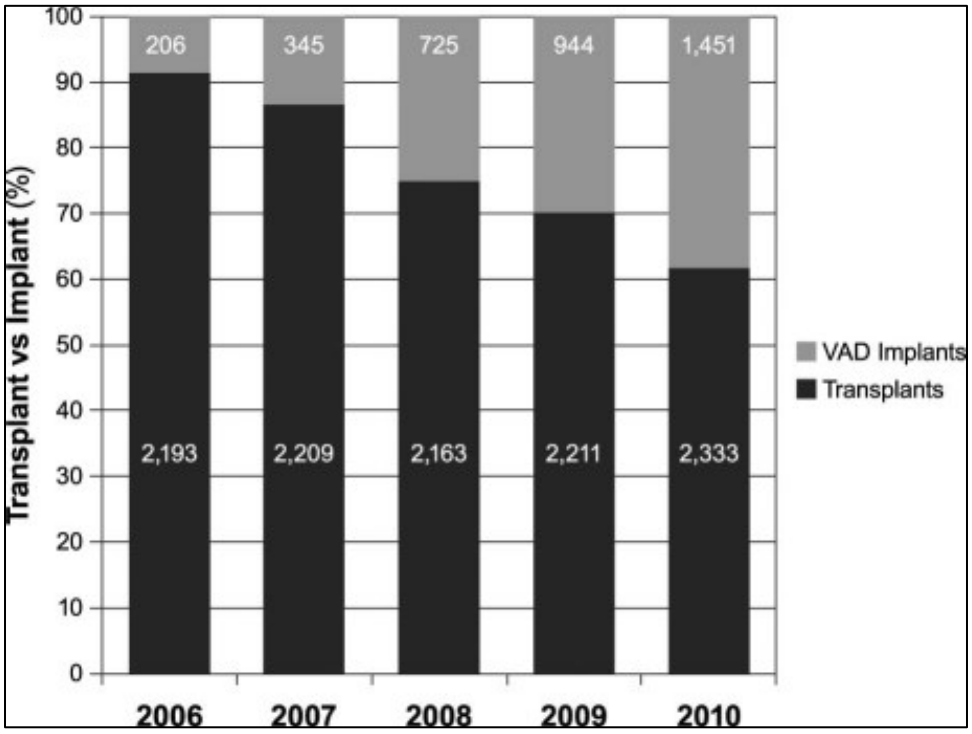


Figure 1: The Number of Left Ventricular Assist Devices (LVADs) Implanted and Transplantations Performed from 2006 through 2010 [13]. The total is set to 100% to show the proportional increase in LVAD implantations. The number of transplantations remained stable.

2.2 The HeartMate II Left Ventricular Assist System (HM II LVAS)

The HeartMate II Left Ventricular Assist System (HM II LVAS) made by Thoratec Corporation, was approved for bridge-to-transplant use in April 2008 and approved for destination therapy in January 2010 [14, 15]. The device is placed just below the diaphragm, with the inflow conduit implanted into the apex of the heart and the outflow attached at the aorta (Figure 2). The HM II LVAS consists of a motor driven pump rotor that propels the blood forward through the LVAD (Figure 3). The rotor spins on blood-lubricated bearings, which are designed for long life [8, 14, 15, 16]. All motor drive and control electronics are outside of the implanted blood pump.

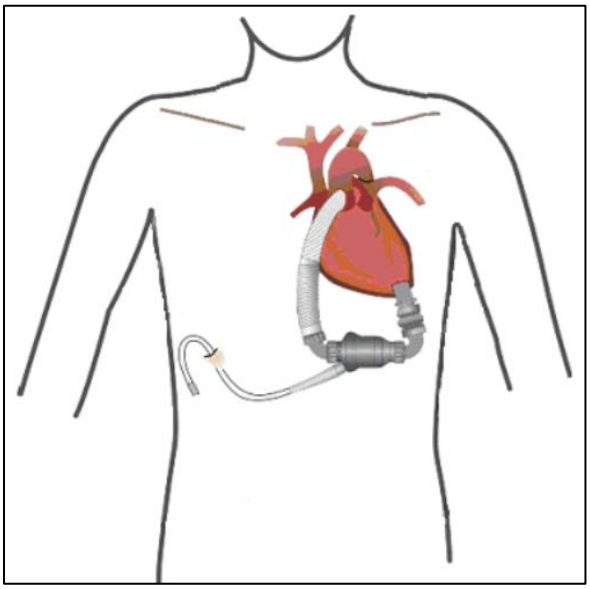


Figure 2: An Implanted Thoratec HeartMate II Left Ventrcular Assist System [14]. The HM II LVAS is implanted within the chest. The system's inflow is placed at the apex of the heart and lies in the left ventricle. The system's outflow graft is attached to the aorta.

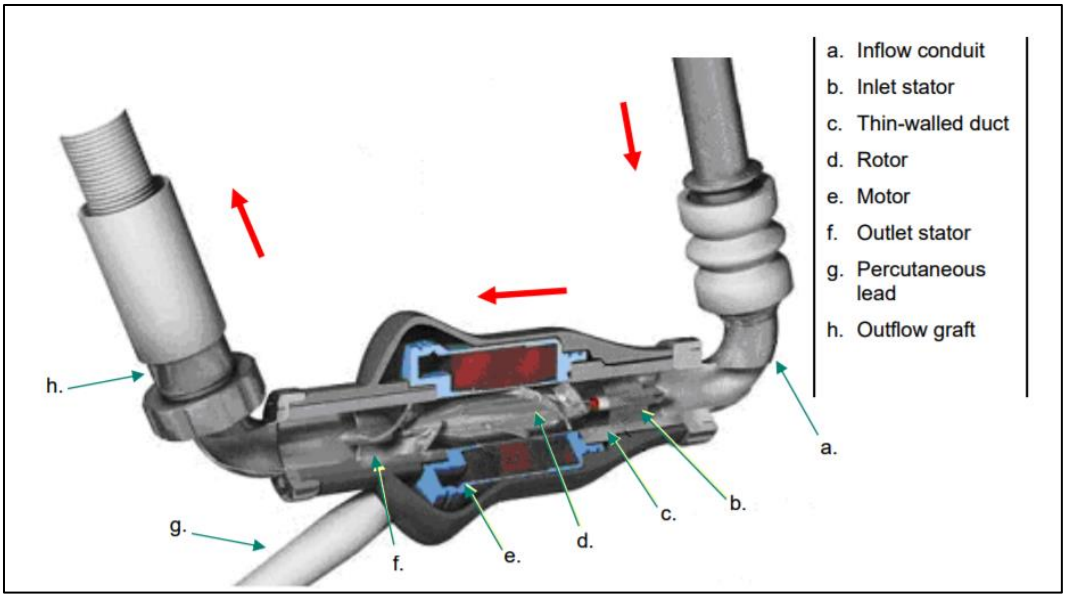


Figure 3: The Thoratec HeartMate II Left Ventricular Assist System Pump [14]. The HM II LVAS utilizes axial flow technology.

The HM II LVAS employs an axial flow pump. Axial flow pumps have continuous flow that follows the native cardiac pulse. Although flow is continuous, the pump output varies over the cardiac cycle. Additionally, the HM II LVAS is valve-less, afterload sensitive, and sensitive to the pressure differential across the pump. Equation (1) – from Thoratec [15] – expresses this relationship:

$$\Delta P = P_{Aortic} - P_{Left\ Ventricle}. \quad (1)$$

The speed range of the HeartMate II is 6,000 – 15,000 rotations per minute (RPM) and corresponds to a flow capacity of 3 to 7 liters per minute (LPM). The implant weight is 370 grams and the implant volume is 124 mL. The inflow and outflow cannulae of the HeartMate II are 16 mm in size [14, 15]

2.3 The HeartWare Ventricular Assist System (HW VAS)

The HeartWare Ventricular Assist System (HW VAS) is a centrifugal, continuous flow pump made by Medtronic. HW VAS is valve-less and utilizes a wide-blade impeller that is magnetically and hydrodynamically suspended to propel flow forward (Figure 4) [17, 18]. There are no touching parts within the pump, which increases the longevity of the device [18, 19, 20]. Motor stators are contained in the front and rear housings. The motor stators provide the active force that helps run the pump. Passive magnets and hydrodynamic thrust bearings are used to suspend and rotate the wide-blade impeller, propelling blood forward through the pump [17, 18, 19]. The wide-blade impeller features three blood flow paths which are designed to enhance blood flow and reduce blood trauma while simultaneously reducing the time that blood travels through the device (Figure 5) [21]. The dual motor stators enhance efficiency and provide redundancy to rotate the impeller [18, 19, 20, 22].

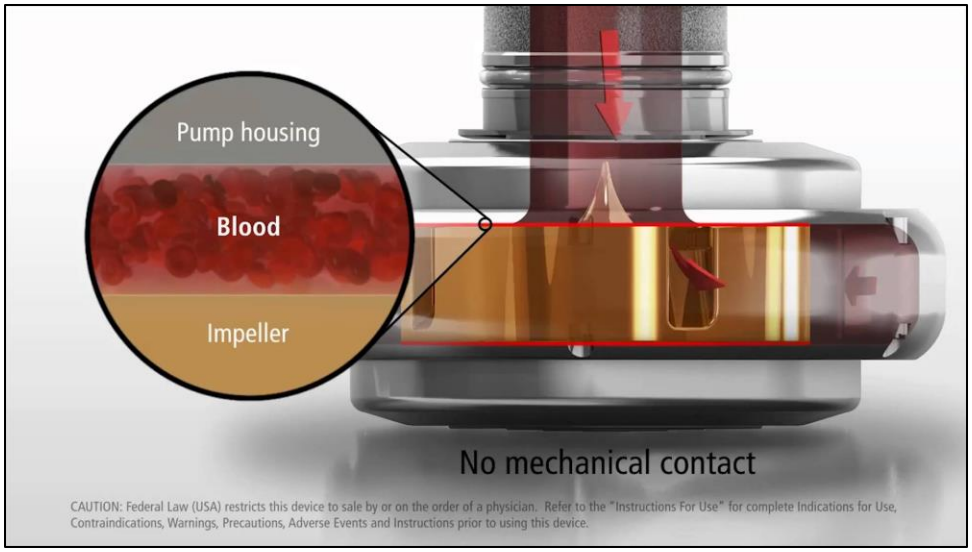


Figure 4: The HeartWare Ventricular Assist System [17]. The HW VAS utilizes a wide-blade impeller that is magnetically and hydrodynamically suspended to provide forward flow.

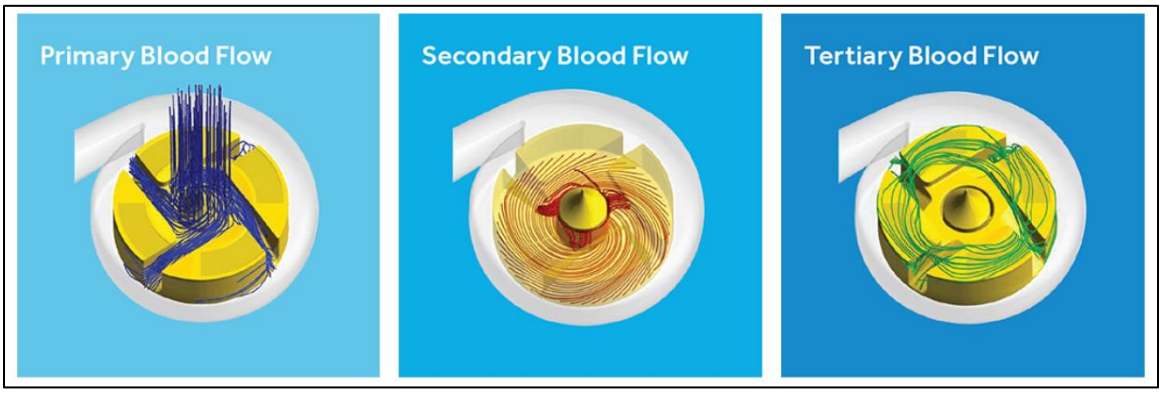


Figure 5: HeartWare Ventricular Assist System Blood Flow [17, 19]. The wide-blade impeller features three blood flow paths: Primary, Secondary, and Tertiary.

The HW VAS is implanted and directly attached to the heart (Figure 6). The integrated inflow allows the device to sit next to the heart with the outflow attached to the ascending aorta. The HW VAS has a speed range of 1,800 to 4,000 RPM and is capable of providing flow up to 10 LPM. Pump flow is preload dependent and afterload sensitive [17, 18, 19].

Figure 6: An Implanted HeartWare Ventricular Assist System [23]. The HW VAS is implanted into the chest. The VAD inflow is cored into the apex of the heart and lies in the left ventricle. The VAD outflow graft is attached to the aorta.

2.4 VAD Use

As previously stated, VADs are used to support heart function and blood flow in people who have weakened hearts. Although VADs are not the first line of defense, when placed appropriately, they can greatly improve the patient's quality of life. VADs are approved for recovery of the native heart, bridge to transplant (BTT), and destination therapy (DT) [14, 16, 19, 24]. A list of indications and contraindications for VADs is shown in Table 1.

Table 1: Indications and Contraindications for VAD Use [2, 15, 16].

VAD Indications	VAD Contraindications
1. Failure to wean from cardiopulmonary bypass 2. Cardiogenic shock following acute myocardial infarction 3. High-risk angioplasty 4. Donor heart failure 5. Peripartum cardiomyopathy 6. Clinical deterioration while awaiting cardiac transplantation 7. Destination therapy criteria: a. NYHA Class IV end-stage LV failure b. Has received optimal medical therapy for at least 60 of the last 90 days c. Has life expectancy of less than two years d. Is not a candidate for cardiac transplant 8. Patient does not respond to conventional therapy (pharmacological support, fluid therapy, IABP if applicable) 9. Common criteria: a. Cardiac index < 2 L/min/m^2 b. Systolic blood pressure < 90 mmHg c. Atrial pressure > 20 mmHg d. Systemic vascular resistance (SVR) > 2100 dynes/sec/cm^{-5} e. Urine output < 20 mL/hour	1. Peripheral vascular disease 2. Cancer 3. Chronic hepatic or renal failure 4. Severe pulmonary disease 5. Permanent CNS damage 6. Sepsis 7. Coagulopathy 8. Age > 70 for BTT; Age > 80 for DT 9. BSA < 1.2 m^2 for the HM II LVAS

2.5 Introduction to Hyperbaric Oxygen Therapy (HBOT)

HBOT is a medical treatment purported to enhance healing secondary to improved tissue oxygen delivery. When an injury occurs, the tissue in the body requires more oxygen to recover and survive. Chronic wounds develop when the natural healing process is disrupted. Disruption of the natural healing process can be caused by advanced age, infection, low blood flow, poor nutrition, diabetes, and decreased levels of oxygen in the blood [3, 4, 5, 8]. HBOT helps chronic wounds heal by increasing the amount of oxygen that the blood can carry, resulting in an increased amount of oxygen reaching the injured tissue [4, 5, 7].

To undergo treatment, patients enter a pressurized single-person or multi-person treatment chamber where there is 100% oxygen and the air pressure is raised above normal. This setting increases the partial pressure of oxygen (PO_2) of atmospheric air and inhaled air, which benefits oxygen exchange in the lungs [3, 4, 7, 8]. The elevated PO_2 is transferred into the blood where it fully saturates the hemoglobin and generates an increased driving pressure for oxygen to enter the tissues, resulting in improved oxygen delivery to cells [4, 7, 8]. Increased oxygen content helps fight bacteria [10] and stimulate the release of growth factors and stem cells [9, 25], and promotes overall healing [4, 9, 10, 25].

In order to achieve maximum benefit, patients often require multiple session of HBOT to produce the desired result. The number of sessions depends on the medical condition that the patient has. Carbon monoxide poisoning may be treated in three visits, while nonhealing wounds may require 20 to 40 visits [3, 4]. Common chamber pressures

for HBOT are between 2.4 ATA and 2.8 ATA. Sessions generally last between 90 and 120 minutes, but may extend up to 8 hours for certain treatments [3, 4].

HBOT is currently an accepted treatment for a wide variety of uses, but there are also some contraindications for its uses (Table 2). Contraindications include untreated pneumothorax and several medications with side effects associated with pulmonary damage, which can be worsened with high PO_2. In some instances, HBOT will still be used if the benefits outweigh the potential risk and some necessary corrections are made. For example, if a patient has claustrophobia they can be administered benzodiazepine as a calming agent prior to HBOT.

Table 2: Indications and Contraindications for Hyperbaric Oxygen Therapy [3, 5].

