LSR LIFE SCIENCE ROBOTICS

ROBERT®

User Manual

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1. INTRODUCTION

This manual describes the ROBERT® product and is aimed at the user of the device, who is defined as the Operator. The manual is to be used as a source of information and instruction manual. The user manual must be read before using ROBERT®.

1.1 About ROBERT®

ROBERT® is a rehabilitation device made by the Danish manufacturer Life Science Robotics ApS and is to be used in, for example, hospitals, healthcare and rehabilitation centres. Development and production is carried out with the highest possible levels of diligence and in compliance with existing European directives and national medical device laws and regulations.

1.2 Classification

ROBERT® is classified as an active therapeutic device that is intended to be used for the administration of and exchange of energy with patients. This is why ROBERT® is classified as a Class IIa device in terms of its type and the degree of protection it offers against electric shock according to EN 60601-1.

2. INTENDED USE

ROBERT® is intended to be used as a rehabilitation device for bedridden patients. When attached to the patient by means of an accessory, ROBERT® is able to perform different types of healthcare, i.e. professionally designed rehabilitation exercises which are unique to each particular patient. The exercises are designed for treating the patients' legs.

2.1 Medical Purpose

ROBERT® is to be used for patients who require rehabilitation after, e.g. a stroke, trauma or the aggravation of existing disorders etc. Any disease or condition that requires repetitive passive or active movements will potentially benefit from the device.

2.2 Application

The following applies to the application of ROBERT®:

- Intended for professional use only – not for home use.
- For indoor use only – under normal temperature and humidity conditions and atmospheric pressure.
- Not to be used in the shower, bathtub or sink.
- Frequency of use: Shall be assessed by a healthcare professional.
- A mobile medical device to be used for patients in need of rehabilitation.

2.3 Qualifications of the Operators

The Operators must be professionals who have received training in a healthcare field, e.g. physiotherapy, occupational therapy or nursing – i.e. they are also defined as healthcare professionals. This is a fundamental requirement, as the operation of ROBERT® requires a knowledge and understanding of basic hygiene and the anatomy of the extremities. No specific technical knowledge is required to use ROBERT®, as the user interface has been designed with this in mind. It is, however, still a requirement that the user manual must be read before using ROBERT®.

3. INDICATIONS AND CONTRAINDICATIONS

The patient population is not restricted to a certain age or disease. It is, however, strongly advised that users follow the recommendations stated in the instructions under ”2. Intended Use”. It is up to the Operator to evaluate whether a particular patient will benefit from specific exercises. Some patients are too unstable or fragile to carry out exercises. Some patients have parchment-like skin, so that the risk of developing pressure sores is too high. ROBERT® is also able to rehabilitate sedated patients, as it is not a requirement for them to be active during the set-up process or the exercises themselves.

3.1 Indications for use

Patients who are potential candidates for treatment with ROBERT®:

- Age: The recommended minimum age – although this is not a binding condition – is 18. The patient’s suitability is to be evaluated by the healthcare professional.
- Weight of the extremity undergoing rehabilitation treatment: <11 kg (equivalent to a body mass of approximately 160 kg).
- Part of the body subject to the exercises: Legs.
- Health: See section ”3.2 Contraindications”. An assessment is to be carried out by the healthcare professional as to whether exercises involving the extremity are contraindicated for each particular patient.
- Patient status: Particular caution is required with regard to sedated patients, patients who are cognitively and physically unstable, patients who are suffering from severe spasticity, epilepsy or muscle contractions and patients with severe brain injury.

3.2 Contraindications

The use of ROBERT® is contraindicated if:

- The patient has unstable fractures in his or her back, pelvis or legs.
- The patient refuses to take part in exercises using ROBERT®.
- The healthcare professional assesses that exercises are not safe due to, for example:
  - High intracranial pressure.
  - Confusion due to a personality disorder, dementia, delirium or the like.
  - Medical instability or frailty.
  - Pressure sores or a risk of developing pressure sores due to fragile skin.
- The patient’s leg weighs more than 11 kg. ROBERT® detects whether the leg is within the limit when it is lifted off of the mattress.
- The movement involved in the exercise is causing the patient pain.

4. WARNINGS AND PRECAUTIONS

Life Science Robotics ApS is exclusively responsible for the safety, reliability and function of the device, subject to the condition that it is used in accordance with this manual.

NOTE: Some pictures/illustrations in this manual may not represent current layout/design; however, information of use and content is fully representative of the current version.

4.1 Precautions

When the set-up is complete and exercises have been initiated, the device can operate without being supervised by a healthcare professional, although in the event of an unforeseen situation, it is advised that a healthcare professional is inspecting the patient from time to time when exercises are being performed. If leaving the patient unattended during exercises, the healthcare professional must provide the patient “play/pause” button to the patient.

The robot arm is approved to lift 11 kg, equivalent to a patient weight of approximately 160 kg. Capacity to lift the extremity may vary from patient to patient depending on the patients´ body composition. If the weight of the extremity is detected to be too high, ROBERT® will not be able to perform the exercises.

Note: The ability of the device to lift to its maximum capacity depends on the angle of the ROBERT® linkage. Only when used in a vertical attached position will the device be able to lift to its maximum capacity.

Use of the device may be restricted in specific exercise directions in order to prevent overloading of the robot arm, e.g. when the front of the ROBERT® device is positioned at the end of the bed or – generally speaking – when movements are performed towards and/or away from the body of the ROBERT® device.

Do not use ROBERT® on patients with contraindications. The healthcare professionals involved must always review the patient’s condition and evaluate whether the patient’s health allows for exercises to be performed with ROBERT®.

The healthcare professional must also evaluate the appropriate duration of the exercise according to the patient’s health and bring the session to an end if continuing the exercises might cause the patient pain or harm.

The accessories supplied must only be used for the lower legs. Do not attach the accessory to any other parts of the body.

Only the accessories supplied may be used with ROBERT®. Do not try to strap anything other than the accessories supplied around the patient’s lower leg.

Pay attention to the movements of the robot arm during system check.

4.2 Warnings

ROBERT® must only be operated by qualified healthcare professionals.

ROBERT® is intended for training with patients only. The device is not a fitness equipment for healthy subjects and does not withstand high intensity training with severe training force and/or speed. Any attempt to do so could compromise safety and damages caused hereof, will not be covered by warranty.

In the event of an emergency situation in which the patient is still connected to ROBERT®, the healthcare professional must press the EMERGENCY button and disconnect the patient from ROBERT®.

The brakes of the ROBERT® device must be engaged not only before ROBERT® is attached to the patient, but also for the entire duration of the exercises. The brakes must not be released until the patient has been detached from the robot arm.

If ROBERT® has been switched on for more than 24 hours, the device must be restarted by switching the power off and on again at the power switch.

In the event of damage to the power supply cords, a replacement must be ordered from Life Science Robotics ApS or from your local ROBERT® representative.

Operators must not use ROBERT® if the device or its accessories display any visual indications of defects and/or if the service life has been exceeded.

Under no circumstances is it permitted for parts or components to be replaced or modified by individuals who have not been qualified by Life Science Robotics ApS. Only replaceable/serviceable parts which are specifically referred to in section ”16.2 Service and maintenance” of this manual may be replaced/serviced – and this may only be performed by qualified personnel.

4.3 General precautions

ROBERT® has been tested and found to comply with the limits for a mobile electrical medical device pursuant to EN 60601-1-2. However, interference may occur in the case of a particular installation. If ROBERT® causes harmful interference to other devices or vice versa, try reprogramming or relocating one of the devices. For further details, please refer to section ”14. Electromagnetic compatibility”.

ROBERT® may only be used at an atmospheric pressure of between 700 hPa and 1060 hPa.

ROBERT® fulfils all technical and legal requirements for use in the European Community, the US, Malaysia and Australia. ROBERT® has not yet been formally reviewed for use outside these areas. Restrictions on its use may apply in some countries outside the areas mentioned above. Please contact your local ROBERT® representative if you are in doubt as to whether ROBERT® may be used in a specific area outside the European Community, the US, Malaysia or Australia.

The embedded Lithium Iron battery in ROBERT® which power the device is not field-replaceable. If you open ROBERT®, the seals will be broken and the ingress protection compromised. The battery in ROBERT® has a minimum lifetime of 5 years. It is always possible to use ROBERT® without any batteries and battery-powered mode is only recommended when ROBERT® is moved from one side of the bed to the other and/or from one patient (room) to another. Otherwise, it is strongly recommended that ROBERT® should be operated using the power cord supplied.

When ROBERT® is not in use it is recommended to charge the device. For faster charging the device shall be in OFF state.

If ROBERT® has shut down due to battery reaching full discharge, upon reapplication of AC input power, use of ROBERT® will be re-enabled and battery charger will commence battery recharge. However, operation on battery will not be available until battery has reached at least 25% recharge.

4.4 Potential risks/side effects

Some patients may experience temporary slight redness of the skin where the accessory has been placed. If the accessory has been attached too tight or for a long time, the patient may start to feel tingling in his or her toes. The tingling stops shortly after the accessory has been removed from the patient’s leg.

5. PRODUCT DESCRIPTION

ROBERT® consists of a robot arm with linkage and a range of accessories which are to be attached to the patient. ROBERT® is fitted with a patient play/pause button and a control interface. The main body of the robot sits on a base frame which has four wheels and brakes. Inside the body there is a control cabinet connected to the robot arm. The body is equipped with a handle to push the device around. (Figure 1).

