Department of Science and Technology
PHILIPPINE COUNCIL FOR HEALTH RESEARCH AND DEVELOPMENT

CLINICAL TRIAL PROTOCOL

PROJECT TITLE:

"TAYÔ Project – Robotic Rehabilitation for the Trunk and Lower Extremity: STAGE 2 – Safety Testing, and Phase 1 of the Clinical Trials"

Under the Program: Establishment of the Institute of Biomedical Engineering and Health Technologies" (IBEHT)

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v.2 February 10, 2023

IMPLEMENTING AGENCY:

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CLINICAL TRIAL PROTOCOL

A Pilot Study among Normal Subjects on the Safety and Functionality of a Locally-Developed Trunk and Lower Limb Rehabilitation Robot

Study Phase: One (1)

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Sponsor: DLSU-IBEHT

Investigational Product: <LLMo (**L**ower **L**imb **Mo**bilization)
Rehabilitation Robot>

Protocol Version and Date: v.2 February 10, 2023

DEFINITION OF TERMS

Applicant
Individual who applied and is undergoing the screening process.

Rehabilitation robot
An autonomous robot designed to improve the mobility of patients with impaired physical functioning.

Conformitè Europëenne (CE)
A marking that indicates that the product has been assessed by the manufacturer and deemed to meet European Union (EU) safety, health and environmental protection requirements.

International Electrotechnical Commission (IEC)
An organization that prepares and publishes international standards for all electrical, electronic and related technologies.

Range of motion (ROM)
Refers to the distance and direction a joint or muscle moves between flexed and extended position.

Hip flexion-extension
Flexion is raising the leg to the front and extension is pushing the leg to the back.

Hip abduction-adduction
Abduction is the movement of a body part away from the body's midline, whereas adduction is the movement of a body part towards the body's midline.

Knee flexion-extension
Flexion is the bending of the knee and extension is the straightening of the knee.

Trunk flexion
A forward movement of the trunk.

Trunk lateral flexion
The movement of the trunk to the left or right, involving shoulder movement towards the hip on each side.

Biofeedback system
The system that can be used to learn to control some of the body's functions.

Functionality
The range of operations the robot and software can perform.

Fully Vaccinated
Refers to those who have had at least two (2) vaccination shots against COVID-19.

Force sensors
A mechanical load, weight, tension, compression, or pressure transducer that transforms an input mechanical load, weight, tension, compression, or pressure into an electrical output signal.

Inclusion criteria
A set of instructions that participants must follow in order to be eligible to be part of the study.

Exclusion criteria
Characteristics that applicants may have that would exclude them from being part of the study.

Exclusion list
List of participants that are not qualified to participate in the study.

LLMo Robot (Lower Limb Mobilization Robot)
A device that is designed to perform trunk and lower limb exercises for rehabilitation.

Participants
Individuals that underwent the screening phase and are qualified to take part in the research study.

Reverse transcription polymerase chain reaction test (RT-PCR)
A test that is both accurate and reliable for identifying COVID-19.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
A virus that causes respiratory illnesses, most notably COVID-19.

Inter-Agency Task Force for the Management of Emerging Infectious Diseases (IATF)
Refers to the organized task force in charge of responding to issues affecting emerging infectious diseases in the country.

High-Efficiency Particulate Air (HEPA)
Refers to an efficiency standard of air filters.

Personal protective equipment (PPEs)
Protective clothing worn to minimize exposure to hazards that can cause serious injuries and illnesses.

Emergency stop button
A highly visible button designed to stop operations on the device.

Iliopsoas / Gluteus maximus
Muscles located at the posterior aspect of the hip joint.

Gluteus medius and adductors muscles
Prime mover of abduction at hip joint.

Hamstrings and quadriceps femoris/ bicep femoris
Muscles located at the anterior and posterior thigh area.

Electrodes
Placed on the skin to detect the electrical activity of the targeted muscle.

Lower Extremity
Refers to the hip, thigh, knee, lower leg, ankle, and foot.

Supine
Lying on the back with face or front upward.

Sitting
In a seated position.

Goniometer
An instrument for determining the available range of motion at a joint.

Peak values
The maximum value reached by an alternating quantity in a single cycle.

Pulse Oximeter
A device that measures the oxygen level (oxygen saturation) of the blood.

T-test
A statistical procedure for determining whether or not the mean difference between two sets of observations is zero.

Safety
The condition of being protected from or unlikely to cause danger, risk, or injury.

STATA 15
Software for statics and data science.

Unity
Software engine platform that the TAYO application runs on

Good Clinical Practices (GCP)

An international quality standard.

Non-Disclosure Agreement (NDA)
A legal agreement that obligates one or more parties to keep private information confidential.

RA 10173 - Philippine Data Privacy Act
A law intended to protect all types of information.

Robot
A system of controllers, actuators and sensors controlled by a software

Potential Failure Mode
A mode in which an equipment or machine failure can occur.

Hazard Score
Computed by multiplying the severity and H ratings.

Mushroom emergency button
A button that is used to stop the operation of a machine or device.

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I. Introduction

Lower limb rehabilitation robots have been researched and developed exceedingly in the previous years. This is in response to the need to treat people suffering from stroke or injury [1]. Rehabilitation through physical therapy is a solution to treat these patients. This helps in the patients' recovery of motor function, regain of impaired limb control, and reduction of the disability rate [2].

Iterations and applications of robotics in rehabilitation have been done because therapy aid robots provide more efficient rehabilitation than manual practices [3]. Robotic rehabilitation devices or exoskeletons may be more supplementary than necessary, but these have the potential to provide economic advantages for doctors and patients. Enabling research to be commercially viable and available to end-users, however, has been a challenge. [4]. Limited evidence on efficacy and safety are among the roadblocks to be overcome in order to achieve extensive use of rehabilitative technologies locally [5].

A multifunctional robot that can perform supine and sitting positions was developed through STAGE1 of the TAYÔ Project. The safety of this locally developed robotic device for lower extremity rehabilitation needs to be ensured before clinical use [6]. The process for hazard management in operational environments is known as the Hazard Identification, Risk Assessment and Control, which was used in measuring the safety of the robot before Clinical Trials. HIRAC is a method of problem solving with the goal of preventing incidents and injuries. This procedure specifies the steps to take in order to manage and control potential dangers or hazards [7].

II. Review of Literature

Worldwide, stroke and injury are two of the leading causes of long-term disability [8]. Locally, approximately 500,000 Filipinos suffer from stroke annually [9]. It is estimated that $350 million to $1.2 billion is needed to meet medical care costs. Largely, health care is private and costs are shouldered by the patient. While hospitalization services in most government hospitals are free, patients are still responsible for financing the purchase of medicines. While there are socially responsible government agencies aiding in the hospitalization cost requirements, only a portion of the gaps are filled. Hence, paying for medical services is a difficult challenge for lower and middle-income groups in the Philippines. It then becomes necessary to find efficient and economical rehabilitation interventions for promoting motor recovery [10].

Robot-assisted therapy is a promising technology for use in rehabilitation therapy through the automation of exercise therapy. There is a need for the patient in the rehabilitation service to be assisted with repetitive exercises that are task-oriented and precise but the evaluation is subjectively done by the therapist, thus assistance from robotic devices are valuable [11]. In the Philippines, a team has been working on a multi-functional robotic device for early trunk and lower limb rehabilitation that complies with the strict local and international medical device safety standards. The team is composed of researchers from De La Salle University - Institute of Biomedical Engineering and Health Technologies (DLSU-IBEHT) with interdisciplinary expertise in fields including bioengineering, electronics, manufacturing, and robotics and experts from the De La Salle Medical and Health Sciences Institute [6].

The robotic device has been designed and will undergo mechanical safety and compliance tests and electrical safety and compliance tests not limited to Basic CE Compliance Testing, IEC 60601-1 Requirements, and IEC 60601-2-52. These will be further discussed in a separate section of this protocol. These tests can specify that the robot can move accurately when powered and stay in the desired positions when unpowered. However, these do not involve tests considering human ergonomics, particularly the positioning of the trunk and lower extremities. The technical investigator needs to perform tests to ensure that the design is in accordance with the comfort level and usability. The tests will be done with the researchers as participants. Such a test is necessary before performing tests with more randomized healthy subjects. Several robot assistive device projects have always been tested directly on humans to identify comfort level, human response to machine programming, and efficacy, as demonstrated by previous studies [12,13,14,15,16].

Locally, there is a study that created a safety checklist for an upper limb rehabilitation device [5]. The study used HIRAC protocol as a guide. This procedure applies to all staff and participants. The procedure consists of 6 steps namely preparation, hazard identification, risk assessment, plan control measures, record keeping, and implementation and review [17]. The risk level of each identified hazard is deduced and listed based on priority from the most serious and likely to happen to less. A risk matrix is commonly used to determine the risk level, providing a summary of both likelihood and severity of the consequences. The other crucial step of the procedure is setting control measures for prevention or reduction of chances for such incidents. The five (5) control measure categories are elimination, substitution, engineering controls, administrative controls, and PPE [17].

In clinical investigation, safety can be defined as an assessment of the acceptability of the risk associated with a technology or drugs. Risks pertain to the measurement of the probability and severity of a harm associated with the use of a medical device. Thus, it concerns the probability of risk to occur and the nature of the risk itself that can occur in a population. [18] This is also attributed as a measure of risks and benefits of medical devices along with the aim of assessing effectiveness of medical devices as compared with the current gold standard in medical practice. [19] Regulatory agencies also require declaring of safety variables for clinical investigations which involves comprehensively recording, monitoring and reporting of serious adverse incidents as part of the safety evaluation of clinical trials. Hence, several clinical trials for medical devices used a number of safety adverse events as one of the outcome measures for safety evaluation. [20,21,22,23] Different pain assessment scale such as Visual Analog Scale (VAS) and Numerical Rating Scale (NRS) were also used as a parameter for secondary outcome and physiological parameters like measurement of heart rate, systolic and diastolic pressure, oxygen saturation and breath rate. [22,23]

Safety standards for medical devices have been addressed by different international organizations, specifically the International Electrotechnical Commission (IEC) and International Organization for Standardization (ISO), with their release of ISO 14971, IEC 60601-1, IEC 62304, IEC 62366, ISO 10993-1 among others. However, among these standards, the ISO 14971 (Medical devices — Application of risk management to medical devices) was considered to be the official standard in risk management of medical devices as it is both recognized by the United States and European Union. Hence, it is the most often used standard for establishing medical device safety. Based on this standard, the risk management process must be composed at least of risk analysis which includes hazard identification and risk estimation, risk

evaluation, risk control, risk control verification and monitoring. Although manufacturers have the freedom in creating internal procedures to meet these risk management processes, ISO 14971 requires specific requirements which includes a plan, a documented process applied to the entire product life cycle, a qualified personnel to perform risk management, ensuring the completeness of risk controls for identified risks, evaluation of overall residual risk, proof that the benefits outweigh the risks, monitoring of production and postproduction information in order to produce inputs for the risk management process, producing a risk management report and creating and maintaining a risk management file, and show the traceability of hazards, risks, risk analysis, evaluation and control and verification of risk control. [24] The Hazard Identification, Risk Assessment and Control (HIRAC) is one of the methods that has been widely used for safety, particularly on the basis of risk management. It also involves and confers to the risk management process of the ISO 14971 which focuses in general on the hazard identification, risk assessment and control and monitoring and review.

End-user involvement and user acceptability were also recognized as essential aspects of developing a robotic system that is involved for healthcare delivery. Usability, safety, comfort, desire for future use in the context of an established treatment program using the robot were some of the aspects measured. [25] Aside from mechanical and electrical validation of the robot in terms of its ability to carry out its function, Jackson et al (2007) also gave emphasis that regardless of the efficiency of robot system's performance, it is unlikely for the patients to be willing to undergo treatment programs if the robotic device does not feel safe and comfortable for them. [26] Moreover, it has been established that consideration and user integration is vital for an efficient and satisfactory human-robot interaction. [27] Studies showed that these aspects were tested using modified survey questionnaires, modified System Usability Scale, Likert scale, Visual Analog Scale, Numeric Rating Scale or open text questions, NASA Task Load Index, Quebec User Evaluation of Satisfaction with Assistive Technology and others. [25,26,27]

III. Study Objectives

A. General Objectives

To determine and perform safety and measure range of motion among healthy adults of the locally developed trunk and lower limb rehabilitation robot.

B. Specific Objectives

1. Conduct safety tests of the robot and robot software with human subjects on the following:
    a. Robot setup
    b. Attachment position of human subject
    c. Passive range of motion procedure
    d. Sit to stand motion
2. Perform and measure the capability of the robot in terms of the following ranges of motion:
    a. supine hip flexion-extension,
    b. supine hip-knee flexion-extension,
    c. supine hip abduction-adduction,
    d. sitting knee flexion-extension,

e. supine trunk forward flexion, and
f. supine trunk lateral flexion
g. sit to stand motion (Hip and knee final range of motion)

3. Compare the results obtained from the measurements of the range of motion (ROM) by the robot's software with the measurements of the ROM performed by the physical therapist for the ff.:
   a. supine hip flexion-extension,
   b. supine hip-knee flexion-extension,
   c. supine hip abduction-adduction,
   d. sitting knee flexion-extension,
   e. supine trunk forward flexion, and
   f. supine trunk lateral flexion
   g. sit to stand motion

IV. LLMo (Lower Limb Mobilization) Rehabilitation Robot

A. Robot Description

LLMo, developed in the TAYÔ Project is a multifunctional robot that can move from supine to sitting positions, as well as from sit to stand position.

The robot can perform range of motion (ROM) exercises while the patient is in supine or sitting positions and through passive training modes as it is structured with hip, knee, main frame and base with different rotating joints, supports and adjustments. The ROMs include hip flexion-extension, hip abduction-adduction, knee flexion-extension, trunk flexion, and trunk lateral flexion. The robot is expected to have direct contact with the user as it operates within the patient vicinity. The parts to be in contact would be the back of the head down to the ankle of the patient.

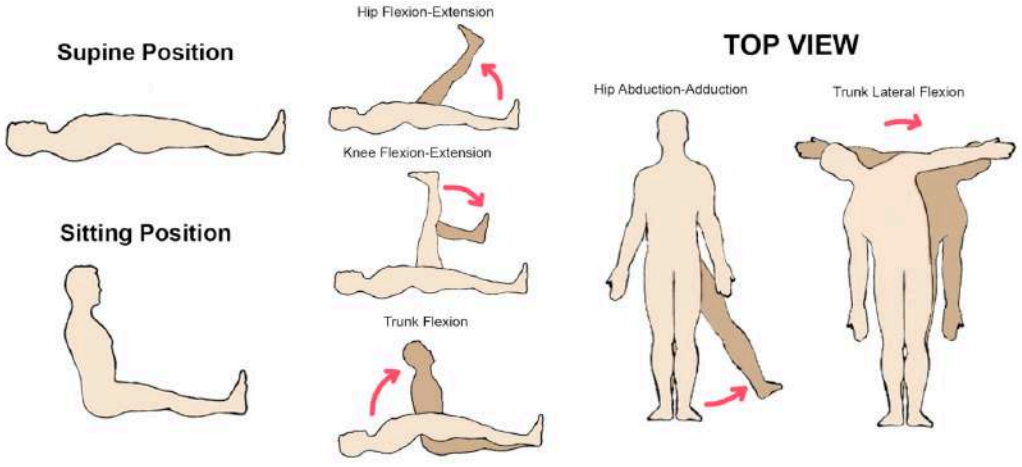

Figure 1. LLMo Rehabilitation Robot Anatomical Movements Capability

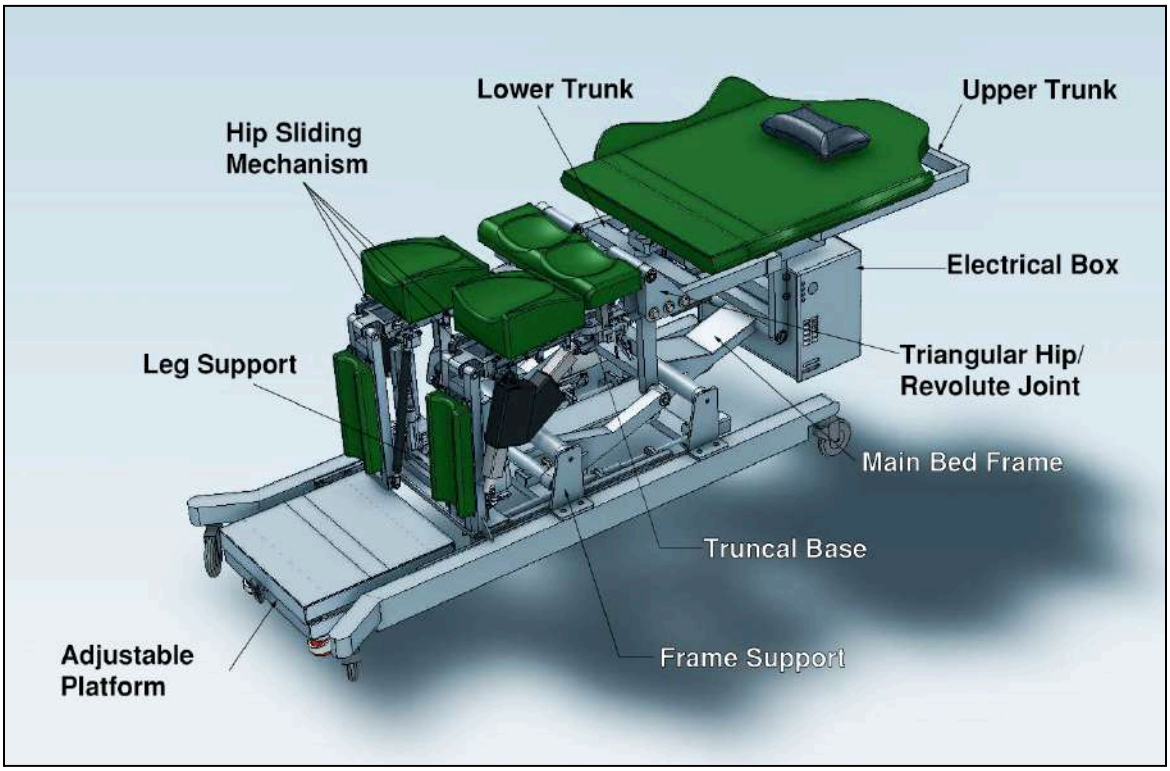

Figure 2. LLMo Rehabilitation Robot

B. Social Value

Lower extremity training requires time and physical effort on the part of the physical therapist (PT). LLMO allows repetitive, intensive, and task specific training which will help unburden the load of therapists which will benefit the hospitals and clinics. Using the robot is energy efficient for the PT in performing Sit-to-Stand activities, which also includes safety and monitoring. LLMO can also be used for assessment and diagnostics as it measures the ROM of the hip, knee, and trunk joints. The use of LLMO allows the therapist to focus on achieving optimal to maximal Sit-to-Stand and standing tolerance activity.

The robot will be an additional tool that will widen the range of treatment options available for the patient and the therapist. LLMO will not only help facilitate early mobilization, its collected data will further help improve the quality in the delivery of services. Especially in the Philippine setting wherein the physical therapists are understaffed.

The robot is meant to augment the health manpower support and shortage in hospitals and clinics due to resignation, migration, and hesitation in handling high risk patients, such as COVID patients needing mobilization. The efficiency and accuracy of the robot in doing ROM will result in faster turnover of PT treatments of patients. The robot prevents fatigue to the PT's as compared to manual exercises and will greatly accelerate the program of assistive movement.

LLMO will allow an objective measure of progress which will help improve the patient's condition, and may serve as a continuous passive ROM Machine with accurate

settings in place. Additionally, LLMO is meant to be manufactured as an affordable assistive robot.

C. Robot Configuration

The initial position of the robot is set to a sitting position before the execution of the activity. The power switch will then be activated and the hip and joints of the robot will be adjusted through the software based on the participant's specifications. The patient emergency stop button will be handed to the study participant so he can stop the robot if the participant would feel uncomfortable.

The patient can be strapped to the robot at the chest, knees (below tibial tuberosity), and ankle (above medial malleolus) to prevent any falls during use. The outer material of the mattress is a synthetic leather which is resistant to water, alcohol, and bleach solutions for ease of cleaning.The straps of the robot are for multiple uses with ample disinfection after every use.

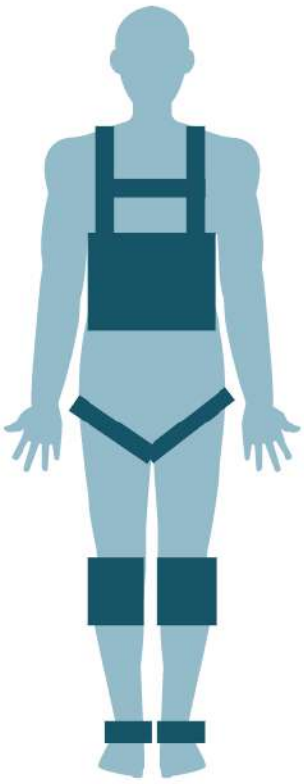

Figure 3. Strap Location

D. Robot Software

The robot is controlled using a proprietary application installed in an android tablet for easy use and access by therapists. The application is designed using Unity and will have access to control the robot, record patient lists, record results of robot use. All data recorded is in accordance with the Data Privacy Law and is further described in the Data Handling and Record Keeping section of this paper. The tablet does not have to

be plugged to an electrical outlet all the time, and will require a local wifi connection to connect and control the robot.

The application in any screen displays the status of the robot connection, server connection and emergency stop button for consistent and easy to understand interface. Every after session, the application requests feedback of the exercises shown in image below.

The robot control through the application will be able to perform specific tasks below:

- Register patient information
- Collect and store patient information
- Create 2 types of user (MD or Therapist)
- Perform Passive Exercise
- Perform Sit to Stand motion
- Perform manual control

Specifically for the clinical trial, the application will remove the variable repetition, and set it to 3 to save time while performing clinical trial

E. Robot Safety Standards

Different relevant standards and compliances were observed in building the LLMo Rehabilitation Robot to ensure its safety standards as a first-in-human trial will be conducted as part of its safety testing and phase 1 of the clinical trial. ISO 15066 (Robots and Robotic devices standard), OSHA 1910.303 which covers minimum safe operating distance of operator with a machine and guarding and safety aspects of a machine similar to but more advanced than written into Philippine OSH Standards rule book covering rules 1200 Machine Guarding and 1210 Electrical Safety, IEC 60601-1-3 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance, RIA R15 for considerations on robots that operate in close proximity with human users and IEC 80601-2-78 the standard for medical robots in physiotherapy which are involved in medical robotic projects were considered and checklists of criteria items were made to ensure the device's compliance. Other non-clinical data gathered from the mechanical and electrical test were summarized (See Appendix I).

To measure safety the team performed HIRAC assessment with a DOLE certified safety officer. Through this assessment, risks are properly identified and carefully controlled and mitigated. Results from the assessment are seen in Appendix D.

V. Methodology

A. Study Participant Eligibility

1. Inclusion and Exclusion Criteria

Inclusion Criteria

Eighteen (18) healthy volunteers will be selected using the criteria found below:

1. Participants should be able to follow instructions.
2. Participants should be at least 5”4’ or 1.63 m to 6”2’ or 1.87 m
3. Participants should weigh less than 200 kg
4. Participants should have full use of their trunk and lower extremities.
5. Participants should agree to have medical clearance sponsored by the research prior to participation. (Validity: 1-2 weeks from appointed clinical study participation)
6. Participants should be fully vaccinated from COVID19 (2 completed doses, with or without boosters)

Exclusion Criteria

Participants with known disabilities, abnormalities or diagnosed medical conditions including, but not limited to: orthopedic or neurological, cardiovascular, pulmonary; are excluded since this study is for healthy participants.

Additionally selected participants will only be coming from De La Salle University - Laguna Campus to minimize health risk from COVID 19 pandemic. Participants with no access to online connection are excluded.

2. Study Participant Selection

a. Recruitment Phase

The team will be gathering six (6) participants for each age group (18-29, 30-45, and 46-60 years old; with equal representation from 2 biological genders). Applicants will be recruited from email or invitation through Help Desk Announcement (HDA) and physical posters in DLSU-Laguna campus.

The post contains information about the rehabilitation robot, what the participants will do in the study, contact information for queries, and a link to Google Forms in case a potential participant is interested to join the clinical trial (see Appendix A.1 and A.2). Before publication, the content will be reviewed and authorized by the investigators.

To determine if a person is eligible to participate in the research, he or she must be between 18-29, 30-45, and 46-60 years old. If the applicant falls within one of these age categories, the next step is to ensure that he or she meets criteria 1 to 6. If the applicant meets these criteria, he/she will be qualified for the next stage, which is the online screening phase and medical interview.

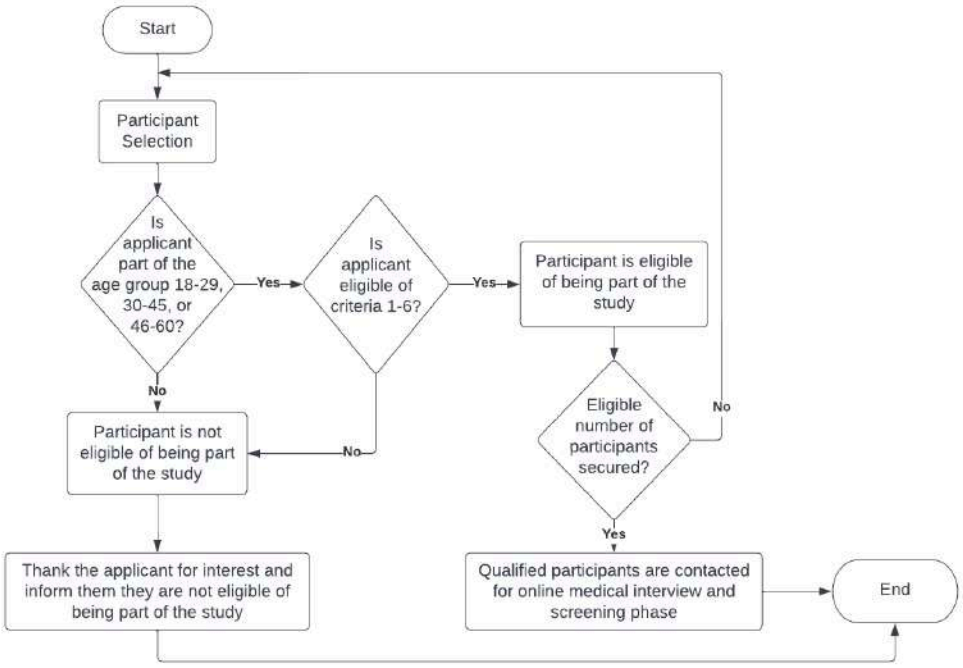

Figure 4. Participant Selection Flowchart

b. Screening Phase

The investigators will review the submitted application forms. Forms with exclusion conditions will be filed under the exclusion list. A notice letter will be sent through email if the potential study participant is not qualified for the trial. This email will also indicate that the application forms submitted will be retained until the study ends in 60 months from the start of the project and be deleted. (See Appendix A.5) Forms that passed the initial recruitment phase will be filed under the “online study briefing” list and will be contacted via email or telephone call for the online study briefing.

c. Online Study Briefing

The application forms of applicants who are qualified will be given to the medical doctor and an appointment for the interview will be set. The participants will then be notified of the clinical trial process. An online briefing through viber, messenger or zoom will be conducted to discuss the overview of the trial procedure and ethical considerations for the study participants.

1. Overview of the Study

A thorough explanation of the trial process including the measurements that will be measured including the range of motion and length of limbs will be given to the study participants. The applicants will be able to ask questions during this process. Furthermore, a video

presentation of the robot which explains its function, use, and practical applications will be presented. The trial procedure will also be discussed which involves the study participant briefing, pre-and post-study evaluation, and monitoring and exercise intervention.

2. Pre-medical Online Interview and Discussion of Ethical Consideration

Medical Investigator through online interviews verifies the information input in the application form. Applicants that have COVID 19 symptoms are excluded from the study. Those who will be as gauged capable of performing the tasks explained and will accept to have their limb measurements done as discussed in the briefing will then opt to sign the informed consent forms. (See Appendix B). The consent forms will include consent for video recording which will be used for further product development purposes. The consent forms will be reviewed by the medical doctor for completeness. Those who will completely sign the consent forms will be regarded as study participants and will be scheduled for a face to face medical clearance and interview with The Medical Clinic South Luzon (TMC). While those who will not consent will be excluded from the study.

The medical clearance tests include the following:

- History and Physical Examination
- Urinalysis
- Fecalysis
- Complete Blood Count
- Chest PA X-ray
- rT-PCR test

Personal numbers and pseudo names will be assigned and used for the identification of data during the study, instead of the study participants' legal names and corresponding details. All data will be referenced to these names, with only the age and gender of the study participants remaining as sensitive personal information in the database. All gathered data during the study will be classified as study records and will be retained according to the DLSU's data retention policy for the project.

d. Face to face Medical Interview and Clearance

The pre-screened participants will go to The Medical Clinic South Luzon (TMC) to do the medical clearance and interview the participants. The clinic is 4 kms away from the campus and a scheduled van transport is available for participants scheduled for medical clearance. The physician will receive a set of medical interview questions (Appendix A.3) from the investigator which is for approval of the physician in charge of the clinic (TMC). In the interview, the TMC physician will screen the listed pre-existing medical conditions and verify if all the inclusion and exclusion criteria are met.

The TMC physician will assess participants' general health, screen for potential medical issues, and ensure that the participant is medically fit

to perform the activities in the study. All notes of the interview will be written on an interview sheet (See Appendix A.4) stapled to the application form.

A consent form for the patient interview is filled up and signed by the participant. All particiapants in the interview will receive letters regarding the decision, retention policy for the application forms and screening phase, data privacy policy.

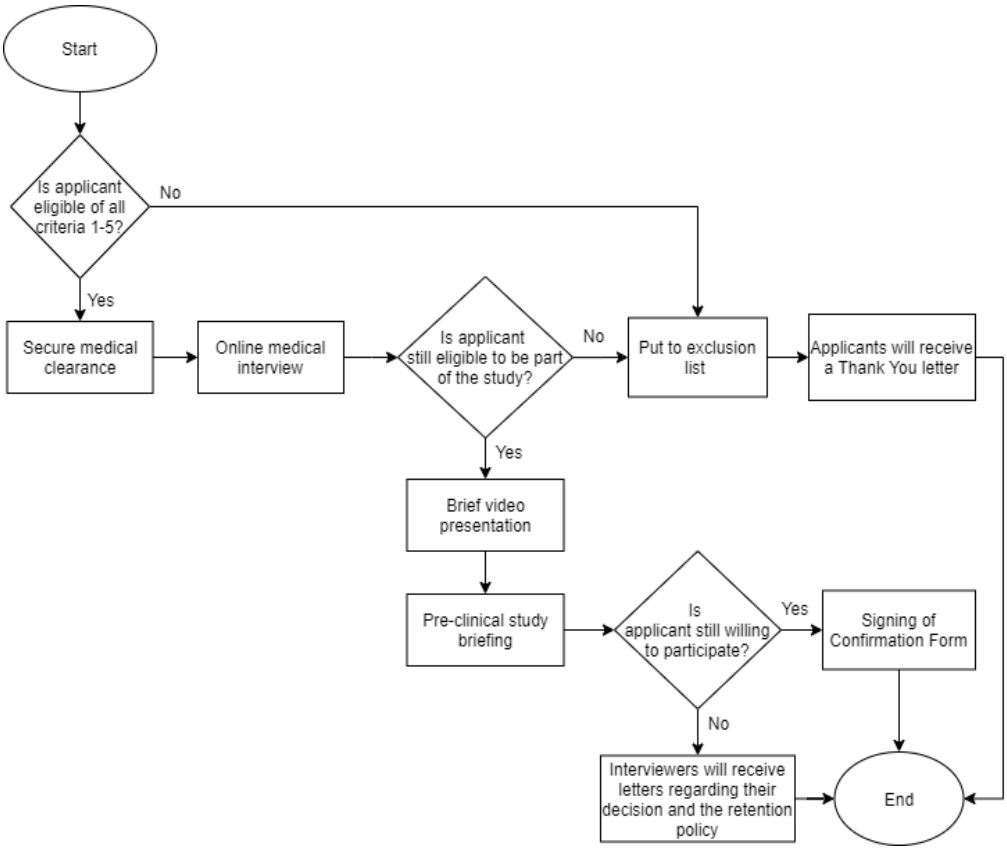

Figure 5. Screening Phase Flowchart

3. Study Participant Withdrawal

The potential study participants during the recruitment, screening and medical interview phase may withdraw from the study anytime. Similarly, the study participant who was already enrolled in the study and signed the informed consent has the right to withdraw prior or after study intervention. The principal investigator may also dismiss the study participants if there is a medical condition that just arose after the participant was examined by the medical doctor, due to adverse events during the exercise activity intervention, or non-compliance with the study intervention. No penalty shall be imposed in the withdrawal situations cited above.

If insurance is already in place once the withdrawal is done, it will not be revoked. The participant, however, will be asked to put into writing the reason for withdrawal for clarification purposes.This is to ensure that transparency is

achieved in the process as the insurance card was paid for by government funds and will need to be properly accounted for.

The enrolled study participant who wishes to withdraw should fill out the following form:

1. Study Participant Withdrawal Form where the reason for withdrawal is indicated
2. Study Participant Off Trial Form to ensure that the study participant left the trial.

If the principal investigator dismissed the study participant, a Study Participant Off Trial Form should also be filled out. Replacing the study participants who withdrew from the study shall still follow the study participant selection process. All data gathered from withdrawn participants will not be used and will be properly disposed of.

B. Study Venue

The research will be conducted inside the Institute of Biomedical Engineering and Health Technologies (IBEHT) Laboratory, Richard L. Lee Engineering and Technology Block, De La Salle University - Science and Technology Complex (DLSU-STC), Biñan, Laguna. During the pandemic, the research area will be located in a well-ventilated space that allows waiting for participants to be separated by six (6) or more feet, with easy access to respiratory hygiene supplies.

