Final Project

Group B5

BMEG 357

April 12, 2024

DHF1 - Needs Assessment

Group B5

BMEG 357

January 26, 2024

Table of Contents

Changes summary

Changes	Description
Stakeholder analysis expanded upon.	To provide a deeper perspective on specific impacts and requirements regarding each stakeholder group.

The Medical Problem:

There is a surge in demand for medical device training of Biomedical Engineering Technologists (BMETs) at the Lower-mainland Biomedical Engineering (LMBME). However, the only options are factory training and in-house training. Factory training on the other hand involves BMETs commuting to factories to receive training, which is too expensive and is limited in availability. In-house training requires instructors to come in to train, which is limited by equipment availability, not as good quality and not as flexible scheduling-wise. According to Young, the client of our project, one training session takes 8 hours to complete.[1] The long training session increases scheduling difficulties and marks the importance of a new training method that is scheduling-free.

Inadequate training due to these cost and time constraints may affect the maintenance quality of medical devices as BMETs who are not properly trained lack experience and knowledge of the devices. According to research conducted by Li, Jiansheng, and others, the maintenance quality of medical equipment directly influences the work efficiency of hospitals and the health outcomes of patients.[2] The consequences can greatly impact hospital operations, as medical facilities rely heavily on the proper functioning of medical devices on a daily basis. Furthermore, Moyimane et al reported that malfunctioning medical devices can lead to compromised patient care, delayed diagnostics, and interruptions to essential healthcare services.[3] As the LMBME team expands, the need for cost-effective and flexible training strategies becomes critical to ensure safety and efficiency within hospitals.

The economic impact of the problem involves many aspects. As Young mentioned, inadequate training may result in increased maintenance costs, as malfunctioning or poorly maintained devices require more frequent repairs and replacements.[1] Malfunctioning or unavailable medical devices also lower the quality of healthcare services provided.[4] Compromised patient care could also result in financial burdens for healthcare facilities as they face potential legal consequences according to the Hospital Act of BC.[5] Additionally, compromised patient care due to malfunctioning medical devices is considered a “Medical Device Incident” and needs to be reported to Health Canada and may result in the device being regulated or removed from the Canadian market.[6] On a broader scale, efficient healthcare services contribute to maintaining overall public health, sustaining societal productivity, and promoting national confidence and economic benefits.[7]

The problem does not just affect stakeholders directly involved, it also impacts healthcare workers, patients, and the general public who rely on the effective functioning of medical devices for quality healthcare services.

Defining the Scope

Our client, LMBME, faces several challenges in providing up-to-date and sufficient training to its numerous BMETs who are responsible for managing over 110,000 medical devices across 27 hospitals in the lower mainland.[8] Specifically, in the scope of this project, LMBME lacks the resources to efficiently provide Becton Dickinson (BD) Alaris infusion system training to its BMETs. As detailed in the project briefing, the specific problems faced by LMBME in providing training are as follows:

<u>Problem 1. Budget constraints:</u> The cost of vendor training sessions can be expensive, and the limited budget restricts the number of training sessions that can be offered each year to BMETs.[8]

- The medical device industry is constantly evolving. In 2020 alone, 332 new class III and IV medical devices were approved for clinical use in Canada.[9] Therefore, restricting the number of BMETs trained each year can pose a significant challenge in keeping LMBME's BMETs up-to-date with the latest advancements in medical devices.

<u>Problem 2. Training space:</u> There is limited adequate space to conduct large-scale training sessions.[8]

- Limited space for each training session necessitates multiple sessions rather than a single large-scale one, potentially putting unnecessary strain on the budget.

<u>Problem 3. Equipment availability:</u> There is a shortage of medical devices available for hands-on training.[8,10]

- The standard training procedure typically requires the BMET to physically handle the device, fostering comfort and confidence for eventual repair attempts.[1] However, a shortage of medical devices available for hands-on training limits the number of BMETs trained each year.[10] Similar to problem 1, this situation has the potential to cause BMETs to fall behind in staying up-to-date with new device maintenance procedures, particularly with the introduction of new medical devices or updates to existing ones every year.

<u>Problem 4. Scheduling constraints:</u> Organizing training sessions within the available time frame is challenging.[8]

- To best optimize the budget, large-scale training sessions would be conducted, minimizing the overall number of sessions. However, scheduling constraints may lead to multiple, smaller sessions being hosted, impacting the budget.

LMBME's problem revolves around the continuous and effective training needed for BMETs in the rapidly evolving field of medical devices. Our task in developing a training methodology for the BD Alaris infusion system is just one instance illustrating the resource constraints faced by LMBME in providing training. This issue is a subset of a broader challenge prevalent in the North American healthcare industry. Shortages of medical devices in the United States[11] and Canada[10] in recent years have made hospitals less likely to lend out numerous devices for large-scale BMET training.[12] Furthermore, the scarcity of medical devices and shortage of qualified instructors[13] contribute to the high costs associated with renting devices or hiring instructors for the training of new BMETs.[1,12]

Analysis of Alternative Solutions

While there are several approaches to training BMETs on medical devices other than factory training and in-house training, they offer trade-offs in different aspects. The following table describes the strengths and weaknesses of various training models.

Table 1. Strengths and Weaknesses of different training methods

Method	**Strengths**	**Weaknesses**
Factory Training[14]	● Fairly established in the industry ● Conducted by experts from the manufacturers ● Comprehensive ● Somewhat flexible schedule	● Higher cost for trainers ● Limited opportunities; fixed schedule, budget constraints ● Large-scale training requirements may not be met
In-House Training[14]	● Less expensive than factory training ● Hands-on interaction with devices ● Tailored to specific equipment	● Incurs expenses in equipment maintenance and space management ● Limited availability of devices ● Limited training size ● Commuting
Online Simulated Training[15,17]	● Cost-effective compared to hands-on methods over time ● Can be accessed remotely ● Not limited by space or scheduling restrictions ● Diverse simulations for training	● Lack of hands-on experience ● Limited realism for physical equipment ● May lack immediate feedback ● Can have a high upfront cost
Recorded Video Training[16]	● Flexible accessibility and repeatability	● Limited interactivity ● Lack of hands-on

	● Consistent information to all BMETs ● Most cost-effective option	experience ● Potential for distractions
Blended Learning Program[18]	● Flexible delivery ● Cost-effective ● Continuous learning	● Resource intensive to develop ● Requires clear communication and guidance

Costs Analysis

Online options can be quite flexible to schedule they often sacrifice the hands-on interactivity that would be crucial in developing one's practical experience.[15] Online simulation training is likely to be more cost-effective long term compared to traditional factory and in-house training, Initial technology and software set-up costs only around $26,896 to $67,241 Canadian dollars.[19] Compared to in-house training, which can cost approximately $3500 for one trainer and has a limited capacity for training sessions,[1] often requires booking multiple trainers, leading to quickly accumulating costs. This leads to long-term spending, as new trainees would require more training sessions, whereas online approaches can be accessed continuously and used repeatedly requiring little maintenance. Recorded training videos are the most cost-effective solution, as prices to commission a training video can cost around $1,500 a minute,[20] and a 20-minute training session for the Infusion Pump[1] would cost a total of $30,000. A blended program may be an effective approach as it can effectively address strengths from both virtual and hands-on methods while minimizing the downside. However, the in-person aspect may require trainers and would end up including hiring costs. To mitigate this, providing a mixed reality solution would be expanding on this idea. It would incorporate a better virtual interaction with hands-on feedback, allowing for an independent hands-on experience without the need for supervision.

Limitations of Current Solution

Currently, the client has a one-time, one-trainer approach that takes place for 8 hours, where training sessions cover principle operation, how parts and sensors work, theory, technical training, preventative maintenance, assembly and disassembly, and troubleshooting common problems.[1] Although they consider it an adequate solution, a one-time session would struggle to build long-term confidence in performing maintenance procedures. Thus an effective training method should address these issues, while also providing a more sustainable approach involving better scheduling flexibility and more cost-effective measures.

Stakeholder Analysis

Perspective of operators

- Reducing patient mortality is facilitated by prompt access to emergency care and the utilization of diagnostic and therapeutic instruments, and improvements in the efficiency of training can significantly raise the rate of success in practical emergency treatment, which is needed by the technicians.[21] Their need is mostly focused on the precision and the effect of virtual training compared to hands-on training. Another need could be the convenience of training since that is one of the major differences between virtual training and traditional physical training.

Perspective of administration works at the hospital

- More skilled BMETs on the ground to keep medical equipment running safely and effectively, and lack of which can make the efforts and investments to improve patient care stymied.[21] For better planning and guidance to the national development of medical service, better virtual interaction training is strongly needed by administration staff. improved training can result in a 35.37% reduction of out-of-service equipment,[22] which is also beneficial to the long-term ongoing development of the health system, and helps hospitals make better investment decisions. The needs of administration are mainly focusing on the sustainability and cost of virtual training. An increase in skilled BMETS will decrease the turnover time between devices being broken and getting fixed as there will be more technicians who are trained to fix them. This is important to hospital administrators as it will enhance the management of medical equipment and resources. Their concerns may stem from the alignment of the training outcomes with hospital goals and regulatory standards.

Perspective of patients

- In the absence of technology that aids in diagnosis and treatment, patients become susceptible to unnecessary pain, distress, compromised health results, and potential fatality.[21] Thus, patients would benefit the greatest from the more efficient training of the operators, and for this reason, any improvement in this area is good for patients. Their needs are mostly how effective the training is since they are the bearers of the operation, and potential consequences of inadequate medical equipment will directly affect their health outcomes.

Perspective of technicians

- For technicians, their greatest need is to understand how to maintain or repair the medical devices, so that they can provide quality maintenance at ease. Technicians can offer the best advice on training needs as well as the overall impact of device maintenance. Also, the quality of maintenance is another important factor. The more effective the medical device maintenance is, the easier it is to operate the devices to deliver services.[22] The reduction of out-of-service devices is the indicator of improved training. Their concerns may stem from the effectiveness of a virtual training program and how comparable it is to the current training methods.

Investigation of Additional Stakeholder Perspectives

When evaluating potential solutions for this issue, it is important to recognize any additional challenges from other stakeholder perspectives. This comprehensive approach will enhance our understanding of the situation, ultimately enabling the development of a more effective solution. As we were unable to interview the majority of stakeholders, our additional problems are still speculative.

When assessing the proposed solution from the perspective of BMETs, there are several considerations that should be assessed. Firstly, concerns may arise regarding the use of virtual reality (VR) sets, as technicians may worry about the accuracy and completeness of training achieved through virtual models as the accuracy and efficacy of similar VR training models implemented in other institutions in the healthcare field still need improvement.[23] Additionally, the need for continuous support and updates to the VR software becomes an important aspect, especially in the event of changes to the biomedical device. Furthermore, there may be apprehensions about the validity and acceptance of VR training credentials within the field of Biomedical Engineering. Addressing these specific perspectives is important to ensuring the successful implementation and acceptance of the mixed reality solution within the biomedical engineering technician community.

When viewed from the perspective of hospital management, there are many key considerations to take into account when assessing the viability of incorporating virtual reality (VR) technology. The cost implications stand out largely,[1] as both the expense of purchasing VR sets and determining the quantity required to meet the hospital's needs must be considered. Additionally, the financial aspects extend to the costs associated with acquiring, training, and maintaining the software programs that instruct BMETs on the device. Another important consideration is the evaluation of performance and outcome measures tied to the implementation of VR technology. Training using computer-aided technologies has been shown to require more evidence to support its effectiveness [24] so it's possible to ensure that the investment aligns with measurable positive outcomes and advancements in healthcare practices. Taking these potential concerns into consideration will enable hospital management to make informed decisions regarding the practicality and financial viability of incorporating VR technology into their healthcare practices.

Lastly, another important stakeholder to take into consideration is the perspective of clinicians. Introducing new training methods, particularly those involving virtual reality (VR), prompts important considerations. Foremost among these concerns would most likely be patient safety, where clinicians seek assurance that the adoption of VR for training enhances, rather than compromises, the quality of care provided to patients. An evaluation of the safety protocols and efficacy of the VR training is essential to address this concern. Additionally, clinicians emphasize the importance of evidence-based practice. Although the use of VR training has increased, there is limited evidence supporting its effectiveness.[25] They require scientific validity and rigorous research to substantiate the effectiveness of the proposed methodology. Demonstrating that VR-based training is as effective as, if not more effective than, traditional methods would be pivotal for gaining clinician confidence. This evidence-based approach ensures that the integration of VR aligns with established clinical practices and contributes positively to patient outcomes. Addressing these clinician perspectives will be instrumental in fostering acceptance and successful implementation of VR training within the healthcare setting.

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Appendix: Contributions

<u>Traye Lin</u>
Characterizing the medical problem, citations, formatting, assisted groupmates with their parts

<u>Nicholas Santoso</u>
Characterizing the scope of the problem, citations

<u>Caden Roberts</u>
Analysis of alternate solutions, cost analysis, and limitations of current solution.

<u>Ghazal Fallahpour Sichani</u>
Investigation of additional stakeholder perspectives

<u>Jingxuan Chen</u>
Stakeholder Analysis

DHF2 - Needs and Specifications

Group B5

BMEG 357

February 09, 2024

Table of Contents

Summary of changes

Change	Description
Added sentences describing tables	As listed, to improve the flow of the report
Split up need 4 into need 4 and 7	Removed scalability from need 4 and converted to new need (7)
Added additional detail to requirement 4	Added “or spoken”
Added detail in eval criteria 1	Added explanation for inflection point
Added detail in eval criteria 4	Added justification for shape of graph

Needs Summary

The aim of our training methodology is to use mixed reality (MR) to provide instruction and foster confidence in biomedical engineering technologists in performing maintenance on a large valve infusion pump. The training is intended to be cost-effective, highly available, sustainable for long-term use, and able to provide real-time feedback.

For the scope of this project, the target market for our developed methodology would primarily include healthcare institutions. Hospitals, clinics, and other healthcare facilities that employ biomedical technologists would be our primary customers. These institutions could use our training methodology to enhance the skills of their staff in maintaining and repairing medical equipment,[1,2] and would also benefit from having more available training for technologists, as more technologists would be readily available to work (rather than have to wait to be trained). Other target markets include educational institutions, as our methodology could be used to supplement their curriculum, and medical equipment manufacturers, as we could eventually work with them to design training lessons for their devices.

The size of the target market varies and depends on specific regulations of training devices, from local BC hospitals, to Canadian healthcare facilities, and to the US market. We can infer the size of the market by looking at the available data and current trends in the mixed-reality and healthcare industry. The global market size in augmented & virtual reality in healthcare was valued at USD 2.5 billion in 2022 and is expected to expand at a compound annual growth rate (CAGR) of 18.8% from 2023 to 2030, with an estimated valuation of USD 8.3 billion.[3] Technological advancements, digitization, government initiatives, rising healthcare expenditure, and growing use of mixed reality for medical training, are some of the fundamental factors anticipated to boost the growth and adoption of mixed reality technology in the healthcare industry. These technologies have wide applications in healthcare including surgeries, diagnostics, rehabilitation, training, and education.[4] Medical device manufacturers would also be a major contributor to our target market, with their market size being estimated at USD 128.8 billion in 2023 and anticipated to grow at a compound annual growth rate (CAGR) of 12.8% from 2024 to 2030.

The primary users of the training process are biomedical technicians, who benefit from not only enhanced professional expertise but also increased confidence in the routine maintenance of medical devices. This is expected to contribute to their job satisfaction and a sense of accomplishment, as they perform their duties with greater ease.

The set-up cost of the training model mainly depends on the device used. We speculated that a virtual reality (VR) headset may be needed to implement our MR training process, and it costs around $750 to $1400 USD per pair. Including software development, cloud services, and other additional costs, the average cost for a full-scale VR training program is $50,000 to $150,000.[5] This will be the estimated set-up cost for our MR training program. AR

Needs statements

This table discusses the needs of the new training model by establishing each need into a statement,, and providing justification for that statement.

