February 12, 2023

Dr. Michael Hegedus
Simon Fraser University
School of Engineering Science
Burnaby, British Columbia
V5A 1S6

CROMA TECH

Re: ENSC 405W Requirements Specification for Croma Tech's S-ROM

Dear Dr. Hegedus,

The attached document outlines the requirements specification for S-ROM, a wearable device with a simple data presentation application used for comprehensively evaluating the range of motion (RoM) of a shoulder.

The specification describes the required features and functionality of our device, including functional, system, user interface, sustainability, safety, and economical factors. The requirements will be defined for different phases of the project, namely, the proof-of-concept prototype, engineering prototype, and final product.

Our team – Ansley Ang, David Bechert, Diego Flores, Luka Cuk, Ritesh Nandakumar, and I – are senior Simon Fraser University engineering students. With our diverse backgrounds in physics, electronics, systems, and computer engineering, we are confident in our ability to complete this project.

Thank you for taking the time to review our requirements specification. For inquiries, please contact our Chief Communications Officer, Ansley Ang, by phone (778-987-4926) or by email (ansleya@sfu.ca).

Sincerely,

Elias Bircher
Chief Executive Officer
Croma Tech

Enclosed: Croma Tech requirements specification document for S-ROM

Requirements Specification: S-ROM

Croma Tech | Company 9

February 12, 2023

Elias Bircher	Chief Executive Officer
David Bechert	Chief Technology Officer
Ansley Ang	Chief Communications Officer
Luka Cuk	Chief Operations Officer
Diego Flores	Chief Financial Officer
Ritesh Nandakumar	Chief Product Officer

Abstract

Many physiotherapists evaluate joint range of motion by feel and personal judgement with the occasional help of a goniometer. Clinical goniometers are handheld joint angle measurement devices used by physiotherapists to quantitatively assess how the patient's range of motion has changed across appointments. The overall range of motion assessment is limited by the accuracy and repeatability of the handheld goniometer measurement, and by the frequency of physiotherapy appointments. Croma Tech aims to enhance the range of motion assessment and recovery process by creating a user-friendly wearable device that provides accurate rotation angle measurements and can be used at home and in the clinic by patients. The additional data acquired from at home assessments will help physiotherapists evaluate the efficacy of certain exercises, identify cases where a patient's range of motion has decreased or increased between assessments, and confirm patients are performing prescribed exercises. This requirements specification document will outline the required features of our device across the proof-of-concept prototype, engineering prototype, and production models. Furthermore, a detailed outline for the proof-of-concept prototype will be included as an appendix.

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Glossary

Term	Definition
Calibration	A configuration procedure that ensures an instrument provides results within an acceptable range of values
Directions For Use	“Full information as to the procedures recommended for achieving the optimum performance of the device, and includes cautions, warnings, contra-indications and possible adverse effects” [1]
Goniometer	An instrument that measures the range of motion at a joint using angles
Overcompensation	Tightening and straining of non-injured muscles caused by changes in normal joint mechanics
PC	Personal Computer
PoC	Proof of Concept
PT	Physiotherapist
RoM	Range of Motion
S-ROM	Shoulder - Range of Motion
Universal Serial Bus (USB)	Specifications for cables, connectors and protocols for connection, communication and power supply between the computer and device

1 Introduction

Physiotherapists (PT) play a key role in the long-term health and quality of life of shoulder injury patients. During a typical appointment, the patient will perform various arm movements for the PT to then assess the range of motion of the shoulder, including shoulder flexion (Figure 1), abduction (Figure 2), and external rotation (Figure 3). A goniometer may be used to record angular measurements for these exercises, but this requires manual operation by a PT and is not very accurate [2]. One example where traditional goniometry is insufficient is trigger point dry needling - a common acupuncture technique used by PTs to assess which muscles in and around the shoulder may contribute to the restricted range of motion [3]. Trigger point dry needling may result in a small range increase and could be difficult to detect with the accuracy and repeatability of a goniometer.

Shoulder injury recovery is not always linear – Range of Motion (RoM) may improve for a patient consistently across sessions before degrading at a future appointment at the surprise of both the PT and patient. Due to the frequency of appointments typically ranging from three times per week to once every two weeks, PTs have a limited dataset at their disposal for assessing injury recovery progress [4].