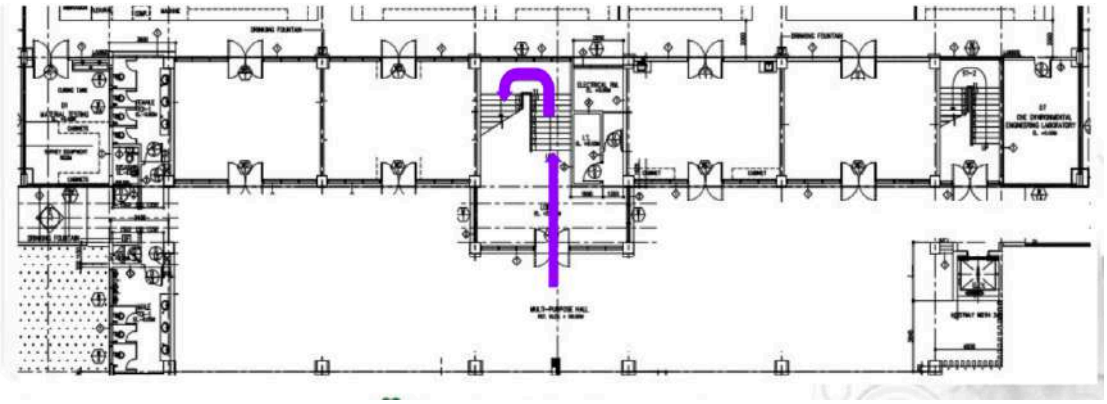

Figure 6.1. Richard Lee Building first floor plan

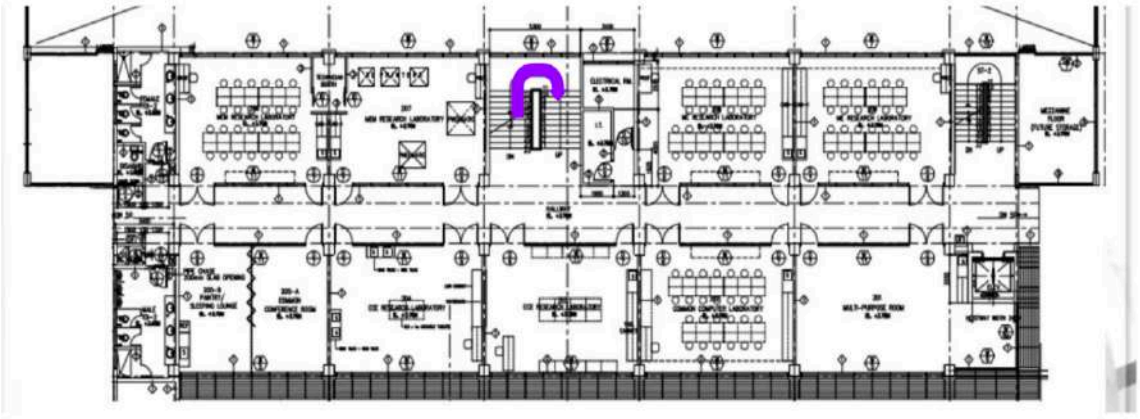

Figure 6.2. Richard Lee Building second floor plan

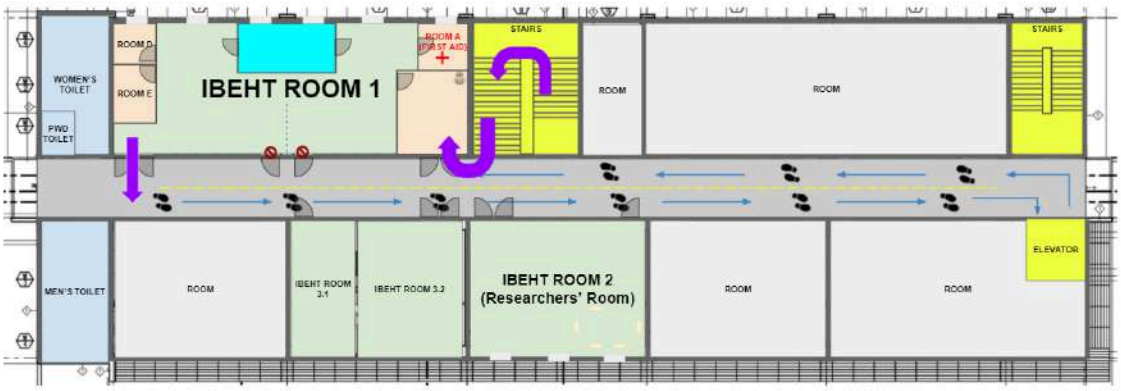

Figure 6.3. Richard Lee Building third floor plan

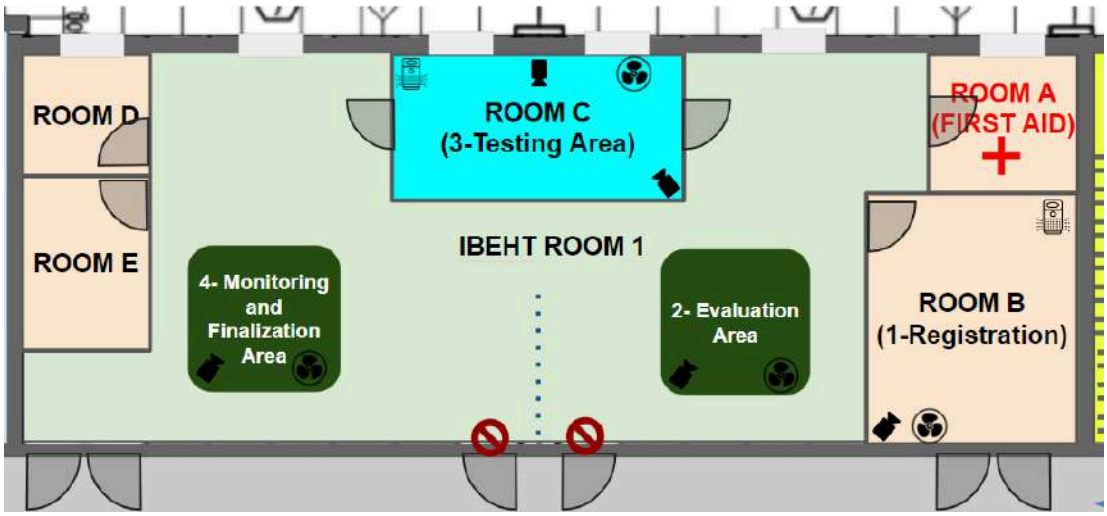

Figure 6.4. Floor plan of the testing area.

There shall be a holding room for participants who arrive early which is located in IBEHT ROOM 3.1. Curtains will be used to cover the doors of Registration room B, with a sign that states “Clinical Trial Ongoing Authorized Personnel Only”. The testing area labeled as Room C is 2.92 x 4.61 m (13.47sqm) in size. All sessions shall be done in an environment with proper

ventilation to ensure air flow from outside to inside and inside to outside the area. An air purifier with a High Efficiency Particulate Air (HEPA) filter will be used to cover the vicinity in which the participant, investigators(MDs, PT and Technical Investigator) and administrative staff will work, allowing a reduction in particulate count and air borne pathogens. Throughout the session, fresh air will be introduced into the room from outside using fans to ensure that the necessary air quality is maintained within the vicinity. A footbath shall be placed at the doorway before entering the trial area using a 1:10 bleach solution. The disinfectant solution will be replaced at the end of every clinical trial day as well as whenever the mixture starts becoming turbid.

C. Health and Safety Management

1. Primary Medical Facility

The DLSU-STC has a complete Health Services Unit (HSU) within 400 meters from the study venue that can provide first aid treatment to the study participants.

One bed is prepared in the clinical trial venue (Room A - See Figure 3.4) for participants that require to take a rest during or after the procedure. An ambulance is also available on standby during the clinical study to transport the patient to the nearest hospital.

2. Side Effects and Study Risks

Based on the technical electrical and mechanical safety evaluation, there are no known side effects in using the LLMo (Lower Limb Mobilization) Rehabilitation Robot but there are negligible risks. Assessment using the framework in ISO 14971, OSHA Machine Guarding Checklists, and OSHA Hazard Identification showed that the machine has hazards that potentially cause medical risks. Low risks include muscular pain, joint pain, soft tissue injury, fracture, abrasion, muscle soreness, fatigue, elevated blood pressure, electrocution, irritation, tingling and contact dermatitis due to aluminum and nickel impurities found on the device's steel and silver-plated section.

Intrinsic risks that are possible to be incurred in this study include muscular pain, muscle soreness, nerve irritation, soft tissue injury, joint pain, abrasion, fracture, fatigue, and elevated blood pressure. Extrinsic risks, on the other hand, include possible body injury caused by lack of rest on the participant’s side, fatigue from traveling towards the testing area, improper use by the device operator, electricity fluctuation or power outage, and environmental temperature changes.

If at any moment, the participant feels any discomfort and requires medical attention, the participant shall immediately be given first aid before bringing him/her to the primary medical facility where a second evaluation should be conducted and if needed a referral is made to the nearest hospital. The cost of treatment for the hospital will be handled by the insurance provided by the study to the participant.

Managing risks would require these items to be monitored before, during, and after usage of the device. Thus, control measures through a plan for risk management which includes technical risk analysis and situational awareness were made. (See Appendix D)

3. Safety and Adverse Events

A. Definition of Safety and Adverse Events

Any incident or situation resulting from the exercise activity intervention in the clinical trial, both unanticipated and described in the risk assessment conducted (Adverse Events), must be recorded and reported regardless of the severity. Similarly, any effect of the robot (Adverse Device Effects), both unanticipated and described in the risk assessment conducted, must also be recorded and reported regardless of the severity.

B. Reporting of Safety and Adverse Events

Adverse Device Effects and Adverse Medical Events must be recorded in the Safety and Adverse Events form. (See appendix C.2) Any effects or events that are considered to be of clinical significance by the medical physicians during the trial must be attended immediately in the primary medical facility. An ambulance must also be on standby in case hospital transfer is needed. Adverse Device Effects and Adverse Medical Events must also be reported to the sponsor, cooperating agency and respective institutional review boards.

D. Trial Design

1. Trial Design

a. General Design

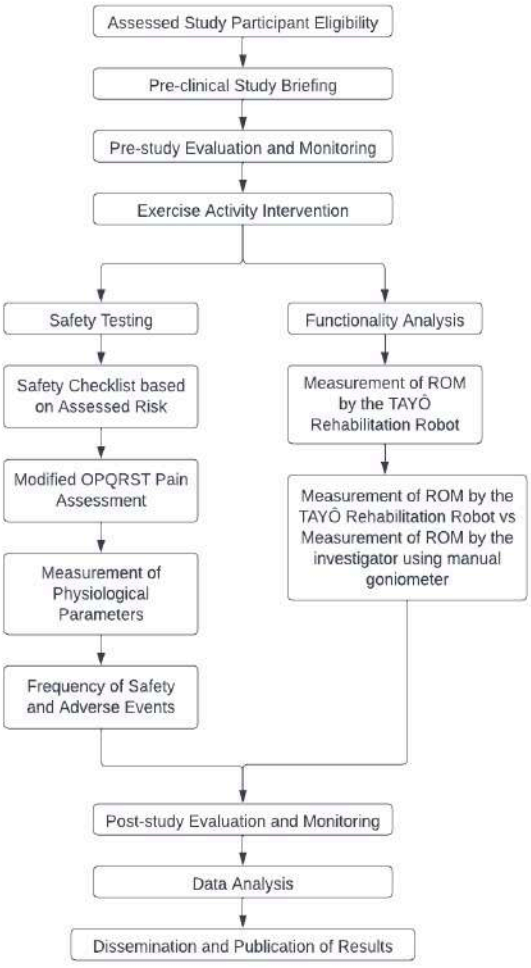

Figure 7.1. Schematic Diagram of the Trial Design

A pilot study among healthy subjects on the safety and functionality of the LLMo (Lower Limb Mobilization) Rehabilitation Robot will be utilized in the clinical trial. Eighteen (18) study participants, six (6) from each age group (18-29, 30-45, and 46-60 years old) will be enrolled in the study. Study participant eligibility will be assessed based on the inclusion and exclusion criteria. Moreover, potential participants will be subjected to a series of phases, specifically, the recruitment phase, screening phase, and face to face medical interview and clearance. The pre-clinical briefing will be conducted during the screening phase to discuss the ethical considerations and process of the trial.

Into the Trial, initial ROM by manual goniometer will be done for ROMs stated in the study as baseline. During the trial, exercise activity intervention will be applied where study participants will be tasked to do a set of different range of motion exercises that will be measured using a manual goniometer and the LLMo Rehabilitation Robot guided by the investigators to assess the robot's capability. Different safety parameters will also be measured for the safety testing. Both pre- and post-evaluation and vital signs monitoring will be observed. Digital evaluation at the end of each set of exercises will also be given. Furthermore, safety compliance

based on HIRAC standards and potential adverse effects or events will be observed during the trial.

Recruitment and screening phase will be done 2 weeks before the study. The clinical study consists of daily trials lasting for 9 working days wherein two (2) participants per day will be subjected to trial. Each day, participants are in trial for 2-3 hours.

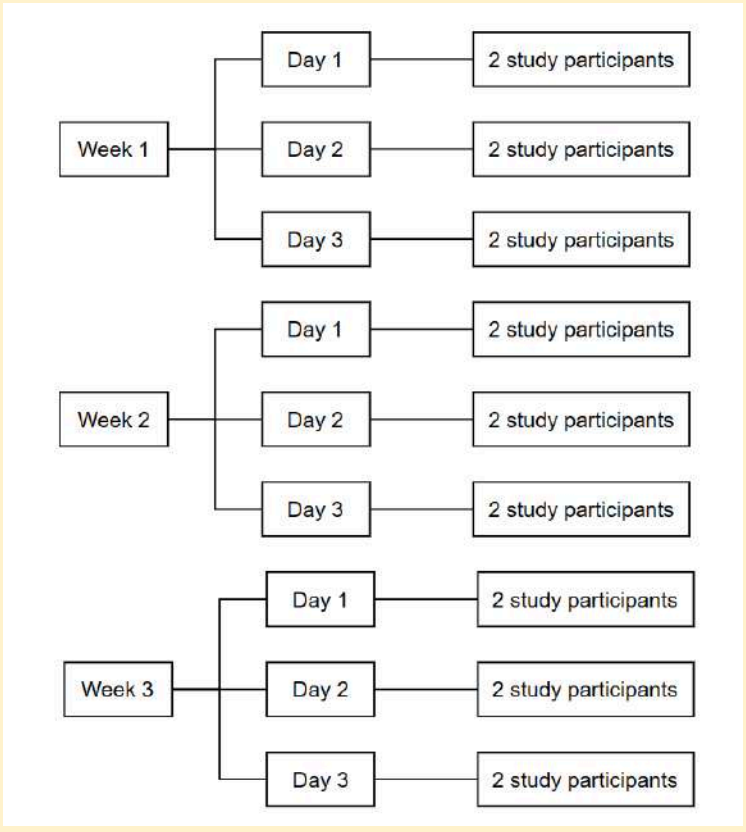

Figure 7.2. Schedule of the Trial

b. Primary and Secondary Endpoints

Primary Endpoints

The primary endpoints of the study include the following parameters:

1. Safety Evaluation of Robot with Healthy Normal Subjects based on:
    a. Safety Test Checklist based on Assessed Risk
    b. Modified OPQRST Pain Assessment Tool
    c. Safety, Feasibility, and Acceptability Questionnaire

2. Measurement of Range of Motion of the LLMo Rehabilitation Robot in terms of:

    a. supine hip flexion-extension,
    b. supine hip abduction-adduction,
    c. sitting knee flexion-extension,
    d. supine trunk forward flexion, and
    e. supine trunk lateral flexion
    f. sit to stand motion

3. Comparison of the Measurement of Range of Motion recorded by the LLMo Robot's software and measurement of range of Motion recorded by Investigator using Manual Goniometer

    a. supine hip flexion-extension,
    b. supine hip abduction-adduction,
    c. sitting knee flexion-extension,
    d. supine trunk forward flexion, and
    e. supine trunk lateral flexion
    f. sit to stand motion

Secondary Endpoints

The secondary endpoints of the study include the following:

1. Frequency of Safety and Adverse Events
2. Physiological Parameters recorded before, during and after the trial (Blood pressure, Heart Rate, Oxygen Saturation

c. Robot Use and Exposure Duration

Table 1: Robot Exposure Duration

Rehabilitation Robot	Time Duration
Attached	2:00 hours
Functioning	2:00 hours
Measuring / Fitting	20 mins

The total time needed to process one participant with a complete set of ROM tests and Sit to stand motion is two (2) hours. The robot is active for the whole two (2) hours for the complete set of tests. Including the pre-session evaluation of the medical doctor and filling up of the survey form, it is expected to take a total of two (2) hours and twenty (20) minutes per participant to finish each session.

d. Definition of End Trial and Discontinuation of the Study

Accomplishing the Study Participant Off Trial form by the study participant after the post-evaluation and vital signs monitoring marks the completion of the participation in the trial. The end of trial is the date when all 18 participants completed the study intervention and other evaluation and monitoring that the complete trial process requires.

Temporary discontinuation of the study shall be observed if there is a case of COVID-19 infection in the study venue,occurrence of any natural disasters such as earthquakes and typhoons, if and when the province of Laguna was raised to Alert Level 3. In such cases, DLSU Laguna protocols will be observed. Please see Appendix K for earthquake, fire, and other evacuation drills. The study shall resume once an advisory is released that the study venue was disinfected and deemed safe for study participants.

2. Trial Procedure

a. Face to face Study Participant Briefing

The participant will be assisted to the testing site, where an organized flow of activities will be introduced as shown in the figure below.

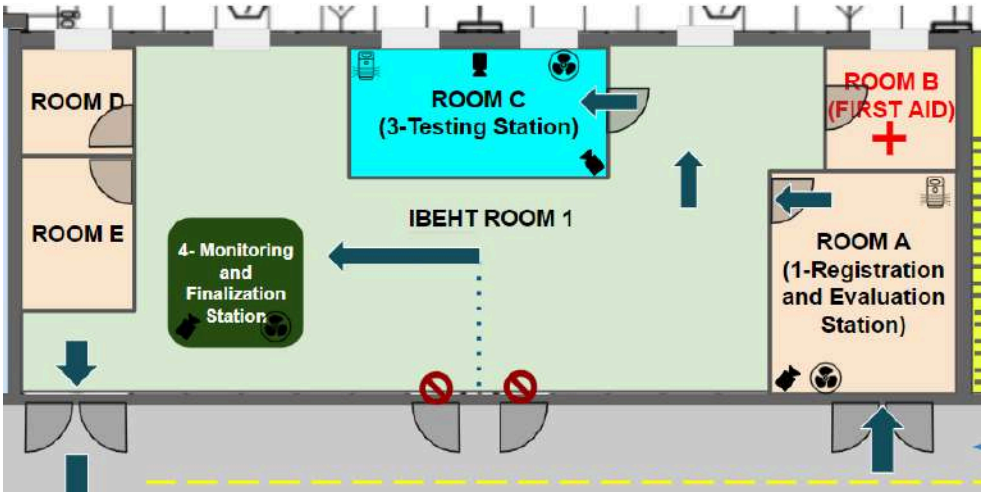

Figure 8.1. Testing Site

The participant will enter Room A for registration, briefing, and vital signs monitoring manned by a staff. The participant will then be asked to wait in the registration area, which will have curtains for privacy, while the technical team prepares. Simultaneously the technical team conducts the robot inspection using safety checklists. Once the physical evaluation and the safety inspection are complete, the participant will proceed to the Testing Area at Room C together with the Investigator.

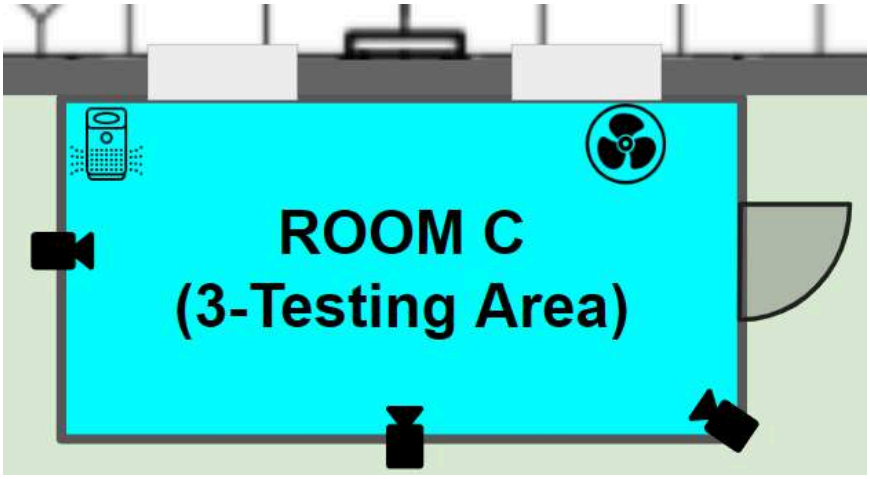

Figure 8.2. Testing Area

Assigned therapists will assist the participant inside the testing area, which is shown in Figure 5.2. A maximum of five (5) people will be allowed inside room C. Cameras are placed inside the testing area for documentation. After completing the trial, the participant exits through the same door, and proceeds to the monitoring and the finalization station.

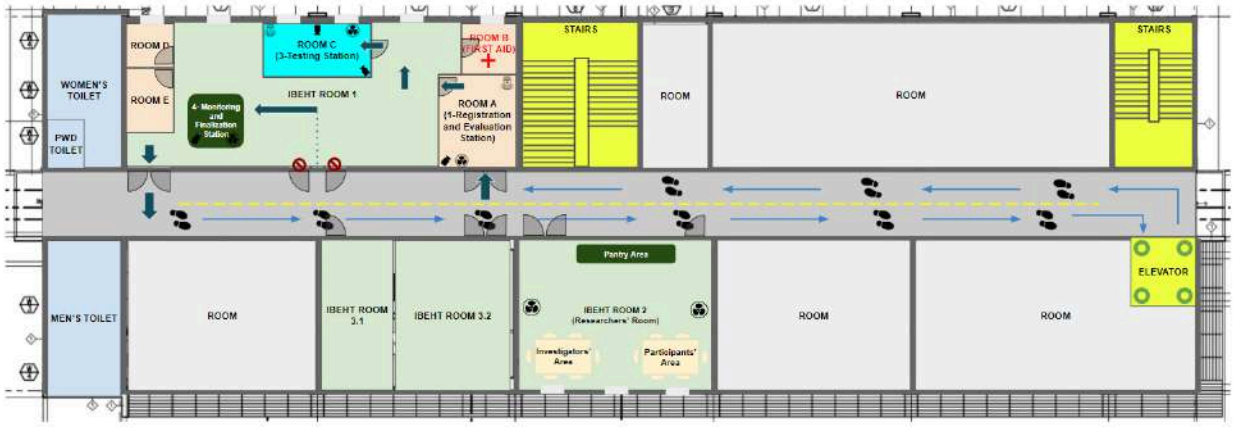

Figure 8.3. Floor Plan

Additionally, the hallway will be divided into two paths for people entering and leaving. As participants will arrive and leave using the elevator shown above, there will be a divider to indicate the separation, and the participants must keep rights for safety and organization. Participants who arrive early will be asked to settle in IBEHT ROOM 3.1, which will serve as the waiting area.

b. Pre-study Evaluation,Vital Signs Monitoring and Trunk and Lower Limb Range of Motion

In the evaluation station, study participants undergo physical evaluation and vital signs monitoring where their blood pressure, heart rate, respiration rate, and oxygen levels are measured and recorded in

Appendix E.6. Range of motion is then measured based on the reference value and methodology from *Magee* and recorded in Appendix E.7.

c. Robot Safety Inspection

The technical team conducts a series of safety testing based on the checklist in Appendix D. This task is carried out while each participant is being informed and evaluated individually (Step 2). The technical investigator then endorses the robot to the medical physician once completed.

d. Exercise Activity

To activate the robot, one (1) investigator must first operate the software. There are preset of three (3) consecutive repetitions that passively move the study participant's trunk, thighs, and lower legs through hip flexion-extension and abduction-adduction, knee flexion-extension, trunk flexion, and trunk lateral flexion on both right and left sides. Rest breaks are provided after the exercise . Each exercise is video recorded for data gathering and product development purposes. The medical investigator constantly monitors the present state of the participant during the whole procedure.

i. Supine Trunk Lateral Flexion

Procedure 1: Supine Passive Trunk Lateral Flexion (20 minutes)

1. In a supine position, baseline range of motion measurement on the study participant is performed manually by the investigator using the goniometer and recorded by pen and paper using the form found in Appendix E.1.

2. The investigator will input the initial position, and final position for the exercise into the software. Once the details are entered, the robot will be programmed and the exercise will be executed by the robot.

3. During the exercise, the software records and displays the exercise angle measurement of the study participant. Next the investigator manually measures the end point position the range of motion using a goniometer.

4. Measurements collated from the goniometer measurement done by the investigator will be recorded by pen and paper in Table 2 found in Appendix E.2.

5. When the end range angle for [exercise] is reached, the robot returns to neutral supine position and is also measured manually by the investigator using a goniometer.

6. Steps 3 through 5 will be done two (2) more times.

7. Vital signs (Blood pressure, Heart rate and Oxygen saturation) will be measured. During the procedure the patient is closely monitored.

8. Modified OPQRST Pain Assessment Tool will be used to assess occurrence of pain among the study participants and Safety Test Checklist based on Assessed Risk will be accomplished to assess the occurrence of the risks and its severity and application of controlled measures.

Supine Hip Flexion-Extension with Knee Extended
(Straight Leg Raising - SLR)

Procedure 2: Passive Hip Flexion with Knee extended in Supine - Range of Movement Evaluation (20 minutes)

Figure 9.1. Supine Hip Flexion

1. In a supine position, baseline range of motion measurement on the study participant is performed manually by the investigator using the goniometer and recorded by pen and paper using the form found in Appendix E.1.

2. The investigator will input the initial position, and final position for the exercise into the software. Once the details are entered, the robot will be programmed and the exercise will be executed by the robot.

3. During the exercise, the software records and displays the exercise angle measurement of the study participant. Next the investigator manually measures the end point position the range of motion using a goniometer.

4. Measurements collated from the goniometer measurement done by the investigator will be recorded by pen and paper in Table 2 found in Appendix E.2.

5. When the end range angle for [exercise] is reached, the robot returns to neutral supine position and is also measured manually by the investigator using a goniometer.

6. Steps 3 through 5 will be done two (2) more times.

7. Vital signs (Blood pressure, Heart rate and Oxygen saturation) will be measured. During the procedure the patient is closely monitored.

8. Modified OPQRST Pain Assessment Tool will be used to assess occurrence of pain among the study participants and Safety Test Checklist based on Assessed Risk will be accomplished to assess the occurrence of the risks and its severity and application of controlled measures.

ii. Supine Hip and Knee Flexion-Extension

Figure 9.2. Supine Hip and Knee Flexion

Procedure 3: Passive Hip and Knee Flexion Extension in Supine - Range of Movement Evaluation (20 minutes)

1. In a supine position, baseline range of motion measurement on the study participant is performed manually by the investigator using the goniometer and recorded by pen and paper using the form found in Appendix E.1.

2. The investigator will input the initial position, and final position for the exercise into the software. Once the details are entered, the robot will be programmed and the exercise will be executed by the robot.

3. During the exercise, the software records and displays the exercise angle measurement of the study participant. Next the investigator manually measures the end point position the range of motion using a goniometer.

4. Measurements collated from the goniometer measurement done by the investigator will be recorded by pen and paper in Table 2 found in Appendix E.2.

5. When the end range angle for [exercise] is reached, the robot returns to neutral supine position and is also measured manually by the investigator using a goniometer.

6. Steps 3 through 5 will be done two (2) more times.

7. Vital signs (Blood pressure, Heart rate and Oxygen saturation) will be measured. During the procedure the patient is closely monitored.

8. Modified OPQRST Pain Assessment Tool will be used to assess occurrence of pain among the study participants and Safety Test Checklist based on Assessed Risk will be accomplished to assess the occurrence of the risks and its severity and application of controlled measures.

Supine Hip Abduction-Adduction

Procedure 4: Passive Hip Abduction-Adduction in Supine - Range of Movement Evaluation (20 minutes)

Figure 9.3. Supine Hip Abduction-Adduction

1. In a supine position, baseline range of motion measurement on the study participant is performed

manually by the investigator using the goniometer and recorded by pen and paper using the form found in Appendix E.1.

2. The investigator will input the initial position, and final position for the exercise into the software. Once the details are entered, the robot will be programmed and the exercise will be executed by the robot.

3. During the exercise, the software records and displays the exercise angle measurement of the study participant. Next the investigator manually measures the end point position the range of motion using a goniometer.

4. Measurements collated from the goniometer measurement done by the investigator will be recorded by pen and paper in Table 2 found in Appendix E.2.

5. When the end range angle for [exercise] is reached, the robot returns to neutral supine position and is also measured manually by the investigator using a goniometer.

6. Steps 3 through 5 will be done two (2) more times.

7. Vital signs (Blood pressure, Heart rate and Oxygen saturation) will be measured. During the procedure the patient is closely monitored.

8. Modified OPQRST Pain Assessment Tool will be used to assess occurrence of pain among the study participants and Safety Test Checklist based on Assessed Risk will be accomplished to assess the occurrence of the risks and its severity and application of controlled measures.

v. Initial Passive Trunk Flexion and Terminal Hip Flexion

Sitting Passive Knee Flexion Extension

Procedure 5: Passive Knee Flexion Extension in Sitting Position (20 minutes)

Figure 9.5. Knee Flexion - Extension (Sitting)

1. The participant's 90-degree sitting position is set through the software. Baseline range of motion measurement on the study participant will be performed manually using a goniometer and shall subsequently be recorded by pen and paper into a form found in Appendix E.1.

2. The investigator will input the number of repetitions, initial position, and final position for the exercise into the software. The repetition count will be set to three (3) repetitions. Once the details are entered, the robot will be programmed and the exercise will be executed by the robot.

3. During the exercise, the software will record and display the knee flexion-extension angle measurement of the study participant. In comparison, the investigator will manually measure the range of motion using a goniometer.

4. Data gathered from the software and the goniometer measurement done by the investigator will be recorded by pen and paper in Table 2 found in Appendix E.2.

5. When the desired angle for knee flexion is reached, the robot will then perform knee extension which is also measured by the investigator manually using a goniometer.

6. Important physiological parameters (Blood pressure, Heart rate and Oxygen saturation) will be measured.

7. Steps 3 through 6 will be done two (2) more times with 5 seconds of rest in between each repetition.

8. Modified OPQRST Pain Assessment Tool will be used to assess occurrence of pain among the study

participants and Safety Test Checklist based on Assessed Risk will be accomplished to assess the occurrence of the risks and its severity and application of controlled measures.

9. With the tablet, the investigator will interview the participant with feedback questions found in the application after the exercise and will subsequently be recorded in the application.

vi. Assisted Sit to Stand and Return to Sit

After Procedure 5, the participant is unstrapped and assisted in getting off the robot. The Technical Investigator then operates the robot to perform sit to stand to show and prepare the participant for the next exercise. Performing sit to stand without the participant at first also serves as a safety precaution.

During the assisted sit to stand and return sit, assess the participant using the Safety and Feasibility Questionnaire from Appendix F.

Procedure 6: Assisted Sit to Stand and return to Sit (20 minutes)

1. The participant's initial position will remain on sitting. Hip and knee range of motion will be manually measured and recorded by the investigator.

2. The investigator should inspect the participant's limbs if they are safely secured with the strap before starting the exercise.

3. The investigator will set the sit-to-stand procedure on the software. Once the participant is secured, the robot will be programmed and the exercise will be executed by the robot.

4. During the exercise, the software automatically collects and records the hip and knee joint range of motion measurement of the study participant. In comparison, the investigator, using a goniometer, must verify by manually measuring the hip and knee ranges of motion.

5. Data gathered from software and the investigator's measurement from the goniometer will be recorded in Table 5 found in Appendix E.3.

6. After completing steps 4 and 5, the investigator proceeds to the stand to return sit procedure by clicking the return to sitting button in the software.

7. Important physiological parameters (Blood pressure, Heart rate and Oxygen saturation) will be measured.

8. Modified OPQRST Pain Assessment Tool will be used to assess occurrence of pain among the study participants and Safety Test Checklist based on Assessed Risk will be accomplished to assess the occurrence of the risks and its severity and application of controlled measures.

9. After the completion of the procedure, the participant will be interviewed by the investigator regarding the procedure.
10. The participant is then unstrapped and assisted in getting off of the robot from a sitting position.

e. Post-Study Evaluation and Vital Signs Monitoring

After the test, the participant will be brought outside of Room C to Area 4 (Finalization and Monitoring Area) where post-study vital signs monitoring will be performed in order to establish the overall health of the participant.. Measurements needed to check include blood pressure, heart rate, and oxygen saturation which will be recorded in Appendix E.6. As part of the post-study evaluation, a video interview with strict identity and voice concealment will be conducted to gather more information about the participant's experience. Furthermore, they will also be questioned about any improvements they would recommend for the current prototype. Once all the tasks are finished, a digital self-administered questionnaire will be accomplished by each participant, as seen in Appendix F. This is to provide a quantitative evaluation of the participant's experience in using the rehabilitation robot.

3. Statistical Plan

a. Sample Size Determination

A total of eighteen (18) study participants, six (6), three (3) females and three (3) males, from each age group (18-29, 30-45 and 46-60 years old) will be admitted to the study. Several guidelines including the ICH-GCP and the Quality Management Standards for Medical Device Clinical Trials (2016) do not have specific sample size reference for clinical trials. Choice of sample size, however, must be justified. Julious (2005) proved in his study that sample size of 12 per study group is the minimum and a good sample size based on feasibility, precision about the mean and variance and regulatory considerations in conducting pilot studies or early stages of clinical trials.[17] Cramer (2016) stated that 20% drop out rate is considered to be acceptable and average dropout rate of clinical trials is 30%. Hence, a 30% dropout rate was considered in determining the sample size. [28]

Moreover, following considerations on the sample size were made:

Conduct of Clinical Trial During Pandemic

Since the COVID-19 Pandemic has not yet come to an end and with the alarming cases of Monkeypox in the world, statistical consideration was made to minimize the risk of acquiring and transmitting these viruses. The clinical trial to conduct will utilize one site only thus, in case of an outbreak in the study site, the clinical trial will be discontinued tentatively unlike in the multisite clinical trial where data from certain affected sites can be excluded from the analysis is an option, as the U.S. Department of Health and Human Services Food and Drug Administration (2020) suggests. [18] Hence, safety of the study participants is prioritized in designing the trial in time of pandemic. Meyer et al (2020) also suggests that determining trial modifications should also be taken into consideration in order to prioritize safety of trial participants and minimize the effect of pandemic to trial integrity. [19]

Small Sample Size in Safety Studies

Use of small sample size is common in Phase I and Phase II of clinical trials. Small sample size is vulnerable to variability and failure to demonstrate effectiveness. Evans et al (2001), however, stated that statistical power of the sample size used in these phases, although small, is adequate. [20] Furthermore, this study does not aim to test the effectiveness of the device but to test its safety and functionality. Indrayan and Mishra (2021) explained that achieving power with a smaller sample size is possible since it gives more space for the study to control the confounders which allows the variance to decrease. This is important in studies which can induce potential harm to the participants such as safety studies. In this case, the study can be done in controlled conditions considering the sample size. In contrast, large samples are not always helpful in some cases as this brings higher possibility of errors and reduced validity. Hence, they concluded that use of large samples is not always more reliable based on the several studies they reviewed (Schnitzer et al., 2003, Krishna et al. 2019, and Roberts et al, 2013).[21]

b. Statistical Method

Descriptive analysis will be used to treat the acquired data from the document potential adverse effects and events in the study whereas to measure the differences between the actual ROM by the robot and the ROM performed by the human participant for the different movements performed during the exercise intervention, Paired T-Test will be used to analyze the closeness of values with each other for the group of participants while the Chi-square test for independence was used to analyze the Safety, Feasibility, and Acceptability of the Robot. Completeness, consistency, and accuracy of the data will be checked before analysis, with incomplete data being discarded.

c. Data Acquisition

Readings from the robot will be continuously compiled by an android device which can be accessed through the computer. Data to be gathered, such as ROM, time, exercises performed, and speed, will be exported into PDFs and a spreadsheet file for convenience. Data processing will be done using Google Sheets spreadsheet. Study tools found in Appendix C.2 to Appendix F will be utilized in digital and paper form for data gathering.

VI. Data Handling and Record Keeping

A. Non-Disclosure Agreement

The research assistants who went through the Good Clinical Practices (GCP) Seminar will be given access to data only after signing a Non-Disclosure Agreement (NDA). They will be directly supervised by the principal investigator for proper handling of information and ensuring privacy and confidentiality.

B. Philippine Data Privacy Act (RA 10173)

Study participants will be assigned pseudo names to avoid easy identification and data being exposed to protect the privacy of the study participants. Data collected both as electronic data and paper files will be stored properly. For electronic data, password-encrypted devices including but not limited to laptop and hard drive will be used for data security. It will be kept based on the data retention policy. Destroying electronic data and paper files will follow the appropriate data deletion to ensure that the data will not be recovered while the paper files will be shredded. Only limited people can access, organize and retrieve the data, specifically, the principal investigator, co-investigator and research assistants and observe the Data Privacy Act. Since the study will utilize the internet in collecting information, the study involved a member who is familiar with cybersecurity to ensure the protection of the data acquired and stored through internet-related systems.

C. Retention Policy

Application forms submitted will be retained until the study ends, 60 months after the start of the project, and then deleted. Data collected through pen and paper are encoded and shredded three (3) weeks after the trial. Personal information and pictures taken are redacted and stored in an encrypted hard drive. Digital forms containing the participants' data are to be stored in an encrypted hard drive. Personal identification data will only be kept for 5 years.

When destroying electronic data, appropriate data deletion methods are done to ensure the data cannot be recovered.

D. Sources of Data

Source data includes all the documents and data entries in the Case Report Form which includes forms and checklists for participant eligibility, demographics and medical history, physical evaluation form and vital signs monitoring form, serious adverse event reporting form, study participant withdrawal form and study participant off trial form. For tracking in case need of follow up, the demographics and medical history will require the participant's full name. However, when deemed healthy these forms will be properly redacted to secure the participants identity. The safety and evaluation forms for the robot will also serve as the source document.

VII. Study Monitoring

A. Duties and Responsibilities of the Research Personnel

The principal investigator has full responsibility for the conduct of the study. This includes participant recruitment, study participant health evaluation, data acquisition, and processed data evaluation. The co-investigator shall assist and guide the principal investigator. He/she shall also help in the coordination, logistics, and documentation of the study. The technical investigator shall handle de-identified data to make a statistical evaluation of the range of motion of the robot versus those of human participants (See Appendix G). Members of the investigator are attached in Appendix L.

