**Cardiovascular Team: Initial Needs Report**

EXSU 620 – Surgical Innovation I

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GLOSSARY

Introduction............................................................................................................................................Pg. 2

Overview

Criteria

Needs.....................................................................................................................................................Pg. 3

1. Valve Sizing

2. Medical Device Charger

3. Instrument Identification

4. Instrument Counting

5. Vessel Imaging

Conclusion...........................................................................................................................................Pg. 13

Appendices..........................................................................................................................................Pg. 14

INTRODUCTION

NEEDS

*Need #1*

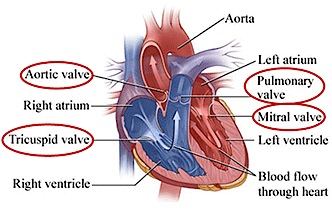
**Need Statement:**

A way to more accurately determine the size of a heart valve during transcatheter valve replacement, in order to increase the accuracy and efficiency of choosing the proper valve.

**Disease State:**

Valvular heart disease is becoming an increasing problem, due to higher life expectancy as well as an aging baby boomer population. For example, the elderly population aged 80 years and above has been expected to increase from 6.9 million in 1990 to about 25 million by 2050. Furthermore, moderate to severe valve disease is prevalent in more than one in eight people aged 75 or older [1].

The four valves of the heart, as depicted in Figure 1, may be affected as a result of congenital birth defects, aging, lifestyle (smoking), injury or related illness. Valve disorders can be classified into the following types: stenosis, prolapse and regurgitation. A stenosis occurs when the valve is sufficiently narrowed or stiffened, mostly due to calcification or plaque build up, which prevents blood from adequately pumping into and out of the heart [3]. A prolapse, also known as floppy valve syndrome, is when the valve leaflets don’t close evenly and collapse backward into the chamber that they are supposed to be sealing off [4]. Mitral valve prolapse is the most common abnormality, affecting two to three percent of the population in the United States, and can lead to serious complications including mitral regurgitation [5]. Regurgitation is the backflow of blood into the improper chamber (opposite direction than it is supposed to flow) as a result of defective valves. Those most at risk for valve disorders are people with a history of high blood pressure, coronary artery disease, rheumatic fever, infective endocarditis, heart attack or failure, arrhythmias, birth defects, or those that have undergone mediastinal (chest) radiation therapy for cancer. While some patients do not present with any symptoms, others can have a gradual or severe onset of symptoms such as: chest pain, palpations, shortness of breath, fatigue, lightheadedness, and swollen feet, ankles, or abdomen. The detection of a heart murmur in patients is a good indication of possible valve problems in the future, and is be monitored periodically [3].



(a)

(c)

(d)

(b)

**Figure 1.** The four valves of the heart: (a) aortic valve, (b) tricuspid valve, (c) pulmonary valve, (d) mitral valve. [2]

Currently, 60 to 70 percent of all valve surgeries performed on the elderly are done to repair aortic stenosis. Patient outcome is largely dependent on age, and higher mortality rates are associated with patients aged 80 and above, as well as those with comordities [1].

**Existing Treatment:**

**Current Market:**

**Classification and Applicable Regulations:**

**Important Stakeholders and Key Opinion Leaders:**

**References:**

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*Need #2*

**Need statement:**

A way to overcome the lack of wireless charging for medical devices that require an external power source, such as ventricle assist device, in patients with congestive heart failure, in order to improve convenience, maintenance, portability and quality of life.

