Informed consent form

Participant (full name): ……

Conducting person (full name): ……

Time and place: ……

Please read the text below carefully and ask the conducting person about anything you do not understand or would like to know.

What is the purpose of this study?

Patients affected by neurological disorders such as Spinal Cord Injury, Multiple Sclerosis, or Muscular Dystrophy struggle to achieve adequate and consistent foot clearance. This leads to the inability to navigate a flight of stairs or increases the risk of tripping and potentially falling while they walk. The weakened muscles of these patients do not allow them to consistently accomplish the two basic movements required for leg progression: forward and upward movement of the leg during swing phase. This project represents the initial research on the potential capabilities of tendon-based systems in providing adequate foot clearance during stair climbing and walking. For simplicity, the project will focus only on assisting the upward movement of the leg. We seek to discover if such systems are capable of providing enough foot clearance to lift the foot above a stair, which is the most demanding scenario we envision.

What is investigated and why?

In this study, we are interested in experimentally finding the forces that are required to lift the foot of a person with our tendon-based device.

Who can participate?

Inclusion criteria	Exclusion criteria
Age between 19 and 64 years old	Mobility problems
Body height between 150 and 195 cm	Neurological disorders
Body weight between 50 and 95 kg	Genetic disorders
BMI between 18.5 and 30	In a dependent or subordinate position to the investigator

Will I be compensated for participating?

No compensation will be provided.

How much time will I be expected to invest?

The approximate time of the whole experimental procedure is 1.5 h.

What are my rights during participation?

Your participation in this study is voluntary. You may cancel your participation at any time without specifying reasons and without any disadvantages.

Which data are collected?

- Personal data, such as age, weight, height, length of thigh, length of shank, circumference of thigh, circumference of shank, will be collected through a questionnaire and will be anonymized.

- Sensor data will be collected during the experiment through load cells, IMU's and EMG sensors

- Video recordings

Personally Identifiable Information (PII), including videos, will be stored in a protected network folder, where only the researcher will have access.

How will my data be handled?

The data will not be shared beyond the study team and will be used anonymized in the report of a MSc thesis

What are my rights to the data?

You may request comprehensive information about the personal data that was collected from you in the study at any time. You also have the right to have it corrected, handed over to you, barred for processing, or deleted. You may revoke your consent to the processing of your personal data at any time without giving reasons.

What are potential risks during the experiment?

During the experiment the following risks could be possible. Together with the risks, the corresponding precautionary measures are mentioned for mitigating the risks:

- COVID risks: The experiment will take place in person in Switzeralnd, therefore the COVID regulations as defined in Switzerland will be followed throughout the whole experiment.
- Mechanical risks: Mechanical risks may be present in the cases where the device collides with the body of the participant. To mitigate those risks, a soft interface between the system and the participant has been created, by using cushioning and other soft materials. Moreover, a whipping risk may arise due to the failure of used dyneema ropes. The selected dyneema ropes are able to withstand the forces that we intend to apply with the setup. We also make sure that the dyneema ropes, in case of failure, do not have direct contact at the participant's skin.
- Electrical risks: Electrical risks may be present due to the usage of battery and wires. To mitigate those risks, the battery is enclosed in a safety box and the wires have shielded with insulation tape where needed.
- Structural risks: Structural risks may be present in case the experimental setup collapses. To mitigate this risk, aluminum profiles with high load-bearing capacity are used.
- Fall risks: Fall risks may be present due to loss of balance of the participant during the experiment. To mitigate this risk, a configuration on the setup has been created that gives the capability to the participant to support himself by using his hands.
- Temperature risks: Temperature risks may be present due to overheating of the used electrical motors. To mitigate this risk, the motors will not be in contact with the human body.
- Physical risks: Physical risks may be present due to excessive application of forces from the electrical motors. To mitigate those risks, a threshold will be used in the software that does not allow the motors to apply forces bigger than this threshold. Moreover, an emergency button is used that allows the participant to immediately deactivate the motors. Finally, the battery that is used is removable and in that way, the system shuts down.
- Societal, psychological, emotional, or political risks are not expected, as the experiment only requires some physical activities from the participant.

	Yes	No
I have read and understood the study information dated _____, or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction	□	□
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason	□	□
I have had enough time to decide about my participation	□	□
I understand that taking part in the study involves filling out a questionnaire, placement of electrodes on my skin, performing simple movements with my legs, video-recording of myself, and using the device that includes components that interact with my body	□	□
I comply with the inclusion and exclusion criteria for participation described above. I am aware of the requirements and restrictions to be observed during the study	□	□
I understand that information I provide will be used in a report for the research purposes of a MSc thesis	□	□
I understand that personal information collected about me that can identify me, will not be shared beyond the study team	□	□
I agree that the experimental data produced during the study can be quoted in research outputs	□	□
I am aware that all the COVID regulations, as defined in Switzerland, will be followed throughout the whole experiment	□	□

Signatures

_____	_____	_____
Name of participant		

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

_____	_____	_____
Researcher name	Signature	Date