VIII. Ethical Consideration

A. Ethical Guidelines

The trial follows both international and national ethical guidelines for medical research involving human subjects. The Belmont Report, Declaration of Helsinki, National Ethical Guidelines for Health and Health-Related Research (Department of Science and Technology - Philippine Council for Health Research and Development, 2017) and Clinical Trial Handbook – Asia Pacific (Philippines) (Macasaet-Acaban and Lee, 2019) were consulted in designing the trial. Moreover, this protocol will be subjected for review by the Institutional Review Board.

B. Informed Consent

Informed consent form contains an information sheet that explains the important details about the trial including the purpose, criteria, procedure, risk and benefits, side effects, and rights of the study participant in joining the study. Included also in the informed consent form is the certification of consent that will serve as proof of agreement to participation will be given to the study participants. An informed consent form will be given both in Filipino and English language. (See Appendix B).

C. Good Clinical Practice

All members of the team involved in the study have acquired Good Clinical Practice (GCP) certification. The ICH E6(R2) addendum, which allows the implementation of clinical trial, management, oversign, conduct, documentation and reporting, ensures human subject protection and data quality [30]. This is complied with by all staff who have received certification.

D. FDA Regulations

The Food and Drug Administration Administrative Order 2018-0002 which explains the guidelines governing the issuance of an authorization for a medical device based on the ASEAN Harmonized Technical Requirements will be followed.

The ASEAN Medical Device Directive 2015 (AMDD) has set clinical investigation standards as observed from Annex 8. A clinical investigation is expected to support the pre-market evaluation. The clinical investigation should follow and identify the Essential Principles found on Annex 1. It should also contain risk management activities in order to identify the residual risks and how the risk will be handled when using the medical device. Lastly, clinical evaluation is also required in order to identify relevant clinical data. On the other hand, a clinical investigation is also necessary for a post-market clinical follow-up studies. All the analysis and its procedures are expected from the product owner.

IX. Liability Insurance for Investigators and Sponsors

The clinical trial has an insurance policy from Insurance Company of North America (hereinafter called Chubb) with a limit of insurance of Php 5,000,000 in aggregate and Php 50,000 per occurrence. This is to provide aid in medical expenses that the principal, co-investigators and participants may acquire. Breakdown of the inclusion and exclusion of the policy are listed in Appendix H.

X. Dissemination and Publication

A. Confidentiality

The proposal for publishing and the actual publication of trial findings must not reveal the identities of study participants or members of their families or communities, jeopardize those participants' privacy as people, members of their families, or members of their communities, or violate the confidentiality of their personal and health information.

B. Dissemination

Regardless of the results, whether they are favorable, unfavorable or inconclusive, it will be released to the public through scientific and other publications. Study participants shall also be informed regarding the results of the clinical trial.

C. Publication

Despite the fact that different institutions and disciplines have their own standards and procedures, the Committee on Publication Ethics (COPE) Council

(2014) ruled that anyone wishing to claim authorship must at the very least guarantee that the work in question was actually completed and that no one else's copyright has been violated.

D. Declaration of Conflict of Interest

DLSMHSI were involved in the design process as consultants for physiology and possible use of the robot. Their medical expertise was used by the research team composed of Dr. Armyn C. Sy and the TAYÔ Project in developing the robot. The project currently maintains an active patent application, which is still in progress.

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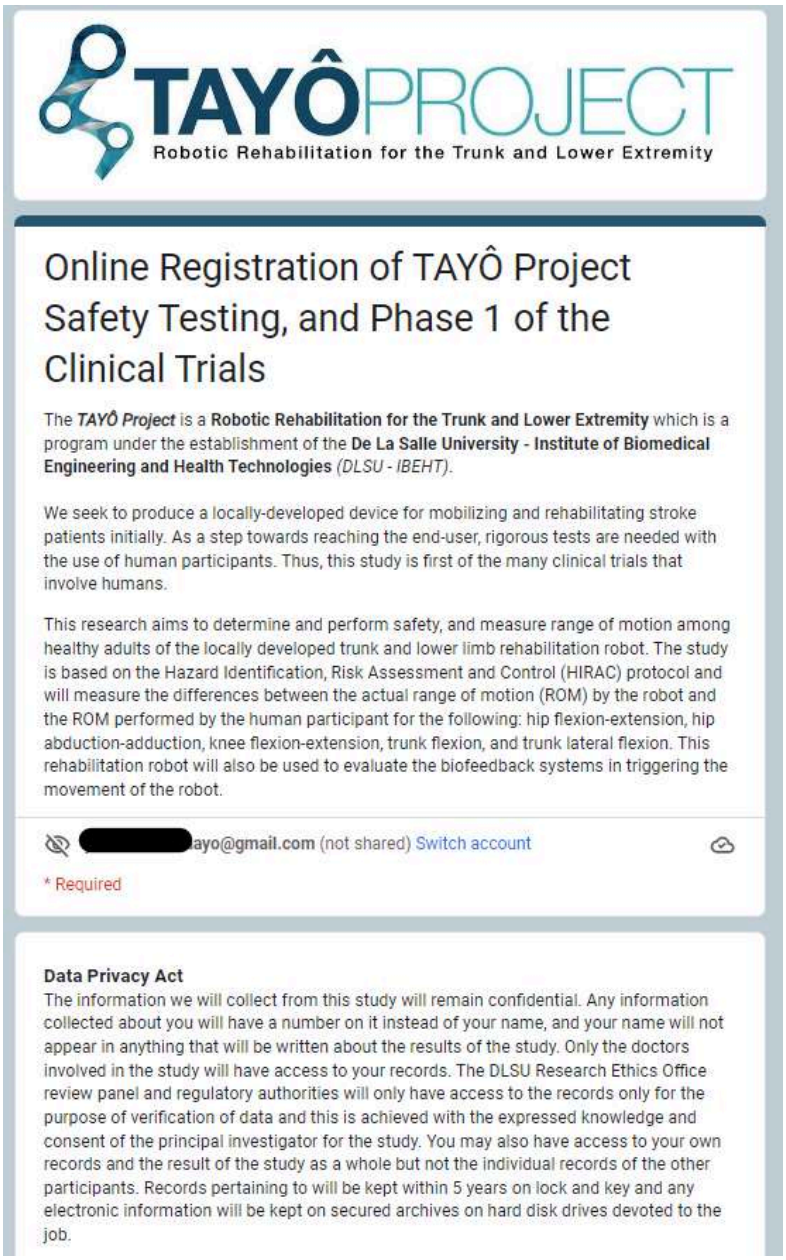
Appendix A: Study Participant Selection

Appendix A.1: Recruitment Phase Survey Questionnaire



TAYÔPROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

Online Registration of TAYÔ Project Safety Testing, and Phase 1 of the Clinical Trials

The ***TAYÔ Project*** is a **Robotic Rehabilitation for the Trunk and Lower Extremity** which is a program under the establishment of the **De La Salle University - Institute of Biomedical Engineering and Health Technologies** *(DLSU - IBEHT)*.

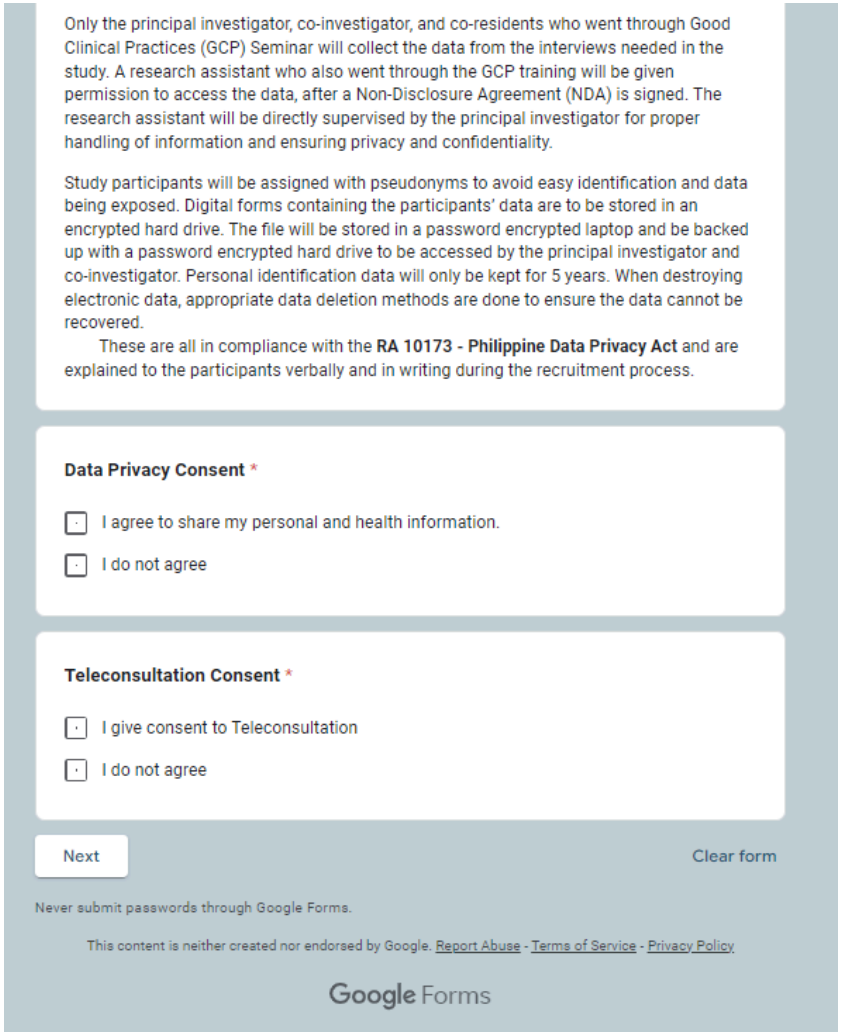
We seek to produce a locally-developed device for mobilizing and rehabilitating stroke patients initially. As a step towards reaching the end-user, rigorous tests are needed with the use of human participants. Thus, this study is first of the many clinical trials that involve humans.

This research aims to determine and perform safety, and measure range of motion among healthy adults of the locally developed trunk and lower limb rehabilitation robot. The study is based on the Hazard Identification, Risk Assessment and Control (HIRAC) protocol and will measure the differences between the actual range of motion (ROM) by the robot and the ROM performed by the human participant for the following: hip flexion-extension, hip abduction-adduction, knee flexion-extension, trunk flexion, and trunk lateral flexion. This rehabilitation robot will also be used to evaluate the biofeedback systems in triggering the movement of the robot.

[redacted]ayo@gmail.com (not shared) Switch account

* Required

Data Privacy Act
The information we will collect from this study will remain confidential. Any information collected about you will have a number on it instead of your name, and your name will not appear in anything that will be written about the results of the study. Only the doctors involved in the study will have access to your records. The DLSU Research Ethics Office review panel and regulatory authorities will only have access to the records only for the purpose of verification of data and this is achieved with the expressed knowledge and consent of the principal investigator for the study. You may also have access to your own records and the result of the study as a whole but not the individual records of the other participants. Records pertaining to will be kept within 5 years on lock and key and any electronic information will be kept on secured archives on hard disk drives devoted to the job.



Only the principal investigator, co-investigator, and co-residents who went through Good Clinical Practices (GCP) Seminar will collect the data from the interviews needed in the study. A research assistant who also went through the GCP training will be given permission to access the data, after a Non-Disclosure Agreement (NDA) is signed. The research assistant will be directly supervised by the principal investigator for proper handling of information and ensuring privacy and confidentiality.

Study participants will be assigned with pseudonyms to avoid easy identification and data being exposed. Digital forms containing the participants' data are to be stored in an encrypted hard drive. The file will be stored in a password encrypted laptop and be backed up with a password encrypted hard drive to be accessed by the principal investigator and co-investigator. Personal identification data will only be kept for 5 years. When destroying electronic data, appropriate data deletion methods are done to ensure the data cannot be recovered.

These are all in compliance with the **RA 10173 - Philippine Data Privacy Act** and are explained to the participants verbally and in writing during the recruitment process.

Data Privacy Consent *

- [ ] I agree to share my personal and health information.
- [ ] I do not agree

Teleconsultation Consent *

- [ ] I give consent to Teleconsultation
- [ ] I do not agree

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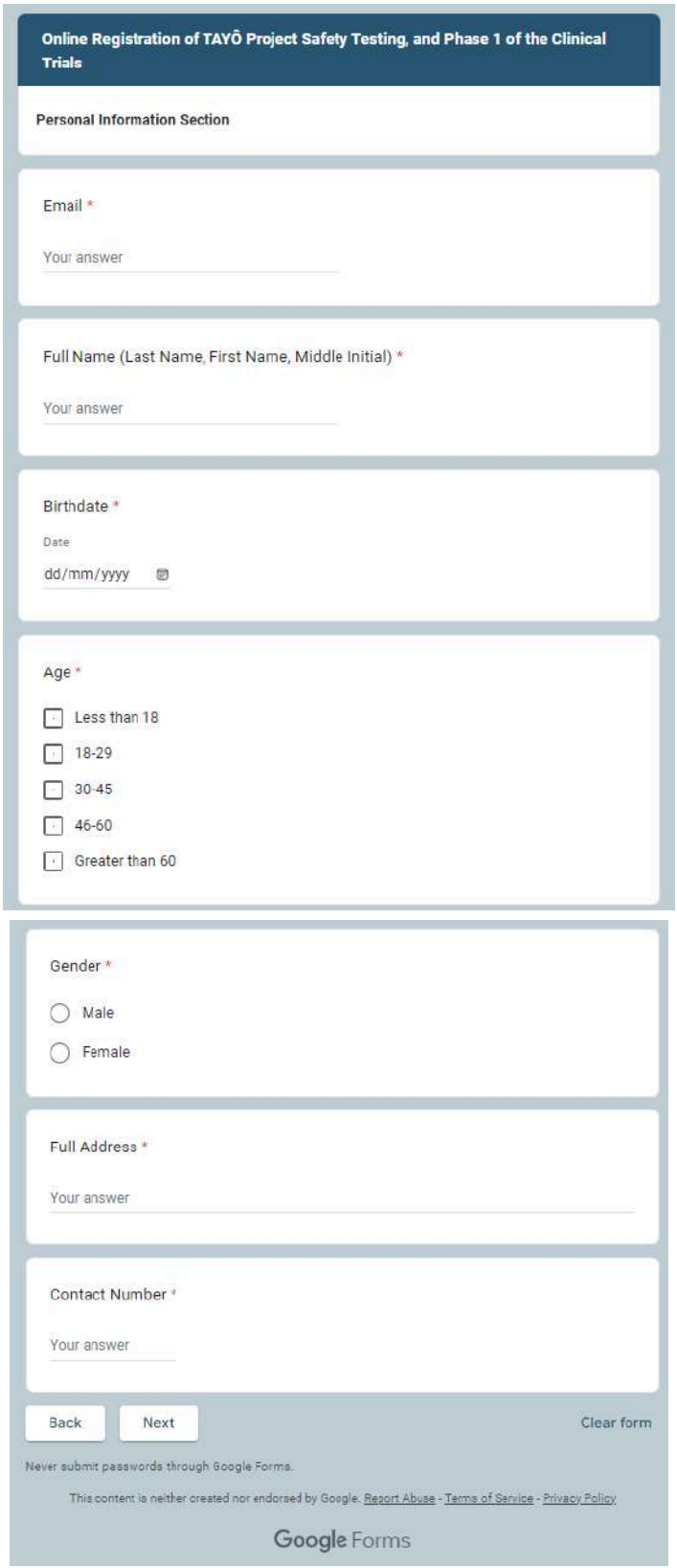
Online Registration of TAYÔ Project Safety Testing, and Phase 1 of the Clinical Trials
Personal Information Section
Email *
Your answer
Full Name (Last Name, First Name, Middle Initial) *
Your answer
Birthdate *
Date
dd/mm/yyyy
Age *
Less than 18
18-29
30-45
46-60
Greater than 60
Gender *
Male
Female
Full Address *
Your answer
Contact Number *
Your answer
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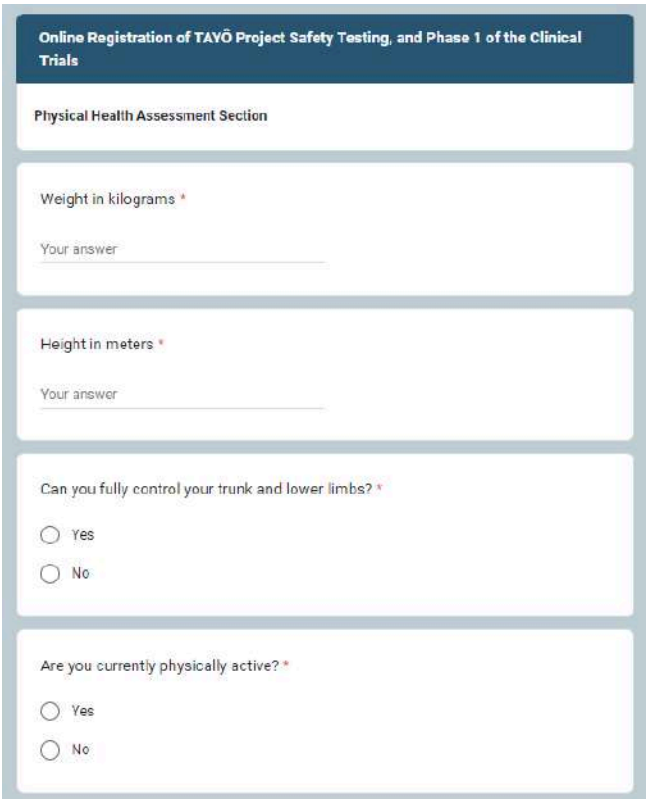


Online Registration of TAYŌ Project Safety Testing, and Phase 1 of the Clinical Trials

Physical Health Assessment Section

Weight in kilograms *

Your answer

Height in meters *

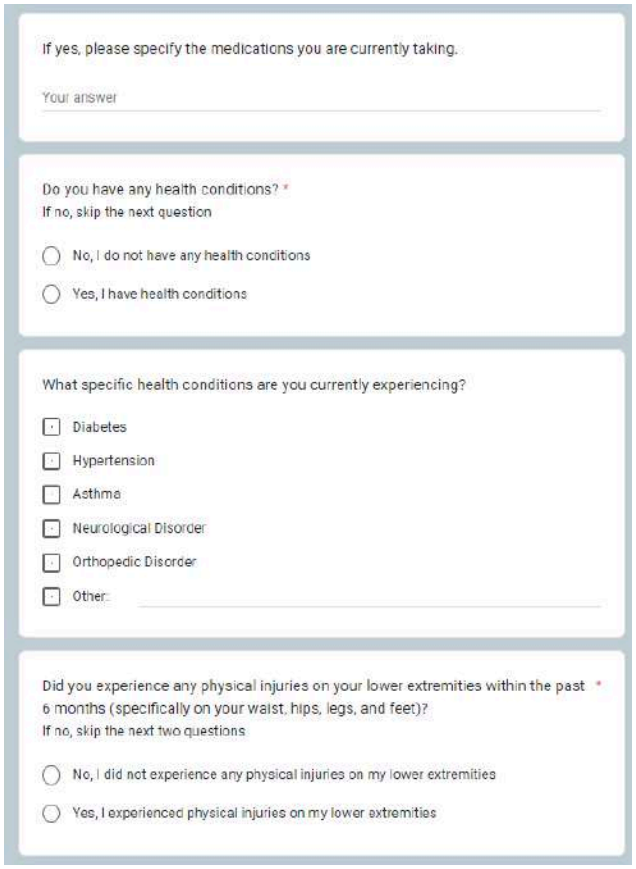
Your answer

Can you fully control your trunk and lower limbs? *

- ◯ Yes
- ◯ No

Are you currently physically active? *

- ◯ Yes
- ◯ No



If yes, please specify the medications you are currently taking.

Your answer

Do you have any health conditions? *
If no, skip the next question

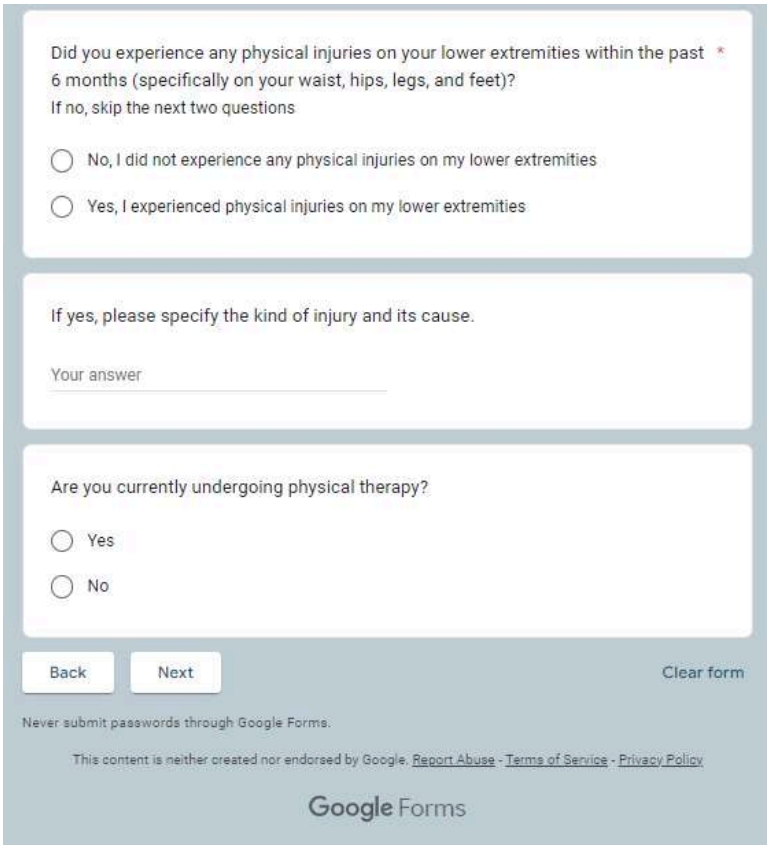
- ◯ No, I do not have any health conditions
- ◯ Yes, I have health conditions

What specific health conditions are you currently experiencing?

- ☐ Diabetes
- ☐ Hypertension
- ☐ Asthma
- ☐ Neurological Disorder
- ☐ Orthopedic Disorder
- ☐ Other:

Did you experience any physical injuries on your lower extremities within the past 6 months (specifically on your waist, hips, legs, and feet)? *
If no, skip the next two questions

- ◯ No, I did not experience any physical injuries on my lower extremities
- ◯ Yes, I experienced physical injuries on my lower extremities


Did you experience any physical injuries on your lower extremities within the past 6 months (specifically on your waist, hips, legs, and feet)? *
If no, skip the next two questions
No, I did not experience any physical injuries on my lower extremities
Yes, I experienced physical injuries on my lower extremities
If yes, please specify the kind of injury and its cause.
Your answer
Are you currently undergoing physical therapy?
Yes
No
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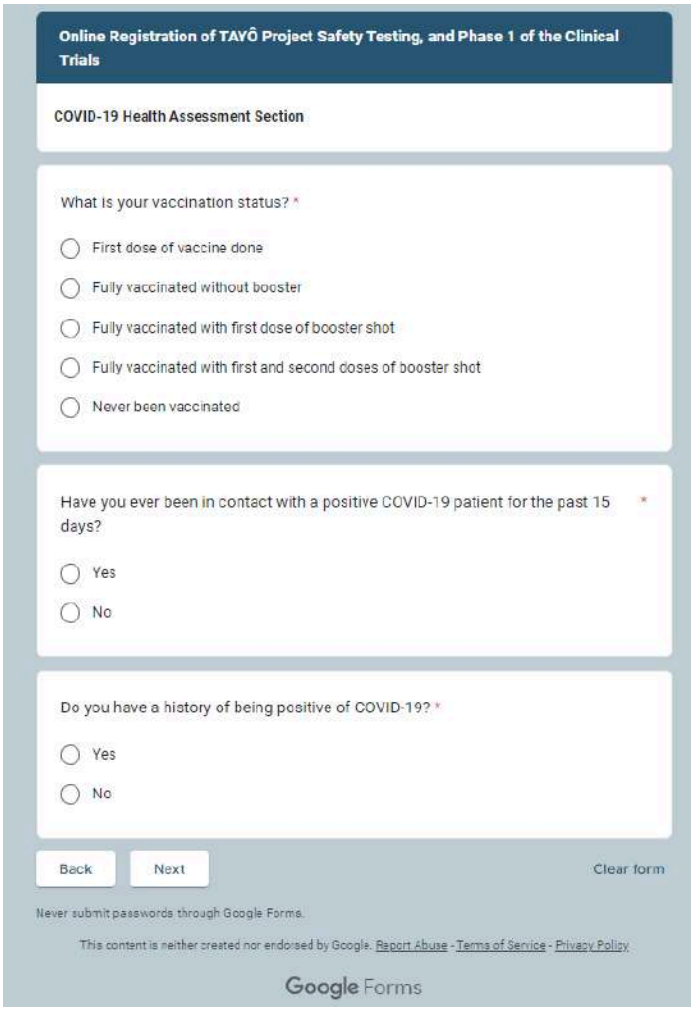
Online Registration of TAYÔ Project Safety Testing, and Phase 1 of the Clinical Trials
COVID-19 Health Assessment Section
What is your vaccination status? *
First dose of vaccine done
Fully vaccinated without booster
Fully vaccinated with first dose of booster shot
Fully vaccinated with first and second doses of booster shot
Never been vaccinated
Have you ever been in contact with a positive COVID-19 patient for the past 15 days? *
Yes
No
Do you have a history of being positive of COVID-19? *
Yes
No
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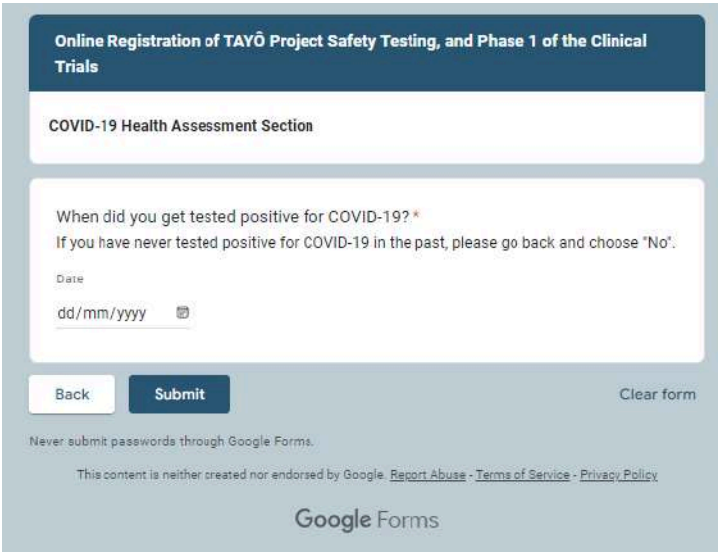
Online Registration of TAYÔ Project Safety Testing, and Phase 1 of the Clinical Trials
COVID-19 Health Assessment Section
When did you get tested positive for COVID-19? *
If you have never tested positive for COVID-19 in the past, please go back and choose "No".
Date
dd/mm/yyyy
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Appendix A.2: Clinical Trial Participants Recruitment Posters


TAYÔPROJECT
IBEHT
CONTRIBUTE TO THE FUTURE OF LOWER LIMB REHABILITATION
If you are 18-60 years old with no complications on the back and legs, you may be eligible to participate in the TAYÔ project clinical trial.
Be part of the first group of people to try the locally developed lower limb rehabilitation robot!
Participants are entitled to the following benefits
• Medical insurance for medical needs relating to the project
• 3D printed keychain
• Gift voucher worth 500 pesos
• Mug/tumbler
• COVID-19 Care kit
Think you're eligible? Visit: bit.ly/3znYYWu


TAKE PART IN REVOLUTIONIZING LOWER LIMB REHABILITATION
If you are 18-49 years old with no complications on the back and legs, you may be eligible to participate in the TAYÔ project clinical trial.
Be part of the first group of people to try the locally developed lower limb rehabilitation robot!
Apply through this link: bit.ly/3znYYWu
Participants are entitled to the following benefits
• Medical insurance for medical needs relating to the project
• 3D printed keychain
• Gift voucher worth 500 pesos
• Mug/tumbler
• COVID-19 Care kit
You can also contact us through this number!
+63916XXXXXXX
TAYÔPROJECT
IBEHT

Appendix A.3: Medical Screening Phase Survey Questionnaire

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Pilot Study among Normal Subjects on the Safety and Functionality of a Locally-Developed Trunk and Lower Limb Rehabilitation Robot

Subject Initials: _____ **Subject ID:** _____
Height: _____in/cm **Exam Date:** _____
Weight: _____lb/kg

Body Mass Index (BMI): ☐ Underweight (<18.5) ☐ Normal (18.5-24.9) ☐ Overweight(>25)

Screening Phase Questionnaire

Check the boxes provided in each question

1. Have you been involved in an accident that affected your trunk and lower limbs? (Specifically, from your hips to your feet)

   ☐ Yes ☐ No ☐ Prefer not to say

2. Can you fully control your trunk and lower limbs?

   ☐ Yes ☐ No ☐ Prefer not to say

3. Are you currently physically active?

   ☐ Yes ☐ No ☐ Prefer not to say

4. Do you go to the gym?

   ☐ Yes ☐ No ☐ Prefer not to say

5. Are you currently experiencing muscle pain or muscle sore on your trunk and lower limbs?

   ☐ Yes ☐ No ☐ Prefer not to say

6. Do you have any existing diseases?

   ☐ Yes ☐ No ☐ Prefer not to say

   If yes, please specify:_____

7. Are you aware of the Clinical Trial that we are conducting?

   ☐ Yes ☐ No ☐ Prefer not to say

8. Have you read the informed consent form provided by the investigators?

   ☐ Yes ☐ No ☐ Prefer not to say

TMC Physician in charge Signature: _____ **Date:** _____

Appendix A.4: Medical Interview Consent Form and Interview Sheet

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

Safety Testing, and Phase 1 of the Clinical Trials

A Controlled Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

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INTERVIEW CONSENT FORM
(ENGLISH)

Greetings in St. La Salle!

The TAYÔ Project: Robotic Rehabilitation for the Trunk and Lower Extremity - STAGE 2: Safety Tests and Phase 1 of the Clinical Trials is funded by the Department of Science of Technology-Philippine Council for Health Research and Development and implemented by the De La Salle University (DLSU) through the Institute of Biomedical Engineering and Health Technologies (IBEHT). We seek to produce a locally-developed device for mobilizing and rehabilitating stroke patients initially. As a step towards reaching the end-user, rigorous tests are needed with the use of human participants, thus, this study is first of many Clinical Trials that involve humans. Moreover, this preliminary study would help determine if the device is safe to be used by the public.

This interview consent form is for participants aged 18-60 years of age who expressed their interest in joining the clinical trial and passed the initial screening process. This interview with a medical doctor will be conducted to assess the participant's general health, to screen for potential medical issues, and to ensure that the participant is medically fit to perform the activities in the study. All notes of the interview will be written on an interview sheet. Applicants who are still willing to participate will sign a certification confirming that he was interviewed and all the information provided during the interview is accurate and updated. Once deemed as approved for the study by the medical doctor, applicants will receive notice letter in their email which includes the data retention policy for the application forms and screening phase.

CONSENT FOR PARTICIPATION IN MEDICAL INTERVIEW

1. I understand that my personal data to be collected is ONLY for the purposes of educational and research use of the De La Salle University (DLSU) and De La Salle Medical Health Sciences Institute (DLSMHSI) community. Photographs, video footage, sound recordings with strict identity concealment can be used for non-commercial information dissemination purposes in print, online and in-campus.

2. Any entity shall NOT be given access to the provided data that may be used for other purposes outside of what is defined in this consent. DLSU-IBEHT SHALL NOT share the information with any other third-party contractors that are used to execute this exercise. All data shared with DLSU-IBEHT shall only be safeguarded and retained for 5 years. During this retention period, the security of the personal information at rest shall be the responsibility of the

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IBEHT
Institute of Biomedical Engineering & Health Technologies
Supported by DOST - PCHRD

ng personal na impormasyon ay magiging responsibilidad ng Personal Information Controller (PIC) at susunod sa mga kinakailangan ng RA 10173. Dapat ding itaguyod ng DLSU-IBEHT ang mga karapatan ng paksa ng datos ayon sa itinakda sa RA 10173 na may integridad at ng *availability requirements*. Pagkatapos ng limang (5) taon, ang datos na nakolekta ay dapat nang itapon at isang sertipiko ng pagtatapon o pagtanggal ang dapat ibigay ng DLSU-IBEHT sa DLSU na may kasamang paglagda at pagkilala mula sa Data Protection Officer nito.

3. Nabasa ko na ang lahat ng impormasyon, o kaya ay nabasa na sa akin ito at naintindihan ko ang nilalaman nito.

4. Nagkaroon ako ng oportunidad para makapag tanong tungkol dito at lahat ng aking mga tanong ay nasagot ayon sa aking kagustuhan.

5. Pumapayag ako na makilahok sa pananaliksik na ito.

Buong Pangalan ng Pasyente _____

Lagda ng Pasyente _____

Petsa _____ (araw/buwan/taon)

Pahayag ng mga Researcher / Taong Tagatanggap ng *consent*

Binasa at naipahayag ko nang malinaw ang laman ng *information sheet* sa pumayag na pasyente, at naisiguro ko, sa lahat ng aking kakayahan, na naintindihan ng pasyente ang laman ng pananaliksik. Kinukumpirma ko na ang pasyente ay nabigyan ng pagkakataon para mag tanong tungkol sa pananaliksik at ang lahat ng tanong ay naisagot ng tama at malinaw; at ang *consent* ay nabigay ayon sa kanilang desisyon. Ang kopya ng *interview consent form* ay ibibigay sa pasyente.

Isinulat na Pangalan ng *Researcher* / Taong Tagatanggap ng *Consent*

_____

Lagda ng *Researcher* / Taong Tagatanggap ng *Consent*

_____

Petsa _____ (araw/buwan/taon)

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TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

Safety Testing, and Phase 1 of the Clinical Trials

A Controlled Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

Personal Information Controller (PIC) and will comply with the requirements of RA 10173. DLSU-IBEHT shall also uphold the rights of the data subject as stipulated in RA 10173 that includes integrity and availability requirements. After the 5-year maximum period, the data collected should be disposed of and a certificate of disposal or deletion shall be provided by DLSU-IBEHT to DLSU duly signed and acknowledged by its Data Protection Officer.

3. I have read the foregoing information, or it has been read to me and understand its contents fully.

4. I have had the opportunity to ask questions about the study and they have been answered to my satisfaction.

5. I consent voluntarily to participate in this study.

Printed Name of Participant _____

Signature of Participant _____

Date _____ (day/month/year)

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the person understands the study. I confirm that the participant was given an opportunity to ask questions about the study and all the questions were answered correctly; and that consent has been given freely and voluntarily. A copy of this informed consent form has been provided to the participant.

Printed Name of Researcher / Person taking the consent

_____

Signature of Researcher / Person taking the consent

_____

Date _____ (day/month/year)

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TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

Safety Testing, and Phase 1 of the Clinical Trials

A Controlled Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

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INTERVIEW SHEET

1. What is your medical history?

    - Do you have allergies?
    - Have you undergone surgeries in the past?
    - Are you taking any medications?

2. Why are you interested in participating in the research?

3. What would be the benefits of participating in the research for you?

4. What are your expectations for the study?

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TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

Safety Testing, and Phase 1 of the Clinical Trials

A Controlled Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

5. Have you participated in a similar study? If yes, describe.

☐ Approved ☐ Disapproved

Approved/Disapproved by: _____

CERTIFICATION

I hereby certify that I was interviewed by a medical doctor and the information I provided in the said medical interview is true and correct to the best of my knowledge.

Furthermore, I acknowledge that I have read and understood the interview consent form and agreed to it. Hence, I give my consent to TAYÔ Project by the Department of Science of Technology-Philippine Council for Health Research and Development and implemented by the De La Salle University (DLSU) through the Institute of Biomedical Engineering and Health Technologies (IBEHT), to collect, use and process my personal information in accordance to Data Privacy Act of 2012.

_____ _____

Signature over Printed Name **Date**

IRB No: Protocol Version and Date:

IBEHT
Institute of Biomedical Engineering & Health Technologies
Supported by DOST - PCHRD

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

Safety Testing, and Phase 1 of the Clinical Trials

A Controlled Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

---

INTERVIEW CONSENT FORM
(FILIPINO)

Ang TAYÔ Project: Rehabilitation for the Trunk and Lower Extremity - STAGE 2: Safety Tests at Phase 1 ng Clinical Trials ay pinopondohan ng Department of Science of Technology-Philippine Council for Health Research and Development at ipinatutupad ng Institute of Biomedical Engineering and Health Technologies (IBEHT) ng De La Salle University (DLSU). Ninanais ng proyektong ito na makalikha ng mga *locally-developed device* upang matulungan ang mga pasyenteng may *stroke* na makakilos muli nang normal. Bilang hakbang tungo sa progresibong pag-aaral nito, kinakailangang magsagawa ang *research institute* ng Clinical Trials kabilang ang mga *target end-user* ng isinagawang aparato o robot. Maliban pa rito, ang pag-aaral na ito ay makakatulong sa pagtukoy kung ligtas bang gamitin ng publiko ang aparato o robot.