Table 1. Need statements of the new training model

Needs statement #	Needs Statement	Justification
1	The trainee should receive real time feedback.	The new training model needs to be able to provide some sort of instructional feedback to the trainee. To most accurately replicate the experience of being at an in-person training session with an instructor, feedback must be given to let the trainee know if what they are doing is correct. As in-person training tends to increase technologist confidence,[6] having real-time feedback will allow for the most emulation of in-person instruction. Real-time feedback is also an important part of training as it helps build proficiency and knowledge retention.[8]
2	The cost of the training methodology should be more cost-effective than the current training model of the LMBME.	As a major driver for the LMBME changing their training methodology is the costs of the current system,[6] the upfront and long-term costs of the new methodology should remain below the costs of the current system.
3	The training methodology should limit obstacles to scheduling a training session.	To ensure optimal usability and accessibility, the new training methodology must minimize the need for scheduling constraints. This approach aims to enhance availability by mitigating limiting factors such as equipment availability, room availability, and supervisor availability within the new training model.
4	The model needs cost-effective maintenance to sustainably accommodate ongoing updates to the training material.	It's crucial for the model to require maintenance that is cost effective. As the training models would need updating to align with technological advancements, and updates to the training model, a system that has costly maintenance would not be sustainable in the long term. The large technological advancements on the pump would occur

		approximately every 5 years.[7]
5	The method of training must be conducted using devices that are user-friendly.	The need for a training solution with an intuitive user interface and accessibility features that accommodate BMETs with varying levels of technological proficiency, enabling seamless adoption and use of the mixed reality training platform.
6	The training process should be self-directed	Training model should be designed to be self-directed. Training should not rely on the presence of a supervisor, having an independent training course, allows for easier scheduling potential and can also reduce training cost.[6]
7	Training method should be scalabe to meet long-term LMBME needs.	Scalable infrastructure must also be considered to ensure the model can facilitate the long-term needs of LMBME. Allowing for training on larger devices to be possible and accessible to BMETs.

Specifications

This table discusses and justifies the requirements of the new training model, as well as what need it refers to from the needs, and the property that it affects.

Requirements

Table 2. Requirements of the new training model

Req #	Need reference	Property	Requirement	Justification
1	1	Level of interaction	The model must engage at least two senses during the learning process.	To ensure the effectiveness of the training program through interactive elements, it should engage several senses used for learning. This also ensures a comprehensive learning experience for the diverse preferences of individuals. Considering that the majority of learners benefit from visual and auditory stimuli, or a combination of the two,[9] the training content should be designed to address at least two senses to optimize the learning

				experience in an interactive way.
2	1	Feedback	The model must provide appropriate/accurate feedback to the trainee during or after the training.	The feedback provided must be accurate. That is to be able to detect mistakes made by the trainee and be able to notify them of the error. The model must also have a low false negative rate, meaning that it will not falsely provide feedback of error when no mistake was made.
3	4	Training capacity	Must have the capabilities to train at least 19 BMETs each year.	Hiring numbers for BMETs fluctuate every year. According to our client, 19 BMETs were hired this year,[7] and this was a higher volume of BMET's than usual, and they will be hiring less in the subsequent years. That is why we decided to set the minimum at 19 BMET's. A higher training capacity is also preferred as it ensures new hires are adequately trained even during peak hiring seasons.
4	8	Instruction clarity	Instructions should be written or spoken in simple English that is understandable by individuals with an IELTS reading score >4.	The training should be accessible to all people regardless of language gaps. This means that it should be accessible to people with limited English. Instructions must be grammatically correct and not use jargon. An IELTS reading score of 4 is defined as someone with "a very basic understanding of English and [they] are more comfortable communicating in familiar situations." .[10]
5	3	Set-up time	The set-up time must be within 7.5 hours. This includes booting, calibrating, and any kinds of preparations that are needed before normal use.	The set-up of the training should be clear, direct, and simple to proceed. An easier setup procedure will decrease the burden for BMETs and increase the accessibility of the training program. The set-up procedure must be within 7.5 hours as required.[7]

Constraints

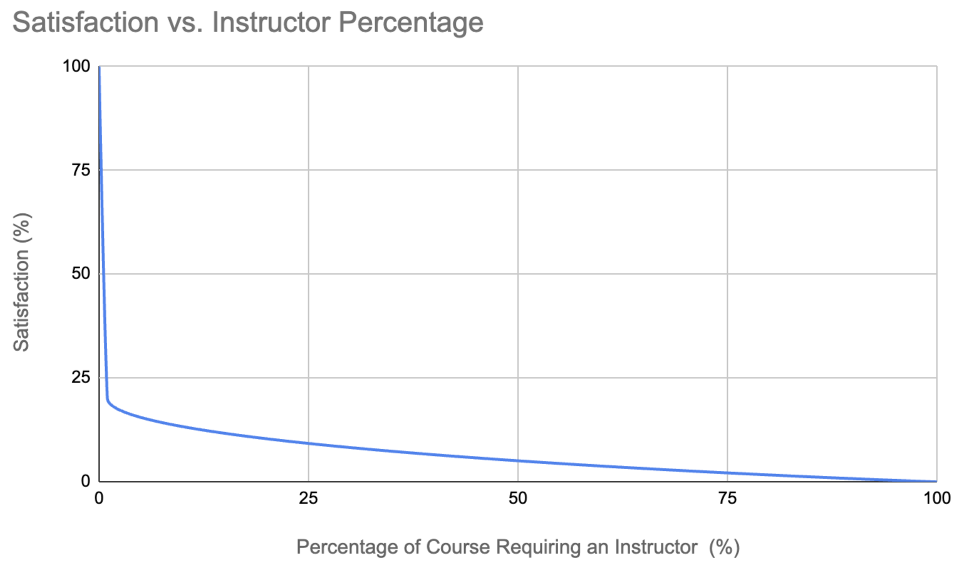
Table 3. Constraints of the new training model

Constraint #	Need reference	Property	Constraint	Justification
1	4	Durability	The device used for training must survive a fall from ~30”, without significant damage.	The average desk height is approximately 30 inches.[11,12,13] A fall from this height will simulate an accidental drop of the device from desk height, covering many potential accidents during regular use. This fulfills the long-term use requirement because if the device can survive a drop from 30 inches, it implies that the device is durable enough to withstand 4-5 years of regular use.
2	N/A	Hardware compatibility with Windows	The training method should be compatible with Windows.	The hospitals operate on Windows computers only .[6] Therefore, the hardware of the training model must be able to run reliably on Windows operating systems.
3	N/A	Prototyping budget	Design prototyping should cost under $150.	As outlined on the course page, each team has a budget of $150 for the design project.
4	2,4	5-year cost	The training method should have a 5-year cost of under $75,000.	Expected yearly growth of 10 BMET hires a year, with the cost for training a BMET on an infusion pump being $1500.[8] Over a 5-year span that is at least 10 BMETs hired/year * 5 years * $1500/BMET = $75 000 per year

5	N/A	Regulation - privacy	All stored data collected from the training session must be stored according to the BC Personal Information Protection Act (PIPA).	Any stored data collected from the training must be confidential,[8] and its storage must abide by the PIPA .[14] This is to ensure the security and privacy of sensitive information, safeguarding the integrity of the biomedical technologists and any individuals involved in the training process.
6	N/A	Regulation - privacy	Any stored data must be stored on Canadian servers. [6]	Storing data on Canadian servers ensures that it is subject to Canadian privacy laws, which may differ from those in the United States or European Union. By storing the documents on Canadian servers, the data is subject to the jurisdiction of Canadian laws and authorities, providing an extra layer of protection for BMET information.

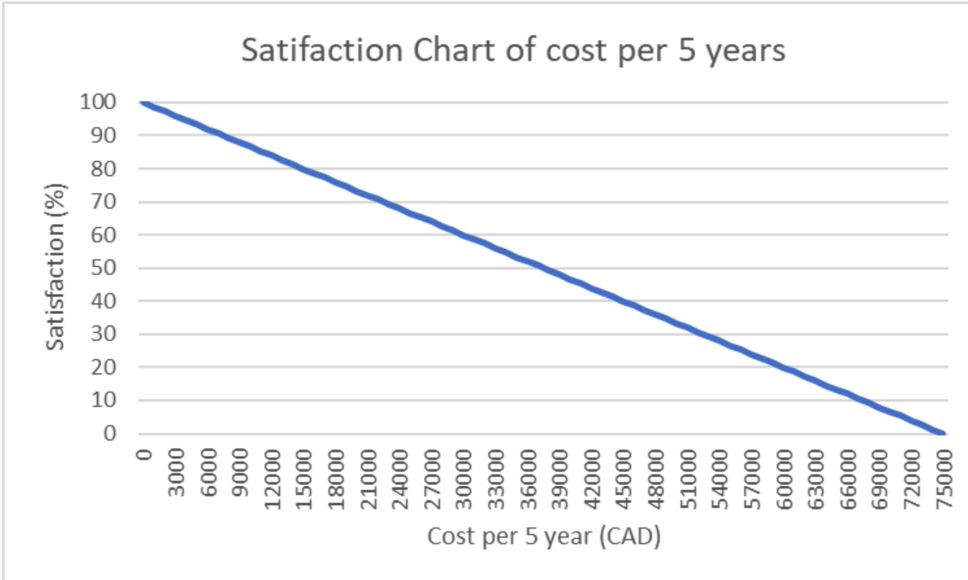
Evaluation Criteria

Evaluation Criteria #1: Portion of training that requires a supervisor	
Description: As the training methodology could be conducted through multiple models, one potential model could be a training session that contains an independent portion as well as a portion that takes place underneath the supervision of an instructor such as a senior and experienced BMET. This satisfaction chart accounts for the satisfaction of the client with regard to the proportion of the training that requires a supervisor.	**Motivation:** Need #3, #4, #6
Satisfaction chart	

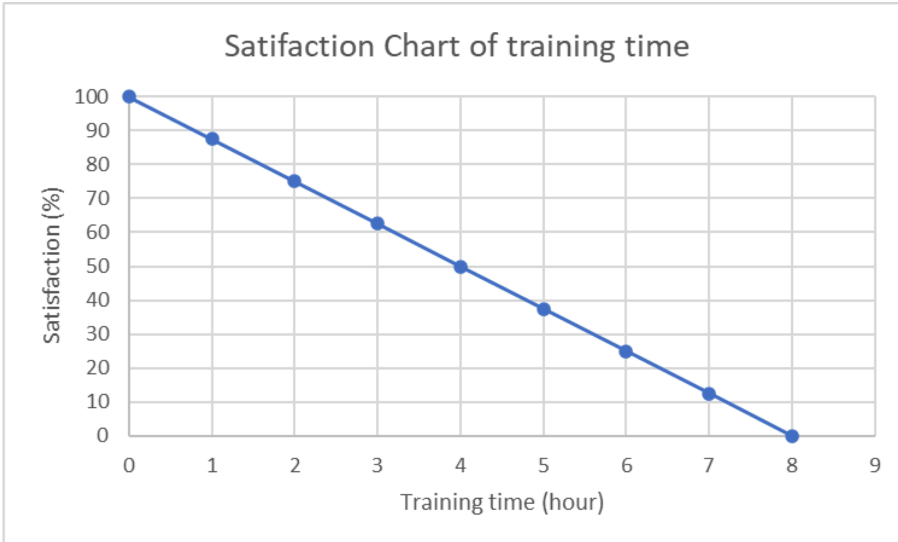


Rationale
In the case where 0% of the training requires a supervisor and the entire session can be conducted independently, this was associated with the most satisfaction. This was determined as there would be no scheduling constraints present for scheduling a time with a supervisor and the BMET would be able to have the training as long as the training device is available. The sharp drop at 1% was on the basis that as soon as an instructor is needed, scheduling becomes a potential barrier, and the dependency on external availability introduces logistical complexities as well as additional costs since the instructor will also need to be paid. From there on the satisfaction decreased linearly with 100% of the training needing supervision corresponding to a satisfaction level of 0%. This was because the current training methodology requires an instructor for 100% of the session

Evaluation Criteria #2: 5-Year cost	
Description: The cost associated with implementing and maintaining a training method over a 5-year period, in Canadian dollars. This includes upfront costs such as software, hardware, and material training acquisition, as well as long term expenses for software licenses, equipment maintenance, hiring trainers, and any other recurring costs over the 5-year span.	**Motivation:** Need #3, Need #5, Constraint #4
Satisfaction chart	


Rationale The training methodology must be more cost-efficient compared to the current industry standard. A more expensive training method would have minimal benefits compared to the current solution, and it would be too expensive to adopt the new solution. The more affordable the methodology the more accessible it will be to BMET's while also saving money in their budget. The satisfaction chart uses a linear curve as the more affordable a solution the higher the satisfaction. The ideal solution should be as cost efficient as possible, therefore we set the maximum satisfaction to be at 0$. The maximum price for a viable solution is set to $75,000 as discussed in constraint #6, this is based on the 5-year cost of the current implementation, any solution more expensive than this is not optimal and thus the satisfaction is the minimum.

Evaluation Criteria #3: Training duration	
Description: The time needed for one training session for one BMET in hours. The training session includes all training items.	**Motivation:** Need #2, Need #3
Satisfaction chart	

<table>
<tr><td colspan="2">
</td></tr>
<tr><td colspan="2">Rationale
The MR training session must be time efficient. The length of the procedure and its clarity should contribute to shortening the training time, which makes scheduling for BMETs much easier. In addition, the shorter training duration also contributes to a lower operating cost. A linear relation is chosen for the training duration satisfaction chart, for that the shorter training time leads to greater satisfaction, while there’s no significant inflection point. The upper bound for training time is 8 hours, which is the current time,[7] while the lower bound is 0, since the shorter training time is better, as long as the training quality is maintained.</td></tr>
</table>

<table>
<tr><td colspan="2">Evaluation Criteria #4: Ease of setup</td></tr>
<tr><td>Description
The level of easiness for setting up the MR program, indicated by the time of This includes booting up and calibrating the device. This may also include downloading any required software or installation of additional hardware components.</td><td>Motivation: Need #8</td></tr>
<tr><td colspan="2">Satisfaction chart</td></tr>
</table>

Contributions

<u>Traye Lin</u>
Worked on needs summary, needs identification, requirement, constraints, evaluation criteria, and helped citations.

<u>Nicholas Santoso</u>
Worked on needs summary, needs identification, requirements, constraints, gantt chart.

<u>Caden Roberts</u>
Worked on needs statements, requirements, constraints, and evaluation criteria.

<u>Ghazal Fallahpour Sichani</u>
Made final edits to all need statements, worked on evaluation criteria, requirements, and citations.

<u>Jingxuan Chen</u>
Generated satisfaction graphs for evaluation criteria. Worked on requirement, evaluation criteria.

Everyone contributed to formatting.

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DHF3 - Concept Generation and Selection

Group B5

BMEG 357

March 02, 2024

Table of Contents

Changes summary

Changes	**Description**
Several citations added to plausibility table, some added to feasibility and scoring.	Citations are included to support and justify several claims and conclusions.
Feasibility table justifications expanded.	Justifications expanded to address the plausibility based on how they do and do not meet project requirements.
Concept ranking for scalability further justified.	Further explanation for why scalability was used to eliminate concepts before moving on to scoring.
Extra paragraph describing final concept.	Providing more clarity for the chosen concept.

Preface: Changes from DHF 2

Evaluation criteria 1, '% of needing supervisor', was revised into a requirement and replaced with a new criteria called ''ratio of components needing scheduling'. This was because all concerts generated are self-directed and would score the same under % of needing a supervisor, making the criteria not valuable in determining the best solution. Changing this criteria into a requirement will ensure all non-self directed concepts to automatically fail. One of the key client needs is to reduce scheduling needs and be self-directed. The new ratio of components needing scheduling criteria takes into account not just self-directiveness, but also equipment availability and room availability. This helps differentiate the concepts better.

