Systematic Application of Extreme-User Experiences: Impact on the Outcomes of an Undergraduate Medical Device Design Module

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Abstract—Extreme-user experiences refer to experiences that simulate the extremes of user abilities like reduced or no visual attention or auditory attention. Inspired by the needs experienced by the users who experience physical or cognitive challenges, extreme-user perspectives can make designers understand their designs from an inclusive design perspective and address the latent needs experienced by their users. Yet, they are seldom leveraged in mainstream designs that may or may not be used by extreme users, for example, medical devices. This study applies the extreme-user experiences along the initial stages of the design process to help design students identify the latent needs of six different medical devices. Students used Activity Diagrams for a systematic application of extreme-user experiences. Six teams with a total of 25 students took part in the study. We apply a latency metric to validate the identified needs and discuss the metric’s impact in evaluating the latency of design needs. Outcomes support the potential of extreme-user experiences in capturing the latent design needs in medical device design and demonstrate the potential of extreme-user experiences in changing designers’ perceptions over their design solutions. The proposed approach aims to help students and medical device design professionals to have a first-person experience on the nuances of user needs that get missed in the current design process. We believe this could lead to future works that focus on designs that reduce the mishaps associated with medical device design.

Keywords—Medical devices, Design methods, Usability, Latent needs.

GLOSSARY

- **Latent needs** Needs that are important yet not obvious or outwardly spoken by the average user.41
- **Latency metric** Proposed measurement to identify an implicit yet critical (latent) need.
- **Extreme-user variables** Factors that impact a user’s experience with a product service or system.24,25
- **Extreme-user** Extreme-user populations comprise the group of users whose needs differ from those of the general population of users of a product, service, or system (PSS). For example, the older adult users and users with reduced physical or cognitive abilities would be examples of extreme users for a product that primarily focuses on the general population.
- **Extreme-user experiences** The process of getting knowledge or skill from doing, seeing, or feeling things inspired by adopting extreme-user perspectives.
- **Simulation tools** Devices that help experience extreme-user inspired perspectives like reduced vision, reduced physical strength, or reduced mobility.

INTRODUCTION

Biomedical Engineering education has evolved significantly over the past 50 years by adapting to the trends and resources available in engineering educa-
Design-embedded education is one such adaptation. With increased awareness on addressing diverse user needs in healthcare, design processes and corresponding design methods are gaining increased attention. As a result, Biomedical Engineering education modules allow students to develop solutions that address practical, challenging, and real-world design issues imposed by medical devices and help them adopt a user-centric approach to address the needs shared by healthcare professionals.

While various adaptations of design processes are available, they all ultimately apply variations of user-centric design methods that encourage creative and innovative mindsets. A user-centric design approach is even more important in medical devices as user interactions form a critical part of a successful healthcare system, mainly due to multiple stakeholders who interact with the medical devices. In addition, medical device design demands compliance towards various other regulatory and ethical factors. Considering these factors that influence medical device design, Lerner et al. define the role of Design in Biomedical Engineering as:

Design in biomedical engineering means the conception, creation, and fabrication of devices, instruments, fixtures, procedures, methods, algorithms, or simulations intended to benefit health and wellness, including means to interrogate, analyse, or otherwise define operating or physical parameters.

It has been a couple of decades since the release of ‘To Err is Human’, which demonstrated a need for Human Factors Engineering (HFE) in healthcare design. There is currently an increase in the attention given to fixing the device rather than fixing the user. As a result, Design processes and HFE approaches strive to ensure the efficient functioning of these devices by considering the physical and cognitive limitations in human abilities. Yet, research works acknowledge that this change in healthcare is still in its developing stage compared to other industry counterparts like aviation. Studies highlight that the increased weightage for error prevention imposes limited opportunities for innovation and consideration for contextual factors. For example, a device that is successful in terms of regulations might not be a real-world success. Therefore, HFE adapts Design Thinking processes to complement user-centric design. Frequently applied user-centric design methods include user interviews, observations, personas, scenarios, user journey maps, and contextual need analysis (CNA). Each of these methods provides opportunities for designers to engage with the users and understand their experiences. For example, user journey maps help capture the user’s interaction with a medical device, touchpoints of user interaction, channels of interactions, and emotions. Whereas contextual need analysis helps capture the influence of various circumstances on the needs experienced by the users. This work complements and extends the current efforts to bring a user-centric mindset through the systematic application of an approach called extreme-user experiences. By applying extreme-user experiences, studies have demonstrated a high impact in bringing creative new perspectives among designers.

The extreme-user experiences in this study are used to enable students to evaluate the usability of their devices under limited physical abilities, thereby leading to a more user-centric design approach that addresses the latent needs among users. The extreme-user experiences provide experiential learning that could be associated with the Behaviorist learning theory (Behaviorism) by John Broadus Watson. The objective of Behaviorism is “to offer conditions that predict and control human beings” where contextual user response could be predicted through appropriate stimulation. In this study, stimulation is provided by means of simulated extreme-user experiences that transform the perception among students. Given that healthcare professionals experience various situational challenges to their physical and cognitive abilities under high-stress scenarios, a systematic adaptation of such extreme-user experiences could help future designers understand the latent yet essential needs that influence user experience.

Assistive and inclusive design research usually apply simulated extreme-user experiences to impose physical restrictions that limit the abilities of designers and students. While engaging actual users is ideal and essential, these experiences can influence and enhance designers’ creativity to approach user needs. Therefore, this research applies wearable simulations as a design tool that imposes situational physical limitations to change designer perspectives and not replace actual user engagement. A previous study with undergraduate students showed that a systematic application framework that guides them through the process is more effective than an intuition-based approach to applying such perspectives. The study presented in this paper shares and extends the systematic approach followed and tested among 25 students from six design teams who worked on six healthcare design projects proposed by the healthcare professionals. The approach discussed in this paper comprises a combination of Activity Diagram and extreme-user experiences. Activity Diagram is a design method used to break down user interactions with a product, service, or system (PSS) using parallel or
sequential blocks (activities) connected through arrows (causality). Each block represents the user’s interactions with the design using action verbs. Extreme-user experiences complement Activity Diagrams by simulating scenarios at boundaries of design opportunity and identifying latent design needs that lead to resultant design insights. A detailed description of the Activity Diagram and the corresponding extreme-user experiences used in this study will be discussed in “Week 3-Phase I” and “Week 4” sections of Research Methodology. In addition, we share the metric that was used to measure the latency of the needs identified by the students. Through this study, we seek answers to the following research questions:

1. How does the systematic approach help adopt extreme-user experiences and impact students’ ability to identify latent user needs in medical device design?
2. What are the key takeaways from applying extreme-user experiences as a curricular intervention to identify latent needs?