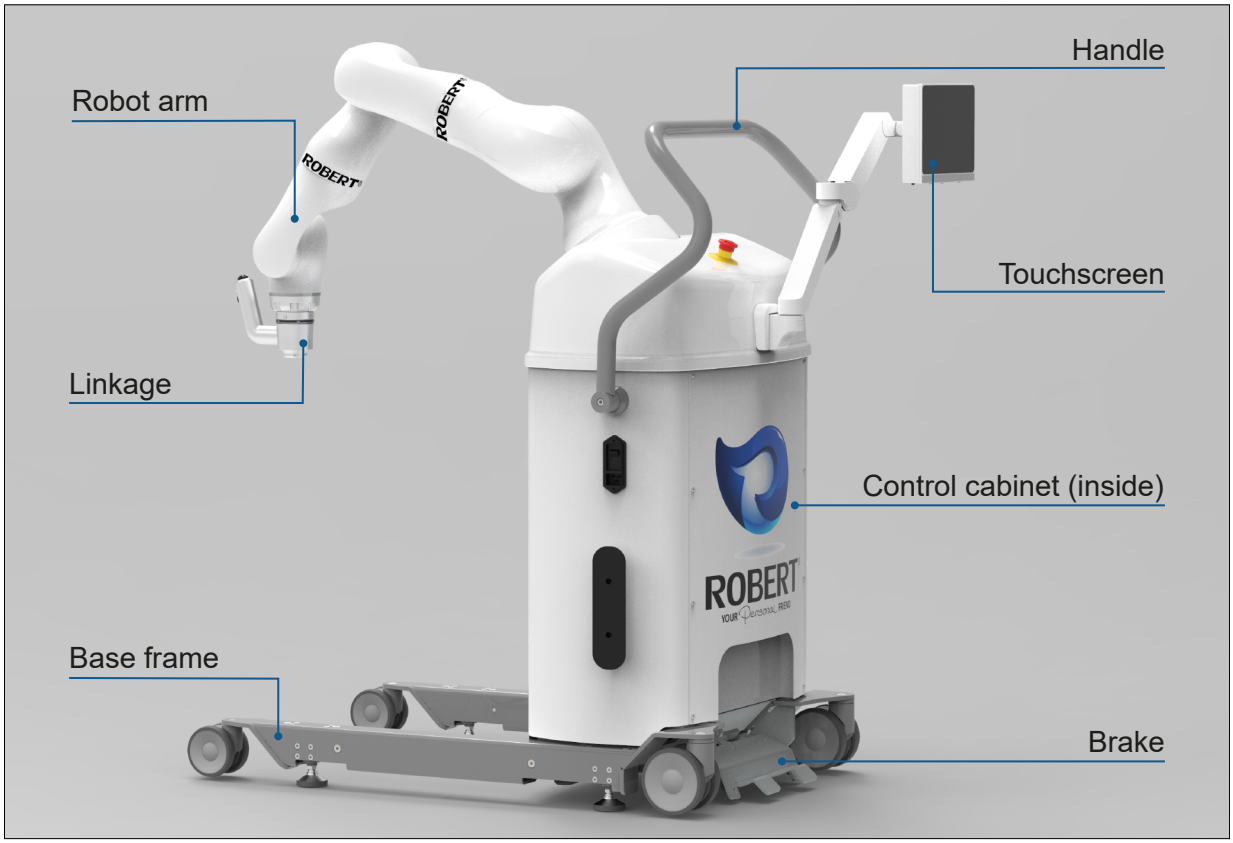


Figure 1: ROBERT® Overview

5.1 ROBERT® Body

The base frame can be pushed under a standard hospital bed. The base frame is designed to ensure the stability of the entire device and helps the Operator to position the device correctly before starting the exercises. The device can be locked by means of the brakes and must not be moved during the exercises. All four wheels of the base frame can turn, allowing ROBERT® to manoeuvre into a small space.

Special handles are designed to provide a reliable method for pushing the device when it needs to be pushed towards the hospital bed or moved from one place to another.

5.2 Control cabinet

The control cabinet for the robot arm is placed inside the ROBERT® body. This controls the functions of the robot arm, as well as safety aspects and the embedded software. It is only available for servicing purposes.

5.3 Buttons

ROBERT® is fitted with a patient “play/pause” button, which is positioned on one side of the ROBERT® body (Figure 2).

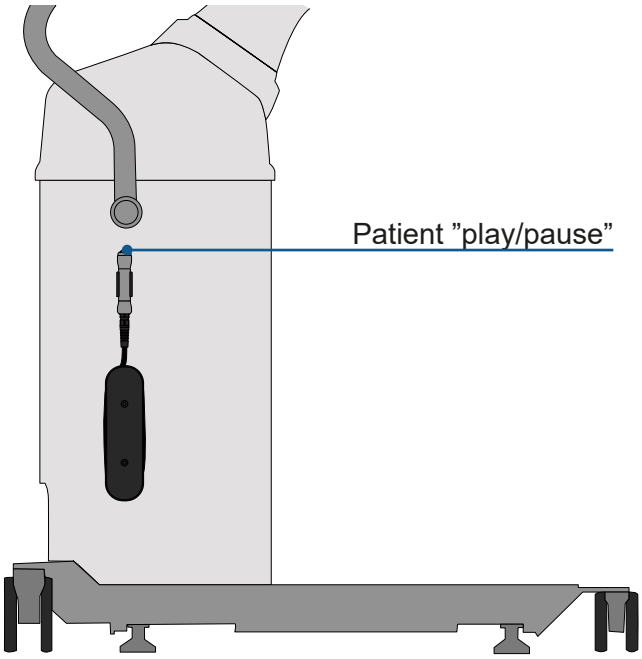


Figure 2: Patient “Play/Pause” Button

The power “on/off” switch is located on the other side of the body (Figure 3).

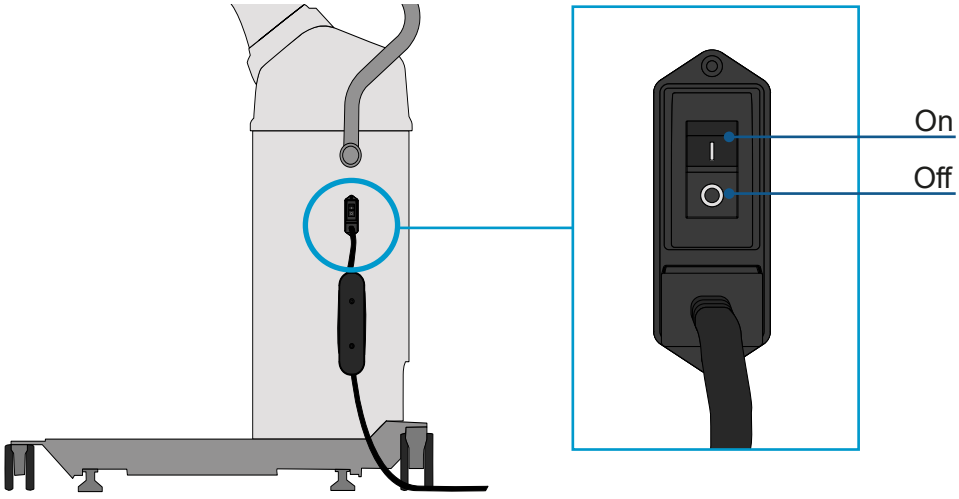


Figure 3: Power “On/Off” Switch

An emergency button is located (Figure 4) in the centre of the body, near the handle.

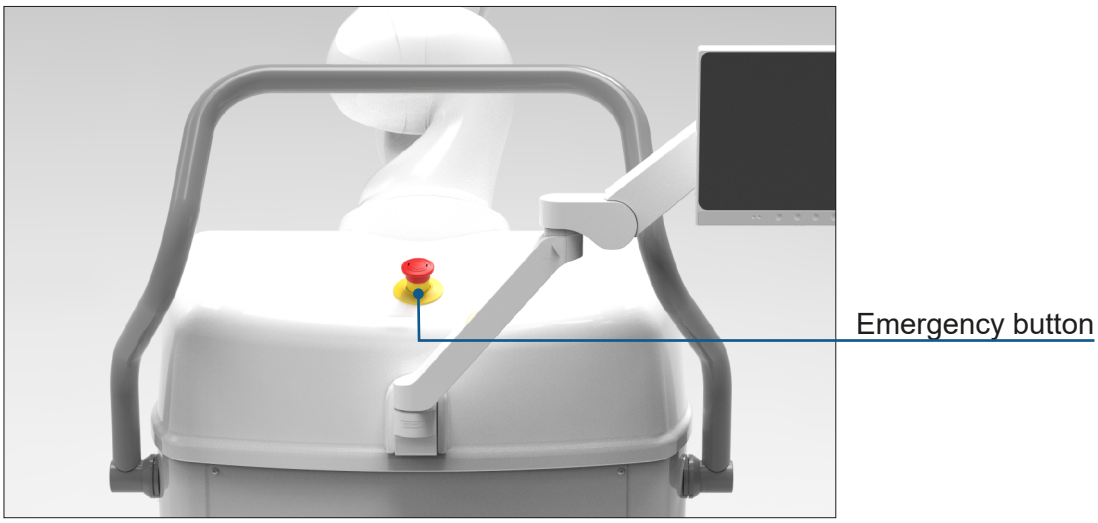


Figure 4: Emergency Button

5.4 Power supply

ROBERT® is equipped with a power supply cord which is to be plugged into the appliance inlet that is placed on the ROBERT® body and to an earthed power outlet. It is recommended to use the supplied C13 power supply cord, and that ROBERT® is powered via the power supply cord at any time when ROBERT® is in use. A battery is placed inside the ROBERT® body and supplies power when ROBERT® is not plugged into an earthed power outlet. If the battery level is low, ROBERT® must be powered by the supplied power cable. Depending on which mode is powering ROBERT®, a corresponding icon is visualized in the upper right corner of the touchscreen, see section ”8.2 ROBERT® battery indications”.

Note: ROBERT® must be powered via the power supply during normal operating mode and only powered via battery when relocating to another patient room or department. When not in use, please leave ROBERT® in OFF state and powered via power cable to insure full battery capacity and longer battery lifetime.

5.5 Power options

To turn on ROBERT® switch the “power switch” to “on” (I). When finished using ROBERT® the device is to be shut down from the “shut down” icon on the touchscreen. This icon is located under the drop-down menu which is located at the upper right corner of the touchscreen (Figure 5). To shut down ROBERT® press the menu icon and then press the “shut down” icon (Figure 6). If a restart is necessary, e.g., after being exposed to high external force, select “restart” (Figure 7) and await the restarting of the device. Make sure no accessory and/or the patient is attached to the robot arm when pressing “restart”.