Evaluation criteria 3, 'Training Duration', was also removed, as after further deliberation, the duration was more dependent on the actual training content being taught rather than the quality of the training that the different concepts had.

1. Function Structure Diagram

Before generating concepts for the training methodology, a Function Structure Diagram (FSD) was generated to provide a high-level overview of the various features and functions each concept should be capable of doing. In the FSD, a gray box labeled "Training system" represents the system boundary, in which the training device's functions are located. The different colored arrows represent the properties of what is being transferred from box to box, either material, energy, or information. Additionally, various inputs and outputs can also be found on the FSD, but outside of the system boundary. Each stage of the training is represented by the colored background inside of the system boundary.

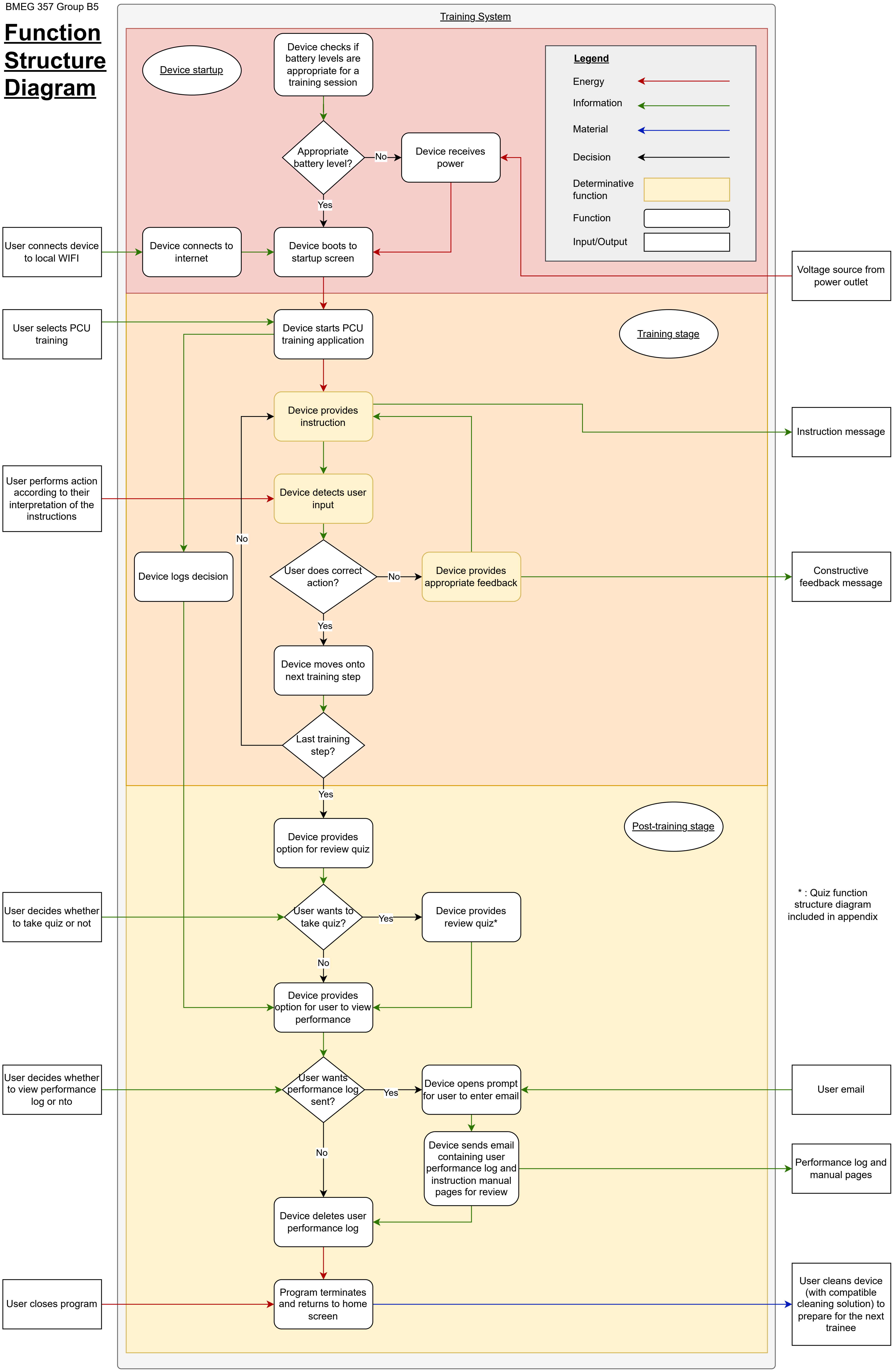
The three training stages detailed in the High-level FSD are as follows: Red: Set-up stage, where the user turns on and the device performs any precursor actions before training starts; Orange: Training stage, the main training loop detailing the instruction and feedback system; Yellow: Post-training stage, containing optional review quiz and performance log review functionality (an FSD of the quiz section can be found in Appendix F). This was done for clarity and for future organizational purposes, where each section can be worked on individually.

Three determinative functions are identified in the FSD: "Device provides instruction", "Device detects user input", and "Device provides appropriate feedback". These functions are what drove the following concept generation stage, and are what differentiates each concept from one another.

Figure 1. High-Level Function Structure Diagram

BMEG 357 Group B5

Function Structure Diagram



2. Concept generation:

The team generated 8 concepts through brainstorming. This included individually generating and writing descriptions of each training method/style, and subsequent discussion of the key functions of each concept. We determined how instruction would be provided, as well as the detection of user input, and feedback, and what other modules or devices would be necessary for the execution of that concept.

Table 1. Concepts generated and concept descriptions

Concept #	Concept Name	Description

1	AR self-guided Module	• Provides instruction: by visual (screen) and auditory (speaker) prompts to guide users through different steps in the maintenance of PCU
		• Detects user input: with built-in cameras and sensors to track hand movement on the PCU
		• Determines and provides feedback: live visual and auditory feedback by programmed display and built-in speaker
		  ○ Module provides visual feedback (i.e. texts in red/green) at the end of each sub-module to indicate whether the user has completed required tasks correctly
		  ○ feedback logs stored using cloud services
		• Module uses AR headset for PCU training
		• Module is composed of sub-modules that break down major steps in the preventive maintenance procedure of PCU

2	Monitor with video recording, paired with camera	See Appendix B.1 for concept sketch.
		• Provides instruction: through recorded videos on the monitor screen and text prompts to guide users; requires a monitor (i.e. computer screen) to be placed at a close distance to the PCU
		• Detects user input: requires a camera to be placed above the laid down PCU (camera facing downwards) and captures user's hand movement
		• Determines and provides feedback: displays visual and auditory feedback on screen and through speaker
		  ○ green checkbox for task completion
		  ○ alert sound for missed tasks

3	Mobile app	• Designed to be a portable and accessible guide for PCU maintenance tasks • Provides quick reference materials, step by step

		instructions, and troubleshooting assistance ● Implements both visual and auditory instructions ● Incorporates multimedia elements like diagrams, 3D models, video tutorials ● Has offline access to essential content aswell as diagnostic tools ● Organized by task specific sub-modules, as well as having a progress tracker to mark completed tasks ● Modules have summary questions at end to ensure understanding of material ● Feedback and rating system for performance on each module ● App has implemented voice commands for hands-free interaction ● App can access camera to submit progress of PCU maintenance through images and recognition software
4	Gloves with motion capture sensors	See Appendix B.2 for concept sketch. ● Provides instruction: no mode of instruction, may require alternative training module to be used along with to guide users ● Detects user input: sensors at finger tips detect accurate hand movement ● Determines and provides feedback: no mode for feedback
5	Simplified mock PCU with built-in pressure sensors	See Appendix B.3 for concept sketch. ● Provides instruction: instruction displayed on PCU screen ● Detects user input: pressure sensors on PCU buttons checks if the correct button has been pressed ● Determine and provide feedback: provide visual and auditory feedback on PCU screen and built-in speaker ● Simplified version of PCU has reduced function but imitate the physical structure of a medical PCU
6	Virtual PCU	See Appendix B.5a for virtual keyboard demonstration. ● Similar to a virtual keyboard, designed to use the virtual keyboard equipment as an interactive tool See Appendix B.5b for concept sketch. ● Provides instruction: instruction displayed on the projected virtual screen ● Detects user input: IR sensors and motion sensors can manage the inputs, including typing, scrolling etc. ● Determine and provide feedback: using programs on the computer to provide visual and auditory feedback

		● The projected virtual keyboard requires no physical contact, prevents potential contact uncomfortness (3D dizziness) and possible sanitation problems.
7	3D Printed PCU	Similar to the Pocket Pelvis AR app design, see Appendix 6 for demonstration. ● Module uses an AR headset to project the screen of the PCU onto the 3D-printed object. ● Screen of the PCU is projected and can be interacted with. ● AR headset has built-in software and IR sensors that recognize hand movement accurately ● Module provides visual feedback (i.e. texts in red/green) at the end of each sub-module to indicate whether the user has completed required tasks correctly
8	VR style	● VR headset, oculus style, generates a 3D model of PCU, either disembodied voice or trainer character model walks trainee through steps ● Training waits for trainee input, if incorrect, resets PCU to position on table and restarts training at that step ● Opens a window in front of the trainee with recap of what they did wrong or the instruction ● maybe in a game quiz with multiple scenarios, if this issue, then what to do? ● Provides instruction: ○ through character model and text windows (audio and visual) ● Detects user input: ○ Through VR interaction with the model PCU ● Determines and provides feedback: ○ Programming the buttons ○ Opens text window and resets environment ■ Text window indicates what the person did and reiterates what needs to be done ■ Text window provides manual reference ○ Repeats instruction

3. Concept screening and evaluation:

After concept generation, we proceed to concept screening based on their plausibility and feasibility. For each concept generated in Table 1, we assessed its plausibility based on estimations on whether it is possible to manufacture or buy and looked at its feasibility by checking if all design requirements were met (see DHF 2, Table 2 for a list of requirements). Table 2 summarizes the results of the plausibility and feasibility estimates of each concept with justifications.

Table 2. Plausibility and Feasibility screening

PLAUSIBILITY		
Concept name	**Justification**	**Result**
VR/AR headset	This concept is plausible as AR and VR technology is commercially available[20], like the Meta Quest 3 which is provided by the course. Additionally, open-source AR/VR development software is also easily accessible for use in this course, like Unity which is free[21].	Pass
Monitor with camera	This concept is plausible as monitor and sensing cameras are commercially available[22]. Monitors are easily programmable to build training modules and display feedback[23]. The camera can also be easily paired with the monitor so that the transferred data can be processed by the monitor.	Pass
Mobile App	The concept is plausible as it features many common functionalities that are found in existing educational and training apps[24]. The software side is possible due to various development tools being accessible to use, some even requiring no coding knowledge[25].	Pass
Gloves with motion capture sensors	This concept is plausible as wearable technology is widely studied and developed[26]. The finger tip sensors used in this concept are also commercially available and can be easily programmed[27].	Pass
Mock PCU with pressure	This concept is plausible as pressure sensor	Pass

sensor	plates can be built into the buttons on a mock PCU. The reduced function PCU can be easily assembled with the sensors using many existing 3D printing and soldering techniques.	
Virtual PCU	This concept would be replicating the idea of a virtual keyboard, using IR sensors and a camera to track user movement and input. Since it is an existing technology it is also commercially available with a relatively low price[28]. The programming of this kind of device is simple, as there are limited functions of this device[28].	Pass
AR and 3D printed PCU	This concept is plausible as AR technology is widely available and the Meta Quest 3 which is being provided by the course is compatible with AR[29]. There is also open-source AR development software that we have access to for the prototyping of this concept[21]. The 3D printed aspect is also feasible as this course provides us access to 3D printers and our team has experience with autocad and 3D printing.	Pass
Feasibility		
Name / Concept Number	**Justification**	**Result**
VR/AR headset	This concept is feasible as it meets all our design requirements. The use of VR/AR elements ensures a level of immersion that satisfies our requirements for both interaction and feedback. Since the software would be developed for BMET's in Canada it would provide instructions in English, satisfying our instruction clarity requirement. The device providing self-lead training means there would be no issue for training capacities as BMETs could be trained year-round and not be burdened by scheduling specific training days. The setup time for VR is also quite reasonable and comfortably passes our requirement[16].	Pass

Monitor with camera	This concept is feasible as it meets all design requirements as it can provide clear instructions and feedback. The set-up time of this concept may be longer than the others but should still take less than 7.5 hours to complete[30]. The device would also meet requirements for training capacity as it could be done individually and would not be limited by group scheduling.	Pass
Virtual PCU	This concept is feasible as it meets all our design requirements, with a connection to a computer. Software running from a computer would be able to provide clear instructions and feedback while responding to user input, ensuring it is an interactive experience. It would also not be limited be training capacities as it would be consistently available ensuring scheduling flexibility. The setup time would also be within the required 7.5 hours as it would only require the stand and device which contains the camera and projector, requiring less time than a VR setup.	Pass
Wearable sensor-based	This concept is not feasible as it fails to provide clear instructions during the training session. It can provide feedback through tactile interactions with the user's skin and sense the user's input on the PCU but does not include a way to guide the user through the maintenance steps of the PCU. Thus the device does not pass our feasibility evaluation, as providing clear instructions is one of our requirements.	Fail
Mock PCU with pressure sensor	This concept is feasible as it meets all the design requirements. This concept is similar to the 3D-printed PCU and the sensor-based wearable device. It's able to detect the user's input through the sensor and display instructions and feedback through the PCU screen. Ensuring it satisfies our requirements for interaction and clear instructions. It would also improve scheduling flexibility through its	Pass

	independent nature, allowing for more BMET training. Set-up time would be quite simple since, it would be a single device, only requiring a power source to function.	
Mobile App	This concept is feasible as it meets all design requirements and contraints, or can be easily modified to do so. For example, compatibility with Windows is possible if it is developed to be cross-platform. It meets the requirements for clear instructions and feedback, while a text-to-speech implementation will ensure the necessary levels of interaction. Training capacity would also be no issue since the portability of the mobile app would allow for multiple synchronous users. Set-up time would also be very minimal since the app would be designed to be user-friendly and ready to go on launch, with download time being the only limitation.	Pass
AR and 3D printed PCU	This concept is feasible as it meets all of our design requirements. The model would be able to provide visual and auditory feedback through the AR headset which satisfies interaction and feedback requirements. The yearly training capacity would have a cap much higher than 19 as training could occur without any external scheduling restrictions, and this satisfies our capacity requirement. The initial set-up time of an AR headset would be 1 hour which meets the set-up time requirement. Finally, the instruction clarity can be designed to meet the associated requirement (see DHF2, Table 2), and can be easily iterated on.	Pass

After plausibility and feasibility screening, only 1 concept (concept 4 – wearable sensor-based) was screened out due to not meeting all design requirements. All other concepts passed both plausibility and feasibility assessments. This leaves 7 concepts to be carried forward into the next stage. However, this is a large number of concepts to be scored based on the evaluation criteria. We planned to move forward only half of these concepts into the scoring stage, therefore, an additional screening stage must be implemented to assess the concepts.

4. Concept ranking

We believe scalability is one of the more important needs in our design. Therefore, we decided to add an additional ranking stage that focuses on evaluating each concept's scalability before proceeding to concept scoring as this need is not easily translatable into evaluation criteria. In doing so, we were able to eliminate concepts that would not meet stakeholder expectations, allowing us to perform a more in-depth scoring analysis on promising concepts.