**RESEARCH METHODOLOGY**

This study engaged 25 students from a Healthcare Design course, where one was a first-year graduate student, and the remaining 24 were senior-year undergraduate students. The age group of the students ranged from 21 to 26 (average 23). All 24 senior-year students were familiar with user-centric design methods from the ‘Introduction to Design’ module they received during their first year, and the graduate student participant had experience working with a design research team. All study procedures complied with the Singapore University of Technology and Design Institutional Regulatory Board (IRB) regulations and approval. The researcher assured the students that their response to the study would not affect their course grades, and the study did not collect any personal identifiers from the students. The following sections detail the research methods used throughout the four-week duration of the study.

*Week 1 and Week 2*

During Week 1 of the course, healthcare professionals from hospitals and medical device design companies shared their project pitches based on the design needs they experienced. Among the 12 proposed projects, students selected six projects on a first-come, first-serve basis. Following are the shortlisted projects with their description.

1. **Catheter guidewire safety** As the name suggests, catheters use guidewires during the catheterisation procedure. Clinicians remove the guidewires once catheter insertion is complete. However, there are rare instances where the guidewire gets left behind in the patient’s body, leading to stringent guidelines/checklists that guide the healthcare professionals—this project aimed to prevent healthcare professionals from leaving the guidewires behind after the catheterisation procedure.

2. **Biopsy needle stabilization** Biopsies is a procedure that helps diagnose pathological tissue with minimal invasion. The needles used for such biopsy procedures are guided freehand to the precise tissue area, but maintaining the angle and precision required is challenging once the clinicians release the needle from their hands. This challenge leads to several iterations, tissue damage, and increased exposure to radiation—this project aimed to design a stabiliser that holds the biopsy needle in place and enhances its usability.

3. **Traction device for shoulder dislocation** A commonly dislocated joint in the human body is the glenohumeral joint at the shoulder. Relocating the dislocated joint could take an hour or two, depending on the availability of a skilled professional. This project wanted a design solution to effectively relocate the shoulder within a short duration without a need for sedation.

4. **Guidewire introducer** Endovascular procedures are a less invasive alternative for more complex surgical procedures. Depending on the procedure, this task demands the healthcare professional to thread the guidewires multiple times to the respective sites for intervention. This project aimed to automate the process of introducing the guidewire to increase the efficiency of the procedures.

5. **Neonatal health monitor** It is crucial to monitor the independent functioning of a Newborn as the baby adapts to the conditions outside the womb. The current capacity at hospitals outnumbers nurses at the ratio of 1:140. Therefore, this project aimed to build a neonatal monitoring system that will aid nurses in monitoring Neonates’ health status.

6. **Cuffless blood pressure measurement** Blood pressure is one of the primary vitals measured at hospitals. However, this demands more time and attention from the nurses, especially the positioning of the cuff. Hence, this project focused on developing a cuffless non-intrusive way to
measure Blood Pressure among hospitalised patients.

During Week 2, the students started their literature reviews, benchmarking, and user interviews to strengthen their understanding of the project and user needs. Following Week 2, Weeks 3 and 4 focused on testing the impact of the systematic application approach for extreme-user experiences. Figure 1 shares the step-by-step research approach followed and their time distribution during Week 3 and Week 4.

**Week 3—Phase I**

Students were introduced to the user interviews and benchmarking to gather user needs as part of the Healthcare Design course syllabus. At the beginning of Week 3, students had a briefing on Activity Diagrams as part of this study. Students were already aware of the Activity Diagrams from their Introduction to Design Course offered during their freshmen year. The briefing, nonetheless, shared an introduction to Activity Diagram, its purpose, implementation, and two worked examples of the Activity Diagrams. Activity Diagrams in the design process are applied as a life-cycle and workflow process to break down users’ actions and expected interactions with a PSS in terms of touchpoints and identify insights in order to improve the overall user experience. In this context, an Activity Diagram is a graphical representation of user activities, where the nodes of the representation are actions performed by users, and arrows, from a starting point to a termination point, connect and illustrate the causality of the actions, either in serial (sequential) or parallel pathways.

Following the initial briefing, each team developed a baseline Activity Diagram for each project, based on their collectively gathered user needs as part of their course. Each team then received one questionnaire for Phase I, and the students filled it out collaboratively as a Team. The questionnaire asked the teams to share their team name, the user needs derived from their user interviews and benchmarking, the source from where they identified the need (for example, the doctor they interviewed), and an Activity Diagram for the existing medical procedure followed in their respective projects. Students listed the user needs they had captured from their user interviews and benchmarking and highlighted any additional needs they could identify from their Activity Diagram. The researcher informed the teams that every team member had to agree with the final set of needs and the Activity Diagram before submitting their questionnaire sheets. Students recorded their responses for each phase of the study using separate questionnaires.

In between Week 3 and Week 4, the Activity Diagrams and needs were verified and transcribed by a design researcher. The researcher printed the transcribed set of needs and Activity Diagrams for each student to refer to during Week 4.

**Week 4—Phase II and Phase III**

Week 4 comprised two phases: Phase II and Phase III. We had 24 students participate in Phase II and Phase III.

Phase II: Teams had their potential design concepts ready for their respective projects by Week 4. Before proceeding to individual responses, teams again generated Activity Diagrams for their likely design concept to ensure common understanding among all teammates. Once the teams collectively shared the Activity Diagrams for their potential design concepts, students were given individual coded questionnaire

![Figure 1](image_url)
sheets and a sheet with the transcribed Activity Diagrams and needs identified during Phase I. Coded questionnaires helped differentiate individual responses without collecting personal identifiers from each student. Students did not flip through the questionnaires until they arrived at the corresponding stages. Each student had 15 minutes to revisit the initial set of needs they had identified as a team and amend them if the needs had evolved in between. The primary purpose of Phase II was to differentiate the effect of Activity Diagrams from that of the combined effect of Activity Diagrams and extreme-user experiences adopted in Phase III.