Ang *interview consent form* na ito ay para sa mga indibidwal na nasa labing walo hanggang anim na pu't (18-60) taong gulang na nagpakita ng kanilang interes na maging kabahagi ng pag-aaral na ito at nasuri mula sa paunang *screening* na siya ay angkop ay may kapasidad na maging kabahagi ng pag-aaral. Ang panayam na ito ay pangungunahan ng doktor na siyang magsasagawa ng pagsusuri sa kalusugan, pag-alam ng posibleng isyung medical at siguraduhing malusog at angkop ang kalusugan ng nais maging kabahagi ng pag-aaral upang maisagawa nang maayos at ligtas ang mga aktibidad na gagawin sa pag-aaral. Lahat ng mga detalye at iompormasyon na binigay sa panayam ay itatala sa *interview sheet*. Pagkatapos ng panayam, isang sertipiko ng pagkumpira ang kailangan lagdaan ng mga nais magpatuloy na makiisa sa pag-aaral bilang katunayan na sila ay nakapanayam at totoo at tamang impormasyong ang kanilang ibinigay sa nasabing panayam.

PAHINTULOT SA BOLUNTARYONG PAKIKIISA SA MEDIKAL NA PANAYAM

1. Nauunawaan ko na ang mga makakalap na impormasyon ay para sa layuning pang-edukasyon at pananaliksik ng komunidad ng De La Salle University (DLSU) at De La Salle Medical Health Sciences Institute (DLSMHSI). Ang mga litrato, *video footage*, mga *sound recording* na mahigpit na pinatatago ang pagkakakilanlan ay maaari lamang gamitin sa hindi pangkomersyal na pagkakalat ng impormasyon sa *print*, *online*, at *in-campus*.

2. Ang sinumang entidad ay HINDI bibigyan ng *access* sa ibinigay na datos na maaaring gamitin para sa iba pang mga layunin sa labas ng kung ano ang tinutukoy sa pahintulot na ito. Ang DLSU-IBEHT AY HINDI ibabahagi ang impormasyon sa anumang iba pang mga third party na kontratista na ginagamit upang isagawa ang pagsasanay na ito. Ang lahat ng impormasyon na ibinahagi sa DLSU-IBEHT ay dapat lamang pangalagaan at panatilihin sa loob ng limang (5) taon. Sa panahon ng pagpapanatili nito, ang seguridad

TAYÔPROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

Safety Testing, and Phase 1 of the Clinical Trials

A Controlled Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

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INTERVIEW SHEET

1. Ano ang iyong *medical history*? (Anu-ano ang mga sakit na iyo ng naranasan?)

    - Mayroon ka bang *allergies*?
    - Ikaw ba ay sumailalim na sa anumang operasyon?
    - Mayroon ka bang iniinom na mga gamot?

2. Bakit ka interesado na makiisa sa pag-aaral na ito?

3. Para sa iyo, ano ang iyong benepisyong makukuha sa pagsali sa ganitong pag-aaral?

4. Ano ang iyong mga inaasahan sa pag-aaral na ito?

IRB No: Protocol Version and Date:

IBEHT
Institute of Biomedical Engineering & Health Technologies
Supported by DOST - PCHRD

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5. Nakiisa ka na ba sa pag-aaral na katulad nito? Kung oo, maaari mo bang ibahagi o ilarawan ang iyong karanasan?

☐ Aprubado ☐ Di aprubado

Aprubado/Di aprubado ni: _____

KATIBAYAN

Sa pamamagitan nito, pinatutunayan ko na ako ay nakapanayam ng isang medikal na doktor at ang impormasyong ibinigay ko sa nasabing medikal na panayam ay totoo at tama sa abot ng aking kaalaman.

Higit pa rito, kinikilala ko na nabasa at naunawaan ko ang *interview consent form* at ako ay sumang-ayon dito. Dahil dito, binibigyan ko ng pahintulot ang TAYÔ Project ng Department of Science of Technology-Philippine Council for Health Research and Development na ipinatupad ng De La Salle University (DLSU) - Institute of Biomedical Engineering and Health Technologies (IBEHT), upang mangolekta, gamitin at iproseso ang aking personal na impormasyon alinsunod sa Data Privacy Act of 2012.

_____ _____

Pangalan at Lagda **Petsa**

IRB No: Protocol Version and Date:

IBEHT
Institute of Biomedical Engineering & Health Technologies
Supported by DOST - PCHRD

Secondary form to inquire about the participant's mental health:

	Extremely 😟	Very Much 😕	Moderately 😐	Slightly 😊	Not at all 😀
Feeling stressed during the activity					
Feeling anxious during the activity					
Feeling uncomfortable during the activity					
Having disturbing thoughts during the activity					
Feeling stressed after the activity					
Feeling anxious after the activity					
Feeling uncomfortable after the activity					
Having disturbing thoughts after the activity					
Feeling tired after the activity					
Trouble moving after the activity					
	Poor 😟	**Somewhat Poor** 😕	**Average** 😐	**Somewhat good** 😊	**Excellent** 😀
Overall, how would you rate your mental health after the activity?					

Other concerns:

Appendix A.5: Notice Letter for Qualified Potential Study Participants

Congratulations!

We have received your intent to be a part of the TAYÔ Project Clinical Trial through the Google forms online registration (**bit.ly/3znYYWu**). We are glad to inform you that you have been accepted as a participant of the Phase 2 Clinical Trial of the TAYÔ Project Clinical Trial. This email will serve as your confirmation.

We are looking forward to working with you!

Julius Noel Banayo
Lead Researcher, TAYÔ Project
Institute of Biomedical Engineering and Health Technologies (IBEHT)
De La Salle University – Manila

TAYÔPROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

Appendix A.6: Notice Letter for Unqualified Potential Study Participants

Thank you for expressing your interest in joining the Phase 2 Clinical Trial of the TAYÔ Project through the Google forms online registration, (**bit.ly/3znYYWu**). Unfortunately, you were not able to qualify with the minimum criteria necessary for the conduction of the clinical trial.

We hope for your collaboration in our next project.

Julius Noel Banayo
Lead Researcher, TAYÔ Project
Institute of Biomedical Engineering and Health Technologies (IBEHT)
De La Salle University – Manila

TAYÔPROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

Appendix A.7: Case report form

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Pilot Study among Normal Subjects on the Safety and Functionality of a Locally-Developed Trunk and Lower Limb Rehabilitation Robot

Subject Initials: **Subject ID:**
Exam Date:

ELIGIBILITY CRITERIA

INCLUSION CRITERIA

Criteria	Yes	No
Patient should be able to follow instructions.		
Patient should have full use of their trunk and lower extremities.		
Patient should also have cardiopulmonary clearance prior to participation.		
Patient should be fully vaccinated and boosted prior to participation.		
Patient must also be willing to undergo RT-PCR Test for COVIDCovid-19 within 3 days prior to the participation.		
Patient should not have experienced any COVID Covid-19 symptoms within the last 7 days.		
Patient should have been subjected to home quarantine for 3 days.		

EXCLUSION CRITERIA

Criteria	Yes	No
Patient with known orthopedic conditions affecting the trunk and lower extremities		
Patient with known neurological conditions affecting the trunk and lower extremities		
Patient with significant cardiac limitations.		
Patient with significant muscle weakness or paresis in selected muscle groups such that it limits the ability to perform specific muscle movements.		

Eligibility Criteria Form checked by: _____

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Pilot Study among Normal Subjects on the Safety and Functionality of a Locally-Developed Trunk and Lower Limb Rehabilitation Robot

Subject Initials: Subject ID:

Exam Date:

DEMOGRAPHICS AND MEDICAL HISTORY CHECKLIST

First Name*:
Middle Name (or initial):
Last Name*:

Birthdate*: ☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

Gender*: (check one)
☐ Male
☐ Female
☐ Unknown or Not Reported

Age*: (check one)
☐ 18-29 years old
☐ 30-45 years old
☐ 46-60 years old

Marital Status*: (check one)
☐ Single
☐ Married
☐ widowed

Contact Information:

Address:		Barangay:
City:	Province:	Zip:
Phone Number: ☐ Home ☐ Work ☐ Cell ☐ Other	Alternate Phone Number: ☐ Home ☐ Work ☐ Cell ☐ Other	Email address:
Preferred method of contact:		

Emergency Contact:

Name:		
Address:		Barangay:
City:	Province:	Zip:
Phone Number: ☐ Home ☐ Work ☐ Cell ☐ Other	Alternate Phone Number: ☐ Home ☐ Work ☐ Cell ☐ Other	Email address:
Preferred method of contact:		

* indicates required field

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

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Medical History

Body System	Diagnosed condition?	Diagnosis/Condition/Surgery	Current Problem
Nervous system	☐ Yes ☐ No		☐ Yes ☐ No
Respiratory system	☐ Yes ☐ No		☐ Yes ☐ No
Cardiovascular system	☐ Yes ☐ No		☐ Yes ☐ No
Muscular system	☐ Yes ☐ No		☐ Yes ☐ No
Skeletal system	☐ Yes ☐ No		☐ Yes ☐ No

Additional Notes: _____

_____

_____

Demographics and Medical History checked by: _____

Appendix B: Informed Consent Forms (English and Filipino)

Appendix B.1: Informed Consent Form (English)

Safety Testing, and Phase 1 of the Clinical Trials

Name of Principal Investigator:
Name of Co-Investigators:

Name of Organization:

INFORMED CONSENT FORM
(ENGLISH)

Greetings in St. La Salle!

The TAYÔ Project: Robotic Rehabilitation for the Trunk and Lower Extremity - STAGE 2: Safety Tests and Phase 1 of the Clinical Trials is funded by the Department of Science of Technology-Philippine Council for Health Research and Development and implemented by the De La Salle University (DLSU) through the Institute of Biomedical Engineering and Health Technologies (IBEHT). We seek to produce a locally-developed device for mobilizing and rehabilitating stroke patients initially. As a step towards reaching the end-user, rigorous tests are needed with the use of human participants, thus, this study is first of many Clinical Trials that involve humans. Moreover, this preliminary study would help determine if the device is safe to be used by the public.

This informed consent form is for participants aged 18-60 years of age who we are asking to participate in our study entitled: Safety Testing, and Phase 1 of the Clinical Trials

Contents of the Informed Consent Form include:

- Information Sheet (Details about the study for your guidance)
- Certificate of Consent (Proof of your agreement to participation with signatures)

INFORMATION SHEET

I am (investigator/researcher) _____ from _____. Together with _____ and _____, we are conducting a research study to demonstrate the safety of a rehabilitation robot. I am going to give you information and invite you to participate in this research. You do not have to decide today whether or not you agree to participate in the research. Before you decide, you can talk to anyone you feel comfortable with. There may be some words that you do not understand, and you are free to ask me to stop as we go through the information and I will take time to explain. If you have questions or clarifications later, you can ask them freely. This consent form will be valid for the duration of the study.

Purpose
This research aims to determine and perform safety, and measure range of motion among healthy adults of the locally developed trunk and lower limb rehabilitation robot. The study is based on the Hazard Identification, Risk Assessment and Control (HIRAC) protocol and will measure the differences between the actual range of motion (ROM) by the robot and the ROM performed by the human participant for the following: hip flexion-extension, hip abduction-adduction, knee flexion-extension, trunk flexion, and trunk lateral flexion. This rehabilitation robot will also be used to evaluate the biofeedback systems in triggering the movement of the robot.

Participant Selection
Eighteen (18) healthy volunteers will be selected using the criteria found below:

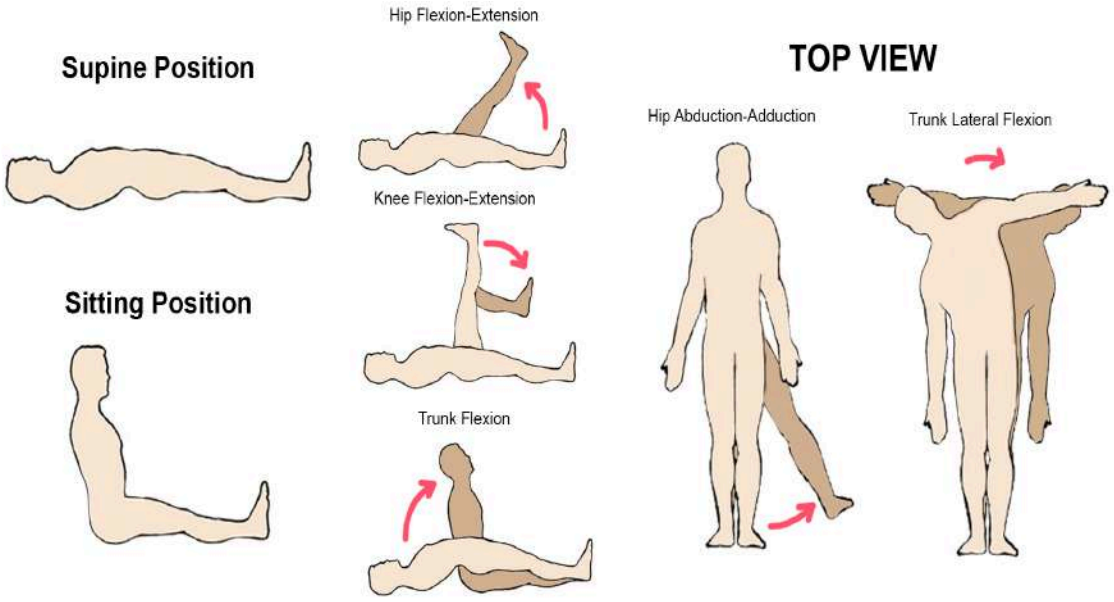
1. Participants should be able to follow instructions.
2. Participants should be at least 5”4’ or 1.63 m to 6”2’ or 1.87 m
3. Participants should weigh less than 200 kg
4. Participants should have full use of their trunk and lower extremities.
5. Participants should agree to have medical clearance sponsored by the research prior to participation. (Validity: 1-2 weeks from appointed clinical study participation)
6. Participants should be fully vaccinated from COVID19 (2 completed doses, with or without boosters)

Exclusion Criteria
Participants with known disabilities, abnormalities or diagnosed medical conditions including, but not limited to: orthopedic or neurological, cardiovascular, pulmonary; are excluded since this study is for healthy participants.
Additionally selected participants will only be coming from De La Salle University - Laguna Campus to minimize health risk from COVID 19 pandemic. Participants with no access to online connection are excluded.

Voluntary Participation
Your participation in this study is voluntary. You will not be asked to consume any food, drink, or drug, nor will you be injected with any medication or substance. The procedure itself does not use any invasive means of recording data.

If you decide not to participate in the study after signing this form, you may do so without penalty. But we would appreciate it if you inform us ahead of time so we can look for another participant. We will also have to ask you to write and sign a letter detailing your reasons for withdrawal for record keeping purposes as government funds were used to purchase insurance for you.

Procedure



Each participant will be oriented by the investigator on the process of using the rehabilitation device and conduct a baseline assessment such as the resting position of the trunk, thigh, lower leg, and foot. Prior to the exercise activity, range of motion is measured by the investigator.
The investigator will then operate the software to activate the device. There will be three (3) consecutive repetitions that will passively move the participant's trunk, thigh, lower leg, and foot within a predetermined range. After the unit is used for basic movements and baseline measurement. The functional composite motion that will be performed by the device will simulate the following motion/s per joint: trunk flexion (while sitting), trunk lateral flexion, hip flexion-extension, hip abduction-adduction, and knee flexion-extension with ranges to be determined by the patient's maximum range of motion. Finally, each participant will accomplish a self-administered questionnaire provided. If there are any questions, you may ask the principal investigator or co-investigators for clarifications.

***Notice*:** If, at any moment, the participant feels uncomfortable, the device has an emergency stop button that is available to both the participant and the assessor. The emergency stop button will immediately halt the sequence of the device and will return to its normal state to diminish any discomfort that has arised prior to pressing the stop button.

Duration
Pre-screening will be held one (1) week before the Clinical Trial. Each subject trial will approximately last for half a day. The total participant-rehabilitation device time of 2 hours and 11 minutes.

Side Effects
Based on the technical electrical safety and mechanical safety evaluation, there should be negligible risk but possible physiological risks may include muscular pain, joint pain, soft tissue injury, abrasion, muscle soreness, dislocation/ fracture, and potential electrocution. If, at any moment, the participant feels any discomfort and requires medical attention, the participant shall immediately be given first aid before bringing him/her to the university clinic for a second evaluation and, if needed, a referral is made to the nearest hospital. The cost of treatment for the hospital will be handled by the insurance procured for the participant by the study.

Medical Insurance
In line with Philippine Clinical Study guidelines, all participants will be issued insurance to cover their medical needs if and when any severe adverse effects are manifested during the course of study.

How the Insurance Applies

This insurance applies to any risk that has been mentioned in the document which could occur during the clinical trial as long as:

1. The risk is caused by an incident during the clinical study that takes place in the coverage territory of the study.
2. The incident did not happen before the policy's retroactive date, if any, or after the policy's expiration date.

This insurance does not apply to the exclusions based on the Insurance Policy document.

Unless specifically provided for under this document, no additional responsibility or liability to pay sums or perform acts or services is covered.

This insurance will be granted to the study participant if and when they agree to sign up to be among the 18 study participants.

For further information regarding each exclusion and more details on the legal matters of the insurance, you may refer to the Insurance Policy document.

Social Value
The robot is meant to augment manpower and support therapists at work. The efficiency of the robot will assist PT's to cater to more patients at a time, as well as prevent fatigue for the PT's, compared to manual exercises. The robot will greatly accelerate the program of assistive movement.

Benefits
There will be medical benefits for the participants in this study. The robot will provide a baseline range of motion measurement for reference in physical activities.

Any person who involves him/herself in this research will be among the first group of the first people in the Philippines to use the first locally developed trunk and lower limb rehabilitation robot. The data gathered in this study may confer benefits to patients all over the country by helping to validate or adjust the robot to conform within the limits of human anatomy for the trunk and lower extremity.

During and after the test, study participants and investigators will receive a variety of items as a token of gratitude, which includes a 3D printed keychain, a gift voucher worth 500 pesos, and a mug/tumbler. A COVID-19 Care kit which contains a liquid disinfectant (800 ml), isopropyl alcohol (500 ml), Bactidol® (120 ml), a health drink (500 ml), a box of disposable face masks

(50 pieces), a digital thermometer, and a box of vitamin C with zinc (20 capsules) will be given to the participants and investigators.

Breakfast, lunch, and snacks are to be provided to the participants and investigators throughout the day. A meal schedule will be followed to maintain an organized flow of the activity.

Data Collection

Personal data which will be collected during the clinical trial are the following below

- Participant's initials (first name, last name, middle initial), age, gender, weight, height
- normal anatomy limits (or sensor data), vital signs, operational entries/logs
- photos and videos

Data collected are for educational and research purposes of the De La Salle University and De La Salle Medical Health Sciences Institute community. Photographs, video footage, and sound recordings with strict identity concealment can be used for non-commercial information dissemination purposes in print, online and in-campus.

Duties and responsibilities of Research Staff

The principal investigator has full responsibility for the conduct of the study. This includes participant recruitment, study participant health evaluation, data acquisition, and processed data evaluation. The co-investigator shall assist and guide the principal investigator. He/she shall also help in the coordination, logistics, and documentation of the study. The technical investigator shall handle de-identified data to make a statistical evaluation of the range of motion of the robot versus those of human participants. For any medical concerns, or side effects during the trial these shall be handled by the university clinic.

Participant access to information and new studies related to the project

Participants will be given access to review and maintain correctness of the personal data before and after the procedure. An electronic copy of the study results that is compatible with any computers will be provided to the participants of the study. Should they wish to participate in future activities related to this study and express this into writing, they will be sent via email information regarding these future activities. In a case of a possible data breach, risk will be assessed by the privacy office and informs the affected participants about the breach.

Study Data Protection Plan

Only the principal investigator, co-investigator, and co-residents who went through Good Clinical Practices (GCP) Seminar will collect the data from the interviews needed in the study. A research assistant who also went through the GCP training will be given permission to access the data, after a Non-Disclosure Agreement (NDA) is signed. The research assistant will be directly supervised by the principal investigator for proper handling of information and ensuring privacy and confidentiality.

Study participants will be assigned with pseudonyms to avoid easy identification and data being exposed. Digital forms containing the participants' data are to be stored in an encrypted hard drive. The file will be stored in a password encrypted laptop and be backed up with a password encrypted hard drive to be accessed by the principal investigator and co-investigator. Personal identification data will only be kept for 5 years. When destroying electronic data, appropriate data deletion methods are done to ensure the data cannot be recovered.

These are all in compliance with the RA 10173 - Philippine Data Privacy Act and are explained to the participants verbally and in writing during the recruitment process.

Confidentiality

The information we will collect from this study will remain confidential. Any information collected about you will have a number on it instead of your name, and your name will not appear in anything that will be written about the results of the study. Only the doctors involved in the study will have access to your records. The Asian Hospital Medical Center - Research Ethics Committee review panel and regulatory authorities will only have access to the records only for the purpose of verification of data and this is achieved with the expressed knowledge and consent of the principal investigator for the study. You may also have access to your own records and the result of the study as a whole but not the individual records of the other participants. Records pertaining to the participants personal information will be kept within 5 years on lock and key and any electronic information will be kept on secured archives on hard disk drives devoted to the job.

Right to refuse or withdraw

The participant does not have to take part in this research if he/she does not wish to do so. If the participant withdraws at any point of the study with the medical insurance in place, insurance coverage issued under Chubbs program will not be revoked. If the patient has decided to proceed with the withdrawal, the researchers will ask the participant to put into writing the reason, for purposes of clarification in record keeping.

Contacts:

If you may have any unforeseen side-effects and concern caused by the robot, please contact:

Dr. Myrna S. Estrada
Co-investigator
0917 378 4198
email: msestrada@dlshsi.edu.ph

Dr. Amiel Adajar
Co-investigator
0917 828 0433
email: acadajar@dlshsi.edu.ph

Ethics

This research has been approved by the Asian Hospital Medical Center - Research Ethics Committee (AHMC-REC) and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints:

Name of AHMC REC Chair: Dr. Benjamin G. Co
email: ahmcirb@asianhospital.com
tel: 8771-9000 loc 8163

CERTIFICATE OF CONSENT

I, _____, as a participant of the Tayô project clinical trial of LEGAL AGE, am giving my consent to the De La Salle University - Institute of Biomedical Engineering Health Technologies (DLSU-IBEHT) for the collection, processing, storage, and eventual disposal of my personal data. Specifically, personal data collected and processed are as follows:

What we collect	Yes	No
I allow the collection of my initials (first name, last name, middle initial), age, gender, weight and height		
I allow the collection of my normal anatomy limits (or sensor data), vital signs, operational entries/logs		
I allow the recording of my motion pictures/video footage with strict identity concealment		

The personal data to be collected is ONLY for the purposes of educational and research use of the De La Salle University (DLSU) and De La Salle Medical Health Sciences Institute (DLSMHSI) community. Photographs, video footage, sound recordings with strict identity concealment can be used for non-commercial information dissemination purposes in print, online and in-campus.

Any entity shall NOT be given access to the provided data that may be used for other purposes outside of what is defined in this consent. DLSU-IBEHT SHALL NOT share the information with any other third party contractors that are used to execute this exercise. All data shared with DLSU-IBEHT shall only be safeguarded and retained for 5 years. During this retention period, the security of the personal information at rest shall be the responsibility of the Personal Information Controller (PIC) and will comply with the requirements of RA 10173. DLSU-IBEHT shall also uphold the rights of the data subject as stipulated in RA 10173 that includes integrity and availability requirements. After the 5 year maximum period, the data collected should be disposed of and a certificate of disposal or deletion shall be provided by DLSU-IBEHT to DLSU duly signed and acknowledged by its Data Protection Officer.

I agree to participate in a safety and acceptability study on the use of a locally-developed rehabilitation robot for functional trunk and lower extremity training using adults with no impairments of the upper extremity. I have read the foregoing information, or it has been read to me and understand its contents fully. I have had the opportunity to ask questions about the study and they have been answered to my satisfaction. I consent voluntarily to participate in this study.

Printed Name of Participant _____

Signature of Participant _____

Date _____ (day/month/year)

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the person understands the study. I confirm that the participant was given an opportunity to ask questions about the study and all the questions were answered correctly; and that consent has been given freely and voluntarily. A copy of this informed consent form has been provided to the participant.

Printed Name of Researcher / Person taking the consent

_____

Signature of Researcher / Person taking the consent

_____

Date _____ (day/month/year)

Appendix B.2: Informed Consent Form (Filipino)

Safety Testing, and Phase 1 of the Clinical Trials

Pangalan ng *Principal Investigator:*
Pangalan ng *Co-Investigators:*

Pangalan ng *Organization:*

INFORMED CONSENT FORM
(FILIPINO)

Ang TAYÔ Project: Rehabilitation for the Trunk and Lower Extremity - STAGE 2: Safety Tests at Phase 1 ng Clinical Trials ay pinopondohan ng Department of Science of Technology-Philippine Council for Health Research and Development at ipinatutupad ng Institute of Biomedical Engineering and Health Technologies (IBEHT) ng De La Salle University (DLSU). Ninanais ng proyektong ito na makalikha ng mga *locally-developed device* upang matulungan ang mga pasyenteng may *stroke* na makakilos muli nang normal. Bilang hakbang tungo sa progresibong pag-aaral nito, kinakailangang magsagawa ang *research institute* ng Clinical Trials kabilang ang mga *target end-user* ng isinagawang aparato o robot. Maliban pa rito, ang pag-aaral na ito ay makakatulong sa pagtukoy kung ligtas bang gamitin ng publiko ang aparato o robot.

Ang *informed consent form* na ito ay para sa mga pasyente na nasa labing walo hanggang anim na pu't (18-60) taong gulang na aming inimbitahan para sumali sa aming pananaliksik na pinamagatang, “Development of a safety checklist for operational use of a locally-developed robotic exoskeleton for functional training using Healthcare Failure Mode and Effects Analysis.”

Nilalaman ng *Informed Consent Form*:
- *Information Sheet* (Impormasyon tungkol sa pananaliksik bilang gabay sa mga kalahok)
- *Certificate of Consent* (Katibayan ng kasunduan na kusang-loob ang pagsali at pinapatunayan ng sariling lagda)

PANGKALAHATANG IMPORMASYON

Ako si (*investigator/researcher*) _____ ng _____. Kasama sina _____ at _____, kami ay nagsasagawa ng isang pananaliksik upang ipakita ang kaligtasan ng isang *rehabilitation robot*. Ako ay nagbibigay ng impormasyon tungkol sa aming pananaliksik at iniinya namin kayo na kami ay tulungan. Hindi kailangan na magdesisyon ngayong araw kung kayo ay papayag o hindi lalahok sa aming pananaliksik. Bago magdesisyon, pwedeng kumausap ng kahit na sino para mapag usapan ang laman ng *informed consent form*. Iisa-isahin namin ang bawat bahagi kaya sa pagkakataon na mayroong salita na hindi naiintindihan, tanungin lamang ang mga *researchers* habang dinadaanan ang impormasyon sa *consent form*. Huwag mahiyang magtanong kung mayroong hindi naiintindihan o gustong malaman. Ang *consent form* na ito ay gagamitin sa buong durasyon ng pananaliksik.

Layunin
Ang pananaliksik na ito ay ginawa para mapag-aralan ang kaligtasan at kakayahan ng isang *locally developed trunk and lower limb rehabilitation robot* base sa protocol ng *Health Identification, Risk Assessment and Control (HIRAC)* at pagkatapos ay susukatin ang pagkakaiba ng *actual range of motion* (ROM) ng robot at ng *range of motion* (ROM) ng tao sa mga sumusunod: *hip-flexion extension, hip abduction-adduction, knee flexion-extension, trunk flexion, at trunk lateral flexion.* Ang *rehabilitation robot* na ito ay gagamitin rin para sukatin and *biofeedback systems* sa galaw ng robot.

Pagpili ng pasyente
labingwalong(18) pasyente ang pipiliin gamit ang criteria na makikita sa baba.

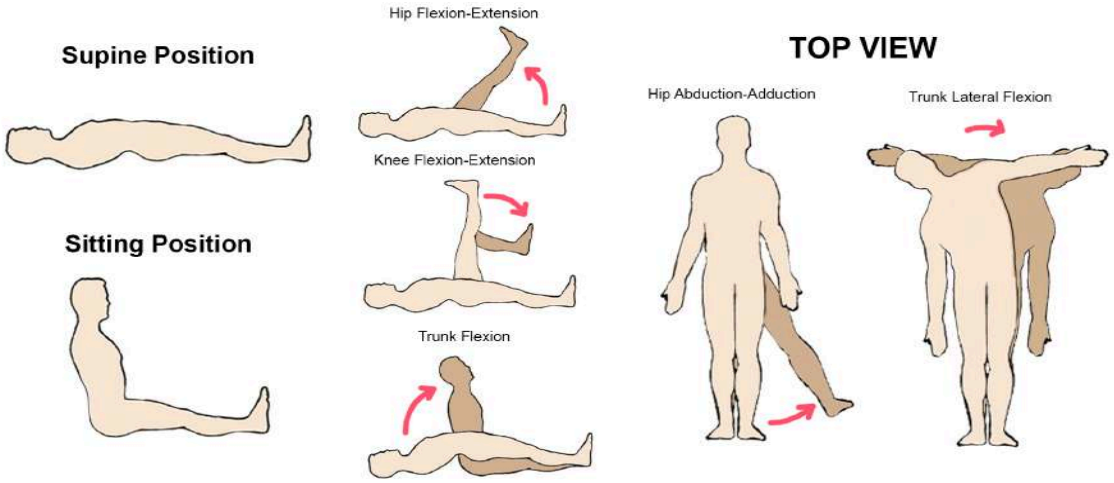
1. Ang pasyente ay dapat marunong sumunod ng mga direksyon.
2. Ang pasyente ay dapat may tangkad na 5”4’ o 1.63 m hanggang 6”2’ o 1.87 m.
3. Ang pasyente ay dapat may timbang na mas mababa sa 200 kg.
4. Ang pasyente ay dapat may kakayahan gamitin ang kanilang *trunk* at *lower extremities.*
5. Ang pasyente ay dapat sumang-ayon na magkaroon ng *medical clearance* na sasagutin naman ng mga mananaliksik bago pa man ang pakikilahok (Bisa: isa hanggang dalawang linggo mula sa itinalagang paglalahok sa *clinical trial*.
6. Ang pasyente ay dapat *fully vaccinated* at *boosted* bago ang pakikilahok (dalawang nakumpletong *doses*, mayron o wala mang *booster*).

Mga Bukod: Pasyente na may *orthopedic* o kaya ay *neurological condition* na naapektuhan ang *trunk* at *lower extremities*, mga mayroong *cardiac limitations* sapagkat may posibilidad na magkaroon ng madaling pagtaas ng *blood pressure*. Ang mga mayroong *muscle weakness* o kaya ay *paresis* na malilimitahan ang abilidad sa paggalaw ng mga importanteng parte ng katawan.

Kusang Pakikisali
Ang pakikilahok sa pananaliksik na ito ay sariling kagustuhan o *voluntary*. Hindi kayo hihilingin na tumanggap ng kahit na anong pagkain, inumin, droga, o kaya ay pasukan ng kahit na anong medikasyon o substansya. Ang proseso na susundan ay hindi rin gumagamit ng agresibong pamamaraan ng pagkuha ng datos.

Kung napagdesisyunang hindi na makakasali sa pananaliksik kahit tapos nang pirmahan ang papel na ito, ang kalahok ay pinapayagan pa ring umatras. Ngunit, mahalaga na masabihan kami agad-agad upang makahanap ng ibang sasali sa pananaliksik. Humihiling din kami na sumulat at pumirma ng isang liham na nagsasaad ng mga rason ng inyong pag-atras para sa dokumentasyon sapagkat *pondo ng gobyerno* ang ginamit sa pagkuha ng *insurance* para sa inyo.

Pamamaraan



Ang bawat pasyente ay tuturuan ng imbestigador sa proseso ng paggamit ng *rehabilitation device* at sa pagsasagawa ng *baseline assessment* tulad ng posisyon pampahinga ng *trunk*, hita, ibabang binti, at paa. Bago pa man magsimulang gawin ang *lower limb exercises*, susukatin ng imbestigador ang *range of motion* ng bawat *exercise*. Susunod dito, sisimulan na ng imbestigador ang pagbukas ng software para mabuksan ang *device*. Magkakaroon ng limang (5) magkakasunod na nagpapagalaw sa *trunk*, hita, ibabang binti, at paa ng kalahok sa loob ng *predetermined range*. Matapos magamit ang *device* para sa simpleng galaw at pagsukat, magsisimula na ang *0* sa kanyang *functional composite motion* kung saan i-sisimulate ang sumusunod na galaw sa bawat *joint*: *trunk flexion (while sitting), trunk lateral flexion, hip flexion-extension, hip abduction-adduction,* at *knee flexion-extension* na may nakasaad na sukat na nakabatay sa sagad na saklaw ng paggalaw ng pasyente. Pagkatapos nito, ang bawat pasyente ay kinakailangang sagutin ang isang *self-administered questionnaire* na ipinapahayag ng mga imbestigador. Kung mayroon katanungan, maaari rin silang tanungin ukol dito.

Babala: Kung sa kahit na anong pagkakataon, ang pasyente ay nagsimulang makaramdam ng sakit o kaya ay hindi naging komportable, mayroong *emergency stop button* ang *device* na abot ng pasyente at ng imbestigador. Sa pagkakataon na napindot ang *emergency stop button,* agad-agad titigil ang *device* at ibabalik ito sa orihinal na posisyon para alisin ang kahit na anong sakit na nararanasan ng pasyente.

Panahong Itatagal

Ang bawat proseso ay tatagal ng mga sampung (10) minuto at ang bawat pasyente ay sasailalim sa prosesong ito ng tatlong (3) beses. Ang kabuuang *participant-rehabilitation device time* ay dalawang (2) oras at labing-isang (11) minuto.

Durasyon

Ang *pre-screening* ay isasagawa isang linggo bago ang *Clinical Trial*. Ang *Clinical Trial* ay inaasahang tatagal ng halos kalahating araw o apat na oras. Ngunit, ang oras na gugulin sa paggamit ng *rehabilitation device* ay aabot lamang ng (2) dalawang oras at (11) labindalawang minuto.

Mga Epekto
Base sa *technical electrical safety and mechanical safety evaluation,* mayroong napakaliit pero posibleng *physiological risks* ang isasagawang Clinical Trials na kabilang ang pananakit ng kalamnan o kasukasuan*, soft tissue injury,* pagkagalos*, muscle soreness, dislocation/fracture,* at *potential electrocution.* Kung sa kahit na anong pagkakataon, nakaramdam ang pasyente ng sakit o kaya ay hindi pagiging komportable, mabibigyan kaagad ito ng *first aid* bago dadalhin sa *university clinic* kung saan titingnan ang sitwasyon at magiging batayan sa pagdala sa pinakamalapit na ospital. Ang pambayad sa ospital ay manggagaling sa *insurance* na kinuha para sa pasyente.

Medical Insurance

Alinsunod sa mga alituntunin sa Philippine Clinical Study, ang lahat ng mga kalahok ay bibigyan ng *insurance* upang mabigay ang kanilang mga medikal na pangangailangan kung may ipinakitang anumang matinding masamang epekto sa panahon ng pag-aaral.

Paano magagamit ang *insurance*?

Ang *insurance* na ito ay maaaring magamit sa ano mang panganib na nabanggit sa dokumentong ito na maaaring mangyari sa panahon ng *clinical trial* hangga't:

1. Ang panganib ay sanhi ng isang insidente sa panahon ng *clinical trial* na naganap sa saklaw na teritoryo ng pag-aaral.
2. Hindi nangyari ang insidente bago ang araw ng pagkabisa ng patakaran, kung mayroon man, o pagkatapos ng araw na matatapos ang patakaran.

Ang *insurance* ay hindi maaaring magamit sa mga isinaad na mga hindi kabilang sa Insurance Policy.

Maliban kung partikular na ipinagkakaloob sa ilalim ng dokumentong ito, walang karagdagang responsibilidad o pananagutan na magbayad ng mga halaga o magsagawa ng mga kilos o serbisyo ang sinasaklaw.

