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IDENTIFYING POTENTIAL DESIGN INTERVENTIONS FOR HEART-LUNG MACHINES

A THESIS SUBMITTED TO
THE GRADUATE SCHOOL OF NATURAL AND APPLIED SCIENCES
OF
MIDDLE EAST TECHNICAL UNIVERSITY

BY

EREN DÖNERTAŞ

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR
THE DEGREE OF MASTER OF SCIENCE
IN
INDUSTRIAL DESIGN

FEBRUARY 2023

Approval of the thesis:

IDENTIFYING POTENTIAL DESIGN INTERVENTIONS FOR HEART-LUNG MACHINES

submitted by **EREN DÖNERTAŞ** in partial fulfillment of the requirements for the degree of **Master of Science** i**n Industrial Design, Middle East Technical University** by,

Prof. Dr. Halil Kalıpçılar
Dean, Graduate School of **Natural and Applied Sciences** ________________

Prof. Dr. Gülay Hasdoğan
Head of the Department, **Industrial Design** ________________

Prof. Dr. Bahar Şener-Pedgley
Supervisor, **Industrial Design, METU** ________________

Examining Committee Members:

Assoc. Prof. Dr. Naz A.G.Z. Börekçi
Industrial Design, METU ________________

Prof. Dr. Bahar Şener-Pedgley
Industrial Design, METU ________________

Assist. Prof. Dr. Erçin Okursoy
Industrial Design, TEDU ________________

Date: 13.02.2023

I hereby declare that all information in this document has been obtained and presented in accordance with academic rules and ethical conduct. I also declare that, as required by these rules and conduct, I have fully cited and referenced all material and results that are not original to this work.

Name Last name : Eren Dönertaş

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ABSTRACT

IDENTIFYING POTENTIAL DESIGN INTERVENTIONS FOR HEART-LUNG MACHINES

Dönertaş, Eren
Master of Science, Industrial Design
Supervisor: Prof. Dr. Bahar Şener-Pedgley

February 2023, 141 pages

Heart-lung machine (HLM) overtakes the functions of the heart and lungs during cardiovascular (open-heart) surgeries. Perfusionists, trained personnel, are in charge of operating, maintaining, and calibrating HLMs.

There are some risks associated with cardiovascular surgery due to mistakes made by perfusionists. This creates adverse effects for patients undergoing cardiovascular surgery, operators using the device, and hospital management. In this study, the functions and working principles of HLM, the needs and expectations of perfusionists, and the experience of perfusionists during cardiovascular surgeries are examined in order to determine the points that can be improved with design interventions in various hospitals in Turkey during 2021-2022. The primary aim of the study is to decrease the frequency of human-based errors in the usage of HLM during cardiovascular surgeries by enhancing the perfusionist's experiences.

Accordingly, literature review is used to become familiar with HLMs, their context and technical considerations. To understand the requirements and expectations of perfusionists regarding the HLMs, user interviews and surveys are carried out. To analyze how perfusionists engage with one another in a given context and pinpoint areas where perfusionists' experiences could be enhanced, user observations are utilized. The research findings are described in a way that is useful to those working on the design of medical devices, product designers, and design researchers.

Keywords: Medical Equipment Design, Heart-Lung Machine, Cardiopulmonary Bypass Machine, Design Research, Operating Room

ÖZ

KALP-AKCİĞER MAKİNELERİNİN POTANSİYEL TASARIM MÜDAHALE ALANLARININ BELİRLENMESİ

Dönertaş, Eren
Yüksek Lisans, Endüstri Ürünleri Tasarımı
Tez Yöneticisi: Prof. Dr. Bahar Şener-Pedgley

Şubat 2023, 141 sayfa

Kalp-akciğer makinesi (KAM), kardiyovasküler (açık-kalp) ameliyatlar esnasında kalp ve akciğer fonksiyonlarını üstlenir. Perfüzyonistler, kalp-akciğer makinelerinin kullanımından, bakımından ve kalibre edilmesinden sorumlu olan eğitimli personellerdir.

Kalp-akciğer makineleri kullanımında perfüzyonist hatalarından dolayı bazı riskler oluşmaktadır. Bu riskler, kardiyovasküler ameliyatı geçiren hastalar, cihazı kullanan hastane çalışanları ve hastane yönetimi için olumsuz etkiler yaratmaktadır. Bu çalışmada, 2021-2022 yıllarında Türkiye'deki çeşitli hastanelerde tasarım müdaheleriyle geliştirilebilecek noktaları belirlemek için KAM'ın işlevleri ve çalışma prensipleri, perfüzyonistlerin ihtiyaç ve beklentileri ve açık kalp ameliyatları sırasında perfüzyonistlerin etkileşimleri incelenmektedir. Çalışmanın temel amacı, KAM kullanımında insan kaynaklı hataları perfüzyonistlerin ameliyat esnasındaki deneyimlerini iyileştirerek azaltmaktır.

Bağlam ve KAM ile ilgili teknik hususlar hakkında bilgi sahibi olmak için literatür taraması kullanılmıştır. Perfüzyonistlerin KAM'lara ilişkin ihtiyaç ve beklentilerini anlamak için kullanıcı görüşmeleri ve anketler gerçekleştirilmiştir. Perfüzyonistlerin belirli bir bağlamda birbirleriyle nasıl etkileşime girdiklerini analiz etmek ve perfüzyonistlerin deneyimlerinin geliştirilebileceği alanları belirlemek için kullanıcı gözlemlerinden yararlanılmıştır. Araştırma bulguları, tıbbi cihazların tasarımı üzerinde çalışanlar, ürün tasarımcıları ve tasarım araştırmacıları için faydalı olacak şekilde sunulmuştur.

Anahtar Kelimeler: Medikal Ekipman Tasarımı, Kalp-Akciğer Makinesi, Kardiyopulmoner Baypas Makinesi, Tasarım Araştırması, Ameliyathane

To my family…

ACKNOWLEDGMENTS

First of all, I want to express my thankfulness to Prof. Dr. Bahar Şener-Pedgley for her encouragement, support, and leadership during the entire process. She always helped me stay motivated and was helpful to me during the process. I'm so glad and proud to have worked with her.

I would also like to express my thanks to Assoc. Prof. Dr. Naz A.G.Z Börekçi and Assist. Prof. Dr. Erçin Okursoy, who participated in my thesis committee, for their valuable contributions and time.

I want to thank Yaren, who was my biggest supporter. I feel so lucky to have her by my side during this journey. Her support and companionship made the process much more enjoyable.

I also want to thank my beloved family for their support and love throughout the process. Many things have been easier to overcome thanks to their support and love.

I would like to thank my managers and co-workers at ASELSAN UGES, perfusionists and hospital managements who contributed. They provided all opportunities during the process. Thanks to their support and contributions, it was possible to design a heart-lung machine, appreciated by users and awarded by International Design Award 2022.

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INTRODUCTION

Every year people having cardiovascular surgery, in other words heart surgery, is increasing. Along with the COVID-19 pandemic that started in early 2020, the number of people who need to have a heart surgery is believed to increase even more dramatically (Salenger *et al.*, 2020). As the Coronavirus infection causes the blood vessel inflammation in some patients and puts pressure on heart, this will mean an increase workload for surgical staff, known as heart (or cardiac) *surgeons*, *anesthesiologists* (the staff who give patients medication before they undergo surgery), operating room nurses or *scrub nurses* (nursing professional who work alongside surgeons), and *perfusionists* (members of a surgical team who operate a heart-lung machine during the heart surgery).

Although heart surgery is a stressful task for all healthcare personnel involved, especially with a high workload, noisy, chaotic operating room environment, and stress, the perfusionists can potentially make errors while using the heart-lung machines (HLM) (Wiegmann *et al.*, 2009). This can result in dramatic damage to the patients and even may lead to death or permanent injuries. Some of these errors are caused by poor device design (i.e., HLM) as it involves complex user interactions (Adams *et al.*, 2018), but such errors can be prevented by enhancing the design of monitoring devices and safety in operating rooms (Charriere *et al.*, 2007). Equipment and usability-related issues are found to be the third most common problem in cardiovascular operating rooms (Cohen *et al.*, 2016). While using HLMs, perfusionists need to be constantly active and aware of the ongoing situation, and HLMs should be used cautiously so as not to make mistakes. There are many mediums e.g., patient monitors, blood gas analyzer printouts, tubing lines, etc. that perfusionists should follow simultaneously during operations. This causes a high cognitive load for perfusionists, and in turn, increases the possibility of making mistakes in the usage of HLMs. In literature, improper uses of HLMs are categorized under eight main topics: problems with alarms, problems with displays, problems with controls, clinical problems, problems with component integration, problems with procedures and communications, problems with workplace design, and other problems (Wiegmann *et al.*, 2009). These issues highlight that there are design-related issues that can be examined regarding HLMs and should be studied holistically. Therefore, reducing the number of design-originated misuses of HLMs can be accomplished by understanding the existing problems of current HLMs that are used by perfusionists. With a user-centered design approach and necessary design interventions, perfusion operations can be done more safely. Therefore, this research aims to provide knowledge for people who work in the design and development of HLMs as well as similar medical devices. The results are revealing design-related problems which perfusionists are facing with the current products in the market, needs and expectations of perfusionists and the experiences with HLMs in its usage context.

With the help of design suggestions for the problems presented in this research, it is believed that perfusionists can become less distracted and can focus more on the surgeons' actions. This will also help them to perform more independently during heart surgeries, and the communication between perfusionists and surgeons will be improved. It is an important issue because communication problems between perfusionists and surgeons are one of the most common problems during cardiovascular surgeries. (Wiegmann *et al.*, 2009). Therefore, with enhanced HLM designs, perfusionists can track data, and take actions properly and on time if the cognitive and physical loads are reduced for them. This can in return increase the success of cardiovascular surgeries, thus more people can heal from heart diseases with less harm.

1.1 Motivation for the Research

The author carried out this research in parallel to his professional work as an industrial designer at ASELSAN UGES looking into how the design of the existing HLMs can be improved. A personal motivation was to identify existing problems of HLMs in the market and to improve the working conditions of the perfusionists with design solutions. The data gathered from the research is believed to contribute to design-related decisions during the development process of future.

1.2 Scope of the Research

This research does not specifically look at the usability/heuristic evaluation of the HLMs, rather it focuses on the HLMs' operation within a wider set of interactions and user experience. The medical performance of HLMs was outside the scope of research. Within this wider scope, interactions between perfusionists and heart-lung machines in three state hospitals in Turkey in different cities (Ankara, Adana and İzmir) were studied during 2021-2022. Three HLM models (LivaNova S5, LivaNova C5 and Spectrum Medical-Quantum Perfusion System) were observed during the cardiovascular surgeries. In addition to these models, Maquet HL20, Terumo Advanced Perfusion System-1, Century Heart-Lung Machine, Pemco Model 5745 Heart-Lung Machine models were also mentioned in survey and interviews. In total, seven different models are mentioned in the results of the field research.

Usage scenarios of the HLMs can be studied under three main stages: i) pre-operation; ii) operation, and iii) post-operation. All stages bring different kinds of interactions and considerations. This research focuses on the "operation" stage.

Operation stage starts with the connection of cannulas[1] to the patients and continues until cannulas are removed from the patients and the surgery area is closed.

Pre-operation and post-operation stages were not included in the scope of the research because “operation” stage was prioritized since the interactions during the surgery would have a direct impact on the patient's health.

1.3 Aim and Objectives of the Research

This research aims to enhance the user experience of the perfusionists in the operating rooms by providing suggestions for design-related problems of current HLMs and other factors that affect perfusionists’ experiences. By offering suggestions for changes to the design of the HLMs, the research aims to eliminate human errors that are increasing the frequency of patient losses.

The following objectives were set for the research:

- to understand what a heart-lung machine is and how it works;
- to review how HLM design has evolved until today;
- to map out the interactions and multiple stakeholder (i.e., surgical staff) experiences within the cardiovascular surgery in operating room;
- to establish ways in which the experience of using/operating HLM can be improved taking into account multiple factors in the operating environment;
- to reach some design specifications for improved HLM design by considering the needs of perfusionists.

[1] “a thin tube that can be put into the body, for example to put in medicine or remove blood.” (Camridge Online Dictionary, 2022)

1.4 Research Questions

The research aimed to find answers to the following questions:

- What are the factors affecting perfusionists' performance during cardiovascular surgeries (e.g., physical, cognitive)?
- What are the expectations of perfusionists from HLMs?
- What are the opportunities for improving the experience of perfusionists while using/operating HLM?

1.5 Overview of the Research

Heart-lung machines have been used in cardiovascular surgeries in operating rooms for many years. A large part of society has little information about the operating rooms in hospitals. Even patients who have undergone cardiovascular surgery cannot recall much information about what the operating rooms look like since they spend most of their time under the influence of anesthesia. Only the related surgical staff, who work in the operating room, know what happens before, during, and after cardiovascular surgeries in the operating rooms. Although the standards and requirements for the rooms can be examined (see Chapter 2), there is no clear information in the literature about the real role/position and usage of the HLMs. Similarly, research about the physical conditions of the operating rooms, HLM-perfusionists interactions, and user experiences (focusing on perfusionists) is limited in the literature.

A fieldwork is planned to understand user experiences of currently used HLMs and to understand perfusionists' behaviors, attitudes, and needs regarding HLMs after reviewing the literature. It was also another aim of the fieldwork to understand the details of the operating rooms where the HLMs are located and to understand the user experiences of perfusionists holistically. The field research was conducted with the participation of more than 30 in total with perfusionists from different provinces of Turkey. For the fieldwork, all necessary permissions were obtained by ASELSAN UGES (see Appendix A).

To fully understand the context of use (of heart-lung machines) and all interactions between surgical staff, environment, and HLMs, a combination of methods was used, including interviews, surveys, and in-situ observations. Using different data collection methods (see Figure 1.1) is believed to help to increase validity, create a more detailed picture of the identified research problem, and approach the research problem from different angles. The research was divided into three main phases:

- Phase 1 - HLMs: Orientation for Function and Usage: Phase 1 explains what the heart-lung machine is, what it is used for, its working principles, parts, and functions of HLM, the evolution of the HLM, the details of models that are mentioned by research participants, the details about perfusionists who use the HLM, and factors and considerations that affect the design of HLMs by using literature research.
- Phase 2 - Perfusionists: Roles, Needs, and Expectations: Phase 2 was carried out to get to know more about the perfusionists, and their needs and expectations from HLMs. The perspectives of perfusionists regarding the HLM models available on the market, their expectations and needs for the HLM functions were examined. In this phase, surveys and semi-structured interviews were used to gather information.
- Phase 3 - HLMs in Operating Room: In-situ Observations and Experiences: In the third phase of the fieldwork, in-situ observations were made during cardiovascular surgeries to study how the heart-lung machine functions, the flow of operation, and the perfusionist’s interactions with the HLM, and surrounding elements (e.g., other devices in the operating room) and other surgical staff.

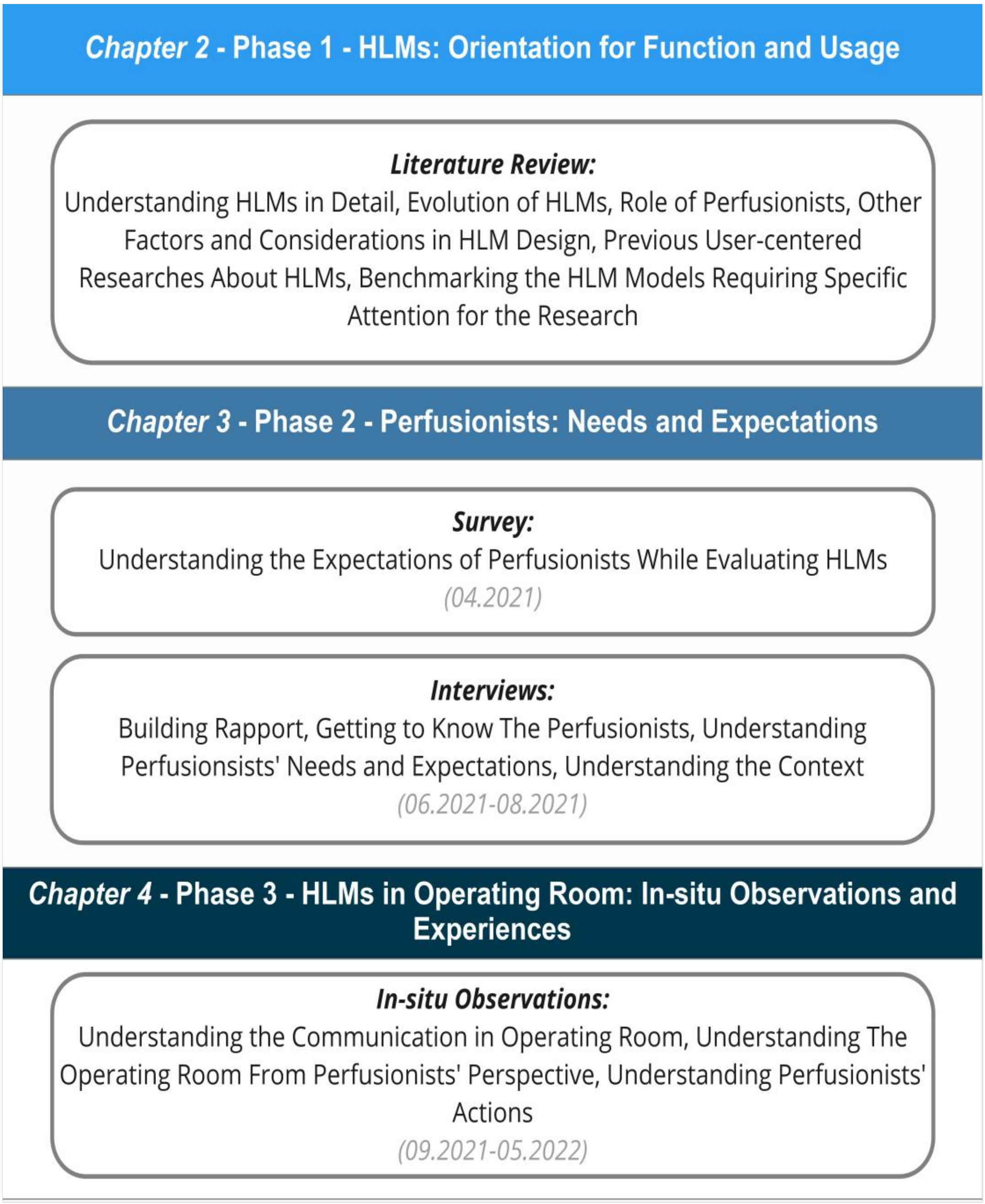

Figure 1.1. Data collection phases and methods used in the fieldwork

1.6 Thesis Structure

The thesis is structured under five chapters:

Chapter 1 – 'Introduction' introduces the topic, motivation of the researcher, scope of the research, objectives of the research, research questions. It also presents the fieldwork from a broad perspective. The chapter ends with the introduction of the structure of the thesis.

Chapter 2 – 'Phase 1 - HLMs: Orientation for Function and Usage' was carried out by using literature research to understand what the HLM is, how it works, who uses it, its historical development, the factors, and considerations that are important in the design of the HLM, and previous user-centered studies about HLMs.

Chapter 3 – 'Phase 2 - Perfusionists: Needs and Expectations' includes survey and interview results and analysis to discuss perfusionists' needs and expectations from HLMs.

Chapter 4 – 'Phase 3 - HLMs in Operating Room: In-situ Observations and Experiences' provides and discusses the results of in-situ observations to understand the usage context and experience of perfusionists during the operations in detail.

Chapter 5 – 'Conclusions, Reflections and Discussions' summarizes the research. It also provides reflections of the researcher about the study and further studies while presenting recommendations for designers and researchers working on the design process of HLMs.

CHAPTER 2

PHASE I – HEART-LUNG MACHINES: ORIENTATION FOR FUNCTION AND USAGE

Heart-lung machines (HLMs) are very complex machines that are unknown to many people, and that is why they need to be used by highly educated operators. Among the public HLMs are known as ‘bypass’ machines. The current chapter, Chapter 2 provides general knowledge about HLMs and the related topics such as their use of context and surroundings in the scope of the thesis. The information presented in the chapter comes from the literature review. Subsequently, the chapter, aims to explain following topics:

- main function and working principles of HLMs,
- HLM operators and their responsibilities,
- evolution of HLMs,
- common and differentiating features of various HLM models,
- details about the context in which the HLMs are used,
- points to be considered when designing HLMs,
- earlier research related to HLMs that are complementary to the scope of the thesis.

The chapter is divided into two parts. Part 1 introduces function and working principles of HLMs, evolution of HLMs, and responsibilities of the perfusionists (as the users of HLM). Part 2 presents the factors to consider when evaluating HLMs, the environment in which they are located/used, the factors affecting the design of the HLMs and previous user-centered research on HLMs.

2.1 Part 1 – Overview of Heart-Lung Machines

In cardiovascular surgeries the motion of heart and lungs should be stopped to let surgeons to reach problematic areas of the heart. This inactivity of heart and lungs can cause great damage to the patients because the blood of the patient is not circulated and oxygenized. In other words, when a heart stops, it is always followed by a respiratory arrest, so after the circulation stops, the cells cease to receive oxygen and, as a result, die. This death of neurons is incurable and means that within seven minutes the patient begins to lose mental abilities (Gallardo-Hernandez & López-Cajún, 2007).

The heart-lung machine (HLM), also known as a cardiopulmonary bypass (CPB) machine, is used for maintaining the circulation of blood and oxygen through the body when the natural blood flow is interrupted during surgery. It basically pumps the patient's blood into a membrane oxygenator (whilst simultaneously oxygenates the blood and removes carbon dioxide) before pumping it back into the body. This replicates the action of the heart and lungs (Sarkar and Parabhu, 2017).

A blood pump within the HLM system pumps the patient's blood from the venous to the arterial site of their vascular system. Additionally, an oxygenator replaces the role of the lung by increasing the amount of fresh oxygen (O_2) in the blood and decreasing the amount of carbon dioxide (CO_2) in the blood (Dhinakaran *et al.*, 2014).

In Section 2.1.1 and Section 2.1.1.1, the chapter "Heart-Lung Machines" by Böckler and Hahn (2011) in Springer Handbook of Medical Technology (Hoffman *et al.*, 2011) will be frequently used as a source to explain the working principles and parts of HLM. It is a well-cited book in relation to explaining the HLMs. Therefore, it is believed to be a reliable source.

2.1.1 Working Principle and Functions of HLM

HLM's main function is, as mentioned in Section 2.1, oxygenating, and pumping the blood. HLMs perform their functions by using mechanical parts called as blood pumps. Based on their functionality, blood pumps can often be divided into two types: roller pumps and centrifugal pumps. The roller pump is made up of a spinning pump arm with two cylindrical rollers attached to it and a pump housing into which a segment of semicircular silicone tubing is placed before being fastened with unique tubing inserts, or tubing fastener mechanisms. According to the rotational speed and direction, the spinning rollers alternately compress the tubing segment and supply the liquid inside the tubing. Centrifugal pumps (rotational blood pumps) use centrifugal forces, a spinning impeller directs the blood in the desired direction. The centrifugal pump has a narrow range of applications due to its technological basis of operation. It may only be used as an arterial/main pump to pump oxygenized blood to the patients. On the other hand, roller pumps can be used for four different functions (Böckler & Hahn, 2011) (see Figure 2.2):

1) Pumping oxygenated blood to the patients: A blood pump actively pumps blood from the cardiotomy reservoir back into the arterial vascular system via the oxygenator and another cannula (see Figure 2.1).
2) Cardiotomy suction: Roller pumps aspirate blood from the surgery area to keep it blood-free by using blood pumps.
3) Vent suction: Roller pumps are connected with tubes which aspirate directly from the heart chambers to avoid the arrested heart from becoming overextended with too much blood, which could result in serious injury.
4) Cardioplegia: Roller pumps are used to provide cardioplegic solutions which are used to stop the movement of heart with volume, timing, and pressure control into the aortic root or specifically into the two coronary ostia (Böckler & Hahn, 2011).

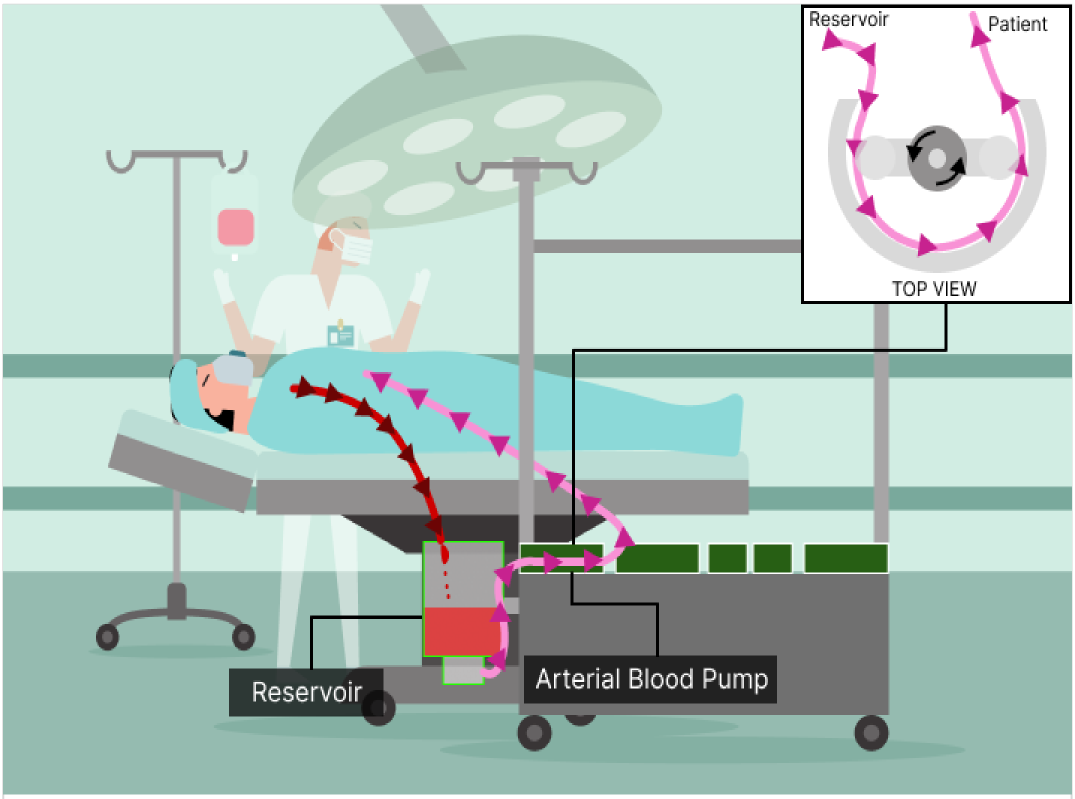

Figure 2.1. Diagram representing how HLM circulates the blood taken from patient

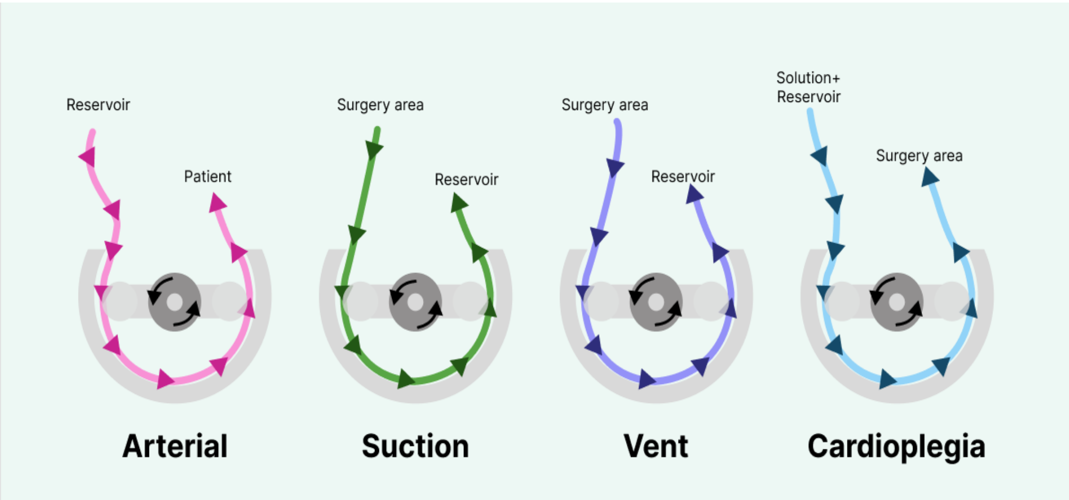

Figure 2.2. Diagram showing the flow in tubing lines with the roller blood pumps in different functions

2.1.1.1 The Parts of HLM

HLMs have various functions which are done by using blood pumps as mentioned in Section 2.1.1. In addition to blood pumps, modern HLMs have eight more components to support functions of blood pumps. In literature, it is defined that most contemporary HLMs consist of nine main components, these are i) mobile console, ii) mast system, iii) blood pumps, iv) control and monitoring devices, v) display and control panel, vi) electronic or mechanical gas blender, vii) anesthetic gas vaporizer, viii) electronic documentation systems, and ix) heater/cooler devices (see Figure 2.3).