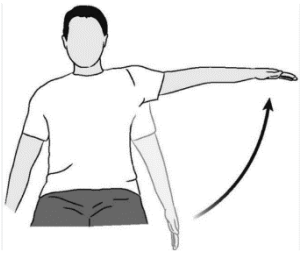

Figure 1: Shoulder flexion exercise [5]

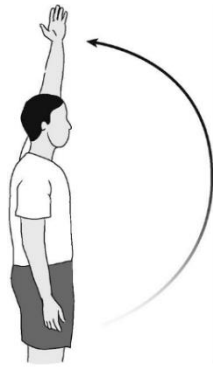

Figure 2: Shoulder abduction exercise [5]

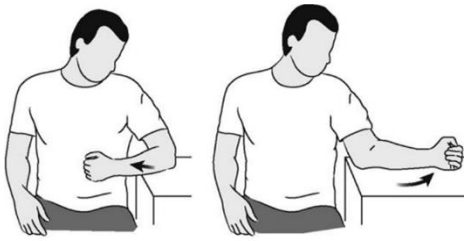

Figure 3: Shoulder external rotation exercise [5]

1.1 Our Solution

Croma Tech strives to help PTs develop tailored recovery exercises and provide in-depth RoM data during these exercises both at home and in-clinic. Our product, S-ROM, will be a device that accomplishes these goals. Our solution will be portable, easy-to-use, and will accurately measure a patient's shoulder's RoM. Physiotherapists can then assign at-home exercises to be performed while using our system. Using an application, patients can follow instructions and perform the exercises prescribed by their PT. The device will track their movements, including the relative angle change of the arm, the smoothness of the motion, and overcompensation from other muscles. Afterwards, the data will be reviewed by the PT, who can evaluate the information. Additionally, our product will allow the PT to confirm that their patients are attempting the exercises at home allowing for better transparency at future appointments.

After interviewing Renzo Carbonel and Tony Macri, practicing PTs, we learned that there are limited ways of monitoring a patient's recovery over a one to two-week period. Patients who are struggling with shoulder injuries likely do not have the technical knowledge needed to understand changes in their recovery. S-ROM aims to bridge this gap by providing quantitative data about the patient's RoM, discovering trends and ultimately working with PTs to speed up patient recovery.

Figure 4: System Diagram of S-ROM, highlights a high-level overview on how our system is intended to work. A user can record their exercises at home or in the clinic. This data can then be used by the PT to gain a more holistic view on the progress of a patient's recovery.