Ang insurance na ito ay ipagkakaloob sa kalahok sa pag-aaral kung at kapag pumayag silang mag-*sign up* para mapabilang sa labing walong(18) kalahok sa pag-aaral.

Para sa karagdagang impormasyon tungkol sa mga hindi kabilang o *exclusions* at higit pang mga detalye sa mga legal na usapin ng *insurance*, maaari kang sumangguni sa Insurance Policy.

Kahalagahan sa Komunidad
Ang robot ay sadyang nilikha upang tulungan at suportahan ang *physical therapist* sa mabibigat na trabaho tulad ng pagbubuhat sa pasyente na makatayo at gawin ang mga nabanggit na *exercises*. Pinapabilis din ng robot ang gawain ng isang *physical therapist* sapagkat maraming pasyente ang kanyang maaasikaso gamit ang robot. Dahil dito, maiiwasang magkaroon ng

fatigue ang mga *physical therapist* kumpara sa tradisyunal na *lower limb rehabilitation*. Kaya naman lubusang mapapadali at mapapabilis ang pagsasagawa ng programa.

Mga Benepisyo
Mayroong ilang mga benepisyong medikal para sa mga magiging kalahok sa pag-aaral na ito. Ang robot ay naglalaman ng *baseline body strength* at sukat ng *range of motion* na maaaring magamit sa *sports activities* at pagsukat sa *strength for work capacity assessment* na magagamit sa pag-*apply* ng trabaho.

Ang sinumang tao na kabilang sa pagsasaliksik na ito ay magiging kabilang sa unang pangkat ng mga tao sa Pilipinas na makakagamit ng *locally developed trunk* at *lower limb rehabilitation robot*. Ang datos na makakalap sa pag-aaral na ito ay mapapakinabangan ng mga pasyente sa buong bansa sa pamamagitan ng pagtulong sa pagpapatunay at pag-aayos ng robot mai-ayon lang ito sa limitasyon ng *human anatomy* para sa *trunk* at *lower extremity*.

Ang mga kalahok at imbestigador ay makakatanggap ng iba't ibang mga gamit bilang pasasalamat sa kanilang pakikilahok sa isasagawang Clinical Trials. Kasama na dito ang isang *3D printed token*, isang *gift voucher* na nagkakahalaga ng limang daang salapi (PHP 500), at *mug*/*tumbler*. Isang COVID-19 care kit na naglalaman ng *liquid disinfectant* (800 ml), isopropyl alcohol (500 ml), Bactidol® (120 ml), isang *health drink* (500 ml), isang box ng mga *disposable face mask* (50 piraso), isang *digital thermometer*, isang box ng vitamin C with zinc (20 capsules) ay ibabahagi rin sa mga kalahok at imbestigador.

Maghahanda rin ng almusal, tanghalian, at *snacks* para sa mga kalahok at imbestigador sa buong araw. Susundan ang *meal schedule* para mapanatiling organisado ang buong *activity*.

Pagkolekta ng datos
Ang personal na impormasyon na makukuha habang isinasagawa ang Clinical Trials ay ang mga sumusunod sa ibaba:

- Inisyal ng pasyente (*first name*, *last name*, *middle initial*), edad, kasarian, timbang, at taas
- *normal anatomy limits* (o *sensor data*), mga *vital sign*, *operational entries/logs*
- mga larawan at video

Ang makakalap na impormasyon ay para sa layuning pang-edukasyon at pananaliksik ng komunidad ng De La Salle University at De La Salle Medical Health Sciences Institute. Ang mga litrato, *video footage*, mga *sound recording* na mahigpit na pinatatago ang *identity* ay maaari lamang gamitin sa hindi pangkomersyal na pagkakalat ng impormasyon sa limbag, *online*, at *in-campus*.

Ang *access* ng pasyente sa impormasyon at bagong pag-aaral kaugnay sa proyekto
Ang mga lalahok na pasyente sa pananaliksik na ito ay mapapahintulutan ng *access* upang suriin at mapanatili ang kawastuhan ng personal na impormasyon bago at pagkatapos ng proseso ng isasagawang Clinical Trials. Ang elektronikong kopya ng mga resulta ng pag-aaral ay maibibigay sa mga kalahok ng pananaliksik na ito. Kung nais nilang lumahok sa mga susunod pang proyekto o aktibidad na may kaugnayan sa pag-aaral na ito at nais ring ipahayag

sa pagsusulat, sila ay mapapadalhan ng imbitasyon ng mensahe ukol sa mga susunod na aktibidad sa pamamagitan ng email.

Plano sa pagproprotekta sa mga nakalap na impormasyon

Tanging ang punong imbestigador, *co-investigator*, at *co-resident* na dumalo sa Good Clinical Practices (GCP) Seminar ang kukuha ng impormasyon mula sa mga isinagawang panayam na kakailanganin sa pag-aaral. Ang isang *research assistant* na dumalo din sa pagsasanay sa GCP ay bibigyan ng pahintulot na i-*access* ang data, pagkatapos malagdaan ang isang Non-Disclosure Agreement (NDA). Ang *research assistant* ay pinangangasiwaan ng punong imbestigador para sa wastong paghawak ng impormasyon at pagtitiyak na mananatiling pribado at *confidential* ang mga ito.

Ang mga pasyente ay itatalaga ng mga pseudonym upang maiwasan ang madaling pagkakakilanlan at paglantad ng mga personal na impormasyon. Ang mga *digital form* na naglalaman ng datos ng mga pasyente ay itatabi sa isang naka-*encrypt* na *hard drive*. Ang *file* ay maiimbak sa isang laptop na naka-*encrypt* at iba-*back up* gamit ang naka-encrypt din na *hard drive*. Ang punong imbestigador at *co-investigator* lamang ang may *access* sa mga ito o nakakaalam ng mga *password*. Ang mga datos na naglalaman ng personal na pagkakakilanlan ay maitatago lamang sa loob ng limang (5) taon. Kapag sinisira ang *electronic data*, ang mga naaangkop na paraan ng pagtanggal nito ay ginagawa upang matiyak na hindi na ito maibalik muli.

Ang lahat ng ito ay bilang pagsunod sa RA 10173 - Philippine Data Privacy Act at naipaliwanag sa mga pasyente sa salita at sulat sa panahon ng proseso ng pangangalap ng mga sasali sa pananaliksik.

Confidentiality

Ang impormasyong makokolekta mula sa pag-aaral na ito ay mananatiling kumpidensiyal. Ang anumang impormasyong nakolekta tungkol sa iyo ay magkakaroon ng isang numero sa halip na pangalan, at ang iyong pangalan ay hindi lilitaw sa anumang isusulat tungkol sa mga resulta ng pag-aaral. Ang mga doktor lamang na kasama sa pag-aaral ang magkakaroon ng *access* sa iyong *records*. Ang *Asian Hospital Medical Center - Research Ethics Committee review pane*l at *regulatory authorities* ang magkakaroon lamang ng *access* sa mga *records* para lamang sa layunin ng pagtiyak ng datos at makakamit ito sa pamamagitan ng kaalaman at pahintulot ng punong imbestigador para sa pag-aaral. Maaari ka ring magkaroon ng *access* sa iyong sariling mga *records* at ang resulta ng pag-aaral sa kabuuan ngunit hindi ang mga indibidwal na tala ng iba pang mga kalahok. Ang mga *record* ay itatago sa loob ng limang taon sa *lock and key* at anumang elektronikong impormasyon ay itatago sa mga tiyak na *archives* sa mga *hard disk drive*.

Karapatang tumanggi o umatras

Ang mga pasyente ay hindi kailangang makilahok sa pananaliksik na ito kung labag sa kanyang kalooban. Kung ang pasyente ay umatras sa anumang punto ng pag-aaral na may *medical insurance*, ang saklaw ng *insurance* na inilabas sa ilalim ng *Chubbs* na programa ay hindi babawiin. Kung nagpasya ang pasyente na magpatuloy sa pag-atras, hihilingin ng mga mananaliksik sa pasyente na isulat ang dahilan bilang paglilinaw sa mga itatagong *record*.

Contacts
Kung mayroong mga hindi inaasahang epekto at pag-aalala sanhi ng *robot*, maaaring kontakin o tawagan sina:

Dr. Myrna S. Estrada
Co-Investigator
0917 378 4198
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Dr. Amiel Adajar
Co-Investigator
0917 828 0433
email: acadajar@dlshsi.edu.ph

Etika
Ang pananaliksik na ito ay inaprubahan ng *Asian Hospital Medical Center - Research Ethics Committee (AHMC-REC).* Maaaring makipag-ugnayan sa kanila sa pamamagitan ng mga sumusunod na impormasyon hinggil sa karapatan ng mga pasyente, kabilang ang kanilang mga hinaing at reklamo:

Pangalan ng *AHMC-REC Chair:* Dr. Benjamin G. Co
email: ahmcirb@asianhospital.com
tel: 8771-9000 loc 8163

SERTIPIKO NG PAHINTULOT

Ako _____ bilang isang kalahok ng *clinical trial* ng proyekto ng TAYÔ, nasa hustong gulang, ay nagbibigay ng aking pahintulot para sa De La Salle University-Institute of Biomedical Engineering & Health Technologies (DLSU-IBEHT) para sa pangongolekta, pagproseso, pag-iimbak, at pagtatapon ng aking personal na impormasyon. Sa partikular, ang personal na datos na nakolekta at naproseso ay ang mga sumusunod:

Mga impormasyon na kakalapin	Oo	Hindi
Aking pinahihintulutan ang pagkuha ng aking *initials* (*first name*, *last name middle initial*), edad, kasarian, timbang, at taas		
Aking pinahihintulutan ang pagkuha ng aking *normal anatomy limits* (o *sensor data*), mga *vital sign*, *operational entries/logs*		
Aking pinahihintulutan ang pag-*record* ng aking mga *motion picture/video footage* na may mahigpit na pagtatago ng aking pagkakilanlan		

Ang makakalap na impormasyon ay para sa layuning pang-edukasyon at pananaliksik ng komunidad ng De La Salle University (DLSU) at De La Salle Medical Health Sciences Institute (DLSMHSI). Ang mga litrato, *video footage*, mga *sound recording* na mahigpit na pinatatago ang pagkakakilanlan ay maaari lamang gamitin sa hindi pangkomersyal na pagkakalat ng impormasyon sa *print*, *online*, at *in-campus*.

Ang sinumang entidad ay HINDI bibigyan ng *access* sa ibinigay na datos na maaaring gamitin para sa iba pang mga layunin sa labas ng kung ano ang tinutukoy sa pahintulot na ito. Ang DLSU-IBEHT AY HINDI ibabahagi ang impormasyon sa anumang iba pang mga third party na kontratista na ginagamit upang isagawa ang pagsasanay na ito. Ang lahat ng impormasyon na ibinahagi sa DLSU-IBEHT ay dapat lamang pangalagaan at panatilihin sa loob ng limang (5) taon. Sa panahon ng pagpapanatili nito, ang seguridad ng personal na impormasyon ay magiging responsibilidad ng Personal Information Controller (PIC) at susunod sa mga kinakailangan ng RA 10173. Dapat ding itaguyod ng DLSU-IBEHT ang mga karapatan ng paksa ng datos ayon sa itinakda sa RA 10173 na may integridad at ng *availability requirements*. Pagkatapos ng limang (5) taon, ang datos na nakolekta ay dapat nang itapon at isang sertipiko ng pagtatapon o pagtanggal ang dapat ibigay ng DLSU-IBEHT sa DLSU na may kasamang paglagda at pagkilala mula sa Data Protection Officer nito.

Pumapayag ako na maging parte ng isang pananaliksik ukol sa kaligtasan at kaayusan ng isang *locally-developed rehabilitation robot* para sa *functional trunk* at *lower extremity training* na gumagamit ng mga pasyente na walang kapansanan sa kanilang *upper extremities.* Nabasa ko na ang lahat ng impormasyon, o kaya ay nabasa na sa akin ito at naintindihan ko ang nilalaman nito. Nagkaroon ako ng oportunidad para makapag tanong tungkol dito at lahat ng aking mga tanong ay nasagot ayon sa aking kagustuhan. Pumapayag ako na sumama sa pananaliksik na ito.

Buong Pangalan ng Pasyente

_____

Lagda ng Pasyente

_____

Petsa _____ (araw/buwan/taon)

<u>Pahayag ng mga R*esearcher* / Taong Tagatanggap ng *consent*</u>

Binasa at naipahayag ko nang malinaw ang laman ng *information sheet* sa pumayag na pasyente, at naisiguro ko, sa lahat ng aking kakayahan, na naintindihan ng pasyente ang laman ng pananaliksik. Kinukumpirma ko na ang pasyente ay nabigyan ng pagkakataon para mag tanong tungkol sa pananaliksik at ang lahat ng tanong ay naisagot ng tama at malinaw; at ang *consent* ay nabigay ayon sa kanilang desisyon. Ang kopya ng *informed consent form* ay ibibigay sa pasyente.

Isinulat na Pangalan ng *Researcher* / Taong Tagatanggap ng *Consent*

_____

Pirma ng *Researcher* / Taong Tagatanggap ng *Consent*

_____

Petsa _____ (araw/buwan/taon)

Appendix C: Health and Safety Management

Appendix C.1: Control Measures for Assessed Hazards

A. MECHANICAL HAZARDS		
A1	Movements (normal or unexpected) of the wheels or the angle of the bed. This could lead to: • Impact • Damage to Property • Injury	Operators and patients could be harmed when within proximity of the machine. • Brake failure may cause bed to keep moving and hit someone or something • Patient in vicinity of the bed while operator is positioning it
A.2	Straps not locked in properly or too loose. This could lead to: • Injury/bruises	Patients could be harmed • Patient could fall when trying to do certain exercises
A.3	Patients could get stuck in an uncomfortable position while on the bed.	Patients could be harmed • UI stops syncing with machine
A.4	Trapping fingers between robot joints could include risk of pinching or crushing.	Patients' fingers could get trapped when trying to get in position for the exercise
A.5	Cutting or piercing of skin with sharp edges and points of the robots.	Patients and operators could be harmed. • Operators could be harmed when working in close proximity with the robot while setting up, maintenance, or doing installations. • Patients could get hit while trying to lie or sit on the bed
A.6	Injuries or equipment damage due to the emergency stop button being out of reach.	Patients and maintenance crew could be harmed. • Patients may get stuck in a dangerous position if the machine starts malfunctioning • Crew doing maintenance could get hurt while inspecting machine closely

B. ENVIRONMENTAL HAZARDS		
B.1	Disorientation which could lead to inability to recognize hazards	Patients and operators could be harmed. • Poor lighting could impair a person's vision • Noisy environment could impair a person's hearing
B.2	Discomfort of patient due to temperature could lead to unfocused patients and operators	Patients and operators could be harmed. • Temperature being too cold could cause shivers which would be uncomfortable for patients and operators • Temperature being too warm could cause discomfort and sweat to patients and operators
B.3	Other materials or furniture near the machine could be harmful for users	Patients and operators could be harmed. • If there is not enough space for people to walk around and operate the machine. • People could get stuck in between heavy objects if the machine starts moving randomly.

C. ELECTRICAL HAZARDS		
C.1	Power failure could cause equipment to move or fall in unexpected ways	Patients and operators could be harmed. • Machine could move unexpectedly and hit the patient or the operator while in the vicinity • Patients could be trapped in an uncomfortable position while on bed • They could also get electrocuted from power supply failure

C.2	Therapy bed could move and cause damage to its surroundings	Patients could get hurt • The therapy bed may cause blunt trauma due to unexpectedly moving in an unintended manner
C.3	People could fall and get injured due to the wires of the machine	Patients could get hurt • The wires are tangled and are in the way of people
C.4	People could get electrocuted from wires and sockets	Patients and operators could be harmed. • Wires that are not properly covered or plugged-in improperly could electrocute people.

D. CONTROL MEASURES	
D.1	Conduct a risk assessment of the final machine and intended use case
D.2	Perform a visual checks and/or proof tests upon commissioning the final machine
D.3	Perform a visual checks and/or proof tests at predefined maintenance intervals
D.4	Ensure brake release tool remains with the robot or in a secure, accessible location at all times
D.5	Ensure machine operators are outside the operating space of the robot whenever possible, except for maintenance
D.6	Appropriate Personal Protective Equipment (PPE) must also be provided
D.7	Machine operators should be appropriately trained or supervised by a trained individual following risk assessment.
D.8	Where possible, the number of fixed items in the path of the robot’s operating space should be kept to a minimum
D.9	Care should be taken with loose items placed on the work surface to prevent knocking by operators or during robot movement

D.10	The installation shall be positioned in such a way that an operator is not prevented from escaping the operating space of the robot
D.11	Machine controls/displays/indicators should be appropriately positioned for ease of access/visibility by operators
D.12	Ensure sufficient lighting around the integration. Particularly around the robot's movement envelope, emergency stop devices and other potential hazards
D.13	Trailing cables or other obstacles at ground level should be tied back, moved or covered to prevent trips or falls
D.14	Ensure the Emergency Stop Button is within easy reach of the operator at all times. Multiple emergency stop devices may be necessary to achieve this.
D.15	Spillable liquids should be kept away from the operating space at all times, unless related to the use case
D.16	Reduce sharp/angular edges on the end effector and other parts of the integration environment wherever possible
D.17	Appropriate fixings and mechanical assemblies should be specified to withstand the expected forces during use. Along with suitable tightening torques or thread locking techniques where appropriate
D.18	The exclusion zone should be sufficient in size to minimize the risk of injury
D.19	The surface on which the robot is placed and the positioning of the robot should be appropriately specified to ensure the stability of the equipment at all times under expected use conditions
D.20	Only the power supply provided shall be used to power the robot
D.21	The equipment should only be installed and used within the specifications stated in the user manual
D.22	Noise levels within the operating area should be kept to a safe minimum where possible, in order to reduce the likelihood of damage to hearing and to maintain an awareness of the environment. Ear protection should be considered where this is unavoidable

D.23	Limit access to machine controls where possible

Appendix C.2: Safety Adverse Reaction Form

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Controlled Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

Subject Initials: _____ **Subject ID:** _____

Exam Date: _____

SAFETY AND ADVERSE EVENT FORM

STUDY PARTICIPANT INFORMATION	
Date of Birth: Age: Contact Number:	Sex: Weight: Height:

SAFETY AND ADVERSE EVENT INFORMATION	
SAFETY AND ADVERSE EVENT ☐ Adverse Device Effect ☐ Adverse Event _ Anticipated _ Unanticipated Date of Experience: End of Experience:	SERIOUSNESS CRITERIA ☐ Death ☐ Life-threatening ☐ Requires hospitalization ☐ Needs medical attention
ACTION TAKEN ☐ Continued ☐ Interrupted ☐ Others:	SAFETY MEASURES ☐ Safety measures were implemented ☐ Safety measures were not implemented
DESCRIBE THE ACTION TAKEN / SAFETY MEASURES IMPLEMENTED	

IRB No: Protocol Version and Date:

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Controlled Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

CAUSALITY ASSESSMENT	REMARKS FOR CAUSALITY ASSESSMENT:
☐ Probably ☐ Possibly ☐ Unlikely ☐ Not related	
DESCRIBE THE DEVICE EFFECT / ADVERSE EVENT	
OUTCOME OF THE DEVICE EFFECT / ADVERSE EVENT	
☐ Recovered/ Resolved ☐ Improved ☐ Deteriorating ☐ Death ☐ Others:	REMARKS ON THE OUTCOME OF THE DEVICE EFFECT / ADVERSE EVENT

I hereby declare that the information above are true and correct to the best of my knowledge.

Signature over Printed Name of Principal Investigator — Date

Signature over Printed Name of Physician on site — Date

IRB No: Protocol Version and Date:

Appendix C.3: Frequency of Safety Adverse Reaction Sheet

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Pilot Study among Normal Subjects on the Safety and Functionality of a Locally-Developed Trunk and Lower Limb Rehabilitation Robot

Frequency of Safety Adverse Event Sheet

	Participant Number																	
Hazards	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
A1																		
A2																		
A3																		
A4																		
A5																		
A6																		
B1																		
B2																		
B3																		
C1																		
C2																		
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D6																		
D7																		
D8																		
D9																		
D10																		
D11																		
D12																		
D13																		
D14																		
D15																		
D16																		
D17																		
D18																		
D19																		
D20																		
D21																		
D22																		
D23																		

checked by: _____ approved by:_____

Appendix D. HIRAC Report

TAYÔPROJECT

Hazard Identification, Risk Assessment and Control (HIRAC)

Date of first review: October 13, 2022
Date of final review: November 18, 2022

Results:

Review #1

Task	Hazard	Risk	Rating			Proposed Control	
			Frequency	Severity	Risk Score	Engineering	Administration
Robot Leg Exercise (ROM)	Open Space underneath cushions that can be reached by fingers that has gap reduction	Fingers Crush Injury	2	2	4	Improve Cushion Design	
	Over Extension of leg during lower limb exercises	Physiological Injury (left)	2	3	6	Put mechanical locks to prevent this from happening	
		Physiological Injury (right)	2	3	6		
	Foot Position difference	Effects to position	1	2	2	Improve cushion	
	Motor hum	Hearing Injury	1	3	3	Inspect what causes the noise, control noise from motor	
	Push towards trunk when lifting leg	Physiological Injury	2	2	4	Improve mechanical design	
	Restraint lock difficult to remove	Limitation for quick response for injured users	1	3	3	Improve strap lock	
Measurement of Joints	Touching Participant Directly - Psychological Hazard	Possible Avenue for Harrassment Claims	1	3	3		Same gender participants to attendants; Ask consent
Security of User with straps during standing position	Rubbing surfaces on skin through clothes	Skin scratches	2	1	2	Improve straps	
Using the machine in any condition	Exposed body parts touching bare metal of machine	Electrocution	1	3	3	Cover exposed body parts	
		Skin Allergy	1	2	2		
			Rating		3.454545455		

Discussion:
The result of the assessment is a HIRAC risk rating of 3.4545. With this, the assessed hazard and risk were acknowledged by the research team and prepared control measures for each item. The research team eliminates, substitutes, puts engineering control measures and administrative control measures to make sure each risk is mitigated.

Review #2

Task	Hazard	Risk	Rating			Control Measures	
			Frequency	Severity	Risk Score	Engineering	Administration
Robot Leg Exercise (ROM)	Open Space underneath cushions that can be reached by fingers that has gap reduction	Fingers Crush Injury	0.5	2	1	Improved cushion design	Proper setup of straps
	Over Extension of leg during lower limb exercises	Physiological Injury (left leg)	1	3	3	Mechanical Limitations from actuator; New padding helps reduce pinching	Set limits indicator for person and emergency button
		Physiological Injury (right leg)	1	3	3		
	Foot Position difference	Effects to position	1	2	2	Proper position of straps	Proper setup of straps
	Unwanted change of movement from sitting position to supine position		0.1	3	0.3	Manual switch set to change modes	
	Motor Hum	Hearing Injury	1	3	3		
	Push towards trunk when lifting leg	Physiological Injury	1	2	2	New padding reduces this occurrence	Emergency button
	Restraint Lock Difficult to move	Limitation for quick response for injured Users	1	3	3		New straps easier to manipulate but comes undone
Measurement of Joints	Touching participant directly - Physiological Hazard	Possible avenue for harassment claims	1	3	3		Same gender participants to attendants
Security of user with straps during standing position	Rubbing surfaces on skin through surfaces	Skin scratches	2	1	2		Use of comfortable sports wear during robot use
Touching the machine in any condition	Exposed body parts touching bare metal of machine	Electrocution	1	3	3	Robot is properly grounded	
		Skin Allergy	1	2	2	Metal used does not causes skin allergy	Use of comfortable sports wear during robot use
			Rating		2.275		

Discussion:
With the control measures prepared from the previous review, the total rating for this second review is 2.275. Control measures are in place for each risk with either engineering and/or administrative hazard control implementation.

---------- END OF REPORT ----------

Test Performed by:

Engr.JULIUS NOEL BANAYO
Research Leader

Checked and approved by:

Engr. VOLTAIRE DUPO
Safety Officer

BESAFE TRAINING & MANAGEMENT CONSULTANCY SERVICES

BeSafe Training Hall, Canlubang Lifestyle Center, Canlubang, Calamba City, Laguna

0921 836 1892 / 0921 545 2209 / marketing@besafeph.net

DOLE-OSHC ACCREDITATION NO. 1030-100521-131

This

CERTIFICATE OF COMPLETION

is awarded to

BO-W-HOM16-22-50299

VOLTAIRE B. DUPO

For having successfully completed the

DOLE Prescribed 40-hour Basic Occupational Safety and Health with Training of Trainers

Pursuant to the provision of Presidential Decree No. 442 otherwise known as the Labor Code of the Philippines, and Rule 1030 of the Occupational Safety and Health Standards (OSHS) and the D.O. No. 16 of the Department of Labor and Employment

Held on August 31 to September 4, 2022 at BeSafe Training Hall, Canlubang Lifestyle Center, Canlubang, Calamba City, Laguna via Zoom Pro Platform

Given this 4th Day of September, 2022

MARY GRACE C. ALBINO, BBM-CMP
President and Founder
BeSafe Training & Management CSY Services

Not Valid Without Dry Seal

JAYPEE O. BATHAN, PIE, MBA
Resident OSH Consultant
Accreditation No.: **1030-062821-OSHC-349**

Appendix E: Testing Activities Results

Appendix E.1: Robot Pre-Test Results

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Pilot Study among Normal Subjects on the Safety and Functionality of a Locally-Developed Trunk and Lower Limb Rehabilitation Robot

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Robot Pre-Test Checklist

Step Number	Result
Step 1: Was the connection between the tablet and the robot successful?	
Step 2: Did each motor respond accordingly through manual control?	

	YES	NO
A. Trunk Flexion (Forward)	A	
B. Trunk Flexion (Backward)	B	
C. Hip Flexion (Forward)	C	
D. Hip Flexion (Backward)	D	
E. Knee Flexion (Forward)	E	
F. Knee Flexion (Backward)	F	
G. Trunk Lateral Flexion (Right)	G	
H. Trunk Lateral Flexion (Left)	H	
I. Hip Abduction/Adduction (Right)	I	
J. Hip Abduction/Adduction (Left)	J	
K. Leg Support (Forward)	K	
L. Leg Support (Backward)	L	

Step 3: What were the actual angle measurements at the following joints when measured using a goniometer when set at ____ degrees on the tablet?	

	ANGLE

A. Trunk Flexion

B. Hip Flexion

C. Knee Flexion

D. Trunk Lateral Flexion

E. Hip Abduction/Adduction

A	
B	
C	
D	
E	

Step 4: How many repetitions did the motors execute when set to ____ repetitions on the tablet?

A. Trunk Flexion

B. Hip Flexion

C. Knee Flexion

D. Trunk Lateral Flexion

E. Hip Abduction/Adduction

	REPS
A	
B	
C	
D	
E	

Step 5: Did all motors move to or remain at initial position when the reset button was pressed?

A. Trunk Flexion

B. Hip Flexion

C. Knee Flexion

D. Trunk Lateral Flexion

E. Hip Abduction/Adduction

F. Leg Support

	YES	NO
A		
B		
C		
D		
E		
F		

Step 6: Did the knee motors move simultaneously and to the same angle when Sit-to-Stand is performed while the leg support locks are unclasped?

Step 7: While the joints were being positioned and the patient emergency button was pressed, did the robot stop?

A. Trunk Flexion
B. Hip Flexion
C. Knee Flexion
D. Trunk Lateral Flexion
E. Hip Abduction/Adduction
F. Leg Support

	YES	NO
A		
B		
C		
D		
E		
F		

Step 8: While the joints were being positioned and the mushroom emergency button was pressed, did the robot stop?

A. Trunk Flexion
B. Hip Flexion
C. Knee Flexion
D. Trunk Lateral Flexion
E. Hip Abduction/Adduction
F. Leg Support

	YES	NO
A		
B		
C		
D		
E		
F		

Step 9: While the joints were being positioned and the emergency pedal was pressed, did the robot stop?

A. Trunk Flexion
B. Hip Flexion
C. Knee Flexion
D. Trunk Lateral Flexion

	YES	NO
A		
B		
C		

E. Hip Abduction/Adduction
F. Leg Support

D		
E		
F		

Step 10: Are all these measurements within the normal range of motion?

Robot Capability in terms of Range of Motion (Study Objective No. 2)

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Controlled Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

ROBOT CAPABILITY IN TERMS OF RANGE OF MOTION (ROM)

Hip Range of Movement Evaluation

Movement	Range of Motion Capability of the Robot		
	Trial 1	Trial 2	Trial 3
Hip Flexion-Extension (Right)			
Hip Flexion-Extension (Left)			
Hip Abduction-Adduction (Right)			
Hip Abduction-Adduction (Left)			

Trunk and Knee Range of Movement Evaluation

Movement	Range of Motion Capability of the Robot		
	Trial 1	Trial 2	Trial 3
Trunk Flexion			
Trunk Lateral Flexion (Left)			
Trunk Lateral Flexion (Right)			
Knee Flexion-Extension (Right)			
Knee Flexion-Extension (Left)			

IRB No: Protocol Version and Date: Page:

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Appendix E.2: Trunk and Knee Range of Movement Evaluation (Study Objective No. 3)

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Pilot Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

Trunk and Knee Range of Movement Evaluation

Movement	Maximum Range According to Investigator's Goniometer reading(degrees)			
	Pre-testing Measurement	Trial 1	Trial 2	Trial 3
Trunk Flexion				
Trunk Lateral Flexion (Left)				
Trunk Lateral Flexion (Right)				
Knee Flexion-Extension (Right)				
Knee Flexion-Extension (Left)				

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Appendix E.3: Hip Range of Movement Evaluation (Study Objective No. 3)

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Pilot Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

Hip Range of Movement Evaluation

ID Code:
Age:
Date:
Time started:
Time finished:

Movement	Pre-testing Measurement	Maximum Range According to Investigator's Goniometer reading(degrees)		
		Trial 1	Trial 2	Trial 3
Hip Flexion-Extension (Right)				
Hip Flexion-Extension (Left)				
Hip Abduction-Adduction (Right)				
Hip Abduction-Adduction (Left)				

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Appendix E.4: Measurement of Physiological Parameters

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Controlled Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

Physiological Parameters Evaluation for Hip Range of Movement Evaluation and Trunk and Knee Range of Movement

Hip Range of Movement

ID Code:
Age:
Date:
Time start:
Time finish

Movement	Maximum Range According to Software (degrees)			Maximum Range According to Investigator's Goniometer reading(degrees)		
	Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3
Hip Flexion-Extension (Right)	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:
Hip Flexion-Extension (Left)	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:

IRB No: Protocol Version and Date: Page:

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Hip Abduction-Adduction (Right)	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:
Hip Abduction-Adduction (Left)	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:

Trunk and Knee Range of Movement

Position	Maximum Range According to Software (degrees)			Maximum Range According to Investigator's Goniometer reading(degrees)		
	Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3
Trunk Flexion	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:
Trunk Lateral Flexion (Left)	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:

Appendix E.5: Modified OPQRST Pain Assessment Tool

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Controlled Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

MODIFIED OPQRST (PAIN ASSESSMENT)

Onset of Event	__During attachment __Movement __After release __Others: Description:
Provocation and Palliation of Symptoms	*Is the pain better or worse with:* **Activity** *(Does walking, standing, lifting, twisting, reading, etc… have any effect of the pain?)* **Position**. *Which position causes or relieves pain? (Sitting, standing, supine, lateral, etc.)*

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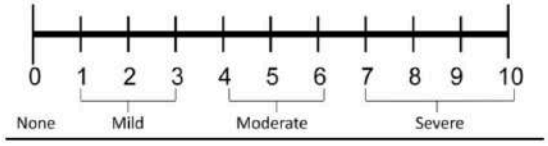
	Adjuvant. (*Which type of medication relieves the pain (Tylenol, Ibuprofen, etc.)? Does the use of heat or ice packs alleviate pain? What type of alternative therapy (massage, acupuncture) have you used before?)* **Does any movement, pressure (such as palpation) or other external factor make the problem better or worse? (***This can also include whether the symptoms relieve with rest.)*
Quality of Pain	__Throbbing __Dull __Aching __Burning __Crushing __Shooting __Others: _____ Description:
Region and Radiation	Location of the pain: _____ Does it radiate? __ Yes __ No

	Description:
Severity	
Timing	*When did the pain occur?* Time: _____ __ Sudden __ Gradual __ Others: _____ *How did it change since the onset?*

*Adapted from University of Florida, College of Medicine – Jacksonville, Pain and Management Initiative

Appendix E.6: Vital Signs and Physical Examination Monitoring

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Pilot Study among Normal Subjects on the Safety and Functionality of a Locally-Developed Trunk and Lower Limb Rehabilitation Robot

VITAL SIGNS AND PHYSICAL EXAMINATION MONITORING

PRE-STUDY EVALUATION MONITORING

Vital Signs:

Time: _____

Temperature:		Respiratory Rate:		Heart Rate:		Blood Pressure:	

Limb Measurements

Right Lower Limb		Left Lower Limb		Right Upper Limb		Left Upper Limb	

Trunk Measurement

Trunk	

Physical Examination:

Body System	Findings * (check one)	Comments (*required if Abnormal)	Clinically Significant* (Y/N)
Eyes	☐ Normal ☐ Abnormal* ☐ Not examined		
Head	☐ Normal ☐ Abnormal* ☐ Not examined		
Neck	☐ Normal ☐ Abnormal* ☐ Not examined		
Shoulders	☐ Normal ☐ Abnormal* ☐ Not examined		
Back	☐ Normal ☐ Abnormal* ☐ Not examined		
Arms	☐ Normal		

	☐ Abnormal* ☐ Not examined		
Hands	☐ Normal ☐ Abnormal* ☐ Not examined		
Chest	☐ Normal ☐ Abnormal* ☐ Not examined		
Abdomen	☐ Normal ☐ Abnormal* ☐ Not examined		
Waist	☐ Normal ☐ Abnormal* ☐ Not examined		
Hips	☐ Normal ☐ Abnormal* ☐ Not examined		
Upper Legs	☐ Normal ☐ Abnormal* ☐ Not examined		
Lower Legs	☐ Normal ☐ Abnormal* ☐ Not examined		
Feet	☐ Normal ☐ Abnormal* ☐ Not examined		
Skin	☐ Normal ☐ Abnormal* ☐ Not examined		

POST-STUDY EVALUATION MONITORING

Vitals Signs:

Time: _____

Temperature:		Respiratory Rate:		Heart Rate:		Blood Pressure:	

Physical Examination:

Body System	Findings * (check one)	Comments (*required if marked Abnormal)	Clinically Significant* (Y/N)

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Pilot Study among Normal Subjects on the Safety and Functionality of a Locally-Developed Trunk and Lower Limb Rehabilitation Robot

Eyes	☐ Normal ☐ Abnormal* ☐ Not examined		
Head	☐ Normal ☐ Abnormal* ☐ Not examined		
Neck	☐ Normal ☐ Abnormal* ☐ Not examined		
Shoulders	☐ Normal ☐ Abnormal* ☐ Not examined		
Back	☐ Normal ☐ Abnormal* ☐ Not examined		
Arms	☐ Normal ☐ Abnormal* ☐ Not examined		
Hands	☐ Normal ☐ Abnormal* ☐ Not examined		
Chest	☐ Normal ☐ Abnormal* ☐ Not examined		
Abdomen	☐ Normal ☐ Abnormal* ☐ Not examined		
Waist	☐ Normal ☐ Abnormal* ☐ Not examined		
Hips	☐ Normal ☐ Abnormal* ☐ Not examined		
Upper Legs	☐ Normal ☐ Abnormal* ☐ Not examined		
Lower Legs	☐ Normal ☐ Abnormal* ☐ Not examined		
Feet	☐ Normal ☐ Abnormal* ☐ Not examined		
Skin	☐ Normal ☐ Abnormal* ☐ Not examined		

Additional Notes: _____

_____

Vital Signs and Physical Examination checked by: _____

Appendix E.7: Magee's Normal Range of Motion

TAYÔ PROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Pilot Study among Normal Subjects on the Safety and Functionality of a Locally-Developed Trunk and Lower Limb Rehabilitation Robot