Table 3. Concepts ranking based on scalability

Concept #	Justification	Scalability Rank
1	The scalability of this concept is hindered by the limited equipment availability for larger machines. For example, the 3D modeling and AR program development would be challenging for large medical apparatus like the MRI machine, but the overall scalability is still higher than most other concepts.	2
2	This concept would likely require more cameras to be placed at different positions and a more complex set-up for larger apparatus like the MRI; thus, the scalability is lower than concept 1 as the AR headset requires more programming work but still easier to set up than this concept, ranking it third.	3
3	The scalability of this concept is hindered by limited equipment availability for larger machines. The scalability is similar to concept 1, ranking it second as well.	2
4	It is not very feasible to create mock medical devices for larger apparatus like the MRI, since mock medical devices designed for training purposes should replicate size and a degree of functionality. Designing and manufacturing larger mock devices would be inefficient and costly, requiring considerations for space, specialized equipment, and materials. Therefore, this concept is ranked the lowest.	5
5	This concept is easily scalable due to only virtual modeling of the apparatus being needed. No physical medical apparatus or prototype is needed. Hence, this concept has the highest rank in scalability.	1
6	It is not very feasible to create 3D printed models of larger machines, but 3D printing would still be easier to manufacture than concept 4, which requires building the	4

	actual device with reduced functions. This ranks the concept fourth in scalability.	
7	This concept is also highly scalable due to only virtual modeling being needed to scale up for larger apparatus. No physical medical apparatus is needed and this concept ranks the first along with concept 5.	1

As shown in the table above, concepts **5** and **7** ranked the highest in scalability and concepts **1** and **3** ranked second. We decided to only move forward with these 4 concepts into the scoring stage because concepts 2, 4, and 6 are not very feasible when it comes to large machine training.

5. Concept Scoring:

We assigned scores on the 4 concepts based on the estimated performance in each evaluation criteria. We estimated the specific performance with each evaluation criteria by researching and backing up with existing data in the performance estimation column. Table 4 details the concept's raw satisfaction score based on the satisfaction curves created during the Needs and Specification stage (see DHF2, Evaluation Criteria section). 'Ratio of components needing scheduling' is the newly added evaluation criteria that uses the satisfaction curve presented in the prefix section named "Changes from DHF2".

Table 4. Concept 1 scoring – AR headset with PCU

Evaluation Criteria	**Performance Estimation**	**Score**
Ratio of components needing scheduling	The AR headset training module would require 3 components to be scheduled: an AR headset, a PCU, and a room. The score is evaluated based on the number of components needing scheduling for this concept compared to that of the traditional vendor training. The vendor training requires 3 components to be scheduled as well, thus, this concept does not reduce the need for scheduling and is given a satisfaction level of 0% (see Appendix C).	0/100
5-year cost	A Microsoft HoloLens 2 is 3500 U.S. dollars and is programmable as it contains a custom-built holographic processing unit. The software development cost of an AR headset training program is at least 50k.[1] The cost for instructional design is minimally $150 USD.[2] So the total minimal costs for an AR headset training model is	3/100

	approximately 53,650 USD, or 72,865 CAD. Additionally, the average lifespan for an AR headset is around 4 to 5 years, therefore, the 5-year costs for this concept would be around 72,865 CAD, scoring a satisfaction of 3% (see Appendix D).	
Ease of setup	Initial setup of Meta Quest 3 which is both an AR and VR headset takes approximately 45 minutes[3]. After the initial setup subsequent setups take approximately 1 minute to power up the device. Based on the evaluation curve for setup time, this scores the concept a satisfaction of 90% (see Appendix E).	90/100

Table 5. Concept 3 scoring – Mobile app

Evaluation Criteria	**Performance Estimation**	**Score**
Ratio of components needing scheduling	A mobile app could require no components in need of renting, as it is assumed that all users will have a personal device that can run the app, and training could be done in the office of the user. However, in the case of the most optimal training, the user would follow instructions from the app while having a physical PCU device present for reference. This sets the number of components needing scheduling to just the PCU, making the ratio 1/3, and scores it at 67% on the satisfaction curve (see Appendix C).	67/100
5-year cost	Based on average costs of educational apps, the price range is between 20k - 50k USD,[4] based on simplicity of the app. Since accessibility is important, the app should be developed for cross-platform between Android and iOS. While also considering the app will be on the simpler side, an estimate development cost of 25k USD seems appropraite.[4] The cost of maintenance will also be on the lower end, since the app will not have a widespread userbase, and only feature the storing of login info. This gives a maintenance estimate of $80 USD a month for hosting,[5] which will total around 5k USD in the 5 years. Lastly the only major feature the app would implement is the voice recognition. Since it only requires a basic level implementation, the cost for such a feature is estimated to be about 2k USD.[6] Thus the total estimated cost is around 32k USD which is $43,460 CAD. This scores a satisfaction of 42% on the curve (see Appendix D).	42/100
Ease of setup	In considering the setup time for a mobile app, the factors to consider are the time it takes to connect to the internet and the time it takes to download. The major consideration here is	97/100

	downloading content for offline use. For this, it is assumed that video content size will be the largest and additional files would be negligible. In this case, we assume that all recorded content is equal in length to the current training method of 8 hours.[7] When considering the download speed the hospital would have of around 10 Mbps,[8] and the filze size of an hour long video at 720p being around 800 MB,[9] then it can be estimated the download time will be around 10.6 minutes. Factoring in the initial app download, basing its size to be around the size of other educational apps, assuming it to be around 200 MB,[10] this adds an additional minute and a half to the set up time, rounding it out at about 12 minutes. This scores a 97% on the satisfaction curve (see Appendix E).	

Table 6. Concept 6 scoring – Virtual PCU

Evaluation Criteria	**Performance Estimation**	**Score**
Ratio of components needing scheduling	The projecting virtual PCU needs only a table to perform a training session, which needs no booking for rooms and use of an actual PCU, this leaves the ratio of component needing scheduling to be 1/3, scoring the concept at 67% on the satisfaction curve (see Appendix C).	67/100
5-year cost	Giving a full scale look, the cost of a well designed projecting virtual PCU for a 5-year-term is 15k,[11] which contains 10k of designing cost, depending on the complexity of the program and the project management, and 5k of maintenance. This scores the concepts a 80% on the satisfcation curve ((see Appendix D). For the designing procedure, the estimated cost is 10k, which is the add up of designing, instruction developing, quality assurance and programing. The program is completely offline-running so no server maintenance and data storing is needed, and the full maintenance can be done by simply replacing the unfunctional projector. For the designing procedure, it costs 5-15k, which is relatively cheap, since the programming is relatively easy and no side-equipments are needed other than a projector, which costs merely $50-120.[12]	80/100
Ease of setup	The set-up time of the virtual PCU is considered to be 15 minutes, which is the initial set-up time instead of the set-up time for each use since it only needs to be powered up after the first use. The reason why the initial set-up takes 15 minutes is that the projector needs calibration for the first use, which is simple and easy to follow and can be done within 15 minutes,[13]	87/100

	this scores the concept a 87% on the satisfaction curve (see Appendix E).	

Table 7. Concept 8 scoring – VR Headset

Evaluation criteria	**Performance Estimation**	**Score**
Ratio of components needing scheduling	The VR training methodology would require 2 components that need to be scheduled for use, the VR headset used to provide instruction and feedback to the trainee, as well as the room the training will take place in. A score of 2 components would score 33% on our satisfaction curve (see Appendix C).	33%
5-year cost	According to a cost analysis by Round Table Learning, the cost of a full VR training program can range, on average, between \$50,000 and \$150,000.[14] This includes the cost of instructional design, programming, modeling, and VR headset expenses. Using this data, \$50,000 was chosen as an upfront cost to accommodate development and equipment expenses, as the program being developed for PCU preventative maintenance would not need to be as complex as more expensive training programs. The environment would not need to be highly detailed, and the training instructions already exist, only needing translation to VR. Additionally, according to a cost analysis of maintenance for VR escape rooms,[15] equipment maintenance costs would be around \$550 annually, covering hardware maintenance, software updates, cleaning, and repair expenses. This totals to \$52,750 over the course of 5 years, scoring 30% on our satisfaction curve (see Appendix D).	30%
Ease of setup	The Meta Quest 2 which is a VR headset has an approximate initial set up time of 1 hour, this includes the time it takes to charge the headset, connect it to the network, and install an application as well as any headset software needed for the headset to run.[16] This scores 87% on our satisfaction curve (see Appendix E).	87%

Table 8. Evaluation criteria weight and Justifications

Criteria	Weight	Justification
# of training	40%	This criteria is considered one of the most important because training

components that need scheduling		availability is one of the main drivers for the development of a new training methodology. As the vendor instructor, equipment and training room all need extensive scheduling, any concept that can remedy scheduling issues should be scored higher than those that do not attempt to address it.
5-year cost	40%	This criteria is considered just as important as the # of components that need scheduling, thus it is weighed similarly. Since most if not all factors of training affect the budget, the cost is extremely important to address as it is an important aspect of satisfying the stakeholder's needs. Due to this importance, all concepts that are much cheaper than the current 5 year cost of training BMETs will be favored.
Ease of setup	20%	Ease of setup, which is quantified through initial setup time, while important, is not as important as the aforementioned evaluation criteria. This sentiment is echoed through the client mentioning that the setup time, as long as it takes less than one work day (~7.5 hours), is ok.[17]

By applying the weights determined in Table 8 and concept raw scores in Table 7, we obtained the following Weighted Decision Matrix (WDM) table. We decided to use a WDM approach to score our concepts because we have used the technique many times and thought it was appropriate for our design process.

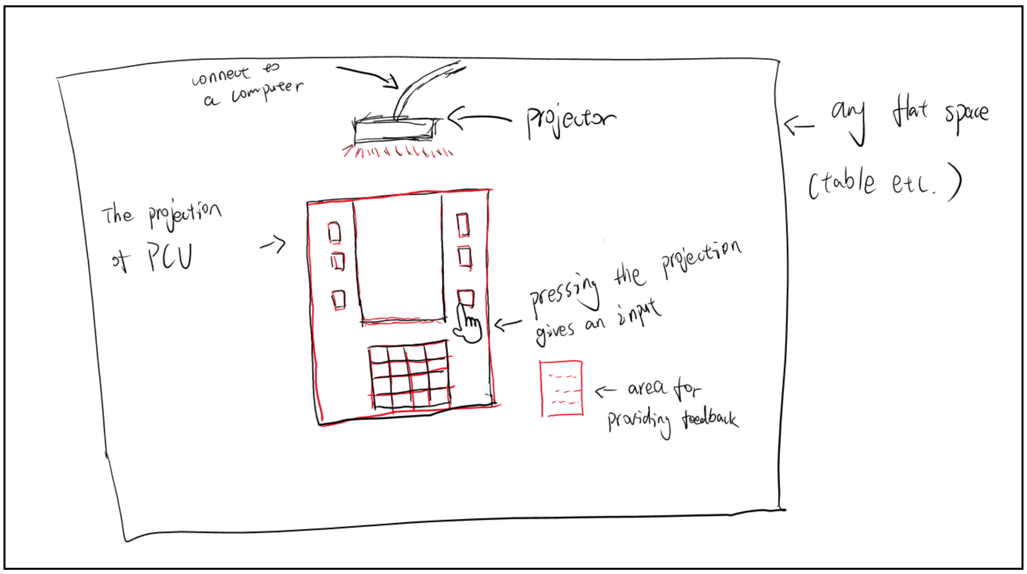
Table 9. WDM results for the 4 concepts

Evaluation Criteria	Weight	Concept 1		Concept 3		Concept 6		Concept 8	
		Raw score	Weighted score	Raw score	Weighted score	Raw score	Weighted score	Raw score	Weighted score
Scheduling need	40%	0%	0%	67%	27%	67%	27%	33%	13%
5-year costs	40%	3%	1%	42%	17%	80%	32%	30%	12%
Ease of setup	20%	90%	18%	97%	19%	97%	19%	87%	17%
		total:	19%	total:	63%	total:	**78%**	total:	43%

6. Presentation of the chosen design concept:

The design for concept 6, a projection of a virtual PCU, was the concept that scored the highest in our weighted design matrix (Table 9). It stands out as the best concept because of several key factors from our evaluation criteria. It eliminates the need for booking rooms and acquiring physical PCU's as only a projection of the PCU is created. Secondly, the cost analysis over a 5-year term demonstrates its affordability, with a total cost of $15,000, comprising $10,000 for design and $5,000 for maintenance. This number is significantly lower than the concepts requiring AR and VR headsets, as the training software alone for those devices ranges around $50,000 just for the development. Additionally, the offline nature of the program eliminates the need for server maintenance and data storage expenses, while maintenance solely involves replacing malfunctioning projectors, simplifying upkeep. Moreover, setup time is minimal, requiring only 15 minutes for initial calibration, after which it simply needs to be powered up for subsequent uses. This setup simplicity, along with the relatively low cost of equipment, makes the projecting virtual PCU concept highly advantageous for training sessions.

Image 1. Concept 6 sketch – Virtual PCU



The Virtual PCU would connect to a computer to host the PCU software. It would use a projector to display an image of the PCU interface on a flat surface. The software would enable the projected image to be interacted with, as user input and movement would be detected by an infrared camera picking up reflected infrared light from a line laser pointed parallel to the tabletop. The specifications for the three components would be similar to what is found in commercial projector keyboards, however instead of projecting a keyboard, it would project the PCU interface[28]. The projector and camera would both be commercially available devices with minimal considerations.

7. Contributions

Traye Lin
Preface, Concept 1, Concept 2, Concept 4, Concept 5, summary for concept screening, ranking, scoring, and WDM, plausibility/feasibility justifications, concept ranking table, concept 1 scoring table, WDM, Appendix, clean-up and formatting, grammar.

Nicholas Santoso
Function Structure diagram, Concept 8, participated in screening, ranking and scoring, evaluation criteria weight justification

Caden Roberts
Concept 3, participated in screening, ranking, and scoring, plausibility/feasibility justifications, concept 3 scoring table, editing and citations.

Ghazal Fallahpour Sichani
Concept 7, participated in screening, ranking, and scoring, Preface changes for DHF 2, summary for concept generation, plausibility and feasibility justifications, citations.

Jingxuan Chen
Concept 6, participated in screening, ranking and scoring, plausibility/feasibility justifications, and concept sketch.

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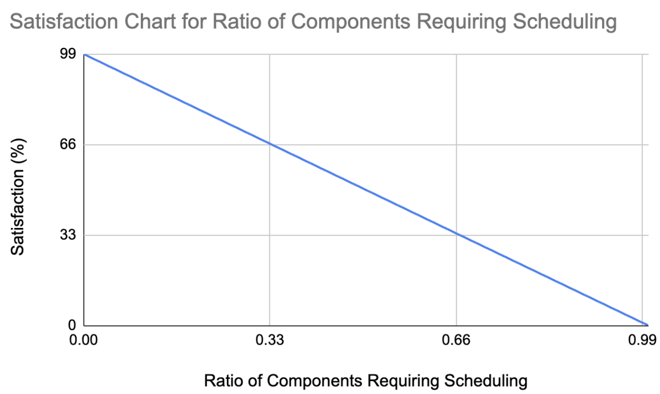
9. Appendix

Appendix A. Updated Evaluation Criteria #1

Evaluation Criteria #1*: ratio of components needing scheduling; **Motivation:** Need #3, Need #6

Description
Different training methodologies could involve different numbers of components that require scheduling. This satisfaction chart accounts for the satisfaction client without regard to the proportion of training that requires scheduling.