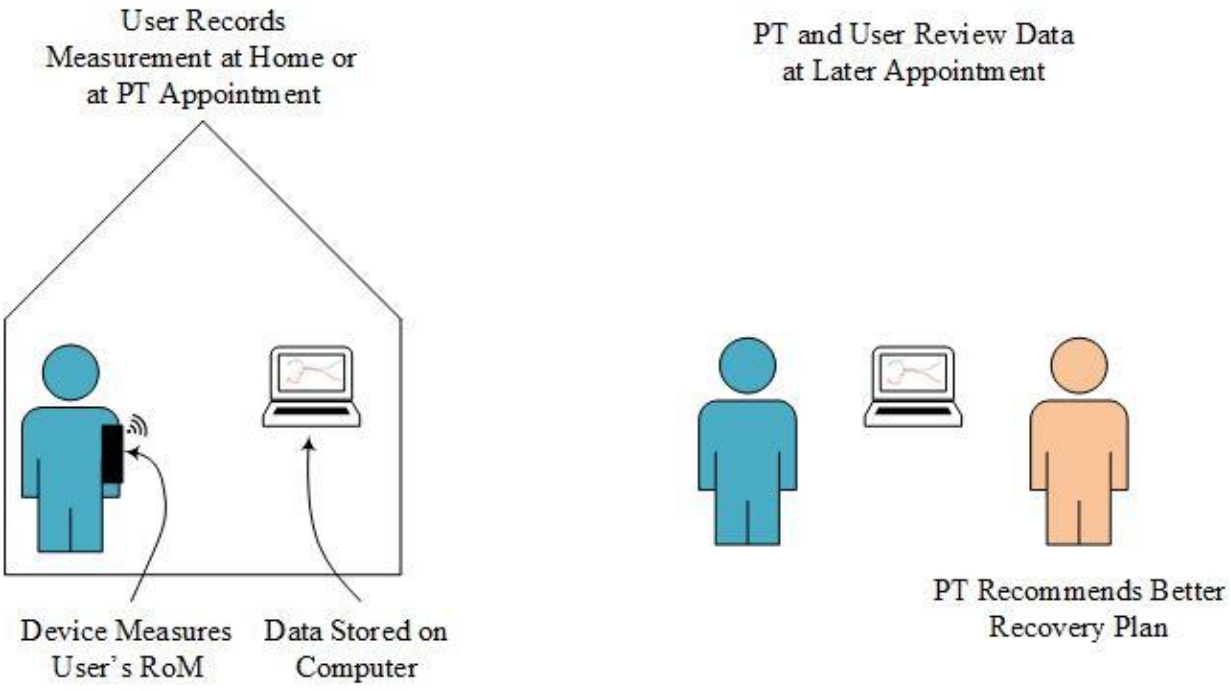

Figure 4: System Diagram of S-ROM

1.2 Requirements Classification

Our specifications will follow the following format:

Req <section #>.<subsection #>.<requirement #>.<project stage>

The following table, Table 1: Project Stage Definition, outlines the meanings of the different project stages in requirements.

Table 1: Project Stage Definition

Project Stage	Meaning
A	Proof of Concept (PoC)
B	Engineering Prototype
C	Production Version

2 Requirement Description

Our product classifies as a medical device within the meaning of section 2 of the Canadian Food and Drugs act: "an instrument, apparatus, contrivance or other similar article, or an *in vitro* reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals" [1].

As per Schedule 1 of the Medical Devices Regulations document of the Food and Drugs Act, our product is a Class I non-invasive device [1]. Class I medical devices do not require a license to be sold or advertised in Canada. However, there are ten applicable Safety and Effectiveness requirements which must be met, and these are highlighted in our requirements listings, 2.5, below.

Beyond the government restrictions, our requirements have primarily been devised in conjunction with a PT and through research.

2.1 Functional Requirements

The following table, Table 2: Functional Requirements, lists the functional requirements of our device. These requirements describe what is expected from our device from an end user's perspective.

Table 2: Functional Requirements

Requirement ID	Requirement Description
2.1.1.A	The system will collect data for a shoulder abduction exercise.
2.1.2.A	The system will collect data for a shoulder external rotation exercise.
2.1.3.A	The system will collect data for a shoulder flexion exercise.

Requirement ID	Requirement Description
2.1.4.A	The measured angles shall be within six degrees of a manual goniometer operated by a PT.
2.1.5.A	The system shall detect non-uniform motion.
2.1.6.A	The system must display and store RoM exercise data along with its corresponding time, date, and exercise type.
2.1.7.A	The device shall detect if a patient tries to overcompensate by using muscles not intended to be engaged during the exercise.
2.1.8.A	The system shall detect and notify the user of improper technique during an exercise.
2.1.9.B	The system shall have variation of less than six degrees between repeated measurements in which the device is removed and put back on.
2.1.10.B	The device shall be designed for easy equipping without external assistance.
2.1.11.B	The system must not take longer than 12 minutes to use for one session (including equipping the device, loading the computer interface, calibration, and completing one repetition).
2.1.12.B	The device shall be storable in a 30 cm x 30 cm x 30 cm space when not in use.
2.1.13.B	The system shall function on both the left and right shoulders.
2.1.14.C	The system shall operate at within the accuracy outlined in 2.1.4.A when used by an adult of an average height (150cm – 193cm).
2.1.15.C	The device shall make accurate measurements for users with tremors.

Our product will target shoulder flexion, abduction and external rotation (2.1.1.A, 2.1.2.A, 2.1.3.A) as they are the most prominent shoulder rotations measured using a goniometer [6] . We aim to achieve an accuracy within six degrees of a measurement made by a physiotherapist using a goniometer (2.1.4.A) to ensure that our product can be similarly qualified. Mr. Carbonel and Mr. Macri outlined to us the importance of noticing jerks during a range of motion exercise as an indicator of continued shoulder pain (2.1.5.A). Furthermore, they noted another nuisance to physiotherapists is the need to manually record the date, time, exercise, and results for range of motion exercises which we will alleviate through requirement 2.1.6.A. In the clinic, physiotherapists can monitor the patient's exercise technique and correct it as necessary. This includes checking for overcompensation, where other muscles in the body tighten to compensate for irregular joint mechanics [7]. Our device will replicate this monitoring without supervision by detecting improper form (2.1.7.A) and overcompensation (2.1.8.A).