Among the questionnaires, students had a list of variables that could influence a user’s experience with their medical devices. The variables included extreme-user experiences like vision, hearing, and other spatial extremes. Appendix A shares the list of extreme-user variables used for the study. Although this study did not apply the environmental extremes, this list helped understand the variables associated with the user’s experience of respective medical devices without receiving guidance from the proposed systematic application framework. Students proceeded to the next phase once they set aside their filled questionnaires.

Phase III: This phase involved identifying and applying simulation tools that reduced physical abilities by using the systematic application approach. Students received a 10-minute briefing on extreme-user experiences and their potential in medical device design. Following this, they had five minutes to familiarise the given wearable simulations.

Figure 2 displays an illustration of the steps implemented during Phase III, and the section that follows elaborates on each step.

Step 1 Identify the extreme-user variables using the Activity Diagram generated for the potential design concepts. Activity Diagram in Fig. 3 was used as an example to explain the approach.

Step 2 Associate each variable to their corresponding wearable simulation tools. Figure 4 was used to guide the students through this step.

Step 3 Use the activity-specific simulation tool to eliminate the respective physical ability and identify the design need(s) imposed by the absence of those physical abilities.

Step 4 Update the Activity Diagram for the potential design concept to accommodate the new set of needs if necessary.

After completing the steps listed above, students were also given a new but same list of user experience variables and asked to select the variables that influenced the user’s experience with their device. This list helped verify if the systematic application approach influenced the student’s awareness of the physical demands imposed while interacting with their medical devices.

**Metric Used: Latency Metric**

Due to the unavailability of any published metric to calculate latency, we developed a metric for latency to understand the impact on the needs identified at each phase. Latency refers to the needs that are important yet not obvious or explicitly spoken by the average or typical user. The metric comprises the factors that define latency, such as impact and the implicit nature of the needs. Three raters used the four factors (Impact, Obviousness, Inefficiency, and Implicit) to rate the needs identified by the participants. The factors ‘Obvious’ and ‘Inefficient’ were used to verify the consistency of responses received for ‘Implicit’ and ‘Impactful,’ respectively. A four-point Likert scale evaluation was adapted to overcome the ‘social desirability bias’ (Garland, 1991) that could influence the ratings. The scale ranged from ‘Strongly Agree’ to ‘Strongly Disagree.’ The raters used the definitions...
below as the key to evaluating the needs based on the four factors used to determine latency.

- Impactful: The need has the potential to create a real difference. This need will delight the user.
- Obvious: In all circumstances, the majority of the users will express this need. If 20 users are interviewed, the majority will share this need.
- Inefficient: This will not have a positive effect on the user experience. It is not going to improve the experience with the product, service, or system.
- Implicit: This is not a standard requirement shared by the user. Not a common requirement given to the designers.

One healthcare professional per project and two researchers applied the latency metric to rate every need shared by the students. The two researchers were consistent across all the projects, and the healthcare professionals rated the projects based on their expertise. Among the two researchers, one researcher was a Ph.D. Candidate with expertise in Biomedical Engineering and over four years of experience in extreme-user research, and the second researcher had expertise in Mechanical Engineering and over three years of experience in design science and computation research. An intraclass correlation coefficient estimate (ICC-1) on SPSS Statistics (Version 25.0.0.1, IBM Armonk, N.Y., USA) was used to run an average measures model for three inconsistent raters. Based on a 95% confident interval of ICC estimate, the raters had a ‘Moderate’ degree (ICC value: between 0.5–0.75) of intraclass correlation for the needs under each of the four latency factors. A follow-up process of calculating a similarity percentage between the raters showed that the two design researchers, on average, had 85% sim-
ilarity, and each of the researchers shared 84% and 73% similarity with the healthcare professionals. The final score for each latency evaluation factor was calculated based on the median of the ratings provided by the three raters. Following this, the flow shared in Fig. 5 was used to determine latency.

In addition to the ratings, the healthcare professionals were requested to share the rationale behind their ratings. This helped understand certain disagreements in the similarity between the researchers and the healthcare professionals. For example, in various situations, the healthcare professionals gave less priority to their own comfort while ensuring the comfort of the patients. Hence, collecting the rationale along with the latency metric could also serve as an effective communication tool with healthcare professionals.

For latency calculation, Table 1 provides an exemplar rating for the needs following a Likert scale, identified for one of the projects that aimed to help the threading of guidewire during the catheterisation procedure. Due to the current rudimentary structure of the metric, we categorised any need that received Strongly Agree (+2) or Agree (+1) for 'Implicit' and 'Impactful,' and Strongly Disagree (−2) or Disagree (−1) for 'Obvious' and 'Inefficient' as 'Latent needs.' For example, based on the latency metric flow shared in Fig. 5, needs 3 and 4 in Table 1 quality as latent needs. The raters discussed and updated the key by addressing the disagreements. The key comprises the following guidelines:

(1) Needs are compared within each team and each phase and not across teams.
(2) A need is considered unique if it did not appear in the set of needs shared during the respective phase.
(3) The needs that are similar but include a specific detail and an end goal that is different from that of the previous needs are still regarded as unique. For example, "easy to modify" will be considered different from "easy to use".
(4) If two needs are separated by "and" and one of them is repeated, the single repeated need is not considered as a unique need.

### EXPERIMENTAL RESULTS

#### Latent Needs

Student outcome evaluations were validated in two dimensions: (1) Impact on Needs: the type of design needs identified by the students during each phase of the study, and (2) Understanding of Extreme-user variables: Number of appropriate extreme-user variables students could identify.