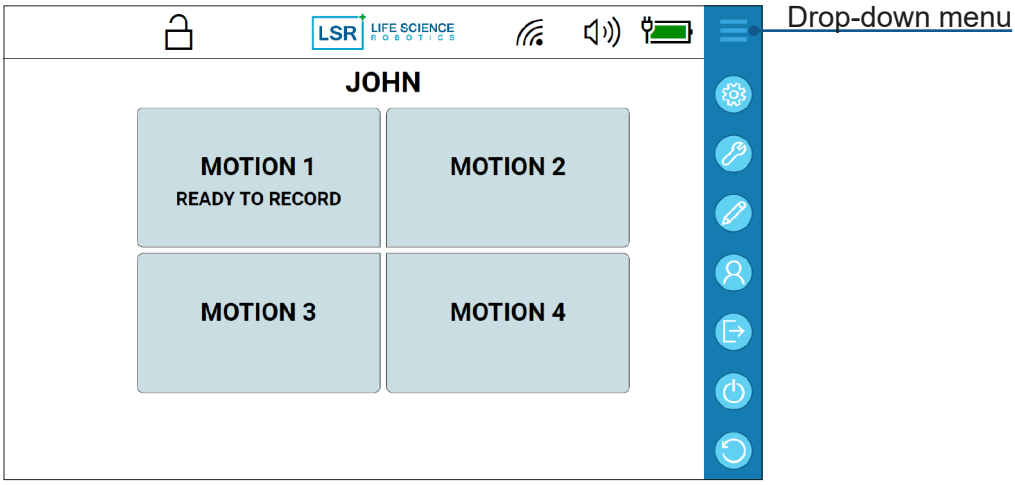


Figure 5: Homescreen with drop-down menu

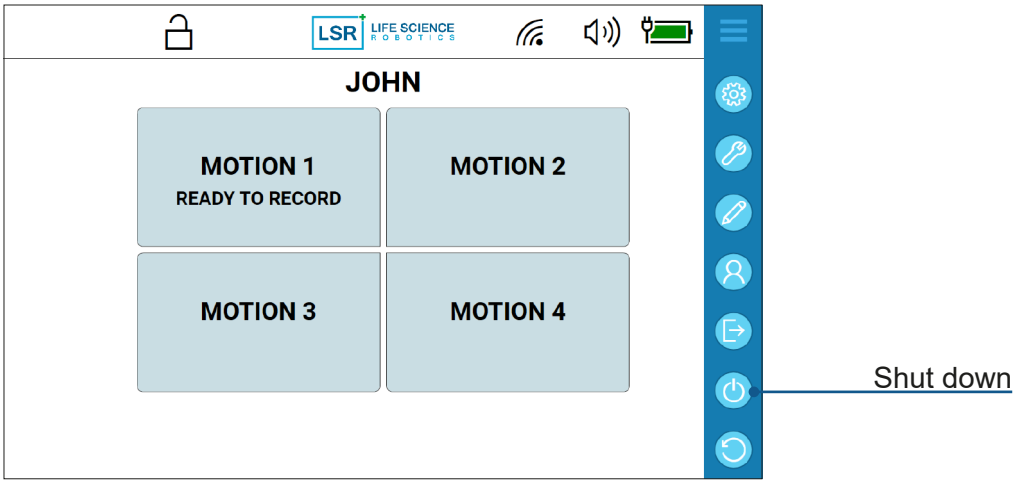


Figure 6: Shut down icon

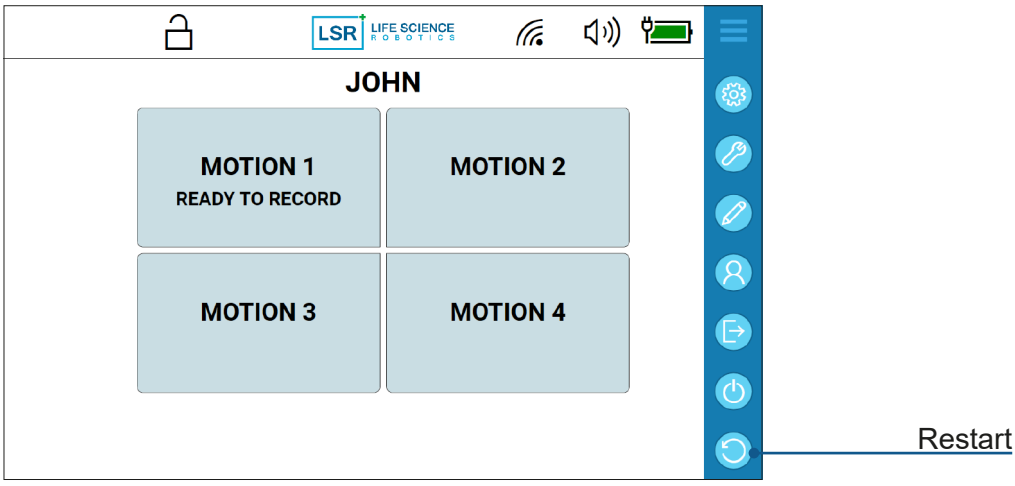


Figure 7: Restart icon

5.6 Robot arm

An essential component of ROBERT® is the collaborative robot arm. With its 7 degrees of freedom, it is able to replicate the movements of the healthcare professional, which allows ROBERT® to exercise and mobilize the patient's leg like a healthcare professional would normally do manually.

5.7 ROBERT® Linkage

The linkage is provided with three buttons; two that are used to connect and disconnect the accessory to/from the robot arm (”quick release” and ”attach”), and one (”record”) to record a motion (Figure 8). The linkage is provided with a light indicator that lights up or flashes in the colours red, yellow or green depending on different situations, see section ”8.1 ROBERT® linkage indications”.

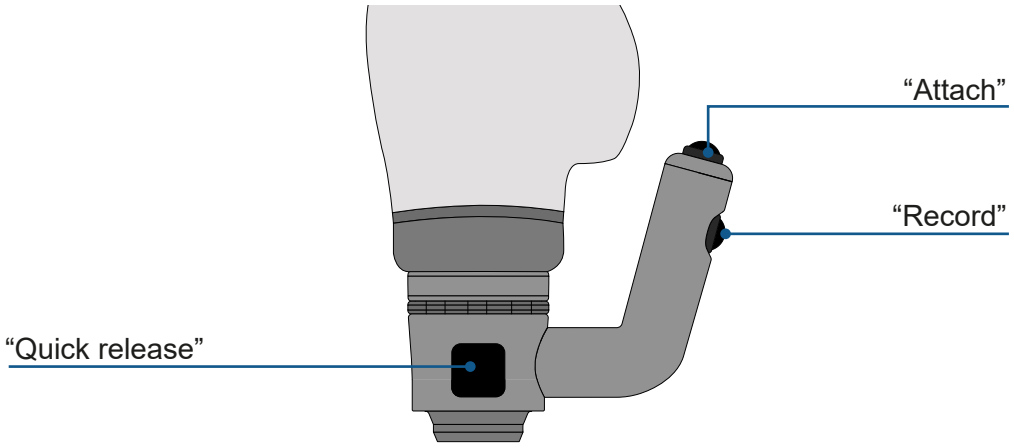


Figure 8: ROBERT® linkage with buttons

5.8 Linkage buttons

The “attach” button on the linkage must be pressed to move and position the robot arm when connecting/disconnecting the patient and to reset a motion.

The “record” button is used to weigh the leg and to record a motion. The button must be pressed once, and the leg is lifted off the mattress and into the starting position. The button can then be pressed and held down to record a motion. During recording of an exercise motion, the robot arm will support lifting the patient leg by 80% of the registered weight.

The “quick release” button is used to detach the patient from ROBERT® by disconnecting the brace or the fixtures from the linkage. If the patient is disconnected from ROBERT® while the leg is resting on the mattress, the “attach” button must be pressed down simultaneously to remove the robot arm. The patient can also be detached by releasing the sheet around the patient's leg.

5.9 Touchscreen

On the body of ROBERT® a touchscreen is attached to a movable arm. The touchscreen operates in two different ways; by default, the touchscreen functions interactively with the Operator and from here exercises can be set and adjusted. The Operator can switch the touchscreen to a patient view where the touchscreen functions as a display from where the patient can keep track of the exercises, see section ”6.7.3 Patient view”. Two types of exercise modes can be chosen from the touchscreen:

- Guided mode: This mode is chosen when the Operator wants ROBERT® to perform passive and active assistive exercises. ROBERT® performs the exercise set up by the Operator. The patient can move with the robot arm by activating the muscles needed to perform the exercise. The patient can also be passive during the exercise and the robot arm will still perform the exercise.
- Active mode: This mode is chosen when the Operator wants ROBERT® to perform active resistive exercises. ROBERT® offers different levels of resistance for the exercise in the direction of start to finish positions as set up by the Operator. The patient has to overcome the resistance to move the robot arm by activating the muscles needed to perform the exercise.
- Combined modes: Active and guided mode can be chosen in combination of sets. A maximum of 8 sets can be set up within a motion. For each set, the mode (active or guided), shall be chosen; thus, making it possible to have e.g., 2 sets in guided mode and then 6 sets in active mode, or it is possible to have e.g., 8 sets in only active mode.