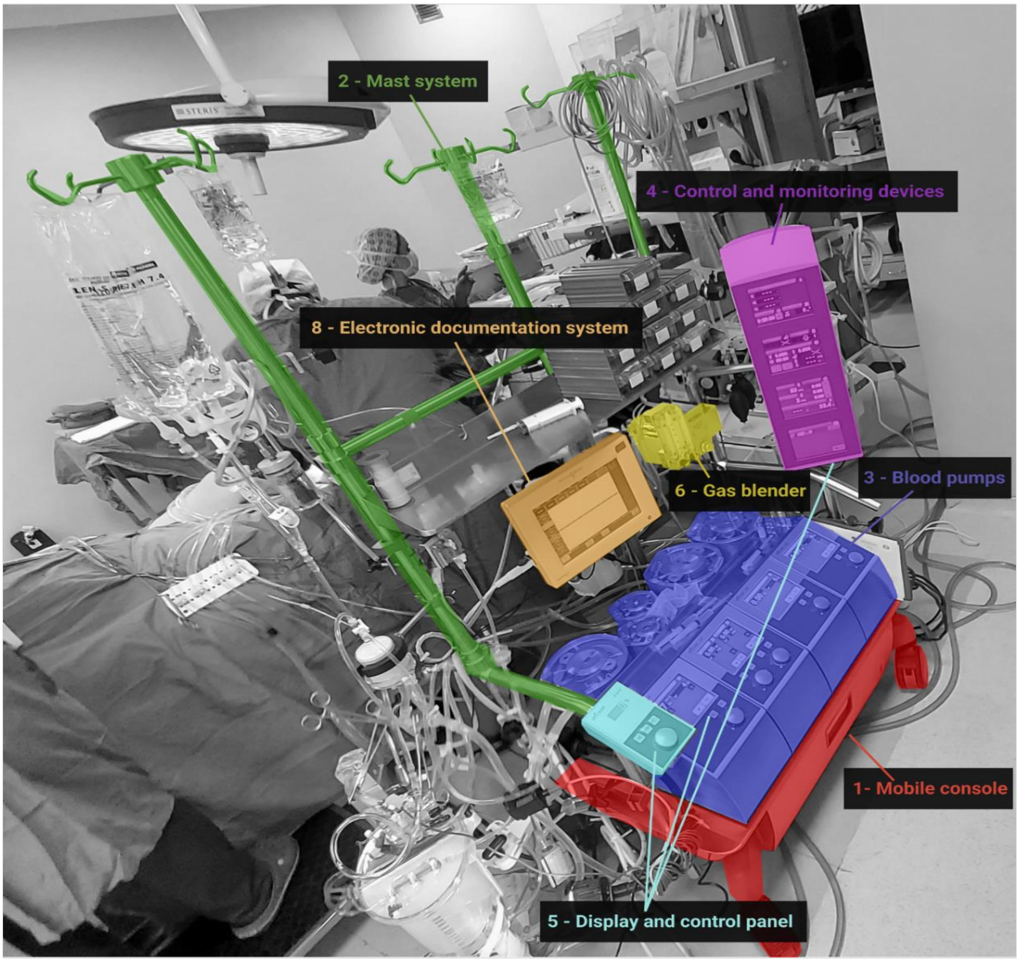

Figure 2.3. HLM parts perfusionists interact with during operations

i. **Mobile console:** Multiple pumps are mounted using a mobile console, which also houses the electronics, backup power source, and power supply.

ii. **Mast system:** The holders for the oxygenator, filters, cardiotomy reservoirs, external pumps, and other devices are mounted using an adjustable mast system on the mobile console.

iii. **Blood pumps:** The blood pumps perform the main functions of HLMs as mentioned in Section 2.1.1. They provide the mechanical flow of liquids in tubing lines.

iv. **Control and Monitoring Devices:** Modern HLMs incorporate systems for monitoring pressure, temperature, oxygen saturation, levels of hemoglobin, blood gasses, electrolytes, and safety features like bubble detectors, oxygen sensors, and reservoir low-level detection alerts (Prabhu & Sarkar, 2017). Control and monitoring devices on the HLMs and their functions are as follows:

- A pressure monitor, which includes sensors, is used to measure the various pressures in the extracorporeal system and to manage the flow rates accordingly.
- A temperature monitor with sensors that can measure and show various system temperatures as well as, if necessary, patient temperatures.
- A level monitor with sensors that can measure and control the volume level in the cardiotomy reservoir and, in turn, adjust the arterial pump flow.
- Bubble monitors in the form of ultrasonic sensors that, when air is found in the system, control the affected pump's flow rate.
- A pulsatile flow profile can be created and controlled using pulsatile flow control.
- Control of the supply of cardioplegia, incorporating pressure and bubble sensors.

- A timer for keeping track of crucial perfusion-related durations and intervals, such as overall perfusion time, aortic clamping time, and reperfusion time.

v. **Display and Control Panel:** Access to all display and control elements is made possible by a display and control panel. Display and control panel provides aspects of the display and control panel stated above in addition to further system details and alert management.

vi. **Electronic or Mechanical Gas Blender:** Electronic or mechanical gas blenders are used to precisely control and display the permanent vacuum on the venous reservoir. Vacuum controllers are used to precisely control and display the ventilation gasses (air, O2, and CO2) that are fed to the gas side of the oxygenator.

vii. **Anesthetic Gas Vaporizer**: Anesthetic gas vaporize enables and shows the injection of a precisely dosed amount of anesthesia gas to the oxygenator.

viii. **Electronic Documentation System:** During perfusion, an electronic documentation system shows and records all relevant data. The ability to evaluate data later for statistical and scientific purposes is made possible by the central storage of all data and the immediate display of that data as a perfusion report.

ix. **Heater-Cooler Device:** The heater-cooler appliance provides water that is between 2 and 42 C in temperature. Modern heater-cooler units have multiple temperature-controlled circuits. Two circuits supply the oxygenator and the heating/cooling mattress, while a third is linked to the cardioplegia system's heat exchanger. The HLM's control panel should have a remote control integrated into it to make operating the device easier and allow it to be put outside the operating room, which would significantly reduce operating room noise. Because the components of heater-cooler systems that convey water unavoidably become contaminated with germs, these appliances have always posed a hygiene concern.

2.1.2 Perfusion and Perfusionist

‘Perfusion’ is a term of French origin and is derived from the word "perfuse", which means pouring and emptying something. Perfusion is also called to the action of nutrition of cells, organs, and tissues. Nutrition is provided by blood for tissues and organs with the heart and veins. This circulatory process through the heart and blood vessels is called “perfusion”. In cardiovascular surgeries, as also mentioned in Section 1.1, it is necessary to disable the cardiopulmonary system to ensure maximum surgical vision and to increase safety (Amaç, 2020).

The perfusionist profession emerged with the advent of cardiac surgery. Perfusionists are professional, health-trained individuals responsible for the management of the extracorporeal circulatory system by using HLM and its related parts (see Section 2.1.1.1).

In many countries of the world, there are criteria for acquiring education and professional titles in order to be able to do it professionally (Amaç, 2020). Perfusionist profession is taught at academic level in Turkey, Europe and America and there are professional legal obligations. In Turkey, the perfusionist profession is subject to certain legal regulations. Only those who meet the conditions specified in the professional law can work as a perfusionist. Occupation, in laws in Turkey; Health professions are defined in the law numbered 1219 on the practice of medicine and medical arts as: "Perfusionist is a health sector professional group that manages extracorporeal blood circulation by using a heart-lung machine under the supervision of relevant medical specialists in interventions to the heart and/or large vessels, who have graduated from faculties or colleges that provide undergraduate education in the field of perfusion or have a master's degree in the field of perfusion after their undergraduate education.". Although the definition of perfusionist in Europe and America shows some changes, it is generally similar.

Perfusionists were initially trained on the clinical cases or in the lab before the introduction of myocardial revascularization and the increase in cardiovascular surgeries, which revealed the need for formal educational training programs (Toomasian, Searles & Kurusz, 2003). The authors also mention that as long as cardiopulmonary bypass is utilized for medical or surgical intervention, perfusionists will be needed. Therefore, understanding the responsibilities of perfusionists is crucial to improve the experience of perfusion. The Texas Health Institute (n.d.) defines perfusionists as medical professionals who operate HLMs during cardiac surgeries and are responsible for ensuring that the patient's blood is properly oxygenated and circulated during the surgical procedure. The duties of the perfusionists (The Texas Health Institute, n.d.; UTHealth Houston, n.d.; Mayo Clinic College of Medicine and Science, n.d.; Belway, Rubens & Tran, 2017) can be summarized as follows.

i) To operate the heart-lung machine,
ii) To manage the extracorporeal membrane oxygenation device (ECMO),
iii) To operate ventricular assist devices,
iv) To evaluate relevant parameters and if necessary, to take necessary actions (during cardiopulmonary bypass and extracorporeal circulation), including patient's physiological parameters, blood gasses and blood biochemistry results; transfusing blood and blood products; applying necessary drugs and medical agents,
v) To ensure the perfusion of isolated organs and extremities,
vi) To help protect donor tissues and organs when necessary.

Even though the perfusionists have a range of duties in hospitals outside heart surgeries, current research focuses on their duties specified in articles i and iv, since others are not directly in the concern of HLMs.

2.1.3 Evolution of Heart-Lung Machines

The discovery of HLMs dates back to 1813, when Le Gallois proposed the first definition of an artificial blood circulation (Clowes, 1969). Then, in 1828, Kay demonstrated that blood perfusion might restore the muscle's ability to contract (Utley, 1986). In 1953, the first successful cardiovascular procedure was carried out with the use of the HLM designed by Gibbon (Cohn, 2003), also known as "cardiopulmonary bypass machine" and considered as one of the most significant clinical advances in the history of cardiac disease and medicine (Hessel, 2014). However, the first model of HLM failed because of the need of the decoding of every aspect of artificial blood circulation, and John Gibbon designed the Model II that finally contributed to the successful human bypass surgery (Cohn, 2003). The design of Model II (see Figure 2.4.) was created with three roller pumps that were modified from Dr. Michael DeBakey's original transfusion pump design made in 1934 for enabling blood transfusion (Passaroni, Silva & Yoshida, 2015).

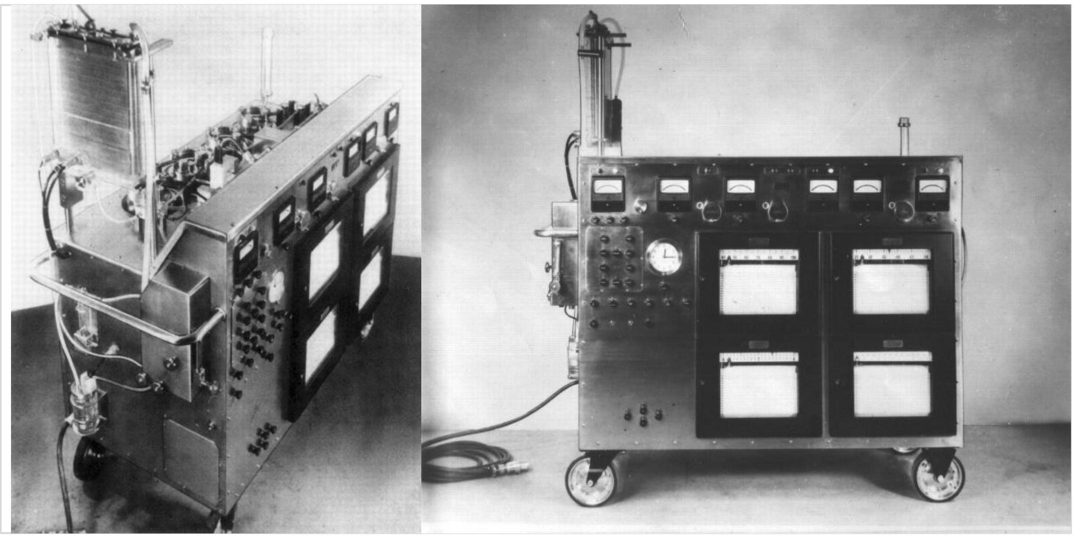

Figure 2.4. Gibbon's heart-lung machine model II (Retrieved from https://www.ahajournals.org/doi/10.1161/01.cir.0000071746.50876.e2)

Many other development teams were inspired to follow Gibbon's steps and improve the project (Stokes & Flick, 1950; Kurusz, 1982). By the late 1950s, a considerable number of manufacturers were producing HLMs. The Mayo-Gibbon device, the first fully commercialized heart-lung machine, created by John Kirklin and colleagues at the Mayo Clinic based on Dr. Gibbon's design, was the most popular HLM in the 1950s and the early 1960s (Kirklin *et al.*, 1955). They refined Model II to control blood flow and pressure and add oxygen to the blood by using a series of wire mesh screens (Speizer, 2019). The overlapping accumulation of the discoveries played an essential role in the further developments. Since then, different HLM models have been developed. Yet, they still have similar working principles in roller blood pumps. In addition to blood pumps, since 1953, additional screens, sensors and controls are added to the HLMs (see Figure 2.5).

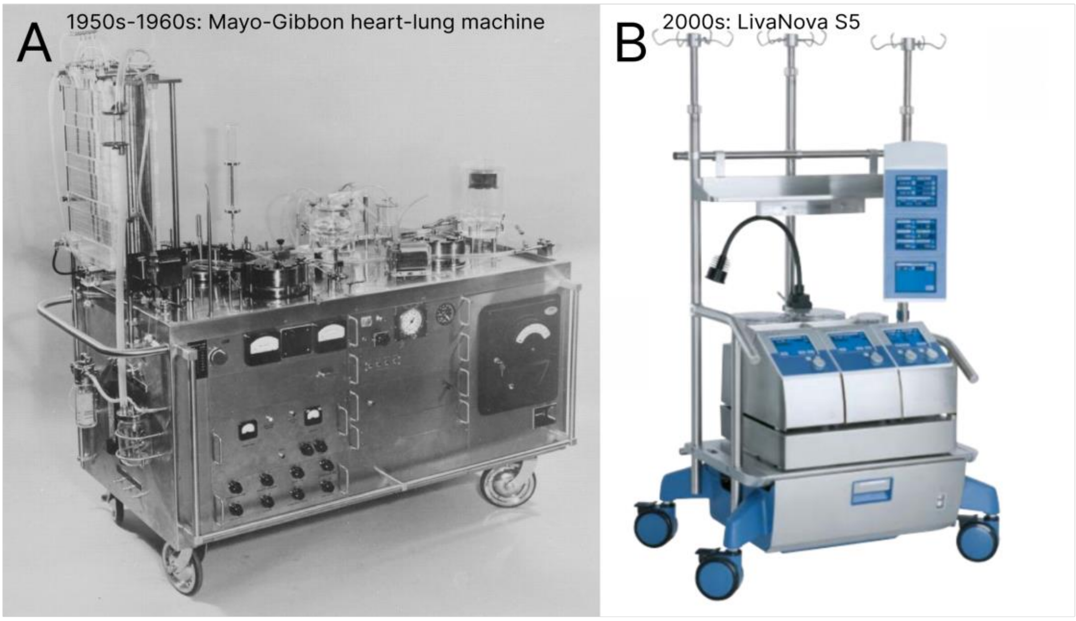

Figure 2.5. Example of a HLM in 1950s and used today A - (Retrieved from: https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.108.830174), B - (Retrieved from: https://l24.im/CP9)

2.1.3.1 Comparison of HLM Models within the Scope of Research

This section aims to provide an understanding of different design approaches of HLM models in the market. The design and working principles of HLMs has not radically changed as explained in Section 2.1.3, yet there are some differences in the properties and usage of HLM models in the market. As it is presented in Figure 2.5., screens have been added to facilitate the work of the perfusionist. According to

Gourlay (2012), the surface area of the machine has been decreased as a result of each advance.

According to Böckler and Hahn (2011), modularity of blood pumps is the primary design element that characterizes the HLMs. The ability to provide perfusionists information about blood gas values is also becoming significant. Blood gas values are normally obtained by using an additional device called as "blood gas analysis device". The device measures blood gas value by using blood samples. Recently, some HLM models can use sensors to provide those values without using blood samples. In addition to these features, positioning of digital interfaces and controls may also differ in each HLM model. This can be another feature that can create differences in the usage of HLMs.

HLM systems' modular design aims to provide user freedom. The whole system can be individually modified to provide HLM configurations that satisfy specific needs of each surgery. The HLM can be used for a range of perfusion jobs with modifications or system extensions that incorporate more monitoring, control, and measuring devices. Depending on the arrangement, modular systems are made up of a simple mobile console that can accommodate one to six roller pumps. They are set up on the console's pump table, and plug connectors are used to link them to the power source and the electronic control. Control panels can contain a variety of control modules since different surgical procedures necessitate varying degrees of monitoring. Pumps that can be placed anywhere on the mast system are also part of the modular design. The semi-modular systems can also use these pumps. Shorter tubing paths, which result in a decrease in the hemolysis of blood by reducing the foreign surface with which the blood comes into contact, is the main benefit of the freely positioned, modular pumps.

By considering criteria mentioned in literature, and examining the differences of HLM models, a chart (see Figure 2.10) is provided to provide an understanding for the approaches of different HLM models that are popular in the market. The models examined were determined by considering the suggestion of a perfusionists, former president of Turkish Perfusionist Association.

This section explains and compares the HLM models by considering the issues mentioned above. The models that will be explained are: LivaNova S5, LivaNova C5, Terumo Advanced Perfusion System-1 and Spectrum Medical – Quantum Perfusion System.

i) LivaNova S5 Model

LivaNova S5 model has two different types of roller pumps. The first type, also called "S5 roller pump 150 and double roller pump 85", can be located on the mobile console, while the second type which is called "S5 mast roller pumps" can be located on mast systems. The first type of pumps on the mobile console can change their place on the mobile console with the other similar roller pumps. This modularity type is called "semi-modular" according to Böckler and Hahn (2011). It has its own touch screen, knob to control blood pump in itself. The S5 mast roller pumps can be located anywhere on masts. This modularity type is called as "modular" (see Figure 2.6).

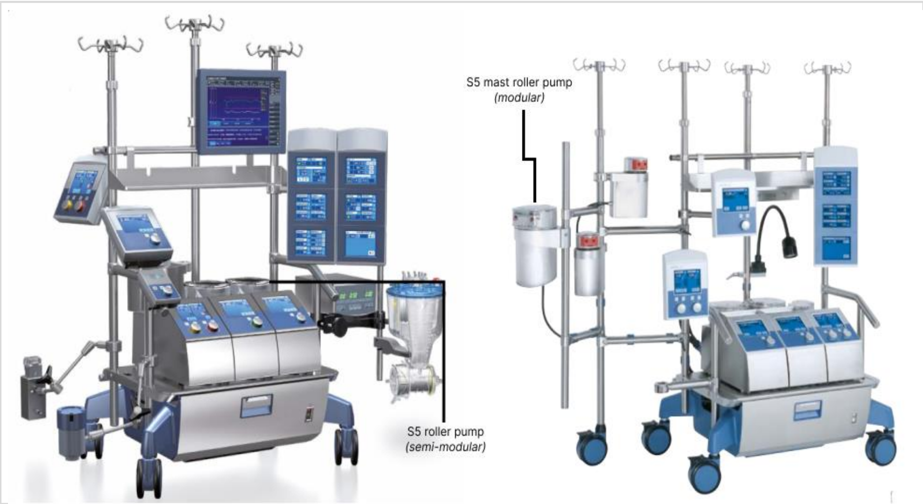

Figure 2.6. LivaNova S5 (Retrieved from: https://l24.im/CP9)

In LivaNova S5 model, all components and functions have their own digital touch screens separated from each other. The model also has a system panel and electronic documentation system with the same modularity as S5 mast roller pumps have. They can be attached and detached according to perfusionists' and surgery needs (LivaNova, 2018).

ii) LivaNova C5 Model

LivaNova C5 model has all the same features with LivaNova S5 model except for the modularity of the roller pumps located on the mobile console (see Figure 2.7.).

Figure 2.7. LivaNova C5
(Retrieved from: https://eurosmed.ru/files/uploads/C5_ENG_V02.pdf)

It does not have the semi-modularity which enables users to change the locations of roller pumps located on the mobile console. It has no modularity for these pumps on the mobile console. Yet, it has the same modularity with the mast roller pumps.

Comparing with S5 model, it provides less flexibility to perfusionists while locating roller pumps on mobile console (Sorin Group, 2010).

iii) Terumo Advanced Perfusion System-1 Model

Terumo Advanced Perfusion System 1 has a main digital touch screen where the system can be monitored and manipulated. It has modular roller pumps that can be located on mobile console and on mast system. The screens on blood pumps are only used for monitoring. The controls of blood pumps are analogue controls (Terumo Cardiovascular Systems, 2006).

Figure 2.8. Terumo Advanced Perfusion System-1
(Retrieved from: https://www.terumo-cvs.com/products/ProductDetail.aspx?groupId=1&familyID=35&country=1)

iv) Spectrum Medical – Quantum Perfusion System Model

Quantum Perfusion System model is the newest HLM model mentioned in the thesis. It has a different approach by means of monitoring and controlling the blood pumps. It has modular roller pumps that can be located various points on the mast system. All the controls and monitoring of components are done from a single monitor. Differently from other systems, the Quantum Perfusion System model has a blood gas analysis function that provide information about blood chemistry without touching the blood with sensors (Spectrum Medical, n.d.).

Figure 2.9. Spectrum Medical – Quantum Perfusion System
(Retrieved from: https://www.spectrummedical.com/quantum-perfusion-for-the-or/quantum-technologies-for-the-or)

	LivaNova S5	LivaNova C5	Terumo Advanced Perfusion System 1	Spectrum Medical-Quantum Perfusion System
Modularity of roller pumps	Semi-modular + Modular pumps	Nonmodular + Modular pumps	Modular pumps	Modular pumps
Component control	Seperate controls for each part	Seperate controls for each part	Seperate controls for each part	Single control point From system panel
Screens for blood pumps	Yes Digital touch Monitoring + Control	Yes Digital touch Monitoring + Control	Yes Digital Monitoring	No
System panel	Separated Digital touch	Separated Digital touch	Single Digital touch	Single Digital touch
Electronic documentation system	Yes Additional screen	Yes Additional screen	Yes Additional screen	Yes From system panel
Blood gas analysis	No	No	No	Yes From system panel

Figure 2.10. Comparison of HLM models

2.2 Part 2 – Use Context and Considerations of HLMs

Part 2 of the Chapter conveys information about use context, the surroundings around HLMs, the standards to be complied with while designing HLM. It is decided to introduce operating rooms including required standards for physical conditions, other medical equipment in the operating rooms, and operating team members to map out the interactions for a better understanding in the use context of HLMs. Then, design considerations of HLMs are presented.

2.2.1 Operating Room

Along with the advancements in technology and healthcare, the medical system and its environments are evolving, resulting in challenges to be more up-to-date, productive, and more in-line with the developments (Guinet & Chaabane, 2003). Changes in surgical needs and practice have influenced how operating rooms and their surroundings are designed (Essex-Lopresti, 1999). It is estimated that 234 million operations are performed annually (Bhasin *et al.*, 2011) therefore a better understanding of operating rooms, which are one of the most important hospital resources (Guerriero & Guido, 2011) is needed to provide a perspective of the operating environment for designers who are involved in designing for healthcare. This section covers the standards of physical conditions in the operating rooms, other related devices in the room as well as the staff work in the operating room and the collaboration between them.

Operating room can be described as a collection of surgical spaces and patient recovery rooms (Guerriero & Guido, 2011) each of which serves for a particular function and is utilized in collaboration with others before, during, and after a surgical procedure (Operating Room Issues, 2018). Therefore, there is a necessity of the proper integration of different areas in the operating room, which makes its layout design complicated (Spagnolo *et al.*, 2013). The layout design of operating rooms may have effects on the position of HLM and perfusionists. The location of perfusionists and HLM can have significance while considering perfusionists' experiences in operating rooms. However, there is no research in the literature showing the effects of operating room layouts on perfusionists' experiences during operations. Therefore, this issue will be investigated in field research.

2.2.1.1 Standards for Physical Conditions in Operating Rooms

In the design process of the operating rooms, the choice of structural elements and surface finishes have an important role since the cleaning of the rooms will be significantly depending on the layouts, fittings, furniture, floor coverings, and finishes (Spagnolo *et al.*, 2013). The role of the operating room and level of procedure taking place in the room must be taken into consideration when determining the size of storage facilities for clean and dirty materials, supplies, equipment, and medications. In addition, clinical decision-making of surgeons during surgery is also influenced by the environment in which they work (Francis, 2009). Therefore, there are standards for physical conditions of the operating rooms in terms of lighting, climate control, electricity, gas supply and fire safety to provide clean units and efficiency.

Ideal lighting is required for a good vision (Wong, Smith & Crowe, 2010). Strong light, an intense area of illumination in the center, good focus, parallel beams, prevented shadows, ease of maneuverability, glare-prevention shielding, and heat reduction with heat-filtering glass are all crucial aspects of optimum lighting (Douglas, 1962; Dawson-Edwards, 1957; Browne, 1956). This situation increases the luminosity in the operating room, which may cause some defects for perfusionists since it can make it difficult to see screens that they monitor and control.

The temperature of the operating room is an important factor both for the patient and for the surgical staff. While there are surveys (Jamjoon, Nikkar-Esfahani & Fitzgerald, 2009; Tham, 2004) conducted to investigate the effects of the temperature on the performance of the medical staff resulting in the contribution of increased temperature, the studies suggest setting the temperature that best suits the patient, showing the general approach in surgeries that prioritizing patient safety. The exposure to a cold operating room may cause patients to get hypothermia which occurs when the core temperature of the body below 36 degrees during the surgery (Kurz, 2008). Therefore, there are methods presented in the studies (Kurz, Sessler & Lenhart, 1996; Wong *et al.*, 2007; Kim *et al.*, 2009) to prevent hypothermia and enhance surgical outcomes such as heated beds and blankets, connected to the heater/cooler device which can be manipulated via using HLMs as mentioned in Section 2.1.1.1. Nonetheless, the ideal environment for surgery is between 19 and 21°C with a relative humidity of 45 to 55% (Douglas, 1962; Wyon, Lidwell & Williams, 1968). This temperature may affect the performance of perfusionists by affecting their well-being, concentration level and clothing.

In the operating room, the ventilation (dilution), air distribution, room pressurization (infiltration barrier), and filtration (contaminant removal) are the specific elements of the airflow system that allow surgical site infections to be contained (Chow & Yang, 2004), and the higher pressure in the operating rooms than in corridors and other areas results in positive pressure which prevents air from flowing from less sterile areas into those that are more sterile (Wenzel, 2010).

All of these factors also may affect the well-being of the staff such as perfusionists in operating rooms, while standards are showing that all details are determined by putting the patient's safety first. This approach may be common for the perfusionists as well. This may contribute to the design process of HLMs while prioritizing the considerations in design decision processes.