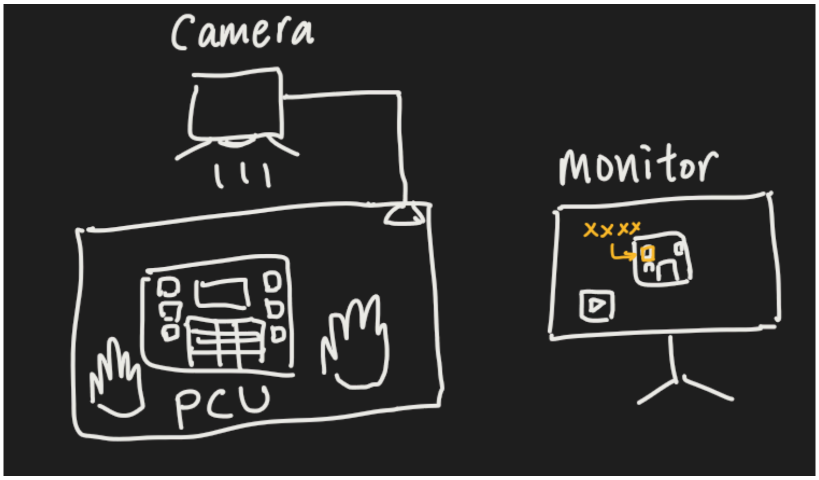
Satisfaction chart:



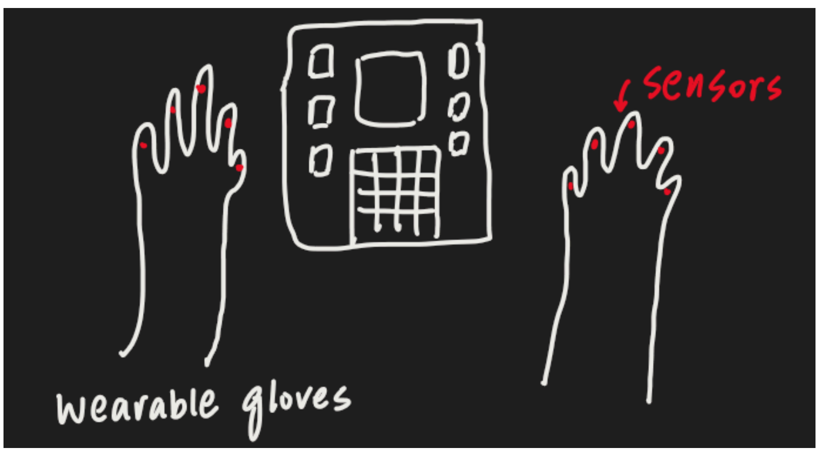
Rationale
The traditional vendor training was used as a benchmark against the new concepts generated. Vendor training requires three components to be scheduled: a supervisor/trainer, a PCU, and a room for the session. Our x-axis is determined to be a ratio of the number of components needed for scheduling compared to the 3 components needed for scheduling for vendor training. For instance, if the ratio is 3/3 (1.00), indicating no improvement was made to reduce scheduling needs, it is associated with a satisfaction level of 0%. A factor of 1/3 (~0.33), meaning the new concept requires only 1 scheduling component, would score 66% in satisfaction, signifying a substantial reduction in scheduling. Similarly, a factor of 2/3 (~0.66) would achieve 33% satisfaction as it shows some improvement in reducing scheduling needs.

Appendix B. Concept Generation Sketches

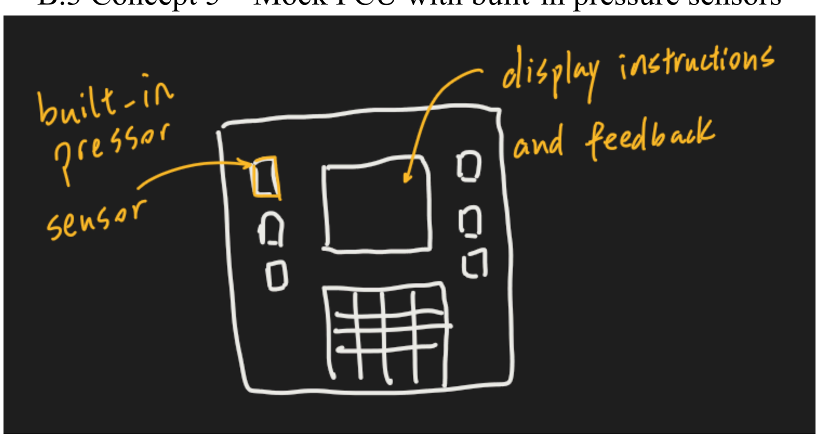
B.1 Concept 2 – Monitor with camera



B.2 Concept 4 – Wearable gloves with motion capture sensors



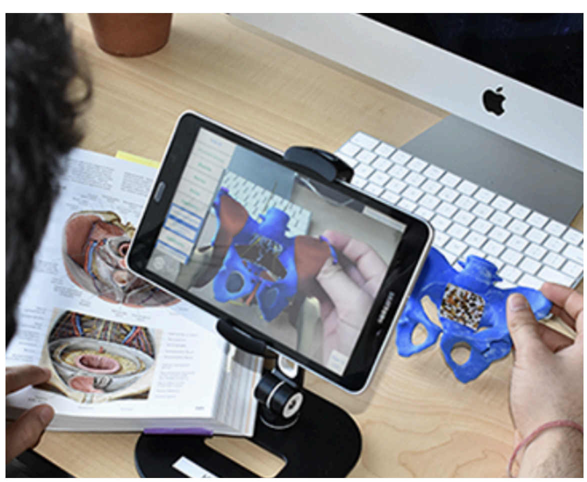
B.3 Concept 5 – Mock PCU with built-in pressure sensors



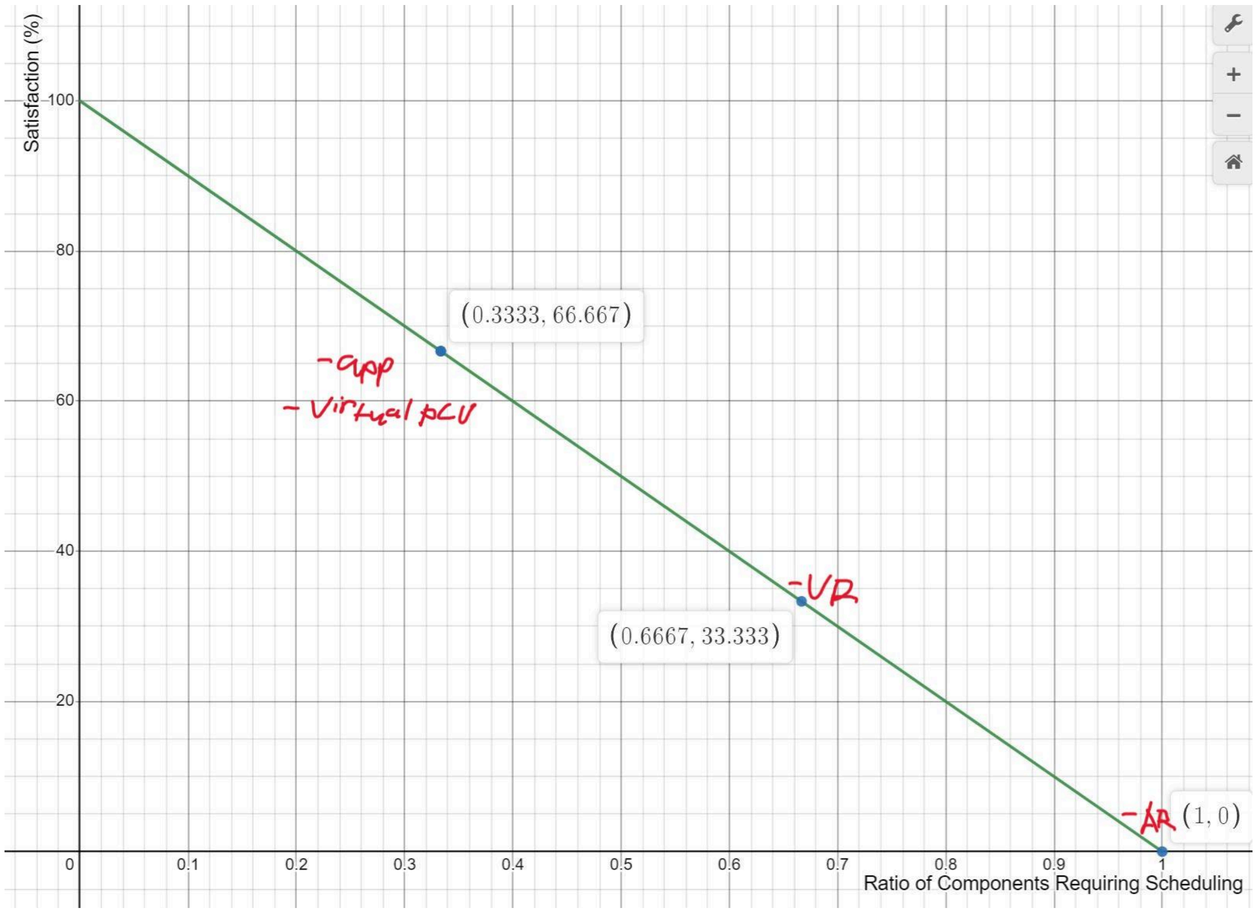
B.5a Concept 6 – Virtual PCU with a virtual keyboard approach[18]

B.5b Concept 6 – Virtual PCU

B.6 Concept 7 – Pock Pelvis AR app approach[19]

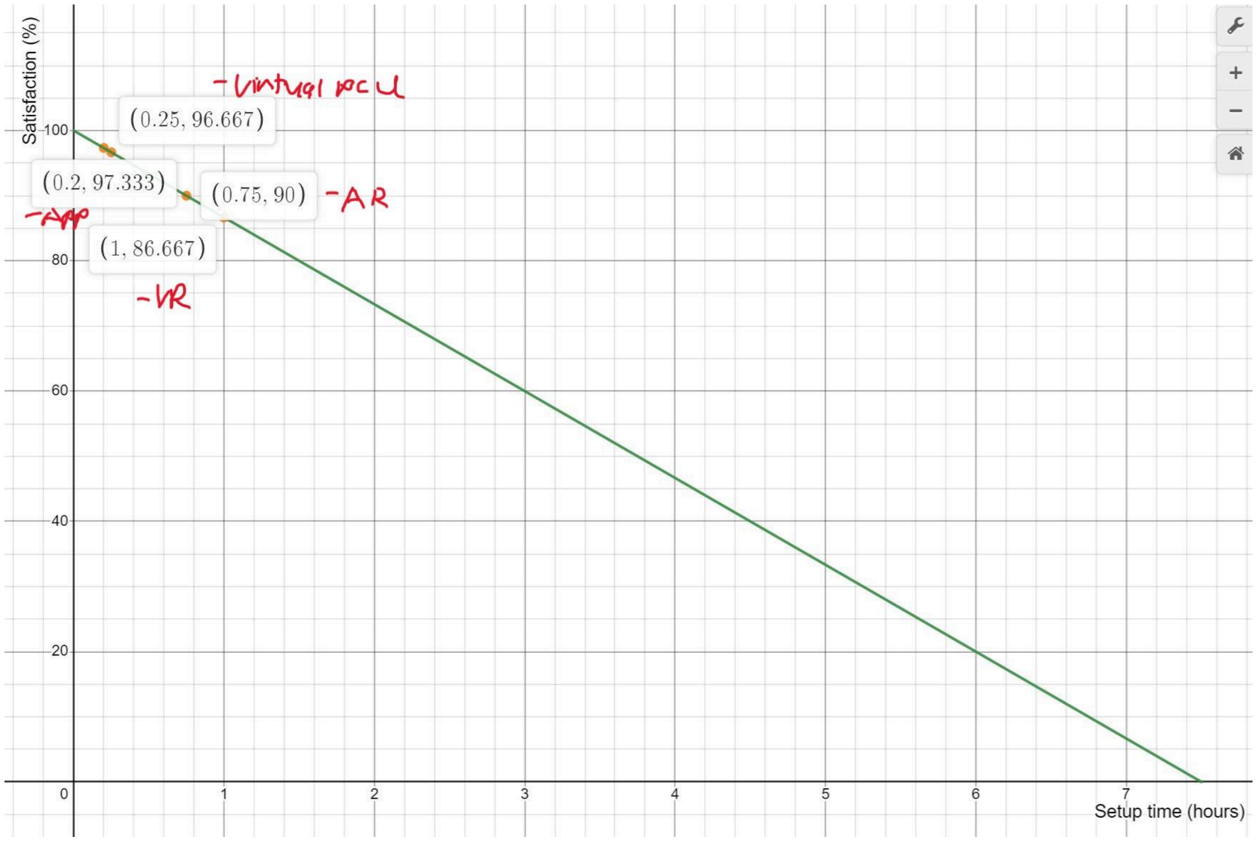


Appendix C. Concept scoring based on evaluation criteria – Ratio of components needing scheduling



Appendix D. Concept scoring based on evaluation criteria – 5-year costs

Appendix E. Concept scoring based on evaluation criteria – Ease of setup



Appendix F. Quiz Function Structure Diagram

DHF4 - Detailed Design and Verification

Group B5

BMEG 357

April 12th, 2024

Table of Contents

Preface:

This document details the construction and validation process of the critical function prototype (CFP) for our solution, the holo-trainer. In order to translate our concept into a CFP, we analyzed our functions from our Function Structure Diagram (FSD) and previous Design History Files (DHF), and reflected on feedback from our pitch by our client and the teaching team. Below we justify why we chose user input detection to be our critical function for this prototype.

Critical function identification

The function in our device that poses the most uncertainty is the user input modality our device employs to register trainee action. Being able to detect user input is one of the device's determinative functions as described in our FSD, and is a crucial part of the main training loop. Input detection was identified as our critical function because it is one of the most complex parts of the system, needing both hardware and software components to function for proper use, and thus has the most areas of uncertainty relative to other determinative functions described in the function structure diagram.

Critical function prototype planning

Prototype description

We intend to prototype the input detection system our device plans on using. As described in DHF-3, the idea behind the holo-trainer's input sensing modality is that a plane of infrared light will be projected near and parallel to the table[1]. With this laser plane established, any user interaction with the tabletop will reflect infrared light towards an infrared camera, where it is then mapped to a coordinate system for use in areas such as button presses. To test that input detection functions as intended, prototype versions of every system component need to be developed and included in our critical function prototype.

Intent of testing

Through this critical function prototype, we seek to answer a few questions and verify some requirements discussed in DHF2 through rigorous testing, such as:

1. How will different room/ambient lightings affect the ability of the program to detect infrared input?
2. How sensitive is the algorithm to infrared noise in the image, and will it lead to false inputs?
3. How effective is a webcam without an infrared filter at picking up infrared light?
4. Will assembly take less than 7.5 hours to complete[2]?
5. How durable is the device, can it meet our durability requirement[2]?

“Must-have” capabilities of the prototype

For this prototype to be considered complete, there are some essential functions the device must be able to perform. First, is that the prototype must be able to detect user input as the user interacts with the tabletop the infrared plane is projected above. Second, is that the prototype must be able to map the infrared images being picked up by the camera to an internal coordinate system to actually be able to use the user data.

Building the prototype

Description of the prototype

The critical function prototype can be split up into 3 components:

- Hardware: Laser circuit design, power supply
- Software: Infrared detection algorithm
- 3D modeling: Design of the camera and laser mount

Hardware:

The hardware consists of the infrared camera, laser diodes and related driver circuit used for this prototype. For this prototype, rather than a full projection of a PCU onto the table, 2 different colored laser diodes were used to represent different buttons on the PCU that would be displayed in the final product. Additionally, an infrared line laser was used as described in section 2 to allow for input detection. The reason for employing infrared technology to detect user input lies in our aim to distinguish between intentional actions and accidental interactions. By utilizing an infrared laser, we can differentiate between a user holding their hand above the table near one of the designated "buttons" and the deliberate act of pressing the button itself. The laser, aligned with the table's surface, ensures that any motions above the table not intersecting with the laser line are disregarded, even if they align with the correct coordinates on the x and y axes.

The infrared camera used for this prototype was not an actual infrared camera, as many infrared cameras and camera modules were either far outside of our allocated budget for this part of the project. Thus our workaround was to use a cheap webcam. We found that inside every webcam lies an infrared filter, so our idea was that if it was removed, it would be able to pick up the infrared light reflected from the user's fingers.