Accuracy in repetition (2.1.9.B) is critical for range of motion measurements as it can help distinguish injuries that are not healing from systematic errors in the apparatus. Additionally, to avoid discouraging users from performing their exercises, requirements 2.1.11.B, 2.1.12.B outline that the system must be easy to use, to store and to transport. It is critical that the user can put on and off the device easily without further injuring their shoulder (2.1.10.B). The remaining

functional requirements relate to user inclusivity. This includes nominal operation for different body sizes (2.1.14.C) within the vast majority of people [8], both shoulders (2.1.13.B), and for users with conditions such as tremors (2.1.15.C) where their exercise motion may not be smooth independent of a shoulder injury.

2.2 System Requirements

The following table, Table 3: System Requirements, outlines the requirements for our overall system behavior and specifications that need to be met to support the functional requirements. This primarily pertains to how the wearable device interacts with the computer interface and the patient.

Table 3: System Requirements

Requirement ID	Requirement Description
2.2.1.A	The device can interface with a computer using a USB wired connection.
2.2.2.A	When connected via USB, the device will not require battery power.
2.2.3.A	The desktop application will be able to store exercise data for multiple sessions.
2.2.4.B	The device can interface over a wireless connection using Bluetooth in addition to the wired USB connection.
2.2.5.B	The device shall use battery power with a minimum life of 1.5 hours when in wireless operation mode.
2.2.6.B	The system shall respond to user input in less than one second.
2.2.7.B	The device may undergo calibration before taking readings, so long as the calibration time does not violate 2.1.11.B.
2.2.8.C	The device shall be at least IPX4 compliant.
2.2.9.C	The device must weigh less than 500g.
2.2.10.C	The system shall function on PCs running Windows 10 or newer.
2.2.11.C	A charging cable shall be included with every system.
2.2.12.C	The desktop application will be able to transfer patient data securely over the Internet and store data to a cloud storage.
2.2.13.C	The device will work as intended within 2000 m of sea level.
2.2.14.C	The device must operate around 10-30 degrees Celsius at a 50-90% humidity level.

Figure 4 depicts the system we will be implementing. For the PoC design, we will focus on the accuracy and robustness of the device. Therefore, requirements 2.2.1.A and 2.2.2.A enables our design process to focus on firmware and sensor selection without worrying about complex power management and PC interfacing. On the other hand, for the engineering prototype, a Bluetooth interface with the PC removes the risk of wires impeding the exercises (2.2.4.B). Without the USB power source, a rechargeable on-device battery unit that can supply 5V at 400mA for 1.5 hours during active usage is required (2.2.5.B, 2.2.11.C). As our device will primarily focus on 3 RoM exercises and physiotherapy appointments typically range from 30 to 60 minutes in length,

1.5 hours of charge time should be sufficient for at least one full day of use (assuming two assessments per day as suggested by Mr. Carbonel) [4].

For the device to collect measurements within an acceptable range of values for different users, we need to add a calibration stage before every use (2.2.7.B). Furthermore, our production version should also be water resistant and sweatproof due to the direct contact with the user's skin (2.2.8.C); according to the IP rating system, IPX4 meets this requirement [9]. The device must be very lightweight to reduce the load on the injured shoulder joint. A 500g device acting as a point force around the center of the arm (roughly 20cm) creates less than 1 N-m of torque and would not significantly load the shoulder (2.2.9.C).

The device should perform nominally in an average Canadian environment that allows the greatest possible customer reach. Requirement 2.2.13.C outlines an altitude level that only excludes 219 million people worldwide [10], while 2.2.14.C covers temperature and humidity specifications for all of Canada [11].

Finally, the remaining system requirements relate to the operation of the desktop application. The system should respond to user input within one second to ensure that both PTs and patients have a smooth user experience (2.2.6.B). For the proof of concept, the patient data will be stored locally on the user's PC (2.2.3.A). However, for the production version, we want to improve this process by transferring the data over the Internet and storing it in cloud storage for PTs to access (2.2.12.C).

2.3 User Interface Requirements

The following table, Table 4: User Interface Requirements, outlines the requirements for the application used by both physiotherapists and their patients which provides the user interface.

Table 4: User Interface Requirements

Requirement ID	Requirement Description
2.3.1.A	The system shall display sensor data in real time on a connected PC.
2.3.2.A	The system shall display the maximum rotation angle achieved from rest for each exercise.
2.3.3.A	The system shall display plots of rotation angle against time in all three planes.
2.3.4.A	The system shall display an indicator for overcompensation during the exercises.
2.3.5.A	The system shall display an indicator for incorrect exercise performance.
2.3.6.B	The user shall be able to see a visual representation of their arms motion during operation.
2.3.7.B	The user shall be able to select an assessment exercise.
2.3.8.B	The system will play a video demonstration of each exercise prior to the beginning of the measurement.