2.2.1.2 Other Related Devices in the Operating Rooms

According to Incision (2022), every operating room should have suction and laparoscopic equipment, if necessary, diathermy equipment, along with an operating table. The literature provides a general view for the essential equipment of the operating rooms; however, the medical instruments vary depending on the type of the surgery and the participating surgical team members who are in charge of using these instruments. For this research, it is important to examine the devices used in cardiovascular surgeries especially by perfusionists to have a better understanding of the procedure-oriented relations between the devices used in the management of surgery, between the surgical team involved in the surgery and between the devices and the surgical team. In the literature, cardiovascular surgery devices cover a wide spectrum of medical instruments (Bell, 2020) from catheters (guiding catheter, access catheter, intubation catheter, etc.) to wound drainage reservoirs and extracorporeal circulation (ECC) equipment. During cardiovascular surgery or any other medical treatment where it is required to artificially sustain or temporarily replace a patient's circulatory or respiratory function, perfusionists are in charge of running extracorporeal circulation equipment, such as the HLM, the artificial heart, devices for blood transfusion, the intra-aortic balloon pump, and various devices for ventricular assist as it was also mentioned in Section 2.1.2. The role of the perfusionists mentioned in Section 2.1.2, and in Section 2.1.1.1, the parts of HLM which is perfusionists operate during cardiovascular surgeries are mentioned in detail. The findings of the literature on devices perfusionists interact with do not provide a comprehensive perspective although it is stated that perfusionists must have access to the perfusion setup as well as data on blood pressure and blood chemistry throughout the perfusion operation. Having various devices in operating room may cause a cognitive load on perfusionists by increasing the stimulus in the context. Therefore, the parts/devices that perfusionists specifically interact during the surgeries will be investigated in detail in field research to understand the effects and functions of them for perfusionists.

2.2.1.3 Staff in the Operating Room

A functioning operating room places patients in the center (Harsoor & Bhaska, 2007) to surround the patient with the surgical staff and medical equipment, and it consists of people with specific roles that require specialized knowledge and abilities, and who work together with the aim of treating patients collaboratively (Booij, 2007). Research conducted by Robertson *et al.* (2017) reviews the studies about operating team members and presents the variety in terms of the inclusion and exclusion of participants. According to that research, there are studies considering perfusionists as additional team members (Stevens *et al.*, 2012) while the others also count healthcare professionals from the fields of pharmacy, critical care, emergency medicine and respiratory therapy as part of the team (Nicksa *et al.*, 2015). Paige and colleagues describe an operating team with seven members (See Figure 2.12) as follows: surgeon, scrub technologist, circulating nurse, nurse anesthetist, evaluation specialist/observer, facilitator/observer and simulation specialist while RNpedia divides the team into two as i) sterile team, including operating surgeon, assistant to the surgeon and scrub person (certified registered nurse or surgical technologist) and ii) unsterile team, consisting of anesthesiologist, circulator, biomedical technicians, radiology technicians or other staff.

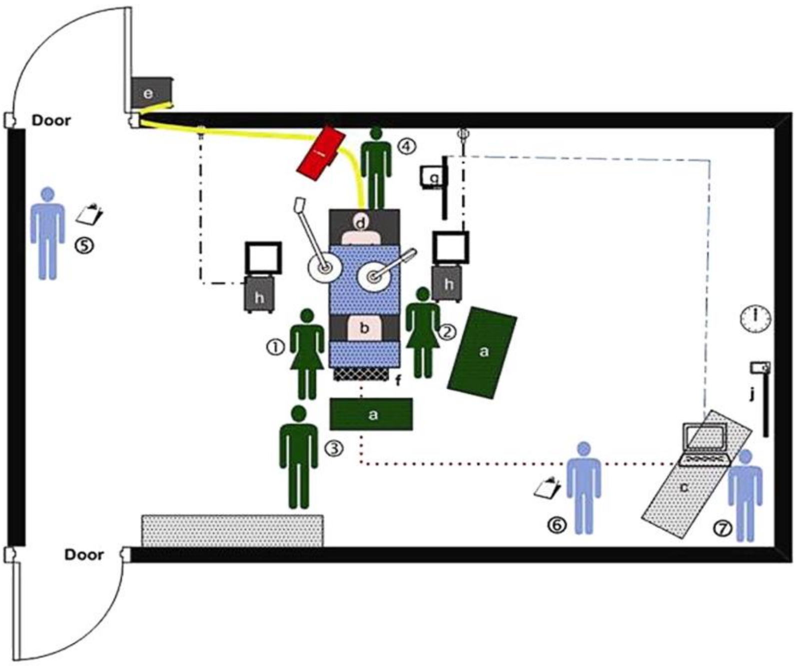

Figure 2.11. Operating theater staff according to Paige *et al.* (2021): (1) Surgeon, (2) Scrub technologist, (3) Circulating nurse, (4) Nurse Anesthetist, (5) Evaluation specialist/observer, (6) Facilitator/observer, and (7) Simulation specialist.

The literature provides limited and varied information about who are involved in cardiovascular surgeries. The findings are mostly based on the team members of the cardiology services of the hospitals, and they do not include the position of perfusionists. Kennedy-Metz *et al.* (2021) state that due to the diverse but interdependent teams providing patient care, in cardiac surgeries, the operating teams consist of surgeons, anesthesiologists, perfusionists, and operating room nurses. In the operating room, cardiovascular perfusionists collaborate with cardiac surgeons, anesthesiologists, physician assistants, surgical technologists, nurses, and other medical professionals (Mayo Clinic College of Medicine and Science, n.d.). This shows the importance of collaboration between team members including perfusionists during the surgeries. Typically, the anesthesiologist stands on the head side of the table with his equipment, the surgeon stands on the right side while the assistant and scrub nurse take position on the left (Incision, 2022), while perfusionists are operating HLMs and surgeons stand next to the patient. In order to understand the exact location and actions of the perfusionists in the operating room, further investigation will be carried out in the fieldwork as literature provides limited information.

2.2.1.4 Collaboration of the Cardiovascular Surgery Team in Operating Room

The presence of numerous devices (see Appendix B) in the operating rooms used for the efficient management of a surgical procedure cause operating team members to face high cognitive load (O'Hanlan *et al.,* 2007; Magrina, 2002). In addition, poor communication between operating team members working independently as well as in close collaboration (Avrunin *et al.*, 2018) has been identified as a contributing factor for some adverse events (Wong, Smith & Crowe, 2010; Sexton, Thomas & Helmreich, 2000; Helmreich & Davies, 1996). This was also mentioned by Wiegmann *et.al* (2009) especially for the usage of HLMs as a major adverse effect on the success rate of HLM usages. Therefore, communication (Greenberg *et al.*,

2007) and collaboration (Mazzocco *et al.*, 2009) are crucial for preventing negative outcomes and ensuring patient safety in the operating room.

In cardiovascular surgeries, perfusionists work in collaboration with cardiac surgeon, anesthesiologist, perfusionist and other medical staff (University of Utah, n.d.). Since cardiac surgeries which perfusionists are the vital members (UTHealth Houston, n.d.) involve several different aspects of perfusion safety, including equipment, safety devices, how perfusion is done, surgical technique, attention, and communication inside the operating room (Palanzo, 2005), strong communication abilities to efficiently interact with surgeons, anesthesiologist, nurses, and other medical staff is required for the perfusionists.

To improve the communication through collaboration and vice versa, it is important to understand the connections between the operating team during the surgery. However, the existing literature highlights the importance of communication and collaboration of surgery team members, yet it does not provide much information about the details of communication and collaboration between perfusionists and other team surgical members throughout the operation. Therefore, communication and collaboration between perfusionists and other staff will be investigated in detail as part of the fieldwork.

2.2.2 Considerations in HLM Design

The healthcare industry is becoming more and more conscious of how poorly designed medical devices have potential to increase the number of errors (Wiklund, 2002). However, despite the high usage rate, the design of the heart-lung machines has not significantly evolved while other high reliability industries, including the nuclear power and aerospace sectors, acknowledged the need of considering human aspects in device design to minimize errors (Wiegmann *et al*., 2009). The literature about design considerations of HLMs are quite limited, and the highlighted concern is safety. Wiegmann *et al.* claim that the entire design of the machine has never been reevaluated from the perspective of use with safety and error control, except for improved mechanical efficiency and biocompatibility. Perfusion related studies have mostly concentrated on recording incidents, resulting in neglecting human factors and the design of machines that may have contributed to perfusion errors (Palanzo, 2005; Mejak & Stammers, 2001).

In design process of medical devices, there are lots of considerations from user demographics, capabilities of the users, operational conditions, restrictions, sturdy materials to withstand accidents, recognizable controllers, switches, and displays (Kaufman-Rivi, Collins-Mitchell & Jetley, 2010) to cleaning and sterilization (Patel, Pope & Neilson, 2012). The existing studies do not address those parameters holistically, however, there are important regulations for medical device developers to consider (Martin *et al.*, 2008) to enter the market. According to Martin *et al.* (2008), for the case of HLMs, the following standards must be met; 93/42/EEC (European Medical Device Directive) or MPG (Medical Device Act), EN 601-1, 601-1-1, EN 601-1-2, EN 601-1-4, EN 601-1-6, and EN 62304. The standards that can be especially beneficial for designers working in the HLM design processes can be grouped and listed as:

- Human-factors, usability: EN 60601-1-6, EN 62366-1
- Symbols, labeling, information to be supplied: EN ISO 15223-1, IEC TR 60878
- Alarm systems: EN 60601-1-8
- Usage procedures of perfusionists: Standards and Guidelines for Perfusion Practice of the AmSECT (The American Society of Extracorporeal Technology)

The standards mentioned in the list do not directly provide the design criteria for HLMs, since HLMs can be classified as “medical equipment”, the standards cover the issues of HLMs in general.

2.2.2.1 Human Centered Research Related to HLM

According to Edmunds (2003), following John Gibbon's invention, scientists spent the first decade studying the pathologic anatomy of the heart; how to diagnose a patient accurately; how to stop, start, incise, suture, and patch the heart; what to monitor and how to do it; how to refine the heart-lung machine; how to create new hardware; how to control oxygen supply and demand by adjusting flows, temperature, and hematocrit; and how to find materials that are compatible with blood. Nevertheless, although the parts and components of HLMs have been improved, overall design has not been reevaluated in terms of use (Wiegmann *et al.,* 2009).

Whilst practicing surgeries, advanced technologies are used (ElBardissi & Sundt, 2012), however, only a few medical devices are designed with the user in mind. Wiegmann *et al.* work on usability of HLMs. They participate in cardiovascular surgeries with surgeons and perfusionists to make observations and to clarify problematic areas. Accordingly, they found several design-related problems in the use of HLMs. They come up with a conclusion showing that systems are not designed in a way that users can easily understand and use the product. The way the authors examined issues encountered by perfusionists can be influential for this research, as well. In the fieldwork, in-situ observations can be used to identify the problems that perfusionists face and to understand the context of use.

2.3 Conclusions

This chapter investigated existing user-centered research about heart-lung machines (HLMs), working principles and functions of HLMs, parts of HLMs, perfusionists, who are in charge of operating the HLM. To provide a comprehensive perspective about the use of HLM, the area where the device is used is also examined with a focus on the physical standards of the operating rooms and interactions both between other related devices in the operating room and between operational staff. However, the results about the design or layout of an operating room are mostly limited with the workflow or the schedule of the operating room despite the numerous living and non-living actors of the procedures. Also, since the opportunities and circumstances provided by the hospitals for the procedures are varying depending on the type and number of the medical equipment, operational teams, as well as the momentary decisions or preferences, the information collected from the literature do not reflect standardized conditions. This brings a need for field research to study the conditions and actions in the operating rooms.

Since the HLM has been used for less than 70 years, the invention of the machine has received most of the attention in the literature. Also, there is a great number of studies focusing on the medical and surgical outcomes of the HLM in terms of blood compatibility, surgery-related complications, and operating room factors. However, there is very limited research carried out on design of HLM as well as the experience of using HLM with a user-centered approach. The results showed that the enhancements on HLM were made by improving the parts of the machine separately, not by exploring the needs and expectations of the perfusionists.

The literature review on the design considerations and previous research studies conducted on HLM could not directly cover required properties of HLMs. The expectations of perfusionists, working principles of HLMs, usage context of HLMs, and criteria for patient safety may be used as design considerations while designing HLMs.

The working principles of HLMs and criteria for patient safety can be understood by using the literature. Yet, there is limited research about the expectations and need of perfusionists and the possible ways to enhance perfusionists' experiences during the operations in the literature. To cover these issues, field research will be done in the scope of this thesis. It will contribute to decision processes in design processes of HLMs and related surroundings, so that perfusionists' experiences can be enhanced and the human-errors in HLM usage can be decreased.

The needs and expectations of perfusionists will be tried to be understood via using survey and user interview methods in following chapter. Following these, in-situ observations will be done to understand the context from perfusionists' perspective. Also, communication between staff, actions of perfusionists and the total experience of perfusionists during the cardiovascular surgeries can be understood by using in-situ observations.

CHAPTER 3

PHASE 2 – PERFUSIONISTS: NEEDS AND EXPECTATIONS

In Chapter 2, heart-lung machines (HLMs), perfusionists and details of use context were introduced. In literature, it is observed that there is no previous research on the expectations and needs of perfusionists from HLMs. Instead, literature included only the clinical and technical expectations from HLMs. In order to understand the needs and expectations of perfusionists regarding HLMs, in this phase of the fieldwork, a survey and semi-structured interviews were carried out.

3.1 Survey

The paper-based survey aimed to reach as many perfusionists as possible working in Turkey to gather their opinions about HLMs. The aim was to understand the criteria that perfusionists consider while evaluating HLMs.

The survey consisted of four sections and six questions in total. Where necessary, additional explanations and images were used to support the questions (see Appendix C). First, the purpose of the research was introduced followed by the following sections (see Appendix B):

i) Demographic information– *Introduction section, (e.g., gender, age, experience level)*

ii) HLM usage frequency– *Q.1, (weekly HLM usage frequency)*

iii) Previous experiences regarding the HLM usage – *Q.2, (models used, usage frequency)*

iv) The features considered while evaluating HLM models in the market – *Q.3, (which HLM models/features were preferred / why?)*

3.1.1 Participant Selection

The survey aimed to reach perfusionists, who work in different hospitals in Turkey with different demographic characteristics and experience levels. In order to gather diverse opinions, no specific criteria were set for participation. An e-mail invite for the survey was sent to all perfusionists, affiliated to the Turkish Perfusionists Association, with the help of the president of the association. The perfusionists, who received the survey questions in a PDF attachment, were informed that the collected information would be kept anonymous, and the participation was on a voluntary basis.

3.2 Results and Analysis of the Survey

In total, 23 perfusionists responded to invitation positively and filled in the survey questions. All responses were forwarded to the researcher by the Perfusionist Association. At this stage, no direct contact between the participants and the researcher was made. An additional objective of the survey was to provide input to user interviews and user observations that will take place in the next stage of the fieldwork. Therefore, the survey analysis revealed perfusionists expectations from the HLMs in general, their opinions about HLMs they used, as well as helping to better understand which aspects in relation to HLMs and HLM usage experience can be examined in more detail in following steps.

3.2.1 Demographics Information

In the first part of the survey, the participants were asked to indicate their age range, level of experience and gender. The age range options were <20, 20-30, 30-40, 40-50 and 50+. For the experience level, options for year intervals offered to the participants were determined according to expert advisory. Usually, perfusionists can start using the HLM on their own after two years of assistantship to other perfusionists during surgeries. Taking 20's age group as a starting scale (approximate age group that professional perfusionists complete undergraduate degree), remaining intervals corresponded to different generations.

In order to understand age, gender and experience levels of the survey participants, the participants were asked to fill in three multiple-choice questions in the introduction section of the survey (see Appendix B). Among 23 participants, there were 16 (69.5%) male and 7 (30.5%) female perfusionists. 1 (4.3%) perfusionist was between 20-30 years old, 10 (43.5 %) participants were between 30-40 years old, 4 (17.4%) perfusionists were between 40-50 years old, and 8 (34.8%) of the participants were above 50 years old. 22 (95.6%) of the participants were using the device for ten and more years while 1 (4.4%) participant was using the HLMs between 0 to 2 years (see Figure 3.1).

Apart from one perfusionist, all participants took part in the survey had more than 10 years of experience. This indicates that the survey results revealed the opinions of experienced perfusionists to a large extent. The fact that none of the respondents was younger than 20 years old indicated that no opinion could have been obtained from the perfusionists who were trainee perfusionists at the time.

Having only a single participant with 0-2 years of experience but no participants in other categories, meant that it was not possible to make comparisons between the participants' experience levels and their needs and expectations.

3.2.2 HLM Usage Frequency

Each cardiovascular surgery may take duration time, and it would be difficult to predict it. For this reason, in order the understand the perfusionists' weekly workload, HLM usage frequency was focused on the number of times rather than the duration of cardiovascular surgeries. Accordingly, the participants were asked to indicate their weekly HLM usage frequency: once a week; 2-7 times a week; 8-15 times a week, more than 15 times in a week.

The perfusionists, who used HLM once a week are usually included in the trainee group, 2-7 times a week often do not have more than one surgery in a day; and 8-15 times a week have at least one surgery a day and some days more than one; and finally, more than 15 surgeries per week represents the overworked perfusionists.

Distributions of the answers of 23 participants to this question can be seen in Figure 3.2. Accordingly, majority of the perfusionists 19 (82.6%) indicated that they used HLMs between 2-7 times in a week, while four of them said that (17.4%) they used HLMs 8-15 times in a week.

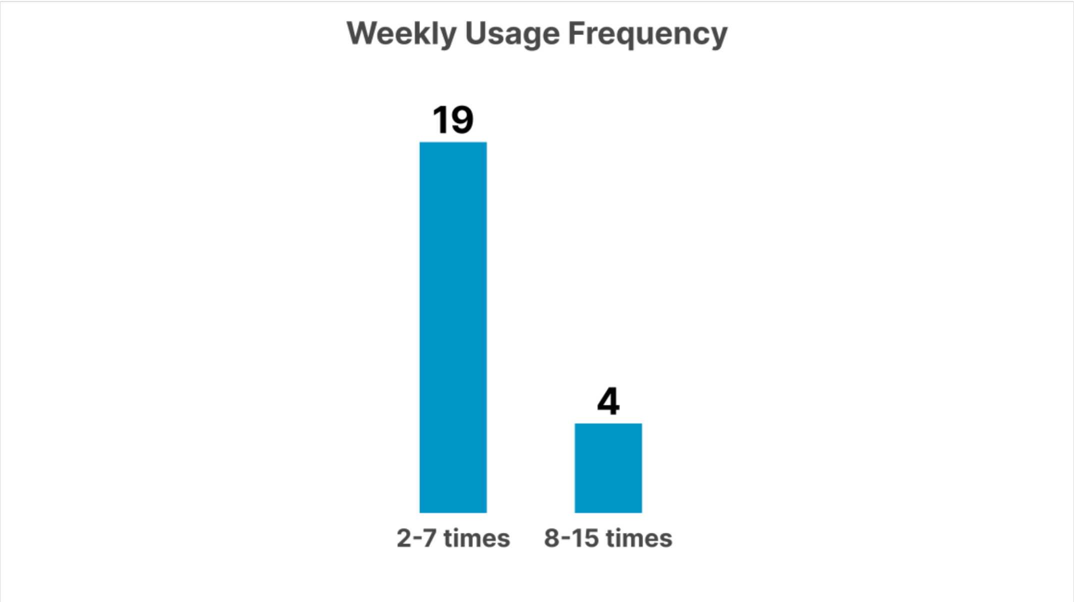

Figure 3.1. Distribution of weekly usage frequency of HLMs across 23 perfusionists

The survey results showed that the participants participated in two to seven operations per week on average. As the participants regularly experienced surgeries, the information they provided in the survey reflected their up-to-date experiences. It can also be inferred that all participants attended at least around 100 surgeries per year (52 weeks x 2 times). Considering that most of them had more than 10 years of experience it would not be incorrect to say that the answers were given by a reliable user group with high level of HLM usage experience.

3.2.3 HLM Experiences Regarding HLM Usage

The participants were asked which HLM models and how many times they used before. This information is useful to analyze the responses of participants in the following question of the survey about the success criteria of HLMs.

In the survey, the participants were presented with commonly available seven HLM models in a list. The models to be presented are decided according to the guidance of a perfusionist with 20 years of experience. The list included the following HLM models: “LivaNova S5”, “LivaNova C5”, “Terumo Advanced Perfusion System-1”, “Maquet HL20”, “Century Heart-Lung Machine”, “Braile Biomedica Bec” and “Spectrum Medical-Quantum Perfusion System”. “Other" option was also added.

Images of the models were provided to the participants to ensure that they can remember which models were questioned (see Appendix B). LivaNova S5 and LivaNova C5 models were grouped together as one choice (i.e., “LivaNova S5/C5”) in the provided list, since there is only a minor difference between these two models. Only difference between these models was modularity of the blood pumps located on mobile console. LivaNova S5 model allows the blood pumps to change their locations on mobile console with other blood pumps, while LivaNova C5 model has fixed blood pumps on its mobile console (see Section 2.1.1.1). Figure 3.2 shows the distribution of HLM models’ usage across 23 participants.

Participants:	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15	P16	P17	P18	P19	P20	P21	P22	P23	TOTAL
LivaNova S5/C5	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	23
Maquet HL20	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓			✓	✓		✓	✓	✓	18
Terumo Advanced Perfusion System 1	✓		✓		✓	✓	✓	✓		✓	✓	✓			✓	✓	✓							12
Century Heart-Lung Machine				✓	✓				✓		✓			✓					✓	✓	✓		✓	9
Braile Biomedica Bec																								0
Spectrum Medical Quantum Perfusion System																								0
Pemco Model 5745 Heart-Lung Machine					✓	✓																		2

Figure 3.2. Distribution of usage of HLM models across 23 participants

Perfusionists may need to use different HLMs in different hospitals or at different times. They are obliged to learn and use the devices regardless of the model. According to the answers given to this question, HLM models and their usage percentage by the perfusionist were as follows: 23 (all of them, 100%) used “LivaNova S5/C5”; 18 (78.3%) used “Maquet HL20”; 12 (52.2%) used “Terumo Advanced Perfusion System 1”; 9 (39.1%) used “Century Heart-Lung Machine”. In the “Other” option, two participants mentioned “Pemco Model 5745 Heart-Lung Machine” as an additional model, which was not included in the original set of options. Whereas, although “Braile Biomedica Bec” and “Spectrum Medical-Quantum Perfusion System” models were in the list, they were not used by any of the participants before. This was a surprising finding as “Spectrum Medical-Quantum Perfusion System” is the latest model available in the market. However, it also shows that at the time that the survey was carried out, it was not widespread in along the survey participants yet.

The fact that all participants had previously used LivaNova branded HLM models may indicate that the answers given to the survey likely to be predominantly in relation to this brand’s models. As Papanek (1985) stated the development of products (goods and services) will continue to have a direct impact on society and the environment, this also indicates that the HLM models which had most influences on the usage habits of the participants is likely to be LivaNova S5/C5 models. Therefore, since design of a product has a significant impact on user behavior and how they interact with it (Norman, 1988), these models require close attention in terms of user-product interaction and functionalities they offer, when the aim is to design devices that are fitting to users' existing usage habits. As mentioned in Section 2.1.3.1, HLM models can have different design approaches to provide some functions to the perfusionists. Some models prefer to have screens on blood pumps while some prefer not to have screens and controls on blood pumps. Similarly, models can provide blood pumps' functionalities in various manners. Since all of the models that are used by participants have similar approach in positioning of the digital user interfaces such as having controls and monitoring features on blood pumps, while making their comments, most participants referred to semi-modular and nonmodular blood pumps with controls and screens on them. The third most used HLM model Terumo Advanced Perfusion System-1, unlike the other models used by participants, provides high modularity for blood pumps. For this reason, the comments of the users of Terumo Advanced Perfusion System 1 model were important for making inferences about the thoughts of perfusionists about the full modularity of the blood pumps with the screens on them. The implications for blood pumps with different modularity capabilities will be explored in following Section. The fact that none of the participants used the Spectrum Medical branded model indicates that the participants have no experience of using HLMs controlled and monitored through a single screen, where blood pumps do not have screens on them.

3.2.4 Criteria of Perfusionists While Evaluating HLM Models

Identifying the models used by each participant in the previous question (see Figure 3.2) helped to understand which models the participants had experienced and which features they took as a reference while evaluating HLMs.

In the survey, the perfusionists were first asked to explain among the HLMs that they had used, which model or models they found "successful". Then, they were asked to give an explanation for what aspects of it they found 'successful' by writing down their answers on the following sentence:

"I find the .... model(s) successful, because ...."

The term 'success' was purposefully not defined so as to gather opinions about success criteria for HLMs from the participants' point of view. As mentioned in the previous section, LivaNova, Terumo, Maquet, Medtronic and Pemco branded HLM models were used amongst the participants. Out of these, LivaNova and Terumo branded models were referred to as being successful. As stated in the previous section, all perfusionists used LivaNova branded models, and 16 (69.6%) of them claimed the LivaNova branded HLM as successful. This can show that the LivaNova S5/C5 models were generally appreciated by the participants. Of the twelve participants, who used Terumo Advanced Perfusion System-1, six (50%) of them described it as being successful. The remaining models (i.e., Brale Biomedical Bec, Century Heart-Lung Machine, Maquet HL20, Pemco Model 5745 Heart-Lung Machine, and Spectrum Medical-Quantum perfusion System) were not mentioned as "successful" model by any of the participants.

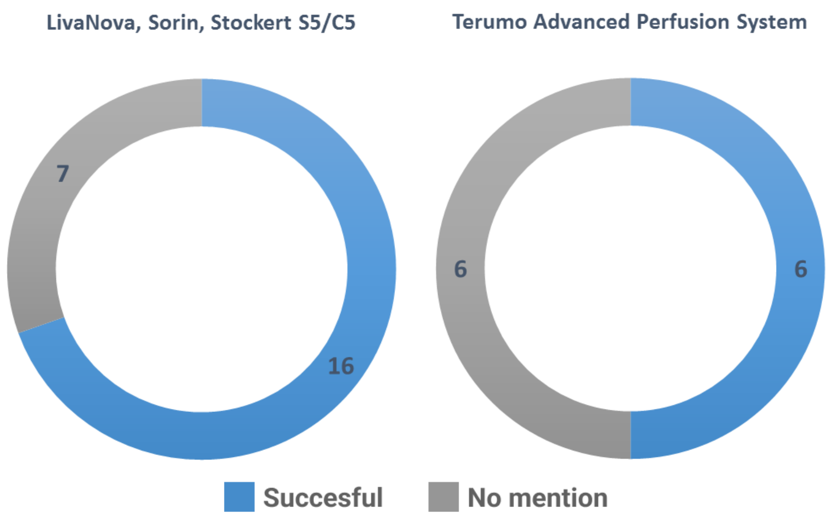

Figure 3.3. LivaNova and Terumo branded HLM models found as "successful"

Answers written by each of the participants to explain the reasons behind finding a model successful were analyzed to find common themes (see Figure 3.4).

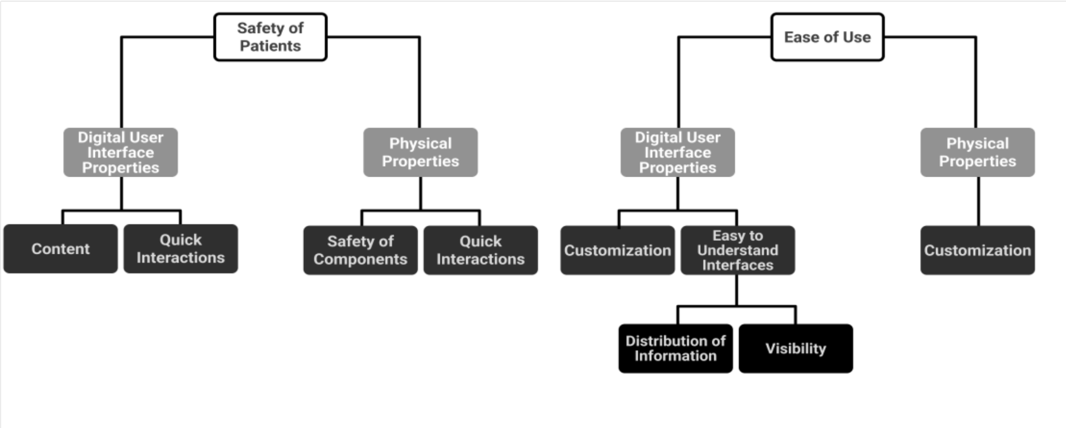

Figure 3.4. Topics that initiated from the analysis of the survey

When analyzing the results of the survey, all criteria mentioned by perfusionists were noted. Then, similar criteria are grouped together. The grouped criteria that were mentioned by participants were given titles. It is analyzed that perfusionists generally evaluate HLM models according to two main topics: i) Safety (of patients) and ii) Ease of use, both of which can be divided into two sub-topics including digital user-interface properties, and physical properties (see Figure 3.4).