Subject Initials: _____ Subject ID: _____

Exam Date: _____

Range of Motion measurement

1. Back

Extension	Flexion
Degrees	Degrees

2. Lateral (Flexion)

Extension	Flexion
Degrees	Degrees

3. Hip (Backward Extension)

Extension	Flexion
Degrees	Degrees

4. Hip (Flexion)

Extension	Flexion
Degrees	Degrees

5. Hip (Adduction)

Extension	Flexion
Degrees	Degrees

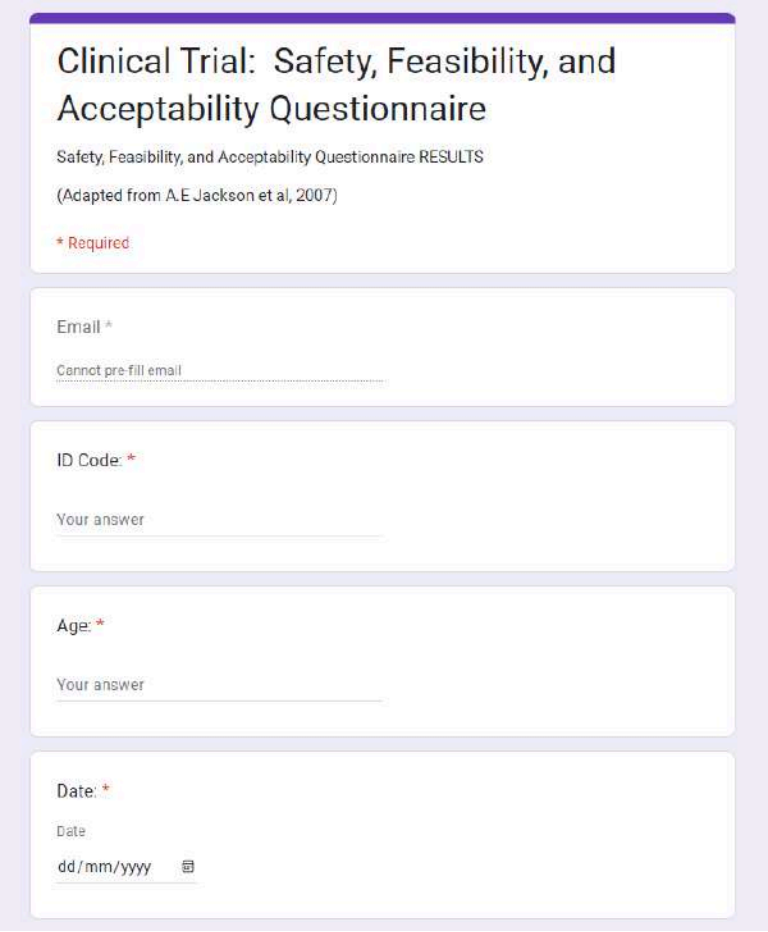
6. Hip (Abduction)

Extension	Flexion
Degrees	Degrees

7. Knee (Flexion)

Extension	Flexion
Degrees	Degrees

Appendix F: Safety Questionnaire Results Session



Clinical Trial: Safety, Feasibility, and Acceptability Questionnaire

Safety, Feasibility, and Acceptability Questionnaire RESULTS

(Adapted from A.E Jackson et al, 2007)

* Required

Email *

Cannot pre-fill email

ID Code: *

Your answer

Age: *

Your answer

Date: *

Date

dd/mm/yyyy

Clinical Trial: Safety, Feasibility, and Acceptability Questionnaire

Section 1: Appearance

The device's appearance is reassuring. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

The device's appearance is intimidating. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

Clinical Trial: Safety, Feasibility, and Acceptability Questionnaire

Section 2: Sound

The sound of the device distracted me. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

The sound of the device irritated me. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

The sound of the device was intimidating. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

Clinical Trial: Safety, Feasibility, and Acceptability Questionnaire

Section 3: Ease of Attachment

The device is easy to attach to my **trunk**. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

The device is easy to attach to my **hips**. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

The device is easy to attach to my **knees**. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

Clinical Trial: Safety, Feasibility, and Acceptability Questionnaire

Section 4: Comfort

Sitting on the device while it was **not moving** was comfortable. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

Sitting on the device while it was **moving** was comfortable. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

The device was comfortable. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

Clinical Trial: Safety, Feasibility, and Acceptability Questionnaire

Section 5: Ease of Release

Releasing my **trunk** from the device was easy. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

Releasing my **hips** from the device was easy. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

Releasing my **knees** from the device was easy. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

Clinical Trial: Safety, Feasibility, and Acceptability Questionnaire

Section 6: Security

My legs felt safe when using the device. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

I felt safe while using the device. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

Clinical Trial: Safety, Feasibility, and Acceptability Questionnaire

Section 7: Pain

Immediately after using the device, I did not feel pain. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

Few hours after using the device, I did not feel pain. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

The day after using the device, I did not feel pain. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

The harness was comfortable. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

Clinical Trial: Safety, Feasibility, and Acceptability Questionnaire

Section 8: Overall positive experience

The exercise tasks were fun. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

The exercise tasks were satisfying. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

The exercise tasks were interesting. *

	1	2	3	4	5	
Strongly Disagree	○	○	○	○	○	Strongly Agree

Clinical Trial: Safety, Feasibility, and Acceptability Questionnaire

Section 9: Comments

Comments:

Your answer

SAFETY QUESTIONS FOR STUDY OBJECTIVE NO.1 (DRAFT)

TAYÔPROJECT
Robotic Rehabilitation for the Trunk and Lower Extremity

A Controlled Study among Normal Subjects on the Safety and Functionality of a Locally-developed trunk and Lower limb rehabilitation robot

SAFETY TESTS

ROBOT SETUP

Assessed Risk	Occurrence (Did the assessed risk occurred?)	Risk Impact	Controlled Measures (Was risk controlled?)
	__ Yes __ No	__Negligible __Limited __Significant __Maximum	__ Yes __ No
	__ Yes __ No	__Negligible __Limited __Significant __Maximum	__ Yes __ No
	__ Yes __ No	__Negligible __Limited __Significant __Maximum	__ Yes __ No

ATTACHMENT POSITION OF HUMAN SUBJECT

Assessed Risk	Occurrence	Risk Impact	Controlled Measures
	__ Yes __ No	__Negligible __Limited __Significant __Maximum	__ Yes __ No
	__ Yes __ No	__Negligible __Limited __Significant __Maximum	__ Yes __ No
	__ Yes __ No	__Negligible __Limited __Significant __Maximum	__ Yes __ No

IRB No: Protocol Version and Date: Page:

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PASSIVE RANGE OF MOTION PROCEDURE

Assessed Risk	Occurrence	Risk Impact	Controlled Measures
	__ Yes __ No	__Negligible __Limited __Significant __Maximum	__ Yes __ No
	__ Yes __ No	__Negligible __Limited __Significant __Maximum	__ Yes __ No
	__ Yes __ No	__Negligible __Limited __Significant __Maximum	__ Yes __ No

Trunk Lateral Flexion (Right)	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:
Knee Flexion-Extension (Right)	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:
Knee Flexion-Extension (Left)	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:	BP: HR: O2sat:

Appendix G: Responsibilities of Project Proponents

Table 8: Responsibilities to be Fulfilled by the Researchers

Research Component	Researcher	Responsibility
Study Venue	Project Leader (DLSU) Technical Investigator (DLSU)	Ensure the research area is well ventilated, and provide respiratory hygiene supplies. Secure necessary permits for facility access for clinical study purposes.
Securing Liability Insurance	Project Leader (DLSU) Technical Investigator (DLSU)	Abide by the guidelines and procedure for securing funds to cover the study principal investigator, co investigator, and participants in the event that the insurance product is secured.
Participant Selection - Recruitment	Technical Investigator (DLSU)	Prepare necessary information and processes for social media posting. Content will be reviewed and authorized by the investigators. Application forms will be made through Google Forms.

Participant Selection - Screening	Principal Clinical Investigator (DLSMHSI-UMC) Co – Investigator (DLSMHS-UMC)	Provide digital application forms to be reviewed and selected by a medical doctor. A list of accepted and unaccepted applicants will be generated, which will include their names and contacts.
Participant Selection - Processing of Rejected and Accepted Applications	Technical Investigator (DLSU)	A thank- you email with a notice that they could not qualify will be sent to the participants in the exclusion list.
Participant Selection - Online Medical Interview	Principal Clinical Investigator (DLSMHSI-UMC) Co-Investigator (DLSMHSI-UMCI)	Give the list of participants and application forms to the doctor to set medical interview and clearance appointments. Provide explanation on the Ethical Considerations to the study

Participant Screening - Face to face Medical Interview and Clearance	The Medical Clinic South Luzon Doctor (TMC)	Perform Medical Interview and Clearance of the selected participants
Participant Briefing - Post-Interview	Technical Investigator (DLSU)	Secure confirmation forms from participants who are still willing to participate, which the doctor will stamp on. Send letters to the applicants regarding the decision and the retention policy.
Participant Briefing - Securing of Medical Insurance for Study Participants	Principal Clinical Investigator (DLSMHSI-UMC) Co-Investigator (DLSMHSI-UMC)	Provide the following information for the participants: goal of the study, functions to be tested on the device, their rights as study participants, releases that are requested by the study proponents, how their data privacy will be preserved, how insurance will be issued for them, and what the procedures to be followed are as participants. Collection of informed consent record and verification of the completeness of the informed consent form details that the willing applicants filled out. Fill the informed consent record with the study documents, and monitor acquisition of health cards.

	Technical Investigator (DLSU)	Assist the study participants with securing their insurance coverage for emergency care by enrollment in specific insurance products that cover them in case of severe adverse reactions. Secure payment details for each participant and generate insurance pending payments list.
Participant Briefing - Payment of Insurance for each Study Participant	Technical Investigator (DLSU)	File cash advance documents to cover insurance costs for all participants whose number is already known. Accept the insurance pending payments list. Pay the insurance of study participants using the project funds thru the cash advance filed prior to application process.
Participant Briefing - Issuance of Insurance Card Products	Technical Investigator (DLSU)	Verify the acquisition of notice of payment and temporary credentials for the participant's enrollment in the insurance program. Monitor the acquisition of the insurance card.

Participant Briefing - Setting of Appointments	Principal Clinical Investigator (DLSMHSI-UMC) Co – Investigator (DLSMHS-UMC)	Schedule meetings, including time, rT-PCR schedule, and provide campus entry passes for the participants.
Data Collection Phase - Infection Control for COVID-19 in Data Gathering Area	Project Leader (DLSU) Technical Investigator (DLSU)	Reschedule when alert level 3 is announced. Provide temperature checkers and a foot bath at the doorway to be changed regularly. Regularly disinfect surfaces, resources and equipment. Provide visual alerts to instruct participants and staff. Screening for SARS-Cov-2, keeping receipts and scanned result copies. Filling out contact tracing forms. All personnel and participants must observe minimum standard health protocols.
Data Collection Phase - Medical Assessment with Study Participant	Principal Clinical Investigator (DLSMHSI-UMC) Co-Investigator (DLSMHSI-UMCI)	Provide sanitation, check physical conditions of the participants such as vital signs, conduct check-ups, and safety checklists including the recording of adverse events and adverse device effects.

Data Collection Phase - Safety Device Evaluation	Technical Investigator (DLSU)	Maintenance and upkeep of robots including testing, writing of test record, repair of robots when necessary and keeping a log of work done. Conduct device tests to check that the device works correctly prior to the start of the data gathering section.
Data Collection Phase - Robot Configuration to Study Participant	Co-Investigator (DLSU-HSI) Technical Investigator (DLSU)	Setting up the robot to initial sitting position and configuring the bed height, length of thigh limb, and body alignment to the participant. The patient emergency stop button is given to the participant to stop the robot when uncomfortable.
Data Collection Phase - Range of Motion	Principal Clinical Investigator (DLSU-HSI) Co-Investigator (DLSU-HSI) Technical Investigator (DLSU)	Measure the trunk, hip, and knee range of motion.

Patient Evaluation Phase	Co-Investigator (DLSU-HSI) Technical Investigator (DLSU)	Monitor post-study vital signs, collection of patient digital evaluation forms, conduct video interviews to gather more information about the participant's experience and feedback.
Data Encryption	Principal Clinical Investigator (DLSU-HSI) Co-Investigator (DLSU-HSI) Technical Investigator (DLSU)	Re-encode data gathered into another group of spreadsheets to ensure deidentification. The new spreadsheets will only contain the participant number and no other personal information. This is done by the SRA and is double checked for accuracy by the co-investigator /PCI.
Data Processing	Principal Clinical Investigator (DLSU-HSI) Co-Investigator (DLSU-HSI) Technical Investigator (DLSU) Bio-Statistician (Contractual)	Enter data into the program intended to be used and generate the results. Bio-statistician is in charge of ensuring the appropriateness of the statistical methods used, as well as interpretation of results.

Writing of Study Reports	Principal Clinical Investigator (DLSU-HSI) Co-Investigator (DLSU-HSI) Technical Investigator (DLSU)	Writing of Study Reports including data interpretation, conclusions and recommendations.
	Project Leader (DLSU) Technical Investigator (DLSU)	Provide proof reading and comments on study reports with regards to form, grammar checks and readability of reports.
Presentation of Study Results	Project Leader (DLSU) Technical Investigator (DLSU)	Coordinate with Clinical Investigators for submission of study results to journals or conferences for publication. File the study results with Philippine FDA for reference purposes.

	Principal Clinical Investigator (DLSU-HSI) Co-Investigator (DLSU-HSI)	File the results with the DLSU-HSI for reference purposes.
Filing of Terminal Reports of TAYO Project	Project Leader (DLSU) Technical Investigator (DLSU)	Create the Terminal Report and narrative for the PCHRD who financed the study. File the necessary supportprivacy documents to the Terminal Report including: Study Reports, Audited Financial Statements
Data Protection – Physical Files or Disks	Project Leader (DLSU) Technical Investigator (DLSU)	Provide the Physical Facility to contain paper records of the study documents like application letters, printed or handwritten physician medical reports on study participants, survey records, session records. These are to be held in a locked fireproof filing cabinet of which the Project Leader is the only one who has access to. Documents will be kept for five years before getting destroyed via shredding or wet pulpification of paper and bleaching. Disks or hard disk drives will be kept also under lock and key.

		Files kept for study participants will be encrypted by the Project leader. These digital information will be classified into two. 1. Data that are personal identifiers will be kept for 5 years and be deleted from the disk using a secure delete feature. Only the principal Investigator can open encrypted files. 2. De-identified data like test results and study survey records will be kept for 20 years. 3. Financial project related documents such as financial audit data, coa reports will be kept by DLSU in perpetuity to ensure compliance with any demands from government auditors regarding government disbursements. Data will be held by CESDR and IBEHT to ensure future compliance. In-case the Project Leader retires/leaves the employment of DLSU, the keys will be turned over to the Director of the Institute of Biomedical Engineering and Health Technologies.

Appendix H: Liability Fund Coverage and Rules

Reserve Fund and Allocation for legal and damage expenses related to severe adverse reactions for study proponents.

Distribution of Liability and Risk

Study Proponents are in-charge of the following aspects of the clinical study.

Table 9: Liability Fund Coverage Roles of Study Personnel

Personnel	Duties	Data Privacy Liability	Adverse Reaction Liability
Principal Investigator	In-charge of screening all participants in-charge of participants care and welfare during the clinical study period	Yes	Yes
Co-investigator	In-charge of record keeping and screening all participants In-charge of participants care and welfare during the clinical study period		
Technical Investigator	In-charge of robot Operation and robot Safety before and During the Period of Clinical Study	No – has no access to health and private data identifiers of participants	Yes – Limited to the proper operation of the device based on programmed testing and periodic maintenance conducted on the unit.

Project Secretary	In-charge of Administrative Requirements, Payments and Securing Insurance for Participants with direct supervision from co-investigator on data handling	Yes – Has access to names of participants and their insurance related activities such as acceptance of cards that will be given by the Co-investigators to each participant.	No – No participation to data gathering activities or conduct of study
Physiotherapist	In-charge of participants care and well fare during the clinical study period	No – Access to Private Information	Yes

Insurance Coverage

A. We will pay on behalf of the “insured” those sums that the “insured” becomes legally obligated to pay as damages because of “bodily injury” or “property damage” arising out of any “clinical study incident” and which results from any performance of “human clinical trials” to which this insurance applies. The amount we will pay for damages is limited as described in section III – Limits of Insurance.

B. How This Insurance Applies

   This insurance applies to “bodily injury” and “property damage” only if:

   1. The “bodily injury” or “property damage” is caused by a “clinical study incident” which results from any performance of “clinical studies” that takes place in the “coverage territory”;

   2. The “bodily injury” or “property damage” did not occur before the Retroactive Date, if any, shown in the Policy Declarations or after the end of the policy period; and

   3. A claim for damages because of “bodily injury” or “property damage” is first made against any “insured”, in accordance with paragraph c. below.

C. A claim by a person or organization seeking damages will be deemed to have been made when notice of such “claim” is received and recorded by any insured or by us, whichever comes first.

All “claims” for damages because of "bodily injury" to the same person, including damages claimed by any person or organization for care, loss of services, or death resulting at any time from the "bodily injury", will be deemed to have been made at the time the first of those “claims” is made against any “insured”.

All “claims” for damages because of "property damage" causing loss to the same person or organization will be deemed to have been made at the time the first of those “claims” is made against any “insured”.

All “claims” for damages because of a single “clinical study incident” will be deemed to have been made at the time the first of those “claims” is made against any insured or against us, whichever is earlier.

D. Defense, Investigation or Settlement

1. We will have the right and duty to defend the “insured” against any “suit” seeking such damages as are set forth in subparagraph a.(1) above. We have the right to settle any such “suit.” However, we will have no duty to defend the insured against any “suit” seeking damages for “bodily injury” or “property damage” to which this insurance does not apply.

2. We may, at our discretion, investigate any “clinical study incident” and settle any “claim” or “suit” that may result.

3. Our right and duty to defend ends when we have used up the applicable Limit of Insurance in the payment of judgments or settlements to which this insurance applies.

No other obligation or liability to pay sums or perform acts or services is covered unless explicitly provided for under Supplementary Payments.

Insurance Exclusions

a. Expected or Intended Injury

“Bodily injury” or “property damage” expected or intended from the standpoint of the insured. This exclusion does not apply to “bodily injury” resulting from the use of reasonable force to protect persons or property; nor does this exclusion apply to “bodily injury” arising out of the known side effects of, or other adverse reactions to, any “pharmaceutical”, “biologic” or “medical device” on humans who are the subjects of your “human clinical trials”.

b. Contractual Liability

"Bodily injury" or "property damage" for which the "insured" is obligated to pay damages by reason of the assumption of liability in a contract or agreement. This exclusion does not apply to liability for damages that the insured would have in the absence of the contract or agreement.

c. Pollution

1. "Bodily injury" or "property damage" arising out of or in any way related to "pollutants", however caused; or

2. Any loss, cost or expense arising out of or attributable to any:

   a. Request, demand, order or statutory or regulatory requirement that any "insured" or others test for, monitor, clean up, remove, contain, treat, detoxify or neutralize, or in any way respond to or assess the effects of, "pollutants"; or

   b. "claim" or "suit" by or on behalf of a governmental authority for "damages" because of testing for, monitoring, cleaning up, removing, containing, treating, detoxifying, neutralizing or in any way responding to or assessing the effects of "pollutants".

d. Damage to Property

"Property damage" to:

1. Property you own, rent or occupy, including any costs or expenses incurred by you, or any other person, organization or entity, for repair, replacement, enhancement, restoration or maintenance of such property for any reason, including prevention of injury to a person or damage to another's property;

2. Premises you sell, give away or abandon, if the "property damage" arises out of any part of those premises;

3. Property loaned to you; or

4. Personal property in the care, custody or control of the insured

e. Damage to Your Product

"Property damage" to "your product" arising out of it or any part of it.

f. Damage to Your Work

"Property damage" to "your work" arising out of it or any part of it and included in the "product completed operations hazard."

g. Damage to Impaired Property or Property Not Physically Injured

"Property damage" to "impaired property" or property that has not been physically injured, arising out of:

1. A defect, deficiency, inadequacy or dangerous condition in "your product" or "your work"; or

2. A delay or failure by you or anyone acting on your behalf to perform a contract or agreement in accordance with its terms.

This exclusion does not apply to the loss of use of other property arising out of sudden and accidental physical injury to "your product" or "your work" after it has been put to its intended use.

h. Recall of Products, Work or Impaired Property

Damages claimed for any loss, cost or expense incurred by you or others for the loss of use, withdrawal, recall, inspection, repair, replacement, adjustment, removal or disposal of:

1. "Your product;"

2. "Your work"; or

3. "Impaired property;"

If such product, work, or property is withdrawn or recalled from the market or from use by any person or organization because of a known or suspected defect, deficiency, inadequacy or dangerous condition therein.

i. Personal injury

"Bodily injury" directly or indirectly caused by "personal injury".

j. Nuclear

Any liability arising out of or resulting directly or indirectly from ionizing radiation or contamination by radioactivity from any nuclear fuel, weapon, isotope, waste or other material whether occurring naturally or otherwise; the radioactive, toxic, explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof; or the storage, transport, assembly, disassembly, maintenance or operation of any nuclear weapon or nuclear component thereof.

k. Asbestos or Asbestos-Containing Products or Materials

Any "bodily injury", "property damage", loss, cost, expense or obligation arising out of or in any way related to the actual, alleged or threatened presence of or exposure to asbestos, asbestos-containing products or material or asbestos dust or fibers.

l. War Or Terrorism

"Bodily injury" or "property damage" however caused, arising, directly or indirectly, out of:

1. War, including undeclared or civil war; or

2. Warlike action by a military force, including action in hindering or defending against an actual or expected attack, by any government, sovereign or other authority using military personnel or other agents; or

3. Insurrection, rebellion, revolution, usurped power, or action taken by governmental authority in hindering or defending against any of these; or

4. "Terrorism", including any action taken in hindering or defending against an actual or expected incident of "terrorism" regardless of any other cause or event that contributes concurrently or in any sequence to the injury or damage.

This exclusion does not apply to acts of “terrorism” by a group opposed to testing “your product” on animals.

m. “Human Clinical Trial”: Clinical Hold

“Bodily injury” or “property damage” arising out of any “human clinical trial” which continues to be conducted after a clinical hold has been placed on that trial by the Food and Drug Administration (“FDA”) Philippines or by any corresponding regulatory body outside the Philippines, and before the FDA or applicable corresponding regulatory body has approved resumption of the trial. This exclusion does not apply to “bodily injury” or “property damage” caused by a “clinical study incident” that takes place before the clinical hold has been placed or after resumption of the “human clinical trial” has been approved.

n. Malpractice in “Human Clinical Trials”

Any malpractice, error, act or omission committed in the rendering of or failure to render professional services or advice by any medical doctor, resident, intern or other person or organization under contract or agreement with an “insured” to administer, review, oversee, direct, conduct, consult on, or perform services for or in connection with the “human clinical trial”. This includes the negligence of the investigator, institution or their servants or agents in failing to follow the protocol.

o. Abuse or Molestation

Actual, alleged, attempted, proposed or threatened sexual, physical or psychological abuse or molestation, including assault and battery, whether or not intended or expected from the standpoint of any “insured”, any perpetrator of the abuse

or molestation, or any other person or organization. This exclusion applies, but is not limited to, any “claim” alleging that the abuse or molestation was contributed to by the insured’s negligent or intentional: employment of; investigation of or failure to investigate; supervision of; reporting, or failing to report, to the proper authorities; retention of; or any other failure to prevent abuse or molestation by; any person or organization whose conduct is alleged to have caused or contributed to the abuse or molestation.

p. Prior Acts or Prior Notice

1. A “clinical study incident” that took place on or before the effective date of this policy, if any “insured” on or before the effective date of this policy knew or could have reasonably foreseen that such “clinical study incident” did or is reasonably expected to give rise to a “claim”; or

2. That has been the subject of any written notice given to a prior insurer on or before the effective date of this policy.

q. Willful and Intentional Non-Compliance

Any “insured’s” willful and intentional act of non-compliance with any rule or regulation promulgated by the United States Food and Drug Administration or by any corresponding regulatory body outside of the United States of America

r. Infringement or Advertising

Infringement of copyright, patent, trademark, trade secret or other intellectual property rights, including infringement of copyright, trade dress or slogan; and any “claim” alleging, based upon, arising out of or attributable to false or misleading advertising.

s. Cross Claims

Any “claim” brought or maintained by or on behalf of any current or former insured in any capacity against another current or former insured.

t. Discrimination

Discrimination, humiliation, or harassment of an individual on any basis including, but not limited to, race, creed, color, age, gender, national origin, religion, disability, marital status or sexual preference, or any other similar classification protected by law. This exclusion does not apply to “claims” arising from the adherence to the inclusion and/or exclusion criteria in a “human clinical trial”.

u. Criminal Violations

Any actual or alleged violation, by the “insured” or with the “insured’s” consent, of any law or regulation imposing criminal penalties or liability.

v. Silica Or Silica-Related Dust

1. "Bodily injury" or “property damage” arising, in whole or in part, out of the actual, alleged, threatened or suspected inhalation of, contact with, exposure to, existence of, presence of or ingestion of, "silica" or "silica-related dust".

2. Any loss, cost or expense arising, in whole or in part, out of the abating, testing for, monitoring, cleaning up, removing, containing, treating, detoxifying, neutralizing, remediating or disposing of, or in any way responding to or assessing the effects of, "silica" or "silica-related dust", by any insured or by any other person or entity.

For the purposes of this exclusion "silica" means silicon dioxide (occurring in crystalline, amorphous and impure forms), silica particles, silica dust or silica compounds. “Silica-related dust” means a mixture or combination of silica and other dust or particles.

w. Unauthorized Clinical Studies

“Clinical studies” not authorized expressly and in advance by the appropriate governmental regulatory authority or which are in clear violation of the conditions of its authorization.

x. Release of Confidential or Proprietary Information

Any liability arising out of or resulting from the actual or alleged improper release or misuse of confidential or proprietary information or protected health information.

y. Delay or Failure to Complete Clinical Studies

Any liability actually or allegedly arising out of or resulting from any delay in the delivery of or failure to complete any “clinical studies”.

Supplementary Payments

We will pay, with respect to any “claim” we investigate or settle, or any “suit” against an insured we defend:

a. All expenses we incur.

b. The cost of bonds to release attachments, but only for the bond amounts within the applicable Limit of Insurance. We do not have to furnish these bonds.

These payments will reduce the Limits of Insurance.

Who is Insured

1. The “Policy Holder”;

2. Your partners, directors, officers, members or managers, but only with respect to their duties to you in their capacity as a partner, director, officer, member or manager

3. Each of the following is also an insured:

    a. Your “employees”, other than you partners, directors, officers members, or managers, but only for acts within the scope of their employment by you or while performing duties related to the conduct of your business. However, none of these “employees” is an insured for:

        1. “Bodily injury”:

            a. To you, to the “policy holder’s” partners, directors, officers, members, managers or to a co-”employee” while in the course of his or her employment or performing duties related to the conduct of your business;

            b. To the spouse, child, parent, brother or sister of that co-”employee” as a consequence of subparagraph (1)(a) above; or

            c. For which there is any obligation to share damages with or repay someone else who must pay damages because of the injury described in subparagraphs (1)(a) or (b) above; or

            d. Arising out of his or her providing or failure to provide professional health care services.

            e. When participating in a “human clinical trial” as a clinical trial subject or participant.

        2. “Property damage” to property:

            a. Owned occupied or used by,

            b. Rented to, or in the care, custody or control of, or over which physical control is being exercised for any purpose by you, any of your “employees” or “policyholder’s” partners, directors, officers, members or managers.

            c. The Policyholder’s “clinical investigators”, “clinical trial contractors” and “site organizations” with whom the policyholder contracts to provide professional advice or demonstration of procedures in connection with a “human clinical trial” as outlined in the written protocol for such “human clinical trial” or in the planning, monitoring or review of a “human clinical trial”; but solely if the “policyholder” is required by written contract to provide such person or entity with this coverage and solely while such

person or entity is acting in such capacity and on the “Policyholder’s behalf. This coverage only applies to “human clinical trials” covered by the policy.

d. The “Policyholder’s” “scientific advisory board” when acting in his/her/its capacity as such, but only with respect to its liability for “clinical study incidents” arising out of the “Policyholder’s” “clinical trials”.

No person or organization is insured with respect to the conduct of any current or past partnership, joint venture or limited liability company that is not shown as a Named Insured in the Policy Declaration.

Limits of Insurance

1. The Limits of Insurance shown in the Policy Declarations and the rules below fix the most we will pay regardless of the number of insureds; “claims” made or "suits" brought; or persons or organizations making “claims” or bringing "suits".

2. The General Aggregate Limit is the most we will pay for all damages under this policy.

3. The Clinical Study Incident Limit is the most we will pay for the sum of all "bodily injury" and "property damage" “claims” arising out of a single “clinical study incident”.

The Limits of Insurance of this policy apply separately to each consecutive annual period and to any remaining period of less than 12 months, starting with the beginning of the policy period shown in the Policy Declarations, unless the policy period is extended after issuance for an additional period of less than 12 months. In that case, the additional period will be deemed part of the last preceding period for purposes of determining the Limits of Insurance.

Conditions

1. Duties in the Event of a “Clinical Study Incident”, Claim or “Suit”

a. You must see to it that we are notified as soon as practicable of a “clinical study incident” which may result in a claim. To the extent possible, notice should include:

1. How, when and where the “clinical study incident” took place;

2. The names and addresses of any injured person and witnesses; and

3. The nature and location of any injury or damage arising out of the “clinical study incident”. Notice of a “clinical study incident” is not notice of a “claim”.

b. If a “claim” is made or “suit” is brought against any insured, you must:

1. Immediately record the specifics of the “claim” or “suit” and the date received; and

2. Notify us as soon as practicable. You must see to it that we receive written notice of the “claim” or “suit” as soon as practicable.

c. You and any other involved insured must:

1. Immediately send us copies of any demands, notices, summonses or legal papers received in connection with the “claim” or “suit”;

2. Authorize us to obtain records and other information;

3. Cooperate with us in the investigation or settlement of the “claim” or defense against the “suit”; and

4. Assist us, upon our request, in the enforcement of any right against any person or organization which may be liable to the insured because of injury or damage to which this insurance may also apply.

d. No insured will, except at that insured’s own cost, voluntarily make a payment, assume any obligation, or incur any expense, other than for first aid, without our consent.

2. Conditions for Loss Settlement

The amount of any loss for which we may be liable under this policy shall be paid within thirty (30) days after proof of loss is received by us and ascertainment of the loss is made either by agreement between the “policyholder” and us or by arbitration; but if such ascertainment is not had or made within sixty (60) days after such receipt by the “policyholder” of the proof of loss, then the loss shall be paid within ninety (90) days after such receipt. Refusal or failure to pay the loss within the time prescribed herein will entitle the “policyholder” to collect interest on the proceeds of the policy for the duration of the delay at the rate twice the ceiling prescribed by the Philippine Monetary Board, unless such failure or refusal to pay is based on the ground that the claim is fraudulent.

3. Legal Action Against Us

No person or organization has a right under this coverage form:

a. To join us as a party or otherwise bring us into a “suit” asking for damages from an insured; or

b. To sue us on this coverage form unless all of its terms have been fully complied with.

A person or organization may sue us to recover on an agreed settlement or on a final judgment against an insured obtained after an actual trial; but we will not be liable for damages that are not payable under the terms of this coverage form or that are in excess of the applicable Limit of Insurance. An agreed settlement means a settlement and release of liability signed by us, the insured and the claimant or the claimant's legal representative.

4. Other Insurance

If other valid and collectible insurance is available to the insured for a loss we cover under this policy, we will have no duty to defend the insured against any "suit" if any other insurer has a duty to defend the insured against that "suit". If no other insurer defends, we will undertake to do so, but we will be entitled to the insured's rights against all those other insurers. We will only pay our share of the amount of the loss, if any, that exceeds the sum of such other insurance, whether such other insurance is stated to be primary, contributory, excess, contingent or otherwise, unless such other insurance is written only as specific excess insurance over the Limits of Insurance provided by this Policy.

5. Representations

By accepting this policy, you agree:

a. The statements in the Policy Declarations are accurate and complete;

b. Those statements are based upon representations you made to us; and

c. We have issued the policy in reliance upon your representations.

6. Examination of the Insured's Books and Records

We may examine and audit the insured's books and records as they relate to this policy at any time during the policy period, or any extensions, and for up to 3 years afterward.

7. Subrogation

In the event of any payment under this policy, we shall be subrogated to the extent of such payment to all the "insureds'" rights of recovery. The "insureds" shall execute all papers required and shall do everything necessary to secure and preserve such rights, including the execution of such documents necessary to enable us effectively to bring suit or otherwise pursue subrogation rights in the name of the "insureds". The "insureds" shall do nothing to prejudice our subrogation rights.

8. Transfer of Your Rights And Duties Under This Policy

Neither you nor any other insured under this policy can assign or transfer any interest in the policy or any of the rights and duties thereunder, without our prior written consent. This includes any “claim” or cause of action against us, whether in contract, tort or otherwise, that relates to or arises in connection with this policy, including any “claim” or cause of action for bad faith.

9. Cancellation and Renewal

a. Cancellation

1. The “policyholder” may cancel this policy by mailing or delivering to us written notice stating when the cancellation will be effective.

2. This Policy shall not be canceled by us except upon prior notice thereto to the “policyholder”, and no notice of cancellation shall be effective unless it is based on the occurrence, after the effective date of this Policy, of one or more of the following:

a. non-payment of premium;

b. conviction of the Insured of a crime arising out of acts increasing the hazards insured against;

c. discovery of fraud or material misrepresentation;

d. discovery of wilful or reckless acts of omissions increasing the hazards insured against;

e. physical changes in the property insured which result in the property becoming uninsurable;

f. discovery of other insurance coverage that makes the total insurance in excess of the value of the property insured; or

g. a determination by the Insurance Commissioner that the continuation of this Policy would violate or would place us in violation of the Insurance Code.

All notices of cancellation shall be in writing, mailed or delivered to the “policyholder” at the address shown in this Policy and shall state (i) which of the grounds set forth in this provision is relied upon, and (ii) that, upon written request of the “policyholder”, we will furnish the facts on which the cancellation is based.

3. If we cancel, the earned premium will be computed pro-rata. If the “policyholder” cancels, any refund due may be less than pro-rata. Premium adjustment may be made at the time cancellation becomes effective. Our check

or the check of our representative mailed to the “policyholder” will be sufficient proof of any refund of premium due.

b. Renewal

Unless we, at least forty-five (45) days in advance of the end of the policy period, mail or deliver to the Insured at the address shown in the Policy Declarations, a notice of intention not to renew this policy or condition the renewal upon reduction of limits or elimination of coverages, the insured shall be entitled to renew this policy upon payment of the premium due on the effective date of renewal.

10. Sole Agent

By accepting this policy, you:

a. Authorize the “policyholder” to act on its own behalf and that of all other Named Insureds with respect to:

1. The giving and receipt of notice of cancellation or non-renewal;

2. Election of any Extended Reporting Period provided under this policy; and

3. The receipt of any return premium that may become payable under this policy;

b. Authorize us to accept payment of any premium, at our discretion, only from the “policyholder”; and

c. Agree that:

1. All Named Insureds are jointly and severally responsible for the payment of all premium; and

2. Our acceptance of payment of premium only from the “policyholder” does not relieve any other Named Insured from responsibility for any payment of premium the “policyholder” fails to make.

11. Alteration, Assignment and Headings

No change in, modification of, or assignment of interest under this policy shall be effective except when made by a written endorsement to this policy which is approved and issued by us with your conformity. The titles and headings to the various parts, sections, subsections and endorsements of this policy are included solely for ease of reference and do not in any way limit, expand or otherwise affect the provisions of such parts, sections, subsections or endorsements.

12. Assistance and Cooperation

The insured shall cooperate with us and provide to us all information and assistance which we reasonably request including without limitation attending hearings, depositions and trials and assisting in affecting settlements, securing and giving evidence, obtaining the attendance of witnesses and conducting the defense of any “claim” covered by this policy. The insured shall immediately forward to us at the address indicated in the Policy Declarations every demand, notice, summons, or other process or pleadings received by the insured or its representatives. The insured shall do nothing that may prejudice our position.

13. Dispute Resolution

All differences as to the amount of any loss covered by this Policy shall be settled by final, binding arbitration under the arbitration rules of the Philippine Dispute Resolution Center, Inc. (PDRCI) in force at the time of arbitration. The dispute shall be referred to an arbitrator to be appointed by the parties in difference, or if they cannot agree upon a single arbitrator, a panel of three (3) arbitrators (“the Panel”) shall conduct the arbitration. Each party shall have the right to appoint one (1) member of the Panel, with the third member to be mutually agreed by the two (2) Panel members appointed by the parties or appointed in accordance with the Rules of the PDRCI. The venue of arbitration shall be in the Philippines and the arbitration proceedings shall be conducted in the English language. Any lawsuit to enforce the arbitration award in the Philippines shall be filed with the competent court of Makati City, Philippines, to the exclusion of all other courts.

14. Governing Law

This Policy shall be governed by and construed in accordance with the law of Philippines.