HBOT Indications	HBOT Contraindications
1. Air or gas embolism 2. Severe anemia 3. Brain abscess 4. Burns 5. Decompression sickness 6. Carbon monoxide poisoning 7. Crushing injury/Compartment syndrome/Other traumatic ischemia 8. Gangrene 9. Infection of skin or bone that causes tissue death 10. Nonhealing wounds 11. Radiation injury 12. Osteomyelitis 13. Sudden sensorineural hearing loss	1. Untreated pneumothorax 2. Bleomycin 3. Cisplatin 4. Disulfiram 5. Doxorubicin 6. Sulfamylon 7. Asthma 8. Claustrophobia 9. Congenital spherocytosis 10. Chronic obstructive pulmonary disease (COPD) 11. Eustachian tube dysfunction 12. High fever 13. Some implanted medical devices 14. Seizures 15. Severe cardiomyopathy or decompensated congestive heart failure 16. Upper respiratory infection (URI)

2.6 The Use of HBOT in Heart Failure Patients

VAD patients often have significant health deficits in addition to their heart failure. Common comorbidities include diabetes mellitus and peripheral artery disease, which themselves increase the risk of non-healing infections and ulcers [26]. Because VADs are not approved for use in HBOT, these patients cannot take advantage of the healing benefits of HBOT.

Even if a person has a VAD placed, their underlying heart condition can still worsen. Many VADs are placed secondary to acute coronary syndrome (ACS), which collectively includes acute myocardial infarction and unstable angina [27] . There is some evidence from small trials to suggest that HBOT, in non-VAD patients, is associated with a reduction in the risk of death [27, 28, 29], the volume of damaged muscle [9, 10, 27], the risk of a major adverse cardiac event [27, 29, 30, 31] , and time to relief from ischemic pain for people who suffer from ACS [27, 32, 33]. The administration of HBOT for ACS treatment is based on the argument that the myocardium is hypoxic, and that HBOT can reverse that hypoxia in areas that are marginally perfused [27]. The improved oxygen availability associated with HBOT may also improve outcome through the effects of oxygen as a modulator of tissue repair. Oxygen has been shown to increase the expression of antioxidant enzymes in both tissues and plasma through an increase in glutathione levels [6, 34]. It has also been shown to prevent the activation of neutrophils in response to endothelial damage, thus modifying ischemia-reperfusion injury [9, 10]. Additionally, HBOT mobilizes stem cells from the bone marrow in a dose-dependent manner and may be important in neovascularization of healing tissue [25]. Yet none of these potential benefits of HBOT therapy are available to VAD patients.

There are additional circumstances that may lead to a situation in which VAD patients may benefit from HBOT. In spring of 2015, employees at Aurora St. Luke's Medical Center were faced with a challenging situation when one of their VAD patients was diagnosed with an arterial insufficiency, calciphylaxis. This condition results in cutaneous necrosis resulting from intravascular calcium deposits. HBOT is often used to facilitate wound healing for patients suffering from calciphylaxis [35]. Another example in which HBOT could be beneficial for VAD patients is if they acquire an air embolism during LVAD implant and initiation. Currently, HBOT therapy is not approved for VAD patients because VAD equipment has not been tested under the pressures utilized in HBOT. There are also concerns about how high pressures might impact hemodynamics in this group of patients.

2.7 Hemodynamic Changes During HBOT

One clinical concern for a VAD patient receiving HBOT is the hemodynamic changes associated with HBOT and the impact they have on VAD function. Multiple studies have investigated these hemodynamic changes associated with an increased pressure within a chamber [7, 36, 37, 38, 39, 40]. Table 3 summarizes the study results of these investigations which collectively show a reduction in both heart rate and cardiac output when placed under pressure. Although such change may not apply to VAD patients because they are relying on the VAD, and not their native heart, such data should be taken into consideration. Previous studies have also reported significant increases in systemic vascular resistance (SVR). This may influence afterload sensitive VADs, such as the HM II LVAS and the HW VAS. Increases in systemic vascular resistance might

lower the VAD output and compromise the circulatory support to the patient. Although VADs have various speeds of operation that could be adjusted to supplement this obstacle, it is not a recommended solution. Therefore, the operation of the VAD in the presence of high afterload pressure should be verified prior to their use in HBOT.

Table 3: Summary of Study Results Investigating Clinical Considerations [7, 36, 37, 38, 39, 40].
SVR = systemic vascular resistance (dynes•sec/cm^2/m^2), HR = heart rate (beats/min), CI = cardiac index (L/min/m^2), LV Work = left ventricle work (kg•m/min/m^2), CO = cardiac output (L/min), LVmWS = left ventricular meridional wall stress (dynes/cm^2), SAP = systolic arterial pressure (mmHg), PR = peripheral resistance (units). *P-value < 0.05 when compared to control.

Author	Subjects	N	Methods	Results			
Kenmure, A.C.F. [37]	Healthy men	20	Air at 1 atm, 100% O_2 at 1 atm, 100% O_2 at 2 atm, 15 min decent time, 45 min duration		**Air**	**O_2 1 atm**	**O_2 2 atm**
				SVR	2,212±403	2,369±459*	2,445±527*
				HR	69±7	65±5*	64±6*
				CI	3.65±0.56	3.35±048*	3.28±0.55*
				LV Work	4.7±0.7	4.4±0.5*	4.3±0.7*
Abel, F.L. [38]	Anesthetized dogs	13	Air at 3 atm, 100% O_2, 100% O_2 at 3 atm, 3-5 min decent time, 30-60 min duration		**Air at 3 atm**	**100% O_2**	**100% O_2 at 3 atm**
				SVR	109.0±8.7	103.9±8.6	119.5±5.6*
				HR	99.3±3.0	96.2±2.0	97.4±3.4
				CO	92.9±4.5	91.1±4.3*	90.3±4.6*
				Cardiac Work	92.5±2.5*	83.0±6.2*	88.2±5.8
Berry, J.M. [36]	Conscious dogs	12	Baseline Air, 100% O_2 at 1 atm, 100% O_2 at 2 atm, 10 min decent time, 30-90 min duration		**Baseline Air**	**100% O_2 at 1 atm**	**100% O_2 at 2 atm**
				SVR	54±3	67±8*	70±3*
				HR	95±6	87±6*	84±4*
				CO	2.0±0.1	1.9±0.2	1.6±0.1*
Molenat, F. [39]	Healthy volunteers	10	Baseline 100% O_2, 6-hour compression profile ranging from 1.6-2 atm while performing light exercise, 6 hr duration		**Baseline 100%**	**100% O_2 at 15 min**	**100% O_2 at 5 hr**
				LVmWS	69±11	81±13*	84±16*
				HR	62±7	69±12	63±11
				CO	6.1±1.1	6.3±0.9	4.9±0.7*
				SAP	124±9	131±15	130±9
Gawthrope, I.C. [40]	Patients and staff	20	Baseline Air, 100% O_2 at 2.4 atm, 30 min duration		**Baseline Air**	**100% O_2 at 2.4 atm**	
				HR	69.7±11.8	64.9±11.3*	
				CO	5.9±2.4	5.3±2.2*	
Whalen, R. [7]	Healthy volunteers	10	Baseline Air, 100% O_2 at 1 atm, air at 3.04 atm, 100% O_2 at 3.04 atm		**Baseline Air**	**100% O_2 at 1 atm**	**100% O_2 at 3.04 atm**
				PR	15.3±3.6	16.0±3.5	17.8±3.8*
				HR	75±8	71±9	63±9*
				CO	60±1.2	5.8±1.1	5.3±1.1*

2.8 VAD Testing in HBOT

Although Thoratec Corporation will not endorse their product for HBOT, three different hospitals have published results of LVAD performance testing in a hyperbaric chamber. At the Sharm Memorial Hospital (SMH) in San Diego, CA, the testing was designed to ensure safe treatment of an 80-year-old male patient who had an HM II LVAS implanted [41]. The patient was referred for HBOT for radiation necrosis of the duodenum and common bile duct after Cyberknife radiation therapy for ampullary adenocarcinoma. SMH's Mechanical Assist Device Department contacted the Thoratec Corporation who informed them that a previous patient had undergone HBOT with the LVAD driver being powered via a power supply outside of the chamber. Additionally, engineers at Thoratec Corporation expressed concern about the use of the controller's battery (Lithium Ion 14 V, 4.8 W-hr). The battery had an upper pressure limit of 795 mmHg and was designed to vent out if the battery became overheated. It was unclear if gas could vent into the device when experiencing the compressive forces of increased pressure.

SMH's Mechanical Assist Device Department tested the driver and battery at 2.4 ATA for 5 minutes with standard decompression, 2.4 ATA for 110 minutes with standard decompression, and 2.8 ATA for 5 minutes with explosive decompression [41]. Additionally, the battery alone was compressed to 7 ATA with explosive decompression. After each decompression, SMH's team inspected the driver and battery and found that there was no visible damage. The driver continued to alarm during each test (as designed to do if disconnected from the patient). After interrogation, the driver was found to be working properly. Following their HM II LVAS testing, the patient commenced with

uncomplicated daily HBOT at 2.4 ATA [41]. They concluded that a patient with the HM II LVAS can safely be treated in a multi-place hyperbaric chamber.

The Hyperbaric Medicine Division of LDS Hospital in Salt Lake City, UT has published two papers discussing their LVAD testing in a hyperbaric research chamber [42, 43]. Their division performed a feasibility study to test the LVAD during hyperbaric conditions by connecting a HM II LVAS to a water-filled mock circulatory system. The pump and controller unit were both placed within the chamber, with power and diagnostics supplied externally via the pump controller's standard power cable. The pump's afterload was adjusted between 80-90 mmHg and the system output was measured using an ultrasonic flow meter. The system was tested at two separate RPM settings in a metal research chamber pressurized between 0.85 ATA and 4.0 ATA. The team at LDS Hospital found that flow was stable across the range of pressures tested at both of their RPM settings [42, 43]. At a setting of 8,800 RPM the flow ranged from 4.17 – 4.19 LPM, and at a setting of 8,400 RPM the flow ranged from 3.96 – 3.99 LPM [42, 43]. No damage to the controller unit or pump occurred during their testing. They concluded that the HM II LVAS functioned normally without any damage [42, 43]. For any future VAD use, the Hyperbaric Medicine Division strongly suggested that there be an appropriate chamber pass-through available for the device's power cable.

In 2016, at the Hennepin County Medical Center (HCMC) in Minneapolis, MN, the HBOT team was presented with an 81-year-old patient that had a HM II LVAS placed in 2012 for ischemic cardiomyopathy [44, 45]. The patient had a history of prostate cancer in 2009 that was treated with radiation and was now suffering from hemorrhagic cystitis causing 12 weeks of hematuria, clots, blood loss anemia requiring

transfusions, and severe bladder spasms. The patient commented, “I’d rather not live than deal with these bladder spasms any longer” [44]. Therefore, HCMC’s HBOT team investigated the safety of an LVAD patient and HBOT.

The team made some adjustments to the HM II LVAS components to ensure safety within the chamber. The team followed the 2015 version of the *National Fire Protection Agency (NFPA) 99 Code* as guidelines for safe use of the medical device within a hyperbaric chamber [44, 45]. NFPA 14.2.8.3.17.5 states that battery-operated devices shall meet the following requirements: “No Li-Ion batteries, batteries shall not undergo charging while located in the chamber, the equipment electrical rating shall not exceed 12 V and 48 W” [44]. In order to follow these requirements, the team removed the lithium ion battery from the system controller to eliminate continuous charging. The team decided to use the HM II LVAS’s Mobile Power Unit (MPU) as a power source because it was determined that 14V Li-Ion battery packs were not safe per NFPA 99. Additionally, the HM II LVAS’s Power Module (PM) has batteries that undergo charging while connected. The MPU power cord was spliced with an explosion/waterproof fitting and the MPU was sealed in a plastic container and purged with 15 LPM of nitrogen for safety (Figure 7). A nitrogen purge is used to displace oxygen to a concentration that will not support combustion if an electrical spark would be generated.

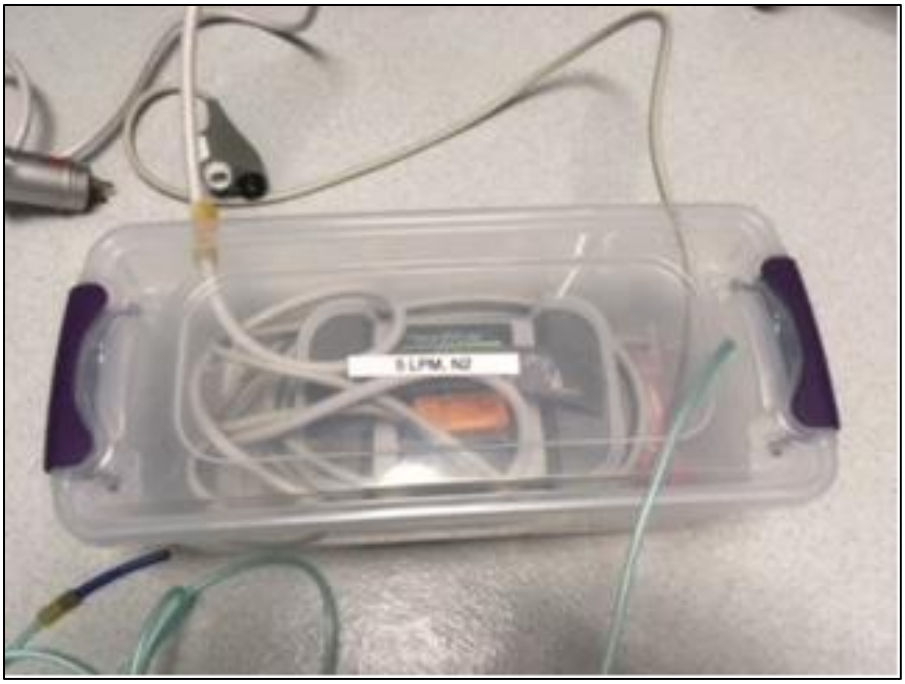


Figure 7: Enclosed Mobile Power Unit [44]. The MPU was enclosed and flushed with 15 LPM of N_2 and 1.3% of O_2.

The HBOT team at HCMC performed three tests prior to approving the HM II LVAS patient for use in HBOT. For their testing, the team placed all components in the multi-place chamber and connected the VAD to a water filled mock circuit to simulate blood flow (Figure 8). During their first test, the chamber was pressurized to 2.8 ATA. The device remained fully functional, but it was noted that the tubing became limp around 2.3 ATA (41 FSW) [44]. Post-decompression, the BioMed and LVAD Coordinator at HCMC inspected the devices and found no visible signs of damage. During the second test, the chamber was pressurized to 2.8 ATA at a rate of 30-foot sea water (FSW) per minute. The chamber remained pressurized at 2.8 ATA for 5 minutes and then max depressed at a speed of 55 FSW/min. The device remained completely functional and following decompression, the BioMed and LVAD Coordinator again

inspected the pump, system controller, and MPU and found that there were no visible signs of damage [44, 45].

For the final test, the HBOT pressurized the chamber to 6 ATA at 25 FSW/min. Around 3.8 ATA (92 FSW), the system controller started to alarm and the controller initiated a self-test [44, 45]. The soft keys on the controller had compressed due to chamber pressure and the relationship defined in Boyle's Law. Equation (2) expresses Boyle's Law:

$$P \propto \frac{1}{V}. \tag{2}$$

Pressure and volume are inversely related in a constant setting. Therefore, as pressure increases, the volume in the system controller decreases causing the soft keys to compress. The BioMed and LVAD Coordinator ensured that the device would continue to work, so the team proceeded with the testing. The device remained functional and following decompression the BioMed and LVAD Coordinator found now visible signs of damage on any of the HM II LVAS components [44, 45]. The functional test log from HCMC is published in Appendix A.

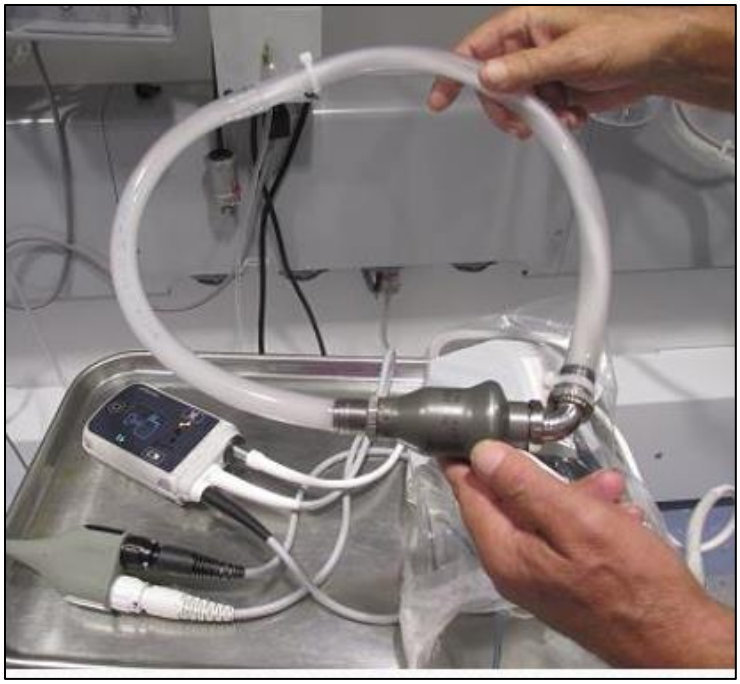


Figure 8: Water Filled Mock Circulatory System [44]. The mock circuit was used to simulate blood flow through the HM II LVAS.