#### Impact on Needs

We evaluated the impact on needs using the number of latent needs identified by the students. Table 2 shares an exemplar set of design needs and the need source/ rationale shared by the students. The need source/ rationale intended to capture if an extreme-user experience inspired the specific need. Appendix B shares a detailed list of needs shared by each team. Table 3 highlights the total number of needs and latent needs identified by the participants of each team. Table 3 also shows the unique number that was used to separate the needs that were not repeated among participants from the same team. Two raters independently coded the needs for their uniqueness within each team and attained an inter-rater agreement of 90%. The raters discussed and updated the key by addressing the disagreements. The key comprises the following guidelines:

| Needs | Need source/rationale | Impactful | Implicit | Obvious | Inefficient |
|-------|-----------------------|-----------|----------|---------|-------------|
| 1. Bio-compatible | Requirements | +2 | -2 | +2 | -2 |
| 2. The product needs to allow for quick and intuitive threading | User | +2 | +1 | +1 | -1 |
| 3. Be integrated with the catheter | User observation | +2 | +1 | -1 | -2 |
| 4. Product needs to be easily handled with one-hand | Ideation | +2 | +2 | -2 | -2 |

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The number of unique and latent needs in Table 3 shows that the students could generate more Unique and Latent needs after applying the extreme-user experiences. In addition, the Activity Diagrams shared by the teams helped compare the changes implemented by the students based on the needs they identified before and after applying the extreme-user experiences. Table 4 shares a few notable changes observed in the Activity Diagrams illustrated by the students. The Activity Diagrams generated during Phase II and Phase III were compared to identify key changes in the user experience breakdown and the design modifications that were inspired after applying the extreme-user experiences.

The students prominently identified needs related to the challenges that could arise due to reduced dexterity, visual attention, distractions, and single-hand usage. For example, students from Project 4 understood the need to make their device reduced-dexterity proof to ensure that the clinicians do not trigger the wrong functions. They also assured that their device is ambidextrous to make it easier for their clinicians. In addition, students identified more user experience-specific needs after applying the extreme-user experiences. They could locate specific touchpoints of user interaction where their design should be more conscious of the use context, especially when there is time constraining. For example, dexterity was a concern when the clinicians had to thread the guidewire during a procedure compared to the dexterity needed to hold a patient’s arm.

**Applying Extreme-User Variables**

The extreme-user variables questionnaire (Appendix A) helped observe the impact of the proposed approach on identifying and applying extreme-user experiences that influence a user’s interaction with a device. The project-specific variables indicated by the students were compared with that of the variables identified for the same project by the design researcher with expertise in extreme-user experiences. Figure 6

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**TABLE 2. Exemplar set of latent and non-latent needs identified by the participants.**

| Exemplar Latent Needs | Need source/Rationale | Exemplar Non-latent needs | Rationale |
|-----------------------|-----------------------|---------------------------|-----------|
| Clear distinction/indication if direction of movement - Lights | Clear indicator | Safety | Some activities are required to be done concurrently |
| The device should be functional under single-handed use, for both left and right hand(s) | | | It should ensure that the exact guidewire used for particular catheter is removed |
| Specific to guidewire used, not easily hacked | | | Visual blindfold |
| The product needs to be less visual with its outputs | | | |
| | | Bio-compatible | |
| | | Emergency stop | |
| | | Intuitive/ergonomic design | |
| | | IoT based alert system | |
| | | Inserted into the body | |
| | | Safety | |
| | | Don’t need training | |
| | | Reduces the fall cases, helps for data collection | |

**TABLE 3. Number of needs, Unique non-repeated needs per group, and the latent needs identified per team during Phase I, Phase II, and Phase III.**

| Projects | Phase I | Phase II | Phase III |
|----------|---------|----------|-----------|
|          | Needs   | Latent needs | Unique needs | Latent needs | Needs | Unique needs | Latent needs | Unique latent needs |
| Project 1: Catheter Guidewire Safety | 5 | 1 | 6 | 4 | 0 | 6 | 4 | 2 | 2 |
| Project 2: Biopsy Needle Stabilization | 8 | 0 | 4 | 4 | 0 | 17 | 13 | 4 | 4 |
| Project 3: Traction Device for Shoulder Dislocation | 9 | 0 | 0 | 0 | 0 | 12 | 11 | 2 | 2 |
| Project 4: Guidewire Introducer | 11 | 1 | 1 | 1 | 0 | 6 | 4 | 2 | 2 |
| Project 5: Neonatal Health Monitor | 5 | 1 | 3 | 3 | 0 | 9 | 8 | 5 | 4 |
| Project 6: Cuffless Blood Pressure Measurement | 5 | 0 | 0 | 0 | 0 | 9 | 9 | 6 | 6 |
| | 43 | 3 | 14 | 12 | 0 | 59 | 49 | 21 | 20 |
shows the similarity in extreme-user variables identified by the design researcher vs. those identified by the students. This similarity was calculated to evaluate the extent to which the students could successfully identify the extreme-user perspectives that are relevant to their projects. The similarity values demonstrated homogeneity in variance, so we proceeded with a paired sample $t$-Test on SPSS Statistics (Version 25.0.0.1, IBM Armonk, N.Y., USA). This increase in similarity between Phase II and Phase III was significant when analysed using a paired sample $t$-Test ($t(22) = 3.5$, $p < 0.005$). Outcomes showed that the students’ ability to determine the appropriate extreme-user variables improved after using the systematic approach along their design process.

Figure 7 shares the number of extreme-user variables identified by at least one student from each team. Interestingly, as indicated in Fig. 7, the systematic application of extreme-user experiences not only helped the students to identify new variables but also