To get in more detail of the top topics (safety of patients and ease of use), the criteria of perfusionists while evaluating HLMs and the features that are related to these criteria were grouped under two sub-topics: digital user interface properties, and physical properties. Under 'digital user interface properties' sub-topic; 'quick interactions', 'easy to understand interfaces', 'customization', and 'content' properties were mentioned by survey participants. Under the physical properties theme, 'quick interactions', 'durability of components', and customization issues were mentioned (see Figure 3.5).

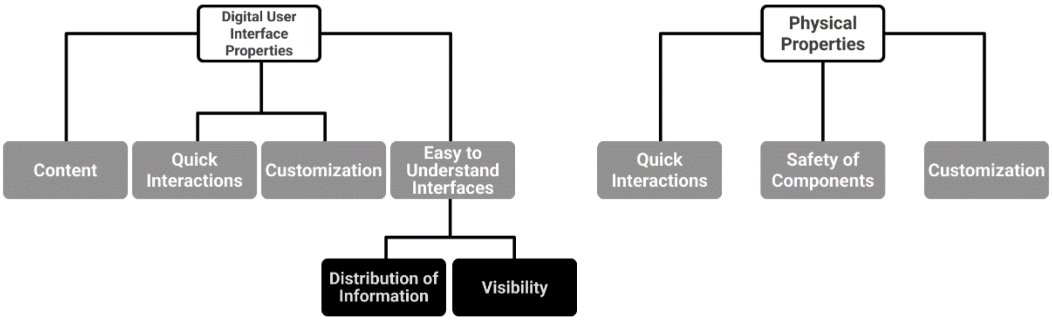

Figure 3.5. Issues under the sub-topics of survey analysis

The details of each expectation (features that correspond the criteria of perfusionist) from HLMs mentioned by participants are explained in following sections.

3.2.4.1 Digital User Interface Properties – Easy to Understand Interfaces

Participants identified that having separate screens (on LivaNova S5/C5 models) and controls for each component eases their usages. This might be because providing the information on directly the related component can help users to map controls and their feedbacks on related parts. This might especially useful while considering the blood pumps since they can be pointed out as the main part of HLMs. Also, giving information by grouping them on separate screens can increase the visibility and availability of information in LivaNova S5/C5 models. In this way, users might be able to remember which field to look for which information. In addition to these issues, having separated screens for each function might be helpful for the safety hesitations of perfusionists since when one screen fails, other parts can maintain their functions differently from having a single touch screen for multiple purposes.

On the contrary, while explaining the success of Terumo branded model, participants identified that having a single screen to monitor all HLM components eases their usages. Having a point to follow general situation of the HLM might be serving perfusionists by reducing their physical and cognitive load by enabling them to see all important information in sight.

Participant also mentioned that the sizes of information and color palette that LivaNova S5/C5 models use are promising for them. This might be important for perfusionists because they can operate HLMs for long durations during the operations. Also, this might be also important for perfusionists who have vision problems.

By combining the success criteria of each model, it is possible to say that perfusionists expect and need proper information grouping, high visibility of information and safety of monitoring screen on HLMs.

3.2.4.2 Digital User Interface Properties – Content

Perfusionists mentioned frequently about the information content provided by LivaNova S5/C5 and Terumo Advanced Perfusion System-1 models. They stated that the information about the HLM and operation is pleasing and enough for operating the HLM for both models. They especially mentioned about the information about sensors connected to HLMs such as pressure, temperature, level, bubble, and flow sensors while explaining the success of models. They might prefer to see as much as information possible about the surgery and HLM during the operations to perform perfusion well.

3.2.4.3 Digital User Interface Properties – Quick Interactions

Perfusionists highlighted the need for taking quick actions while using HLMs. They mentioned about the advantages of having touch screens for quick interactions. Having "one touch" interaction on user interfaces might speed up the actions of perfusionists when needed. Also, this might be useful for perfusionists in emergency cases because as mentioned in Chapter 1, the death of patients occurs when the blood is not well circulated for seven minutes, so that every second counts during the surgeries for perfusionists.

Perfusionists also mentioned the ability to deactivate all the sensor systems quickly while evaluating LivaNova S5/C5 and Terumo Advanced Perfusion System-1 models as successful. This might be because the sensor systems can take automatic actions according to the alerts. Perfusionists may require disabling these automatic actions and take over the responsibility of the device when they think it is needed. These show that perfusionists prioritize the provided safety for patients by HLM models while evaluating the success of the models. In other words, perfusionists expect HLMs to be safe for patients, and it is one of the main criteria for them.

3.2.4.4 Digital User Interface Properties – Customization

Ability to configure information on digital screens is mentioned as a good feature to have in HLMs. Perfusionists might need to choose to show an information or not regarding their expectations for each surgery or their usage habits. This feature might also be appreciated because perfusionists need to feel more sense of belonging to the HLM models that they are using.

3.2.4.5 Physical Properties – Quick Interactions

As physical properties, participants of the survey mentioned the importance of taking required actions quickly in emergency situations physically as they expect from user interfaces. They highlighted the ease of changing tubing lines' blood pumps from one to another. This might show that blood pumps can fail during the surgeries, and perfusionists can change the placement of tubing lines from one roller pump to another to recover. This might have created a hesitation for perfusionists while using HLMs. The hesitation about the failure of blood pumps can show that perfusionists prioritize safety of the patients.

3.2.4.6 Physical Properties – Safety of Components

The failure of component might happen because of variety of reasons during the surgeries such as a hit by a falling piece or spillage of liquid on them. It is (again) possible to interfere that perfusionists prioritize safety of patients. It is supported with both participants who evaluated Terumo Advanced Perfusion System-1 and LivaNova S5/C5 models as successful. Terumo branded model is claimed to be successful thanks to its combination of analogue and digital controls. This might highlight the hesitation to touch controls since Terumo branded HLM does not have any touch screens on blood pumps. While evaluating Terumo Advanced Perfusion System-1's success a perfusionists highlighted the battery backup of the HLM model. This might show again the hesitations of perfusionists about failure of HLM components in power cut. They might be thinking the worst cases, and they may need to be sure that HLM can performs in such cases to make patients have minimum damage.

3.2.4.7 Physical Properties – Customization

Terumo Advanced Perfusion System-1 was evaluated as "successful" thanks to its modular blood pumps. Participants highlighted the advantages of having modular blood pumps such as enhanced reachability and ease of configuring the HLM. Having such physical customization facilities on HLMs may be serving to adapt HLMs for different perfusionists in differentiating body dimensions, which can contribute the ergonomics and comfort. Also, this might be useful to configure the HLMs regarding the needs of each operation.

3.2.5 Reflections on the Analysis of the Survey

In the survey, it is seen that perfusionists expect high patient safety and ease of use from HLMs. Ease of use and patient safety can be a part of all success criteria that were mentioned by the participants. It clearly shows that perfusionists hesitate to harm patients while operating the HLMs. The HLM models should consider these expectations of perfusionists. Section 3.2.4. provided criteria that perfusionists consider while evaluating HLMs were mentioned in the survey in groups to understand in which aspects perfusionists consider ease of use and safety of patient.

The survey provided a general understanding on what do perfusionists expect from HLMs. Yet, it could not provide the detailed reasonings to why do perfusionists need ease of use and safety of patient. It was only possible to make some inferences and guesses about the results while analyzing the survey by the researcher. To understand the details of the issues mentioned in the analysis of the survey (i.e., content, quick interactions, customization, easy to understand interfaces, safety of components), semi-structured interview method will be used. In semi-structured interviews, more expectations and needs of perfusionists can also reveal, while it is helping to explain the survey analysis.

3.3 Semi-structured Interviews

The literature review (see Chapter 2) helped to get familiarized with the technical details and the state-of-the-art of HMLs. Then, the survey helped to understand the needs and expectations of the perfusionists by asking them about their criteria of success for HLMs. Their responses shed light on the expectations from HLMs (see Section 3.2.4).

After survey, it was preferred to utilize the semi-structured user interview method that have gained popularity as a preferred method in qualitative research and in research in general (Riessman 2008; Silverman, 2010), particularly in healthcare research (Britten, 1995; Legard, Keegan & Ward, 2003) in order to understand the results of this survey in more detail through the perspectives of the participants reflecting the descriptions of their own experiences in the context (Kvale & Brinkman, 2009). The literature shows that user interviews are frequently conducted following the survey studies, because qualitative research enables in-depth analysis of individual experiences, where researchers aim to comprehend participants' perspectives (Hennink, Hutter, & Bailey, 2010).

Researchers working on user research often emphasize the importance of building rapport with research participants (Hannabuss, 1996). In the present research, this was also an important point to make the user group (i.e., perfusionists) more open and willing to share information.

In order to discuss and clarify the issues mentioned in Section 3.2.4 in more detail, to reveal new issues regarding to perfusionists' needs and expectations, and to build rapport between researcher and perfusionists semi-structured interviews were conducted.

3.3.1 Interview Venue and Equipment

Interviews with the perfusionists were planned on a face-to-face basis in the hospital environment. Interviews were held in meeting rooms reserved for perfusionists within the heart surgery departments of the hospitals, paying attention to the social distancing rules during the COVID-19 pandemic. Despite the COVID-19 conditions, the main reason for arranging face-to-face meetings was to understand the environment in which perfusionists were spending their time in general (outside the operating room), and to create an atmosphere of mutual trust. All interviews were audio recorded using mobile phones and important points were noted down on paper.

3.3.2 Participant Selection for the Interview

ASELSAN UGES and a hospital in Ankara collaborated during the development process of a new HLM. One cardiac surgeon and seven perfusionists, who work for the hospital in Ankara, contributed as project partners. In addition to this project partnership, ASELSAN UGES obtained the necessary permissions for the interviews as mentioned in Chapter 1 (see Appendix A).

The names of the hospitals and perfusionists will not be directly given in this thesis because of the confidentiality issues. Instead, they will be referred anonymously using their locations to be distinguished. Accordingly, Ankara Hospital A" and "Adana Hospital A" contributed to interviewing process.

Following the project partnership agreement between ASELSAN UGES and Ankara Hospital A, a meeting session with the perfusionist team was arranged by the personnel working at ASELSAN UGES, authorized to establish relations with external stakeholders. The session aimed to meet with the project partner perfusionists, to get information about their HLM usages, problems they experience and to understand their general needs and expectations regarding the usage of HLMs.

In the first interview session, it was possible to meet the perfusionists working at the Ankara Hospital A, Department of Cardiovascular Surgery by their availability. In other words, the researcher did not have a prior information about whom and how many perfusionist were available for interviewing due to the instantaneously changings in surgery schedules.

3.3.3 Interview Procedure

Two interview sessions in Ankara Hospital A, and two interview sessions in Adana Hospital A took place with nine perfusionists and a surgeon in total. All interview sessions were carried out in Turkish as the participants were native Turkish speakers. During the interviews, the participants were encouraged to talk about their current and past experiences about HLMs, with follow-up questions posed to understand their thoughts and feelings.

Interviews carried out with participants in a group setting because of their availability and the time constraints. The breakdown of the interview sessions including participant distribution and duration can be seen in Figure 3.6.

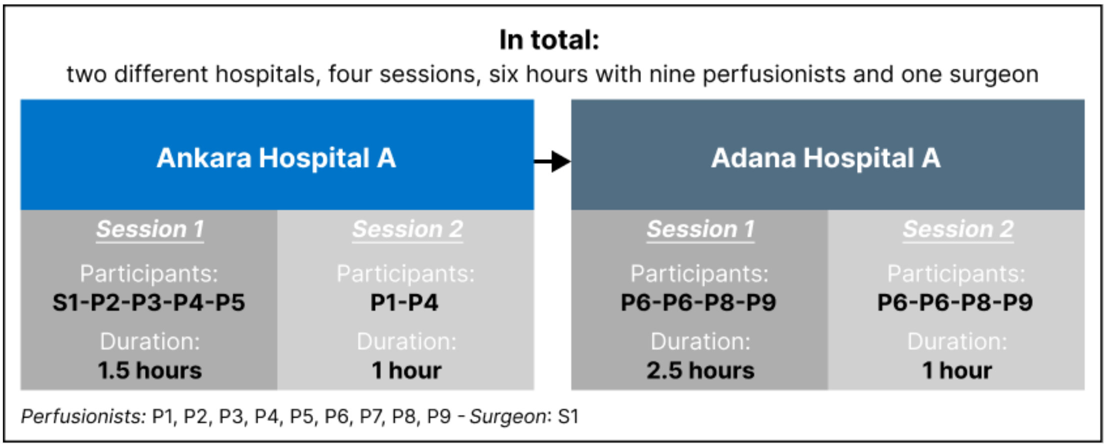

Figure 3.6. The breakdown of the interview sessions including participant distribution and session duration

In Ankara Hospital A two interview sessions were carried out. The first interview session was held with a group of five participants in Ankara Hospital A. One heart surgeon and four perfusionists with varied experience levels attended the session.

At the beginning of the session, all participants and the researcher introduced themselves. The participants were reminded about the purpose of the interview and their consent was obtained verbally during the audio recording that the conversations would be recorded and used only for the research purposes.

Following these, some warm-up questions were asked. After a brief introduction and warm-up questions, the participants talked about the heart-lung machine and the general operating room environment. The researcher asked six pre-prepared questions during the session (see Appendix C). After all the questions were answered, the first session was concluded by thanking the users and a break was given.

Following this meeting, one more interview session was carried out in the same hospital with two perfusionists. Both perfusionists attended the first session. The researcher specifically requested separate meetings with them to allow them to express themselves more comfortably after the first group session.

Other two sessions were held in Adana Hospital A, each with the same group of four perfusionists. In the first session in Adana, perfusionists preferred to demonstrate what they were talking about. To do that, they invited researcher to where HLMs were kept and maintained before the cardiovascular surgeries. Following the demonstrations, perfusionists and researcher moved to a meeting room to continue with the second part of the session. The topics mentioned in the first session were discussed in more detail in the second session. Same interview procedure was followed as in Ankara Hospital A. Then, in second session in Adana, the questions shown in Appendix C were covered, and perfusionists shared their thoughts and ideas about HLMs.

3.3.4 Interview Results and Analysis

In all interview sessions the researcher took notes. Researcher's notes, audio recordings and videos were re-examined to not to miss any of the topics mentioned in the sessions. Recordings were transcribed into Microsoft Word for the analysis process. The purpose of the user interviews was to understand perfusionists' needs and expectations from HLMs. Moreover, interviews aimed to have variety of information, which can also be unexpected, about HLM and perfusionists. Therefore, all of the topics mentioned are noted during the interviews.

Analysis of user interviews was carried out in several steps:

- The answers to questions given by the perfusionists were written on post-it notes on Miro Board platform.
- The statements were grouped together to create themes (see Figure 3.7).

Figure 3.7. Analysis process of interviews

- The post-it notes were then sub-divided into smaller groups according to the issues they are focusing on. The sub-divided post-it groups were then assigned a heading by considering the titles used in the survey (see Figure 3.8).

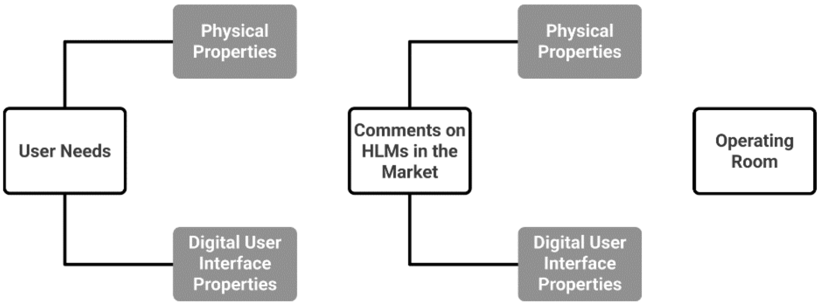

Figure 3.8. Grouping the statements under themes for interview analysis

- The post-it notes under the same headings were merged/gathered (see Figure 3.9).

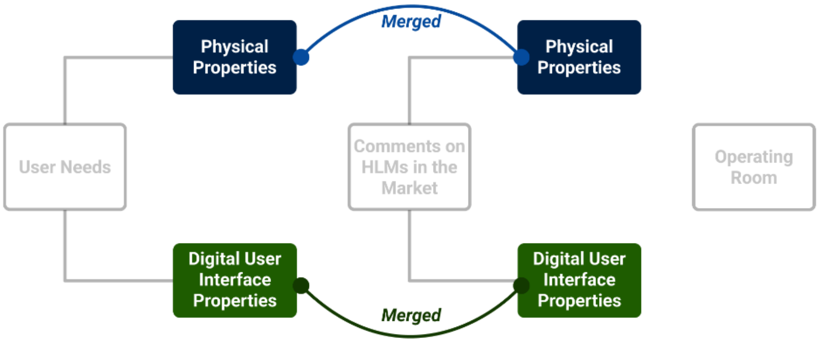

Figure 3.9. Merged headings during the interview analysis

- The merged/gathered post-it notes divided into smaller groups and assigned with headings similar to the ones used in survey analysis (see Figure 3.10).

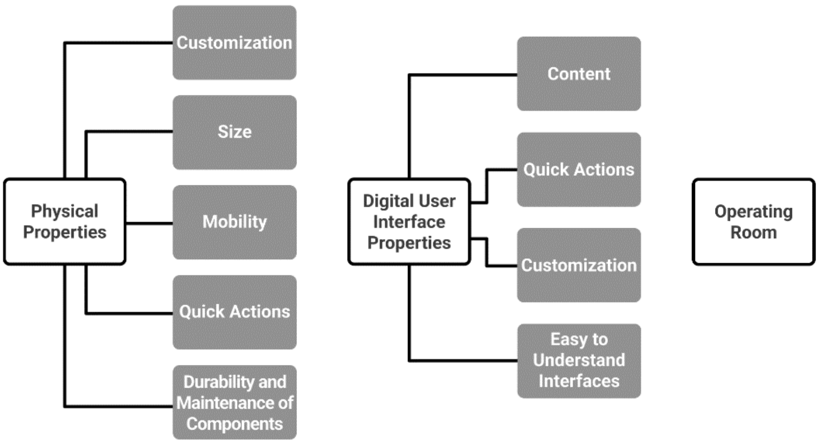

Figure 3.10. Headings revealed in the analysis of interviews

- Finally, the content of each post-its groups are explained as a summary of the statements gathered together.

At the end of the analysis, 13 groups were obtained under three main headings: “Physical properties”, “Digital user interface properties” and “Other”. Each group will be presented in detail in following sections. All statements mentioned by participants during the interviews were written on post-it notes and grouped together under the headings that can be seen in Figure 3.10. Some statements were mentioned more than once by the participants, while some of them were mentioned only once. The analysis of the interviews includes all of the statements which are in the scope of the research under the headings and explains the details of headings regarding to the statements written on post-it notes.

3.3.4.1 Physical Properties – Customization

HLM models in the market can provide some customization features. As it was mentioned in Chapter 2, some models can provide modularity for blood pumps. In addition to this, some HLM models can provide perfusionists different mobile consoles according to the demand of them, while some HLM model give perfusionists a chance to adapt and modify mast systems by selling additional accessories. These customizations can be done according to the needs of each operation and perfusionists' wishes. It also helps to enhance the marketing operations according to the perfusionists in interviews. In this way, HLMs can be configured for different purposes, and they can be adaptable to different hospitals.

According to all participants of the interviews, blood pumps are the core of HLM functions. Perfusionists give high importance to the fact that the modularity and adjustments of blood pumps such as occlusion (adjustment for squeezing tubing lines in roller pumps) and tube insertions. Participants of the user interviews claimed that the mechanical adjustments of the blood pumps should be made easily by every perfusionists according to changing tubing sets and operation needs. In addition to these, participants mentioned that roller blood pumps should have high modularity to allow perfusionists to keep the tube sets in the shortest way possible, which reduces the hemolysis of blood for patients, and to configure the arrangement of blood pumps according to body dimensions of each perfusionists to operate HLM comfortably, showing similarity with the results of survey.

In general, expecting precise mechanical properties from roller blood pumps shows that perfusionists evaluate roller blood pumps by considering the patient safety in their mind. Also, high level of modularity to configure the HLM for comfort shows that perfusionists need for ease of use.

3.3.4.2 Physical Properties – Size

According to the participants of user interviews, HLMs should be designed as compact as possible, as the size of the HLMs defines how close they can be positioned to patients in congested operating rooms without restricting the movement of the perfusionists and other staff around the patient. When the HLM is closer to the patient, due to the shortened tube line length, blood hemolysis (i.e., the destruction of red blood cells) can also be reduced (see Section 2.1.3.1) for patients and the HLM becomes more compatible with different size operating room since it can also fit into small environments. Perfusionists explained that to reduce the general size of an HLM, some brands allow the blood pumps to be positioned vertically with modular blood pump designs (e.g., Terumo Advanced Perfusion System-1, Spectrum Medical-Quantum Perfusion System) on top of each other. In this way, the HLM can fit in a much narrower space compared to side-by-side blood pump arrangements.

Perfusionists also mentioned that they stand by or sit at one side of HLMs during the operations. It is not easy for them to reach interaction areas on HLMs when the blood pump arrangement is planned horizontally (e.g., LivaNova S5/C5), but compact sizes allow perfusionists to have clear reach to interaction areas.

Therefore, in relation to ‘size’, compact HLM sizes are preferred as they: allow HLMs to fit into small operation rooms; help to position HLMs closer to the patient to reduce the blood hemolysis; provide clear reach to controls.

3.3.4.3 Physical Properties – Mobility

Perfusionists in Adana Hospital A mentioned that HLMs must be easy to move. They explained the need for improved mobility by demonstrating how hard to move a HLM model (i.e., LivaNova C5 model). The model that they used to demonstrate has a 156 kg of mobile console with its fixed roller blood pumps according to the product catalogue by Sorin Group (2010). The hardness to move this model might be because of its heavy design. The weight of HLM models differentiate according to the components they use, but since LivaNova S5/C5 models are popular in Turkey, it is possible to say that perfusionists in Turkey have problems with moving the HLMs. The standard (EN 60601-1) mentioned in Section 2.2.2. also highlights the importance of mobility.

Some HLMs are kept outside the operating room (in Adana Hospital A) before surgeries to prepare them for cardiovascular surgery or sometimes, when an emergency case arrives to the hospital, perfusionists need to quickly move the HLM from one room to an operating room. Improved mobility of HLMs can definitely help to shorten the required time to start emergency surgeries, and the physical strength level expected from perfusionists can be reduced. The reduced physical strength requirement to move HLMs can help perfusionists who have trouble moving the HLM. This mobility feature is (in its core) expected for ease of use and patient safety.

3.3.4.4 Physical Properties – Quick Actions

As mentioned before, in emergency situations, HLMs should be set ready for the surgery. In such cases, perfusionists require to reach "on/off" controls of the HLMs easily. In addition to these, during the interviews the participants mentioned about extreme case scenarios, where HLM may fail. For example, they highlighted a scenario when a roller pump fails. In such a case, especially if the blood pump is used to pump the blood to the patient, it creates a real chaos in an operating room.

Luckily, although none of them experienced this, they were all concerned about the possibility of it. Therefore, they claimed that in such an emergency/failure situation the tubing sets should be taken out easily from the broken roller pump and it should be connected to another roller pump working properly. To achieve this, perfusionists suggested to have modular roller pump mechanisms that can easily be replaced during the surgeries.

The concerns about the HLM failure during emergency cases and the suggestions about having modular roller pump mechanisms show that perfusionists are afraid of causing damage on patient when a system fails. To prevent it, they need actions and interactions that can be done easily and quickly since time works against them in such cases.

3.3.4.5 Physical Properties – Durability and Maintenance of Components

Perfusionists' biggest concern was the failure of the system as it could cause harm on patients. In relation to this, they mentioned the importance of durability of HLM components. To prevent failures, perfusionists expressed the need for high-capacity batteries that HLM components could run in case of a power cut.

Moreover, there were other concerns listed by the perfusionists about the potential risks exist in the operating room. For example, an unexpected hit to HLM by the staff, which can create a high risk for HLM, the staff and to patient. Perfusionists suggested to have full-lock mechanisms wheels for such cases because if HLM moves, it can cause tubing sets to break down, which can cause a great damage on the patient being operated. Also, avoiding sharp edges (or protecting them) on HLM design to prevent any harm on staff is necessary.

The potential risk of liquid spillage on device during the surgeries was another point mentioned by the participants. They said that the device should be well protected against liquids not to harm any electronic components.

In the interviews, perfusionists mentioned about the issues outside of an operating room. For example, all HLM components should be durable to resist harsh conditions such as exposure to chemicals, fluid, and ultraviolet rays to survive maintenance and cleaning processes. Material selection and design decisions should also be made accordingly. Periodic maintenance and check for the components should be done to perform the surgeries safely by perfusionists.

Also, some periodic maintenance should be done by technical services. HLM models should inform perfusionists periodically when it is needed to be controlled and calibrated by technicians. Perfusionists stated that they may have problems in reaching the technical services responsible for the maintenance of the models they have, and, in some cases, they cannot use the HLMs even though they are needed. They also mentioned that the processes of repairing broken, malfunctioning parts, or supplying new ones is challenging for them.

3.3.4.6 Digital User Interface Properties – Content

During the heart surgery, perfusionists rely on lot of information for monitoring the perfusion. Some participants expressed that Spectrum Medical-Quantum Perfusion System model can provide data about blood-gas level different from other HLM models in the market, and this feature was highly appreciated in interviews. Differently from the other models in the market, Spectrum Medical branded model can provide blood gas values without a need for using an external blood gas analysis device on its digital screen thanks to the sensors integrated. This feature was not mentioned in the survey because (probably) none of the participant had any experience with the model.

The diverse source of information in perfusion is vital as it directly affects patient health and the decisions of the perfusionist. Apart from the information provided by HLMs, information from different devices in the operating rooms is also needed by perfusionists. While perfusionists were talking about their “dream HLM model”, they highlighted having various of information on HLM itself with the help of integration with other devices. For example, blood gas analysis machine was one of the equipment mentioned by the participants. Similarly, a live streaming showing the heart on HLM interfaces was another feature mentioned by the participants. This feature was mentioned in relation to increased collaboration between the perfusionist and the surgeon as they can foresee the expectations of surgeons during the operation with live streaming.

3.3.4.7 Digital User Interface Properties – Quick Actions

During the interviews perfusionists mentioned that they could be distracted during the surgery. Thus, the HLM should give the necessary warning information clearly. In such situations, perfusionists require quick and easy interaction with HLM. Some perfusionists mentioned the importance of having touch screens in the survey. In interviews, perfusionists also mentioned about the advantages of having digital touch screens for quick actions. Even though, they mentioned their concerns about making mistakes on touch screens, touch screens were preferable option in emergency cases.

3.3.4.8 Digital User Interface Properties – Customization

Interview results show that each perfusionist may have a different style of using/interacting with HLMs' digital user interfaces. For example, while some perfusionists prefer to see certain information on the monitor others may find it confusing and may not to prefer to see them on screen.

Additionally, the information provided by sensors could be monitored on the information screens on HLMs, and they give alarms according to the threshold limits determined by the perfusionist. There is no exact value when the sensors should give alarms, the thresholds can be changed according to the type of the surgery and to the preference of each perfusionist. In such cases, perfusionists should be offered customization to increase their ease of use.

3.3.4.9 Digital User Interface Properties – Easy to Understand Interfaces

In order to not to cause complexity and to ensure that perfusionists can access the data quickly, it is preferred by the perfusionists to group the relevant data on HLM screens. They also mentioned that they could use HLMs while moving around the operating room. In such cases, they require to see user interfaces from a distance. As mentioned by a perfusionist: *"The proper usage is where we do not need to leave the HLM during the surgery, yet in practice, we may need to leave HLM during the surgery".* To allow perfusionists to see the user interface from a distance, user interface elements need to be "big (enough) and visible".

Perfusionists expressed that they prefer to see some information in a cluster. This clustering can be done by using individual screens for each function or relevant information can be grouped on a single screen.

3.3.4.10 Operating Room

In the operating room, perfusionists, surgeons, nurses and anesthetists work as a team. As suggested in literature and confirmed by the perfusionists during the interviews, verbal communication between perfusionists and surgeons is of critical importance. Perfusionists must apply the commands of surgeons and give clear verbal feedback on their implementation to surgeons. In addition, perfusionists are responsible for informing surgeons about the status of the operation. The ability of the whole team to work in coordination with each other and to be in constant communication is an important factor in the success of the surgeries, suggested by the perfusionists. The design of HLM should consider this situation not to disturb communication between perfusionists and others. For example, the HLM alarms that cause high noise in operating room should be able to be muted by perfusionists not to disturb the communication between surgical staff.