Prior to beginning patient treatment, the HBOT team at HCMC established safety procedures for device failure. All of the staff reviewed a Training Competency Validation which included how the HM II LVAS works, how to operate the system, how to perform function assessments, and emergency care and management for the patient. The Emergency Department (ED) at HCMC was notified and prepared for the LVAD Patient and the LVAD Coordinator was onsite during the first patient treatment. Emergency LVAD Procedures were kept on hand with emergency contact numbers readily available. Additionally, an emergency spare battery was kept on standby [44]. The final precaution that the HBOT team took was identifying what to do in case the LVAD fails. They determined that standard Advanced Cardiovascular Life Support (ACLS), including chest compressions and defibrillation, could be used along with vasoactive drugs. Most

LVADs have some innate forward flow due to an intact aortic valve and for their specific patient, the HBOT team determined that they would have a 30-minute response time to get the LVAD running again or surgery would be required. Following the establishment of the safety procedures, the HBOT team at HCMC commenced HBOT with the 81-year-old HM II LVAS patient. They completed 44 uncomplicated treatments at 2.4 ATA in a multi-place chamber [44, 45]. Post-HBOT, the patient was asymptomatic and his quality of life was greatly improved.

3. Project Goal

As previously stated, in 2015 the employees at Aurora St. Luke's Medical Center were faced with a situation when one of their VAD patients was diagnosed with an arterial insufficiency, calciphylaxis. HBOT is often used in this condition to facilitate wound healing. However, because of the VAD and the unknown clinical and mechanical associated risks with VAD use in HBOT, the team denied the hyperbaric treatment. To benefit all VAD patients who suffer from significant health deficits -- in addition to their heart failure – and who could benefit from HBOT, it is time to address the perceived risk of placing an untested foreign device within a chamber. NFPA 99 Code 14.2.9.3.2 states that "all equipment shall be rated, or tested and documented, for intended hyperbaric conditions prior to use" [46].

The goal of this study was to determine if two common VADs and their components would properly function in a mono-place chamber that was pressurized to 2.8 ATA and then decompressed at two different speeds. The specific hypothesis tested

was that the LVADs and their components would maintain function throughout the duration of the testing without suffering any damage from the pressurized chamber. Specifically, LVAD flow would be maintained within 1 LPM of the initial flow rate at various chamber pressures. Assuming appropriate function, as determined by meeting the NFPA 99 Code for safe use of the medical device within a hyperbaric chamber, an additional intent was to complete an Electronic Device Approval Form for the Biomedical Engineers at Aurora St. Luke's Medical Center. This form would assist the engineers in identifying any required alterations to the LVAD's components to complete HBOT for an LVAD patient, and the form would additionally provide test results confirming proper LVAD function within a hyperbaric chamber.

4. Methods

In order to test the function of the VAD at HBOT pressures, specifications for suitable VAD performance were obtained from the Biomedical Engineering Department at Aurora St. Luke's Medical Center. The main specification was that if HBOT were to be implemented with a VAD patient, the AD output could not decrease more than 1 LPM from the patient's baseline flow rate. This specification was assessed by monitoring VAD flow (Q_{VAD}) in a mock circulatory loop placed inside a mono-place chamber, while incrementally increasing the chamber pressure until reaching a therapeutic level of 2.8 ATA. The goal of this testing protocol was to ensure the axial flow pump in the HM II LVAS and the wide-blade impeller in the HW VAS would maintain flow at the pressures required for HBOT. The HM II LVAS was set to 9,200 RPM and the HM VAS was set to

2,600 RPM. Each respective speed setting is a standard setting for the typical LVAD patient [14, 15, 16].

The mock circuit (Figure 9, Figure 10, Figure 11) used to test the VAD was constructed with 3/8 inch tubing and one 3/8 inch - 3/8 inch straight tubing connector with a leur lock for de-airing purposes. The VAD flow, Q_{VAD}, was monitored using a 3/8 inch tubing flow probe (Sarns Flow Sensor 6382). The flow was displayed on a second patient monitor (A Med Systems Inc. Multimotor Control Console MCC-01). Monitoring equipment was placed within the mono-place chamber to avoid altering the monitoring wires for data transmission through the door of the chamber. The monitors were viewed from outside the chamber (Figure 12) and data were recorded in Microsoft Excel.

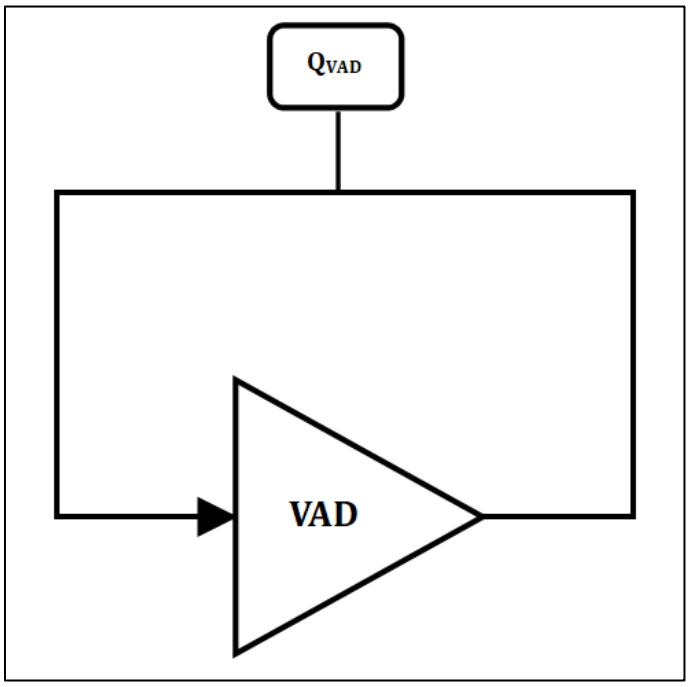


Figure 9: Circuit Diagram. This basic, water-filled mock circuit utilizes the VAD in question and a flow probe.

Figure 10: HeartMate II LVAS Circuit Setup. This circuit was used to test the functionality of the VAD when placed in hyperbaric conditions. The system controller and mobile power unit were placed in the chamber with the circuit.

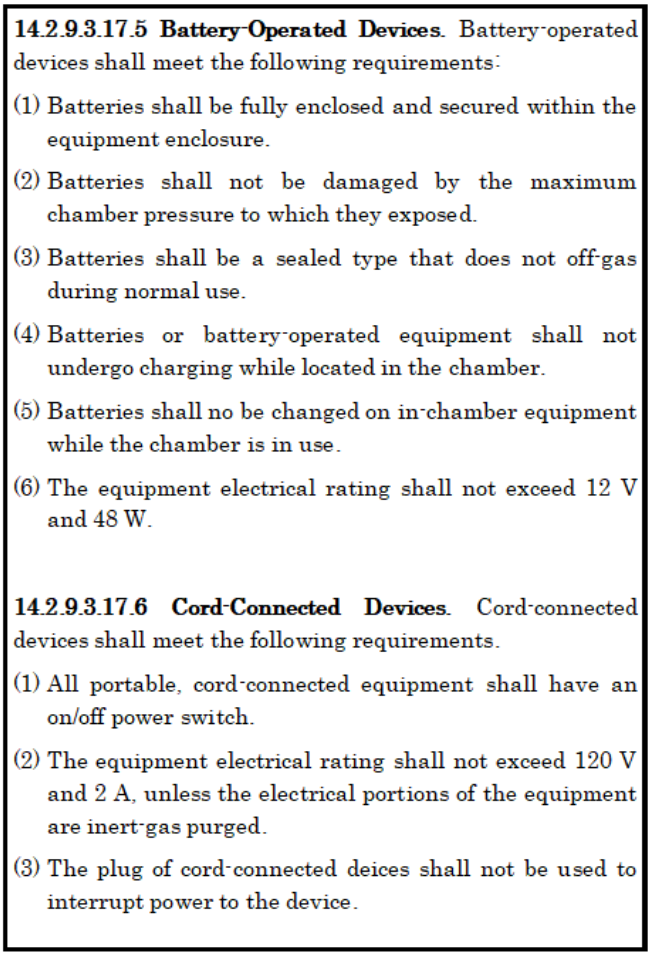
Figure 11: HeartWare VAS Circuit Setup. This circuit was used to test the functionality of the VAD when placed in hyperbaric conditions. The system controller and AC power adapter were placed in the chamber with the circuit.

Figure 12: The Mono-Place Chamber Located at MSOE. The chamber was manufactured by Sechrist and pressurized by a Jun-Air Compressor. The mock circuit and monitoring equipment were placed inside the circuit and powered using an AC power strip.

The Thoratec HeartMate II and HeartWare VADs were tested separately utilizing the same basic circuit. The only difference between the two tests was the tubing size and connectors needed to incorporate the VAD inflow and outflow ports. The Thoratec HeartMate II required ½ inch inflow and outflow tubing, while the HeartWare required ¾ inch inflow tubing and 3/8 inch outflow tubing.

Prior to testing, the Hyperbaric Facilities chapter of the 2018 edition of NFPA 99 Code was reviewed [46]. NFPA 99 Code is intended to protect against the elevated fire risks known to exist in a pressurized air environment. Per NFPA 99 Code 14.3.2.1, "All equipment used in the hyperbaric chamber shall comply with Section 14.2, including the following: (1) All electrical and mechanical equipment necessary for the operation and maintenance of the hyperbaric facility (2) Any medical devices and instruments used in the facility" [46]. LVADs qualify as category two of NFPA 99 Code 14.3.2.1; therefore, NFPA 99 Code Section 14.2 was followed.

NFPA 99 Code 14.2.9.3.17.5 Battery-Operated Devices and Code 14.2.9.3.17.6 Cord-Connected Devices both apply to the LVADs in question (Figure 13). The lithium ion battery was removed from the HM II LVAS's system controller to comply with NFPA 99 Code 14.2.9.3.17.5 (4) that states "batteries or battery-operated equipment shall not undergo charging while located in the chamber" [46]. When the battery was removed from the system controller, the controller alarmed, warning the user that the backup battery had been disconnected. The controller and the VAD still functioned; however, the VAD flow was not able to be monitored on the controller without clicking the system controller button to scan through the menu. This meant that once the circuit was in the chamber, the flow was not able to be monitored by the system controller, which is why a flow probe was connected to the circuit. The HM II LVAS's mobile power unit (MPU) was used to power the device inside the chamber. Within the mono-place chamber, there is a power strip that is used for AC power. In a standard mono-place or multi-place chamber at a medical center that utilizes 100% F_iO_2, the power cord from the MPU would be spliced with an explosion/waterproof locking to prevent any possible spark. Additionally, the MPU would be enclosed in a plastic container and purged with nitrogen (N_2) to displace oxygen and prevent combustion from a spark. However, the mono-place chamber located at the Milwaukee School of Engineering (MSOE) was used for testing and this chamber pressurizes with room air only. Because of this, the standard power cord for the MPU was used and the MPU was not N_2 purged.



14.2.9.3.17.5 Battery-Operated Devices. Battery-operated devices shall meet the following requirements:

(1) Batteries shall be fully enclosed and secured within the equipment enclosure.

(2) Batteries shall not be damaged by the maximum chamber pressure to which they exposed.

(3) Batteries shall be a sealed type that does not off-gas during normal use.

(4) Batteries or battery-operated equipment shall not undergo charging while located in the chamber.

(5) Batteries shall no be changed on in-chamber equipment while the chamber is in use.

(6) The equipment electrical rating shall not exceed 12 V and 48 W.

14.2.9.3.17.6 Cord-Connected Devices. Cord-connected devices shall meet the following requirements.

(1) All portable, cord-connected equipment shall have an on/off power switch.

(2) The equipment electrical rating shall not exceed 120 V and 2 A, unless the electrical portions of the equipment are inert-gas purged.

(3) The plug of cord-connected deices shall not be used to interrupt power to the device.

Figure 13: NFPA 99 Code Excerpt [46].

The HW VAS requires two power sources to be connected to the controller at all times. The first power source used was the HW VAS AC adapter, which was plugged into the power strip within the chamber. Again, in a hospital setting that utilizes 100% F_iO_2, the cord would be spliced with an explosion/waterproof locking. When the AC adapter is plugged into the controller, the HW VAS functions solely from AC power. However, the controller still requires a battery to be connected as the second power source in case of a power failure. The recommended environment conditions for the HW VAS battery is 700-1060 hPa (Appendix B) and the use of the battery in hyperbaric

pressures was not recommended by the Medtronic Representative working with the Biomedical Engineer's at Aurora St. Luke's Medical Center. Common chamber pressures range from 2,300 hPa to 2,800 hPa. When the battery was removed, the controller alarmed but the HW VAS continued to function. For testing, the battery was removed from the chamber and the controller was allowed to alarm.

Each VAD was tested by increasing the mono-place chamber pressure from 1.0 ATA to 2.8 ATA in increments of 0.3 ATA. Q_{VAD} was recorded at each increment in a data collection table template that was generated in Microsoft Excel (Table 4). Change in VAD flow was calculated using Equation (3) in which Q_{VADn} is the data point in question, and Q_{VAD0} is the initial data point for that trial. Thus, Equation (3):

$$Q_{VAD_n} - Q_{VAD_0} = \Delta Q_{VAD}. \quad (3)$$

Once the mono-place chamber reached 2.8 ATA, the pressure was maintained for 10 minutes and the circuit was monitored for any changes. VAD flow was recorded at the 5-minute mark and the 10-minute mark. For the first round of testing, after 10 minutes at 2.8 ATA, the pressure release valve of the chamber was opened to 50% (Figure 14), the pressure was set to zero, and the master valve was turned to emergency vent. The chamber was returned to the atmospheric pressure and the decompression time was recorded. The components of the VAD circuit and the flow were monitored during the decompression process. Once the chamber reached atmospheric pressure, the VAD flow was again recorded. This test was repeated three times for each VAD.

Table 4: Data Collection Template.

Chamber Pressure, $P_{Chamber}$ [ATA]	VAD Flow, Q_{VAD} [LPM]	Change in VAD Flow, ΔQ_{VAD} [LPM]
1.0	8.2	0
…	-	-
1.9	8.18	-0.02
…	-	-
2.8	8.22	0.02
…	-	-
1.0 @ Post Decompression	8.19	-0.01

Figure 14: Mono-place Chamber Pressure Release Valve Opened 50%.

For the second round of testing, after 10 minutes at 2.8 ATA, the chamber was emergently vented and the pressure release valve of the chamber was opened 100% (Figure 15), the chamber pressure was set to zero, the master valve was turned to emergency vent, and the emergency vent button was pressed. This was used to simulate any scenario that would require immediate patient access in a chamber and HBOT interruption. Once again, VAD flow and the VAD circuit were monitored during the decompression process and the decompression time was recorded. This was repeated three times for each VAD.

Figure 15: Mono-place Chamber Pressure Release Valve Opened 100%.

The mono-place chamber at MSOE displays the temperature within the chamber. Temperature in the chamber starts at room temperature and then as pressure increases inside the chamber, temperature increases as well. This phenomenon can be explained by the relationship defined in Gay-Lussac's Law, which states that pressure and temperature are directly related. Thus, Equation (4):

$$P \propto T \quad or \quad \frac{P_1}{T_1} = \frac{P_2}{T_2}. \tag{4}$$

The highest chamber temperature during the trial was recorded; usually, this occurred at 2.8 ATA. During emergency ventilation, temperatures drop below room temperature. The lowest temperature reached during emergency ventilation was recorded. Temperatures were monitored to ensure the temperature remained in the rated operating temperature range for each device.

4.1 Additional Testing

During planned tests, air was visible in the circuit under the conditions of altering pressures. Prior to each trial and during the descent to the pressure of 2.8 ATA, no air was visible in the circuit. However, after the ascent back to standard atmospheric pressure, a significant amount of air became visible in the circuit for both the HM II LVAS and the HW VAS (Figure 16). Because of this, the following additional test was performed to eliminate the VADs as the possible source of air. A third mock circuit was created using 3/8 inch tubing and one 3/8 inch – 3/8 inch straight tubing connector with a leur lock for de-airing purposes. This VAD-less mock circuit was filled with water and de-aired by attaching a stopcock to the leur lock and filling the tubing with a 60 cc

syringe. The HM II LVAS water-filled mock circuit, the HW VAS water-filled mock circuit, and the new VAD-less water-filled mock circuit (Figure 17) were all placed in the mono-place chamber after visually inspecting the circuits to ensure that they were air free. The VADs were not powered and no monitoring equipment was used. Four trials were completed by pressurizing the chamber from 1.0 ATA to 2.8 ATA, maintaining the pressure at 2.8 ATA for 10 minutes, and then decompressing the chamber back to 1.0 ATA. In two of the four trials, the chamber was emergency vented for rapid decompression. In the other two trials, the chamber was slowly vented and returned to standard atmospheric pressure. Following each trial, the circuits were visually inspected for air.