| Specific activity illustration—Phase II | Specific activity illustration—Phase III | Type of design change |
|---------------------------------------|----------------------------------------|-----------------------|
| **Adjust needle**                     | **Grip Needle with Instrument**        | Modifications to accommodate single-hand usage when multiple tasks happen in parallel |
| **Insert Needle**                     | **Adjust needle Trajectory**           | Introduced a button to avoid triggering the guidewire by accident |
| **Adjust trajectory**                 | **Insert Needle**                     | Introduced an informative display to help non-experts |
| **Incorrect**                         | **Identify green button to reel introductor** | |
| **Insert guidewire the device**       | **Press button to trigger reel**       | |
| **Remove needle**                     | **Remove the Cool Beans device**       | |
| **Remove the introducer**             | **Remove the Cool Beans**              | |
| **Trigger it so that it needs the introducer** | **Identify green button to reel introductor** | |
| **Remove the Needles Holder**         | **Trigger the Cool Beans to reach the clinical site** | |
| **Incorrect**                         | **Remove the introducer**              | |
| **Grip Needle with Instrument**       | **Remove the introducer**              | |
| **Identify green button to reel introductor** | **Press button to trigger reel**       | |
| **Press button to trigger reel**       | **Remove the Cool Beans device**       | |
| **Measurement complete**               | **Device reads out value and shows it on screen** | |
| **Device reads out value and shows it on screen** | **Green LED shows to indicate healthy, red to indicate unhealthy, device reads healthy or negative** | |
| **Identify green button to reel introductor** | **Press button to trigger reel**       | |
| **Press button to trigger reel**       | **Remove the Cool Beans device**       | |
| **Measurement complete**               | **Device reads out value and shows it on screen** | |
| **Green LED shows to indicate healthy, red to indicate unhealthy, device reads healthy or negative** | **Press button to trigger reel**       | |
| **Identify green button to reel introductor** | **Press button to trigger reel**       | |
| **Press button to trigger reel**       | **Remove the Cool Beans device**       | |
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| **Identify green button to reel introductor** | **Press button to trigger reel**       | |
| **Press button to trigger reel**       | **Remove the Cool Beans device**       | |
| **Measurement complete**               | **Device reads out value and shows it on screen** | |
| **Green LED shows to indicate healthy, red to indicate unhealthy, device reads healthy or negative** | **Press button to trigger reel**       | |
helped them filter out the irrelevant variables they identified during Phase II. Refer to Appendix C for the cumulative results of each extreme-user variable identified during Phase II and Phase III by the students from each project. Since the students individually identified the extreme-user variables, the numbers in Appendix C indicate the total number of students who identified the corresponding variable as an extreme could influence the user’s interaction with their device.

**Student Feedback** The students also rated the extreme-user experiences and shared their feedback on ways to improve the method. On a scale of one to five, with one being "extreme-user experiences being not at all helpful" and five being "extremely helpful." The following two questions and a Likert scale were used to understand the practicality of applying extreme-user experiences during the design process.

- How helpful was applying Extreme User Perspectives with User Activities?

1: Not at all 2: Slightly 3: Moderately 4: Very 5: Extremely

- Do you foresee yourself applying Extreme User Perspectives with User Activities in future projects?

1: Not at all 2: Slightly 3: Moderately 4: Very 5: Extremely

On average, the helpfulness of extreme-user experiences scored 3.26, and their applicability in future projects scored 3.21 among the students. This rating varied among students depending on the type of project and the extent to which the teams had already addressed the demands identified using extreme-user experiences in their respective designs. For example, Project 4, Guidewire Introducer, already had a simple design that reduced the varying physical abilities needed for catheterisation. In the case of Project 4, the healthcare professional had specifically requested to reduce physical ability demands like visual attention. Nonetheless, there is a need for future work to focus on improving the understanding of the approach.

Students were also asked to comment further on their responses, but not all students shared their feedback. Few exemplar feedback from the participants includes a request for more tools that simulated limited dexterity and greater emphasis on the need to break down every single step while building the Activity Diagram.

**FIGURE 6.** Similarity in extreme-user variables (physical parameters) identified by the researcher and the students (with standard error).

**FIGURE 7.** Number of extreme-user variables identified by at least one team member during Phase II and Phase III.
DISCUSSION

This study uses systematic application of extreme-user experiences to identify latent user needs in the medical device design curriculum and provides a latency metric to assess the outcomes. The results show that the students could identify a significantly higher number of latent needs after applying the extreme-user experiences. Similarly, they were able to identify a greater number of extreme-user experiences appropriate for their devices. Following are the inferences from the outcomes of this study as responses to the research questions raised earlier.

How Does the Systematic Approach Help Adopt Extreme-User Experiences and Impact Students’ Ability to Identify Latent User Needs in Medical Device Design?

While we aim to improve the robustness of the latency metric in our future works, the metric as such served as a tool to assess and understand students’ responses to the systematic approach.14,44 The assessment outcomes showed an overall increase in the number of needs, including latent needs, generated by the students. In addition, students could identify specific user interaction-based needs that the users could experience while interacting with their designs. For example, it can be observed from Appendix B that the majority of needs from Phase I focused on generic medical device design requirements like biocompatibility, safety, and other direct needs shared by the clinicians, whereas Phase III included needs that specifically focused on the user’s interaction with the device and the challenges associated with the same. In addition, we also identified the following gaps that proper guidance could fix while applying the extreme-user experiences.

The responses shared by the students show a disparity in their understanding of certain extreme-user variables (Appendix C). For example, most students did not state spatial awareness as a user-experience variable that influences the user’s interaction with the product. Whereas, in reality, spatial awareness has a strong influence on a healthcare professional’s attention.2,45 This could be observed in Project 4, where the design aims to help physicians thread a guidewire during a surgical procedure that demands increased spatial attention. Yet, neither of the students from Project 4 identified this variable.

Similarly, while height could be associated with the need to stand while interacting with the product, students did not interpret it in such a manner. For example, the extreme-user variable questionnaire had ‘Other’ as an option to fill in any variable not captured in the list (Appendix C). Students used this option to list ‘the need to stand while interacting with the product’ as a variable. These discrepancies reflect a lack of understanding of such variables. Implying the difference in perception over physical demands that influence a user’s interaction with a medical device. This could be mitigated if the students are provided with clear distinctions and examples for different extreme-user experiences.

Although students identified physical factors such as vision, hearing, and hand usage as impacting extreme-user variables, only a few linked physical challenges to extreme-user variables. Previous studies have highlighted that an individual’s personal connection to extreme-users could impact their response to extreme-user experiences.50 It would be useful to understand if any such personal influences could influence participants’ ability to associate the extreme-user variables with the overall user experience. This understanding would be essential, especially while designing home healthcare solutions handled by a wide range of users, unlike the devices used in clinical settings. Home healthcare is one area of application where designers could use the proposed approach to evaluate the inclusiveness of specific designs. This inference is in line with the approach followed by the Cambridge Engineering Design Centre,20,40,57 where they used user activities to calculate the exclusion imposed by a device.