Requirement ID	Requirement Description
2.3.9.B	The user and PT shall be able to view and compare data from earlier exercises on their current recovery plan.
2.3.10.B	The system shall be capable of importing and exporting data to an Excel/CSV file with clear labels.
2.3.11.B	The system shall store exercise measurement data locally on the PC.
2.3.12.B	The system should provide instructions on how to properly calibrate the device.
2.3.13.B	The user shall be able to reset the exercise measurement.
2.3.14.B	The user shall be able to turn the system on and off.
2.3.15.B	The system shall display a battery percentage indicator.
2.3.16.C	The system shall upload measurement data to the cloud via a user account.

The user interface requirements are heavily derived from conversations with licensed PTs and their preferences. Most of them will be included in the engineering prototype design as they are supplementary to our main PoC. Real time data (2.3.1.A) displaying maximum rotation angle (2.3.2.A) plots in all planes (2.3.3.A), and a simple model of an arm moving (2.3.6.B) will provide PTs with a quick visual quantification of the patient's range of motion and verification that the system works as intended. For further analysis, data from previous assessments can be stored and reviewed to evaluate the relative recovery (2.3.10.B, 2.3.11.B, 2.3.12.B, 2.3.13.B).

During the exercise, if a patient attempts to overcompensate, the system will notify the user and or PT through an indicator that the motion was not purely through the rotation of the arm (2.3.4.A). Video demonstrations of the selected exercises will remind patients of the correct exercise form (2.3.7.B, 2.3.8.B) and an additional indicator will display if a patient has incorrectly performed an exercise (2.3.5.A).

Device calibration will be crucial to ensuring an accurate measurement is taken and this must be communicated to the user effectively (2.3.13.B). From the in-clinic point of view, PTs utilize Practice Management Software to store their patient's medical records. According to our interviews with Mr. Carbonel, the Jane app is one example that he personally uses for recording and tracking patient data; therefore, our system should be able to import and export data to and from these software applications to better integrate with PT's current systems [12](2.3.16.C). While there may not be a specific format that is held as a standard, having clear labels for each point of data will increase our compatibility (2.3.11.B).

If there are any issues with the device, the user must be able to reset the measurement taken (2.3.13.B) as well as to be able to turn the system on and off to power cycle (2.3.14.B). Battery indicators let the patient, or the PT know in advance if they need to charge their device (2.3.15.B).

2.4 Sustainability Requirements

The following table,

Table 5: Sustainability Requirements, outlines what steps we will take to ensure we develop and distribute our product sustainably.

Table 5: Sustainability Requirements

Requirement ID	Requirement Description
2.4.1.A	Our device will have easily removeable components for replaceability.
2.4.2.C	The product shall use 100% biodegradable packaging.
2.4.3.C	Fabrics used for the sleeve shall be sourced sustainably.
2.4.4.C	Fabrics used for the sleeve shall be durable to sustain 5 years of regular use without degrading performance.
2.4.5.C	A basic user manual supplementary to the Directions For Use (DFU) will be supplied strictly electronically.
2.4.6.C	The device shall have a rechargeable battery.

Our sustainability requirements will be met through clever design and use of renewable parts. If any part of the system breaks or malfunctions, the modular design (2.4.1.A) will allow for the easy replacement of a singular part and not the entire system, reducing the amount of waste created. Furthermore, using materials that do not contribute to our landfills (2.4.2.C), are sourced from socially, economically, and environmentally conscious suppliers (2.4.3.C), and are made durably to limit resource utilization and landfill additions where necessary (2.4.4.C, 2.4.6.C) are all actions we will take to minimize our environmental impact.

In addition, since our product requires a desktop application to record and display information, we will distribute supplementary instructions through the same desktop application to decrease the amount of paper distributed with the product (2.4.5.C).

2.5 Safety Requirements

The following table, Table 6: Safety Requirements, outlines the practical and legal safety requirements for our device.

Table 6: Safety Requirements

Requirement ID	Requirement Description
2.5.1.A	The product must not exceed a surface peak operating temperature of 43ºC [1, 13].
2.5.2.A	Every material used in the device shall be compatible with skin contact [1].
2.5.3.B	The product shall have all electronics sufficiently shielded from the user to prevent electric shock [1].