During the interviews, perfusionists mentioned about differences in the use of HLMs based on changing physical conditions of operating rooms and procedures in each hospital. According to hospital's procedures, some functions can be provided by using different methods. For example, in some hospitals the solution to stop the heart is given by using the roller blood pumps of HLM, while in some hospitals they are provided with some external systems that are not related with HLMs.

In addition to these, perfusionists mentioned that the interior design of operating rooms can be re-considered according to the positioning of HLMs. They mentioned that they have some operation room layouts which challenge them while operating HLMs. This issue will be investigated in more detail thanks to the in-situ observations in following Chapter.

3.4 Discussion on the Needs and Expectations of the Perfusionists

This section combines the results of the survey and interviews carried out with the perfusionists and a surgeon as detailed in the current chapter. It can be concluded that high level of safety for patients and ease of use during the cardiovascular surgeries are the two most important expectations of perfusionists while designing HLMs. Perfusionists need to feel secure while using the HLMs. To provide them with the sense of "security", HLMs should provide high level of safety for patients because if a failure occurs because of HLMs, perfusionists are the ones who are responsible to operate the machine. Similarly, when perfusionist make a mistake in the usage of HLMs, patients can suffer, which can affect perfusionists' career and psychology negatively. To reduce the possibility of making mistakes, HLMs should be designed with ease of use in mind.

The issues (quick interactions, customization, safety/durability of components, content, easy to understand interfaces) mentioned in the survey could be explained and detailed thanks to the interviews. In addition to the issues in the survey, new issues (size, mobility, surgical staff communication, maintenance, miscellaneous) revealed in the interviews. Some of the topics that revealed in the survey and interviews could not be understood by using these both research methods.

Interviews showed that perfusionists may need to leave HLMs during the operations, which was an unexpected result. Similarly, the effects of operating room layouts on the performance of perfusionists was not expected as a result in interviews.

In-situation observations will be done to detail all of the interactions of perfusionists during the cardiovascular surgeries. In addition to these, in-situation observations will cover contextual issues and HLM usage scenarios in detail. It will also be beneficial to compare literature, survey, and interview outcomes with the “reality”.

CHAPTER 4

PHASE 3 – HEART-LUNG MACHINES IN OPERATING ROOM: IN-SITU OBSERVATIONS AND EXPERIENCES

The Phase 3 of the fieldwork aimed to identify details of the context during cardiovascular surgeries, heart-lung machine (HLM) usage scenarios of perfusionists, and to explore the factors that affect perfusionists' experiences during the operations. In Chapter 2, the operation context, and the role of perfusionists were presented with the help of literature review. In Chapter 3, needs and expectations of perfusionists were presented based on the survey and interviews results. Safety thus trusts to HLMs, and ease of use were identified as the top two most important needs and expectations as a result of survey and interview results combined. However, even though the responsibilities of perfusionists in Chapter 2 were explained, the details of perfusionists' experiences in operating rooms were not covered in previous chapters. Some issues such as staff in operating room, and physical conditions of operating rooms were also mentioned in Chapters 2 and Chapter 3. They all lacked the information about how do perfusionists interact with them during cardiovascular surgeries. To cover these issues, and identify problems encountered during the operations by perfusionists, in-situ observations were planned.

Chapter 4 presents the venue and equipment, procedure, details of selection of attended cardiovascular surgeries and result and analysis of eight in-situ observations. The chapter also explores the perfusionists' experiences during operations and portrays the problems identified in-situ observations. As stated in the previous Chapters, all necessary permissions were secured by ASELSAN UGES for participating in observation.

4.1 In-Situ Observations

The research reported in previous chapters was carried out outside the context of use. When examining products requiring high interaction, the importance of conducting research in context has been mentioned a lot in literature, since it enables researchers to find out about the interactions and user behaviors in their natural environments (Mays & Pope, 1995). When the users are given the opportunity to show what they are talking about, it becomes easier to understand the subject, and it is easier to evaluate their experiences in a holistic framework. Although information about how the HLM functions is compiled in Chapter 2, it was also necessary to observe how the perfusionists actually use the HLMs, as observation provides information on the impact of the physical environment (Mulhall, 2003) where can manipulate the performance of the perfusionist, and observational data can be used to support or confirm the findings from other research methods (Gray, 2009). In line with the study of Hijikata et al. (2012) presenting that user intervention may result in increase in prediction and satisfaction, users can often develop their own unique usage methods. For this reason, while both the literature and the out-of-context interviews portray the ideal situation, the observations in the environment can be helpful in revealing the truth. From this point of view, following the literature research, survey and user interviews, making observations in the context provides a holistic understanding of the use scenarios, to make sense of the issues that emerged in the previous stages, to reveal new issues.

Due to the fact that the subject required technical knowledge, some actions taken by the perfusionists during the observations may not be understood by the researcher. In these situations, the researcher can ask questions to understand the subject and the behavior. This is critical for accurate analysis of the observation (Mulhall, 2003) and to avoid misinterpretations.

4.1.1 Observation Venue and Equipment

Observations took place in three different hospitals (Ankara Hospital A, Adana Hospital A and İzmir Hospital A). In addition to Ankara Hospital A and Adana Hospital A that contributed for interviews, also İzmir Hospital A contributed to the in-situ observations. In total, three different cities, six operation rooms and eight cardiovascular surgeries was attended by the researcher.

In all cases, during the observations the researcher was positioned behind the heart-lung machine (HLM) in the operating rooms in a way to not to distract and obstruct the perfusionist or any other surgical team member. Due to the COVID-19 measures, social distancing was also considered. Since the operating rooms are sterile environments, hygiene rules were followed, and appropriate clothes were worn during participation in the surgeries. During the operations, an observation sheet template was used for taking notes (see Appendix D). In addition, photographs, videos, and audio recordings were taken using a mobile phone camera in situations that would be difficult to explain by taking notes. During the recordings, special care was given to not to record any information about the patient who was being operated.

4.1.2 Observation Procedure

Perfusionists that would be observed were informed about the attendance of the researcher by the chief perfusionist. The researcher and the perfusionists met with each other before going to operating rooms. The researcher and perfusionists introduced themselves to and had a brief conversation before the surgeries. The perfusionists were told by the researcher to behave as they would without the researcher in the room. They were informed that all recorded data would be kept anonymous and not be shared with third parties. Verbal approval and consent of the perfusionists were obtained at the beginning of observations. Then, the researcher took notes on an observation sheet which was prepared before the operation (see Appendix D). When needed, the researcher asked questions to the perfusionists to understand the actions in operating room. In some cases, the researcher needed to take photos and videos. After the operation, the researcher thanked to the perfusionists and left the operating room.

4.1.3 Selection of Cardiovascular Surgeries to Observe

Perfusionists' schedules are weekly planned. After the chief perfusionists in Ankara, Adana and İzmir shared their weekly calendars with the researcher, the surgeries to be participated were determined together. To arrange the dates for observations, the chief perfusionists at each hospital were contacted. The chief perfusionists assisted in establishing the necessary conditions for the researcher and obtaining permissions from the hospital management.

All surgeries involved adult patients. Due to the high risk of pediatric and infant surgery procedures, the researcher did not prefer to participate in these types of surgeries for in-situ observations to not to out additional stress to surgical team members. The researcher preferred to attend the surgeries that are expected to be less stressful so that the researcher could easily ask his questions in operating room. Moreover, there were limited options to attend the surgeries in hospitals because of COVID-19 restrictions during the time.

The aim of the researcher was to participate in a large number of operations from the very beginning to the end. However, due to the limited number of visits to the operating rooms, the initial procedures of some surgeries could not be attended. In some cases, the researcher moved to another operating room when the attended operation was over to observe some operations from the moment they could start. The pre-operative stage could not be observed in such cases, as the surgery in the next operating room had been already begun.

4.1.4 Observation Results and Analysis

The researcher participated in eight different cardiovascular surgeries, two in Adana Hospital A, five in Ankara Hospital A, and one in Izmir Hospital A, during 2021-2022. The use of the LivaNova S5, LivaNova C5 models at six surgeries and Spectrum Medical–Quantum Perfusion System in two surgeries were studied. All the observations were made in state hospitals in six different operating rooms. In all surgeries, HLMs were used by two perfusionists. In total, twelve perfusionists were observed during operations, since same perfusionists had a role in more than one surgery on different days. A total of 27 hours of usage of HLMs were investigated during cardiovascular surgeries (see Figure 4.1).

	Operating room (OR)	Perfusionist (P)	HLM model	Duration
Ankara Hospital A	OR1	P1, P2	LivaNova S5	5 hours
	OR2	P3, P4	LivaNova S5	2 hours
	OR3	P5, P6	Spectrum Medical - Quantum Perfusion System	4 hours
	OR2	P1, P7	LivaNova S5	1.5 hours
	OR3	P4, P5	Spectrum Medical - Quantum Perfusion System	2 hours
Adana Hospital A	OR4	P8, P9	LivaNova C5	4 hours
	OR5	P9, P10	LivaNova C5	2.5 hours
İzmir Hospital A	OR6	P11, P12	LivaNova S5	6 hours

Figure 4.1. Distribution of in-situ observations

After attending eight in-observations, the notes that were taken during the operations and the recorded visual media were transcribed and outcomes were transferred onto the post-it notes on Miro Board. The visual media (photos and videos) was transcribed by combining the visual information with the notes and audial information recorded in videos. The post-it notes were then grouped according to their similar content and were assigned with appropriate headings. In following sections, these headings, content, and insights gained will be explained in more detail.

The summary of the outcomes for the analysis process will be explained with supporting visuals. The visuals are prepared in black and white to not to alert the readers as they include blood scenes. Also, the faces of the surgical team members and various symbols were blurred in the images to keep them anonymous. The results and analysis of the observations will be presented under three main headings: communication, operating room from perfusionists' view, interactions, and actions of the perfusionists.

4.1.4.1 Perfusionists' Communication During Operations

As explained in Sections 2.2.1.3 and 2.2.1.4, staff with different responsibilities participate in cardiovascular surgeries. For example, perfusionists communicate with surgeons, anesthetists, nurses, and other medical staff during the operations. The literature review, survey and interview results showed the importance of communication, yet they could not fully uncover the details of communication between perfusionists and other operating room staff. In-situ observations are used to identify the details.

The communications happen before, during and after the surgery. The communication frequency increased during the surgery periods. In all observed surgeries, at least two perfusionists, two nurse anesthetists, and one circulating nurse were in the operating room. In addition, the number of surgeons increased in certain parts of the operations and decreased in certain parts. But, in all observed surgeries, at least one surgeon was in performing the surgery while commanding the staff in the operating room.

In interview analysis, it was mentioned that the cardiovascular surgeries require high collaboration between staff. Surgeons are the main authority in operating rooms. Perfusionists take actions when surgeons give them a command, therefore clarity of communication is crucial (Wiegmann *et al.*, 2009) the aim was to understand the details of the communications from the perfusionists' perspective. Figure 4.2 presents the communication flow between the perfusionist and other surgical team members. and will be discussed in detail later in this section.

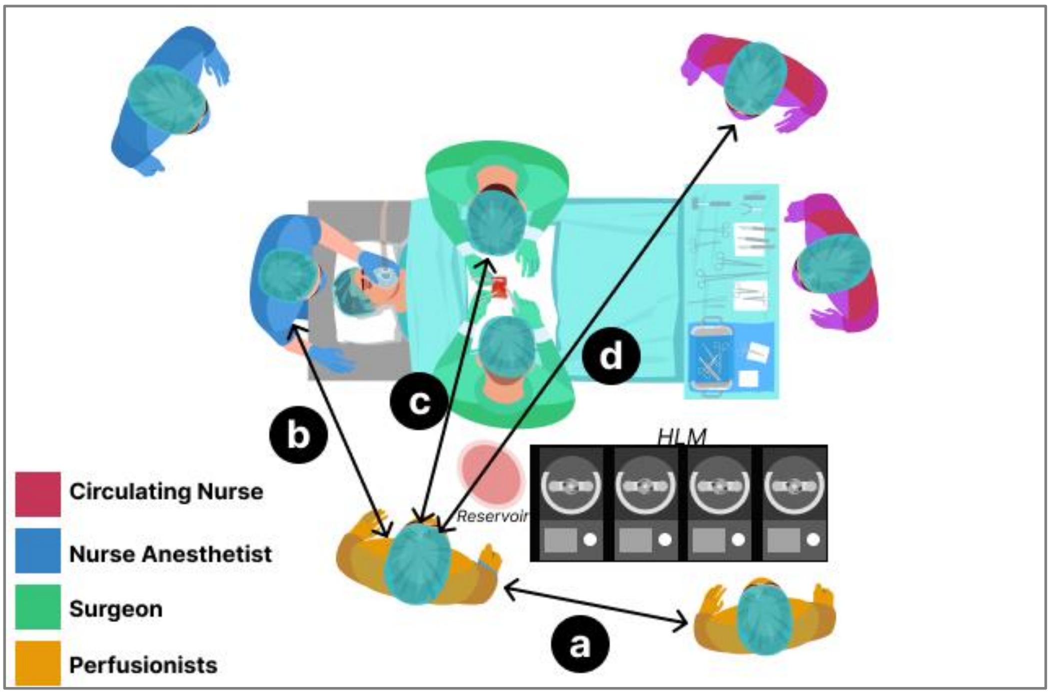

Figure 4.2. Communication flow of perfusionists during operation
a) perfusionist-perfusionist; b) perfusionist-anesthetist; c) perfusionist-surgeon; and d) perfusionist-nurse

In all observations, the perfusionists were speaking louder than normal. In this regard, a perfusionist said: "We need to have a loud voice so that everyone can hear us correctly and get the necessary information". This may affect the performance of perfusionists during the surgeries by adding a physical load to them. While designing operating rooms and HLMs, the voice in the operating room should be considered. For example, if HLM makes too much noise while working, it can cause additional load on perfusionists by making them talk louder. Also, if operating rooms can be designed accordingly, perfusionists can talk in lower voice. Therefore, thanks to the design interventions, the communication between perfusionists and other operating room staff can be eased.

a) Perfusionist-Perfusionists Communication

In all surgeries observed, two perfusionists participated in the surgery: One was the responsible member and the other one was in the assisting role. There were trainee perfusionists in two of the surgeries as assistant perfusionists, in the remainder, both of the perfusionists were professionals. The observations revealed that the two were always located side by side at one side of the HLM (see Figure 4.3).

Figure 4.3. Position of two perfusionists

The main perfusionists, who were in charge of using the HLM, were seated close to the reservoir and the blood pump as they interact with these components. They also gave periodical tasks to assistant perfusionists to take the necessary actions. For example, changing the pump speed, bringing necessary equipment and tools, filling in necessary forms, sending the blood sample to the blood gas device and bringing the results back. The assistant perfusionists usually monitored the digital screens on HLM and informed the main perfusionists about the state.

In summary, the main perfusionist makes the decisions for all actions that will affect the patients, gives commands to assistant perfusionist when needed. Assistant perfusionists report back to the main perfusionists about the information they follow on digital screens or printouts. Having an assistant perfusionists for each "main perfusionists" can be because of the need for support. They cannot perform the surgeries properly when a support is lacking especially for getting information from various devices and interfaces. It shows that required information to evaluate perfusionists action can become so hard to follow for only one perfusionists. It clearly highlights a problem about the complexity of operating HLMs. This complexity can be decreased with design interventions.

b) Perfusionist-Anesthetist Communication

The interaction between these two professionals can be described as less intense than that of the perfusionist-to-perfusionist. Perfusionists can communicate with anesthetist for getting necessary information, starting / finishing the operation, injecting the necessary solutions into the blood (through the reservoir). In addition, sometimes anesthetists can go to the blood gas analysis device with a blood sample taken from reservoir to check the blood gas values, and these values are evaluated by perfusionists and anesthetists together. The conflicts may occur because of the uncertainty about who will do the required actions for obtaining blood gas values in a certain frequency (once in 15-30 mins). These conflicts can cause a decrease in the efficiency of communication. During the observations, it became obvious that when all staff is clear about who is responsible for obtaining blood gas values, the communication is undisrupted. Perfusionists are interrupted by this communication while operating HLMs. They interact with anesthetist for evaluating the needed solutions and convincing anesthetist to make them help for blood gas analysis regularly. By design interventions, the communication between perfusionists and anesthetists can be minimized and be improved.

c) Perfusionist-Surgeon Communication

Surgeons are the surgical staff members who give instructions during the operations, and all other staff members follow their directives. While perfusionists are normally responsible for operating HLM by their own, surgeons are in communication with perfusionist to instruct perfusionist about the actions they want from the HLM when they need. Both surgeons and perfusionists may talk out loud to inform the surgical team members about the actions they are about to do, or they already have completed. Surgeons may ask questions to perfusionists to obtain information they are interested in such as the liter-per minute (LPM) value of main blood pump. To let all operating room staff hear about their actions, perfusionists and surgeons talk loudly. Also, surgeon and perfusionists require feedback from each other about the reflections of their actions.

Even though surgeons have feedback from the perfusionists once about the perfusionist have done the required action, they want to be sure about it by re-asking. Here, it is understood that communication between surgeon-perfusionist and HLM should be improved since there is a need for improved feedbacks. The HLM is a machine that surgeons cannot follow during the operations, due to the location of the HLMs and the work that requires the surgeon to focus on. Surgeons need sometimes to perceive the information about the situation of HLMs by themselves, which can be a consideration for design of HLM and operating room.

d) Perfusionist-Nurse Communication

The surgical team members that perfusionists interact at least are the nurses. They usually communicate with each other for exchanging necessary equipment.

Therefore, the communication between perfusionist-surgeon, perfusionist-perfusionist and perfusionist-anesthetists have greater importance during the cardiovascular surgeries. Perfusionists and nurses do not expect to hear from each other since they are rarely interacted. Because of this it might be sometimes not very clear that perfusionists are calling out to nurses. This can cause a delay in the actions of perfusionists. To solve this, design interventions can be used to standardize the language and verbal communication.

4.1.4.2 Operating Room from Perfusionists' Perspective

During the observations, it was observed that perfusionists prefer not to use HLMs alone, and they get support from another perfusionist to follow information they need while operating HLMs. It is also suggested in "Standards and Guidelines for Perfusion Practice of the AMSECT" (2016 that support staff shall be available on site to assists the primary perfusionist during the operations. Therefore, HLMs were operated by two perfusionists during the observations.

With the better understanding of the actions of the perfusionists, including what they do, how they do, what information that they follow, and when, the patient monitoring through HLMs can be improved with design interventions. Accordingly, this section highlights the perfusionists actions, interaction with HLMs, and their importance.

The results of the observations show that, perfusionists receive visual information from 14 different sources in operating rooms (see Figure 4.4), except from the audial information such as verbal communication during the operation by other surgical team members, which was mentioned in Section 4.1.4.1, and alarms on HLM.

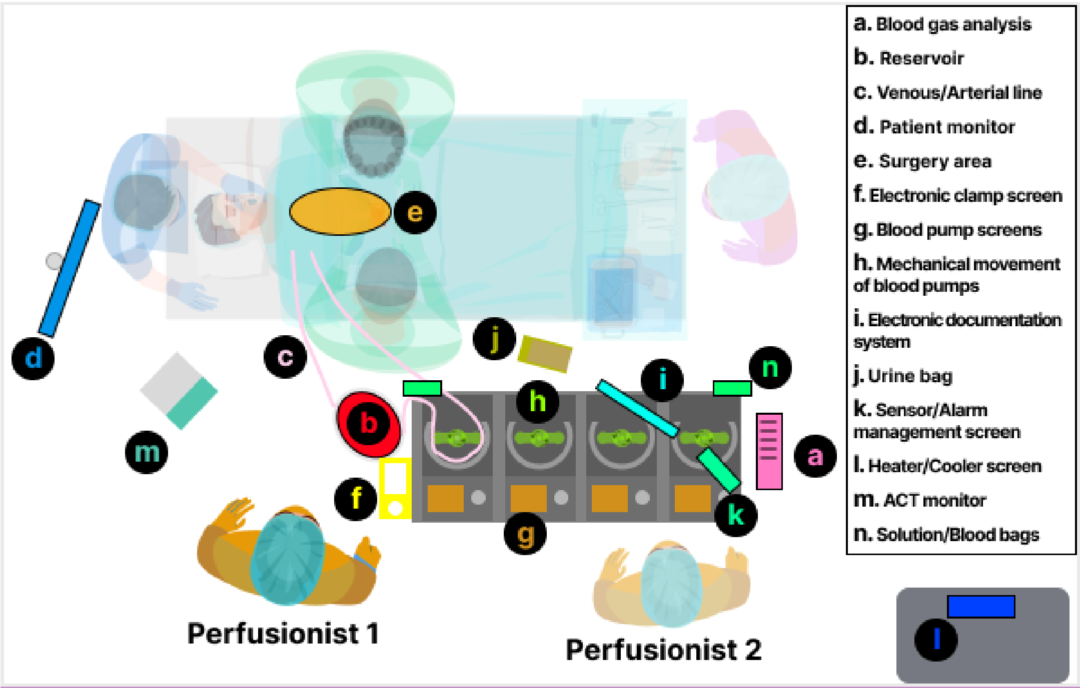

Figure 4.4. Visual information sources for perfusionists

Figure 4.4 summarizes the results of observations made in six operating rooms. However, the layout of the HLM and staff members is only representative and combines the similarities in all operating rooms observed by the researcher. The figure also illustrates the number of mediums controlled by the perfusionists as well as their common locations. The mediums are identified during observations and clarified by questions asked to perfusionists about what they were specifically checking. Each of the medium is assigned with a letter and will now be explained in detail to reflect the observation results.

a) Blood Gas Analysis Report

The report in the form of a paper printout containing the blood gas values is brought to the operating room and delivered to the perfusionist in every 15-30 minutes (see Figure 4.5). The perfusionist checks the information from blood gas analysis device in a form of a paper printout and gather them. Perfusionists need to check blood gas values in a frequency to compare them with the data in the previous printouts (see

Figure 4.6). In this way, perfusionists and anesthetists take the right decisions about what to inject to the reservoir. All perfusionists emphasized that it is one of the most important data for patient health and surgical follow-up. The importance of it was also mentioned in Section 3.3.4.6.

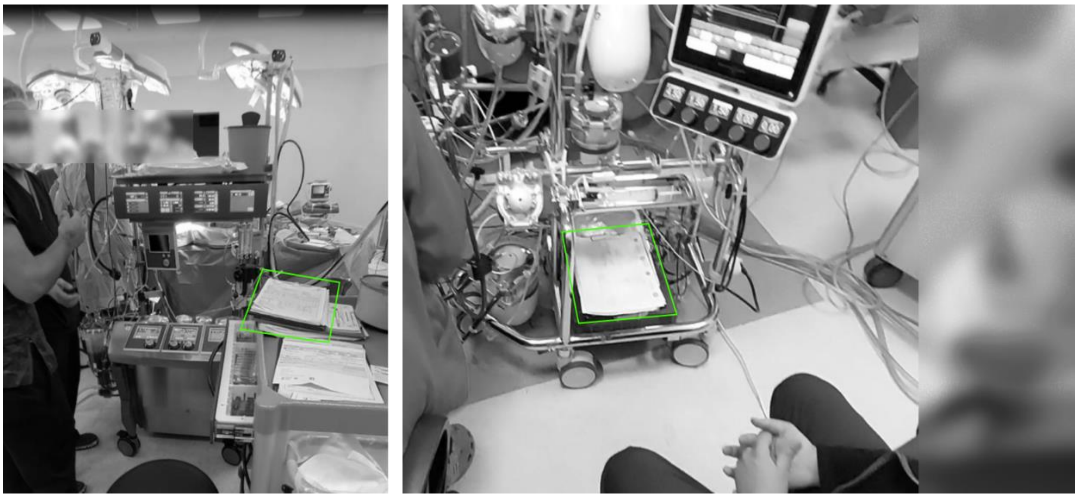

Figure 4.5. – Blood gas printout locations

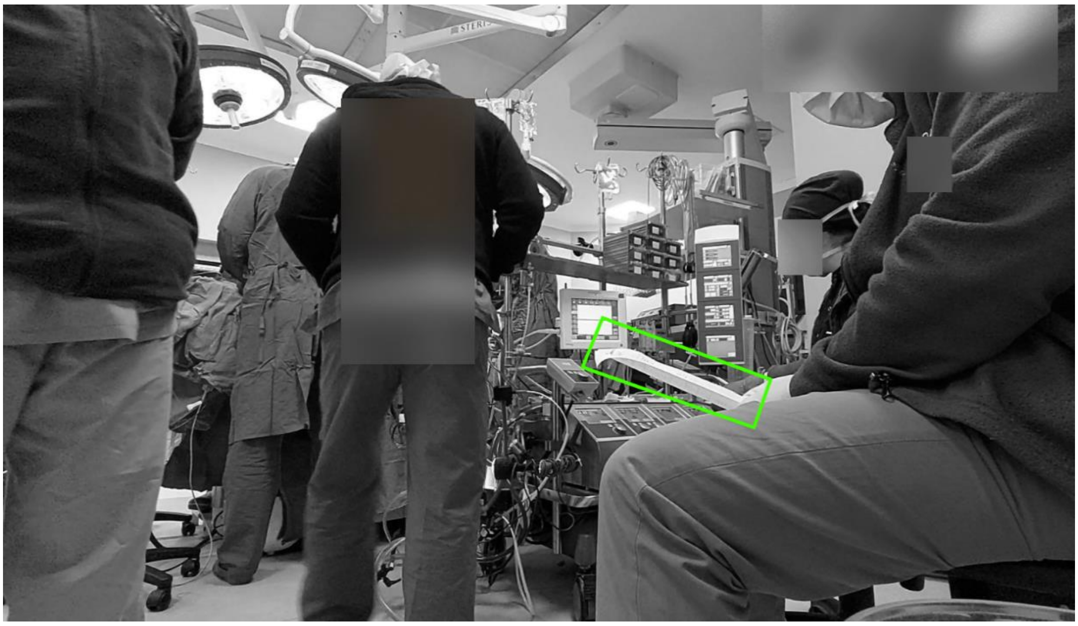

Figure 4.6. – Perfusionist checking blood gas values

Even though, Spectrum Medical–Quantum Perfusion System model has an integrated blood gas measurement feature which does not directly take blood sample to analyze the values, it was observed as not being a totally solved problem for the perfusionists as they need high precision in the measurement of this information provided by blood gas analysis device. Having the values printed on papers can be problematic for perfusionists since they need to keep their record during the surgeries. This creates a design opportunity to digitalize the flow of information and integrate new features to the HLMs, which might be integrating blood gas analysis device measurement system into HLMs or increasing the precision of measurements without taking blood samples.

b) Reservoir

Venous blood from the patient is collected in the reservoir (see Chapter 2). After a certain amount of blood is collected into the reservoir, perfusionists pump the blood to the patients by using blood pumps, allowing blood to pass through the paths to be cleaned. For this reason, there must be a certain amount of blood in the reservoir constantly during the operation. A decrease in the blood level below certain levels may cause risky situations. To prevent this, various sensors can be placed in the reservoir (see Figure 4.7).

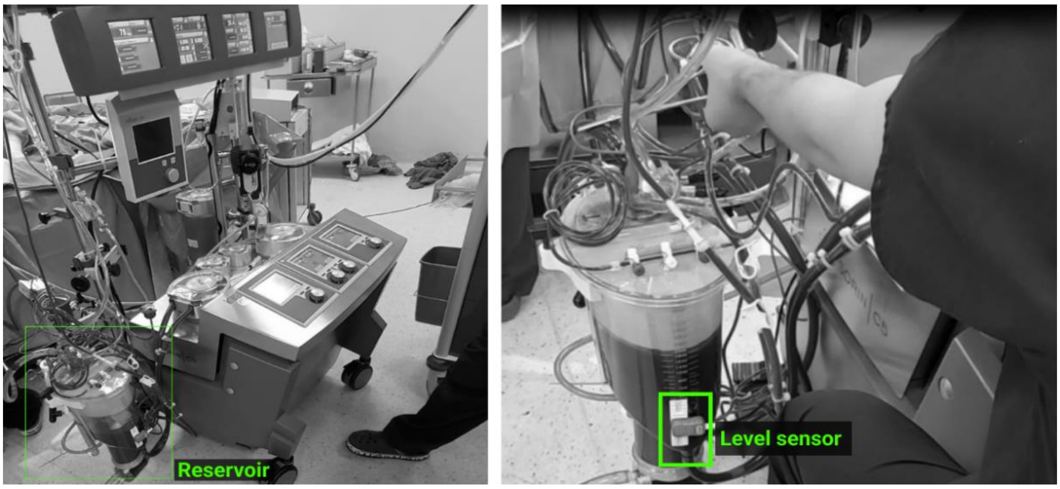

Figure 4.7. Location of reservoir and level sensor on reservoir

Although the sensors provide information and alerts about the amount of blood at critical levels, perfusionists often check the color and amount of blood in the reservoir to be sure the level of blood is not below certain levels in reservoir. This makes perfusionists to look downward while operating the HLM, since the reservoir is always located under the height of patients' beds and perfusionists' eye-level. If the perfusionists are located at the opposite side of the reservoir, they may trouble to see reservoir. The visibility of the reservoir and the blood level can be enhanced by design interventions.

c) Venous/Arterial Line

Information about flow rate in tubing lines is provided via digital interfaces with the help of sensors used on HLMs. Although perfusionists see this information from the digital interfaces, they still feel the need to physically check the flow in the tubing lines. The color of the blood in these tubing lines, the amount of flow and bubbles can be observed by looking at venous and arterial lines. This information is critical for perfusionists, and they pay particular attention to arterial and venous lines (Figure 4.8).