**Disease state:**

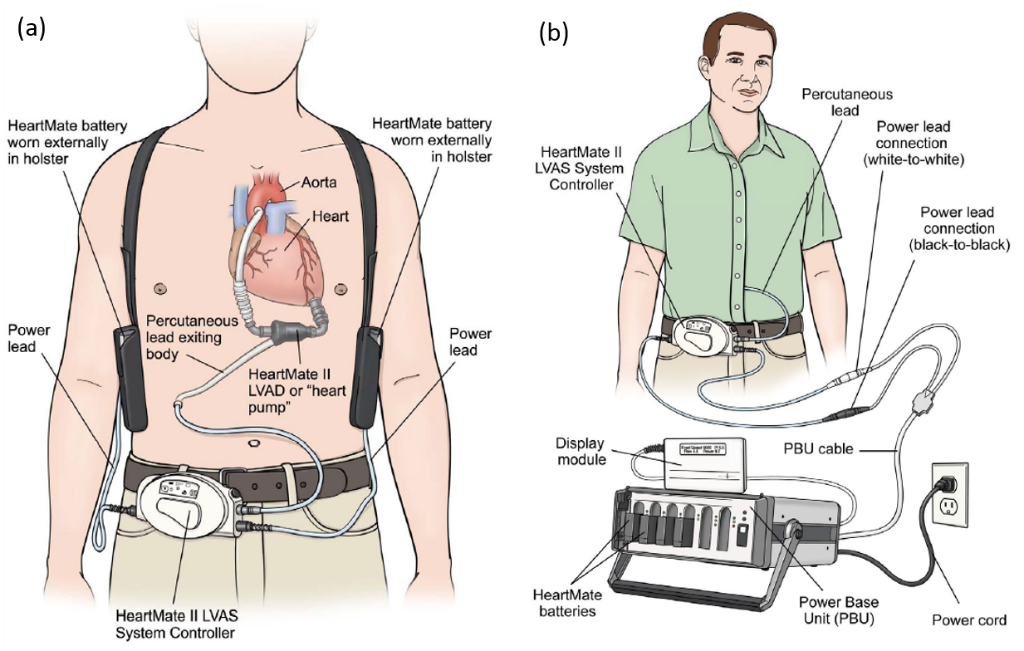
Heart failure (HF) is a global pandemic affecting at least 26 million people worldwide and is increasing in prevalence. Currently, 5.7 million people in the United States have HF, but the projections are worrisome since it is expected that, by 2030, more than 8 million people will have this condition, accounting for a 46 % increase in prevalence [1].

 HF is a condition that the [heart](https://www.webmd.com/heart-disease/rm-quiz-know-heart)'s pumping power is lower than healthy level. In heart failure, [blood](https://www.webmd.com/heart/anatomy-picture-of-blood) moves at a slower flow-rate and hypertension occur in the heart. Consequently, the heart is not capable of pumping demanded oxygen and [nutrients](https://www.webmd.com/a-to-z-guides/tc/major-nutrients-in-food-topic-overview) to the body. The cardiac muscles respond to this situation either by extra [stretching](https://www.webmd.com/fitness-exercise/features/how-to-stretch) to or by becoming stiffer and thicker through the remodeling process. In response to this situation, the [kidneys](https://www.webmd.com/kidney-stones/picture-of-the-kidneys) retain more fluid (water), and salt; which consequently results in water builds up in the arms, legs, [ankles](https://www.webmd.com/fitness-exercise/picture-of-the-ankle), feet, [lungs](https://www.webmd.com/lung/picture-of-the-lungs). The term congested and [congestive heart failure](https://www.webmd.com/heart-disease/guide-heart-failure) is used to describe the condition. Some of the congestive heart failure risk-factors are [high blood pressure](https://www.webmd.com/hypertension-high-blood-pressure/default.htm), [valve disease](https://www.webmd.com/content/pages/9/1675_57850.htm), [thyroid](https://www.webmd.com/women/picture-of-the-thyroid) disease, [kidney disease](https://www.webmd.com/a-to-z-guides/understanding-kidney-disease-basic-information), [diabetes](https://www.webmd.com/diabetes/default.htm), and heart defects [2].

**Existing Treatment and Problem:**

Doctors and healthcare team may recommend medication or surgery and may suggest lifestyle changes such as healthy eating and physical activity. Patients take a combination of drugs. Depending on the severity and nature of heart failure, the doctor may also recommend surgery or device therapy to treat patient’s condition. Heart failure also could be treated by a bi-ventricular pacing, suiting the patient clinical condition. The VADs are small implantable devices that act to compensate the pumping function of the heart and assist in circulating blood throughout the body. Patients with VADs can be discharged from the hospital and have an acceptable quality of life. An LVAD pumps blood from the left, whereas RVAD pumps from of the right ventricle towards the body [3]. VADs systems consist pump, system controller, power source, power leads, batteries and battery clips as shown in Figure 2.