While a few students did not indicate certain associated extreme-user variables, their rationale for their needs shows the influence of such variables. For example, all but one student from Project 4 did not identify any of the primary extreme-user variables provided in their variable list (Appendix C). Yet, the same student listed the need “The device needs to have dexterity proof controls so that the clinician does not accidentally operate the wrong functions at the wrong time. This is a single-handed dexterity issue” shared in Appendix B for “Guidewire Introducer”. Therefore, the impact of applied extreme-user experiences could be even higher than reflected in the data. It would be helpful to capture the rationale behind a user need, to understand the outcomes in an educational setting.3,15,16

The needs identified by a few participants focused more on the applied extreme-user perspective than on the design aspects of the device, thereby listing accommodation for extreme-user experience as a need (Appendix B). For example, needs like ‘support single hand interaction’ or just ‘dexterity.’ Such needs do not share the design aspects, like which component needs to support single-hand interaction or dexterity. While this may reflect the understanding developed towards user experiences, it does not provide a direct design
functionality that needs to be addressed. A systems function representation that focuses on the desired actions from a device could help transform the user functions to device functions.23

What are the Key Takeaways from Applying Extreme-User Experiences as a Curricular Intervention to Identify Latent Needs?

The needs and Activity Diagrams shared by the students helped assess the design changes that appeared after applying the extreme-user perspectives. Detailed observations from the needs and activity diagrams generated by the students include:

(a) Increase in design accommodations that addressed specific physical demands that would affect the user experience. For example, the design modifications accommodated instances where the users would find it challenging to use both hands (refer to Table 4).

(b) Detailed understanding of user-interaction-related needs. The systematic application of extreme-user experiences encouraged the student to break one need into many levels with different understanding. This led to an understanding of a simple need given by the end-user by decomposing it, relating it to various stages of the device’s life cycle use. For example: ‘Ease of use’ was a common need identified before experiencing the extreme-user perspective. Whereas, as shown in Appendix B, after experiencing the extreme-user perspectives, students listed more specific design needs like ‘Easy to adjust (strength and dexterity) and Easy to use (less demand on memory)’ to ease the users’ experience with their design.

(c) Students had an increased awareness of the physical and cognitive abilities needed to interact with their devices.9,10 The majority of the needs shared in Appendix B, after applying the extreme-user experiences, demonstrate its association with the user’s interactions with their devices.

(d) Identification of instances where users will need to be informed about the device’s status and how this information should not rely on visual attention alone. For example: ‘Audio cue for the readings. Give readings without visuals.’ shared by students from Project 6 to inform nurses of the blood pressure values (Appendix B).

(e) Learned to consider ‘use environment’ and contexts (Appendix C) during the early stage of the design.55 This led to an increase in needs that addressed any potential user-interaction-related error or mishap. For example, the students from Project 2 identified “Both hand usage- some activities have to have two hands to complete, and some activities are required to be done concurrently” by considering the additional needs experienced by the healthcare professionals.

The main limitation of our study is the small sample size. Any future expansion of this work needs to test the effectiveness of a wider sample size. Nonetheless, the research reported in this paper demonstrates statistically significant findings and provides a foundational study for advancing Biomedical Engineering education and related educational fields. Based on the student ratings and feedback received for extreme-user experiences, it would be impactful to expand the set of extreme-user experiences adopted for the systematic application framework and increase the granularity of the user activities captured using Activity Diagrams. An additional limitation to this study is that it did not capture user feedback on the impact of extreme-user experiences for the final design of the medical devices. It would be important for future works to capture how extreme-user experiences could benefit end-user experience/interaction with a medical device.

In our future work, we aim to make the proposed approach more systematic by incorporating it with the findings from cognitive load theory. Cognitive load theory states that a user’s mental demand increases when multiple interactions simultaneously rely on the same resource centre or modality.12,39,53 For example, spatial and visual attention are linked to the same resource centre in the brain. Therefore, a key question for future expansion of the proposed approach is how might we guide designers to identify appropriate interactions where extreme-user perspectives could be applied and thereby generate user-interactions that reduce the mental demand experienced by healthcare professionals?

The study presented in this paper applies a new latency metric that was adapted to evaluate the needs generated by the students. This metric is basic and useful but still at its rudimentary state of development. Further advancement and validation of this latency evaluation metric will be needed for future studies. Nevertheless, the responses received from healthcare professionals who used the latency metric helped understand their perspective over the generated needs. Therefore, future work may look into adapting the metric to establish good communication with healthcare professionals. Another potential application of
this metric could be to rank the ideas based on their latency and user preference. For example, needs that receive Strongly Agree for both 'Implicit' and 'Impactful,' and Strongly Disagree for both 'Obvious' and 'Inefficient' can be a 'High Priority Latent needs.' Needs that receive Strongly Agree for 'Implicit' and Agree for 'Impactful' or vice versa, and Strongly Disagree for 'Obvious' and Disagree for 'Inefficient' or vice versa can be 'Medium Priority Latent needs.' Another limitation in terms of the latency metric is that the raters were not trained to ensure that their understanding of the four latency factors was aligned with each other. As stated by Douglas and Purzer,14 "Validity is never quite over. It is a goal we strive for, but given the nature of educational variables, the process of reevaluating the appropriateness of an instrument’s use is ongoing." Therefore, even though the rationale behind the scores helped understand certain discrepancies as described in "Metric Used: Latency Metric" section, future works should aim to test the robustness of the evaluation criteria as well. In addition, expanding the metrics to include the quality of the needs identified would also make the evaluation more robust.

Similarly, the needs that receive Agree for both 'Implicit' and 'Impactful' and Disagree for both 'Obvious' and 'Inefficient' can be a 'Low Priority Latent needs.' It is to be noted that latent needs are not necessarily the primary needs, but they add value to the users’ primary, more obvious needs. This ranking of needs could help student teams to include the needs that would delight the user. Although this study did not place higher weightage on student feedback, the observations shared in Section 3.1.3 shows that more emphasis on student feedback would help understand opportunities for future iterations of the approach.