Figure 16: Air in the Water-Filled Mock Circuit Following Trial Completion. The air is circled in red. Both the HM II LVAS water-filled mock circuit and the HW VAS water-filled mock circuit generated air.

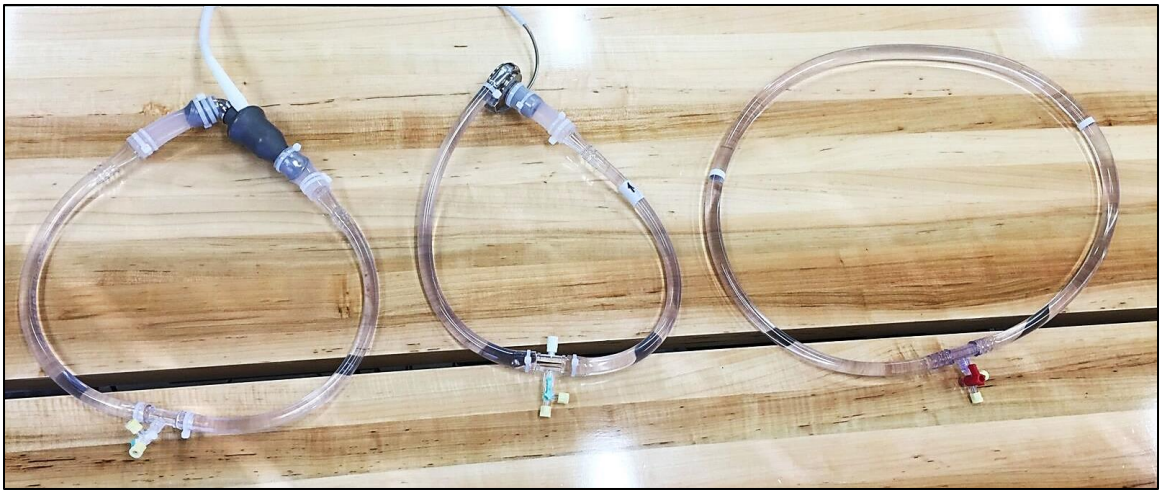


Figure 17: Three Water-Filled Mock Circuits. From left to right: The HM II LVAS water-filled mock circuit, the HW VAS water-filled mock circuit, the VAD-less water-filled mock circuit.

4.2 Statistical Analysis

Throughout testing, the flow rate of each VAD was recorded. Table 5 assigns a number as an identifier for each pressure increment during the trial at which VAD flow was recorded. The collected data were transferred from Microsoft Excel into Minitab 18 for analysis. The chamber pressure identifiers were used to created scatterplots of the collected data in Minitab 18 (Minitab Inc.). To address any flow inconsistency between each trial, the change in VAD flow was used for data analysis to permit easy comparison of data collected in all six trials. To test the hypothesis that the VAD flow would remain within 1 LPM of the initial flow rate during an increase in chamber pressure, a one-sample t-test was performed on the absolute value of the change in VAD flow data collected for each VAD. The absolute value function was used to make all change in flow values positive. All data analysis was performed in Minitab 18 (Minitab Inc.) with a $p<0.05$ considered significant.

Table 5: Chamber Pressure Identifiers Assigned for each Pressure Increment at which VAD Flow was Recorded.

Chamber Pressure Identifier	Chamber Pressure [ATA]
0	1.0
1	1.3
2	1.6
3	1.9
4	2.2
5	2.5
6	2.8
7	2.8 @ 5 min
8	2.8 @ 10 min
9	1.0 @ Post Decompression

5. Results

The HM II LVAS maintained flow within ±0.25 LPM of the VAD's initial flow for each trial (Figure 18). The average change in VAD flow for the HM II LVAS over all hyperbaric pressures was 0.048 ± 0.04 LPM, which was significantly less than 1 LPM ($p < 0.05$). Trials 1 through 3 utilized slow decompression to return to 1.0 ATA, while Trials 4 through 6 utilized emergency ventilation to return to 1.0 ATA. The HM II LVAS remained completely functional for the entirety of testing. The VAD, the mobile power unit, and the system controller were inspected after each trial, finding no visible damage. Following testing, the HM II LVAS was returned to the Biomedical Engineers at Aurora St. Luke's Medical Center for inspection. There was no damage found to any of the HM II LVAS components.

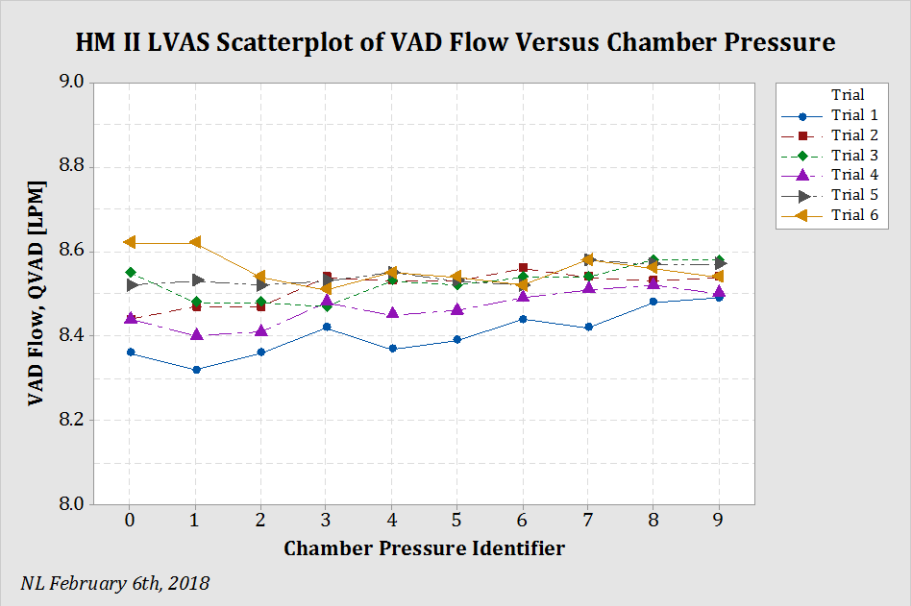


Figure 18: HM II LVAS Scatterplot of Change in VAD Flow Versus Chamber Pressure. The change in VAD flow was calculated using the data that was collected for the HM II LVAS. The change in VAD flow was plotted as a visual to confirm that the VAD maintained flow appropriately at the different pressure increments.

The HW VAS maintained flow within ±0.50 LPM of the VAD's initial flow for each trial (Figure 19). The average change in VAD flow for the HW VAS over all hyperbaric pressures was 0.055 ± 0.08 LPM, which was significantly less than 1 LPM ($p < 0.05$). Trials 1 through 3 utilized slow decompression to return to 1.0 ATA, while Trials 4 through 6 utilized emergency ventilation to return to 1.0 ATA. The HW VAS remained completely functional for the entirety of testing. The VAD, the AC adapter, and the controller were inspected after each trial, finding no visible damage. Following testing, the HW VAS was returned to the Biomedical Engineers at Aurora St. Luke's Medical Center for inspection. There was no damage found to any of the HW VAS components.

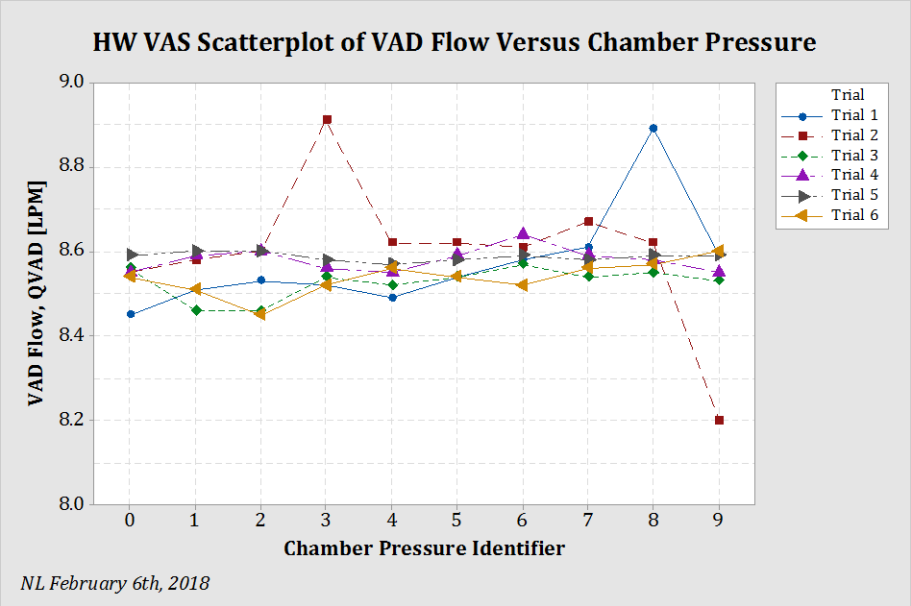


Figure 19: HW VAS Scatterplot of Change in VAD Flow Versus Chamber Pressure. The change in VAD flow was calculated using the data that was collected for the HW VAS. The change in VAD flow was plotted as a visual to confirm that the VAD maintained flow appropriately at the different pressure increments.

The temperature in the chamber remained in the recommended operating range for all components of the HM II LVAS and the HW VAS (Table 6) [15, 47]. The coldest temperatures inside the chamber occurred during emergency ventilation, while the warmest temperatures in the chamber occurred at 2.8 ATA. When considering all of the trials, the minimum temperature that the chamber reached was 51°F and the maximum temperature that was reached was 84°F.

Table 6: Minimum and Maximum Temperature Data and Decompression Time. * minimum temperature of all trials. ** maximum temperature of all trials.

VAD	Trial Number	Temperature Minimum [°F]	Temperature Maximum [°F]	Decompression Time [s]
HM II LVAS	1	65	77	413
	2	68	80	439
	3	70	82	424
	4	51*	83	43
	5	53	84**	44
	6	52	83	48
HW VAS	1	66	78	472
	2	68	80	435
	3	68	81	440
	4	51*	81	45
	5	51*	81	46
	6	52	84**	44

5.1 Additional Testing Results

Following the completion of four trials in the mono-place chamber with three water-filled mock circuits, the circuits were inspected for air. A very small amount of air was visible in the HM II LVAS water-filled mock circuit. Micro-air bubbles were found in the HW VAS water-filled mock circuit and the VAD-less water-filled mock circuit. The micro-air was initially determined to be dismissible after comparing the results to the air found in Figure 16. However, visible air bubbles developed after allowing the three water-filled mock circuits to hang, untouched overnight. The micro-air in each circuit combined to form significant air bubbles in all three circuits (Figure 20).

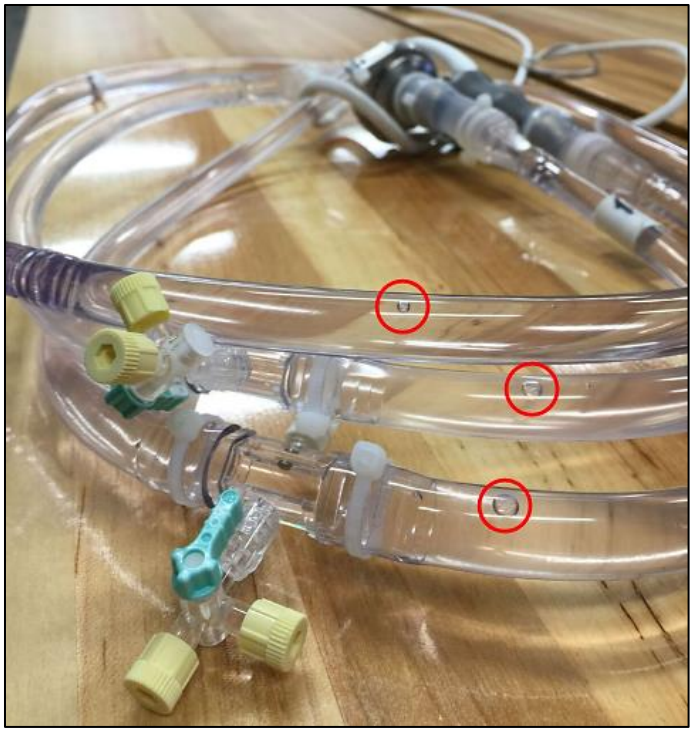


Figure 20: Air in the Three Water-filled Mock Circuits. The air in each circuit is circled in red. The circuits are as follows, from top to bottom: the VAD-less water-filled mock circuit, the HM II LVAS water-filled mock circuit, and the HW VAS water-filled mock circuit.

6. Discussion

The main goal of this study was to determine if two common VADs would adequately function at therapeutic pressures of HBOT. The specific hypothesis tested was that the LVADs and their components would maintain function throughout the duration of the testing without suffering any damage from the pressurized chamber. One parameter used to assess adequacy of VAD function was the ability of the VAD to maintain flow within 1 LPM of the initial flow at the different pressures in the mono-place hyperbaric chamber. At all applied pressures in the mono-place chamber, the average change in VAD flow for the HM II LVAS was 0.048 ± 0.04. This was

determined to be significantly less than 1 LPM. At all applied pressures in the mono-place chamber, the average change in VAD flow for the HW VAS was 0.055 ± 0.08 LPM. This was significantly less than 1 LPM. Both VADs met the required specification that the VAD maintain flow within 1 LPM.

Following testing, both the HM II LVAS and HW VAS functioned normally. Through visual inspection, it was determined that none of the VAD components suffered damage from the pressurized chamber. The VADs and their components functioned appropriately throughout the entirety of testing despite the applied chamber pressures and different decompression speeds. For the HM II LVAS, this result matched the findings of previous investigations [42, 43, 44, 45]. The HW VAS does not have previously published results of HBOT testing for comparison, but the results of the present test indicate no dysfunction when in a pressurized environment.

Because air was identified in the water-filled mock circuits for each VAD, additional testing was performed with a VAD-less circulatory loop. Based on the results of the additional testing, the VADs can be eliminated as a possible source of air in the circuit. The air appeared in the VAD-less water-filled mock circuit and in both VAD circuits even when they were not running. Previous studies were reviewed to confirm that the VAD did not generate air [42, 43, 44, 45]. There was likely micro-air in the water-filled mock circuits prior to testing in the mono-place chamber. This micro-air was most likely trapped within the pump or tubing connectors, making it not visible at atmospheric pressure. The pressure change during testing, specifically during the ascent from 2.8 ATA to 1.0 ATA, caused the air to expand in accordance with Boyle's Law (Equation 2). The pump then propagated the air enough to become easily visible during testing. In

order to confirm this, additional testing should be completed. The circuit pressure should be monitored to see how the change in the chamber pressure affects the pressure within the circuit itself.

6.1 Recommendations

First, although the additional testing results indicate that the VADs were not a source of air during testing, additional testing should be completed for verification. The pressure change within the mock circuit should be monitored to better understand how the hyperbaric chamber is affecting the VAD circuit independent of the VAD.

Secondly, additional components of both the HM II LVAS and the HW VAS should be tested at therapeutic pressures within a chamber. The 2018 NFPA 99 Code no longer prohibits lithium ion batteries from being placed into a chamber. However, batteries must be pretested minimally to the maximum pressure that they will experience during HBOT. If approved, the lithium ion batteries may be used to power the VADs during HBOT. The benefit of this is that it would eliminate the power disconnect controller alarm for the HW VAS. More research into battery use inside hyperbaric chambers should be completed before initiating any testing with batteries at high pressures.

Finally, the HeartMate III Left Ventricular Assist System (HM III LVAS), made by Abbott Laboratories, has recently been FDA approved for bridge-to-transplant and bridge-to-myocardial recovery [48]. The Biomedical Engineers at Aurora St. Luke’s have seen a decrease in HM II LVAS implants and an increase in HM III LVAS implants.

Currently, the HM III LVAS is still considered a study pump and Abbott Laboratories has not given a non-clinical use HM III LVAS to the Biomedical Engineers at Aurora St. Luke's. Once available, the HM III LVAS and its components should be tested at therapeutic pressures within a chamber.

6.2 Limitations

A possible limitation in this study's results is that all testing was completed using tap water rather than blood. It is possible that if testing were to be repeated using blood, results may differ because of the use of a liquid with different viscosity. Additionally, 100% FiO_2 was not utilized in the mono-place chamber at MSOE. Therefore, extra precautions such as N_2 purging and the use of non-explosive/waterproof fittings were not used. Prior to patient use, precautionary equipment alterations should be completed and the VADs should be tested.