15. Suit Against the Company

If a “claim” is made and rejected and an action or suit is not commenced either in the Insurance Commission

or in any court of competent jurisdiction within twelve (12) months from receipt of notice of such rejection or,

in case of arbitration taking place as provided herein, within twelve (12) months after due notice of the award made by the arbitrator or arbitrators, then the “claim” shall for all purposes be deemed to have been abandoned and shall not thereafter be recoverable hereunder.

16. Article 1250 of the Civil Code

It is hereby declared and agreed that the provision of Article 1250 of Republic Act No. 386, as amended, otherwise known as the Civil Code of the Philippines, which reads: “In case of extraordinary inflation or deflation of the currency stipulated should intervene, the value of the currency at the time of the establishment of the obligation shall be the basis of payment”, shall not apply in determining the extent of liability under the provisions of this policy.

Appendix I: Summary of Tests Conducted on the Unit

Republic of the Philippines
Department of Science and Technology
Advanced Science and Technology Institute
in collaboration with
Electronic Industries Association of the Philippines Inc.
ELECTRONICS PRODUCT DEVELOPMENT CENTER
EPDC Bldg., MIRDC Cpd., Gen. Santos Ave., Bicutan, Taguig City
www.epdc.dost.gov.ph

Product Safety Testing Laboratory

Product Safety Test Report

TAYÔ Trunk and Lower Limb Rehabilitation Robot

Prepared for

DLSU – Institute of Biomedical Engineering and Health Technologies
2401 Taft Ave, Malate, Manila, 1004 Metro Manila, Philippines

Date Received: November 9, 2021
Test Start Date: November 9, 2021
Test Completed: November 18, 2021

Test Report Number: PSL-2111-017
Issue Date: November 19, 2021

Test Performed by:	Checked by:	Approved by:
RAFFY B. APOSTOL	JULIUS T. SOLOMON	VICTOR B. GRUET
Product Safety Engineer	EMC & Test Engineering Head	Operations Head

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INPUT TEST

Equipment Used

Manufacturer	Description	Model	TEID	Serial Number
Hioki	Power Meter	PW3335	PW569	181028569
Preen	AC Source	AFC-11005G	PS904	F319040085

Test Data

Input Voltage	Frequency	Measured Current	Measured Power	Loading Condition
162 V	60 Hz	0.3899 A	62.29 W	Standby Mode
198 V	60 Hz	0.3498 A	69.37 W	Standby Mode
237.6 V	60 Hz	0.3263 A	77.62 W	Standby Mode
290.4 V	60 Hz	0.3069 A	89.17 W	Standby Mode
162 V	50 Hz	0.3916 A	63.55 W	Standby Mode
198 V	50 Hz	0.3560 A	70.63 W	Standby Mode
237.6 V	50 Hz	0.3309 A	78.72 W	Standby Mode
290.4 V	50 Hz	0.3079 A	89.50 W	Standby Mode

Input Voltage	Frequency	Measured Current	Measured Power	Loading Condition	Remarks
162 V	60 Hz	1.4938 A	232.88 W	Full Load	Motor is Working
198 V	60 Hz	1.1545 A	228.63 W	Full Load	Motor is Working
237.6 V	60 Hz	0.9882 A	239.28 W	Full Load	Motor is Working
290.4 V	60 Hz	0.8090 A	234.94 W	Full Load	Motor is Working
162 V	50 Hz	1.4241 A	230.82 W	Full Load	Motor is Working
198 V	50 Hz	1.2172 A	241.24 W	Full Load	Motor is Working
237.6 V	50 Hz	1.0468 A	248.85 W	Full Load	Motor is Working
290.4 V	50 Hz	0.8927 A	259.37 W	Full Load	Motor is Working

Compliance Criteria

- Input current and power shall not go beyond 110% of its rating upon full load condition.

Figure 1. Input Test Setup

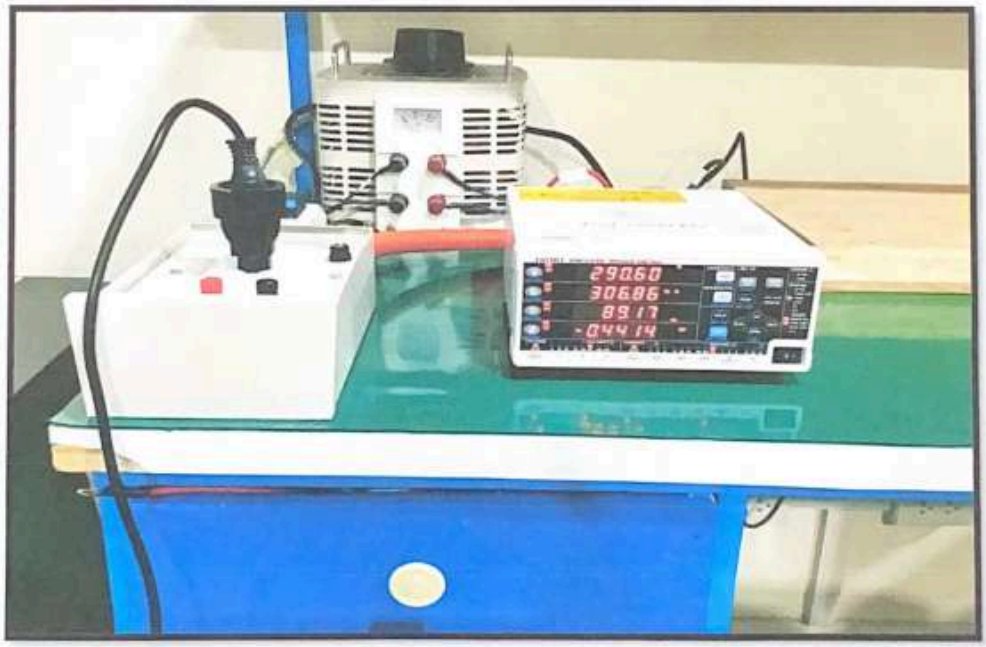

Figure 2. Input Test Power Meter reading

GROUND CONTINUITY TEST

Equipment Used

Manufacturer	Description	Model	TEID	Serial Number
ED&D	Ground Impedance Tester	GC 2000	GI337	N12490337

Test Data

Applied Current	Duration	Verdict
25 A	60 seconds	Pass

Compliance Criteria

- At the end of the test, the resistance of the protective bonding conductor, calculated from the voltage drop shall not exceed 0.1Ω and the protective bonding conductor shall not be damaged.

Remarks:

- Protective earthing conductor should have sufficient current-carrying capacity. Wires and terminals for protective bonding conductor must be suitable to handle at least 16 Amperes.
- Accessible conductive parts that might assume a hazardous voltage in the event of a single fault shall be reliably connected to the main protective earthing terminal of the equipment

Figure 3. Ground Continuity Test Setup

Figure 4. Ground Continuity Tester reading

---------- END OF REPORT ----------

Republic of the Philippines
Department of Science and Technology
Advanced Science and Technology Institute
in collaboration with
Electronic Industries Association of the Philippines Inc.
ELECTRONICS PRODUCT DEVELOPMENT CENTER
EPDC Bldg., MIRDC Cpd., Gen. Santos Ave., Bicutan, Taguig City
www.epdc.dost.gov.ph

EMC Testing Laboratory

Verification Data

Applicant	:	DLSU – IBEHT
Address	:	DLSU Laguna Campus, LTI Spine Road, Laguna Blvd, Biñan, Laguna
Product Description	:	Trunk and Lower Limb Rehabilitative Device
Model No.	:	Trunk and Lower Limb Rehabilitative Device
Serial Number	:	1
Hardware Rev.	:	IBTP001
Software Rev.	:	0.6.0
		1.2.0
Standards	:	**CISPR 11:2016, EN 55011 2017:** Conducted Emission **CISPR 11:2016, EN 55011 2017:** Radiated Emission **IEC 61000-4-2:2008:** Electrostatic Discharge **IEC 61000-4-3:2010:** Radiated Immunity **IEC 61000-4-5:2014:** Surge Transients **IEC 61000-4-6:2013:** Conducted Immunity **IEC 61000-4-8:2019:** Power Frequency Magnetic Field **IEC 61000-4-11:2020:** Voltage Dips, Short Interruptions and Variations
Operating Conditions	:	Mode 1 – 4 Linear Actuators Mode 2 – 3 Stepper Motor
Date of Receipt	:	October 28, 2021
Date of Test	:	October 28, 2021 to November 09, 2021
Issue Date	:	November 19, 2021
Result	:	**Radiated Emission – Compliant Class A** **Conducted Emission – Compliant Class A** **Electrostatic Discharge – Compliant Criterion C** **Radiated Immunity – Compliant Criterion A** **Surge Transients – Compliant Criterion A** **Conducted Immunity – Compliant Criterion A** **Power Frequency Magnetic Field – Compliant Criterion A** **Voltage Dips, Short Interruptions and Variations - Compliant Criterion B**
Test Performed by	:	Hans Patrick Biaco (EMC Test Engineer)
Reviewed by	:	Julius T. Solomon (Head, EMC and Test Engineering)
Approved by	:	Victor Garet (Operation Manager)

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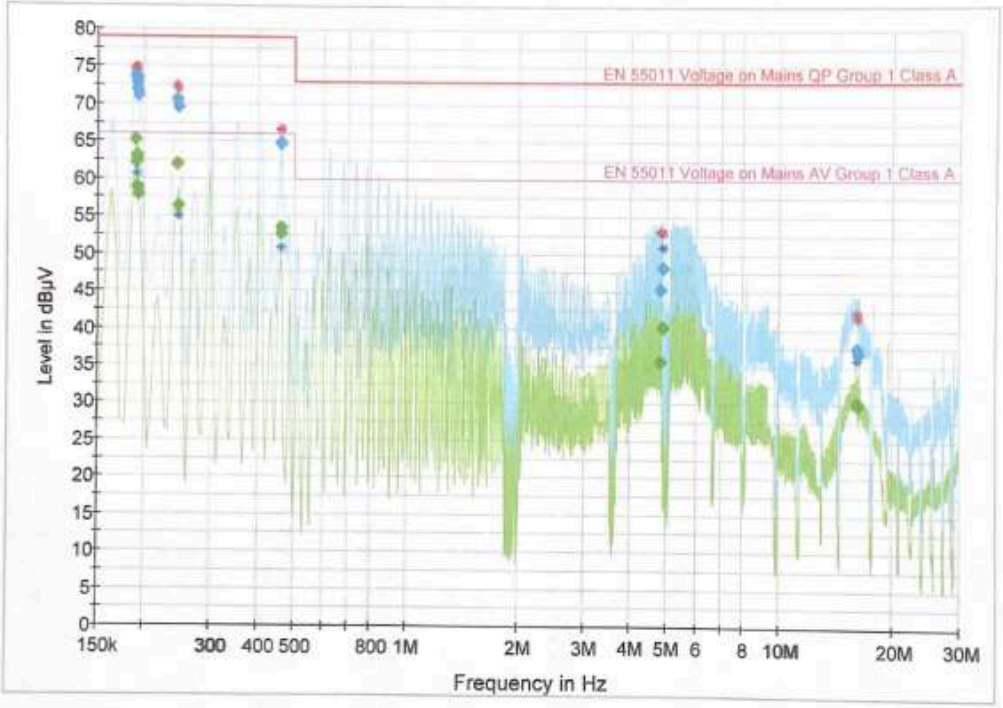
Conducted Emission Test Result

Site: Shielded Room	Date of Test: November 03, 2021
Limit: CISPR 11 Class A Group 1	**Time:** 12:20 PM
Probe: ENV216	**Test Performed By:** Hans Patrick Biaco
EUT: Trunk and Lower Limb Rehabilitative Device	**Polarity:** Line1
	Power: AC 230V, 60Hz
Temperature: 26.9°C	**Humidity:** 43%
Test Mode: Mode 1 – 4 Linear Actuators	
Test Result: Passed	**Remarks**: Only 1 power supply used

Full Spectrum



Critical_Freqs

Frequency (MHz)	MaxPeak (dBµV)	Average (dBµV)	Limit (dBµV)	Margin (dB)	Bandwidth (kHz)	Line	Filter	Corr. (dB)	Comment
0.189500	74.96	61.98	79.00	4.04	9.000	L1	ON	9.6	12:26:41 PM - 11/3/2021
0.190000	74.50	---	79.00	4.50	9.000	L1	ON	9.6	12:26:41 PM - 11/3/2021
0.190300	72.90	---	79.00	6.10	9.000	L1	ON	9.6	12:26:41 PM - 11/3/2021
0.190400	74.91	---	79.00	4.09	9.000	L1	ON	9.6	12:26:41 PM - 11/3/2021
0.190500	74.32	60.58	79.00	4.68	9.000	L1	ON	9.6	12:26:41 PM - 11/3/2021
0.191600	71.66	58.65	79.00	7.34	9.000	L1	ON	9.6	12:26:41 PM - 11/3/2021
0.243500	72.53	---	79.00	6.47	9.000	L1	ON	9.6	12:26:41 PM - 11/3/2021
0.245300	72.02	54.98	79.00	6.98	9.000	L1	ON	9.6	12:26:41 PM - 11/3/2021
0.460200	66.74	50.84	79.00	12.26	9.000	L1	ON	9.6	12:26:41 PM - 11/3/2021
0.461400	66.66	---	79.00	12.34	9.000	L1	ON	9.6	12:26:41 PM - 11/3/2021
4.802900	53.16	---	73.00	19.84	9.000	L1	ON	9.6	12:26:41 PM - 11/3/2021
4.899600	52.94	50.95	73.00	20.06	9.000	L1	ON	9.6	12:26:41 PM - 11/3/2021
16.119200	42.34	35.94	73.00	30.66	9.000	L1	ON	9.7	12:26:41 PM - 11/3/2021
16.172000	41.65	---	73.00	31.35	9.000	L1	ON	9.7	12:26:41 PM - 11/3/2021

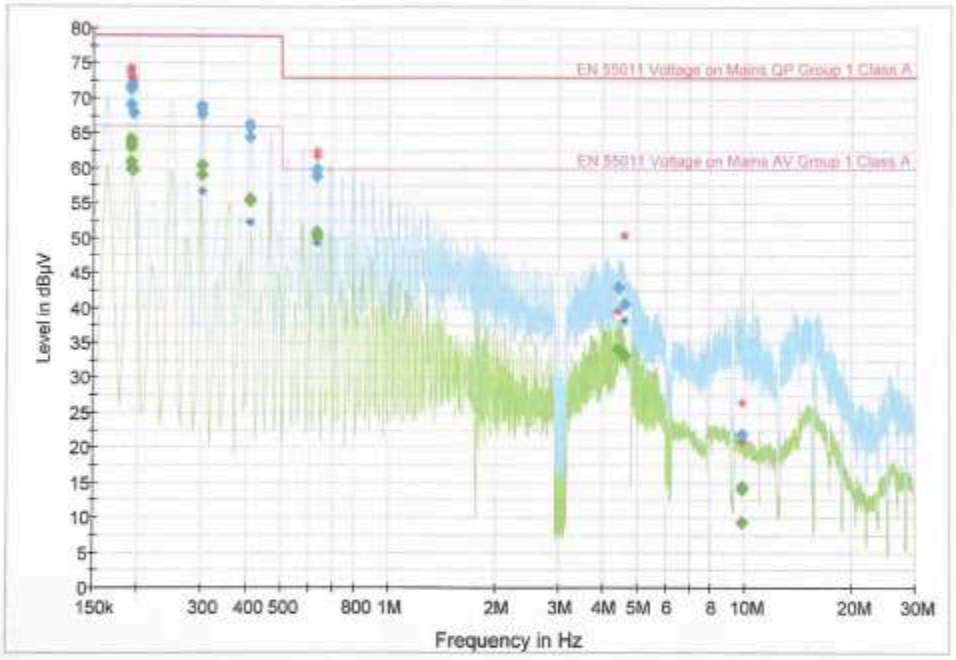
Final_Result

Frequency (MHz)	QuasiPeak (dBµV)	Average (dBµV)	Limit (dBµV)	Margin (dB)	Bandwidth (kHz)	Line	Filter	Corr. (dB)	Comment
0.189500	---	65.28	66.00	0.72	9.000	L1	ON	9.6	12:26:49 PM - 11/3/2021
0.189500	73.80	---	79.00	5.20	9.000	L1	ON	9.6	12:26:49 PM - 11/3/2021
0.190000	---	62.28	66.00	3.72	9.000	L1	ON	9.6	12:26:55 PM - 11/3/2021
0.190000	71.99	---	79.00	7.01	9.000	L1	ON	9.6	12:26:55 PM - 11/3/2021
0.190300	---	58.99	66.00	7.01	9.000	L1	ON	9.6	12:27:02 PM - 11/3/2021
0.190300	72.95	---	79.00	6.05	9.000	L1	ON	9.6	12:27:01 PM - 11/3/2021
0.190400	---	63.17	66.00	2.83	9.000	L1	ON	9.6	12:27:08 PM - 11/3/2021
0.190400	73.76	---	79.00	5.24	9.000	L1	ON	9.6	12:27:08 PM - 11/3/2021
0.190500	---	63.04	66.00	2.96	9.000	L1	ON	9.6	12:27:14 PM - 11/3/2021
0.190500	73.34	---	79.00	5.66	9.000	L1	ON	9.6	12:27:14 PM - 11/3/2021
0.191600	---	57.91	66.00	8.09	9.000	L1	ON	9.6	12:27:20 PM - 11/3/2021
0.191600	71.20	---	79.00	7.80	9.000	L1	ON	9.6	12:27:20 PM - 11/3/2021
0.243500	---	62.01	66.00	3.99	9.000	L1	ON	9.6	12:27:26 PM - 11/3/2021
0.243500	70.64	---	79.00	8.36	9.000	L1	ON	9.6	12:27:26 PM - 11/3/2021
0.245300	---	56.46	66.00	9.54	9.000	L1	ON	9.6	12:27:32 PM - 11/3/2021
0.245300	69.59	---	79.00	9.41	9.000	L1	ON	9.6	12:27:32 PM - 11/3/2021
0.460200	---	52.72	66.00	13.28	9.000	L1	ON	9.6	12:27:39 PM - 11/3/2021
0.460200	64.76	---	79.00	14.24	9.000	L1	ON	9.6	12:27:38 PM - 11/3/2021
0.461400	---	53.57	66.00	12.43	9.000	L1	ON	9.6	12:27:45 PM - 11/3/2021
0.461400	64.81	---	79.00	14.19	9.000	L1	ON	9.6	12:27:44 PM - 11/3/2021
4.802900	---	35.68	60.00	24.32	9.000	L1	ON	9.6	12:27:52 PM - 11/3/2021
4.802900	45.28	---	73.00	27.72	9.000	L1	ON	9.6	12:27:52 PM - 11/3/2021
4.899600	---	40.31	60.00	19.69	9.000	L1	ON	9.6	12:27:58 PM - 11/3/2021
4.899600	48.26	---	73.00	24.74	9.000	L1	ON	9.6	12:27:58 PM - 11/3/2021
16.119200	---	30.29	60.00	29.71	9.000	L1	ON	9.7	12:28:04 PM - 11/3/2021
16.119200	37.57	---	73.00	35.43	9.000	L1	ON	9.7	12:28:04 PM - 11/3/2021
16.172000	---	29.95	60.00	30.05	9.000	L1	ON	9.7	12:28:10 PM - 11/3/2021
16.172000	36.83	---	73.00	36.17	9.000	L1	ON	9.7	12:28:10 PM - 11/3/2021

Note: Measure Level (dBµV) = Reading Level (dBµV) + Factor (dB). Factor (dB) = Cable Loss (dB) + LISN Factor (dB).

Site: Shielded Room	Date of Test: November 03, 2021
Limit: CISPR 11 Class A Group 1	**Time:** 2:50 PM
Probe: ENV216	**Test Performed By:** Hans Patrick Biaco
EUT: Trunk and Lower Limb Rehabilitative Device	**Polarity:** Neutral
	Power: AC 230V, 60Hz
Temperature: 26.9°C	**Humidity:** 43%
Test Mode: Mode 1 – 4 Linear Actuators	
Test Result: Passed	**Remarks:** Only 1 power supply used

Full Spectrum



Critical_Freqs

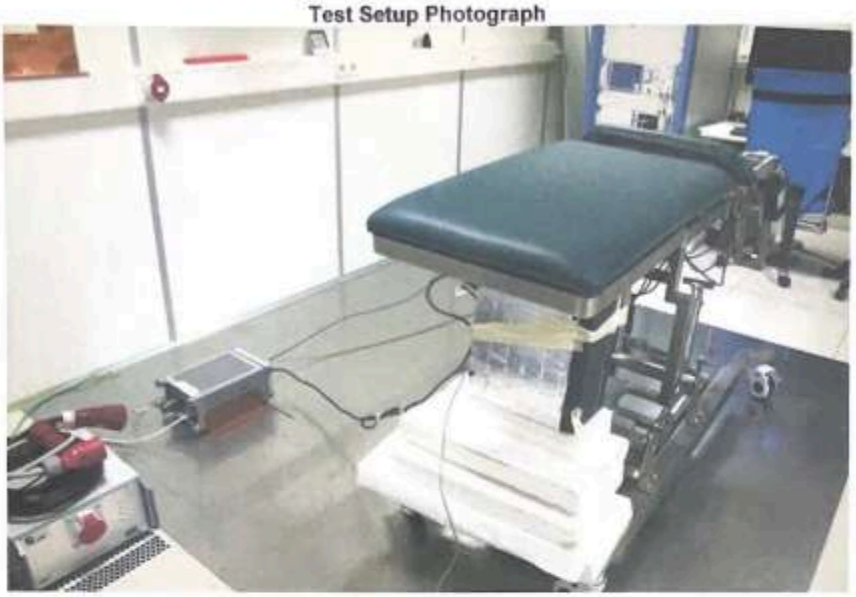
Frequency (MHz)	MaxPeak (dBµV)	Average (dBµV)	Limit (dBµV)	Margin (dB)	Bandwidth (kHz)	Line	Filter	Corr. (dB)	Comment
0.189700	73.78	—	79.00	5.22	9.000	N	ON	9.6	2:52:53 PM - 11/3/2021
0.189700	74.44	—	79.00	4.56	—	N	ON	9.6	1:38:46 PM - 11/3/2021
0.190000	73.12	59.80	79.00	5.88	9.000	N	ON	9.6	2:52:53 PM - 11/3/2021
0.190600	74.10	60.78	79.00	4.90	9.000	N	ON	9.6	2:52:53 PM - 11/3/2021
0.190900	74.45	60.02	79.00	4.55	9.000	N	ON	9.6	2:52:53 PM - 11/3/2021
0.193400	72.69	—	79.00	6.31	9.000	N	ON	9.6	2:52:53 PM - 11/3/2021
0.298800	69.10	—	79.00	9.90	9.000	N	ON	9.6	2:52:53 PM - 11/3/2021
0.299200	68.80	56.68	79.00	10.20	9.000	N	ON	9.6	2:52:53 PM - 11/3/2021
0.407100	66.00	52.31	79.00	13.00	9.000	N	ON	9.6	2:52:53 PM - 11/3/2021
0.407600	66.56	—	79.00	12.44	9.000	N	ON	9.6	2:52:53 PM - 11/3/2021
0.626200	62.58	—	73.00	10.42	9.000	N	ON	9.6	2:52:53 PM - 11/3/2021
0.626800	61.81	49.45	73.00	11.19	9.000	N	ON	9.6	2:52:53 PM - 11/3/2021
4.404900	39.54	—	73.00	33.46	9.000	N	ON	9.6	2:52:53 PM - 11/3/2021
4.611200	50.46	38.15	73.00	22.54	9.000	N	ON	9.6	2:52:53 PM - 11/3/2021
9.839000	20.88	—	73.00	52.12	9.000	N	ON	9.7	2:52:53 PM - 11/3/2021
9.845900	26.49	21.66	73.00	46.51	9.000	N	ON	9.7	2:52:53 PM - 11/3/2021

Final_Result

Frequency (MHz)	QuasiPeak (dBµV)	Average (dBµV)	Limit (dBµV)	Margin (dB)	Bandwidth (kHz)	Line	Filter	Corr. (dB)	Comment
0.189700	—	63.57	66.00	2.43	9.000	N	OFF	9.6	2:53:00 PM - 11/3/2021
0.189700	71.83	—	79.00	7.17	9.000	N	OFF	9.6	2:53:00 PM - 11/3/2021
0.190000	—	64.14	66.00	1.86	9.000	N	OFF	9.6	2:53:11 PM - 11/3/2021
0.190000	71.73	—	79.00	7.27	9.000	N	OFF	9.6	2:53:11 PM - 11/3/2021
0.190600	—	60.95	66.00	5.05	9.000	N	OFF	9.6	2:53:17 PM - 11/3/2021
0.190600	69.17	—	79.00	9.83	9.000	N	OFF	9.6	2:53:17 PM - 11/3/2021
0.190900	—	62.97	66.00	3.03	9.000	N	OFF	9.6	2:53:23 PM - 11/3/2021
0.190900	71.27	—	79.00	7.73	9.000	N	OFF	9.6	2:53:23 PM - 11/3/2021
0.193400	—	59.73	66.00	6.27	9.000	N	OFF	9.6	2:53:29 PM - 11/3/2021
0.193400	67.96	—	79.00	11.04	9.000	N	OFF	9.6	2:53:28 PM - 11/3/2021
0.298800	—	60.50	66.00	5.50	9.000	N	OFF	9.6	2:53:34 PM - 11/3/2021
0.298800	68.71	—	79.00	10.29	9.000	N	OFF	9.6	2:53:34 PM - 11/3/2021
0.299200	—	59.17	66.00	6.83	9.000	N	OFF	9.6	2:53:40 PM - 11/3/2021
0.299200	67.72	—	79.00	11.28	9.000	N	OFF	9.6	2:53:40 PM - 11/3/2021
0.407100	—	55.65	66.00	10.35	9.000	N	OFF	9.6	2:53:46 PM - 11/3/2021
0.407100	64.51	—	79.00	14.49	9.000	N	OFF	9.6	2:53:46 PM - 11/3/2021
0.407600	—	55.33	66.00	10.67	9.000	N	OFF	9.6	2:53:52 PM - 11/3/2021
0.407600	66.05	—	79.00	12.95	9.000	N	OFF	9.6	2:53:52 PM - 11/3/2021
0.626200	—	50.93	60.00	9.07	9.000	N	OFF	9.6	2:53:58 PM - 11/3/2021
0.626200	59.97	—	73.00	13.03	9.000	N	OFF	9.6	2:53:58 PM - 11/3/2021
0.626800	—	50.28	60.00	9.72	9.000	N	OFF	9.6	2:54:04 PM - 11/3/2021
0.626800	59.02	—	73.00	13.98	9.000	N	OFF	9.6	2:54:04 PM - 11/3/2021
4.404900	—	34.08	60.00	25.92	9.000	N	OFF	9.6	2:54:10 PM - 11/3/2021
4.404900	42.89	—	73.00	30.11	9.000	N	OFF	9.6	2:54:09 PM - 11/3/2021
4.611200	—	33.25	60.00	26.75	9.000	N	OFF	9.6	2:54:15 PM - 11/3/2021
4.611200	40.67	—	73.00	32.33	9.000	N	OFF	9.6	2:54:15 PM - 11/3/2021
9.839000	—	14.09	60.00	45.91	9.000	N	OFF	9.7	2:54:21 PM - 11/3/2021
9.839000	21.91	—	73.00	51.09	9.000	N	OFF	9.7	2:54:21 PM - 11/3/2021
9.845900	—	9.26	60.00	50.74	9.000	N	OFF	9.7	2:54:27 PM - 11/3/2021
9.845900	14.44	—	73.00	58.56	9.000	N	OFF	9.7	2:54:27 PM - 11/3/2021

Note: Measure Level (dBµV) = Reading Level (dBµV) + Factor (dB). Factor (dB) = Cable Loss (dB) + LISN Factor (dB).

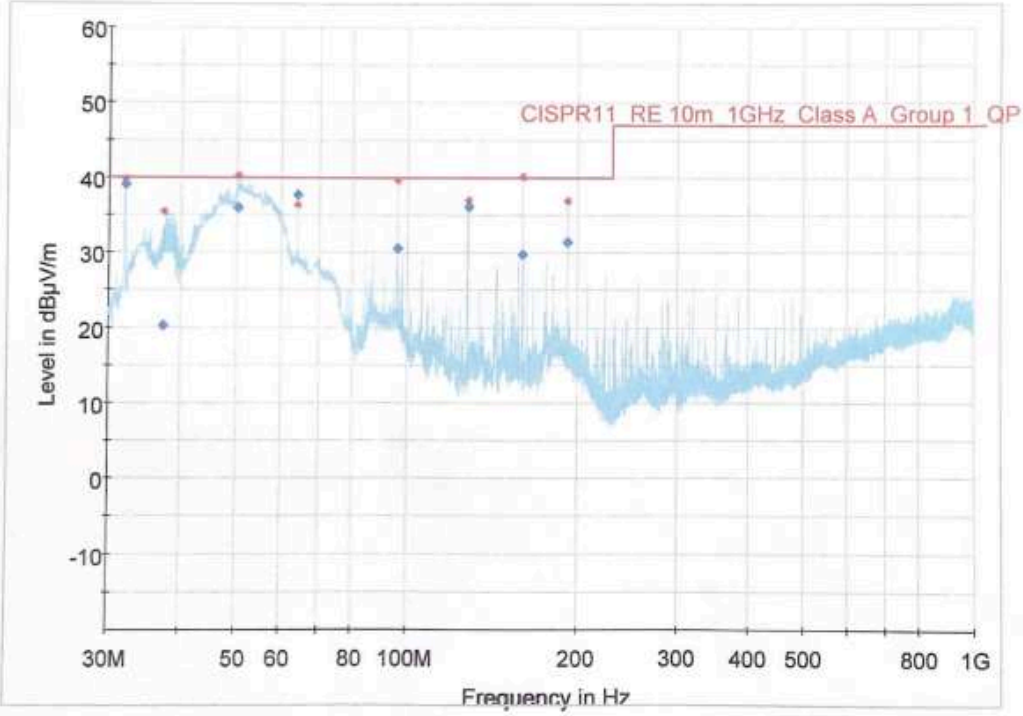
Test Setup Photograph



Radiated Emission Test Result

Site: SAC	**Date of Test:** November 02, 2021
Limit: CISPR11 RE 10m 1GHZ Class A Group 1	**Time:** 8:00 AM
Probe: 3142E	**Test Performed By:** Hans Patrick Biaco
EUT: Trunk and Lower Limb Rehabilitative Device	**Polarity:** Vertical and Horizontal
	Power: AC 230V, 60Hz
Temperature: 26.4°C	**Humidity:** 36%
Test Mode: Mode 2 – 3 Stepper Motor	
Test Result: Passed	**Remarks:** Added shielding to stepper motor and to the system

Full Spectrum



Critical_Freqs

Frequency (MHz)	MaxPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB)	Comment
31.98	39.74	40.00	0.26	100.0	V	0.0	-28.1	11:31:15 AM - 11/2/2021
37.33	35.44	40.00	4.56	190.0	V	0.0	-31.5	12:54:20 PM - 11/2/2021
50.37	40.30	40.00	-0.30	231.0	V	177.0	-35.8	12:31:52 PM - 11/2/2021
63.95	36.30	40.00	3.70	148.0	V	106.0	-35.9	12:42:39 PM - 11/2/2021
95.96	39.55	40.00	0.45	190.0	V	69.0	-33.6	12:08:44 PM - 11/2/2021
127.92	37.01	40.00	2.99	107.0	V	142.0	-34.0	11:55:58 AM - 11/2/2021
159.84	40.09	40.00	-0.09	394.0	V	105.0	-33.1	11:44:50 AM - 11/2/2021
192.00	36.86	40.00	3.14	100.0	V	177.0	-31.9	12:20:31 PM - 11/2/2021

Final_Result

Frequency (MHz)	QuasiPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB)	Comment
31.98	39.00	40.00	1.00	120.000	100.0	V	0.0	-28.1	11:31:57 AM - 11/2/2021
37.33	20.17	40.00	19.83	120.000	190.0	V	0.0	-31.2	12:54:52 PM - 11/2/2021
50.37	35.89	40.00	4.11	120.000	231.0	V	177.0	-35.8	12:32:25 PM - 11/2/2021
63.95	37.73	40.00	2.27	120.000	148.0	V	106.0	-35.9	12:43:18 PM - 11/2/2021
95.96	30.57	40.00	9.43	120.000	190.0	V	69.0	-33.6	12:09:13 PM - 11/2/2021
127.92	36.13	40.00	3.87	120.000	107.0	V	142.0	-34.0	11:56:35 AM - 11/2/2021
159.84	29.71	40.00	10.29	120.000	394.0	V	105.0	-33.1	11:45:04 AM - 11/2/2021
192.00	31.36	40.00	8.64	120.000	100.0	V	177.0	-31.9	12:21:10 PM - 11/2/2021

Note: Measure Level (dBµV) = Reading Level (dBµV) + Factor (dB). Factor (dB) = Cable Loss (dB) + LISN Factor (dB).