In addition to the shut down and restart function, the drop-down menu in the upper right corner of the touch screen also contains a settings menu (Figure 9) with the option to adjust several parameters. These options are explained in the following:

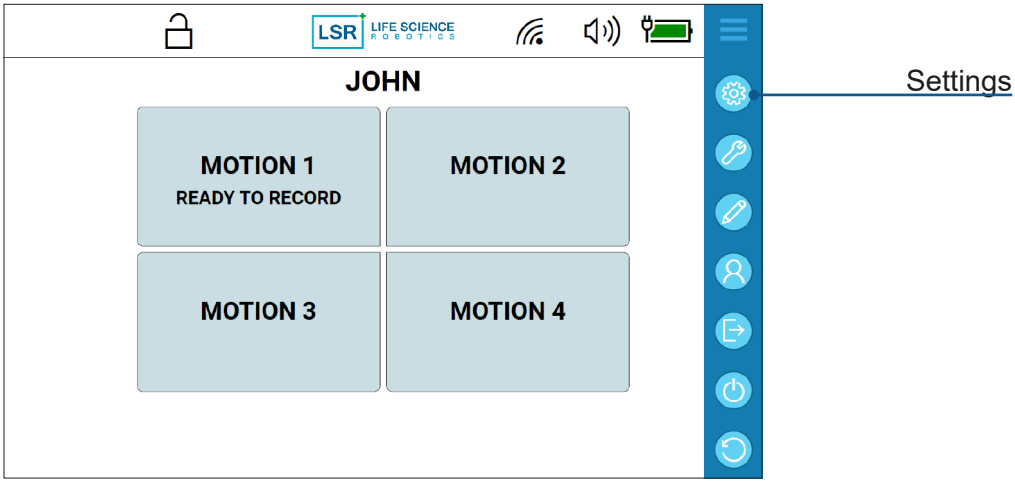


Figure 9: Settings menu in drop-down menu

Sound

The sound setting (Figure 10) allows the operator to adjust sound indications to assist the patient when performing exercises. This will enable the patient to focus on the movements and allowing them to know when repetitions are performed correctly. The sound indications can be turned on/off individually and adjusted from level 1-10 and/or muted altogether. The device remembers the settings from the previous adjustment even after shutdown. Four types of sound indications can be chosen from the settings menu on the touchscreen:

- Motion start: This sound provides a countdown sound to indicate the patient can start exercising.
- Motion end: This sound provides a completion sound to indicate the end of a complete motion, the patient can stop exercising.
- Repetition start (Active): This sound provides a signal to indicate the reaching of the starting point of a repetition. Thereby the patient knows that he/she is at the beginning of a repetition. This sound is only active in Active mode and not in Guided mode.
- Repetition end: This sound provides a signal to indicate the reaching of the end point of a repetition. Thereby the patient knows that he/she has completed the full length of that specific repetition.

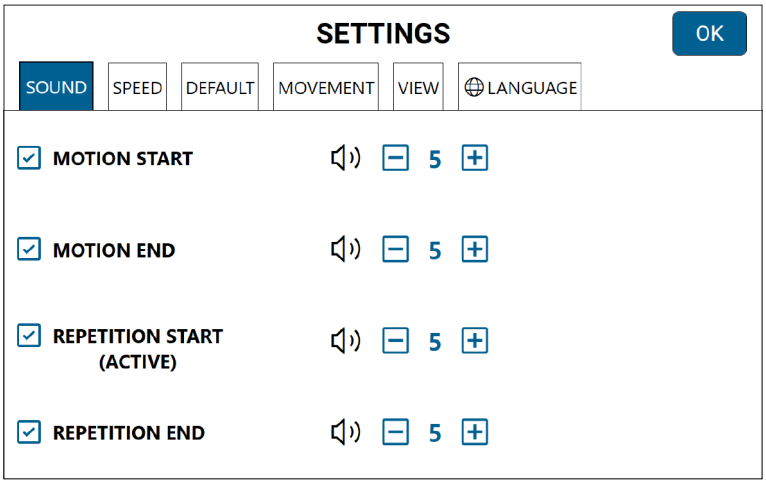


Figure 10: Sound settings in the Settings menu

Speed (Guided)

This setting allows you to adjust the speed by which a guided motion is executed. The setting however, also applies to the return speed in active mode. The speed can be set in 3 settings: low, medium and high.

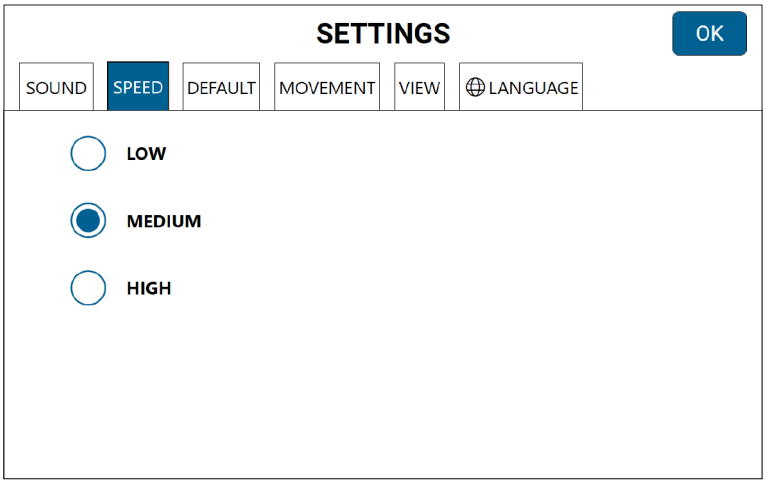


Figure 11: Speed settings in the Settings menu

Default

This setting allows you to adjust the default parameters, specifically:

- Break time (Motion), meaning the time in seconds before starting the next motion.
- Break time (Set), meaning the time in seconds before starting the next set.
- Repetitions (Active), meaning default number of repetitions when setting up sets in active mode
- Repetitions (Guided), meaning default number of repetitions when setting up sets in guided mode
- Resistance, meaning default level of resistance when setting up sets in active mode

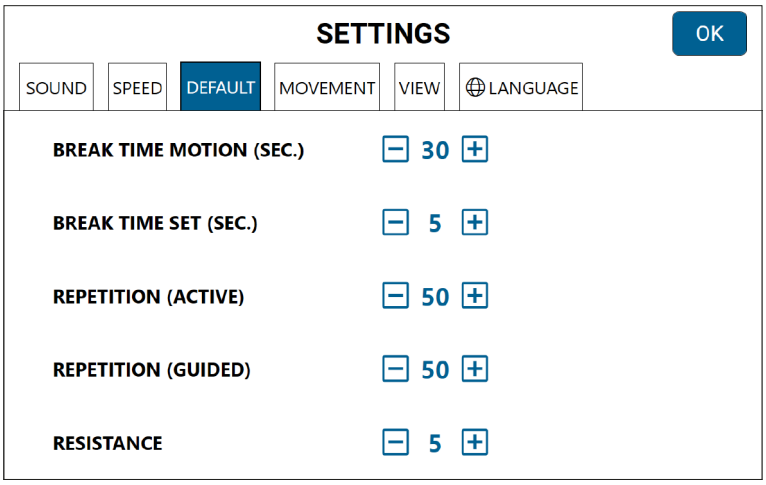


Figure 12: Default settings in the Settings menu

Movement

This setting allows you to enable/disable the following settings:

- Automatic return, meaning the device will automatically return to repetition start position if the patient has had a standstill in active mode of more than 2 seconds at the end position of an exercise repetition.
- Assisted completion (Active), meaning the device will automatically complete the exercise repetition if the patient at any position in active mode has had a standstill of more than 2 seconds.
- None, meaning none of the above are chosen; hence the device does not return movement in active mode, if the patient does not move.

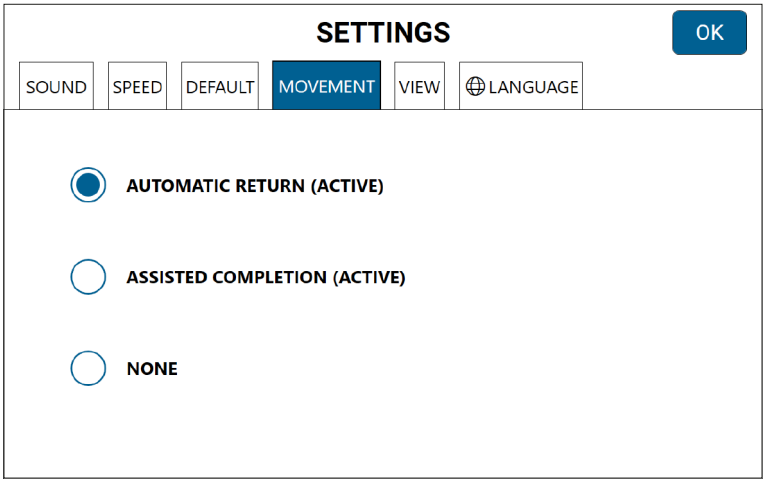


Figure 13: Movement settings in the Settings menu

View

This setting allows you to control the amount of graphical supportive measure in patient view.

- Simplified patient view, meaning a reduced number of graphical measures in guided and active mode respectively. Specifically, only the progress bar, the repetitions and the resistance level (active) are visible.

If simplified patient view is not selected for any modes, the full number of graphical measures will be displayed including the force indicators are visible.

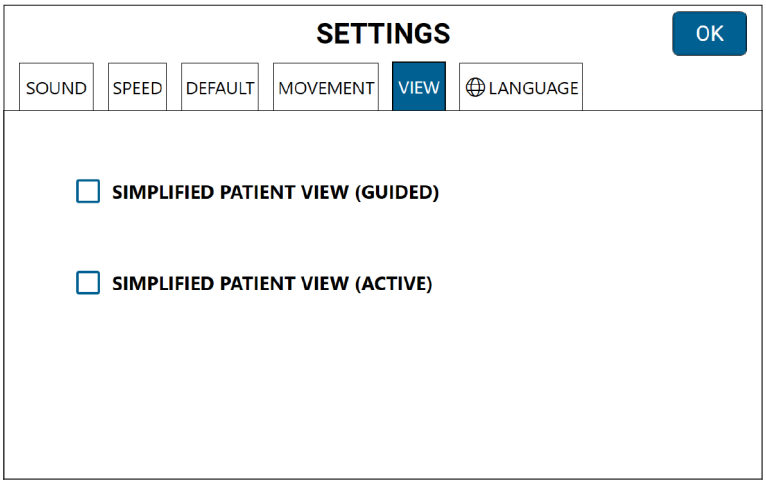


Figure 14: View settings in the Settings menu

Language

This setting allows you to set the language of the Touch screen.