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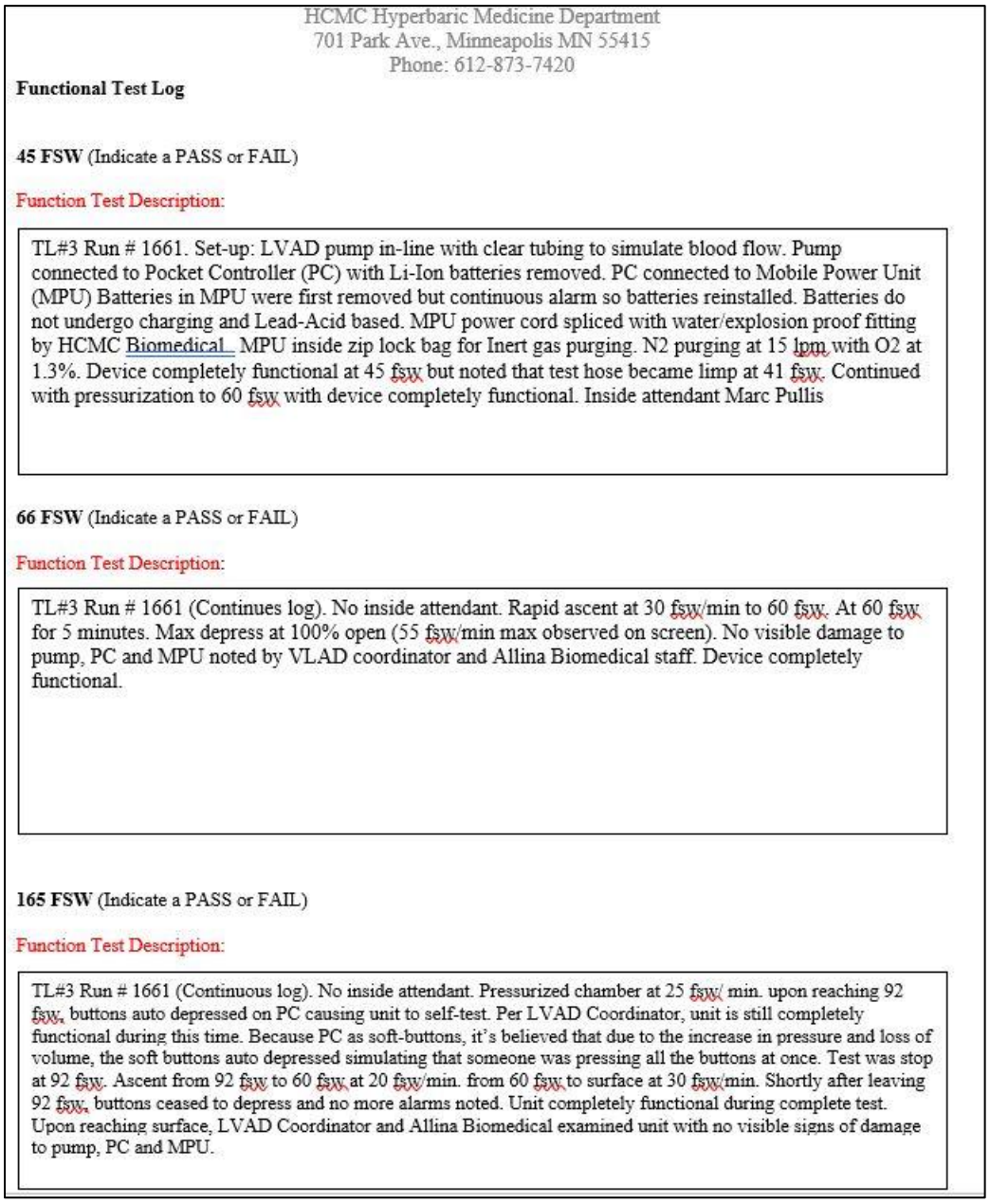
Appendix A: HCMC Functional Test Log



HCMC Hyperbaric Medicine Department
701 Park Ave., Minneapolis MN 55415
Phone: 612-873-7420

Functional Test Log

45 FSW (Indicate a PASS or FAIL)

Function Test Description:

TL#3 Run # 1661. Set-up: LVAD pump in-line with clear tubing to simulate blood flow. Pump connected to Pocket Controller (PC) with Li-Ion batteries removed. PC connected to Mobile Power Unit (MPU) Batteries in MPU were first removed but continuous alarm so batteries reinstalled. Batteries do not undergo charging and Lead-Acid based. MPU power cord spliced with water/explosion proof fitting by HCMC Biomedical. MPU inside zip lock bag for Inert gas purging. N2 purging at 15 lpm with O2 at 1.3%. Device completely functional at 45 fsw but noted that test hose became limp at 41 fsw. Continued with pressurization to 60 fsw with device completely functional. Inside attendant Marc Pullis

66 FSW (Indicate a PASS or FAIL)

Function Test Description:

TL#3 Run # 1661 (Continues log). No inside attendant. Rapid ascent at 30 fsw/min to 60 fsw. At 60 fsw for 5 minutes. Max depress at 100% open (55 fsw/min max observed on screen). No visible damage to pump, PC and MPU noted by VLAD coordinator and Allina Biomedical staff. Device completely functional.

165 FSW (Indicate a PASS or FAIL)

Function Test Description:

TL#3 Run # 1661 (Continuous log). No inside attendant. Pressurized chamber at 25 fsw/ min. upon reaching 92 fsw, buttons auto depressed on PC causing unit to self-test. Per LVAD Coordinator, unit is still completely functional during this time. Because PC as soft-buttons, it's believed that due to the increase in pressure and loss of volume, the soft buttons auto depressed simulating that someone was pressing all the buttons at once. Test was stop at 92 fsw. Ascent from 92 fsw to 60 fsw at 20 fsw/min. from 60 fsw to surface at 30 fsw/min. Shortly after leaving 92 fsw, buttons ceased to depress and no more alarms noted. Unit completely functional during complete test. Upon reaching surface, LVAD Coordinator and Allina Biomedical examined unit with no visible signs of damage to pump, PC and MPU.

Figure A-1: Hennepin County Medical Center Functional Test Log.[1]

[1] Pullis M. 2016. Successful Treatment of a LVAD Patient with HBO at 2.4 ATA. PowerPoint from the Annual Scientific Meeting of the Undersea and Hyperbaric Medical Society. *Undersea and Hyperbaric Medicine*.

Appendix B: HW VAS Recommended Environmental Conditions

Table B-1: HW VAS Recommended Environmental Conditions.[2]

Recommended environmental conditions

Component	Temperature Range	Relative Humidity	Atmospheric Pressure
Controller	Operating: -20 to +50°C (-4 to +122°F)	Operating: 15% - 95%	Operating: 700 -1060 hPa
	Storage and Transport: -20 to +50°C (-4 to +122°F)	Storage and Transport: 10% - 93%	Storage and Transport: 500 -1060 hPa
Controller AC and DC Adapter	Operating: -20 to +50°C (-4 to +122°F)	Operating: 15% - 95%	Operating: 700 -1060 hPa
	Storage and Transport: -40 to +70°C (-40 to +158°F)	Storage and Transport: 10% - 93%	Storage and Transport: 500 -1060 hPa
Battery	Operating: +10 to +40°C (+50 to +104°F)	Operating: 15% - 95%	Operating: 700 -1060 hPa
	Storage and Transport: -20 to +25°C (-4 to +77°F)	Storage and Transport: 10% - 93%	Storage and Transport: 500 -1060 hPa

Recommended environmental conditions (continued)

Component	Temperature Range	Relative Humidity	Atmospheric Pressure
Battery Charger	Operating: +10 to +40°C (+50 to +104°F)	Operating: 30% - 75%	Operating: 700 -1060 hPa
	Storage and Transport: -40 to +70°C (-40 to +158°F)	Storage and Transport: 10% - 93%	Storage and Transport: 500 -1060 hPa
Monitor and Monitor AC Adapter	Operating: +5 to +40°C (+41 to +104°F) Monitor only; 0 to +40°C (+32 to +104°F) Monitor AC Adapter only	Operating: 15% - 95%	Operating: 700 -1060 hPa
	Storage and Transport: -40 to +70°C (-40 to +158°F)	Storage and Transport: 10% - 90%	Storage and Transport: 500 -1060 hPa

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Appendix C: Raw Data

Table C-1: Raw Data Collected for the HW VAS.

Trial	Chamber Pressure Identifier	Chamber Pressure, $P_{Chamber}$ [ATA]	VAD Flow, Q_{VAD} [LPM]	Change in VAD Flow, ΔQ_{VAD} [LPM]	Absolute Value of Change in VAD Flow, $\lvert\Delta Q_{VAD}\rvert$ [LPM]	Decompression Speed
Trial 1	0	1.0	8.45	0.00	0.00	Slow
	1	1.3	8.51	0.06	0.06	
	2	1.6	8.53	0.08	0.08	
	3	1.9	8.52	0.07	0.07	
	4	2.2	8.49	0.04	0.04	
	5	2.5	8.54	0.09	0.09	
	6	2.8	8.58	0.13	0.13	
	7	2.8 @ 5 min	8.61	0.16	0.16	
	8	2.8 @ 10 min	8.89	0.44	0.44	
	9	1.0 @ Post Trial	8.59	0.14	0.14	
Trial 2	0	1.0	8.55	0.00	0.00	Slow
	1	1.3	8.58	0.03	0.03	
	2	1.6	8.6	0.05	0.05	
	3	1.9	8.91	0.36	0.36	
	4	2.2	8.62	0.07	0.07	
	5	2.5	8.62	0.07	0.07	
	6	2.8	8.61	0.06	0.06	
	7	2.8 @ 5 min	8.67	0.12	0.12	
	8	2.8 @ 10 min	8.62	0.07	0.07	
	9	1.0 @ Post Trial	8.2	-0.25	0.25	
Trial 3	0	1.0	8.56	0.00	0.00	Slow
	1	1.3	8.46	-0.10	0.10	
	2	1.6	8.46	-0.10	0.10	
	3	1.9	8.54	-0.02	0.02	
	4	2.2	8.52	-0.04	0.04	
	5	2.5	8.54	-0.02	0.02	
	6	2.8	8.57	0.01	0.01	
	7	2.8 @ 5 min	8.54	-0.02	0.02	
	8	2.8 @ 10 min	8.55	-0.01	0.01	
	9	1.0 @ Post Trial	8.53	-0.03	0.03	

Table C-1: Raw Data Collected for the HW VAS (Continued).

Trial	Chamber Pressure Identifier	Chamber Pressure, $P_{Chamber}$ [ATA]	VAD Flow, Q_{VAD} [LPM]	Change in VAD Flow, ΔQ_{VAD} [LPM]	Absolute Value of Change in VAD Flow, $\lvert\Delta Q_{VAD}\rvert$ [LPM]	Decompression Speed
Trial 4	0	1.0	8.55	0.00	0.00	Fast
	1	1.3	8.59	0.04	0.04	
	2	1.6	8.6	0.05	0.05	
	3	1.9	8.56	0.01	0.01	
	4	2.2	8.55	0.00	0.00	
	5	2.5	8.59	0.04	0.04	
	6	2.8	8.64	0.09	0.09	
	7	2.8 @ 5 min	8.59	0.04	0.04	
	8	2.8 @ 10 min	8.58	0.03	0.03	
	9	1.0 @ Post Trial	8.55	0.00	0.00	
Trial 5	0	1.0	8.59	0.00	0.00	Fast
	1	1.3	8.6	0.01	0.01	
	2	1.6	8.6	0.01	0.01	
	3	1.9	8.58	-0.01	0.01	
	4	2.2	8.57	-0.02	0.02	
	5	2.5	8.58	-0.01	0.01	
	6	2.8	8.59	0.00	0.00	
	7	2.8 @ 5 min	8.58	-0.01	0.01	
	8	2.8 @ 10 min	8.59	0.00	0.00	
	9	1.0 @ Post Trial	8.59	0.00	0.00	
Trial 6	0	1.0	8.54	0.00	0.00	Fast
	1	1.3	8.51	-0.03	0.03	
	2	1.6	8.45	-0.09	0.09	
	3	1.9	8.52	-0.02	0.02	
	4	2.2	8.56	0.02	0.02	
	5	2.5	8.54	0.00	0.00	
	6	2.8	8.52	-0.02	0.02	
	7	2.8 @ 5 min	8.56	0.02	0.02	
	8	2.8 @ 10 min	8.57	0.03	0.03	
	9	1.0 @ Post Trial	8.6	0.06	0.06	

Table C-2: Raw Data Collected for the HM II LVAS.

Trial	Chamber Pressure Identifier	Chamber Pressure, $P_{Chamber}$ [ATA]	VAD Flow, Q_{VAD} [LPM]	Change in VAD Flow, ΔQ_{VAD} [LPM]	Absolute Value of Change in VAD Flow, $\lvert\Delta Q_{VAD}\rvert$ [LPM]	Decompression Speed
Trial 1	0	1.0	8.36	0.00	0.00	Slow
	1	1.3	8.32	-0.04	0.04	
	2	1.6	8.36	0.00	0.00	
	3	1.9	8.42	0.06	0.06	
	4	2.2	8.37	0.01	0.01	
	5	2.5	8.39	0.03	0.03	
	6	2.8	8.44	0.08	0.08	
	7	2.8 @ 5 min	8.42	0.06	0.06	
	8	2.8 @ 10 min	8.48	0.12	0.12	
	9	1.0 @ Post Trial	8.49	0.13	0.13	
Trial 2	0	1.0	8.44	0.00	0.00	Slow
	1	1.3	8.47	0.03	0.03	
	2	1.6	8.47	0.03	0.03	
	3	1.9	8.54	0.10	0.10	
	4	2.2	8.53	0.09	0.09	
	5	2.5	8.53	0.09	0.09	
	6	2.8	8.56	0.12	0.12	
	7	2.8 @ 5 min	8.54	0.10	0.10	
	8	2.8 @ 10 min	8.53	0.09	0.09	
	9	1.0 @ Post Trial	8.54	0.10	0.10	
Trial 3	0	1.0	8.55	0.00	0.00	Slow
	1	1.3	8.48	-0.07	0.07	
	2	1.6	8.48	-0.07	0.07	
	3	1.9	8.47	-0.08	0.08	
	4	2.2	8.53	-0.02	0.02	
	5	2.5	8.52	-0.03	0.03	
	6	2.8	8.54	-0.01	0.01	
	7	2.8 @ 5 min	8.54	-0.01	0.01	
	8	2.8 @ 10 min	8.58	0.03	0.03	
	9	1.0 @ Post Trial	8.58	0.03	0.03	

Table C-2: Raw Data Collected for the HM II LVAS (Continued).

Trial	Chamber Pressure Identifier	Chamber Pressure, $P_{Chamber}$ [ATA]	VAD Flow, Q_{VAD} [LPM]	Change in VAD Flow, ΔQ_{VAD} [LPM]	Absolute Value of Change in VAD Flow, $\lvert\Delta Q_{VAD}\rvert$ [LPM]	Decompression Speed
Trial 4	0	1.0	8.44	0.00	0.00	Fast
	1	1.3	8.40	-0.04	0.04	
	2	1.6	8.41	-0.03	0.03	
	3	1.9	8.48	0.04	0.04	
	4	2.2	8.45	0.01	0.01	
	5	2.5	8.46	0.02	0.02	
	6	2.8	8.49	0.05	0.05	
	7	2.8 @ 5 min	8.51	0.07	0.07	
	8	2.8 @ 10 min	8.52	0.08	0.08	
	9	1.0 @ Post Trial	8.50	0.06	0.06	
Trial 5	0	1.0	8.52	0.00	0.00	Fast
	1	1.3	8.53	0.01	0.01	
	2	1.6	8.52	0.00	0.00	
	3	1.9	8.53	0.01	0.01	
	4	2.2	8.55	0.03	0.03	
	5	2.5	8.53	0.01	0.01	
	6	2.8	8.52	0.00	0.00	
	7	2.8 @ 5 min	8.58	0.06	0.06	
	8	2.8 @ 10 min	8.57	0.05	0.05	
	9	1.0 @ Post Trial	8.57	0.05	0.05	
Trial 6	0	1.0	8.62	0.00	0.00	Fast
	1	1.3	8.62	0.00	0.00	
	2	1.6	8.54	-0.08	0.08	
	3	1.9	8.51	-0.11	0.11	
	4	2.2	8.55	-0.07	0.07	
	5	2.5	8.54	-0.08	0.08	
	6	2.8	8.52	-0.10	0.10	
	7	2.8 @ 5 min	8.58	-0.04	0.04	
	8	2.8 @ 10 min	8.56	-0.06	0.06	
	9	1.0 @ Post Trial	8.54	-0.08	0.08	

Appendix D: HeartMate II Electrical Device Approval Process Form

ELECTRICAL DEVICE APPROVAL PROCESS

PURPOSE

The Medical Device Approval Process is a method used to systematically evaluate and mitigate the risk of a medical device to be used inside a Hyperbaric Chamber. It is to ensure the safety of all hyperbaric chamber occupants at Aurora St. Luke's Medical Center in Milwaukee, WI. The NFPA 99 Standard for Health Care Facilities, 2018 Edition, Chapter 14, Section 14.3.2.1 "All equipment used in the hyperbaric chamber shall comply with Section 14.2, including the following: (1) All electrical and mechanical equipment necessary for the operation and maintenance of the hyperbaric facility (2) Any medical devices and instruments used in the facility." The testing process at Milwaukee School of Engineering serves as an aid in selection, testing, modification, documentation, and approval of medical devices for use in the hyperbaric chamber environment.