Requirement ID	Requirement Description
2.5.4.B	The device must not have any sharp edges [1].
2.5.5.B	The device shall be designed in such a way that will not harm the user at any point during the RoM exercises [1]
2.5.6.B	"During the projected useful life of a medical device, its characteristics and performance shall not deteriorate under normal use to such a degree that the health or safety of a patient, user or other person is adversely affected." [1]
2.5.7.B	'If a medical device consists of or contains software, the software shall be designed to perform as intended by the manufacturer, and the performance of the software shall be validated.' [1]
2.5.8.B	"The characteristics and performance of a medical device shall not be adversely affected by transport or conditions of storage, taking into account the manufacturer's instructions and information for transport and storage." [1]
2.5.9.B	The device shall be easily removed for sanitization.

Our primary safety requirements are guided by the government of Canada's Medical Device Regulations, including 2.5.1.A - 2.5.8.B. These regulations are intended to ensure the overall safety for the user and maintain the intended quality provided from the device.

Since our product is intended for repeated use in physiotherapy clinics, ensuring the device can be sanitized repeatedly, 2.5.9.B is a key requirement. Also, the system may be used directly in contact with skin, therefore ensuring the system is not made from a well-known skin irritant is important (2.5.2.A). Finally, we must be conscious that the device is designed to not impede any of the complex shoulder rotations performed during an assessment in a way that may hurt the user (2.5.5.B).

2.6 Economical Requirements

The following table, Table 7: Economical Requirements, lists the requirements related to the economic feasibility of our product.

Table 7: Economical Requirements

Requirement ID	Requirement Description
2.6.1.B	The engineering prototype device shall cost less than $350.
2.6.2.C	The device shall be transported in rigid packaging able to protect it from falls above 4.15 meters.
2.6.3.C	Device should cost less than $50 when produced to scale.

The overall engineering prototype will be designed with cost in mind (2.6.1.B) so that the production version can be produced relatively inexpensively (2.6.3.C). A lower product cost

allows the consumer, the physiotherapist, to justify the investment cost when upgrading from their current measurement system. Furthermore, to save any costs due to replacing a damaged item during shipping, the transport packaging and the device shall undergo drop testing from the maximum permitted truck height in Canada of 4.15 meters (2.6.2.C) [14].

3 Conclusion

Croma Tech strives to develop an innovative shoulder RoM assessment device to enable more tailored injury recovery plans. S-ROM will provide detailed information about the shoulder as it progresses through three distinct exercises as well as provide trends over a period of a few weeks to a few months. PTs will be able to monitor the patient's shoulder recovery progress and evaluate and improve their recovery plan. The requirements outlined in this document highlight the need and use cases for our product which will help guide us in creating a device that can compete with and improve on existing technologies. By abiding by these requirements, learning from practicing PTs, and following government regulations, we are confident in developing a device well equipped for improving shoulder injury recovery while keeping the patients safe, costs low, and minimizing the environmental impact.

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5 PoC Appendix

Croma Tech will work towards meeting the following functionality requirements for our PoC presentation:

- A wearable device that can measure the rotation angle for shoulder flexion, abduction, and external rotation within the accuracy outlined in 2.1.4.A.
- The device will be calibrated for use by one person during the demonstration
- A computer interface connected to the device through USB to visualize the patient's real-time RoM for each exercise including:
    - An angle vs. time chart between all three axes
    - Maximum angle achieved (i.e., RoM)
    - Incorrect exercise performance
    - A measure of overcompensation
    - A record of time, date, and exercise performed

Our primary challenge will be obtaining measurements that are highly accurate and repeatable while being minimally invasive. This will be greatly impacted by our sensor choice. We will explore and test many options for the measurement, including novel ideas, to mitigate the risk.

No matter how accurate our sensors are, if we are unable to convey the information effectively, the data is less valuable. Therefore, a computer interface is required to ensure that we can display the maximum angle, and an angle vs time plot. It is critical that this works efficiently and smoothly to ensure that users can obtain the necessary information.

Another key functionality of our device will be detecting overcompensation and improper exercise performance in absence of a PT. A drawback of current digital goniometers is that they are limited to measuring inclination or other rotation angles only. While this may be helpful for physiotherapists in-clinic, it will not be able to detect if at-home users are properly performing the exercises. This will be the most difficult challenge as overcompensation is present in many forms and may vary across users.