**SUMMARY**

This paper shares an approach for a systematic application of extreme-user perspectives to complement, extend and integrate into design processes that are adapted for medical device design education. The outcomes share the impact observed on student projects that addressed six real-world medical device design opportunities proposed by clinicians who interact with the respective devices. This study is part of a larger framework that systematically applies extreme-user experiences throughout the design process.47,48 We believe the approach shared in this paper will help medical device design students and professionals to utilise a first-person experience on the foundations and nuances of user needs that get missed in current design processes and, thus, create and build better designs for more robust medical device design.
**APPENDIX B: NEEDS IDENTIFIED WITH AND WITHOUT EXTREME-USER EXPERIENCES**

| Project                  | Needs identified without Extreme-user experiences | Needs identified with Extreme-user experiences |
|--------------------------|---------------------------------------------------|------------------------------------------------|
| Catheter Guidewire       | Phase I                                           | Phase III                                      |
| Safety                   | 1. Integrated into Seldinger’s procedure- compatible with current equipment  |
|                          | 2. Fool-proof mechanism                           | 1. Quick threading                            |
|                          | - not reliant on human efforts                    | 2. Auto-check to ensure guidewire ejection      |
|                          | - not operated through weak visual clues          | 3. Single hand usage                          |
|                          | 3. Specific to guidewire used, not easily hacked  | 4. Quick and intuitive threading               |
|                          | 4. Cannot overly lengthen procedure duration-> should be doable < 10mins  | 5. Less visual with its outputs [not working on visual reminders] |
|                          | 5. Low change in cost-price                       | 6. Reduce visual demand                       |
|                          | Phase II                                          |                                                |
|                          | 1. Ease of use                                    |                                                |
|                          | 2. Biocompatibility                               |                                                |
|                          | 3. Ensure guidewire removal                       |                                                |
|                          | 4. Prevent procedure without removal of guidewire |                                                |
|                          | 5. Biocompatible                                  |                                                |
|                          | 6. Intuitive/ergonomic                           |                                                |
| Biopsy needle stabilization | Phase I                                         | Phase III                                      |
|                          | 1. Stability                                     | 1. Single hand use                            |
|                          | 2. Sterility                                     | 2. Easy to adjust (strength and dexterity)     |
|                          | 3. CT-Scan Compatible material                   | 3. Easy to use (less demand on memory)         |
|                          | 4. High degree of freedom                         | 4. Small volume- do not hinder movement        |
|                          | 5. Ease of setup                                 | 5. Transparent to CT-Scan- Reduce Visual obstruction |
|                          | 6. Weight                                        | 6. Design needs to be user friendly, single hand usage |
|                          | 7. Ergonomic                                     | 7. Size and shape of our product must be catered to single hand usage |
|                          | 8. Price                                         | 8. Thin/palm size-hand size/ comfortable to operate |
|                          |                                                  | 9. Single hand dexterity-small mechanisms/parts of the needle that the clinician has to manipulate |
|                          |                                                  | 10. "Both hand usage- some activities have to have 2 hands to complete, and some activities are required to be done concurrently” |
|                          |                                                  | 11. "Vision- The entire procedure requires vision to complete” |
|                          |                                                  | 12. Device needs to be obvious enough          |
|                          |                                                  | 13. Device needs to be small enough to hold easily (Ergonomics) |
|                          |                                                  | 14. Device is easily operable, Requires less strength & easy to adjust |
|                          |                                                  | 15. Dexterity- device needs to have suitable grip & size to allow for easier usage/ manipulation |
|                          |                                                  | 16. Vision- device needs to have parts that are large enough to be easily visualised due to constant interaction |
|                          |                                                  | 17. Both hand usage- due to nature of holding needle, device should be functional under single-handed use, for both left and right hand(s) |
| Project                      | Needs identified without Extreme-user experiences | Needs identified with Extreme-user experiences |
|-----------------------------|--------------------------------------------------|------------------------------------------------|
| **Phase II**                |                                                 |                                                 |
| 1. Robustness               |                                                 |                                                 |
| 2. Manoeuvrability          |                                                 |                                                 |
| 3. Accuracy                 |                                                 |                                                 |
| 4. Durability/ Strength     |                                                 |                                                 |
| **Traction device for**     |                                                 |                                                 |
| shoulder dislocation        | 1. Safe shoulder dislocation reduction           | Phase III                                      |
|                             | 2. No sedation treatment                        | 1. Doctor start treatment - > ease of initial set-up (includes action & speed, time) |
|                             | 3. Minimal manual assistance (Nurse)             | 2. Doctor verification - > A signalling system to notify the doc when the procedure is over to come & check |
|                             | 4. Short time consumption (10-15 mins)          | 3. "Visual aspect: Able Sighted- to gain information from pre and post x-rays/ visual understanding of the patient's condition" |
|                             | 5. Fits arm sizes/ sides left/right              | 4. "Physical Stable- Stable stance and motion is required to manually perform the treatment" |
|                             | 6. E-stop (Safety)                              | 5. Strength to perform reduction               |
|                             | 7. Ease of setup and use for the Nurse          | 6. Dexterity to hold on to patient arm         |
|                             | (reduce time consumption)                        |                                                 |
|                             | 8. Wipe down disinfectant                       | 7. Vision and dexterity to identify/verify effectiveness |
|                             | 9. Non bulky design                              | 8. Need to have grip on the patient's wrist    |
| Phase II                    |                                                 | 9. Need to view if humeral head enters socket   |
| NIL                         |                                                 | 10. Need stand on the floor to apply force on patient's arm |
|                             |                                                 | 11. Need to hear when humeral head enters socket |
|                             |                                                 | 12. Need to see x-ray to determine if treatment can be done |
| Guidewire introducer        | Phase I                                          | Phase III                                      |
|                             | 1. Handheld device                              | 1. "The device needs to have dexterity proof controls so that the clinician does not accidentally operate the wrong functions at the wrong time- This is a single handed dexterity issue" |
|                             | 2. Can fit in various dimensions of wires       | 2. Clear distinction/ indication if direction of movement- Lights/ clear indicator |
|                             | 3. Electronically controlled                    | 3. "Coil guidewire & soak in water:            |
|                             | 4. Splash proof                                 | 4. Reverse the reeling of wire to be distinguished: |
|                             | 5. Eo sterilization compliance                  | 5. Different button (varying colours) - > to clearly identify reeling in and reeling out" |
|                             | 6. Ambidextrous usage                           | 6. Ambidextrous usage at handle & trigger part |
|                             | 7. <10 sec operation                            |                                                 |
|                             | 8. Hulas/ wires threading                       |                                                 |
|                             | 9. Dummy proof                                  |                                                 |
|                             | 10. Emergency stop                              |                                                 |
|                             | 11. Allow 2 directional movement                 |                                                 |
| Phase II                    |                                                 |                                                 |
|                             | 1. Easy to insert wire/ catheter/etc. x fast    |                                                 |
| Project                        | Needs identified without Extreme-user experiences | Needs identified with Extreme-user experiences |
|-------------------------------|--------------------------------------------------|-----------------------------------------------|
| Neonatal health monitor       | Phase I                                          | Phase III                                     |
|                               | 1. Safely wake the baby up without injury         | 1. Reduce the frequency on the need of both hand usage |
|                               | 2. Using hypo allergenic materials in contact with neonates’ skin | 2. Reduce the need for nurse to attend to baby if there is a false alarm |
|                               | 3. Integration to current system. Leverage on existing devices used in the hospital | 3. Reduce the frequency of nurse having to visually inspect if baby is breathing |
|                               | 4. Device/product should be user friendly         | 4. The device/solution should monitor the vital data from infant and alert caretaker with minimum/zero human intervention |
|                               | 5. Reasonably priced, cost effective solution    | 5. The device/solution should control oxygen flow without human intervention |
|                               | Phase II                                         | 6. The device should wake up baby without the help of a nurse |
|                               | 1. Notify nurse if neonate still doesn’t breathe even with the oxygen stimuli | 7. Reduce the need for finger dexterity by automating the process |
|                               | 2. IOT based alert system                        | 8. Reduce the need for both hand usage by having another system to achieve the same outcome |
|                               | 3. Alert nurses even when if system shows success in walking baby | 9. Reduce the frequency or urgency to visually inspect the baby by using a system that automates |
| Cuffless blood pressure measurement | Phase I                                      | Phase III                                     |
|                               | 1. Precision and accuracy                        | 1. Remove the use of cuffs                    |
|                               | 2. Intrusiveness                                 | 2. Get an alternative way of measuring BP without getting pressure physically |
|                               | 3. Repeatability                                 | 3. Make aged nurses/doctors easily press the buttons |
|                               | 4. Price                                         | 4. Read off values                            |
|                               | 5. Ease of use                                   | 5. Audio cue for the readings. Give readings without visuals |
|                               | Phase II                                         | 6. Eliminate need of stethoscope              |
|                               | NIL                                              | 7. Must be able to operate with one hand      |
|                               |                                                  | 8. Low dexterity friendly                     |
|                               |                                                  | 9. Should not rely on sound or vision only    |
## APPENDIX C: CUMULATIVE RESULTS OF EACH EXTREME-USER VARIABLE IDENTIFIED DURING PHASE II AND PHASE III BY THE STUDENTS FROM EACH PROJECT (P1–P6)