Currents VADs must always have power, either from batteries or electricity from the wall outlet. A power module or AC adaptor is used when the patient is not active, like when he is watching TV. It must be used when he is sleeping. Patients can get up and do things away from the power unit by using a pair of rechargeable batteries. Batteries are got fully charge in about 4 hours. Doing regular activities like reading a book or walking at normal pace, battery last 4 to 6 hours. By checking an indicator on the controller, the batteries should be exchanged when their charge falls below 25% capacity. Spare, fully charged batteries should always be available. Doing the literature showed that having a portable wireless charger which can be carried by patients and doesn’t need electricity plug, can provide more convenience in daily life, the durability of battery charge, no need to carry backup charged batteries.



**Figure 2.** Implanted and worn components of VADs (a) during battery-power operation (b) during tethered operation connected to PBU. (Courtesy of Thoratec Corp., FL, USA)

**Current Market:**

In 2012 heart failure was responsible for an estimated health expenditure of around $31 billion (£22.5 billion), equivalent to more than 10 % of the total health expenditure for cardiovascular diseases in the United States (US). Projections are even more alarming, however, with total costs expected to increase by 127 % between 2012 and 2030 [4].

The global market for cardiac assistive devices is projected to close at 1.4 Billion in 2017. Ventricular assistive devices (VADs) are the major segment of the market with 63%. The market has shown a promising compound average growth rate (CAGR) of 8.6% between 2010 and 2017. The reports reveal that US market composes 55% of the global market of cardiac assistive devices and has expanded with a CAGR of 10.9%. The global CAGR for VAD market segment is reported to be 11.3% between 2010-2017 [5]. There are currently several manufacturers for VADs. As explained before, all use battery charging system that should be plugged into wall outlet and wait for at least 4 hours to get fully charge and keep backup batteries. Table 1 shows examples of various VADs available in the market which their batteries and chargers are carried in a backpack [6], [7].

**Table 1**. Various VADs available in the market which their batteries and chargers are carried in a backpack.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product** | **Manufacturer**  **Regulatory status** | **Image** | **Battery/Charger** | **Market Share10** |
| [**HeartMate II® LVAD**](https://www.mylvad.com/content/st-jude-heartmate-ii%C2%AE-lvad) | Thoratec [8]  CE Marked  FDA  (Bridge to Transplant and Destination Therapy) |  | Charging time  4 Hours  Usage time  8-10 Hours | 48% |
| [**HeartWare® LVAD**](https://www.mylvad.com/content/heartware%C2%AE-lvad) | HeartWare [9]  CE Marked  FDA  (Bridge to Transplant) |  | Charging time  4 Hours  Usage time  4-6 Hours | 10%  Approx. |
| [**Jarvik 2000 FlowMaker**](https://www.mylvad.com/content/jarvik-2000-flowmaker%C2%AE-lvad) | Jarvik Heart [10]  CE Marked  Involved in an FDA-approved phase II clinical pivotal trial |  | Charging time  5 Hours  Usage time  7 Hours | - |
| **Berlin Heart** | Berlin Heart [11]  CE Marked  FDA  (Bridge to Transplant) |  | Charging time  5 Hours  Usage time  8 Hours | - |

**Classification and Applicable Regulations:**

The battery chargers have been classified as a class 1 by FDA-CDRH in the US. Also, As per EEC/2017/745 and CMDCAS, those are classified as a *class-I* medical device. The applicable regulatory framework in each case is as follows:

|  |  |  |
| --- | --- | --- |
| **FDA** | **CE** | **HEALTH CANADA** |
| **Device Classification:**  I  **Product Code:**  KRF  **Regulation Number**:  CFR 870.3670 | **Device Classification:**  I  **Regulation:**  EEC/2017/745 | **Device Classification:**  I  **Regulation:**  CMDCAS |

**Need Criteria:**

To the best of the author's knowledge, the proposed need is subjected to the following criteria:

1. Lightweight, easy to carry
2. No need to backpack for reserve battery set
3. Firmware to track flows and battery charge with phone application

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*Need #3*

**Need Statement:**

A way to improve surgical instrument identification for operating room staff, students and residents during surgical training programs, in order to accelerate their acquaintance with new instruments and sets.

**Disease state:**

During the surgeries that we observed, and in all surgeries in general, the communication between all the medical staff located in the same operating room is essential : there are often more than 10 people in the room, and many machines that make noise, so it is important that everyone expresses themselves in the clearest possible way, and likewise it is essential that everyone knows perfectly his role and what is expected of him in order to minimize the number of misunderstandings and to limit the general time of the procedure.