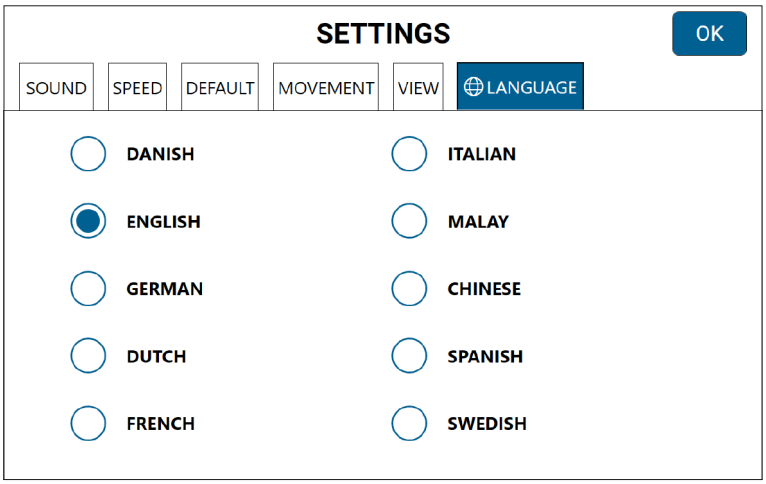


Figure 15: Language settings in the Settings menu

5.10 Accessories

ROBERT® includes accessories to be used to connect the patient's leg to the robot arm. These accessories consist of a brace and two types of fixtures, all with a connector to the linkage. The brace and fixtures are provided with textile sheets, straps and pillows, and are described in the following:

5.10.1 ROBERT® Brace

The brace is provided with textile sheets of varied sizes and a pillow of pressure-absorbing material for the lower leg (Figure 16). The sheet must be fixed to the brace and wrapped around the patient's leg.

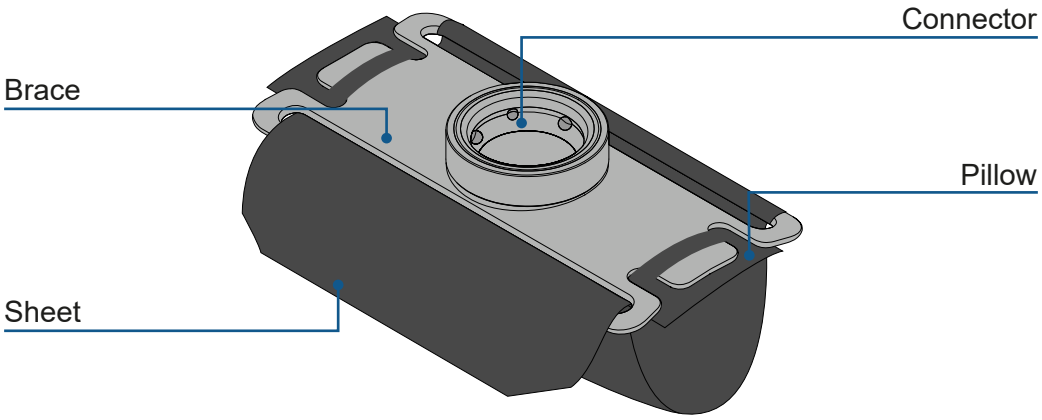


Figure 16: ROBERT® Brace

5.10.2 ROBERT® Fixtures

The fixtures are provided with textile sheets of varied sizes, a pillow of pressure-absorbing material for the lower leg, foot straps to fix the foot and heel pillows of varied sizes in pressure-absorbing material for the heel (Figure 17 and Figure 18). The sheet must be fixed to the fixtures and wrapped around the patient's leg and the foot straps shall be fixed to the footplate.

The Fixture No.1 is recommended for supine positioned exercises.

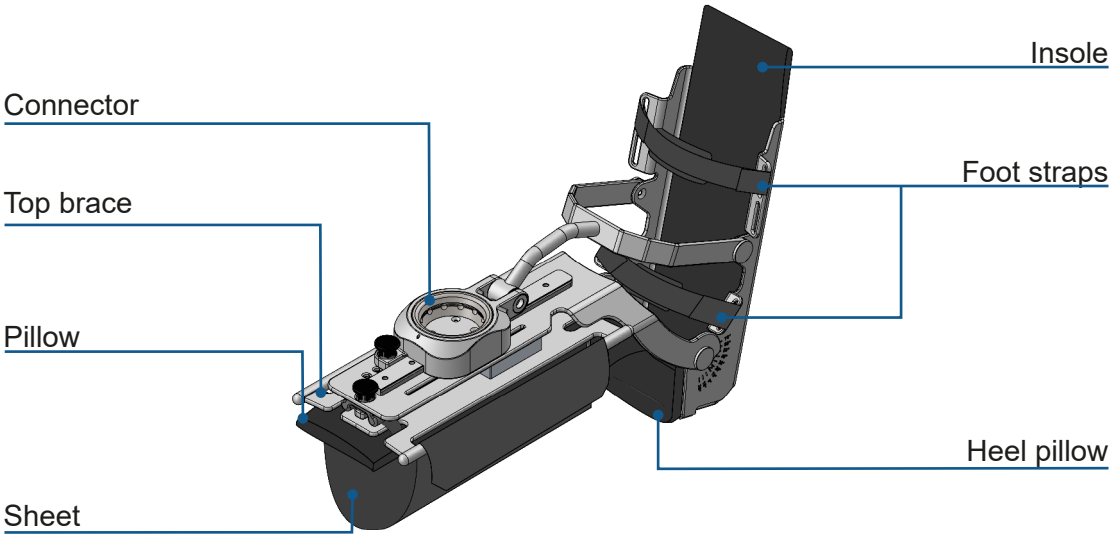


Figure 17: ROBERT® Fixture No.1

The Fixture No.2 is recommended for lateral positioned exercises.

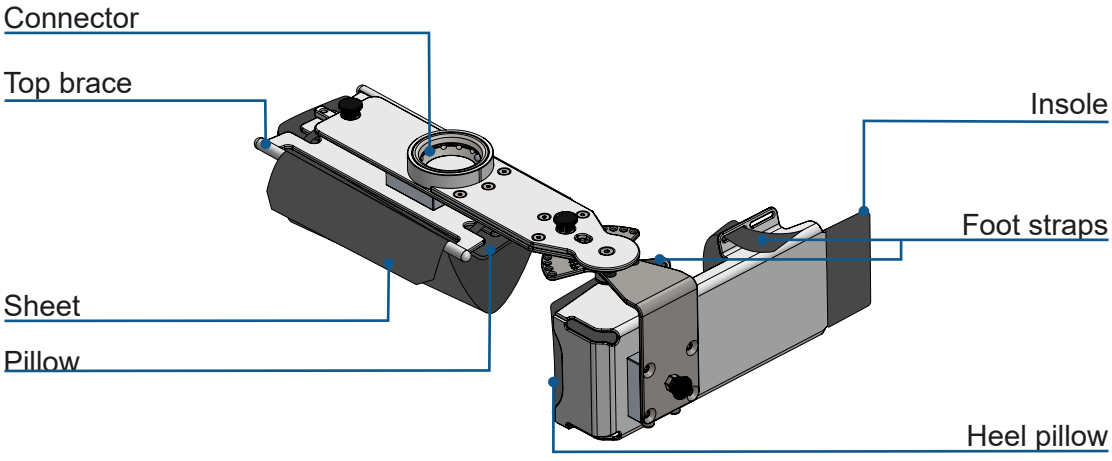


Figure 18: ROBERT® Fixture No.2

6. HOW ROBERT® WORKS - NORMAL OPERATING MODE

The following sequences describe the handling of ROBERT® during normal use.

6.1 Mounting the accessory

1. Make sure that the patient is lying supine or laterally, with both legs stretched out, depending on the planned exercise.
2. Inspect the patient and evaluate her/his condition and inform the patient about the following exercises.
3. Mount an accessory on the lower patient's leg with the connector pointing upwards. The mounting of the brace and the fixtures is described in the following:

6.1.1 ROBERT® Brace:

Place the sheet under the lower patient's leg just below the knee, and place the brace on the front or the side of the lower leg and attach the brace to the lower leg as illustrated (Figure 19 and Figure 20). Tighten the sheet to fit the leg, without creating discomfort for the patient. The brace can be used for both supine and lateral exercises.

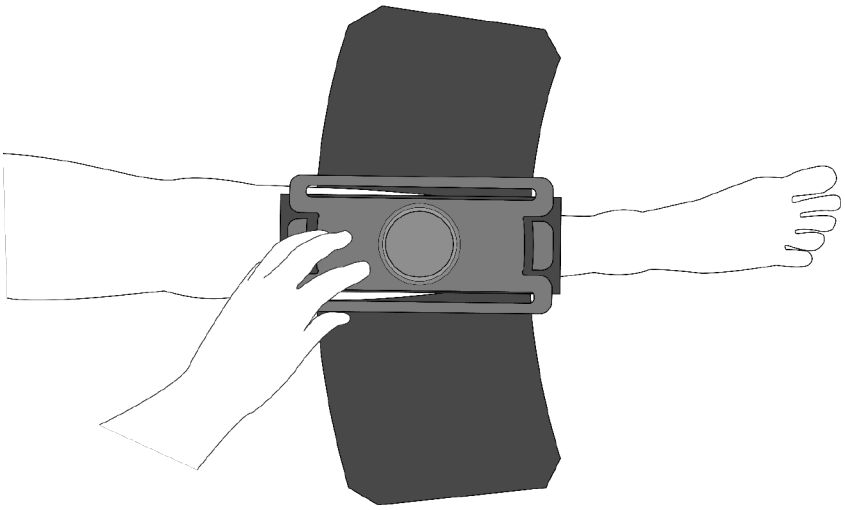


Figure 19: Positioning of the brace on the tibia

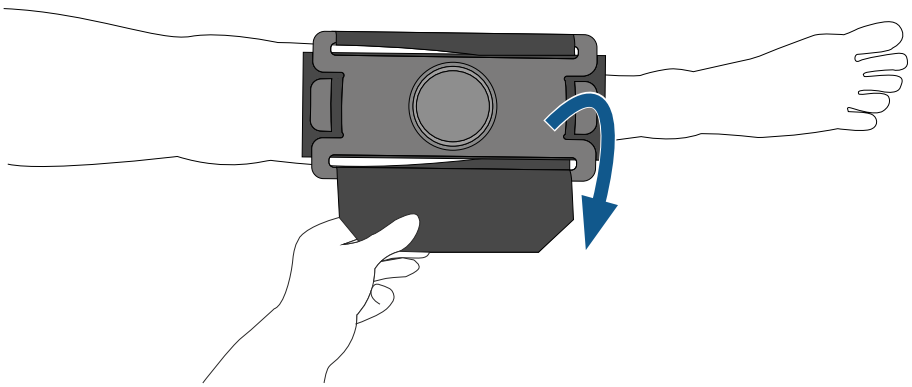


Figure 20: The sheet is placed through the holes, and attached using the velcro

6.1.2 ROBERT® Fixture No.1

Adjustment

The fixture no.1 can be adjusted in two different ways to better fit the patient's lower leg and foot:

1. To adjust the length of the top plate, pull the first rotary button upwards. Adjust the length of the top plate by sliding it forwards or backward. The position is locked when the button falls into place with a "clicking" sound (Figure 21).