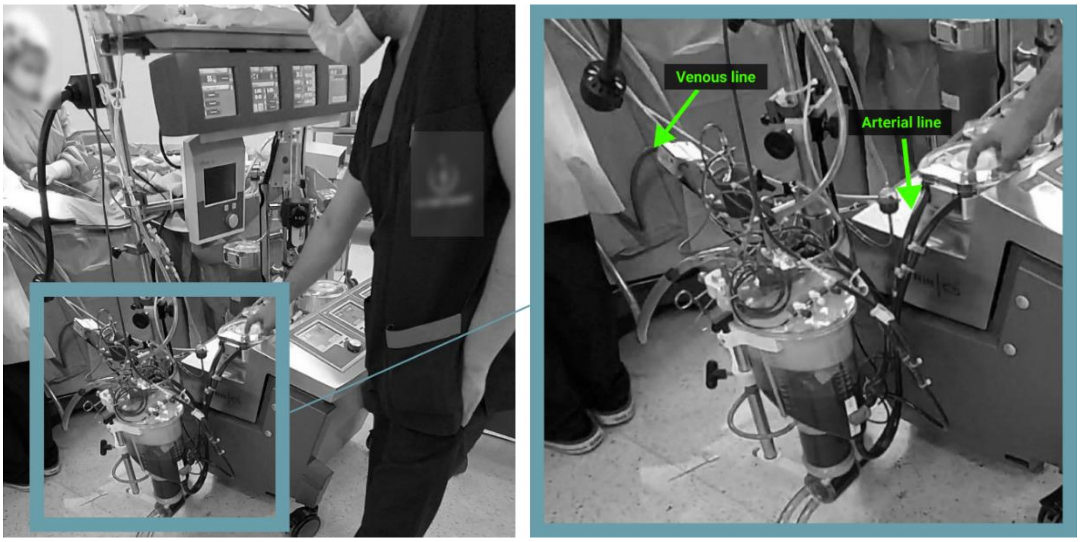

Figure 4.8. Arterial and venous lines

The color of the blood in arterial and venous lines is critical for perfusionists. The venous and arterial lines should also be providing blood flow without any obstruction such as kinking or pinching. In fact, it was observed in the observations that LED lights were used towards these tubing lines to observe the color differences and flow in lines well. It may not be easy for perfusionists to see the lines properly because of the unorganized tubing lines connected to reservoir. It can bring a cognitive load on perfusionists.

As it was also concluded in the survey and user interviews that perfusionists prioritize the safety of patients. Even though they use sensor and digital interfaces to monitor some information, perfusionists also prefer to check these physically. As was reported in ‘reservoir’ section, perfusionists do not like relying on machine feedback only. They like double-checking. This makes the visibility of the physical parts critical while considering the design of HLMs.

d) Patient Monitor

Patient monitors are usually positioned close to the patient's head in operating rooms (see Figure 4.9). All the staff in the operating room follow the data on the monitor. The observations in the operation rooms revealed that patient monitor is one of the most vital information sources for the perfusionist and they check the monitor quite frequently while at the same time interacting with HLM. This could cause potential distractions to perfusionists to realize what happens on the HLM. In addition, monitors were usually placed not in an optimal angle and position for perfusionists. For this reason, perfusionists should turn their heads towards this screen to see it while simultaneously manipulating HLM (Figure 4.10).

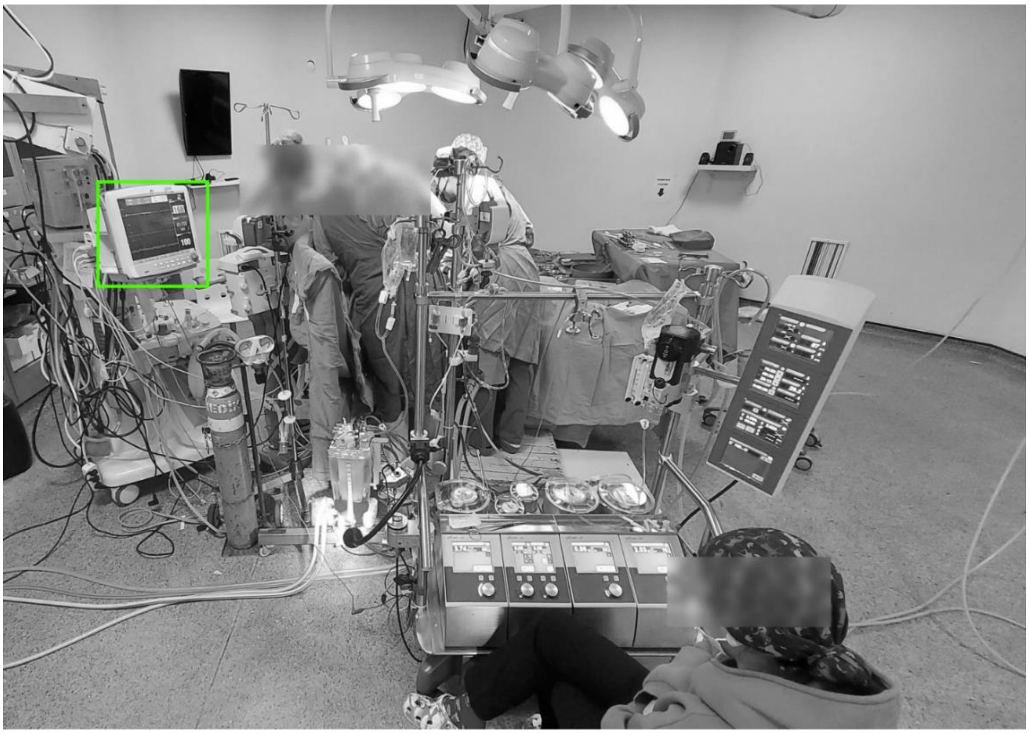

Figure 4.9. The location of patient monitor

Figure 4.10. Perfusionist checking patient monitor

This can lead to ergonomically problematic working positions and excessive physical fatigue. In user interviews, requests were previously made to show the data of some devices in operating room on HLMs. Combining the findings from user interviews and in-situ observations, it is clear that perfusionists struggle to check certain information in operating rooms and one of them was the information on patient monitors.

e) Surgery Area (on the patient's body)

The actions of perfusionists directly affect the patient's condition and the area where the surgery is performed. Especially when a HLM is used for ventilation and suction (see Section 2.1.1), the effects of blood pumps can easily be seen in the areas where the surgery is performed (e.g., rib cage). After performing such functions, perfusionists control the surgery area to observe the effects of the action they had taken. Since none of the observed surgeries had cameras to show the surgery area on live, the perfusionists needed to get up and visually inspect the operating area (see Figure 4.11).

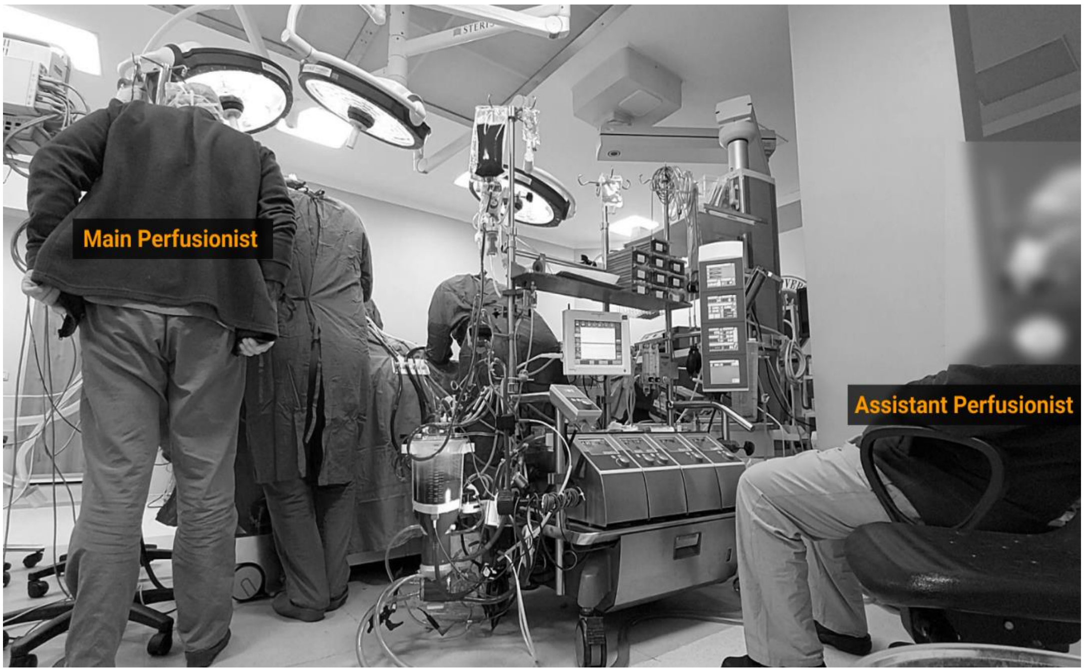

Figure 4.11. Main perfusionist checking surgery area

In interviews, it was mentioned that perfusionists may leave HLMs during the operations. It is also observed that leaving the HLM to check surgery area may cause a risk by delaying detection of adverse situations that may occur in the heart-lung machine (HLM). When perfusionists left the HLM, they had hard time to understand the situation of HLM. To understand, they asked assistant perfusionists questions about the HLM's situation. This problem can be solved with different approaches. One may be eliminating the need for getting up, or another may be letting perfusionists properly control HLM even when they leave HLM.

f) Electronic Clamp Screen

Perfusionists usually use equipment called 'clamps' to stop or slow down the flow in tubing lines. The clamps can be electronically integrated to HLMs. They have external screens or corresponding areas within the screens that show how much the perfusionist tighten/squeeze a line. (see Figure 4.12).

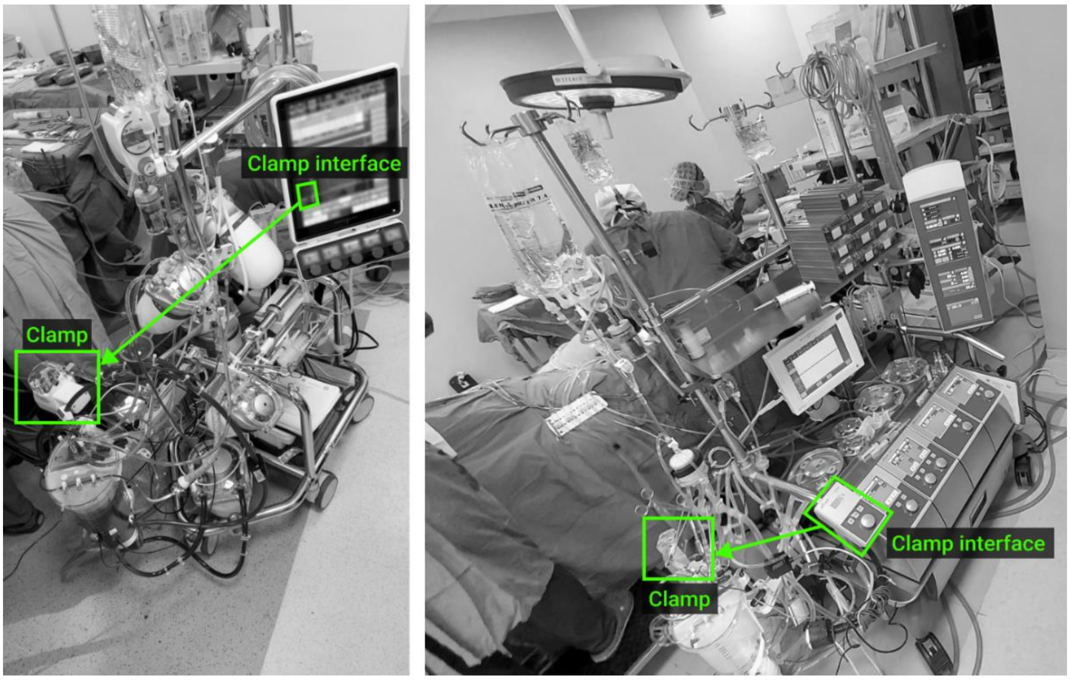

Figure 4.12. Electronic clamp screens and electronic clamps on different models

The frequency of checking this screen increases especially during surgical entrances, and the end-of-surgery procedures. Since the component which squeezes the tubing line is physically separated from its user interface, the mapping of the controls and component itself may become critical for perfusionists. The mapping between them can be enhanced visually by design interventions.

g) Blood Pump Screens

Perfusionists check blood pump screens to see whether roller or centrifugal pumps are rotating at the correct speed and providing flow at proper rates. The speed information is displayed on the digital interfaces (Figure 4.13). During observations, it is noticed that liter-per-minute (LPM) value on blood pumps is frequently checked by perfusionists and sometimes by surgeons. The mostly checked user interface of blood pumps is the arterial pump's interface. Perfusionists constantly check the LPM of the arterial/main blood pump, which is always located closer to the reservoir.

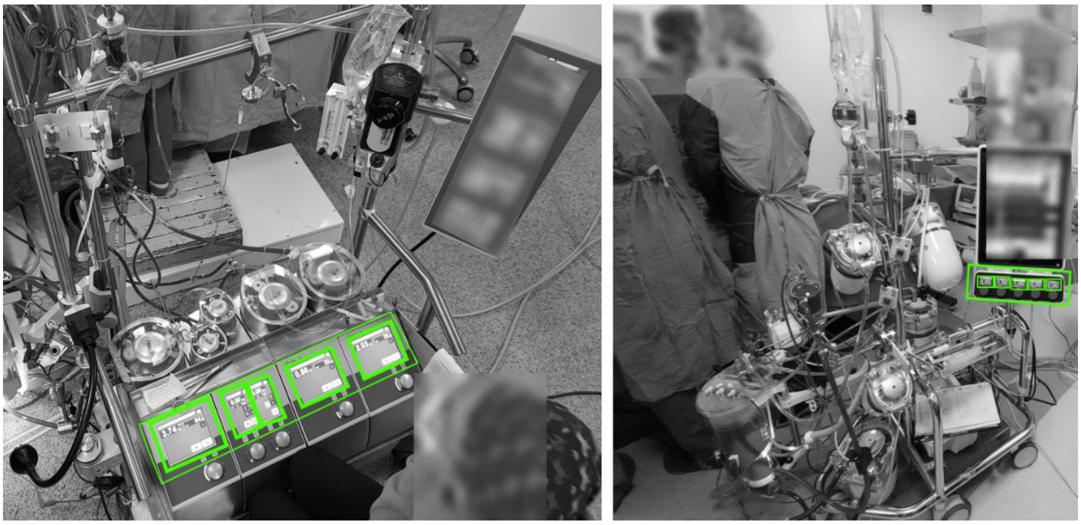

Figure 4.13. Blood pump screens in two different models observed

Using the blood pump closer to the reservoir as main/arterial blood pump makes blood pumps to be located at left or right according to the layout of the operating room. Perfusionists prefer to sit next to the main/arterial blood pump. This indicates that perfusionists need to see LPM of the arterial blood pump constantly during the surgeries together with the reservoir and arterial and venous tubing lines. Therefore, the visibility of blood pump screens when perfusionists are located closer to the reservoir has critical importance for perfusionists. This consideration plays an important role in the design of HLMs.

h) Mechanical Movement of Blood Pumps

In some HLM models such as Spectrum Quantum Perfusion System, blood pumps' digital user interfaces and their mechanical parts can be separated. Perfusionists, in all HLM models, can monitor pump rotation rates by seeing the exact values on blood pump screens. However, perfusionists constantly monitor the rotation of the mechanical parts of the blood pumps when speed changes are made or to make sure that the pump can rotate at the rates displayed on the digital interfaces. The reason for doing this might be that although there is a set speed in the system by using a knob and digital screen, there is a possibility that a foreign object has entered the pump's rotating mechanism and/or the tubing lines may have been damaged by because of the mechanical movement. In order to be sure about these issues, perfusionists also visually check the mechanical parts of the blood pump. For this reason, the HLM manufacturers may have preferred to design the pump mechanism covers/lids transparent. However, when blood pumps are placed out of sight of perfusionists (this occurs more often in Spectrum Medical-Quantum Perfusion System model since it has high modularity for their blood pumps), this can make it difficult for perfusionists to see the mechanical movement of blood pumps. Therefore, HLM designs which the blood pumps are located in visible areas for perfusionists provide higher visibility. During the observations, it was noticed that the Spectrum Medical branded HLM presented problems to provide a such visibility to perfusionists with this respect when arterial blood pumps are located away from perfusionists (see Figure 4.14). Perfusionists had to move to check the mechanical movement of blood pumps.

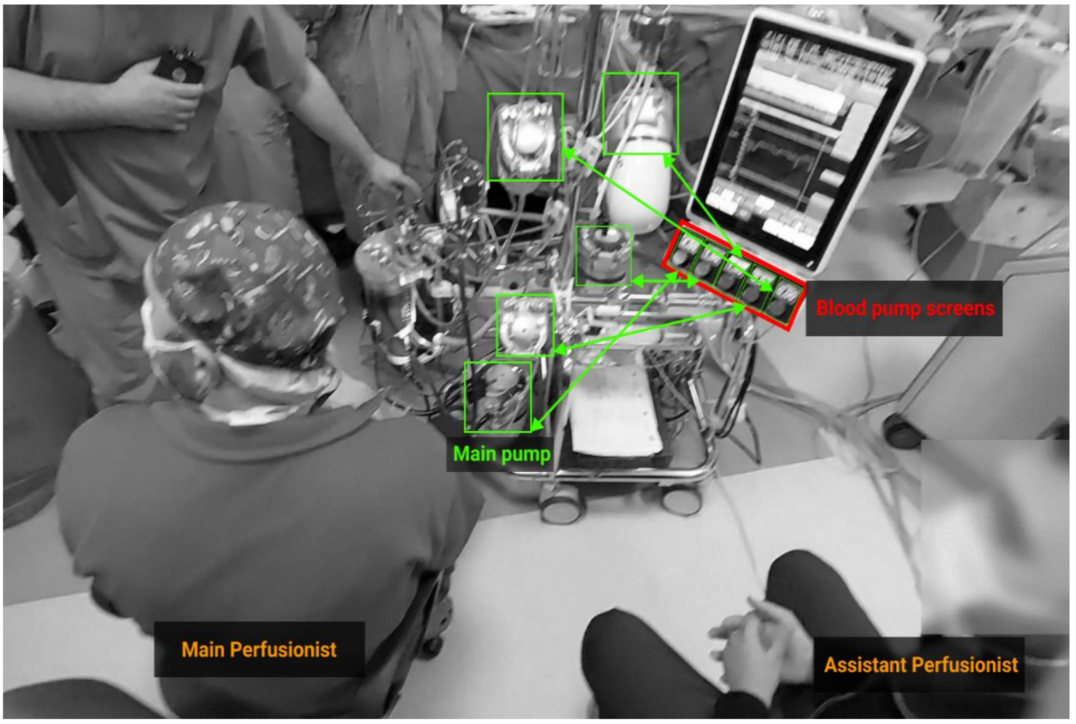

Figure 4.14. Blood pump screens and mechanical parts of blood pumps on Spectrum Medical-Quantum Perfusion System

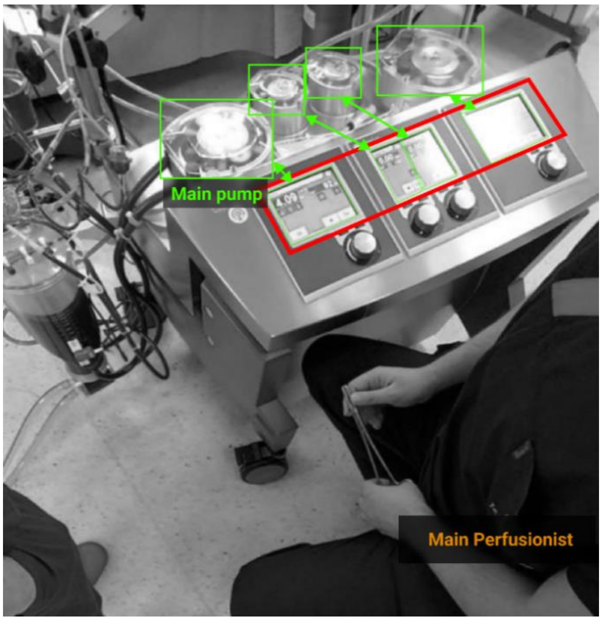

Figure 4.15. Blood pump screens and mechanical parts of blood pumps on LivaNova C5

i) Electronic Documentation System

Electronic documentation system can be found as an external screen or as a submenu of a screen on HLMs. It helps to monitor information such as history of value changes during surgeries (see Figure 4.16).

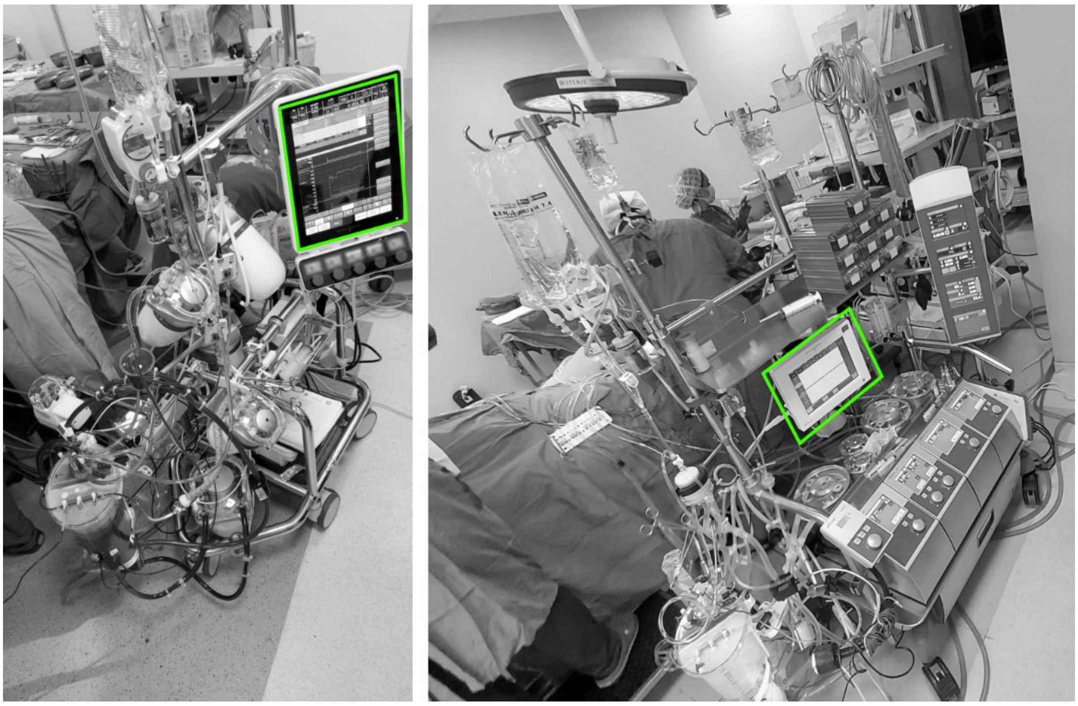

Figure 4.16. Different approaches of Spectrum Medical-Quantum Perfusion System and LivaNova S5 models for electronic documentation systems

These screens are generally controlled and used before and after surgery. During surgery, although perfusionists may refer to the screen to review some graphs, they are controlled and used very rarely compared to other mediums mentioned under Section 4.1.4.2. This made it difficult to evaluate the usage of screen by the researcher. Therefore, it can only be thought that the role of the screen has less importance during the operation for perfusionists. Only, it can be said that this screen should not overwhelm other screens on HLM.

j) Urine Bag

During the surgeries, the amount of patient’s urine gathered in the bag is also checked by perfusionists. This bag is located on the ground between HLM and patients’ bed where surgeons and nurses are. It is observed that the perfusionists could not see the urine bag from the positions they stayed, and they had to move. This causes perfusionists to stand up during the operation, which adds an additional physical workload to them. Even though it is not checked frequently comparing with the other mediums mentioned in this section, it is one of the hardest medium to be controlled because of obstacles in perfusionists’ vision. The visibility of the urine bag can be increased with the design of mobile consoles. The visibility of urine bag was higher for perfusionists who are using Spectrum Medical – Quantum Perfusion System model comparing with LivaNova S5/C5 models thanks to its open structure.

k) Sensor/Alarm Management Screen

Sensors integrated in HLM components provide information about the alert situations. Perfusionists are informed visually and audibly by the alarms, and they prioritize them (see Figure 4.17), and they take actions accordingly. Some HLM models (e.g., LivaNova S5, LivaNova C5) had individual, integrated screens for each function such as for alarms, while Spectrum Medical-Quantum Perfusion System model had only one screen to monitor and control everything, including alarms. It was analyzed that perfusionists prefer to have a specific area for alarms. In observations, it is also seen that perfusionists feel comfortable when they see the areas specified for alarms empty.

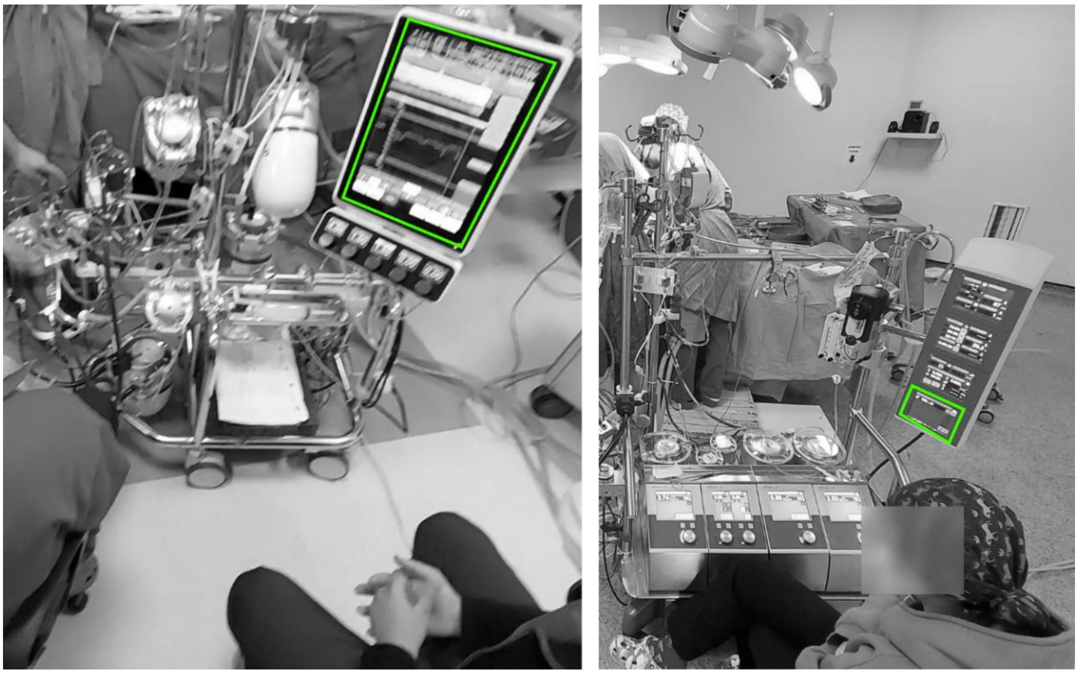

Figure 4.17. Location of screens for alarms in two different HLM models

It is not possible to suggest how often perfusionists check the alarm screen(s). However, positioning of the alarm screens and their visibility are vital to help perfusionists to notice, and to take quick and proper actions.

l) Heater/Cooler Screen

Heater/cooler unit can be monitored via an interface on the HLM as well as its own screen. Usually heater/cooler unit is detached from the HLM and patient bed (Figure 4.18) because of hygiene reasons therefore the perfusionists prefer to monitor on HLM screens.