Given the number of rules of hygiene and safety that must be respected, the number of instruments to be known, the training is often longer for the operating room staff. It is for these reasons that a surgeon will have to take a longer formation than most of the other doctors, or that a nurse will have to undergo additional specialized training up to several years to assist the surgeries in operating room.

Moreover, most of the time, advances in medical research cause the evolution of certain operative techniques, or even the appearance of new ones, and the training of surgeons is therefore often continuous throughout their careers, so that they can update their knowledge according to the more recent discoveries.

Thus training is one of the most important aspects for the acquisition of skills of the personnel who will be present in the OR.

**Existing treatments:**

With the arrival on the market of new technologies, we realize that the immersive aspect of a training makes it much more effective. Thus we have seen the emergence in recent years of a surgical training system using virtual reality in simulation centers, which is a system more and more used today to train in practice, so that surgeons can really feel the need for the precision needed to pass a procedure, practice using tools on materials with mechanical properties close to human tissues, etc.

However apart from these practices reserved for surgeons, the immersive training offer for other people that can be found in an operating room is quite limited. In the majority of cases, this is limited to theoretical learning followed by practical training.

It is therefore completely possible that a health professional arriving the first day in an operating room is lost with all the medical jargon, the names of the instruments used and all the procedures to follow in order to respect the hygiene and safety standards.

**Current market:**

The contribution margin per hour of operative time is the hospital income generated by a surgical case, when all variable costs of hospitalization and supply are subtracted. Consequently the economic impact of repeated errors due to the human factor can be estimated: an operating room that supports excessive surgery times can cause the hospital to lose its financial margin if the surgeons are slow, if the staff in the operating room is not responsive enough, if too many instruments are used even if not needed, etc. On average, every minute in an operating room costs the hospital about 62 US dollars (Alex Macario, 2010).

Poor preparation of surgical instruments in the operating room, poor communication or lack of staff knowledge are just as many reasons that can increase the length of the procedure, and thus impose additional costs on the hospital.

For the moment, there is no training aid for staff other than internships and simulation (with or without virtual reality) for surgeons and anesthesiologists.

**Classification:**

Our innovation would take the form of an immersive visual tool that could use augmented reality, for example, or use voice recognition to link the surgeon's demands to what nurses need to do (which machine to check, which instrument to grab and give, etc ...) so that the staff could use it to better identify tools and machines in the OR, apply their knowledge effectively during their formation, and allow a more immersive learning without being in internship.

Thus, as a non-invasive device that does not come into contact with the patient, it’s the rule 7 that applies: it is therefore a Class I device.

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*Need #4*

**Need Statement:**

A way to reduce the tediousness of counting surgical instruments in every surgery, which will increase the efficiency of medical procedures, lighten the workload of operating room staff, and decrease surgical complications caused by human error.

**Problem and Disease State:**

Surgeons utilize an array of instruments during every procedure. Before a surgery begins, counting all available surgical instruments such as scissors, scalpels, tubes, sponges and so on is a standard and important practice. At the conclusion of surgery, the stuff in OR should count all surgical instruments as well, if the count is different, it is clear that an instrument has been left. Retained surgical instrument (RSI) is any instruments accidentally left inside a patient’s body following a surgery. Apparently, this sever mistake could lead to significant health injuries, repeated surgery, even in some cases death of patient [1]. Therefore, the surgical instruments counting is an indispensable and essential process during a surgery.

At present, the surgical instruments counting process generally is undertaken by human.

Thus, mistakes in counting process is inevitable, according to a study which reported to the Annals of Surgery that mistakes in instruments counts happened in 12.5% of surgeries [2]. An inaccurate count can occur when nurses are deprived of sleep, especially when the surgical operation is particularly difficult, long and mentally draining, when the operation is an emergency, or when there are unforeseen changes in the procedure [3]. The Association of Operating Room Nurses published an uptodate.com policy in 2015 recommending the points below that are widely used in the United States hospitals [4] Specifically, counting should be performed at the following time points during the surgical procedure: before the procedure begins (initial count); whenever new additional items are used during the operation; before the surgeon closes the body cavity; when the surgeon begins to close the wound; and when the surgeon closes the skin (final count) [5]. Therefore, counting surgical instruments is a tedious and boring work, it requires lots of manpower, thus it is a heavy work for nurses.