Software:

The software for this project was a program written in python using the opencv library. OpenCV was used for this prototype as it is a very common and well documented library for computer vision available in both Python and C++. Python was used in this prototype due to its simple syntax relative to C++ and our team’s experience with the language. The program that needed to be designed was the input detection loop.

The loop functions as follows:

1. Check for camera input
2. A frame containing infrared light shining off the user's fingers is collected by the camera
3. This frame is then thresholded for HSV values fitting the infrared light in the frame
    a. This basically only allows certain pixels within an HSV range to pass on, resulting in an image whose only non-black part are the user's fingers
4. The envelope from thresholding is then passed into a contour detection function where a shape can be drawn around the input
5. The centroid of this shape is then calculated and mapped to a coordinate system corresponding to the camera's resolution, and the centroid coordinates are displayed.
6. Return to 1

Laser mount:

This mount is meant to hold the camera, electronics and lasers. The mount comprises four main parts: the base, the adjustable arm, the neck junction, and the holder for the lasers and the camera. The angle of connection between the base and the arm is adjustable, providing a wider range of camera sight angles and offering a larger choice of working areas. The length of the arm is also adjustable to accommodate projections of different sizes. The junction that connects the upper arm to the laser/camera holder is designed to hold the holder at a fixed angle, with potential for future adjustment.

Early planning stages

The early planning stages of this project mainly surrounded fleshing out and sketching what our critical function prototype would look like. We initially performed a brainstorming-style of visualization, taking in ideas and sketching how they would look (Appendix A, Fig 1.), and then moving on with the most feasible and promising concept (Appendix A, Fig 2.).

Safety plan

To develop a physical CFP for the holotrainer, a safety plan needed to be developed to avoid injuring ourselves and/or other groups during development. The main components we needed to watch out for when testing are the various laser diodes we intended to use to project spots on the table. Lasers at high enough power are notorious for damaging eyesight as well as cameras without the proper precautions. Keeping this in mind, we elected to buy lasers that are rated lower than class IIIB and class IV (which require eye protection)[3], and are well below a power rating able to do any long lasting damage by looking at it indirectly. Alongside this, our plan for safe use of the lasers is to not shine it in anyone's eyes, as even though they are low power, direct exposure could still cause damage.

Documentation of build process

As this project was split up into various sections, each component of the project was worked on in parallel with one another. This section is thus split up into those components.

Software:

Developing the algorithm for this project required us to learn and use the various features in the OpenCV library. In summary, the program for our CFP was developed little by little, adding features as needed as we started to acquire a better understanding of the functions needed for user input detection.

First, we leveraged OpenCV's examples for color detection and created a sample code that could access a webcam and detect a set color, which functions by thresholding the frame for HSV values within a certain range as detailed in the prototype description. The example image below uses HSV values for the color blue, as it picks up the water bottle in the threshold mask (Fig 1.). Following this, we then moved into input processing, contour drawing and centroid calculation. This is done to be able to draw a shape around our detected item to display on the live camera feed. We started by researching mask processing methods, in which we found that we could increase the size of color inputs for clearer shapes through a process called dilation. We then researched centroid calculation functions to ensure accurate positioning and then moved onto experimentation with contour drawing which led us to decide on drawing a rectangle around the contour, as irregular shapes sometimes caused display bugs and inaccurate representations. This choice provides clarity in visual representation (Fig 2.).

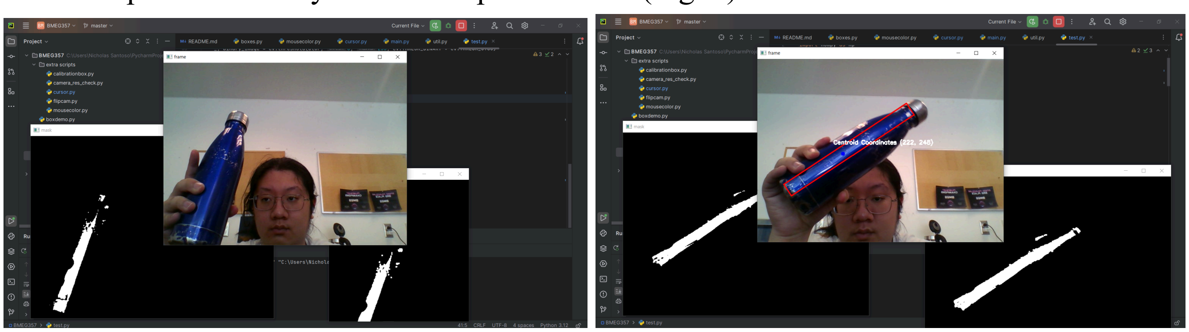


Fig 1,2. Implementation of color mask (left); Implementation of contour drawing (right)

Next, we developed a coordinate system to map the grid to the camera frame resolution. This facilitated easy centroid coordinate calculation, crucial for accurately detecting input regions. We then developed input areas represented as squares drawn onto the camera frame. If the centroid passes into one of these squares, indicating a valid input region, the box turns a different color. This setup allows us to test the functionality of the centroid coordinate system ensuring its accuracy and reliability

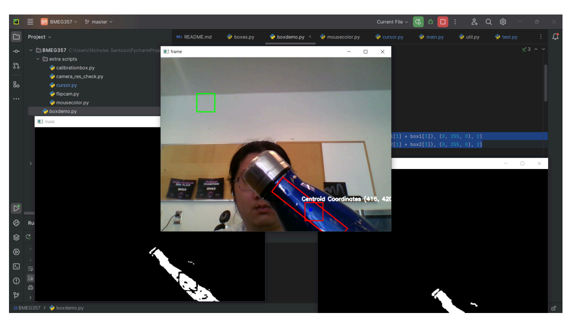


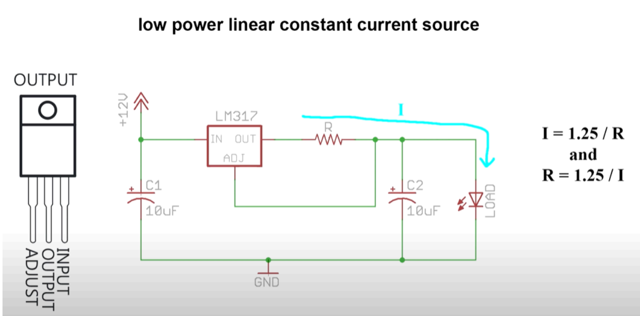
Fig 3. Implementation of input region

in detecting user input (Fig 3.). With this, the main backbone of our concept's software is complete, leaving only calibration with the camera's infrared input, and implementation with the hardware and 3D modeled stand.

Hardware:

The main hardware components of the holotrainer are the laser diodes and infrared camera. While initially sourcing components, we found that infrared cameras are much too expensive and would put us over budget. Our solution to this was to use a normal webcam, but to make some alterations beforehand. As all cameras can technically pick up infrared light, what many webcam manufacturers do is that they place an infrared filter over the lens, screening out infrared lights. So all we had to do was remove this filter by opening up the camera and we would be left with a usable camera that takes in infrared input. This camera would then plug into a computer using its USB cable, and be used alongside the software.

The second hardware component of this project are the laser diodes used by the holotrainer to project "buttons" onto the tabletop. We found however, that like most loads, it is bad practice to connect the load directly to the power supply with no protection/driver circuit as it could damage the component. So we researched laser driver circuits online and found that we needed a current regulator IC to prevent dangerous current fluctuations (Fig 4.) In which we then ordered, constructed the circuit on a breadboard and tested it (Fig 5.). Completing this section of the prototype.



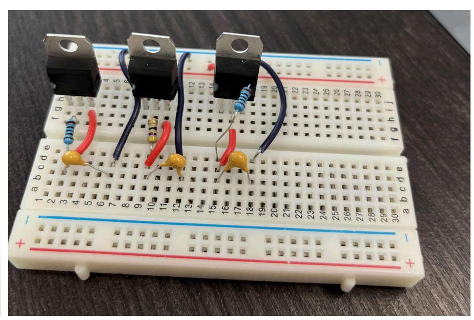


Fig 4,5. Schematic of laser driver circuit adapted from:
Constant current power supply and laser / LED driver tutorial (left); Prototype circuit on breadboard (right)

Laser mount:

The stand design primarily aims to fulfill specific functions, utilizing SolidWorks as the modeling tool. The initial component designed was the stand's base (Appendix A, Fig 3). It necessitates significant weight to lower the center of gravity, thus enhancing stability. Consequently, the base is solid, while the other components feature a hollow structure. To enable adjustable connection angles, a bolt and nut connecting method was selected, allowing flexibility in angle adjustment. The bolt hole diameter is 5mm, accommodating an M5 bolt, ensuring ample friction for securing the arm.

Subsequently, attention shifted to the arm design. To facilitate arm length adjustment, the arm consists of two parts: an upper arm for connecting to the laser/camera holder, and a lower arm for connection to the base (Appendix A, Fig 4). The lower arm width is set to 15mm, shorter than the 25mm M5 bolt, facilitating assembly. The upper arm incorporates a gravity lock-up structure for the laser/camera holder, maintaining it at a fixed angle while enabling future angle adjustment using a pin.

The laser/camera holder accommodates a 10mm-diameter red laser, a 7mm-diameter green laser, and a webcam (Appendix A, Fig 5). The lasers are inserted into designated holes with appropriate diameters, while space in the middle is left blank for the webcam.

An additional bolt hole add-on is affixed to the original bolt hole on the base, elevating the bolt hole (Appendix A, Fig 7). Connection between the holder and the upper arm is achieved through a gravity lock-up structure. The holder is inserted sideways into the track at the back, then rotated to the front through the central track.

Putting it all together:

Once all the components of the prototype were complete (algorithm finished, circuit breadboarded, laser mount 3D printed), everything had to be put together for our CFP. The first thing that was done was to test the laser driver circuit + lasers diodes with the input detection software. To do this, we started by mapping the input regions to areas around where the laser diode projected onto the table (Fig 7.). This was mainly done by applying the coordinate system defined earlier as to detect where the lasers are in the space and create a box around them. The lasers were connected to its requisite driver circuit on the breadboard and the entire thing was powered using a 9V battery (Fig 6.).

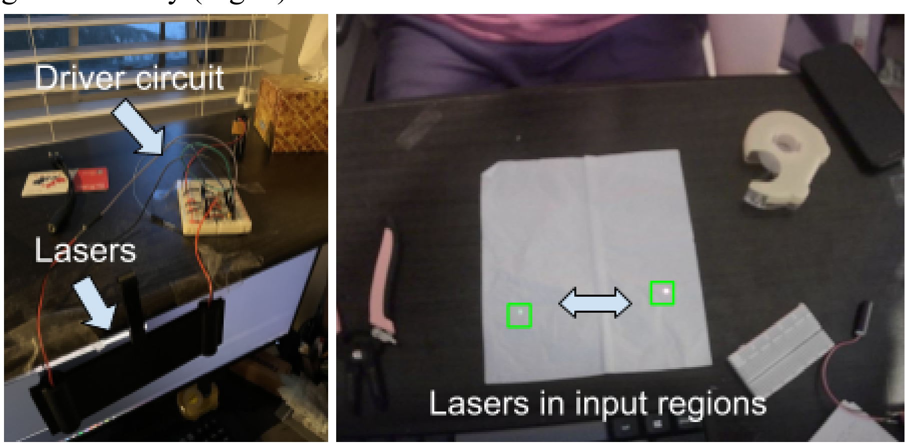


Fig 6,7. Laser setup for testing (left); Camera feed of setup with input regions (right)

Next, we connected the infrared laser to our circuit, and tested to see how well our strategy translated to real life. After calibrating the color detection threshold to that which corresponds to our infrared light reflecting off of the user's fingers, the lasers and program were turned on for testing (Fig 8.).

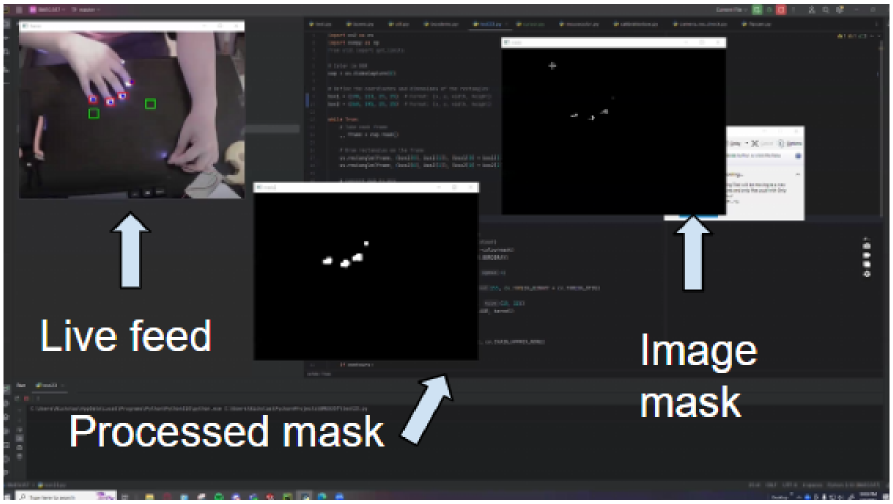
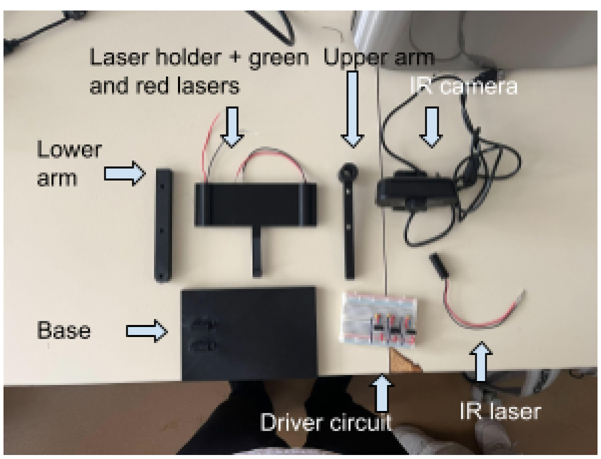


Fig 8. Infrared light detection algorithm testing with laser

Next, the 3D printed frame was assembled to finalize the positions of where the lasers would point on the screen, as well as the camera's field of view. The stand was assembled using the 3D printed parts and held together using various nuts and bolts. The resulting final CFP can be seen in the final prototype visualization section.

Visualizations of final prototype

The following are pictures of the components of, as well as the fully assembled CFP (Fig 9,10). The code of the python script running is too long to include in the body of this DHF, and can be found in Appendix C, section 1.



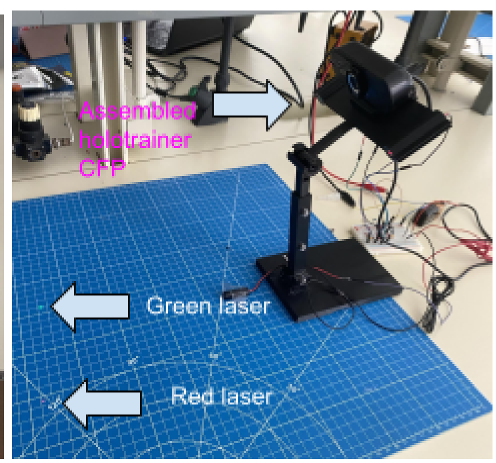


Fig 9,10. CFP final prototype, disassembled (left); CFP final prototype, assembled (right)

Evaluate the prototype

To evaluate our prototype, verification tests were done, including the test of assembly, which mainly focused on the time of assembly plus setup, and also if the stand can hold the weight of lasers and camera, as well as the test of input-response, which mainly focused on if the program can successfully detect and correctly respond to the user input, which is pressing the button represented by laser points of different color.