MSOE HYPERBARIC MEDICINE ELECTRICAL DEVICE APPROVAL TEAM

A Hyperbaric Medicine Medical Device Approval Team shall be established and consist of the following members:

MSOE M.S. Perfusion Student
MSOE Mono-Place Chamber Coordinator (BME Professor)
MSOE Perfusion Program Director
Hyperbaric Medicine Safety Director
Hospital Biomedical Engineering Representative

All members of the Medical Device Approval Team will be required to review the Medical Device Approval Form for each new or modified medical device, and indicate their approval by signing the Medical Device Approval Letter prior to use in the hyperbaric chamber. The Medical Device Approval Team may approve the device as presented or with conditions which must be specified on the Letter of Medical Device Approval. The Medical Device Approval Team must determine if each subsequent device of the same make and model must be individually tested and to what extent.

a. No testing required on subsequent devices
b. Each subsequent device receives full function testing
c. Each subsequent device receives abbreviated testing as determined by the Hyperbaric Medicine Safety Director and the Biomedical Engineering Representative.

PROCESS

Requests for medical device approval should be submitted to the Hyperbaric Medicine Safety Director at Aurora St. Luke's Medical Center for consideration. The Safety Director will pass the device, manuals, and approval forms to the Biomedical Engineering representative for visual inspection and schematic review. The device will be disassembled to whatever extent is necessary to complete the examination. Post inspection, the Safety Director may pass the device approval forms directly to the Medical Device Approval Team if reasonable data exists from the manufacturer, other facilities, or journal documentation. If inadequate data exists the Safety Director will enlist the assistance of appropriate personnel to perform device testing. Upon

completion of successful testing, all documentation of the testing process will be forwarded to all Medical Device Approval Team members for review and approval. All Team members are required to sign-off on each device prior to use in the hyperbaric chamber. Any member of the Medical Device Approval Team may disapprove a device or request further documented evidence or testing at any time prior to approval. All paperwork will be coordinated and maintained by the Hyperbaric Medicine Safety Director.

REQUEST FOR ELECTRICAL MEDICAL DEVICE APPROVAL

Type of device: Left Ventricular Assist Device

Manufacturer: Thoratec Corporation

Model: HeartMate II

What is the reason for the new equipment or modification of an existing device:

Approve use for future LVAD patients who may benefit from HBOT at Aurora St. Luke's Medical Center in Milwaukee, WI.

Is the device designed and rated for use with hyperbaric chambers? **NO**

Is this device used at any other hyperbaric facilities? **YES**

What testing/modifications did they perform?

Facility: HCMC in Minneapolis, MN

Contact: Marc Pullis

Phone: 612-873-7420

Per NFPA code: Spliced MPU power cord with explosive/waterproof fitting, N2 purged MPU
3 tests at various chamber pressures and decompression speeds. No damage detected.
Pt. commenced uncomplicated daily HBO tx's

What testing/modifications did they perform?

University of California, San Diego

Facility:

Contact:

Phone: 760-452-2222

Pre-NFPA code allowing Li-Ion battery inside of chamber.
Explosive decompression to 7 ata (battery only)
Pt. commenced uncomplicated daily HBO tx's

Has the device been written about in any journals (insert info)?

Undersea and Hyperbaric Medicine Journal. 45(1):89–93

Operator's Manual? YES

Service Manual? NO

Comments:

Worked with Dr. Larry Fennigkoh and David Glowacki to perform testing at MSOE.

Submitted by: Nick LaRue

Date of submission: February 22, 2018

NOTE: Attach all pertinent documentation

NFPA 99 (2018) GUIDELINES

Note: Place an "X" through each bullet for "Yes" and leave bullet blank for "No".

For additional comments reference the NFPA number and add notes to the Bio-electronics Comments section at the end.

GENERAL WIRING AND EQUIPMENT GUIDELINES

14.2.9.3 The general rules of 14.2.9.3.1 through 14.2.9.3.17.6 shall be satisfied in the use of electrical devices and equipment. These requirements are intended to protect against the elevated fire risks known to exist in a pressurized air environment and shall not be construed as classifying the chamber interior as a Class I (as defined in NFPA 70, Article 500) hazardous location.

☒**14.2.9.3.1 Equipment or equipment components installed in, or used in, the chamber shall not present an explosion or implosion hazard under the conditions of hyperbaric use.**

☒**14.2.9.3.2 All equipment shall be rated, or tested and documented, for intended hyperbaric conditions prior to use.**

☒**14.2.9.3.3 Only the electrical equipment necessary for the safe operation of the chamber and for required patient care shall be permitted in the chamber.**

☒**14.2.9.3.4 Only portable equipment necessary for the logistical and operational support shall be permitted in the chamber during manned pressurization.**

☐**14.2.9.3.5 Where conformance with Class I, Division 1 requirements is specified in 14.2.9.3.7, conformance with Class I, Division 2 requirements shall be permitted to be substituted.**

NOTES:

14.2.9.3.2 HM II LVAS has been previously tested and documented in hyperbaric conditions.

14.2.9.3.3-4 Only HM II LVAS components required to maintain function were placed in the chamber. The flow monitor would not be placed in chamber during patient treatment.

WIRES AND CABLES

☐**14.2.9.3.6 Wires and cables used inside the chamber shall be resistant to the spread of fire by complying with 14.2.9.3.6.1 or shall be contained within equipment described in 14.2.9.3.6.2.**

☐**14.2.9.3.6.1 Wires and cables shall comply with the spread of fire requirements of "UL Flame Exposure, Vertical Tray Flame Test" in UL 1685, *Standard for Vertical-Tray Fire-Propagation and Smoke-Release Test for Electrical and Optical-Fiber Cables*, or shall exhibit**

damage (char length) not to exceed 1.5 m (4 ft. 11 in.) when performing the CSA "Vertical Flame Test – Cables in Cable Trays," as described in CSA C22.2 No. 0.3-M, *Test Methods for Electrical Wires and Cables*.

☐**14.2.9.3.6.2 Wires and cables that form an integral part of electrical equipment approved or listed specifically for use inside hyperbaric chambers, including patient leads, shall not be required to comply with the requirements of 14.2.9.3.6.1.**

NOTES:

Complies within limits of medical devices to the IEC 60601-1-2:2001 + A1:2004 & IEC 60601-1-2:2003

Meets Fire Casualty, and Electrical shock hazard requirements of UL 60601-1

14.2.9.3 WIRING METHODS

☐**14.2.9.3.7.1 Fixed wiring shall be installed in threaded RMC or IMC conduit utilizing the following waterproof components:**

(1) Threaded metal joints
(2) Fittings
(3) Boxes
(4) Enclosures

☒**14.2.9.3.7.2 A continuous ground shall be maintained between all conductive surfaces enclosing electrical circuits and the chamber hull using approved grounding means.**

☐**14.2.9.3.7.3 All threaded conduit shall be threaded with an NPT standard conduit cutting die that provides a 19-mm taper per 0.3 m (0.75 in. taper per 1 ft.)**

☐**14.2.9.3.7.4 All threaded conduit shall be made wrench-tight to prevent sparking when fault current flows through the conduit system.**

☒**14.2.9.3.7.5 Wiring classified as intrinsically safe for any group location and installed in accordance with Article 504 of *NFPA 70* shall be permitted.**

☐**14.2.9.3.7.6 Threaded, liquid-tight flexible metal conduit installed in accordance with Article 350 of *NFPA 70* shall be permitted when protected from damage by physical barriers such as equipment panels.**

☐**14.2.9.3.8 Drainage. Means of draining fixed conduit and fixed equipment enclosures shall be provided.**

NOTES:

14.2.9.3.7.1: N/A (Non-fixed wiring) 14.2.9.3.7.3-14.2.9.3.7.4 & 14.2.9.3.7.6 & 14.2.9.3.8: N/A (No conduit)

DOES DEVICE HAVE A FLEXIBLE ELECTRICAL CORD? YES

☐**14.2.9.3.9 Flexible Electrical Cords. Flexible cords used to connect portable utilization equipment to the fixed electrical supply circuit shall meet all the following requirements:**

(1) They shall be of a type approved for extra-hard use in accordance with Table 400.4 of *NFPA 70*.
(2) Electrically conductive casings of all portable equipment for use inside the chamber shall be grounded.
(3) They shall meet the requirements of 501.140 of *NFPA 70*.

☒**14.2.9.3.9.1 The normal cord supplied with the portable utilization equipment shall be permitted when the portable device is rated at less than 2 A and the cord is positioned out of traffic and protected from physical abuse.**

Amp Rating: 1 amp

NOTES:

Meets Fire Casualty, and Electrical shock hazard requirements of UL 60601-1 Complies within limits of medical devices to the IEC 60601-1-2:2001 + A1:2004 & IEC 60601-1-2:2003 MPU has 110-240V and 1 AMP max input.

DOES THIS DEVICE HAVE RECEPTACLES INSTALLED INSIDE THE CHAMBER? YES

☒**14.2.9.3.10.1 Receptacle shall be waterproof.**

☒**14.2.9.3.10.2 Receptacles shall be of the type providing for connection to the ground conductor of the flexible cord.**

☒**14.2.9.3.10.3 Receptacles shall be supplied from isolated power circuits meeting requirements of 14.2.9.4.2.**

☒**14.2.9.3.10.4 The design of the receptacle shall be such that sparks cannot be discharged into chamber environment when plug inserted or withdrawal under electrical load.**

☒**14.2.9.3.10.5 One of the following shall be satisfied to protect against inadvertent withdrawal of the plug under electrical load:**

(1) The receptacle-plug combination shall be of the locking type.

(2) The receptacle shall carry a label warning against unplugging under load, and the power cord shall not present a trip hazard for personnel moving in the chamber.

NOTES:

The MSOE chamber does not utilize FiO2. Because of this, nonexplosive/waterproof fittings were not used. In a chamber that utilizes 100% FiO2, the power cords would be spliced with nonexplosive/waterproof fittings.

DOES THE DEVICE HAVE ANY SWITCHES? NO

☐**14.2.9.3.11 Switches. Switches in the fixed wiring installation shall be waterproof.**

☐**14.2.9.3.11.1 Switch make and break contacts shall be housed in the electrical enclosure so that no sparks from arcing contacts can reach the chamber environment.**

NOTES:

DOES THE DEVICE HAVE A TEMPERATURE RATING? YES

☒**14.2.9.3.12 Temperature. No electrical equipment installed or used in the chamber shall have an operating surface temperature in excess of 85°C (185°F).**

Surface Temperature:

84 °F max chamber temp

NOTES:

Per Thoratec Manual, MPU can reach surface temps up to 131 degrees F.

DOES THE DEVICE HAVE ANY EXPOSED LIVE ELECTRICAL PARTS? NO

☐**14.2.9.3.13 Exposed Live Electrical Parts. No exposed live electrical parts shall be permitted, except as specified in 14.3.9.3.13.1 and 14.2.9.3.13.2.**

☐**14.2.9.3.13.1 Exposed live electrical parts that are intrinsically safe shall be permitted.**

☐**14.2.9.3.13.2 Exposed live electrical parts that constitute patient monitoring leads, which are part of electromedical equipment, shall be permitted provided that they meet the requirements of 14.2.9.3.17.**

NOTES:

DOES THE DEVICE CONTAIN ANY MOTORS? NO

☐**14.2.9.3.14 Motors. Motors located in the chamber and that are not a component of medical equipment shall meet one of the following requirements:**

(1) They shall comply with 501.125 (A)(1) of *NFPA 70*.

(2) They shall be totally enclosed in accordance with 501.125 (A)(2) or 501.125 (A)(3) of *NFPA 70*.

☐ **Is the motor a brushless, intrinsically safe motor?**

NOTES:

This device contains no motors. The LVAD contains a rotary screw pump inside the chest cavity.

IS THIS EQUIPMENT LOW VOLTAGE/POWER? YES

☒**14.2.9.3.16 Low-Voltage, Low-Power Equipment. The requirements of 14.2.9.3.16 through 14.2.9.3.16.5 shall apply to sensors and signaling, alarm, communication, and remote-control equipment installed or used in the chamber for operation of the chamber.**

☒**14.2.9.3.16.1 Equipment shall be isolated from main power by one of the following means:**

(1) **Design of the power supply circuit.**
(2) **Opto-isolation.**
(3) **By other electronic isolation means.**

☐**14.2.9.3.16.2 Circuits such as headset cables, sensor leads, and so forth, not enclosed as required in 14.2.9.3.7, shall meet one of the following requirements:**

(1) **They shall be part of approved intrinsically safe equipment.**
(2) **They shall be limited by circuit design to no more than 28 V and 0.5 A under normal or circuit-fault conditions.**

Voltage: 14-16 V **Amps:** Unknown

NOTES:

14.2.9.3.16.2: Pocket Controller Li-Ion batteries are to be removed.

DOES THIS DEVICE HAVE OR CONTAIN SPEAKERS? YES

☒**14.2.9.3.16.3 Chamber speakers shall be of a design in which the electrical circuitry and wiring is completely enclosed.**

☐**14.2.9.3.16.4 The electrical rating of chamber speakers shall not exceed 28V rms and 25 W.**

Voltage: **Watts:**

☐**14.2.9.3.16.5 Battery-operated, portable intercom headset units shall meet the requirements of 14.2.9.3.17.5 for battery-operated devices.**

NOTES:

Speakers are integrated into the device. These are not chamber speakers. MPU speakers would be enclosed with an inert gas (N2) if the chamber utilized 100% FiO2.

IS THIS EQUIPMENT PORTABLE PATIENT CARE RELATED? YES

14.2.9.3.17 Portable Patient Care–Related Electrical Appliances.

☒**14.2.9.3.17.1 The appliance shall be designed, constructed, inspected, and maintained in accordance with Chapter 10.**

☐**14.2.9.3.17.2 The electrical and mechanical integrity of the appliance shall be verified and documented through an ongoing maintenance program as required in Chapter 10.**

☒**14.2.9.3.17.3 The appliance shall conform to the requirements of 14.2.9.3.1 and 14.2.9.3.12.**

☐**14.2.9.3.17.4 Appliances that utilize oxygen shall not allow oxygen accumulation in the electrical portions of the equipment under normal and abnormal conditions.**

NOTES:

14.2.9.3.17.1: Complies within limits of medical devices to the IEC 60601-1-2:2001 + A1:2004 & IEC 60601-1-2:2003 14.2.9.3.17.2: Temporary device. Biomedical Engineers would inspect new patient's equipment prior to use. 14.2.8.3.17.4: Appliance does not utilize O2.

IS THIS DEVICE BATTERY OPERATED OR CONTAIN BATTERIES? YES

☐**14.2.9.3.17.5 Battery-Operated Devices. Battery-operated devices shall meet the following requirements:**

(1) Batteries shall be fully enclosed and secured within the equipment enclosure.
(2) Batteries shall not be damaged by the maximum chamber pressure they are exposed to.
(3) Batteries shall be of a sealed type that does not off-gas during normal use.
(4) Batteries or battery-operated equipment shall not undergo charging while located in the chamber.

(5) Batteries shall not be changed on in-chamber equipment while the chamber is in use.
(6) The equipment electrical rating shall not exceed 12 V and 48 W.

Voltage: 1.5 V / EA **Watts:** 2.4 W / EA

What is the expect life of battery (in months)? N/A

How long will device run on battery (in hours)? N/A

Battery type? 3 Alkaline AA Batteries

NOTES:

Three Standard Alkaline AA Batteries, non-rechargeable and will not be changed inside the chamber.

IS THIS A CORD CONNECTED DEVICE? YES

☒**14.2.9.3.17.6 Cord-Connected Devices. Cord-connected devices shall meet the following requirements:**

(1) All portable, cord-connected equipment shall have an on/off power switch.
(2) The equipment electrical rating shall not exceed 120 V and 2 A, unless the electrical portions of the equipment are inert-gas purged.
(3) The plug of cord-connected devices shall not be used to interrupt power to the device.

Voltage: 110-240 V **Amps:** 1 A

NOTES:

The MPU would be N2 purged in a chamber that utilizes 100% FiO2.

The MSOE chamber does not utilize FiO2. Because of this, N2 purging was not used.