**Existing solutions:**

In order to solve this problem, Israel RFID (radio frequency identification) medical solution provider Haldor Advanced Technologies developed ORLocate system based on passive RFID tags, it can monitor and track the surgical instruments and consumables before, during and at the conclusion of the surgical procedure [6]. Penelope robot system designed by Micheael R.T can also count surgical instruments [7]. However, these two methods are more complex and the price is pretty high, the cost of each system is more than $100,000 [8]. Moreover, these systems are rely on tags, they need add some tags to the instruments, hence the fabrication process of surgical instruments may be changed, this property brings some difficulties to these systems be used widely.

**Current market:**

According to the data from the National Center for Health Statistics, 48 million surgical inpatient procedures were performed in the United States in 2009 [9]. And the number of cases in which surgical instruments are left behind during a procedure in the United States has been estimated at around 1500 cases per year, while approximately 88% of these cases occur in a situation where the surgical instruments counts were declared “correct” [10]. Medicolegal and compensation costs associated with RSI are high, even if there has been little or no harm to the patient. Costs vary from $37,041 to $ 2,350,000 per incident, with an average cost per case estimated at $95,000 [11]. If a more accurate and efficient surgical counting approach can help hospital to avoid these losses, it will benefit to both hospitals and patients.

**Need criteria**

1. The aiming approach should not change the fabrication process of surgical instruments.
2. The aiming approach should be more accurate than these existing approaches.
3. The aiming approach should be easy to use.
4. The aiming approach should be low-cost.

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*Need #5*

**Need Statement:**

A better way to distinguish vessels that need to undergo bypass in pre-operative imaging for the coronary artery bypass graft (CABG) procedure, in order to speed up diagnosis, and to increase the accuracy of medical professionals in emergency cases.

**Existing treatments:**

Coronary artery bypass is the usual treatment for relieving the symptoms of coronary artery disease. Obviously the patient can change his lifestyle or take a medical treatment that could help him feel better, but the CABG procedure is the more frequent. It is an open heart surgery where the person is placed in general anesthesia. Blood circulation during the operation is managed by a heart-lung machine, which allows the surgeon to clamp the aorta, and use a vein taken in the leg to bridge the aorta coronary artery. It is also possible to perform the same surgery without heart-lung machine (heart-beating surgery), to avoid the technical complications of the machine. This operation normally lasts between 3 and 6 hours.

The problem of this disease is that the diagnosis is not always easy to emit, and the treatment is heavy and intense for the patient: there is a potential drug treatment depending on the patient's health; he will have an open heart surgery, that will result in an a long and crippling scar all over the chest, with a certainly low but present possibility of death (about 1% if the patient has never had heart problems before that, sometimes more), followed by a hospital stay of up to one week; titanium wires in the chest that have been used to close the rib cage; and medications during the rest of his time life to reduce cardiac work and reduce the risk of potential future heart attacks. Similarly, if the surgeon does not see the problem during the imaging preceding the diagnosis, we can miss an operation that could have saved the patient.

Obviously, there may be additional tests and interventions done, for example a percutaneous coronary intervention PCI, where a thin, flexible tube with a balloon at its end is inserted through the vessel to push the clogging plaque against the  wall artery; sometimes a stent can be used during PCI. But if the imaging was effective enough to ensure the accuracy of the diagnosis, it would avoid additional costs due to these tests and interventions whose the only purpose is to reassure the doctor on his decision.

**Important stakeholders:**

The important stakeholders concerned by this problem and by a potential solution would be all cardiac surgeons, because a significant modification of the preoperative procedures would require something to inform them, through a formation for example. Also, the Association of Cardiovascular and Thoracic Surgeons of Quebec could do it, because they represent every cardiac surgeon in Quebec.

**Classification:**

Our solution would be to improve existing imaging techniques by implementing a software that could help physicians to make a decision about the diagnosis or the size of the material to be used, by noticing in a more explicit way vessels with a smaller diameter that could require a CABG procedure. Thus, as a software dedicated to an active diagnostic device whose erroneous reading could represent a danger for the patient (for example if the software does not locate an artery that deserves a bypass), we can apply the rule 10 and classify this innovation as a Class III medical device.

6. Possible regulations that would have to be in place (what ISO would you need, etc.)

7. Access to key opinion leaders

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CONCLUSION

APPENDICES