| User Demography | Ethnicity | Gender | Language | Age (Older) | Age (Kids) | Height | Physical Challenges | None (Anyone can use my product) | Other | Temperature | Weather | Space required | Height at which the product is placed | Sound | Other | Visual | Auditory | Tactile (Touch) | Spatial | Memory | Physical | Strength | Both hand usage | Finger Dexterity | Olfactory (Smell | Gustatory (Taste) | Other |
|-----------------|-----------|--------|----------|-------------|------------|--------|---------------------|------------------------------------|------|-------------|---------|---------------|-------------------------------|--------|-------|--------|---------|----------------|--------|--------|-----------|----------|----------------|----------------|----------------|----------------|---------|
| Phase II        |           |        |          |             |            |        |                     |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
| P1 (n = 4)      | 1         | 1      | 1        | 1           | 3          | 1      | 2                   |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
| P2 (n = 5)      | 1         | 1      | 1        | 1           | 3          | 1      | 2                   |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
| P3 (n = 4)      | 1         | 1      | 1        | 1           | 3          | 1      | 2                   |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
| P4 (n = 4)      | 1         | 1      | 1        | 1           | 3          | 1      | 2                   |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
| P5 (n = 4)      | 1         | 1      | 1        | 1           | 3          | 1      | 2                   |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
| P6 (n = 4)      | 1         | 1      | 1        | 1           | 3          | 1      | 2                   |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
| Phase III       |           |        |          |             |            |        |                     |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
| P1 (n = 4)      | 2         | 1      | 2        | 2           | 3          | 2      | 2                   |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
| P2 (n = 5)      | 2         | 1      | 2        | 2           | 3          | 2      | 2                   |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
| P3 (n = 4)      | 1         | 1      | 3        | 3           | 3          | 2      | 2                   |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
| P4 (n = 4)      | 1         | 1      | 3        | 3           | 3          | 2      | 2                   |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
| P5 (n = 3)      | 1         | 1      | 3        | 3           | 2          | 2      | 2                   |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
| P6 (n = 4)      | 1         | 1      | 3        | 3           | 2          | 2      | 2                   |                                    |      |             |         |               |                               |        |       |         |         |                |        |        |           |         |                |                  |                |          |          |
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**AUTHOR CONTRIBUTIONS**

Author SR conceived of the study, designed the experiments, implemented the study, performed statistical analysis, and drafted the manuscript. Author SK participated in the design of the experiments and coordination and helped draft the manuscript. Author KHO helped draft the manuscript. Author KLW participated in the design of experiments, facilitated the statistical analysis, and helped draft the manuscript. All authors read and approved the final manuscript.

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**DATA AVAILABILITY**

The raw data supporting the conclusions of this article are available from the corresponding author on reasonable request.

**CODE AVAILABILITY**

Not applicable.

**CONFLICT OF INTEREST**

The author(s) declare that there is no conflict of interest.

**ETHICAL APPROVAL**

All study procedures followed the regulations and approval from the SUTD International Regulatory Board (IRB).

**CONSENT TO PARTICIPATE**

Signed informed consents were obtained from students and clinicians whose work are analysed and provided as examples in the article.

**CONSENT FOR PUBLICATION**

Signed informed consents were obtained from students and clinicians whose work are analysed and provided as examples in the article.

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