GAS PURGING

☒**14.2.9.3.18 Gas Purging. Gas purging of AC and DC equipment used inside the chamber shall be permitted using inert gas or air.**

NOTES:

The MPU would be N2 purged in a chamber that utilizes 100% FiO2.

The MSOE chamber does not utilize FiO2. Because of this, N2 purging was not used.

14.3.2 EQUIPMENT

☒**14.3.2.1 All equipment used in the hyperbaric chamber shall comply with Section 14.2, including the following:**

(1) **All electrical and mechanical equipment necessary for the operation and maintenance of the hyperbaric facility.**
(2) **Any medical devices and instruments used in the facility.**

☐**14.3.2.1.1 Use of unapproved equipment shall be prohibited. (See 14.3.1.6.4.3.).**

☒**14.3.2.1.2 The following devices shall not be operated in the hyperbaric chamber unless approved by the safety director for such use:**

(1) **Portable X-ray devices.**
(2) **Electrocautery equipment.**
(3) **High-energy devices.**

☒**14.3.2.1.3 Photographic equipment employing the following shall not remain in the chamber when the chamber is pressurized:**

(1) **Photoflash.**
(2) **Flood lamps.**

☒**14.3.2.1.4 The use of Class 1 or Class 2 lasers as defined by ANSI Z136.3, *American National Standard for the Safe Use of Lasers in Health Care*, shall be permitted.**

☒**14.3.2.1.5 Equipment known to be, or suspected of being, defective shall not be introduced into any hyperbaric chamber or used in conjunction with the operation of such chamber until repaired, tested, and accepted by qualified personnel and approved by the safety director. (See 14.3.1.3.2.).**

☒**14.3.2.1.6 Equipment that does not meet the temperature requirements of 500.8 (A), 500.8 (B), and 500.8 (C) of *NFPA 70* shall not be permitted in the chamber.**

☒**14.3.2.2 The following shall be all-metal to the extent possible:**

(1) **Oxygen containers.**
(2) **Valves.**
(3) **Fittings.**
(4) **Interconnecting equipment.**

☒**14.3.2.3 The following shall be compatible with oxygen under service conditions:**

(1) Valve seats.
(2) Gaskets.
(3) Hose.
(4) Lubricants.

☒**14.3.2.4 Equipment used inside the chamber requiring lubrication shall be lubricated with oxygen-compatible material.**

☒**14.3.2.4.1 Factory-sealed antifriction bearings shall be permitted to be used with standard hydrocarbon lubricants in Class A chambers that do not employ atmospheres of increased oxygen concentration.**

☒**14.3.2.5 Equipment made of the following shall be prohibited from the chamber interior:**

(1) Cerium.
(2) Magnesium.
(3) Magnesium alloys.

☒**14.3.2.6 In the event that radiation equipment is introduced into a hyperbaric chamber, hydrocarbon detectors shall be installed.**

☒**14.3.2.6.1 In the event that flammable gases are detected in excess of 1000 ppm, radiation equipment shall not be operated until the chamber atmosphere is cleared.**

NOTES:

LVADs have not been approved by their manufactures. This testing is a tool used to approve the device for use at Aurora St. Luke's Medical Center.

Biomedical Evaluator's Signatures:

Biomedical Engineer: Date: 2/22/2018

Comments:

Biomedical Engineer: Date:

Comments:

Biomedical Director: Date:

Comments:

HYPERBARIC FUNCTION TESTING

- The device to be tested should be prominently labeled "NOT APPROVED FOR PATIENT USE" prior to testing.

- If approved for chamber use the "NOT APPROVED FOR PATIENT USE" label should be replaced with a "HYPERBARIC MEDICINE ONLY" label.

- If the device receives approval "with conditions", the device must be clearly labeled with the specifics of the conditions and a hyperbaric Policy / Procedure will be created to address the use of the device in the chamber and the nature of the conditions.

- When approved for use and where appropriate, the electrical plug should be changed to a chamber compatible plug.

- Refer to the device's operation manual to establish a list of functions which must be verified for function and accuracy at all pressures for which the device will be utilized.

- Accuracy for the purpose of hyperbaric testing is defined as the amount of tolerance as specified in the device operation manual. (Ex. ±5%)

- When a function has a useful range, the device will be tested at 15, 50, & 85 percent of the range if appropriate, unless specified by the safety director.

- Function testing will be conducted at the expected therapeutic range of hyperbaric pressure and at various decompression speeds, unless otherwise specified by the safety director.

- After completion of testing, the Function Test Log will be completed by the MSOE M.S. Perfusion Student and filed to the Hyperbaric Medicine Safety Director. A copy of the Function Test Log is to accompany the Request for Medical Device Approval for all team members to review.

- Implosion / Explosion testing will be performed on all devices unless this requirement is waived by a joint decision of the Safety Director and the Biomedical Engineer. (Implosion / Explosion testing will consist of a rapid compression from surface pressure to the maximum chamber pressure) with a bottom time of a minimum of 10 minutes, immediately followed by a rapid decompression to surface. The device is visually inspected and function tested at surface pressure and the cycle is repeated 3 times.)

- If the device fails function testing, it may be retested after modifications are made. All modifications must be clearly documented and presented with the request for approval to the Medical Device Approval Team for evaluation.

- If the device fails to pass the testing process it must be checked out by the biomedical engineering department prior to removing the "NOT APPROVED FOR PATIENT USE" label.

- Devices that have failed function testing will be returned to the vendor, returned to the Biomedical Engineers at Aurora St. Luke's Medical Center, or rendered inoperable and discarded so it cannot be used for patient care.

Functional Test Log

Surface to Therapeutic Pressures: **PASS**

Function Test Description:

The HM II LVAS, the MPU, and the system controller were all placed in MSOE's monoplace hyperbaric chamber. The Li-Ion battery was removed from the system controller to eliminate continuous charging. The HM II LVAS was connected to a water-filled mock circuit and set to 9,200 RPM. The chamber was pressurized from 1.0 ATA to 2.8 ATA, maintained at 2.8 ATA for 10 minutes, and then the chamber vent was opened to 50% and the chamber was allowed to return to surface pressure. This process was repeated three times. The HM II LVAS and its components maintained function at each applied pressure and were inspected following decompression to find that the equipment suffered no damage.

Additional Testing: PASS / FAIL

Function Test Description:

Implosion / Explosion Testing: **PASS**

Function Test Description:

The HM II LVAS, the MPU, and the system controller were all placed in MSOE's monoplace hyperbaric chamber. The Li-Ion battery was removed from the system controller to eliminate continuous charging. The HM II LVAS was connected to a water-filled mock circuit and set to 9,200 RPM. The chamber was pressurized from 1.0 ATA to 2.8 ATA, maintained at 2.8 ATA for 10 minutes, and then the chamber vent was opened to 100% and the chamber was emergently decompressed to surface pressure. This process was repeated three times. The HM II LVAS and its components maintained function at each applied pressure and were inspected following decompression to find that the equipment suffered no damage.

Letter of Electrical Device Approval

We, the undersigned members of the MSOE Hyperbaric Medicine Medical Device Approval Team have reviewed the Medical Device Approval Form for the **Thoratec HeartMate II Left Ventricular Assist System** and hereby **approve** its use within the multi-place hyperbaric chambers at Aurora St. Luke's Medical Center in Milwaukee, WI.

This device is:

☐ APRROVED
☐ APPROVED With the following limitations (See comments below)
☒ APPROVED With the following modification (See comments below)
☐ NOT APPROVED

Subsequent devices of the same make and model will require:

☐No testing
☒Full function testing
☐Abbreviated testing (Identified by the Hyperbaric Medicine Safety Director and the Biomedical Engineering Representative)

Signature indicting the above is true at the best of your knowledge (Check Box indicates electronic signature):

☒MSOE M.S. Perfusion Student:	Nick LaRue	Date:	2/22/18
☐MSOE Mono-Place Chamber Coordinator:		Date:	2/22/18
☐MSOE Perfusion Program Director:		Date:	2/22/18
☐Biomedical Representative:		Date:	2/22/18
☐Hyperbaric Medicine Safety Director:		Date:	

Comments / Limitations / Modifications:

The HM II LVAS and its components properly functioned at various applied pressures in MSOE's monoplace hyperbaric chamber.

Prior to patient treatment inside a hyperbaric chamber, the MPU power cord should be spliced with a nonexplosive/waterproof fitting. Additionally, the MPU should be Nitrogen purged.

The setup should be tested within the multiplace chamber that is located at Aurora St. Luke's Medical Center prior to initiating patient treatment.

Appendix E: HeartWare Electrical Device Approval Process Form

ELECTRICAL DEVICE APPROVAL PROCESS

PURPOSE

The Medical Device Approval Process is a method used to systematically evaluate and mitigate the risk of a medical device to be used inside a Hyperbaric Chamber. It is to ensure the safety of all hyperbaric chamber occupants at Aurora St. Luke's Medical Center in Milwaukee, WI. The NFPA 99 Standard for Health Care Facilities, 2018 Edition, Chapter 14, Section 14.3.2.1 "All equipment used in the hyperbaric chamber shall comply with Section 14.2, including the following: (1) All electrical and mechanical equipment necessary for the operation and maintenance of the hyperbaric facility (2) Any medical devices and instruments used in the facility." The testing process at Milwaukee School of Engineering serves as an aid in selection, testing, modification, documentation, and approval of medical devices for use in the hyperbaric chamber environment.

MSOE HYPERBARIC MEDICINE ELECTRICAL DEVICE APPROVAL TEAM

A Hyperbaric Medicine Medical Device Approval Team shall be established and consist of the following members:

MSOE M.S. Perfusion Student
MSOE Mono-Place Chamber Coordinator (BME Professor)
MSOE Perfusion Program Director
Hyperbaric Medicine Safety Director
Hospital Biomedical Engineering Representative

All members of the Medical Device Approval Team will be required to review the Medical Device Approval Form for each new or modified medical device, and indicate their approval by signing the Medical Device Approval Letter prior to use in the hyperbaric chamber. The Medical Device Approval Team may approve the device as presented or with conditions which must be specified on the Letter of Medical Device Approval. The Medical Device Approval Team must determine if each subsequent device of the same make and model must be individually tested and to what extent.

a. No testing required on subsequent devices
b. Each subsequent device receives full function testing
c. Each subsequent device receives abbreviated testing as determined by the Hyperbaric Medicine Safety Director and the Biomedical Engineering Representative.

PROCESS

Requests for medical device approval should be submitted to the Hyperbaric Medicine Safety Director at Aurora St. Luke's Medical Center for consideration. The Safety Director will pass the device, manuals, and approval forms to the Biomedical Engineering representative for visual inspection and schematic review. The device will be disassembled to whatever extent is necessary to complete the examination. Post inspection, the Safety Director may pass the device approval forms directly to the Medical Device Approval Team if reasonable data exists from the manufacturer, other facilities, or journal documentation. If inadequate data exists the Safety Director will enlist the assistance of appropriate personnel to perform device testing. Upon completion of successful testing, all documentation of the testing process will be forwarded to all Medical Device Approval Team members for review and approval. All Team members are

required to sign-off on each device prior to use in the hyperbaric chamber. Any member of the Medical Device Approval Team may disapprove a device or request further documented evidence or testing at any time prior to approval. All paperwork will be coordinated and maintained by the Hyperbaric Medicine Safety Director.

REQUEST FOR ELECTRICAL MEDICAL DEVICE APPROVAL

Type of device: Left Ventricular Assist Device

Manufacturer: Medtronic

Model: HeartWare

What is the reason for the new equipment or modification of an existing device:

Approve use for future LVAD patients who may benefit from HBOT at Aurora St. Luke's Medical Center in Milwaukee, WI.

Is the device designed and rated for use with hyperbaric chambers? **NO**

Is this device used at any other hyperbaric facilities? **NO**

What testing/modifications did they perform?

Facility:

Contact:

Phone:

What testing/modifications did they perform?

Facility:

Contact:

Phone:

Has the device been written about in any journals (insert info)?	

Operator's Manual?	YES	Service Manual?	NO

Comments:

Worked with Dr. Larry Fennigkoh and David Glowacki to perform testing at MSOE.

Submitted by:	Nick LaRue
Date of submission:	February 22, 2018

NOTE: Attach all pertinent documentation

NFPA 99 (2018) GUIDELINES

Note: Place an "X" through each bullet for "Yes" and leave bullet blank for "No".

For additional comments reference the NFPA number and add notes to the Bio-electronics Comments section at the end.

GENERAL WIRING AND EQUIPMENT GUIDELINES

14.2.9.3 The general rules of 14.2.9.3.1 through 14.2.9.3.17.6 shall be satisfied in the use of electrical devices and equipment. These requirements are intended to protect against the elevated fire risks known to exist in a pressurized air environment and shall not be construed as classifying the chamber interior as a Class I (as defined in NFPA 70, Article 500) hazardous location.

☒**14.2.9.3.1 Equipment or equipment components installed in, or used in, the chamber shall not present an explosion or implosion hazard under the conditions of hyperbaric use.**

☐**14.2.9.3.2 All equipment shall be rated, or tested and documented, for intended hyperbaric conditions prior to use.**

☒**14.2.9.3.3 Only the electrical equipment necessary for the safe operation of the chamber and for required patient care shall be permitted in the chamber.**

☒**14.2.9.3.4 Only portable equipment necessary for the logistical and operational support shall be permitted in the chamber during manned pressurization.**

☐**14.2.9.3.5 Where conformance with Class I, Division 1 requirements is specified in 14.2.9.3.7, conformance with Class I, Division 2 requirements shall be permitted to be substituted.**

NOTES:

14.2.9.3.2 HW VAS has not been previously tested and documented in hyperbaric conditions. That was the goal of this study.

14.2.9.3.3-4 Only HW VAS components required to maintain function were placed in the chamber. The flow monitor would not be placed in chamber during patient treatment.

WIRES AND CABLES

☐**14.2.9.3.6 Wires and cables used inside the chamber shall be resistant to the spread of fire by complying with 14.2.9.3.6.1 or shall be contained within equipment described in 14.2.9.3.6.2.**

☐**14.2.9.3.6.1 Wires and cables shall comply with the spread of fire requirements of "UL Flame Exposure, Vertical Tray Flame Test" in UL 1685, *Standard for Vertical-Tray Fire-Propagation and Smoke-Release Test for Electrical and Optical-Fiber Cables*, or shall exhibit**

damage (char length) not to exceed 1.5 m (4 ft. 11 in.) when performing the CSA "Vertical Flame Test – Cables in Cable Trays," as described in CSA C22.2 No. 0.3-M, *Test Methods for Electrical Wires and Cables*.

☐**14.2.9.3.6.2 Wires and cables that form an integral part of electrical equipment approved or listed specifically for use inside hyperbaric chambers, including patient leads, shall not be required to comply with the requirements of 14.2.9.3.6.1.**

NOTES:

Complies within limits of medical devices to the IEC 60601-1-2:2001 + A1:2004 & IEC 60601-1-2:2003 Meets Fire Casualty, and Electrical shock hazard requirements of UL 60601-1

14.2.9.3 WIRING METHODS

☐**14.2.9.3.7.1 Fixed wiring shall be installed in threaded RMC or IMC conduit utilizing the following waterproof components:**

(5) Threaded metal joints
(6) Fittings
(7) Boxes
(8) Enclosures

☒**14.2.9.3.7.2 A continuous ground shall be maintained between all conductive surfaces enclosing electrical circuits and the chamber hull using approved grounding means.**

☐**14.2.9.3.7.3 All threaded conduit shall be threaded with an NPT standard conduit cutting die that provides a 19-mm taper per 0.3 m (0.75 in. taper per 1 ft.)**

☐**14.2.9.3.7.4 All threaded conduit shall be made wrench-tight to prevent sparking when fault current flows through the conduit system.**

☒**14.2.9.3.7.5 Wiring classified as intrinsically safe for any group location and installed in accordance with Article 504 of *NFPA 70* shall be permitted.**

☐**14.2.9.3.7.6 Threaded, liquid-tight flexible metal conduit installed in accordance with Article 350 of *NFPA 70* shall be permitted when protected from damage by physical barriers such as equipment panels.**

☐**14.2.9.3.8 Drainage. Means of draining fixed conduit and fixed equipment enclosures shall be provided.**

NOTES:

14.2.9.3.7.1: N/A (Non-fixed wiring) 14.2.9.3.7.3-14.2.9.3.7.4 & 14.2.9.3.7.6 & 14.2.9.3.8: N/A (No conduit)

DOES DEVICE HAVE A FLEXIBLE ELECTRICAL CORD? YES

☐**14.2.9.3.9 Flexible Electrical Cords. Flexible cords used to connect portable utilization equipment to the fixed electrical supply circuit shall meet all the following requirements:**

- **(4) They shall be of a type approved for extra-hard use in accordance with Table 400.4 of *NFPA 70*.**
- **(5) Electrically conductive casings of all portable equipment for use inside the chamber shall be grounded.**
- **(6) They shall meet the requirements of 501.140 of *NFPA 70*.**

☐**14.2.9.3.9.1 The normal cord supplied with the portable utilization equipment shall be permitted when the portable device is rated at less than 2 A and the cord is positioned out of traffic and protected from physical abuse.**

Amp Rating:

NOTES:

Meets Fire Casualty, and Electrical shock hazard requirements of UL 60601-1 Complies within limits of medical devices to the IEC 60601-1-2:2001 + A1:2004 & IEC 60601-1-2:2003 14.2.9.3.9.1 The AC adapter has 110-240V and 140 VA max input, 15 V and 3.3 A output. In a chamber that utilizes 100% FiO2, this power cord would be splice with a nonexplosive/waterproof fitting.