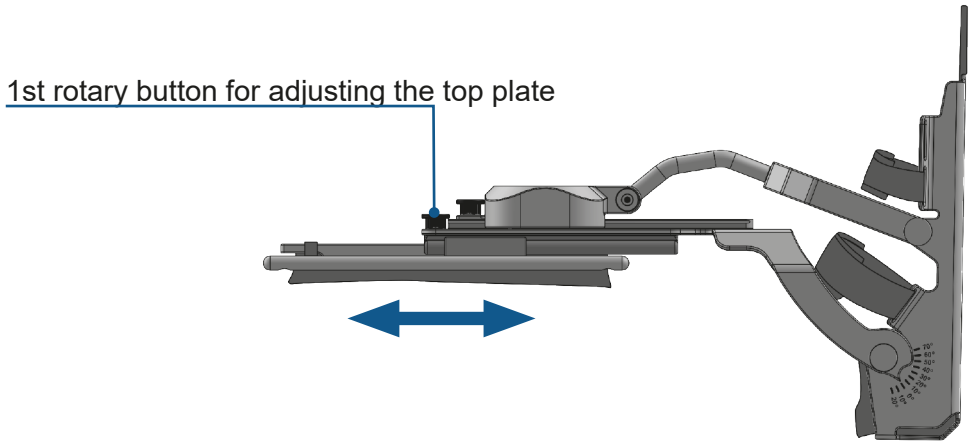


Figure 21: Adjustment of top plate

2. The angle of the footplate can be adjusted to a locked angle of -20° to 70° at an interval of 10° by pulling the second rotary button (Figure 22). Move the sleigh into position. The position is locked when the button falls into place with a "clicking" sound.

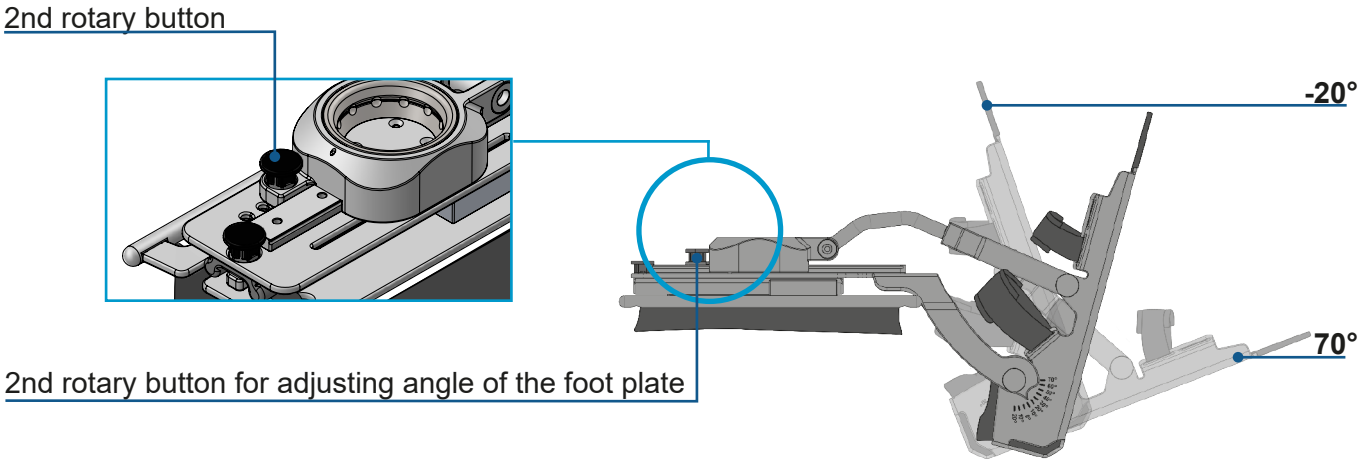


Figure 22: Adjustment of angle of foot plate

To enable plantar or dorsal exercises of the foot, pull the rotary button (as also used for angle position) and turn it slightly to one side. This will unlock the sleigh (Figure 23). It is recommended not to unlock the sleigh until after weighing the leg, see section ”6.6 ROBERT® detects the weight of the patient’s leg”. For all exercises other than plantar or dorsal exercises, the sleigh should be in locked position.

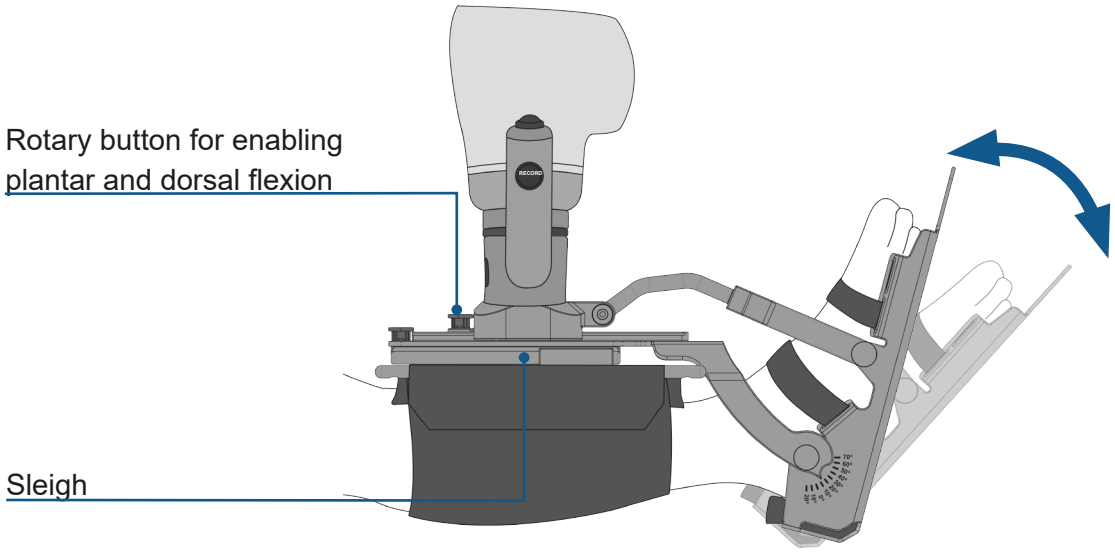


Figure 23: Enabling plantar and dorsal flexion

Mounting

Place the fixture over the lower leg and the foot on the footplate with the insole (Figure 24). Attach the fixture to the lower leg and foot as illustrated (Figure 25).

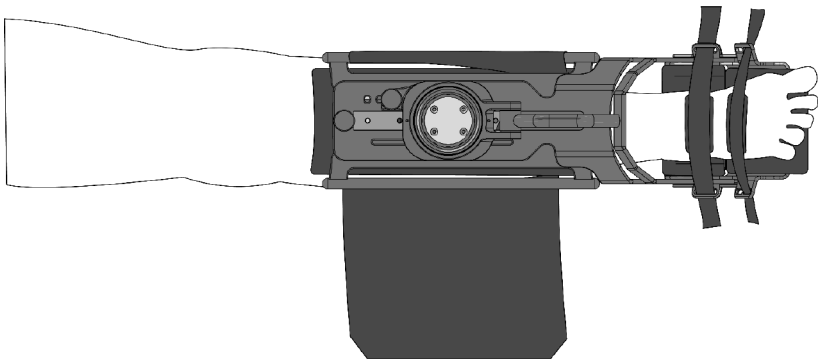


Figure 24: Positioning the fixture around the foot

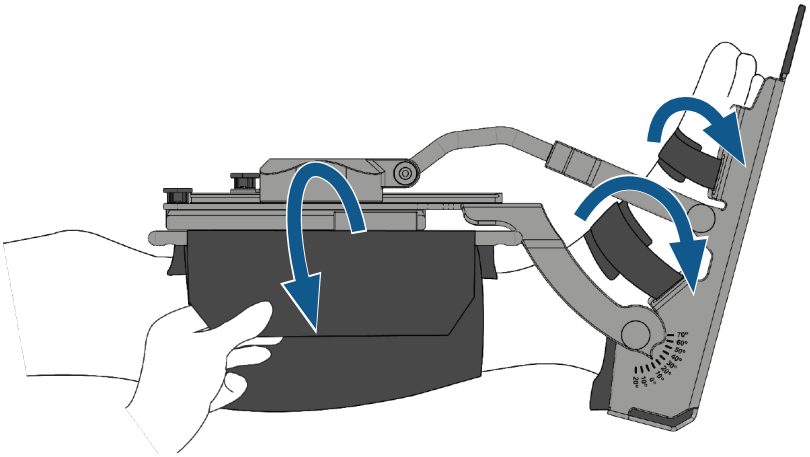


Figure 25: Slide the sheet through the holes, and close the velcro. Attach the footstraps accordingly

6.1.3 ROBERT® Fixture No.2

Adjustment

The fixture no.2 can be adjusted in different ways to better fit the patient's lower leg and foot:

1. To adjust the length of the top plate, pull the first rotary button upwards. Adjust the length of the top plate by sliding it forwards or backward. The position is locked when the button falls into place with a "clicking" sound (Figure 26).