Test Setup Photograph

30MHz to 1GHz setup

ESD Test Result

Basic Standard:	IEC 61000-4-2
Discharge Impedance:	330 ohm/ 150 pF
Discharge Voltage:	Direct Application of Discharge: ➢ Air Discharge: 2kV/ 4kV/ 8kV/ 15kV ➢ Contact Discharge: 2kV/ 4kV/ 6kV/ 8kV Indirect Application of Discharge: ➢ Horizontal & Vertical: 2kV/ 4kV/ 6kV/ 8kV
Polarity:	Positive and Negative
Number of Discharge:	Direct Application of Discharge: ➢ Air discharge: 10 single discharges per test point ➢ Contact Discharge: 10 single discharges per test point Indirect Application of Discharge: ➢ Horizontal & Vertical: 10 single discharges per orientation
Discharge Mode:	Single Discharge 1 second minimum

Site:	Transient Immunity Testing Room	**Date of Test:**	November 5, 2021
Temperature:	26.9ºC	**Humidity:**	49 % RH
EUT:	Trunk and Lower Limb Rehabilitative Device	**Supply:**	230V, 60Hz
Test Mode:	Mode 1 – 4 Linear Actuator	**Test Performed By:**	Hans Patrick Biaco
Performance Criteria:	Criterion C		

Direct Application of Discharge

Air Discharge									
Test Points	**Test Levels**								**Remarks**
	2kV		**4kV**		**8kV**		**15kV**		
	P	**N**	**P**	**N**	**P**	**N**	**P**	**N**	
1	✓	✓	✓	✓	✓	✓	✓	✓	(±) Passed
2	✓	✓	✓	✓	✓	✓	✓	✓	(±) Passed
3	–	–	–	–	–	–	–	–	No Discharge
4	✓	✓	✓	✓	✓	✓	✓	✓	(±15kV) Stopped Functioning, Manual Restart
5	✓	✓	✓	✓	✓	✓	✓	✓	(±15kV) Stopped Functioning, Manual Restart
6	–	–	–	–	–	–	✓	✓	(±15kV) Stopped Functioning, Manual Restart
7	–	–	–	–	–	–	✓	✓	(±15kV) Stopped Functioning, Manual Restart
8	✓	✓	✓	✓	✓	✓	✓	✓	(±) Passed
9	✓	✓	✓	✓	✓	✓	✓	✓	(±) Passed

Notes: (–) No discharge **(x)** Failed **(✓)** Passed

Contact Discharge									
Test Points	**Test Levels**								**Remarks**
	2kV		**4kV**		**6kV**		**8kV**		
	P	**N**	**P**	**N**	**P**	**N**	**P**	**N**	
1	✓	✓	✓	✓	✓	✓	✓	✓	(±) Passed
2	✓	✓	✓	✓	✓	✓	✓	✓	(±) Passed
3	–	–	–	–	–	–	–	–	No Discharge
4	✓	✓	✓	✓	✓	✓	✓	✓	(-8kV) Stopped Functioning, Manual Restart
5	✓	✓	✓	✓	✓	✓	✓	✓	(-8kV) Stopped Functioning, Manual Restart
6	–	–	–	–	–	–	–	–	No Discharge
7	–	–	–	–	–	–	–	–	No Discharge
8	✓	✓	✓	✓	✓	✓	✓	✓	(±) Passed
9	✓	✓	✓	✓	✓	✓	✓	✓	(±) Passed

Notes: (–) No discharge **(x)** Failed **(✓)** Passed

Indirect application of Discharge

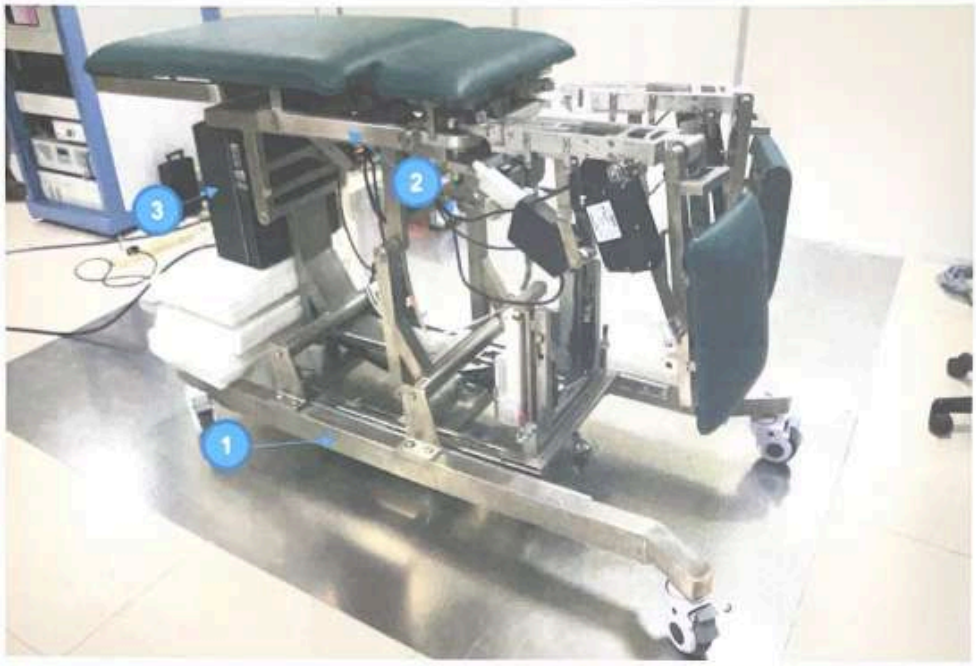
Vertical Coupling Plane											
Test Points	Test Levels										Remarks
	2kV		4kV		6kV		8kV				
	P	N	P	N	P	N	P	N			
Front	✓	✓	✓	✓	✓	✓	✓	✓			(±) Passed
Rear	✓	✓	✓	✓	✓	✓	✓	✓			(±) Passed
Left	✓	✓	✓	✓	✓	✓	✓	✓			(±) Passed
Right	✓	✓	✓	✓	✓	✓	✓	✓			(±) Passed

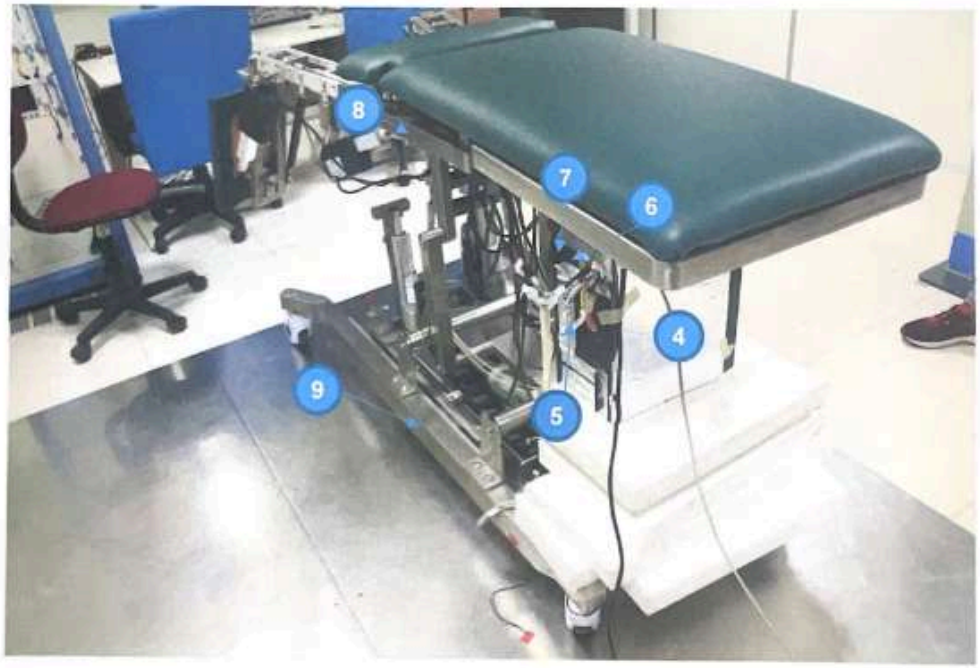
Notes: (–) No discharge **(x)** Failed **(✓)** Passed

Horizontal Coupling Plane											
Test Points	Test Levels										Remarks
	2kV		4kV		6kV		8kV				
	P	N	P	N	P	N	P	N			
Rear	✓	✓	✓	✓	✓	✓	✓	✓			(±) Passed

Notes: (–) No discharge **(x)** Failed **(✓)** Passed

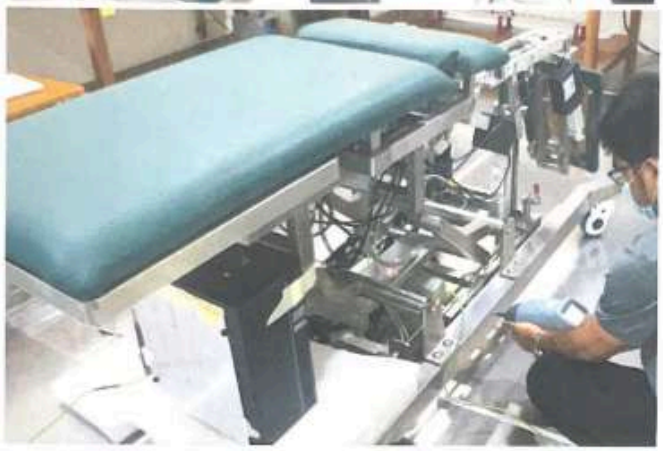
Test Points



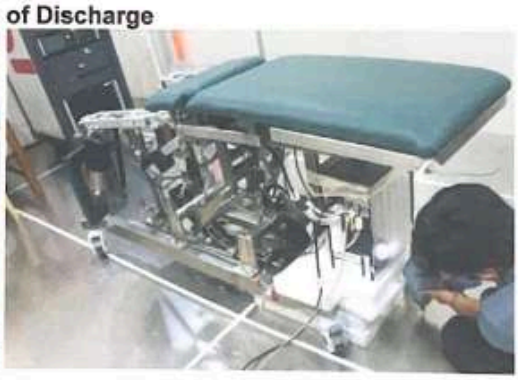


ACTUAL TEST SETUP

Direct Application of Discharge



Indirect Application of Discharge



Radiated Immunity Test Result

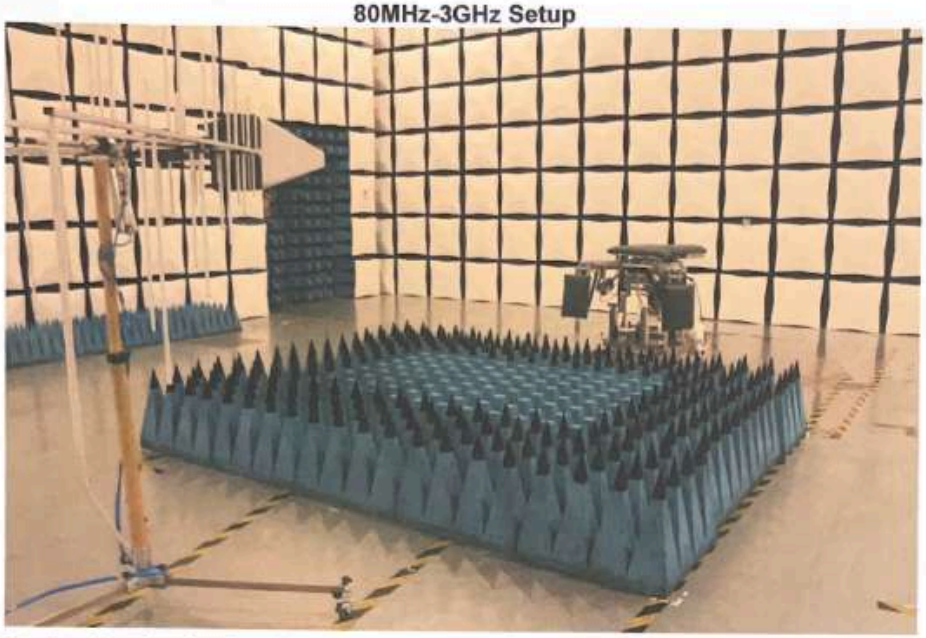
Basic Standard:	IEC 61000-4-3
Frequency Range:	80MHz ~ 3GHz
Field Strength:	3 V/m
Modulation:	1kHz Sine Wave, 80%, AM Modulation
Frequency Step:	1% of preceding frequency value
Dwell Time:	1s
Polarity of Antenna:	Horizontal and Vertical
Test Distance:	3m for 80MHz ~ 3GHz
Antenna Height:	1.55m for 80MHz ~ 3GHz
EUT Supply:	230V, 60Hz

Site:	Semi-Anechoic Chamber	**Date of Test:**	November 04, 2021
Temperature:	24.8°C	**Humidity:**	34% RH
EUT:	Trunk and Lower Limb Rehabilitative Device	**Supply:**	230V, 60Hz
Test Mode:	Mode 2 – 3 Stepper Motor	**Test Performed By:**	Hans Patrick Biaco
Performance Criteria:	Criterion A		

Frequency (MHz)	Polarity	Azimuth	Field Strength (V/m)	Result	Observation
80 – 3000	V / H	0° / Front	3	Passed	Compliant
80 – 3000	V / H	90° / Left	3	Passed	Compliant
80 – 3000	V / H	180° / Rear	3	Passed	Compliant
80 – 3000	V / H	270° / Right	3	Passed	Compliant

ACTUAL TEST SETUP

80MHz-3GHz Setup



Surge Immunity Test Result

Basic Standard:	IEC 61000-4-5
Test Voltage:	AC Power Port: **500V, 1kV**
Polarity:	Alternate P-N
Phase Angle:	0° / 90° / 180° / 270°
Coupling:	L-N / L-PE/ N-PE/ L-N-PE
Pulse repetition time:	60 s

Site:	Transient Immunity Testing Room	**Date of Test:**	November 8, 2021
Temperature:	28.3ºC	**Humidity:**	55% RH
EUT:	Trunk and Lower Limb Rehabilitative Device	**Supply:**	230V, 60Hz
Test Mode:	Mode 1 – 4 Linear Actuator	**Test Performed By:**	Hans Patrick Biaco
Performance Criteria:	Criterion A		

TEST LEVEL	EUT Mode	Polarity	Imp	Phase	Repetition time (tr)	Events	Coupling	Sync	Status
500V	Mode 1	Pos/Neg	2 Ω	0º/90º/180º/270º	60s	5	L-N	ON	Passed
500V	Mode 1	Pos/Neg	12 Ω	0º/90º/180º/270º	60s	5	L-PE	ON	Passed
500V	Mode 1	Pos/Neg	12 Ω	0º/90º/180º/270º	60s	5	N-PE	ON	Passed
500V	Mode 1	Pos/Neg	12 Ω	0º/90º/180º/270º	60s	5	L-N-PE	ON	Passed
1000V	Mode 1	Pos/Neg	2 Ω	0º/90º/180º/270º	60s	5	L-N	ON	Passed
1000V	Mode 1	Pos/Neg	12 Ω	0º/90º/180º/270º	60s	5	L-PE	ON	Passed
1000V	Mode 1	Pos/Neg	12 Ω	0º/90º/180º/270º	60s	5	N-PE	ON	Passed
1000V	Mode 1	Pos/Neg	12 Ω	0º/90º/180º/270º	60s	5	L-N-PE	ON	Passed

ACTUAL TEST SETUP

Conducted Immunity Test Result

Basic Standard:	IEC 61000-4-6
Frequency Range:	150kHz ~ 80MHz
Field Strength:	3 V
Modulation:	1kHz Sine Wave, 80%, AM Modulation
Frequency step:	15 % of preceding frequency value
Dwell Time:	1s
Coupling Device	CDN M016

Site:	Shielded Room	**Date of Test:**	November 05, 2021
Temperature:	25.6°C	**Humidity:**	43% RH
EUT:	Trunk and Lower Limb Rehabilitative Device	**Supply:**	230V, 60Hz
Test Mode:	Mode 1 – 4 Linear Actuator	**Test Performed By:**	Hans Patrick Biaco
Performance Criteria:	Criterion A		

CDN M016

Field Strength	EUT Mode	Frequency Step	Dwell Time	Modulation Type	Modulation Frequency	Modulation Depth	Status
3V	Mode 1	1%	1s	AM	1kHz	80%	Passed

ACTUAL TEST SETUP

SETUP FOR CND

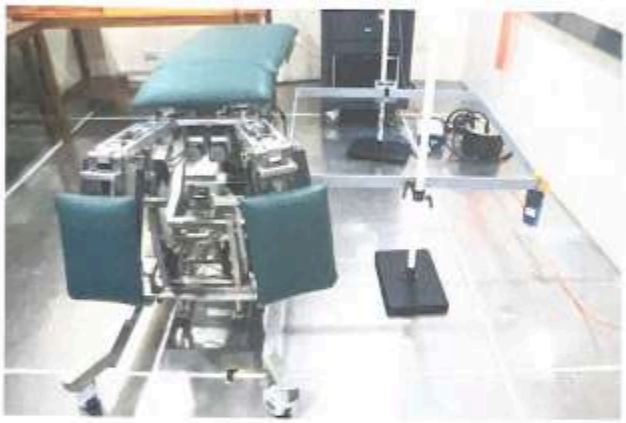
Power Frequency Magnetic Field Immunity

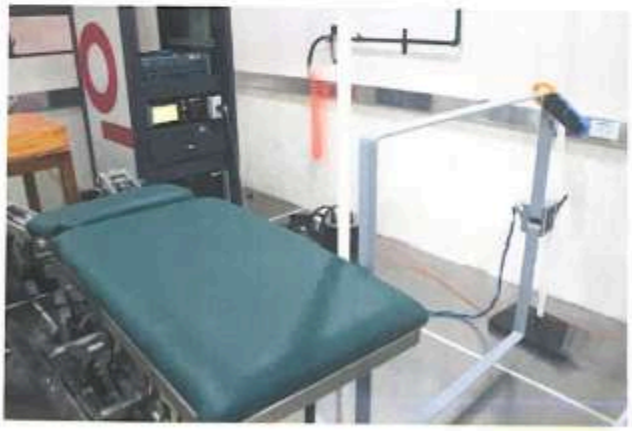
Basic Standard:	IEC 61000-4-8
Frequency Range:	60Hz
Field Strength:	30 A/m
Observation Time:	1 minute
Inductance Coil:	Rectangular type, 1m x 1m

Site:	Transient Immunity Testing Room	**Date of Test:**	November 09, 2021
Temperature:	28.6°C	**Humidity:**	54% RH
EUT:	Trunk and Lower Limb Rehabilitative Device	**Supply:**	230V, 60Hz
Test Mode:	Mode 1 – 4 Linear Actuator	**Test Performed By:**	Hans Patrick Biaco
Performance Criteria:	Criterion A		

Direction	Field Strength (A/m)	Observation Time	Result	Observation
Left (Vertical)	30	60s	Passed	Functional
Left (Horizontal)	30	60s	Passed	Functional
Rear (Horizontal)	30	60s	Passed	Functional
Right (Vertical)	30	60s	Passed	Functional
Right (Horizontal)	30	60s	Passed	Functional

ACTUAL TEST SETUP





Voltage dips, short interruptions and variations

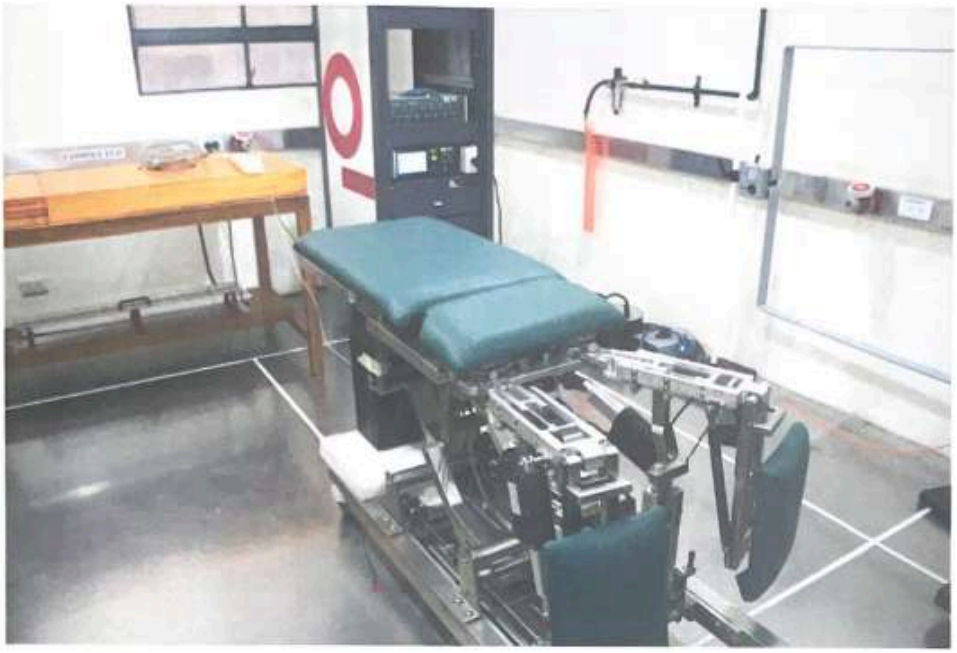
Basic Standard:	IEC 61000-4-11
Nominal Voltage:	230Vac
Voltage Dips:	0%/ 70%
Test Duration time:	1 cycle/ 30 cycles/ 300 cycles
Interval Between Events:	10 s
Phase Angle:	0°
Events:	3 times

Site:	Transient Immunity Testing Room	**Date of Test:**	November 09, 2021
Temperature:	28.6ºC	**Humidity:**	54% RH
EUT:	Trunk and Lower Limb Rehabilitative Device	**Supply:**	230V, 60Hz
Test Mode:	Mode 1 – 4 Linear Actuator	**Test Performed By:**	Hans Patrick Biaco
Performance Criteria:	Criterion B		

EUT Mode	Voltage Dips	Nominal Voltage	Test Duration Time (td)	Repetition time (tr)	Events	Phase Angle	Sync	Status
Active	0%	220Vac	1 cycle	10s	3	0º	ON	Passed
Active	70%	220Vac	30 cycles	10s	3	0º	ON	Passed

EUT Mode	Voltage Interruptions	Nominal Voltage	Test Duration Time (td)	Repetition time (tr)	Events	Phase Angle	Sync	Status
Active	0%	220Vac	300 cycles	10s	3	0º	ON	Passed

ACTUAL TEST SETUP



In-house Mechanical Specification Testing

Date of testing: August 30, 2022

Required equipment:

- Various weights (5kg, 10kg, 15kg and 20kg)

Methodology: Different types of loads are placed in the center of gravity of the targeted motion and are subjected to motor movement. The goal of the testing is to determine if the robot is capable of moving with the subject weight. Maximum weight in this testing is only up to 20kg due to lack of equipment.

Result:

Exercise: Right Hip Flexion-Extension
Position: Supine

Load	Can the robot perform maximum range of motion
No load	Yes
5 kg	Yes
10 kg	Yes
15 kg	Yes
20 kg	Yes

Exercise: Left Hip Flexion-Extension
Position: Supine

Load	Can the robot perform maximum range of motion
No load	Yes
5 kg	Yes
10 kg	Yes
15 kg	Yes
20 kg	Yes

Exercise: Right Hip and Knee Flexion-Extension
Position: Supine

Load	Can the robot perform maximum range of motion
No load	Yes
5 kg	Yes
10 kg	Yes
15 kg	Yes
20 kg	Yes

Exercise: Left Hip and Knee Flexion-Extension
Position: Supine

Load	Can the robot perform maximum range of motion
No load	Yes
5 kg	Yes
10 kg	Yes
15 kg	Yes
20 kg	Yes

Exercise: Left Hip Abduction
Position: Supine

Load	Can the robot perform maximum range of motion
No load	Yes
5 kg	Yes
10 kg	Yes
15 kg	Yes

20 kg	Yes

Exercise: Right Hip Abduction
Position: Supine

Load	Can the robot perform maximum range of motion
No load	Yes
5 kg	Yes
10 kg	Yes
15 kg	Yes
20 kg	Yes

Exercise: Trunk Lateral
Position: Supine

Load	Can the robot perform maximum range of motion
No load	Yes
5 kg	Yes
10 kg	Yes
15 kg	Yes
20 kg	Yes

Movement: Supine to Sitting Position

Load	Can the robot perform maximum range of motion
No load	Yes
5 kg	Yes
10 kg	Yes

15 kg	Yes
20 kg	Yes

Exercise: Knee Flexion-Extension
Position: Supine

Load	Can the robot perform maximum range of motion
No load	Yes
5 kg	Yes
10 kg	Yes
15 kg	Yes
20 kg	Yes

Conclusion:
At the end of the test, the robot is capable of moving all exercises throughout the whole range of motion up to 20kg of weight.

---------- END OF REPORT ----------

Test Performed by:

Engr. CHRISTIEN RAMOS
Research Associate

Checked by:

Engr. JULIUS NOEL BANAYO
Research Leader

Appendix J: Gantt Chart of the Clinical Trial Process

	Month 1				Month 2				Month 3			
	1	2	3	4	1	2	3	4	1	2	3	4
Recruitment Phase												
Screening Phase												
Medical Interview Phase												
Pre-clinical Study Briefing												
Study Participant Briefing												
Pre-study Evaluation and Monitoring												
Robot Safety Inspection												
Exercise Activity Intervention												
Post-study Evaluation and Monitoring												
Data Acquisition												
Data Analysis												
Publication of Results												

Appendix K: De La Salle University - Laguna Campus Disaster Preparedness Drill

SDMC – Laguna Campus

28 September 2022

TO : SDMC MEMBERS

THRU : DR. JONATHAN R. DUNGCA
Vice President for Laguna Campus and Dean of the College

FROM : LTC MELECIO Y CASTILLO PA (RET)
Director, Security and Safety Unit

RE : Earthquake Drill Plan

Greetings in St. La Salle!

The attached Earthquake Drill Plan guidelines/tasking of each and every Section, Group/Teams who are the main performers of this exercise are similar to our just concluded Fire Drill.

Identical with the previous one, our primary customers are the employees and students wherein they must continue the learning on disaster emergency actions and must not fail to recall of everything that we are doing during rehearsals. The mastery of the proper movements following the SOPs will set them free of being harm and will prevent them being prey by their own faults.

Unannounced drill will be done this July 19, 2018 and the succeeding will be every semester of school year.

This is applicable to the different Sector of operations at DLSU-Manila, Laguna Campus.

Listed below are the coverages of the five sectors

- v ***Sector 1 MRR Building, Shrine***

- v ***Sector 2 LC 1 Building***

- v ***Sector 3 LC 2 Building***

- v ***Sector 4 Guest House, Dormitory, Covered Court, St. Matthews Gymnasium***

- v ***Sector 5 Hangar, Innovation, Clean Building and Courtyard Dormitory***

Duties and Responsibilities during Earthquake Drill

Command Center:

- Ø Under the supervision of the Incident Commander (Vice President and Dean of College for Laguna Campus), approved/disapproved the different positions of personnel in the School Disaster Management Council (SDMC).

- Ø Coordinate with the different offices in the campus for the available basic equipment/ materials on hand needed by various groups and teams of the (SDMC) and to provide lacking requirements on the need basis.
- Ø Suggest training needs of the SDMC.
- Ø Coordinate with LGUs and NGOs regarding emergency situations and updates.
- Ø Provide the whole campus with an Evacuation Route Plan and a Site Evacuation Plan.
- Ø Identify locations of Command Center and different posts of the various support and field operations.
- Ø Identify primary and secondary evacuation areas within the campus.
- Ø Ensure availability of Covid Marshals

Admin/Finance Section:

- Ø Co-located at the Command Center
- Ø Release pertinent information to the following:
  - · Parents and/or guardians of STC students
  - · Family of STC personnel
  - · Stakeholders
  - · Radio, TV, Social Media
- Ø Provide funds support for the purchase of the following:
  - · Needed equipment
  - · Food water and medicines
- Ø Conducts head counting to all employees
- Ø Consolidate all personnel attendance at the tally board to identify absent, missing, injured evacuated and etc
- Ø Report result of counting to the Incident Commander

Operations Section:

- Ø Co-located at the Command Center

Ø Supervise the operations of the following Groups/Teams of the IMT (ATTACHMENT "A)

Ø Deploy respondents according to the needs in the area

Ø Observe and implement Covid-19 Protocols

Logistics Section:

Ø Co-located at the Command Center

Ø Provide logistical support to the respondents and evacuees upon request in coordination with the Admin/Finance Chief for financial support and Operations Chief for the distribution of supplies needed

Ø Provide fuel & lubricants to the Service Support Team upon request

Communication Group:

Ø Co-located with the Command Center

Ø During earthquake epoch, communicate by means of telephone, radio or messengers to all friendly units/office in the immediate vicinity for reinforcement/augmentation to the school Fire Brigade Team, Rescue Team, Medical Team, Security & Traffic Team

Ø Upon request of the Fire Brigade Team after noticing of fire break out, coordinate with the different Fire Units in the area

Ø Inform members of SDMC and the rest of SDMC community about the incident immediately

Warning and Evacuation Group:

Ø In-charge of the Evacuation Area

Ø Ensure orderly evacuation from the building

Ø Assign the most qualified employees to act as the **Over-all Officer in-Charge** in every floor of each building to make certain for a commendable performance

Ø Make sure that the employees and students are serious on what they are doing during the rehearsals

Ø Make it habit that even it is a drill, apply an orderly evacuation from the building

- Ø Teachers and Officer in-charge to practice a quick ***grabbing of the Classroom Go Kit and Office Go Kit*** and important documents, equipment and available cash in moving out of the classrooms and offices during evacuation

- Ø Employees and students to utilize all identified safe exits for evacuation during drills

- Ø Apply the DCH, walk fast, keep right, buddy system, none utilization of elevator and to put somethings to cover the head (books, bags, go kits and etc) to those who has no helmets.

- Ø Assign at least one inspector each in every floor of the four Sectors to look for possible left behind personalities

- Ø Report immediately any case of injury or medical emergency

- Ø Turn-over all evacuated injured personnel to the medical Team for their disposition.

- Ø Assign personnel to conduct headcounts to both the students and the employees and take note of missing and injured personnel if there is any

- Ø Report results of head counting and to report it to the Command Center

- Ø Ensure proper release of students as per DLSU Manila, Laguna Campus Emergency Fetching Procedure.

- Ø Report to Operations section status and updates regarding the condition of the students and personnel in the evacuation areas

- Ø Ensure that Covid-19 Protocols is observed

Fire Brigade Group:

- Ø Upon sensing of an earthquake **DCH** and while on that position, all eyes around the area looking/observing for possible fire break out and identification of safe exits

- Ø **If there is fire,** immediately take all the available firefighting equipment (Fire Hose, Fire Extinguishers) defending on the degree of fire.

- Ø Lay down the fire hose and connect it to the fire hydrants. Note, no breaking of the cabinet glass and never open the water hydrants during drills until told to do so

- Ø Grab the fire extinguisher as part of the exercise but never open it without advised

- Ø Make sure all posted roving guards who were part of the Fire Brigade were properly briefed and understood on what they are going to do during fire drill

- Ø Avoid pointing the water hose and fire extinguisher to personnel to avoid accident.

Ø Report the serviceability of all fire alarm, fire hydrants and fire extinguishers after the drill

Ø **In no fire,** assist the Warning and Evacuation Team in guiding all personnel going down outside of the building

Search and Rescue Group:

Ø Place standby at the Command Center on call for immediate deployment

Ø In a given scenario, rescue all personnel trapped inside of a collapsed structure

Ø Turn-over rescued personalities to Medical Team for First Aid, Evaluation and for possible evacuations

Ø Make sure that all rescuers are equipped by all available paraphernalia provided by DLSU Manila, Laguna Campus during drills

Medical Group;

Ø Establish Temporary Clinic at the Evacuation Area (Please see the sketched of the Lower Football Field) to cater minor injuries and be ready for evacuation of casualties to the nearest Hospital.

Ø Make sure that the school ambulance is ready for evacuation of casualties parked adjacent to Temporary Clinic.

Ø In-coordination with the Warning and Evacuation Team and Search and Rescue Team, receive all victims for proper treatment and evacuation to the nearest hospital in the area if necessary.

Ø Ensure the availability of oxygen and other breathing apparatus/gears for those who were suffering from breathing difficulties.

Ø Monitor health situation of UBISOFT personnel at Evacuation Area (Artificial Turf Football Field) for evacuation of casualties to the nearest Hospital and to cater minor injuries if necessary.

Ø Manage the patients Tally Board (Must include name, type of injury, condition, location in the Medical Team Post or Hospital).

Ø Coordinate with the Transportation Team for the availability of additional vehicle during evacuations to the nearest hospitals.

Security and Traffic Group:

- Ø Automatically cordon the surroundings of all the damaged facilities for traffic purposes and to prevent entry of unauthorized personnel
- Ø Make all road nets a priority lane for responders vehicles and school ambulance
- Ø Assist the Warning and Evacuation Team in ensuring orderly movement of all students and personnel going to the evacuation areas, including the late comers and those who got separated from their classes or groups
- Ø Close and secure the main gate
- Ø Provide personnel at the Evacuation Area to assist the Warning and Evacuation Team during the release of students to their fetchers
- Ø During Earthquake without fire, allow fetchers vehicles to get inside the campus after a go signal coming from the Command Center; with fire, fetchers vehicles are not authorize to get in.
- Ø Man the parking areas for the emergency vehicles, including the designated Heli Pad
- Ø Ensure that only responder's trucks and ambulance are allowed to get in and out of the Campus without delay.
- Ø LC2 road (road going to LC2) and portion of Animo Road will be close for Fetchers but open for School Bus, Ambulance and Responders Vehicles.

Damage Control Group:

- Ø Initially co-located at the Command Center
- Ø To proceed to the area after clearing and to assess the amount of damages and the possibility of utilization/non utilization of offices and classrooms
- Ø Monitor the identified High Risk Facilities in every Sector for possible collapse structures
- Ø Submit an assessment report to the Command Center on the stability of burned facilities
- Ø Coordinate with the Security Team for restriction of unauthorized personnel on the damage facilities to avoid accident
- Ø To deploy teams during this drill as required by the Command Center

Other Instructions;

Preparation Stage;

- Ø Conduct meetings prior to drills to review the group/individual tasking
- Ø Practice and ensure that members of your group can properly execute **DCH** in different scenarios and follow the evacuation route plan. (IS students must practice; College students must be reminded)
- Ø Always be conscious of unsafe spots in your office/classroom (e.g. boxes blocking the door, loose electric fans, broken window, etc…) and inform them to the Security and Safety Office as soon as possible.
- Ø Know the location of Go Kits in your classrooms and offices
- Ø Update personnel assignment to the IMT
- Ø Be familiar to the entrance of the new Evacuation Areas
- Ø FMO to maintain the cleanliness of the designated EA
- Ø Make wide opening for the entrance of students coming from MRR, LC1 & LC2 buildings
- Ø Ubisoft – to make similar organization of personnel during emergency and make sure that their tasking will be understood and executed well

During an Emergency or a Drill;

- Ø At the onset of earthquake, all must properly execute the **DCH**
- Ø As soon as situation is **CLEAR,** the Office in-charge/Faculty will lead the members of the group to evacuate. ***Note:*** Office in-charge/Faculty should look outside and make sure the **green flag** is up before leading the group outside
- Ø Remind each other to be calm and alert
- Ø Primary Evacuation Area - Lower Football Field

  Area2 – Artificial Football Field (Innovation, Hangar & Clean Bldg)
- Ø Alternate Evacuation Area - IS Football Field
- Ø Parking Areas;

- University Drive (entrance lane to DLSU only) if there is no fire break out to give way to incoming Fire Trucks
- Westgrove road adjacent to the university gate
- LC1 front Lobby (no fire break out)

Ø Vehicles with fetchers who were already inside the Campus during earthquake will be the first priority to fetch students after validation of Student Fetcher's Card.

Ø Student releasing point will be in front of the Evacuation Area.

Ø Lateral Coordination among Section, Groups and Teams is authorized.

Ø HELI Pad -IS Football Field. .

Ø Staging Area - is the Main Parking Area.

Ø Command Center – Lower Field Batting Cage.

Ø Communication – Handheld Radios, Cellular Phone, Landline and Messenger.

Ø New Incident Management Team (IMT), ATTACHMENT "A"

Ø Friendly Units/Offices within Santa Rosa and Binan City, ATTACHMENT "B"

Ø Updated Evacuation Site Plan ATTACHMENT "C"

Ø High Risk facilities ATTACHMENT "D"

Ø DLSU Manila, Laguna Campus Radio Net Diagram "Rizal" is in effect. ATTACHMENT "E"

<u>After an Emergency or a Drill;</u>

Ø The Office in-charge/Faculty will lead the members of the group back to the classroom and office.

Ø Conduct after activity review.

ATTACHMENT:

"A" – Incident Management Team (IMT)

"B" - Friendly Units/Offices

“C” – Evacuation Site Plan

“D” – High Risk facilities

“E” – Radio Net Diagram “Rizal”

Appendix L: Curriculum Vitae

Name	Profile	Role
Prof. Nilo T. Bugtai, PhD	Director, Institute of Biomedical Engineering and Health Technologies	**Program Leader** ● Provides the direction of research activities ● Coordinates with collaborators and other team members for the direction of the research
Armyn C. Sy, PhD	Associate Professor, Manufacturing Engineering and Management Department	**Project Team Member** ● Coordinates with PL and other team members for the direction of the research ● Oversees the mechanical and electrical design components and its integration
Engr. Julius Noel Banayo (Lead Researcher)	Bachelor of Science (B.Sc.) in Electronics Engineering	**Lead Researcher** ● Lead researcher for the duration of the project and key contact person for the project's activities ● Overall design, fabrication and assembly of the prototype ● Prepares technical reports and research papers ● Management of project personnel and other administrative tasks
Charles Jethro Belamide	Bachelor of Science (B.Sc.) in Manufacturing Engineering	**Research Associate** ● Performs research activities on the software components of the device both the Android application and the various Kinect-based games ● Responsible for executing design changes as per inputs from medical collaborators ● Helps in the preparation of technical reports and research papers.

Czaryn Dianne Ompico	Bachelor of Science (B.Sc.) in Manufacturing Engineering	**Research Associate** ● Performs research activities on the electrical and control system of the device ● Cooperates with the fabricator and provides technical reports ● Helps in the preparation of technical reports and research papers..
Engr. Christien Ramos	Bachelor of Science (B.Sc.) in Mechanical Engineering	**Research Associate** ● Performs research activities on the mechanical components of the device ● Cooperates with the fabricator and provides technical reports ● Helps in the preparation of technical reports and research papers.
Renneir Valdez	Bachelor of Science (B.Sc.) in Business Administration	**Project Assistant II** ● Acts as clerical assistant of the project ● Handles all related clerical work of the project ● Guarantees that all reports are submitted on time to the DOST-PCHRD
Myrna S. Estrada, MD	Physical Medicine & Rehabilitation, De La Salle University Medical Centre, Dasmariñas, Cavite	**Medical Collaborator** ● Responsible for writing the Clinical Trial Protocol ● Provide expert's opinion on medical feasibility and clinical significance of the proposed device ● Participation in the design conceptualization and performance testing of the device prototype
Amiel C. Adajar, MD	College of Rehabilitation Science, De La Salle Health Sciences Institute, Dasmariñas, Cavite	**Medical Collaborator** ● Responsible for writing the Clinical Trial Protocol ● Provide expert's opinion on medical feasibility and clinical significance of the proposed device ● Participation in the design conceptualization and performance testing of the device prototype
Abegail Abegan-Unto, PTRP	Physical and Rehabilitation Medicine	**Medical Collaborator** ● Responsible for writing the Clinical Trial Protocol ● Provide expert's opinion on medical feasibility

	Department, De La Salle University Medical Center, Dasmariñas, Cavite	and clinical significance of the proposed device ● Participation in the design conceptualization and performance testing of the device prototype
Lorraine Faeldon. MD	Medical Specialist, Institute of Biomedical Engineering and Health Technologies	**Medical Consultant** ● Assisted in writing the Clinical Trial Protocol ● Provide expert's opinion on medical feasibility and clinical significance of the proposed device ● Participation in the design conceptualization and performance testing of the device prototype