Laser holder testing

Two tests were performed using the 3D printed laser holder. The first is a setup time test, which requires that our setup time, which includes assembly and calibration, takes less than 7.5 hours as defined by our setup time requirement[2]. The second test aims to validate our durability requirement, which states that the device must be able to survive a 30” fall[2], whose purpose is to make sure that our product can withstand wear and tear.

The first test was performed by assembling the 3D printed components of the stand, mounting the lasers, calibrating the detection threshold and camera angle. The results of this test are generally positive, with the overall assembly taking approximately 1 hour, with 15 minutes attributed to physical mount assembly and 45 minutes taken to calibrate the program. This falls within our setup requirement, and thus passes this test.

The second test was performed by dropping the assembled frame with mounted electronics by a height of 30” onto various surfaces: laminate, carpet, and hardwood. This test was performed 3 times for each surface, with the general result being the same across all trials. After the drop, all wires, components and 3D printed parts stayed intact and continued to function. However, the camera, which was mounted simply by balancing it on top of the frame, fell off. This technically fails the test as the device does not function without reassembling a component, however, this was immediately fixed by applying an adhesive to the camera, preventing it from falling off.

In conclusion, through the holder testing, the stand is proved to have a qualified structural strength, which is sufficient to withstand long term use, and the setup time is proved to be within the time requirement. Future tests could include tests related to prolonged usage, to see how long the device will function without overheating (also tests long term use appropriateness).

Input-response Testing

The purpose of these tests is to validate our main concept for user input detection, as well as answer some of the questions outlined in the ‘intent of testing’ section earlier in this report. This first test aims to evaluate how well the device is able to detect and process user input in different lightings. In this test, the CFP was assembled in various rooms, one of the team member’s bedrooms, a living room, and the makerspace, with the CFP already calibrated to the bedroom. Once the program was booted up, a few observations were made. The first is that in the makerspace, no input was detected at all, indicating that calibration needed to be done for the device to function. The second is that in brighter spaces (like the makerspace and living room), the program struggles to pick up infrared light, as it essentially is a filter for brightness values, so a bright room would let unintended inputs (noise) pass. The key takeaway from this test is that calibration needs to be done in every room, which will add to the setup time.

The second test considers how well the program is able to detect user input. This test used a calibrated program, and evaluated how many times out of 50 presses, user input is registered, which is indicated by a square on the camera feed turning red (refer to input region implementation image). The results of this test are very favorable, as out of 50 presses, 50 inputs were registered, indicating that our device performs its critical function well. However, something to note is that despite being calibrated to the testing room, there were some inputs coming from objects in the background, indicating that the valid range is too wide. Future work would entail limiting this range, which could have a negative effect on the number of inputs registered.

Through testing, we were able to answer the questions outlined in the beginning of this DHF, validate our prototype against our requirements, and implement quality of life changes for the minimally viable product.

Risk analysis + FMEA

To ensure the safety and efficacy of our design, a comprehensive assessment of potential failure modes is conducted. The assessment followed the Failure Modes and Effects Analysis (FMEA) format shown in Table 1 below. We identified failure modes that are important to device functionality and user safety. The definitions of Severity and Occurrence values are justified in Appendix B, Table 2 to ensure clarity. To score the risk levels for each failure mode identified, we used a risk assessment matrix that considers both Severity and Occurrence values. The risk level value determined can be used to examine whether it is a low, intermediate, or high risk factor.

Table 1. Failure Modes and Effects Analysis

No.	Failure Mode	Effect	Cause	Severity	Occurrence	Risk Level
1	Camera failed to connect to the PC	Weak connections may impede the device's ability to capture user input. For example, if the camera connection is interrupted, the button stroke that the user just made on the projected PCU may be lost and not captured. This will hinder the training quality and result in less optimal training outcomes. Also, poor connection issues may require frequent checking and	Connection issues or software problems may cause bad connections between the camera and the PC. Loose wires lead to interrupted connections during training sessions.	[2] Connection issues will not cause any bodily damage to users but may impair device functionality. Interrupted connections require manual re-connection and or assistance from the IT department. This creates inconvenience and hinders the user experience of the training session.	[3] Connection issues may occur occasionally during the course of device usage for training purposes. This is because the device will be used frequently as it is portable and easy to set up for PCU training, and therefore will have a higher chance of having connection issues as cables might wear out due to repeated insertions and extractions. However, the connection between the camera and the PC uses USB cables, and they generally have high connection quality and product	[6] This is an intermediate risk.

		interruptions of the training session and contribute to poor overall training quality.			quality.	
2	Stand break	If the stand breaks, the projection system no longer works efficiently as the laser units will not be able to accurately project virtual PCU at a specified height and the camera will not be able to capture user input effectively or entirely.	A mechanical failure in the stand can be caused by excessive force applied to the stand. This will likely occur during the setup or adjusting phase when users are trying to connect the camera to the PC or adjust the camera and laser heights. Additionally, there might be material breakdowns from improper maintenance or cleaning methods.	[2] The mechanical breakdown of the stand does not pose any bodily harm to the users but hinders the device's functionality. It also brings inconvenience as repair and or replacement will be necessary to continue the training sessions.	[2] The durability of the stand should be long since it was carefully designed to withstand load in all directions. However, parts of the stand are 3D printed and are made of plastic material and can be subjected to a higher chance of brittle failure and other material failures due to increased temperature or aggressive loading.	[4] This is a low risk.
3	Overheating of the device	Possibly increases the temperature around the area. High temperatures for long periods of time may damage the device's functionality as the heat may damage the electrical components in the lasers and camera. This impairment of the electrical components may cause more heat to build up, resulting in amplification of the device's overheating. High temperatures may heat up the cables and potentially burn the user's skin when setting up or disconnecting the device with a PC.	If the device is unable to dissipate heat properly it can cause the device to accumulate heat quickly while the device is in use.	[3] Overheating of the device may cause burns on users' skin when setting up or contacting the device's surface. This potential burn would be mild in level of severity and would not require medical attention.	[2] Since all computational work is done on the PC side and no control board is used in our design, the likelihood of overheating is small. Additionally, the only component that may be subjected to overheating is the laser units during long periods of usage. However, users do not have to directly touch the laser units during training as they only will contact the surface whether the virtual PCU is projected onto. Even in cases where the height of lasers needs to be adjusted, users can use the non-thermally conductive stands to do so without having to contact the lasers.	[6] This is an interme diate risk.

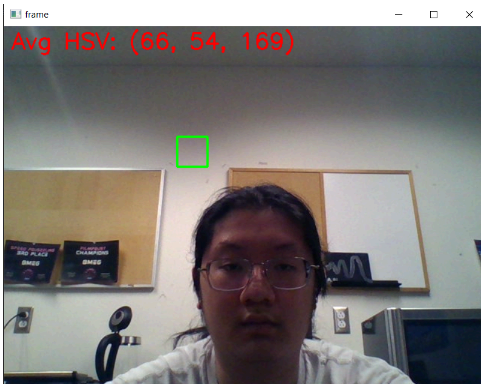
This risk assessment matrix follows the Greenlight Guru Risk Acceptability Matrix[4]. (Appendix B, table 1) The acceptability matrix allows precise quantification of the risks associated with our prototype. When defining the occurrence scale, we also took inspiration from the Medical Device Design: Innovation from Concept to Market by Ogrodnik Peter in Appendix C of Chapter 9[5], and the definitions are listed in Appendix B, table 2.

Prototype modifications

After testing and evaluation, some changes were made to the CFP to better address requirements, and improve quality of life while using the device. These changes are summarized below:

Modification	Justification
Added color calibration script to device library	During testing, we sought to answer various questions related to IR sensing and input processing. In short, we found that due to our sensing modality, our device would need to be calibrated depending on the room the training would be taking place in. Initially, calibration would be done through trial and error, taking a long time, but with this script which displays the average HSV value in a small area around the cursor, no trial and error is needed. This is a quality of life change. (Fig 11; Appendix C, section 2)
Created a holder for the IR laser	During the development of the stand, the designer neglected to include a place for the IR laser to rest. This resulted in us having to continuously adjust the laser every time it rolled out of place. To resolve this, a holder was printed to secure the IR laser (Fig 13). This is a quality of life change.
Developed text to speech instructions to be implemented with the lasers	Sometime during testing, we found that our critical function prototype did not address one of our design requirements, that training must engage at least 2 senses during the session. To resolve this, text to speech was implemented so that as an instruction is displayed on screen, it is also read out to the user. This is demonstrated in our demo video, as this DHF medium is not appropriate for demonstration.
Implemented check for camera connection	As identified during FMEA, and observed during testing, if there are any camera interruptions during the training session, the script closes and the training stops, wasting the user's time. To prevent this, a check was implemented into the main loop, which checks for a valid frame, and halts training until a valid frame appears again. This check mitigates the risk detailed in the FMEA section by lowering severity due to the program not shutting down immediately after being cut off. (Appendix C, section 3)
Implemented heat vents into laser holder	As identified during FMEA, overheating can cause permanent damage to the device, resulting in early replacement. Heat vents were implemented in the laser holder to prevent the laser from overheating. Heat vents were chosen rather than a heatsink because as it stands currently, if a heatsink was built into where the lasers lie in the laser holder (in between the laser holder and laser diode), there would be nowhere else for the heat to dissipate as it is an enclosed space, essentially making a heatsink useless. (Fig 12)

Due to limited makerspace equipment availability and time constraints, we were not able to fully integrate the changes outlined above for our final iteration of the prototype. However, these functions and design features could easily be included for future work. These changes were tested and verified independently, for example we checked that the IR laser holder could properly hold the laser and attach to the base. We also validated the text to speech instructions with the OpenCV software model, as well as tested the color calibration scripts. However we were not able to integrate all of these changes together due to the constraints previously mentioned.



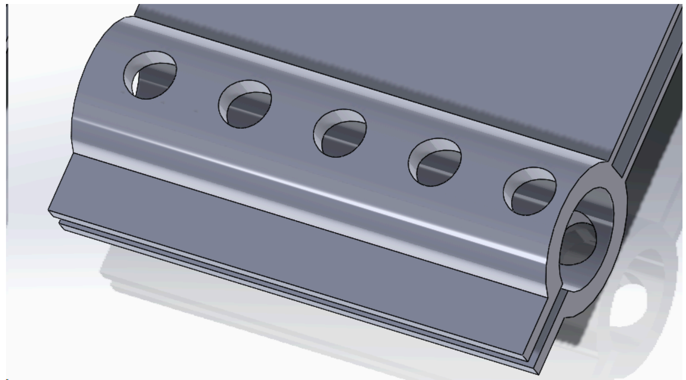


Figure 11,12. Color calibration script in action (cursor is green box) (left); Vents implemented in laser holder (right)

Figure 13. Printed IR laser holder

In conclusion, our final critical function prototype consists of the previously discussed holotrainer, with the aforementioned changes that we developed in subsequent iterations to improve the design of our first iteration. The IR laser holder was designed and added to the front of the stand so that the laser could be properly fixed in place. The color calibration scripts were added as a solution to the many attempts of trial and error that the initial iteration required for the calibration. The text-to-speech instructions were added as the first iteration did not have this function which was necessary for the design requirements to have been met. Finally, the FMEA showed us that heat vents and a camera connection check were necessary to add to our initial iteration to mitigate the risks that were previously discussed. Our final iteration of the CFP for the holotrainer is a reflection of the results we obtained from many checks of testing, verification, and FMEA analysis.