DOES THIS DEVICE HAVE RECEPTACLES INSTALLED INSIDE THE CHAMBER? YES

☒**14.2.9.3.10.1 Receptacle shall be waterproof.**

☒**14.2.9.3.10.2 Receptacles shall be of the type providing for connection to the ground conductor of the flexible cord.**

☒**14.2.9.3.10.3 Receptacles shall be supplied from isolated power circuits meeting requirements of 14.2.9.4.2.**

☒**14.2.9.3.10.4 The design of the receptacle shall be such that sparks cannot be discharged into chamber environment when plug inserted or withdrawal under electrical load.**

☒**14.2.9.3.10.5 One of the following shall be satisfied to protect against inadvertent withdrawal of the plug under electrical load:**

(3) The receptacle-plug combination shall be of the locking type.

(4) The receptacle shall carry a label warning against unplugging under load, and the power cord shall not present a trip hazard for personnel moving in the chamber.

NOTES:

The MSOE chamber does not utilize FiO2. Because of this, nonexplosive/waterproof fittings were not used. In a chamber that utilizes 100% FiO2, the power cords would be spliced with nonexplosive/waterproof fittings.

DOES THE DEVICE HAVE ANY SWITCHES? NO

☐**14.2.9.3.11 Switches. Switches in the fixed wiring installation shall be waterproof.**

☐**14.2.9.3.11.1 Switch make and break contacts shall be housed in the electrical enclosure so that no sparks from arcing contacts can reach the chamber environment.**

NOTES:

DOES THE DEVICE HAVE A TEMPERATURE RATING? YES

☒**14.2.9.3.12 Temperature. No electrical equipment installed or used in the chamber shall have an operating surface temperature in excess of 85°C (185°F).**

Surface Temperature:

84 °F max chamber temp

NOTES:

Per Medtronic Manual, the HW VAS and components can reach surface temps up to 122 degrees F.

DOES THE DEVICE HAVE ANY EXPOSED LIVE ELECTRICAL PARTS? NO

☐**14.2.9.3.13 Exposed Live Electrical Parts. No exposed live electrical parts shall be permitted, except as specified in 14.3.9.3.13.1 and 14.2.9.3.13.2.**

☐**14.2.9.3.13.1 Exposed live electrical parts that are intrinsically safe shall be permitted.**

☐**14.2.9.3.13.2 Exposed live electrical parts that constitute patient monitoring leads, which are part of electromedical equipment, shall be permitted provided that they meet the requirements of 14.2.9.3.17.**

NOTES:

DOES THE DEVICE CONTAIN ANY MOTORS? NO

☐**14.2.9.3.14 Motors. Motors located in the chamber and that are not a component of medical equipment shall meet one of the following requirements:**

(3) They shall comply with 501.125 (A)(1) of *NFPA 70*.

(4) They shall be totally enclosed in accordance with 501.125 (A)(2) or 501.125 (A)(3) of *NFPA 70*.

☐ **Is the motor a brushless, intrinsically safe motor?**

NOTES:

This device contains no motors. The LVAD contains a centrifugal pump inside the chest cavity.

IS THIS EQUIPMENT LOW VOLTAGE/POWER? YES

☒**14.2.9.3.16 Low-Voltage, Low-Power Equipment. The requirements of 14.2.9.3.16 through 14.2.9.3.16.5 shall apply to sensors and signaling, alarm, communication, and remote-control equipment installed or used in the chamber for operation of the chamber.**

☒**14.2.9.3.16.1 Equipment shall be isolated from main power by one of the following means:**

(4) Design of the power supply circuit.
(5) Opto-isolation.
(6) By other electronic isolation means.

☐**14.2.9.3.16.2 Circuits such as headset cables, sensor leads, and so forth, not enclosed as required in 14.2.9.3.7, shall meet one of the following requirements:**

(3) They shall be part of approved intrinsically safe equipment.
(4) They shall be limited by circuit design to no more than 28 V and 0.5 A under normal or circuit-fault conditions.

Voltage: 14.8 V Max **Amps:** Unknown

NOTES:

DOES THIS DEVICE HAVE OR CONTAIN SPEAKERS? YES

☒**14.2.9.3.16.3 Chamber speakers shall be of a design in which the electrical circuitry and wiring is completely enclosed.**

☐**14.2.9.3.16.4 The electrical rating of chamber speakers shall not exceed 28V rms and 25 W.**

Voltage: **Watts:**

☐**14.2.9.3.16.5 Battery-operated, portable intercom headset units shall meet the requirements of 14.2.9.3.17.5 for battery-operated devices.**

NOTES:

Speakers are integrated into the controller. These are not chamber speakers..

IS THIS EQUIPMENT PORTABLE PATIENT CARE RELATED? YES

14.2.9.3.17 Portable Patient Care–Related Electrical Appliances.

☒**14.2.9.3.17.1 The appliance shall be designed, constructed, inspected, and maintained in accordance with Chapter 10.**

☐**14.2.9.3.17.2 The electrical and mechanical integrity of the appliance shall be verified and documented through an ongoing maintenance program as required in Chapter 10.**

☒**14.2.9.3.17.3 The appliance shall conform to the requirements of 14.2.9.3.1 and 14.2.9.3.12.**

☐**14.2.9.3.17.4 Appliances that utilize oxygen shall not allow oxygen accumulation in the electrical portions of the equipment under normal and abnormal conditions.**

NOTES:

14.2.9.3.17.1: Complies within limits of medical devices to the IEC 60601-1-2:2001 + A1:2004 & IEC 60601-1-2:2003 14.2.9.3.17.2: Temporary device. Biomedical Engineers would inspect new patient's equipment prior to use. 14.2.8.3.17.4: Appliance does not utilize O2.

IS THIS DEVICE BATTERY OPERATED OR CONTAIN BATTERIES? YES

☐**14.2.9.3.17.5 Battery-Operated Devices. Battery-operated devices shall meet the following requirements:**

(7) Batteries shall be fully enclosed and secured within the equipment enclosure.
(8) Batteries shall not be damaged by the maximum chamber pressure they are exposed to.
(9) Batteries shall be of a sealed type that does not off-gas during normal use.
(10) Batteries or battery-operated equipment shall not undergo charging while located in the chamber.

(11) **Batteries shall not be changed on in-chamber equipment while the chamber is in use.**

(12) **The equipment electrical rating shall not exceed 12 V and 48 W.**

Voltage: | **Watts:**

What is the expect life of battery (in months)? N/A

How long will device run on battery (in hours)? N/A

Battery type?

NOTES:

Li-Ion external battery packs were not used to power the device during testing. These battery packs should be tested separately prior to any patient use.

IS THIS A CORD CONNECTED DEVICE? YES

☒**14.2.9.3.17.6 Cord-Connected Devices. Cord-connected devices shall meet the following requirements:**

(4) **All portable, cord-connected equipment shall have an on/off power switch.**

(5) **The equipment electrical rating shall not exceed 120 V and 2 A, unless the electrical portions of the equipment are inert-gas purged.**

(6) **The plug of cord-connected devices shall not be used to interrupt power to the device.**

Voltage: 100-240 V **Amps:**

NOTES:

The AC adapter would be N2 purged in a chamber that utilizes 100% FiO2.

The MSOE chamber does not utilize FiO2. Because of this, N2 purging was not used.

GAS PURGING

☒**14.2.9.3.18 Gas Purging. Gas purging of AC and DC equipment used inside the chamber shall be permitted using inert gas or air.**

NOTES:

The AC adapter and controller would be N2 purged in a chamber that utilizes 100% FiO2.

The MSOE chamber does not utilize FiO2. Because of this, N2 purging was not used.

14.3.2 EQUIPMENT

☒**14.3.2.1 All equipment used in the hyperbaric chamber shall comply with Section 14.2, including the following:**

(3) All electrical and mechanical equipment necessary for the operation and maintenance of the hyperbaric facility.

(4) Any medical devices and instruments used in the facility.

☐**14.3.2.1.1 Use of unapproved equipment shall be prohibited. (See 14.3.1.6.4.3.).**

☒**14.3.2.1.2 The following devices shall not be operated in the hyperbaric chamber unless approved by the safety director for such use:**

(4) Portable X-ray devices.

(5) Electrocautery equipment.

(6) High-energy devices.

☒**14.3.2.1.3 Photographic equipment employing the following shall not remain in the chamber when the chamber is pressurized:**

(3) Photoflash.

(4) Flood lamps.

☒**14.3.2.1.4 The use of Class 1 or Class 2 lasers as defined by ANSI Z136.3, *American National Standard for the Safe Use of Lasers in Health Care*, shall be permitted.**

☒**14.3.2.1.5 Equipment known to be, or suspected of being, defective shall not be introduced into any hyperbaric chamber or used in conjunction with the operation of such chamber until repaired, tested, and accepted by qualified personnel and approved by the safety director. (See 14.3.1.3.2.).**

☒**14.3.2.1.6 Equipment that does not meet the temperature requirements of 500.8 (A), 500.8 (B), and 500.8 (C) of *NFPA 70* shall not be permitted in the chamber.**

☒**14.3.2.2 The following shall be all-metal to the extent possible:**

(5) Oxygen containers.

(6) Valves.

(7) Fittings.

(8) Interconnecting equipment.

☒**14.3.2.3 The following shall be compatible with oxygen under service conditions:**

(5) Valve seats.
(6) Gaskets.
(7) Hose.
(8) Lubricants.

☒**14.3.2.4 Equipment used inside the chamber requiring lubrication shall be lubricated with oxygen-compatible material.**

☒**14.3.2.4.1 Factory-sealed antifriction bearings shall be permitted to be used with standard hydrocarbon lubricants in Class A chambers that do not employ atmospheres of increased oxygen concentration.**

☒**14.3.2.5 Equipment made of the following shall be prohibited from the chamber interior:**

(4) Cerium.
(5) Magnesium.
(6) Magnesium alloys.

☒**14.3.2.6 In the event that radiation equipment is introduced into a hyperbaric chamber, hydrocarbon detectors shall be installed.**

☒**14.3.2.6.1 In the event that flammable gases are detected in excess of 1000 ppm, radiation equipment shall not be operated until the chamber atmosphere is cleared.**

NOTES:

LVADs have not been approved by their manufactures. This testing is a tool used to approve the device for use at Aurora St. Luke's Medical Center.

Biomedical Evaluator's Signatures:

Biomedical Engineer: Date: 2/22/2018

Comments:

Biomedical Engineer: Date:

Comments:

Biomedical Director: Date:

Comments:

HYPERBARIC FUNCTION TESTING

- The device to be tested should be prominently labeled "NOT APPROVED FOR PATIENT USE" prior to testing.

- If approved for chamber use the "NOT APPROVED FOR PATIENT USE" label should be replaced with a "HYPERBARIC MEDICINE ONLY" label.

- If the device receives approval "with conditions", the device must be clearly labeled with the specifics of the conditions and a hyperbaric Policy / Procedure will be created to address the use of the device in the chamber and the nature of the conditions.

- When approved for use and where appropriate, the electrical plug should be changed to a chamber compatible plug.

- Refer to the device's operation manual to establish a list of functions which must be verified for function and accuracy at all pressures for which the device will be utilized.

- Accuracy for the purpose of hyperbaric testing is defined as the amount of tolerance as specified in the device operation manual. (Ex. ±5%)

- When a function has a useful range, the device will be tested at 15, 50, & 85 percent of the range if appropriate, unless specified by the safety director.

- Function testing will be conducted at the expected therapeutic range of hyperbaric pressure and at various decompression speeds, unless otherwise specified by the safety director.

- After completion of testing, the Function Test Log will be completed by the MSOE M.S. Perfusion Student and filed to the Hyperbaric Medicine Safety Director. A copy of the Function Test Log is to accompany the Request for Medical Device Approval for all team members to review.

- Implosion / Explosion testing will be performed on all devices unless this requirement is waived by a joint decision of the Safety Director and the Biomedical Engineer. (Implosion / Explosion testing will consist of a rapid compression from surface pressure to the maximum chamber pressure) with a bottom time of a minimum of 10 minutes, immediately followed by a rapid decompression to surface. The device is visually inspected and function tested at surface pressure and the cycle is repeated 3 times.)

- If the device fails function testing, it may be retested after modifications are made. All modifications must be clearly documented and presented with the request for approval to the Medical Device Approval Team for evaluation.

- If the device fails to pass the testing process it must be checked out by the biomedical engineering department prior to removing the "NOT APPROVED FOR PATIENT USE" label.

- Devices that have failed function testing will be returned to the vendor, returned to the Biomedical Engineers at Aurora St. Luke's Medical Center, or rendered inoperable and discarded so it cannot be used for patient care.

Functional Test Log

Surface to Therapeutic Pressures: **PASS**

Function Test Description:

The HW VAS, the AC adapter, and the controller were all placed in MSOE's monoplace hyperbaric chamber. The Li-Ion external battery pack was removed as a power source for the controller causing an alarm (missing power source alert). The HW VAS was connected to a water-filled mock circuit and set to 2,600 RPM. The chamber was pressurized from 1.0 ATA to 2.8 ATA, maintained at 2.8 ATA for 10 minutes, and then the chamber vent was opened to 50% and the chamber was allowed to return to surface pressure. This process was repeated three times. The HW VAS and its components maintained function at each applied pressure and were inspected following decompression to find that the equipment suffered no damage.

Additional Testing: PASS / FAIL

Function Test Description:

Implosion / Explosion Testing: **PASS**

Function Test Description:

The HW VAS, the AC adapter, and the controller were all placed in MSOE's monoplace hyperbaric chamber. The Li-Ion external battery pack was removed as a power source for the controller causing an alarm (missing power source alert). The HW VAS was connected to a water-filled mock circuit and set to 2,600 RPM. The chamber was pressurized from 1.0 ATA to 2.8 ATA, maintained at 2.8 ATA for 10 minutes, and then the chamber vent was opened to 100% and the chamber was emergently decompressed to surface pressure. This process was repeated three times. The HW VAS and its components maintained function at each applied pressure and were inspected following decompression to find that the equipment suffered no damage.

Letter of Electrical Device Approval

We, the undersigned members of the MSOE Hyperbaric Medicine Medical Device Approval Team have reviewed the Medical Device Approval Form for the **Medtronic HeartWare Ventricular Assist System** and hereby **approve** its use within the multi-place hyperbaric chambers at Aurora St. Luke's Medical Center in Milwaukee, WI.

This device is:

☐ APRROVED
☐ APPROVED With the following limitations (See comments below)
☒ APPROVED With the following modification (See comments below)
☐ NOT APPROVED

Subsequent devices of the same make and model will require:

☐No testing
☒Full function testing
☐Abbreviated testing (Identified by the Hyperbaric Medicine Safety Director and the Biomedical Engineering Representative)

Signature indicting the above is true at the best of your knowledge (Check Box indicates electronic signature):

☒MSOE M.S. Perfusion Student:	Nick LaRue	Date:	2/22/18
☒MSOE Mono-Place Chamber Coordinator:		Date:	2/22/18
☒MSOE Perfusion Program Director:		Date:	2/22/18
☒Biomedical Representative:		Date:	2/22/18
☐Hyperbaric Medicine Safety Director:		Date:	

Comments / Limitations / Modifications:

The HW VAS and its components properly functioned at various applied pressures in MSOE's monoplace hyperbaric chamber.

Prior to patient treatment inside a hyperbaric chamber, the AC adapter should be spliced with a nonexplosive/waterproof fitting. Additionally, the AC adapter and controller should be Nitrogen purged.

The setup should be tested within the multiplace chamber that is located at Aurora St. Luke's Medical Center prior to initiating patient treatment.

Perfusion

Thesis Approval Form

Masters of Science in Perfusion – MSP

Milwaukee School of Engineering

This thesis, titled "Considerations Associated for Left Ventricular Assist Device Patients Receiving Hyperbaric Oxygen Therapy," submitted by the student Nicholas LaRue, has been approved by the following committee:

Faculty advisor: _____ Date: _____

Dr. Ronald Gerrits

Faculty member: _____ Date: _____

Dr. Larry Fennigkoh

Faculty member: _____ Date: _____

Mr. Gary Shimek