Figure 4.18. The location and interfaces of heater/cooler unit

However, in all in-situ observation sessions, perfusionists complained about the cables going in/out between heater/cooler unit and HLM as it caused an obstacle in the operation room. Therefore, some of the perfusionists preferred to use heater/cooler unit independently without connecting it to the HLM. Instead, they needed to walk across to check the displayed information since it was a cable-free option. Independent heater/cooler unit inevitably creates restriction in the room layout and additional effort for the perfusionist. Alternative cable-free designs, better solution for communicating the information between the unit and HLM (e.g., through alternative technologies) can be amongst potential directions.

m) Automated Coagulation Timer (ACT) Monitor

During in-situ observations, ACT is found to be another critical information for perfusionists during the operation. They are checked by perfusionists after dose of heparin and after starting the operation. ACT devices can be located on various places in operating rooms. There is no standardized position in operating room for them. In the observations, they were usually placed not in an optimal angle and position for perfusionists. Perfusionists needed turn their heads towards the ACT device when they needed. It increases the required motion of perfusionists while using the HLM, which can be problematic. The position of ACT information should be standardized according to the position of perfusionists. Thanks to this, perfusionists can know where to look at when they need to see the information.

n) Solution/Blood Bags

Solution/Blood bags are used for containing various types of solutions. They are placed on mast systems on HLMs (see Figure 4.19). Perfusionists need to check the level of them to operate safely. However, they do not receive any direct feedback when solutions are finished. For example, there is no sensor that helps to inform perfusionists about the amount of liquid rest in the bags, therefore they need to be located within eyesight. This may not be always possible, but still perfusionists need to control them. The design of HLMs should provide proper positions for the bags. Also, their visibility and the situation requiring constantly checking them can be improved thanks to the design interventions.

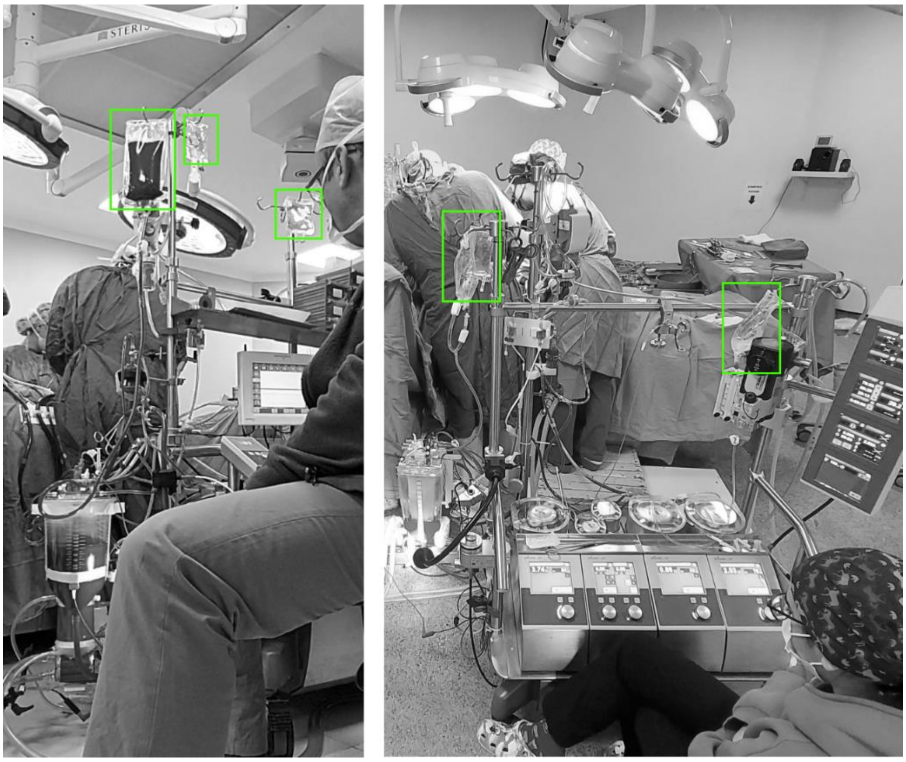

Figure 4.19. Location of solution/blood bags

4.1.4.3 Interactions and Actions of Perfusionists

Previous section concentrated on what perfusionists control/check during the operations. In this section, the interactions, and actions of perfusionists in operating rooms will be explained based on observation results. This is believed to help teams focusing on a heart-lung machine design to understand which areas the interactions are concentrated, and which issues should be prioritized during design phases.

Figure 4.20 illustrates the perfusionists' movement pattern with lettered dotted arrows during surgical operations. Accordingly, a) Interactions with blood gas analysis device, b) Interactions with reservoir, c) Interactions with tubing lines and clamping, d) Interactions with blood pump controls, e) Interactions with electronic documentation system, f) Interactions with alarms and sensors, g) Interactions with heater/cooler unit, h) Interactions with blood/solution bags, i) Interactions to take needed equipment.

The explanation of the action means will be detailed in the section.

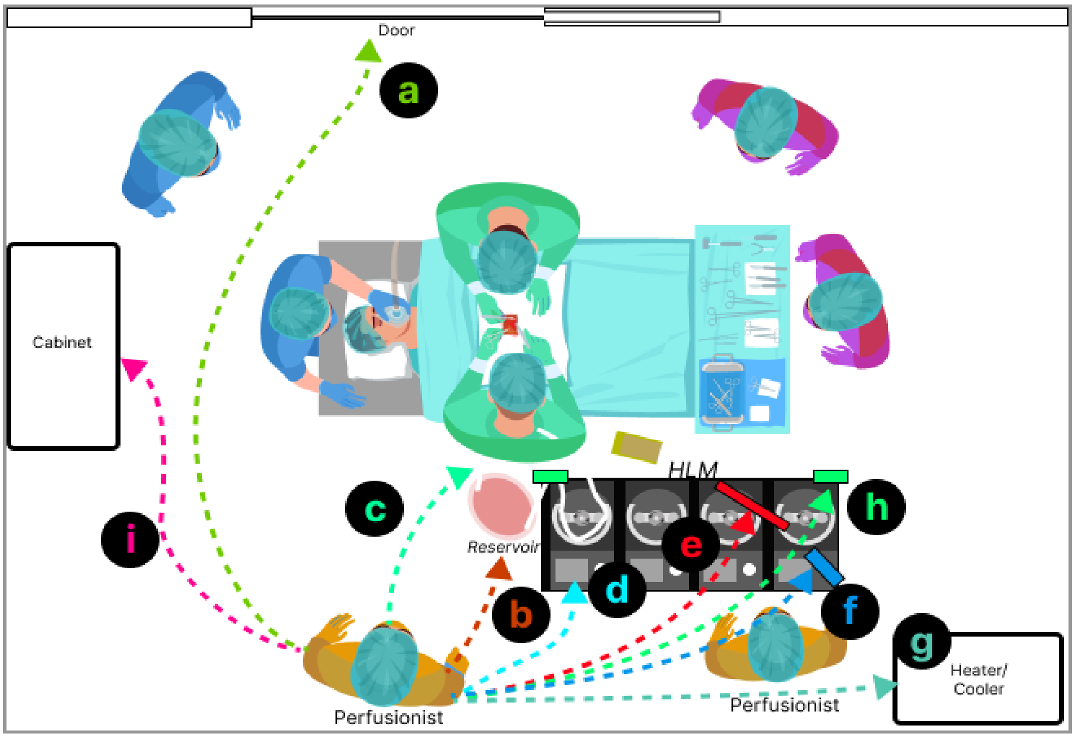

Figure 4.20. Mapping of the movement and actions of perfusionists

a) Interactions with Blood Gas Analysis Device

It was observed that the blood gas analysis devices were located outside the operating rooms in a common room so that all perfusionists can use them. Due to insufficient number of blood gas analysis devices, sometimes the device needed to be used in simultaneous cardiovascular surgeries running in different operating rooms. The blood gas values are measured every 15-30 minutes (depending on the preferences of perfusionists and the patient's case) during the operations. Even though some HLM models, for example the Spectrum Medical – Quantum Perfusion System model, have integrated blood gas measurement sensors which helps perfusionists by decreasing their frequency of using blood gas analysis device, perfusionists prefer to use blood gas analysis device for its high precision in its measurement.

This situation requires at least having one additional person from the operating room to go out and bring printout papers from the blood gas analysis device. In case of malfunction or maintenance need of the blood gas measurement device, it may take longer to transmit the printout with the blood gas values to the relevant operating room personnel (anesthetists and perfusionists). Usually, assistant perfusionists take the blood sample, bring the printout, and write down some of the blood gas values onto the sheet in order to keep a record of them (see Figure 4.21).

Figure 4.21. Assistant perfusionist taking note of blood gas values on paper

As mentioned, because perfusionists need high precision in the measurement of blood gas values they prefer to use blood gas analysis device. This causes perfusionists to leave the HLM, which may increase risks in the usage of HLMs by making only one perfusionist perform until the other one comes back. If the blood gas value measurement could be done precisely without a need to leave HLM, the risks could be decreased. Also, if the values obtained by the blood gas analysis device could be provided to the screens that can be seen by perfusionists while operating HLM, it could help them to get values, record and follow them in a more efficient way.

b) Interactions with Reservoir

Reservoir is one of the most frequently interacted components by the perfusionists during operations. They directly interact with the reservoir to inject solutions and drugs into it (after evaluating the situation with anesthetists) by using syringes, and to take blood samples for blood gas analysis. Interactions with the reservoir are usually carried out by assistant perfusionists and may result in uncomfortable posture as can be seen in Figure 4.22).

Figure 4.22. Assistant perfusionists taking blood samples and injecting solutions

c) Interactions with Tubing Lines and Clamping

Perfusionists can change the amount of flow in tubing lines by using mechanical or electronic clamps. Electronic clamps have their own user interfaces and controls, whereas mechanical clamps are used by directly squeezing the tubing lines. Perfusionists usually use clamps in coordination with the blood pumps in a simultaneous manner (see Figure 4.23). This can be a challenging task not only because of the coordination requirements, but also the complexity and messiness of the tubing lines attached to the reservoir. Especially, when perfusionists use mechanical clamps, they always need to consider where to squeeze the lines from. This can be challenging for them. Additional visuals on lines that will be used as arterial or venous line can be used to direct perfusionists to highlight their location.

If mechanical clamps can be fixed in their positions without squeezing the lines, it can be easier for perfusionists to squeeze the correct lines in each usage. For the electronic clamps, the need for coordination between blood pumps and the clamp can be eased with digital user interface designs or algorithms that can automate the coordination of these components.

Figure 4.23. Perfusionist interacting with blood pump and clamp simultaneously

d) Interactions with Blood Pump Controls

As mentioned in Section 2.1.1.1, blood pump controls are one of the display and control panel elements of HLMs. Perfusionists are responsible for adjusting the speed of the blood pumps for each separate task in surgeries according to ry.

Perfusionists can manipulate the speed of flow in tubing lines by changing the rotation speed of pumps by controlling them via knobs for each blood pumps. There are various purposes of blood pumps such as pumping the blood to the patient, ventilating the heart, giving the cardioplegia to the surgery area, and sucking the blood from surgery area. During the observations, the perfusionists mostly interacted with the arterial/main blood pumps. The exact number of interactions was not counted, but the observations clearly showed that, arterial blood pump controls were the most interacted component compared to any other part information/feedback obtained from different mediums mentioned in Section 4.1.4.2, commands from the surgeon and the on-going conditions on during the surges of HLM. One of the perfusionists with 18 years of experience mentioned that: “95% of our interactions with the HLM are the one with arterial blood pump” to highlight their usage frequency of the main blood pumps.

e) Interactions with Electronic Documentation System

As mentioned before, the surgical operation has three distinctive usage scenarios, “pre-operative”, “operation” and “post-operative”. Interactions with electronic documentation system usually occur at “pre-operative” and “post-operative” stages. Perfusionists use these systems to configure and to follow data. They usually do not require to manipulate these screens during the operations. Therefore, during the observations they do not need to be close to the perfusionists for possible interactions.

f) Interactions with Alarms and Sensors

During the observations, it was noted that one of the most important functionalities offered by the HLM was giving alerts in the situations when the patient’s vital measures were out of safe range. Perfusionists try to eliminate situations causing an alarm, but when it happens, they direct their attention to alarms. This makes the interactions with alarms one of the most important interactions. By considering this, the interactions with alarms should be designed fool-proof because in such situations, perfusionists take actions in a rush. The standards such as EN 60601-1-8, EN 60601-1-1-6 mentioned in Section 2.2.2 can guide designers to reduce the risks in such situations.

g) Interactions with Heater/Cooler Unit

Interactions with heater/cooler unit can be done by using HLM screens or the screens and controls placed on the unit itself. During the observations, the assistant perfusionists usually preferred to manipulate the settings of the heater/cooler by using the controls placed on the unit according to temperature instructions given by the main perfusionist. This required moving next to the unit.

When asked, they mentioned that in order to use the heater-cooler unit over HLM, they need to connect the devices to each other with a cable. The cable can create an obstacle in the room for operating room staff. Therefore, even if it is more difficult, they do not prefer to connect HLM and heater/cooler unit.

This shows the problem of the connection between two units in operating room. Their controls could be done from a single point by not creating any physical obstacle in operating room to solve the problem.

h) Interactions with Blood/Solution Bags

During the surgical operations, perfusionists are likely to use some solutions or additional blood resources contained in bags. Perfusionists interact with the bags hung on mast systems on HLMs (see Section 2.1.1), when they need to adjust the flow rate, or to replace them with the newer ones on masts. They rarely interact with the bags during the operations. They get up and take new solutions bags by leaving the HLM for a short period. Getting up to get solution bags can be challenging for perfusionists if the solution bags are stored in a location away from perfusionists. Not to make perfusionists walk much to get them, their location for storage should be considered while designing the layout of operating rooms.

i) Interactions to Take Needed Equipment

During the operation, perfusionist may need different tools/items such as mechanical clamps, solution and drug containers, syringes, and folders. For ease of reach, these are usually stored on the HLM surfaces (see Figure 4.24).

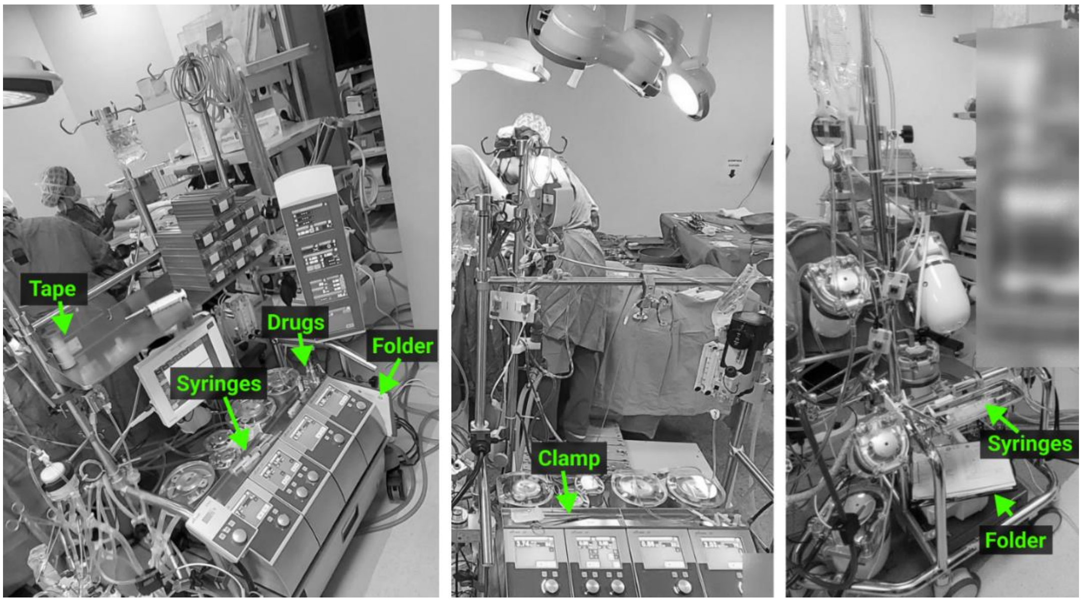

Figure 4.24. The items stored on HLMs

Especially, when only mechanical clamps are used in operations, perfusionists need to get them quickly. They can sometimes drop the clamps from the HLM because there is no safe storage provided (see Figure 4.25). Dropping them cause perfusionists to lose time as the clamps need to be sterilized or replaced. These show us that storage areas on HLMs have high importance for quick interactions. The design of storage areas can decrease the time for perfusionists while searching for needed items/tools. This can increase their experience with HLMs.

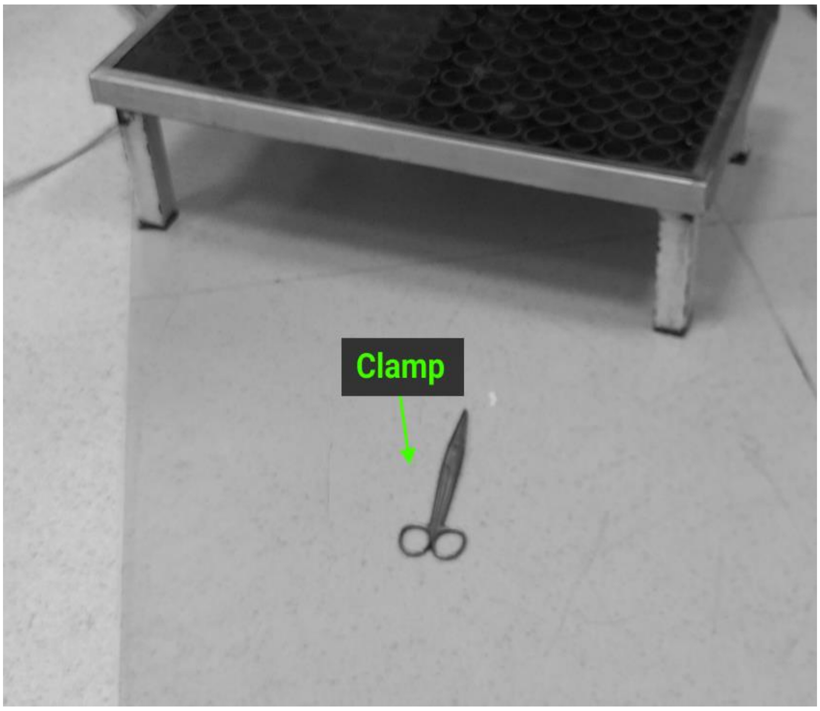

Figure 4.25. A clamp dropped on the floor during the operation

CHAPTER 5

CONCLUSIONS, REFLECTIONS AND DISCUSSION

The final chapter will give answers to research questions in light of the literature review combined with 3-phase fieldwork. Findings will be summarized in categories, design recommendations about HLMs will be made and suggestions will be given for further studies.

5.1 Summary of the Field Research

The field research included Chapter 3 and Chapter 4. In Chapter 3, a survey and interviews were used to explain needs and expectations of perfusionists. In Chapter 4, in-situ observations were used to investigate the problems of perfusionists during the surgeries.

In total, 23 perfusionists participated in the survey. In the survey, there was a high-experienced participant population, whose age distribution was 30-40 and 50+, all but one participant had more than 10 years of experience and had up-to-date knowledge and frequently used heart-lung machines. If we look at the HLM models that these participants used before, it was usually LivaNova S5/C5, Maquet HL20 and Terumo Advanced Perfusion System-1 models, respectively. For this reason, the comments given by the user group were based on their experiences with these HLM models.

The results of the survey revealed the expectations of perfusionists from HLMs as safe and easy usage. While commenting about the criteria they consider while evaluating HLM models in the market, the participants mentioned about physical and digital user interface properties. In relation to physical properties, they highlighted issues about quick interactions, safety of components and customization.

In relation to digital user interfaces, quick interactions, content, customization, and easy to understand interfaces were discussed.

During interviews, it was seen that perfusionists demand safety for patient and ease of use from HLMs as it was revealed in survey. Additionally, as physical properties, perfusionists highlighted their expectation about mobility and size. Also, they mentioned some issues about staff in operating room, maintenance, and other uncategorized issues. Interviews also helped to elaborate on the issues revealed in the survey.

In Chapter 4, the interactions of perfusionists, operating room from perfusionists' perspective and communication interactions of perfusionists during operations were explained in detail under three themes (i.e., perfusionists' communication during operations, operating room from perfusionists' perspective, interactions, and actions of perfusionists). Communication between the perfusionists and other surgical team members was explained under four headings (i.e., perfusionist-perfusionist, perfusionist-anesthetist, perfusionist-surgeon, perfusionists-nurse).

While explaining the operating room from perfusionists perspective 14 mediums that provide visual information for perfusionists were explained. These were blood gas analysis, reservoir, venous/arterial line, patient monitor, surgery area, electronic clamp screen, blood pump screen, mechanical movement of blood pumps, electronic documentation system, urine bag, sensor/alarm management screen, heater/cooler screen, ACT monitor, solution/blood bags.

The interactions of perfusionists during the operation were explained under nine headings. The interactions were; interaction with blood gas analysis device, interactions with reservoir, interactions with tubing lines and clamping, interactions with blood pump controls, interactions with electronic documentation system, interactions with alarms and sensors, interactions with heater/cooler unit, interactions with blood/solution bags and interactions to take needed equipment.

In-situ observations helped to understand the problems of perfusionists during the surgeries. In each section, the identified problems were discussed while explaining the details of actions of perfusionists, communication of perfusionists and the information provided visually to perfusionists. The identified problems can be grouped under five topics:

i. Issues about digital user interfaces on HLM
ii. Issues about physical requirement of perfusionists
iii. Issues about storage
iv. Issues about communication
v. Issues about operating rooms

The results of observations supported the results of the survey and interviews. In-situ observations allowed to directly study the complexity of interactions performed by the perfusionists, as well as their cognitive and physical load. This also helped to clarify perfusionists' needs and expectations resulted from the survey and interviews. It explained their needs about content, customization, quick interactions, understandability, and safety of components.

A detailed checklist will be presented in Section 5.3.1.1. taking into account all of the topics covered in the research. This checklist lists the required issues to design a successful HLM, based on the field research done here and personal, professional experience of the researcher.

5.2 Revisiting Research Questions

The research tried to find answers to three main questions. Combination of methods were used to answer the questions in a three-phased fieldwork. Phase 1 (Heart-Lung Machines: Orientation for Function and Usage) of the fieldwork aimed to introduce HLMs, their functionality, evolution of HLMs, the factors and considerations that are important in the design of the HLM by making use of literature review. Phase 2 (Perfusionists: Needs and Expectations) of the fieldwork included a survey with 23 perfusionists and a follow-up interviews with nine perfusionists and a heart surgeon to understand their needs and expectations of from HLMs. Finally, Phase 3 (Heart-Lung Machines in Operating Room: In-Situ Observations And Experiences) of the fieldwork involved the researcher observing eight cardiac surgeries in operation rooms to understand the usage context and experience of perfusionists during the operations in detail.

The fieldwork also helped to map out the interactions and multiple stakeholder (i.e., surgical staff) experiences within the cardiovascular surgery in operating room; to establish ways in which the experience of using/operating HLM can be improved taking into account multiple factors in the operating environment; to reach some design suggestions for improved HLM design by considering the needs of perfusionists.

In this section, the answers given by revisiting the questions are brought together and summary answers are presented to following research questions.

- What are the factors affecting perfusionists' performance during cardiovascular surgeries (e.g., physical, cognitive)?
- What are the expectations of perfusionists from HLMs?
- What are the opportunities for improving the experience of perfusionists while using/operating HLM?

5.2.1 What Are the Factors Affecting Perfusionists' Performance During Cardiovascular Surgeries? (e.g. physical, cognitive)

In order to understand the factors that affect the performance of perfusionists during surgery, first of all, a comprehensive literature search was conducted on the areas of responsibility of perfusionists, the duties and functions of heart-lung machines and what their parts do, the features of existing HLMs and the environment in which HLMs are used. In addition to these, a user-centered study examining the behavior of perfusionists by Wiegmann *et. al.* (2009) was examined. Insights were gained about variety of duties that perfusionists have while operating the HLMs, different design approaches for HLM designs across different models, and how operating room layout and collaboration between operating room staff can affect the work of perfusionists.

The survey and interview results both showed that perfusionists' needs and expectations from HLM are prioritised around the safety of patients and ease-of-use of the HLM. Having hesitations about HLM failure and patient safety can create a cognitive load on perfusionists. Also, perfusionists mentioned the importance of quick interactions and information content on HLMs in the survey and interviews. In observations, it was seen that they expect these to ease their monitoring of various information sources. Observations showed that having variety of mediums around the operating room can cause a high cognitive load on perfusionists. Additionally, interviews showed that there are some issues related with physical aspects that can challenge the perfusionists, such as mobility and size of the HLM. These can affect the workflow and performance of the perfusionists during operatiions.

Since the information gathered from reviewing the literature as well as from the survey and interview results represent the ideal situations that perfusionists relayed, in-situ observations helped to investigate the "reality". Another purpose of the observations was to examine the overall experience of perfusionists. In this way, the factors affecting perfusionists were tried to be understood from a broader perspective.

The researcher participated as an observer in eight different cardiovascular surgeries (see Section 4.1.2), All the behaviors of the perfusionists during the operations were examined by taking notes, videos and photographs. When necessary, the researcher clarified the actions taken in the operating room by asking immediate questions to the perfusionists. The observations helped to gather information on diverse topics that was not possible to clarify from the literature, and sometimes from the survey and interview results. When the literature review, interviews, survey and observation results are brought together the factors that perfusionists are influenced while carrying out their responsibilities can be listed as follows.

- Quality of communication and collaboration with the operating room staff
- Clear distribution of tasks across operating room staff
- Perfusionist's level of experience
- Performing alone or with someone (i.e., second perfusionist)
- Comfort of the perfusionist
- Size and layout of the operating room
- Visibility of the operating area
- Locations and visibility of related information and interactions
- Ergonomic reach zone (for components)
- Distance to required equipment
- Design of storage areas
- Size of the HLM
- Feeling safe (using HLM)
- The variety of content provided via HLMs

5.2.2 What Are the Expectations of Perfusionists From HLMs?

Expectations of perfusionists from HLMs were tried to be uncovered by the survey and user interviews. First, through survey, the features they like within existing HLM models were identified, the functions and issues that perfusionists cared about HLMs were revealed as a result. In the user interviews, the criteria revealed in the survey were explored, additionally, new topics were also uncovered. According to the results of user interviews and the survey, the expectations of perfusionists from HLMs can be listed as follows:

- High visibility and intelligibility of the information provided by HLM
- Decreasing the risks for patients
- Decreasing the hemolysis of blood

- Providing sufficient information about the surgery
- Quick and easy interactions
- Allowing customizations

5.2.3 What Are the Opportunities for Improving the Experience of Perfusionists While Using/Operating HLM?

To answer this question, literature review, survey and interviews, and in-situ observation results were used. The literature provided information about the-state-ort-art situation in general, and helped to identify some of the design features of current HLM models in the market. In relation to this, Chapter 2 introduced the current situation that can be improved. Related medical equipment design standards were also provided.

As mentioned in Chapter 1, the research was motivated from a professional design project as part of the researcher's role in designing an improved HLM for the company he was working for. The fieldwork results helped identify pain points and come up with new design proposals. Due to confidentiality reasons, it cannot be shared in the content of the thesis. Yet, according to this design research and the inferences in the design process, suggestions are presented in the following. Apart from aspects that could be improved in heart-lung machine design, other considerations can also be considered to improve the overall experience of the perfusionist. The opportunities that can be used to improve perfusionists' experiences identified are as follows:

i. Developing features that can reduce risks for patients
ii. Developing solutions that consider differentiating operating room layouts
iii. Considering communication and collaboration with operating rooms staff
iv. Providing sufficient information in an efficient way
v. Decreasing the physical requirements of perfusionists
vi. Increasing the understandability of digital user interfaces

vii. Allowing customizations

In following Section 5.2.3.1, a checklist is provided for designers who are involved in designing HLMs. Design intervention suggestions are provided in the checklist to benefit from these opportunities mentioned here.