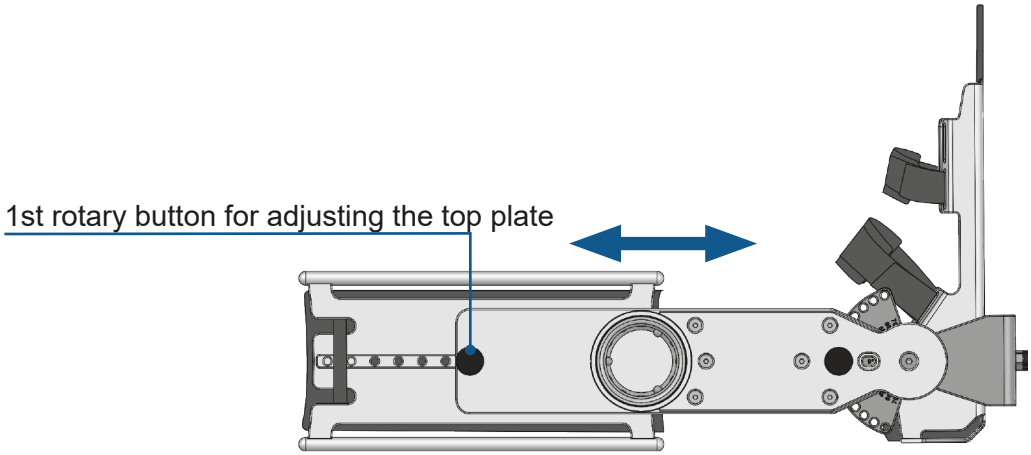


Figure 26: Adjustment of top plate

2. To adjust the height of the foot plate, pull the second rotary button outwards. Adjust the height of the foot plate by moving it upwards or downwards. The position is locked when the button falls into place with a ”clicking” sound (Figure 27). If the fixture no.2 is to be used for the other side, simply pull the foot plate completely of, turn it, and slide it into position.

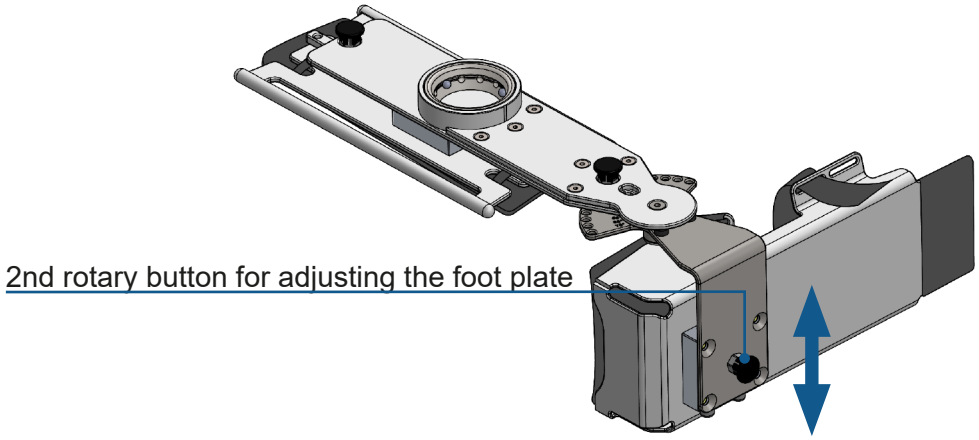


Figure 27: Adjustment of foot plate

3. The angle of the footplate can be adjusted to a locked angle of -20° to 70° at an interval of 10° by pulling the third rotary button (Figure 28). Angle the foot plate suited for the patient. The position is locked when the button falls into place with a ”clicking” sound.

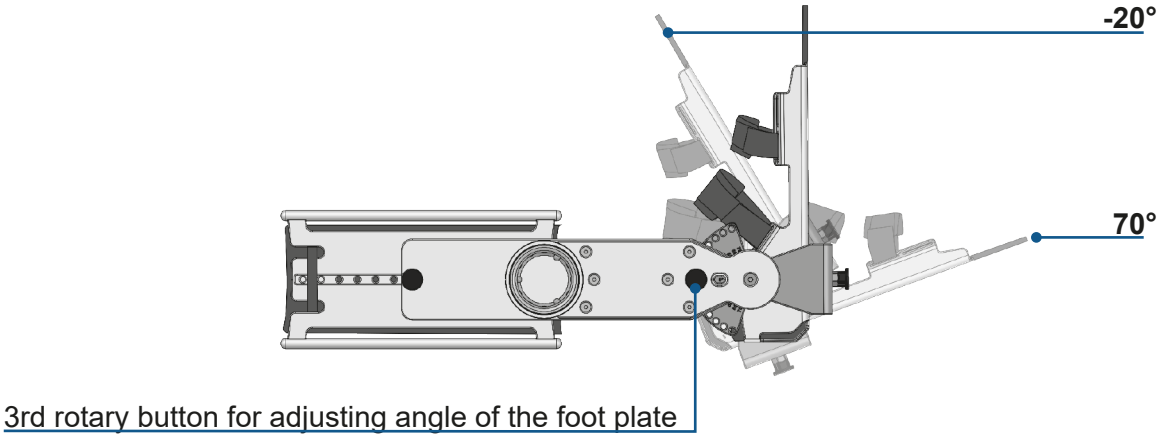


Figure 28: Adjustment of angle of foot plate

Mounting

Place the fixture over the lower leg and the foot on the footplate with the insole (Figure 29). Attach the fixture to the lower leg and foot as illustrated (Figure 30).

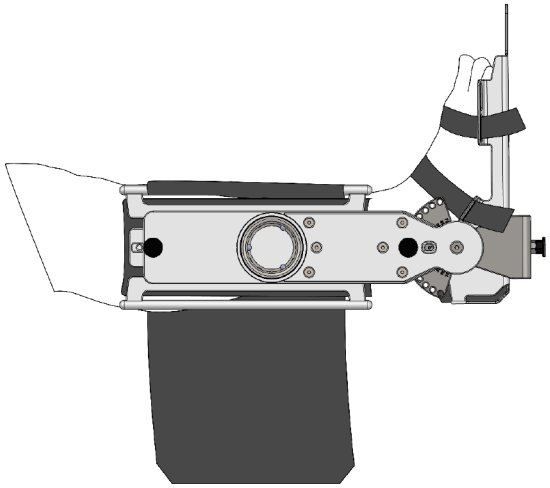


Figure 29: Positioning the fixture around the foot

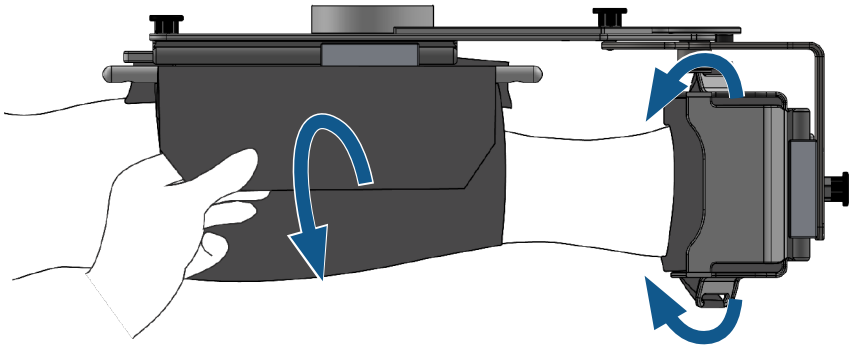


Figure 30: Slide the sheet through the holes, and close the velcro. Attach the footstraps accordingly

6.2 Prepare ROBERT® for exercises

1. Place ROBERT® close to the bed with the robot arm positioned away from the patient (Figure 31).

Figure 31: Positioning ROBERT®

2. Activate the brakes by pressing down the footswitch (Figure 32).

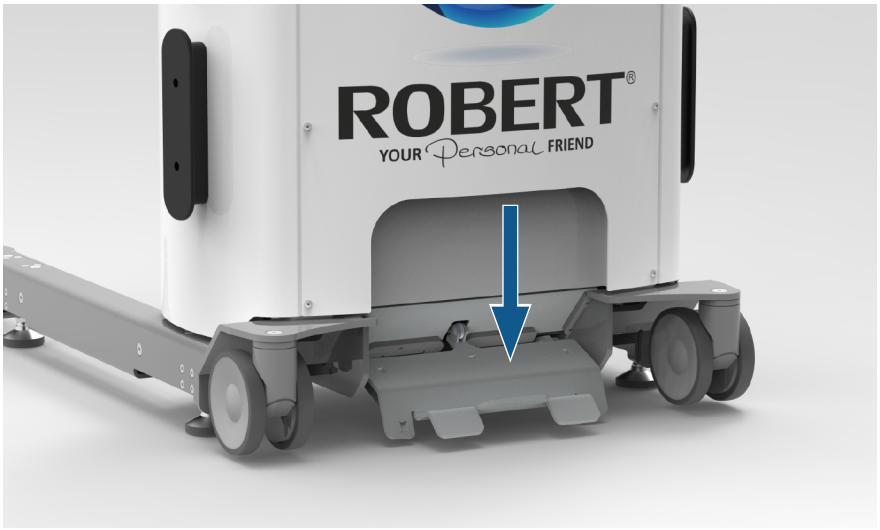


Figure 32: Braking ROBERT®

3. Plug the power supply cord into the device inlet on the ROBERT® body and into a power outlet.

6.3 Start-up ROBERT®

1. Turn on the “power switch” located on the side of the body. The device is turned on by switching the “power switch” to “on” (I) whereafter it flips back to centre position. Likewise, to turn it off switch the ”power switch” to ”off” (0) (see Figure 3 page 9). It is recommended to have the deivce connected to a power outlet at all times to avoid shut down due to a low battery. When ROBERT® is turned “on”, the touchscreen will also turn on and start booting the ROBERT® software system (Figure 33).

NOTE: Make sure no accessory is attached to the robot arm when turning ROBERT on.

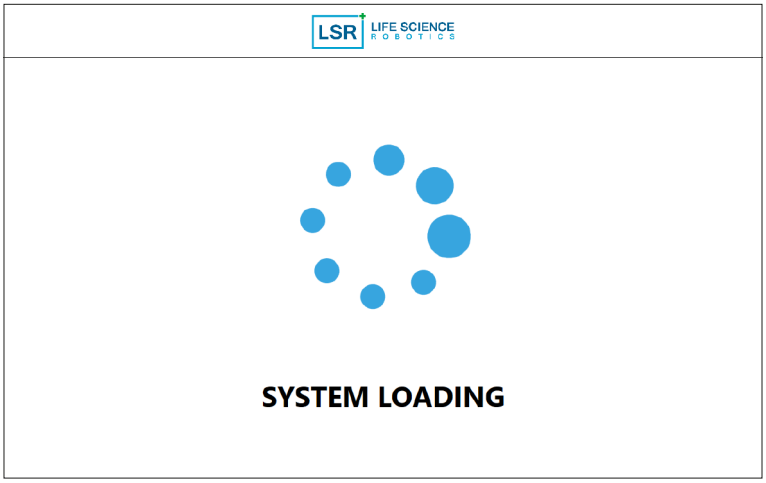


Figure 33: System booting on touchscreen

2. After approximately one and a half minutes, ROBERT® will perform a system check by first performing small movements in every joint of the robot arm, lifting the arm and then returning the robot arm to the home position. During the system check the light indicator flashes yellow, see section ”7.3 System check”. When the system check is finalized, the light indicator turns off. The display changes to the device start screen and ROBERT® is ready for use.