Appendix A: Additional Figures

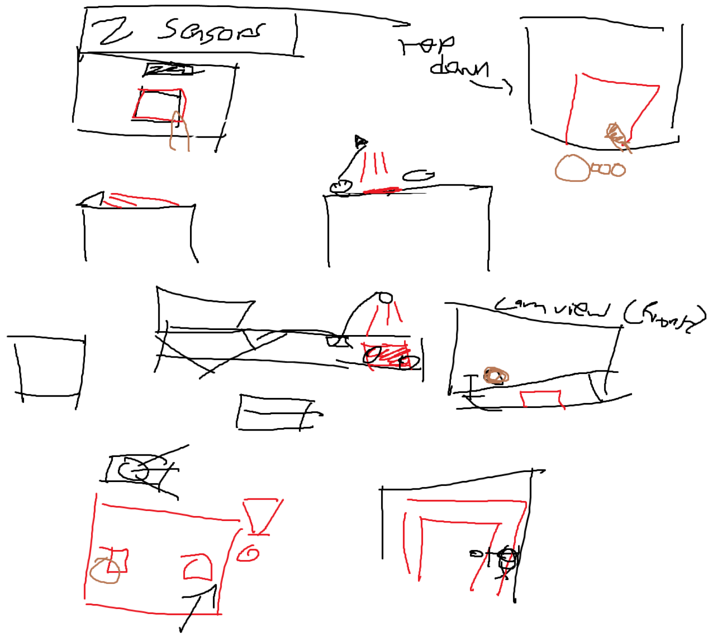


Fig 1. Initial sketches of holotrainer on table

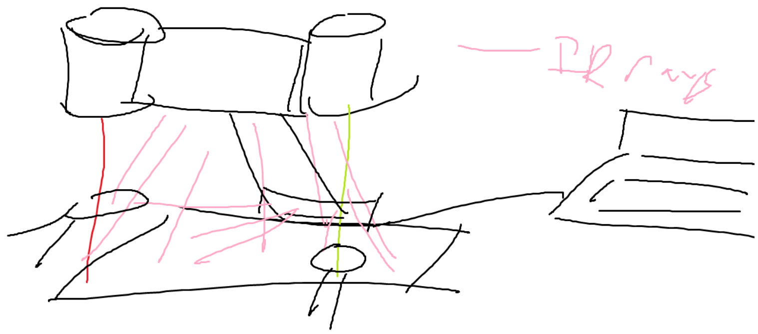


Fig 2. Fleshed out illustration of holotrainer CFP

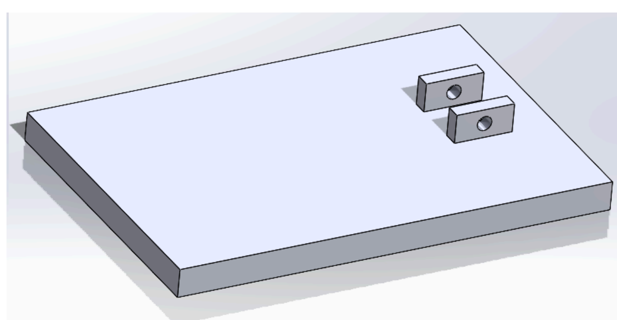


Fig 3. The base of the stand

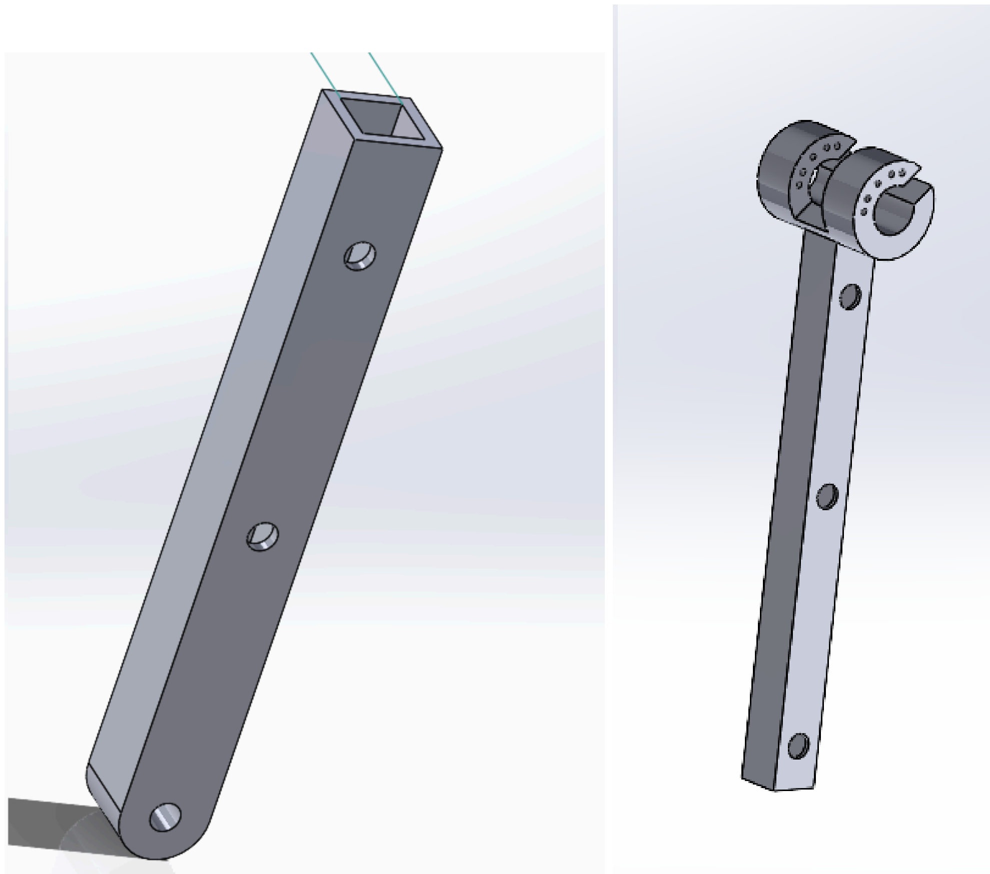


Fig 4. The lower (left) and upper (right) arm

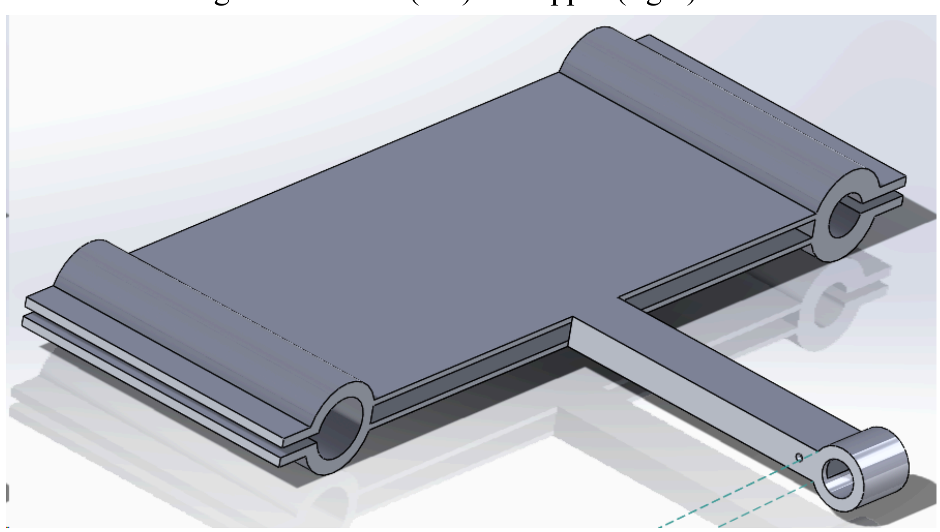


Fig 5. The laser/camera holder

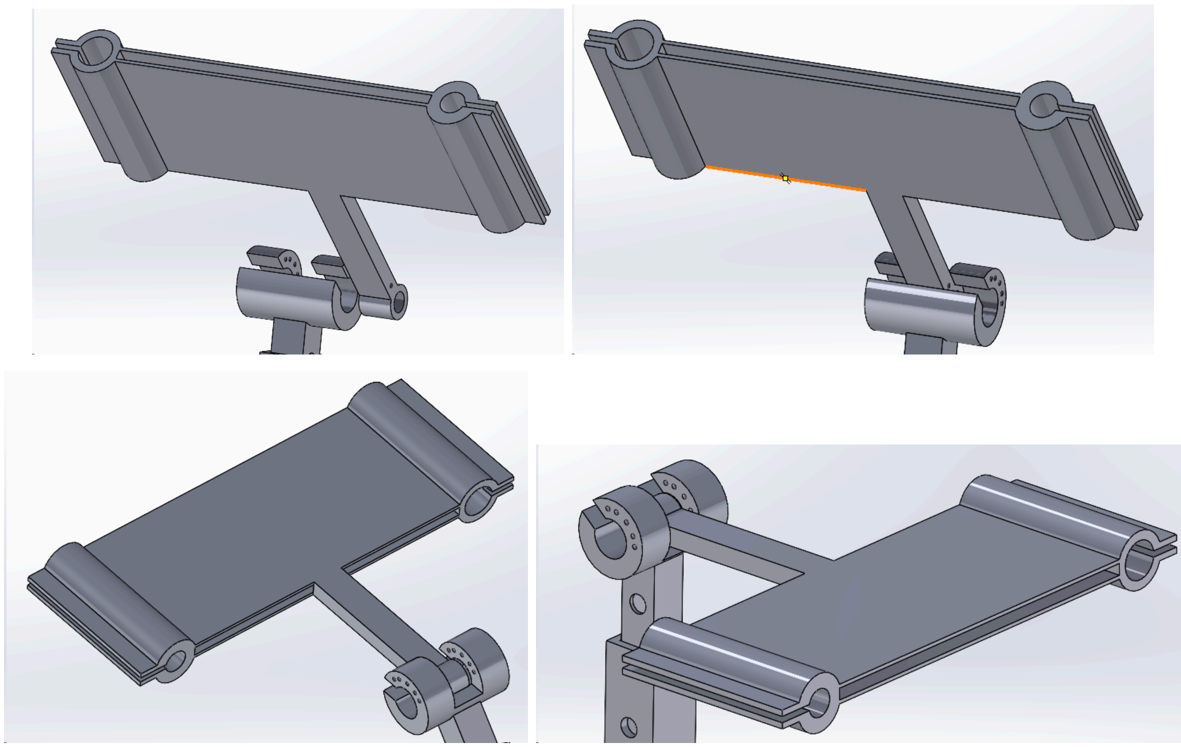


Fig 6. The procedure of the connection between upper arm and laser/camera holder

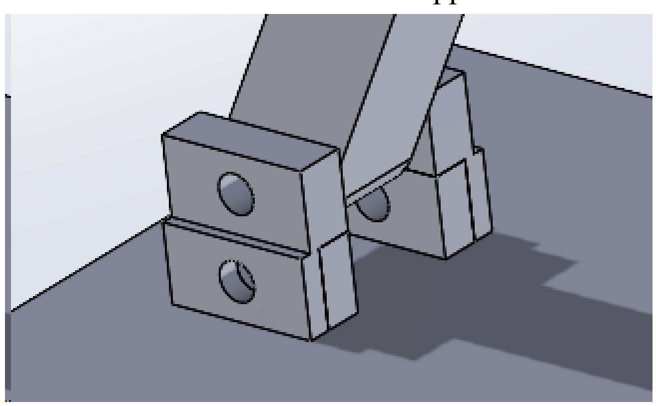


Fig 7. The bolt hole add-on

Appendix B: Additional tables

Table 1. Risk Matrix

Legend: → Low Risk → Intermediate Risk → High Risk		**Severity**				
		Negligible - 1	**Minor - 2**	**Serious - 3**	**Major - 4**	**Critical - 5**
Occurrence	**Improbable - 1**	1	2	3	4	5
	Remote - 2	2	4	6	8	10
	Occasional - 3	3	6	9	12	15
	Probable - 4	4	8	12	16	20
	Frequent - 5	5	10	15	20	25

Table 2. Definitions of Severity and Occurrence Scale

Severity Scale	
Negligible - 1	No physical harm to users and no effect on product functionality. Minor inconvenience and less ideal user experience.
Minor - 2	No physical harm to users and a small effect on device functionality. Minor inconvenience and hindered user experience that may require assistance to resolve.
Serious - 3	Minor physical harm to users that do not require medical attention. Major impairment to device performance that requires assistance to resolve.
Major - 4	Major physical harm to users that requires medical attention or treatment. Serious impairment to device performance that may require replacement or assistance to resolve.
Critical - 5	Severe physical harm to users; could cause long-term trauma. Major impairment in device performance that may not be resolvable.
Occurrence Scale	
Improbable - 1	Less than 1 in 100,000,000 or once per year
Remote - 2	Between 1 in 10,000 to 1 in 100,000 or once per half-year

Occasional - 3	Between 1 in 1000 to 1 in 10,000 or once per quarter
Probable - 4	Between 1 in 100 to 1 in 1000 or once per week
Frequent - 5	More than 1 in 100 or once per day

Appendix C: Screenshots of commented code

Section 1: Code for CFP input detection main loop (pre changes)

```
import cv2 as cv
import numpy as np


# Color in BGR
cap = cv.VideoCapture(1)

# Define the coordinates and dimensions of the rectangles
center1 = (197, 381)
center2 = (397, 392)
box_width = 25
box_height = 25

# Calculate top-left corner coordinates of the boxes based on the center coordinates
box1 = (center1[0] - box_width // 2, center1[1] - box_height // 2, box_width, box_height)
box2 = (center2[0] - box_width // 2, center2[1] - box_height // 2, box_width, box_height)

while True:
    # Take each frame
    _, frame = cap.read()

    # Draw rectangles on the frame
    cv.rectangle(frame, (box1[0], box1[1]), (box1[0] + box1[2], box1[1] + box1[3]), (0, 255, 0), 2)
    cv.rectangle(frame, (box2[0], box2[1]), (box2[0] + box2[2], box2[1] + box2[3]), (0, 255, 0), 2)

    # Convert BGR to HSV
    hsv = cv.cvtColor(frame, cv.COLOR_BGR2HSV)

    # Define range of color in HSV
    lower_colour = np.array([0, 0, 200])
    upper_colour = np.array([0, 0, 255])
```

```

    # Threshold the HSV image to get only color colors
    colourmask = cv.inRange(hsv, lower_colour, upper_colour)
    colour_regions = cv.bitwise_and(frame, frame, mask=colourmask)
    colour_gray = cv.cvtColor(colour_regions, cv.COLOR_BGR2GRAY)

    blur = cv.GaussianBlur(colour_gray, ksize: (5, 5), sigmaX: 0)
    # Otsu thresholding
    _, binary_image = cv.threshold(blur, thresh: 0, maxval: 255, cv.THRESH_BINARY + cv.THRESH_OTSU)

    #mask processing
    kernel = 30*cv.getStructuringElement(cv.MORPH_RECT, ksize: (10, 10))
    closed = cv.morphologyEx(binary_image, cv.MORPH_CLOSE, kernel)
    dilate = cv.dilate(closed, kernel, iterations=1)

    # find contours
    contours, _ = cv.findContours(dilate, cv.RETR_TREE, cv.CHAIN_APPROX_NONE)

    # Check if any contours are found
    if contours:
        for contour in contours:
            area = cv.contourArea(contour)
            if area > 100:  # Adjust this threshold as needed
                rect = cv.minAreaRect(contour)
                box = cv.boxPoints(rect)
                box = np.intp(box)
                cv.drawContours(frame, contours: [box], contourIdx: 0, color: (0, 0, 255), thickness: 2)
```

```
            M = cv.moments(contour)
            if M["m00"] != 0:
                cx = int(M["m10"] / M["m00"])
                cy = int(M["m01"] / M["m00"])

                # Draw centroid
                cv.circle(frame, (cx, cy), 5, (255, 0, 0), -1)
                centroid_coords = "Centroid Coordinates (%d, %d)" % (cx, cy)

                # Check if centroid is inside either of the rectangles
                if box1[0] <= cx <= box1[0] + box1[2] and box1[1] <= cy <= box1[1] + box1[3]:
                    cv.rectangle(frame, (box1[0], box1[1]), (box1[0] + box1[2], box1[1] + box1[3]), (0, 0, 255), 2)
                if box2[0] <= cx <= box2[0] + box2[2] and box2[1] <= cy <= box2[1] + box2[3]:
                    cv.rectangle(frame, (box2[0], box2[1]), (box2[0] + box2[2], box2[1] + box2[3]), (0, 0, 255), 2)

    cv.imshow('frame', frame)
    cv.imshow('mask', binary_image)
    cv.imshow('mask2', dilate)
    k = cv.waitKey(5) & 0xFF
    if k == 27:
        break

cv.destroyAllWindows()
```

Section 2: Code for color calibration script

```
import cv2 as cv
import numpy as np

# Initialize global variables to store mouse position and average HSV value
mouseX, mouseY = -1, -1
avg_hsv = None
box_size = 20  # Initial box size

# Mouse callback function to update mouse position
def update_mouse_pos(event, x, y, flags, param):
    global mouseX, mouseY
    if event == cv.EVENT_MOUSEMOVE:
        mouseX, mouseY = x, y

# Function to compute the average HSV value of the region around the mouse cursor
def compute_avg_hsv(frame, x, y, box_size):
    # Extract the region around the mouse cursor
    region = frame[max(0, y - box_size):min(frame.shape[0], y + box_size),
                   max(0, x - box_size):min(frame.shape[1], x + box_size)]

    # Convert the region to HSV color space
    hsv_region = cv.cvtColor(region, cv.COLOR_BGR2HSV)

    # Compute the average HSV value
    avg_h = int(np.mean(hsv_region[:, :, 0]))
    avg_s = int(np.mean(hsv_region[:, :, 1]))
    avg_v = int(np.mean(hsv_region[:, :, 2]))

    return (avg_h, avg_s, avg_v)

```

```python
# Start capturing from the webcam
cap = cv.VideoCapture(0)

# Create a window and set the mouse callback function
cv.namedWindow('frame')
cv.setMouseCallback('frame', update_mouse_pos)

while True:
    # Capture frame-by-frame
    ret, frame = cap.read()

    # Draw a rectangle around the mouse cursor
    cv.rectangle(frame, (max(0, mouseX - box_size), max(0, mouseY - box_size)),
                 (min(frame.shape[1], mouseX + box_size), min(frame.shape[0], mouseY + box_size)),
                 (0, 255, 0), 2)

    # Compute the average HSV value of the region around the mouse cursor
    avg_hsv = compute_avg_hsv(frame, mouseX, mouseY, box_size)

    # Display the average HSV value
    if avg_hsv is not None:
        cv.putText(frame, f'Avg HSV: {avg_hsv}', (10, 30), cv.FONT_HERSHEY_SIMPLEX, 1, (0, 0, 255)

    # Display the frame
    cv.imshow('frame', frame)
```

```python

    # Check for key presses
    key = cv.waitKey(1)
    if key == ord('q'):  # Quit the loop if 'q' is pressed
        break
    elif key == 63232:  # Increase box size when 'up' arrow key is pressed
        box_size += 5
    elif key == 63233 and box_size > 5:  # Decrease box size when 'down' arrow key is pressed (minimum size is 5)
        box_size -= 5

# Release the capture and close all windows
cap.release()
cv.destroyAllWindows()
```

Section 3: Camera check function

```python
# Function to check if camera input is detected
def is_camera_input_available(cap):
    # Check if the capture object is opened and whether frames are being read
    return cap.isOpened() and cap.grab()
```

```python
# Initialize timer variables
timeout = 10  # Timeout in seconds
start_time = cv.getTickCount()

while True:
    # Check if camera input is available
    if not is_camera_input_available(cap):
        # Pause processing if no camera input is detected
        print("No camera input detected. Pausing...")
        while not is_camera_input_available(cap):
            pass  # Wait until camera input is detected
        print("Camera input detected. Resuming...")
        start_time = cv.getTickCount()  # Reset the timer
```

```python
    # Check if the timeout has been exceeded
    elapsed_time = (cv.getTickCount() - start_time) / cv.getTickFrequency()
    if elapsed_time > timeout:
        print("Timeout exceeded. Pausing...")
        while is_camera_input_available(cap):
            pass  # Wait until camera input is lost
```

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