5.2.3.1 Suggestions to Improve Experience of Perfusionists While Using/Operating HLM

In previous Section 5.2.3. while answering the question about how the experience of perfusionists during the operations can be improved, seven opportunities were presented. To benefit from these opportunities, and to provide perfusionists better experiences, some design interventions can be done. These design suggestions will be provided as a checklist. The checklist is created by using the results of literature and fieldwork combined. Since the researcher had gained experience in designing HLM, some personal/professional suggestions are added to the checklist. People who are interested in or responsible for designing HLMs can benefit from the checklist.

i) Developing Features That Can Reduce Risks for Patients

In the survey and user interviews, it was seen that perfusionists prioritize safety of patients while evaluating HLMs. They expect HLMs to be safe and function in extreme cases. They also expect HLMs to harm patients' blood at minimum levels. To achieve these, following suggestions can be provided:

- Batteries used for HLMs should be long-lasting in case of a power cut
- The materials and mechanisms should be designed by considering their durability. The material decisions should be taken accordingly.
- At least one blood pump that can be used as arterial blood pump should be placed as close as possible to reservoir and patients to reduce the tubing line length, which decreases the hemolysis of blood.

- Alarms should be distinguishable and clear enough to direct perfusionists about the alert given, and necessary actions.
- Some autonomy features should be added in case of distraction of perfusionists.
- HLM design should provide connection points for reservoir under the level of patient bed to let blood flow thanks to gravity.
- HLM design should prevent components from any damages because of accidental hits, liquid spillages.
- HLM design should provide enough space for storing required blood/solution bags and needed equipment while using HLM.
- Touch screens should be used to help perfusionists to take quick action while controlling user interfaces in emergency cases.
- The components (when broken) should be replaced easily and quickly during the operations.
- The actions that can affect safety of patients should be visible and easy to access.

ii) Developing Solutions That Consider Differentiating Operating Room Layouts

During the in-situ observations and as the outcome of the literature review, it was noted that operating rooms may have different layouts even though there are some standards for their layout. Apart from the layouts, operating rooms may also differ in their sizes. To be able to meet the differentiating needs of operating rooms, the following suggestions can be provided:

- The dimensions of HLM should be reduced to the minimum to make them suitable for cramped operating room environment.
- The mediums that perfusionists frequently check during the operations should be located in operating room according to the position of perfusionists to reduce the movements of perfusionists.

- The equipment that perfusionists may require should be located close to the HLMs to reduce the movement of perfusionists.
- HLMs should not have sharp edges or corners to prevent any harm because of any undesirable accidents.
- HLMs should be stable they staff in operating room hit them accidentally. They should not move during the operations. To achieve this lock systems on wheels can be used.
- HLM and heater/cooler units should be integrated in a way that does not cause any mess in the operating room like cable connections cause.

iii) Considering Communication and Collaboration with Operating Rooms Staff

As it was suggested that communication and collaboration have vital importance during the cardiovascular surgeries by Wiegmann *et al.* (2009). This was also supported by the fieldwork results as the perfusionists were observed to be constantly in interaction with other operating room staff during the operations to communicate and collaborate with each other. The suggestions to enhance these interactions can be listed as:

- Task distribution between staff should be clear for all staff.
- A standardized communication language should be used between staff to decrease the confusion. It is especially important for critical actions such as changing the flow rate of arterial blood pump.
- HLMs' user interfaces should also be visible for operating room staff, in addition to perfusionists.
- Some additional equipment can be used to increase the audibility of communication between perfusionists and surgeons because of the loudness of operating rooms.

- HLMs should not make unnecessarily loud noises not to affect communication between staff negatively. If possible, audible alarms can be distinguishable so that all operating room staff can understand the alert.

iv) Providing Sufficient Information in an Efficient Way

The survey and interview results showed that the perfusionists expect HLMs to provide a variety of information during the surgeries. During in-situ observations, it was also realized that they control many other information soruces while controlling the HLM. To make monitoring processes easier for the perfusionists, the following can be suggested:

- Sensor integrations should be increased. For example, color identifying sensors can be used to differentiate the color of blood in arterial and venous lines.
- Surgery area should be visible to the perfusionists via HLM’s digital user interfaces by using/integrating cameras.
- The devices such as blood gas analysis device, patient monitor, ACT monitor should be integrated with HLMs, so that they can be monitored in HLM’s digital interfaces.
- Blood gas analysis devices should be located in operating rooms, or HLM sensors’ precisions should be improved to evaluate blood gas values constantly. Moreover, some integrated blood gas measurement systems to HLMs can be designed.
- Position of the mediums that perfusionists monitor should be decided in a way that perfusionists can easily see.

v) Decreasing the Physical Demand of Perfusionists

In-situ observations showed that perfusionists need to constantly move during the surgeries. They sometimes need to leave the HLM and to not cause any mistakes they prefer to work not alone but with a perfusionist partner. To improve their experience, the physical load they have can be decreased by following suggestions:

- HLMs should be easy to move. It can be achieved by decreasing the weight of components or increasing the capabilities of mechanisms that help them to move such as wheels.
- Operating room layouts should consider the required actions by perfusionists and optimize their movements.
- Reachability of components should be increased by providing modular blood pumps and reducing the size of HLM.
- Regular breaks should be provided for perfusionists by letting them change with another perfusionists during the operations
- HLMs should have some automation features that reduce the need of physical coordination such as changing the speed of blood pumps while clamping and monitoring patient monitor.
- Perfusionists should be positioned in a place from where they can reach and monitor their mostly interacted components such as reservoir, arterial/venous lines, arterial blood pump controls and information, arterial blood pump's mechanical part.
- HLMs should provide proper storage areas that standardize the location of critical equipment that perfusionists use.
- Blood gas measurements should be done precisely without needing to go out of the operating room.

vi) Increasing the Understandability of Digital User Interfaces

Ease of use was one of the mostly mentioned issues when HLM models were evaluated in the survey and during the interviews. Perfusionists monitor a lot of information during the operations, and they take actions accordingly. Therefore, they need clear user interfaces which do not cause any confusion. To achieve this, the following suggestions can be made:

- Related information should be grouped together according to their meanings.
- The information should be provided with a visual hierarchical order according to their importance for perfusionists.
- The contrast of colors used in interfaces should let perfusionists get information easily while not causing them eyestrain.
- The information architecture should be designed according to the needs of perfusionists.
- Perfusionists' habits and experiences with popular models in the market should be considered. The design solutions can benefit from them to ease the training process of perfusionists.
- Proper size of screens should be used for adequate size for visual elements on user interfaces.

vii) Allowing Customizations

The survey and interview results revealed that perfusionists need some of the HLM features to be customizable. To achieve this:

- Modular blood pumps should be used to let perfusionists locate them where they prefer.
- Some features on digital user interfaces should be provided to let perfusionists customize and personalize according to needs of surgery and perfusionists.

5.3 Limitations of the Research and Reflections of the Researcher

The COVID-19 pandemic was one of the factors that had a significant impact on the research. During the pandemic, many hospitals did not want to admit researchers into operating rooms. Another reason, regardless of a pandemic, the operating rooms have high levels of precautions in terms of hygiene. The COVID-19 pandemic has also created problems in terms of face-to-face meetings. Especially in the early stages of the research, there were problems in contacting people to conduct user interviews and arranging meetings. All scheduled meetings were held wearing masks, which added a level of difficulty to communicate with perfusionists.

Ideally, all interviews were planned individually. Due to challenging conditions in pandemic interviews were mostly conducted in a group setting. Some participants were more willing and enthusiastic compared to others in group interviews whereas the others expressed their opinions less. However, the researcher gathered opinions of multiple perfusionists, which as a whole gave insights about their needs and expectations.

In addition, the fact that the field of research requires a lot of knowledge has been a challenging process for the researcher. In the early research stages, the researcher had to take time to understand the subject. Complexity of the subject made it hard to understand the user group at the beginning. The terminology used between the perfusionists also created difficulties in terms of communication between the researcher and perfusionists. However, after getting used to the terminology that perfusionists use, the communication between the researcher and perfusionists improved dramatically, and became smooth. This improvement in communication can be beneficial for further research since the researcher can have smoother conversations with perfusionists.

During the in-situ observations in the operating rooms, trying not to be positioned in a way that would obstacle the work of any of the operating room personnel, trying not to distract the perfusionist during the operation, and in some cases not being able to ask questions to the perfusionists were challenging situations for the researcher. It was also challenging to take part in cardiac surgery observations since the researcher was not trained as a healtcare personel. Luckly, all the attended surgeries ended with positive outcomes.

Arranging the appropriate time and environment for the observations was another challenging issue. Perfusionists' schedules and not being able to attend surgeries that include high risks for patients caused the researcher to attend only adult patients' surgeries that have low risks.

There are a lot of HLM models in the market. Popularity and the usage rate may verry from country to country. In this research, only a few HLM models were integrated because of their accessibility in the studied hospitals.

5.4 Further Research and Recommendations

Within the scope of this thesis, the expectations, needs of the perfusionists and the general experience they have, were investigated. The research was conducted by prioritizing the interactions of perfusionists during heart surgeries. For this reason, before and after operation (e.g., preparing HLM for surgery, maintenance of HLM) processes were not examined in detail within the scope of research. These two processes are also important in order to improve the experience of perfusionists in hospitals. Future research can cover the issues about before and after operations as well.

This research was carried out in three cities in Turkey during 2021-2022. Although the perfusionists' general concerns, needs and expectations may remain similar, some of the specific observations may become out of date they as the HLM designs, the practice of using heart-lung machines and regulations evolve day by day. New emerging technologies, changes in the perfusionists' training methods, developing methods in cardiovascular surgeries may significantly affect the expected features from HLMs and the job descriptions of the perfusionists in the future. Therefore, in future research it would be necessary to relate the needs and expectations with these in mind. In addition, conducting similar studies in different countries will be beneficial for the development of an international, inclusive understanding.

5.4.1 Recommendations for Designers

As mentioned earlier, the researcher started the topic with a professional motivation, while at the same time working as an industrial designer, responsible for both the design of the device and digital user interfaces of a HLM. Throughout the research, the researcher professionally managed the design processes in parallel with the research outcomes. Although these are not direct outcomes of the fieldwork, the researcher's professional design duties affacted the progression of the fieldwork and the decisions about the research methods to be included in the methodology. Within these processes, there are some recommendations and professional reflections that can be put forward especially for designers.

Since HLMs are very complex devices by their nature, new information is constantly being learned during the design process. At the very beginning of the design process, it is almost impossible to complete the entire design if a previous design process for HLMs has not been managed yet. For this reason, managing the HLM design process by diving into parts will enable designers to work more accurately. In this way, the design process should be managed in smaller parts: once an overall conceptual design has been created, designers can manage the design process by focusing on different parts of the device. Since the blood pumps are among the most critical functions of the device, it can be suggested that the design process can start with the design of the blood pumps after determining the general interaction design approach.

In this process, it is essential to get ideas and expert information from different groups of perfusionists who participate in different types of surgeries. In particular, the adoption of the "research through design" approach (Dorst, 2011) in the design process makes a great contribution to the improvement of the design by making trial and error quickly. In order to do this, it is critical to get ideas from users by making lots of low-fidelity models during the design process. For the 3D design of the device, making models in real size (1:1) makes an important contribution to better evaluation of ergonomics issues and for all the stakeholders working in the project to work more efficiently.

As it is often repeated in the research, the most important criterion by perfusionists is "patient health". Designers should always make decisions by prioritizing patient health. For example, if a decision that improves the ergonomics of the perfusionist adversely affects the patient's health, then the factor that affects the patient's well-being should be prioritized so that both hospital management and perfusionists can use the device more resentful.

Another suggestion that can be made to designers is to gain extensive knowledge in order to be able to master every detail about the device and to offer a holistic approach, which was the case in this research. In this way, design decisions that affect each other with a domino effect can be made in a proper way. It is hoped that this thesis illustrates this important point to designers in this sense. If designers cannot find any chance to attend in-stu observations, it can be suggested for them to communicate with perfusionists to ask them to demonstrate their usages of HLMs. By this way, the interaction patterns of perfusionists during the surgeries can be visualized and understood.

Since the standards, defined in the literature, play a critical role in the certification processes of medical equipment, designers should always consider compliance with these standards. In addition, proper documentation to justify design decisions should be made for certification processes.

5.4.2 Recommendations for Design Researchers

The HLM is used in contexts that most people are not familiar with. Majority of literature covers clinical studies. For this reason, there is limited literature that design researchers can benefit from. Therefore, it is hoped that this thesis could be a useful source for design researchers as well as for designers.

It is important for design researchers to understand the device and its basic working principles. Following a general understanding of the device, the user group and the context of use should also be well understood. In this way, researchers can develop an inclusive understanding. To do this, researchers should pay particular attention to fieldwork studies about HLMs. Because most investigators have difficult access to the operating room environment, contextual information here can also be obtained from the many online videos on this topic.

Researchers should clearly define the purpose of their research. Since HLMs are a complex machines both in terms of usage and technology, each subject related to the HLM needs special attention. For example, many exposed issues, such as the before and after operation usage scenarios (e.g., preparing HLM for surgery, maintenance of HLM) of the HLM, which are beyond the scope of this thesis, are also worth focusing on. In order to include scopes like this, design researchers should primarily understand the HLM’s uses "during surgery" and gain a broad understanding of other issues as well.

One of the most important recommendations to researchers is to develop close relationships with perfusionists during the research process. Perfusionists are the most valuable resources to learn about the practical use of the technical details of the HLM. If the researchers cannot develop close relationships with perfusionists, there is an increased risk of collecting incomplete information in terms of practical uses. Perfusionists may convey their thoughts and usage practices incompletely or "as it should be" if they are not comfortable with the communication with the researcher. This may cause researchers to conduct incomplete/missing research.

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APPENDICES

A. Permissions

aselsan
Ulaşım, Güvenlik, Enerji, Otomasyon ve Sağlık Sistemleri Sektör Başkanlığı
Transportation, Security, Energy, Automation and Healthcare Systems Business Sector

ASELSAN ÖZEL

Konu: Eren Dönertaş'ın Yüksek Lisans tez çalışması kapsamında yürüttüğü alan çalışmasına dair gerekli izinler hk.

Sayın İlgili,

Eren Dönertaş, ASELSAN UGES'de MTM biriminde endüstriyel tasarımcı olarak çalışmaktadır. Kendisinin Orta Doğu Teknik Üniversitesi, Endüstriyel Tasarım Bölümü'nde, Prof. Dr Bahar Şener-Pedgley danışmanlığında 'kalp-akciğer makinelerinin tasarımı' alanında yürütmekte olduğu tez çalışması kapsamında yapmış olduğu tüm anket, mülakat, inceleme ve gözlemlere dair etik ve diğer gerekli izinler kurumumuz tarafından sağlanmıştır.

Saygılarımla bilgilerinize sunarım.

Umut Ç
Proje Yöneticisi

Tarih: 01.11.2022
İmza:

ASELSAN-UGES 1 / 1 **Tarih 01.11.2022**
Sistemdeki güncel revizyon kodu ve tarihi taşıyorsa geçerlidir - It is valid only if it has the current revision code and date in the system.

ASELSAN ÖZEL

B. Survey Questions

1

(Heart-lung machine survey)

Kalp Akciğer Makinesi Anketi

Bu anket, ASELSAN UGES tarafından hazırlanmış olup tasarlanacak olan kalp-akciğer makinesi için perfüzyonistlerin kalp-akciğer makinaları hakkındaki fikirlerini öğrenmek amacıyla sizlere iletilmektedir. Yapacak olduğunuz katkı bizler için çok değerlidir. Katılımınız için teşekkür ederiz.
(This survey was prepared by ASELSAN UGES to gather your ideas for the design process of a new HLM. Your contributions are so valuable for us, thanks.)

Giriş) Kişisel bilgiler: **(Introduction) Personal information)**

Cinsiyet: (Gender)

○ Kadın (Female) ○ Erkek (Male) ○ Diğer (Other)

Yaş: (Age)

○ <20 ○ 20-30 ○ 30-40 ○ 40-50 ○ 50+

Aktif çalışma süresi: (Active work experience)

○ 0-2 yıl (years) ○ 3-5 yıl (years) ○ 5-10 yıl (years) ○ 10+

1) Kalp akciğer makinesi kullanım sıklığı: (Heart-lung machine usage frequency)

○ Haftada 1 veya daha az (once or less in a week)
○ Haftada 2-7 (2-7 times in a week)
○ Haftada 8-15 (8-15 times in a week)
○ Haftada 15+ (15+ times in a week)

Kalp akciğer makineleri değerlendirmesi: **(Heart-lung machine evaluation)**

*Bu bölümde kalp-akciğer makineleri ile **(Görsel 2)** ilgili fikirleriniz değerlendirilecektir.*

(In this section your thoughts about heart-lung machine models (Figure 2) will be evaluated)

2) Aşağıdaki kalp-akciğer makinesi modellerinden hangi modelleri kullandınız? ***(Görsel 2)***
Kullanmış olduğunuz kalp-akciğer makinesi modellerini kullanım sıklığını belirtiniz.

(Which heart-lung machine models (Figure 2) did you use? Identify the usage frequency of the ones that you used before)

○ LivaNovaS5/C5 → *Kullanım sıklığı:* (Usage frequency) ○ 1-5 kez (times) ○ 5-10 kez (times) ○ 10-20 kez (times) ○ 20+ kez (times)

○ Terumo [Advanced Perfusion System] → *Kullanım sıklığı:* (Usage frequency) ○ 1-5 kez (times) ○ 5-10 kez (times) ○ 10-20 kez (times) ○ 20+ kez (times)

○ Maquet HL20 → *Kullanım sıklığı:* (Usage frequency) ○ 1-5 kez (times) ○ 5-10 kez (times) ○ 10-20 kez (times) ○ 20+ kez (times)

○ Century Heart-Lung Machine → *Kullanım sıklığı:* (Usage frequency) ○ 1-5 kez (times) ○ 5-10 kez (times) ○ 10-20 kez (times) ○ 20+ kez (times)

○ Brale Biomedica Bec → *Kullanım sıklığı:* (Usage frequency) ○ 1-5 kez (times) ○ 5-10 kez (times) ○ 10-20 kez (times) ○ 20+ kez (times)

○ Spectrum Medical-Quantum Perfusion System → *Kullanım sıklığı:* (Usage frequency) ○ 1-5 kez (times) ○ 5-10 kez (times) ○ 10-20 kez (times) ○ 20+ kez (times)

○ Diğer: .... → *Kullanım sıklığı:* (Usage frequency) ○ 1-5 kez (times) ○ 5-10 kez (times) ○ 10-20 kez (times) ○ 20+ kez (times)

(Heart-lung machine survey)

Kalp Akciğer Makinesi Anketi

3) Kullanmış olduğunuz kalp-akciğer makinesi modelleri arasından hangilerini en başarılı buluyorsunuz? Lütfen yanıtınızı sebepleriyle birlikte açıklayınız.
(Which heart-lung machine models do you find successful? Please explain your answers with the reasons.)

- ○ LivaNovaS5/C5
- ○ Terumo [Advanced Perfusion System]
- ○ Maquet HL20
- ○ Century Heart-Lung Machine
- ○ Brale Biomedica Bec
- ○ Spectrum Medical-Quantum Perfusion System
- ○ Diğer: ....
  (Other)

modellerini başarılı buluyorum. Çünkü...

(I find the .... model(s) successful, because ....)

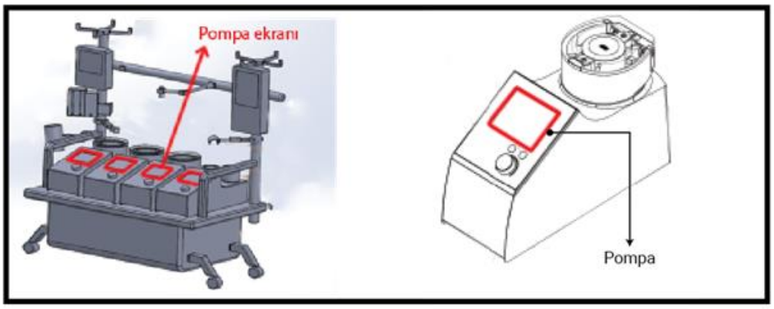
3

(Heart-lung machine survey)

Kalp Akciğer Makinesi Anketi

Örnek Görseller

(Visual examples)



Görsel 1 - Temsili Kalp-akciğer Makinesi ve Pompa Gösterimi

(Figure 1) (Heart-lung machine and visualization of a pump unit)

Görsel 2 - Kalp-akciğer Makinesi Modelleri

(Figure 2) (Heart-lung machine models)

C. Interview Questions

1. Can you introduce yourself?

2. What is heart-lung machine? Why are they used? Can you tell me whole process of usage? Can you explain all of your interactions with HLM?

3. Can you explain the general context of usage? Can you explain the relationships of operating room staff? What are your considerations about the usage of HLM in surgeries? How do you decide where to locate HLM?

4. Do you have specific stories that you want to mention about the usage of HLM?

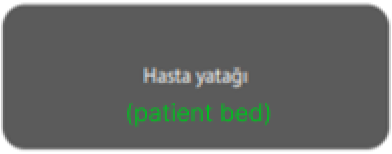
5. What kind of properties do you like/dislike in current HLMs? Why?

6. If you were designing a heart-lung machine, how would you do it? What properties would it have?

D. Note Taking Sheet for In-situ Observations

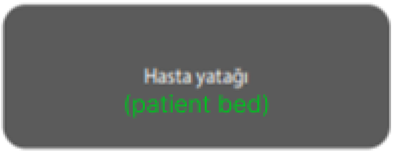
Cihazın oda içerisindeki yerleşimi, oda içi cihazların, çalışanların konumları/görevleri:

(The location of HLM, other devices in the room, and staff, also role of staff)

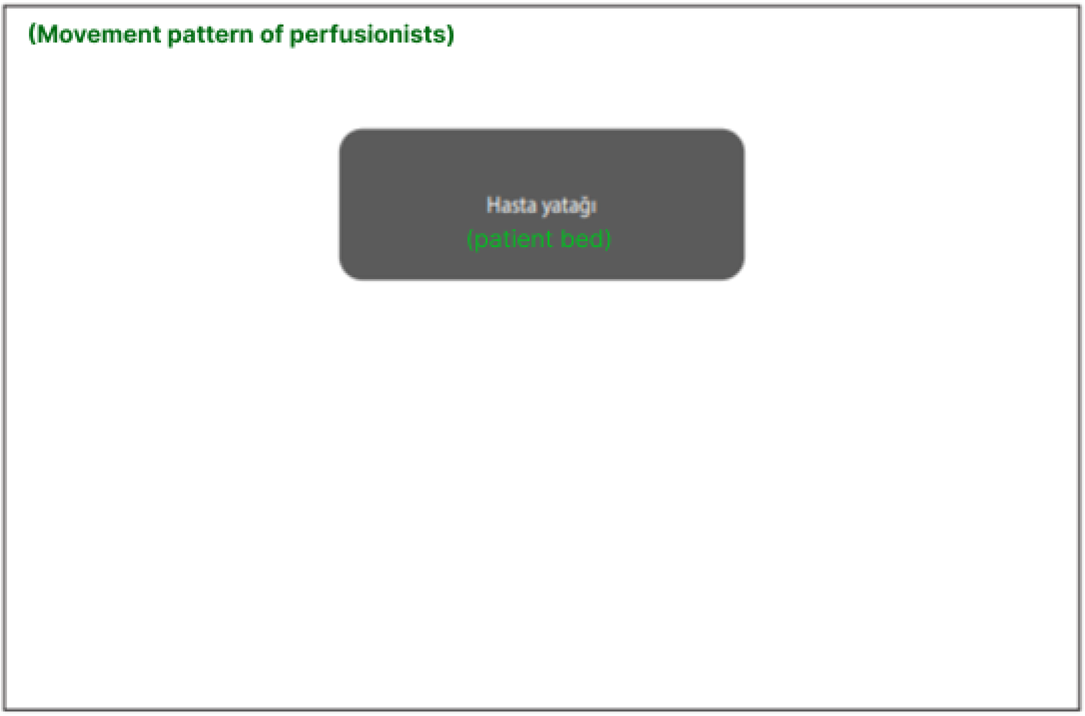


Cihaz üzerinde komponent yerleşimleri(pompa, ekranlar, sensörler):

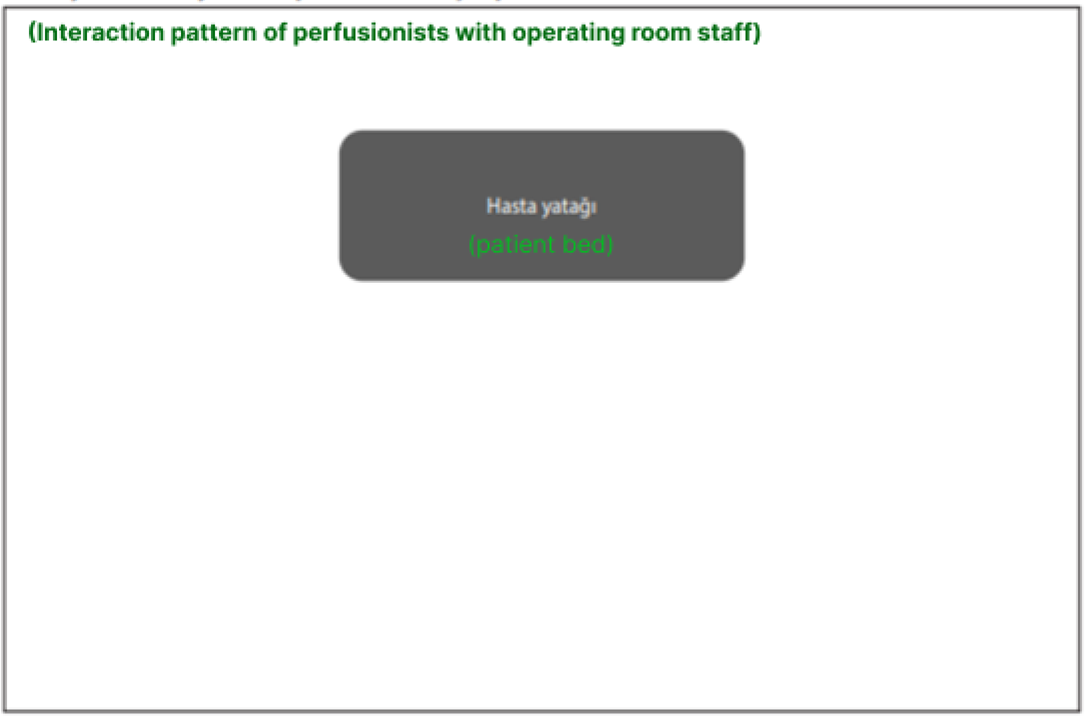
(The location of components on HLM (pumps, screens, sensors))



Perfüzyonist hareket pattern:



Perfüzyonist-ameliyat odası personeli etkileşim pattern:



Harici bağlanan atılabilir komponentler (Rezervuar, venöz tubing, arter tubing vb.) (Disposables)

Kan gazı karıştırıcı (mixer) (Blood gas mixer)

Sensör ekranları (sadece LivaNova için geçerli) (Sensor screens (only for LivaNova))

Isıtıcı-soğutucu ünite: (Heater-cooler unit)

Venöz klemp (mekanik veya elektronik): (Venous clamp(mechanical or electronic)

Arter Pompa:
(Arterial pump)

Suction Pompa:
(Suction pump)

Ventilasyon1 Pompa:
(Ventilation 1 pump)

Ventilasyon2 Pompa:
(Ventilation 2 pump)

Kardiyopleji 1 Pompa:
(Cardioplegia 1 pump)

Kardiyopleji 2 Pompa:
(Cardioplegia 2 pump)

Cerrah1: (Surgeon 1)
Cerrah2: (Surgeon 2)
Anestezist: (Anesthetist)
Ameliyathane hemşiresi: (Operating room nurse)
Diğer perfüzyonist: (Other perfusionist)

Ameliyat:
(Surgery)

Ameliyat tipi:
(Type of surgery)

Ameliyat süresi:
(Duration of surgery)

Ameliyat cihaz hazırlama süresi:
(Duration of HLM preperation)

Cihazı kullanan perfüzyonist sayısı:
(Number of perfusionists using HLM)

Perfüzyonistin yaptığı işlemler:
(The actions that perfusionists do)