Be aware of the movements during system check. The device must be turned away from the patient/bed!

3. If the device has the Data Collection Module installed the device requires a user login to access the use of it (Figure 34).

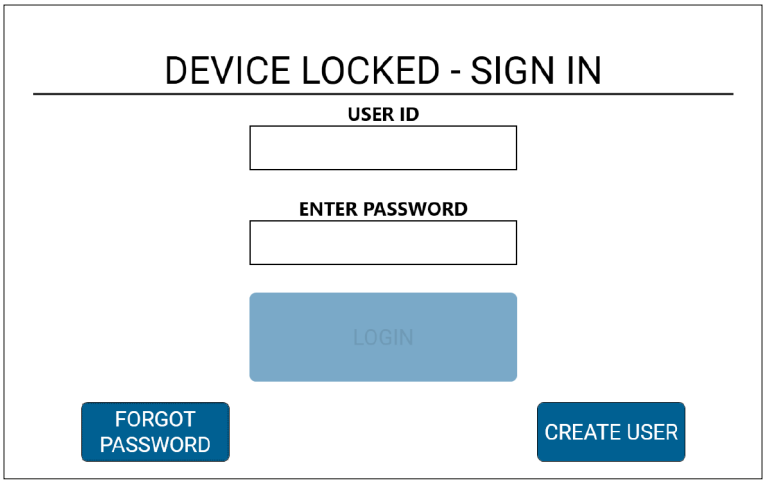


Figure 34: User login

A unique user login must be created for every user of the device. User ID and password is selected during setup.

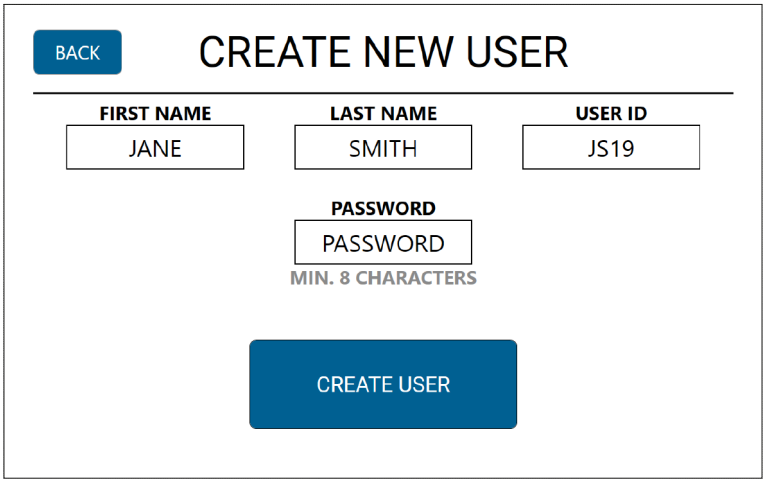


Figure 35: New User setup

A Master password must be entered to confirm the creation of a new user. The Master password is the serial number of the device in the format “SNXXXXX”. In case you forget your password, the Master password is also used to reset the user password.

4. Upon user login you are directed to the start screen.

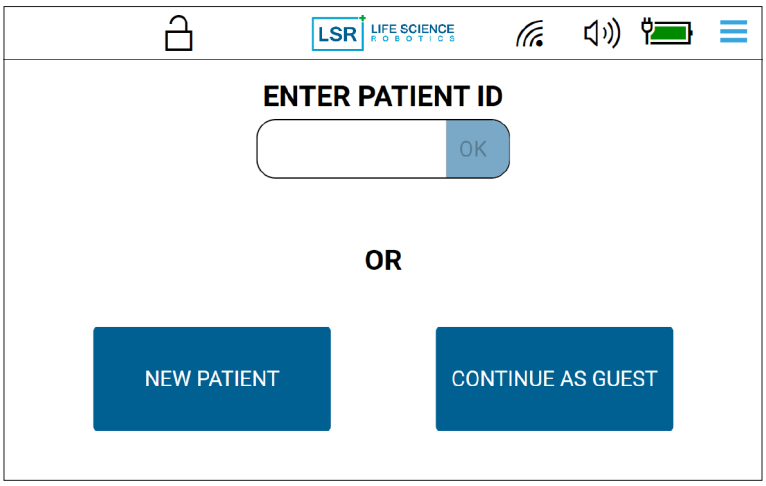


Figure 36: Start screen

5. At any time after entering patient ID you can lock the access to patient data by pressing the ”lock” icon at the top of the screen (Figure 37). To access patient data again, you must sign in with your user login. The device will anyhow lock the access to patient data if there has been no activity, meaning activations of features on the screen and/or the buttons of the device after 10 min.

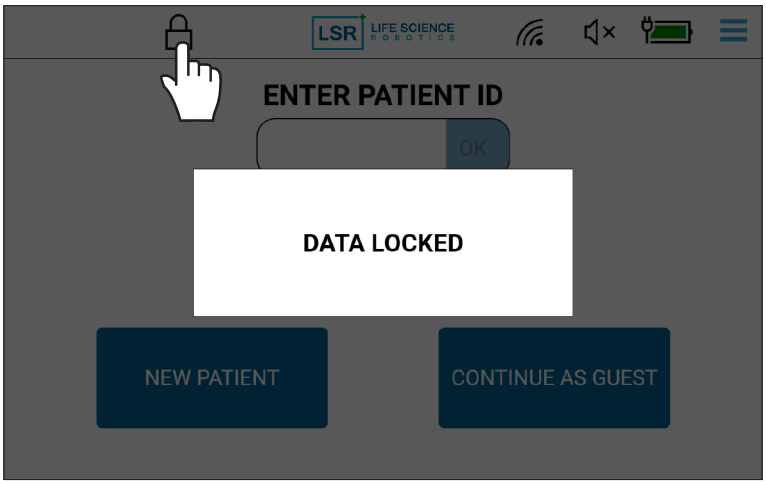


Figure 37: Lock the access to patient data

Also, if wanting to lock the use of the device, you can do so in the dropdown menu (Figure 38). This will disable all features and it will not be possible to use the device until you have signed in again, or when a new user has logged in.

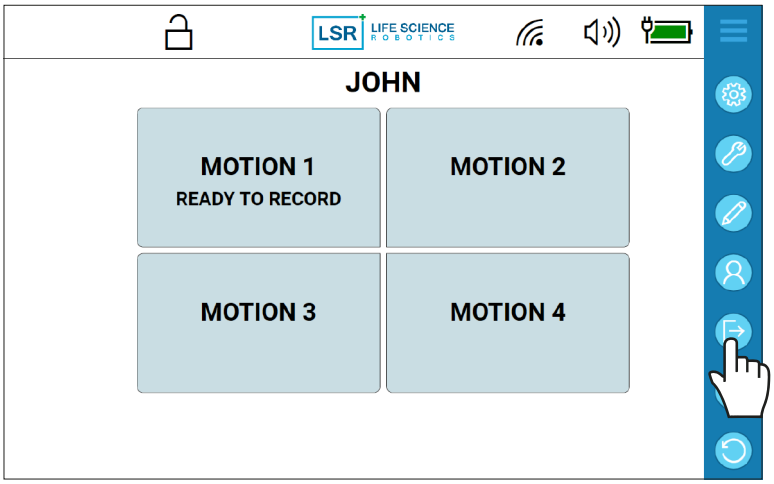


Figure 38: Lock the device

It is not possible to lock the use of the device while performing exercises. If there has been no activity, meaning no exercise motions, no activations of features on the screen and/or the buttons of the device, the device will automatically lock the use of the device after 10 min.

6. Position ROBERT® with the front towards the bedside, with the base frame under the bed. ROBERT® can also be positioned with the front at the end of the bed.

7. Activate the brakes by pressing down the footswitch.

Make sure the brakes are engaged before attaching the patient to ROBERT®!

6.4 Patient setup

1. If the device does not have the Data Collection Module installed, please proceed to section 6.5, otherwise depending on if the patient has used ROBERT® before or not, please perform one of the following:

   1a. Press ”continue as guest” if you do not want to record patient specific data and/or want to utilize previous training setups.

   1b. If the patient has previously trained with ROBERT®, enter patient ID and press OK (Figure 39). Patient ID is a combination of patient initials (2 letters) and patient date of birth (6 numbers), so e.g. JD600203, if patient name is John Doe and date of birth is 3rd of February 1960.

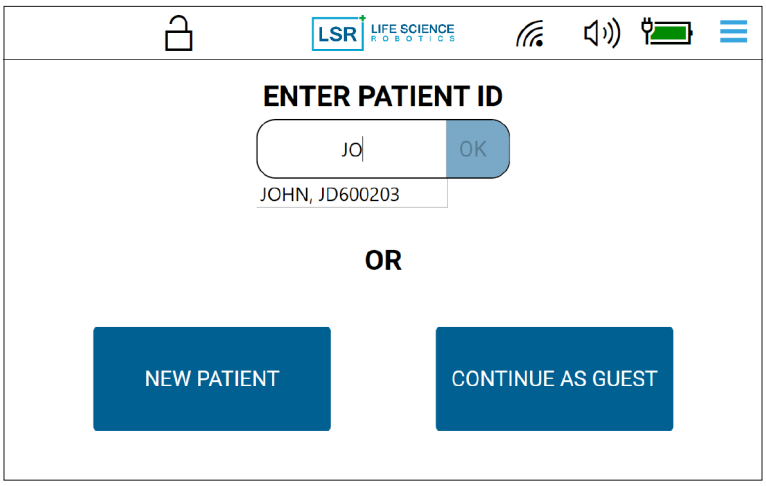


Figure 39: Existing patient

1.c If the patient is new to ROBERT®, press “new patient” (Figure 39) and fill in the data of the patient (Figure 40), and then press “save”. Hereafter you are asked to confirm patient creation (Figure 41)

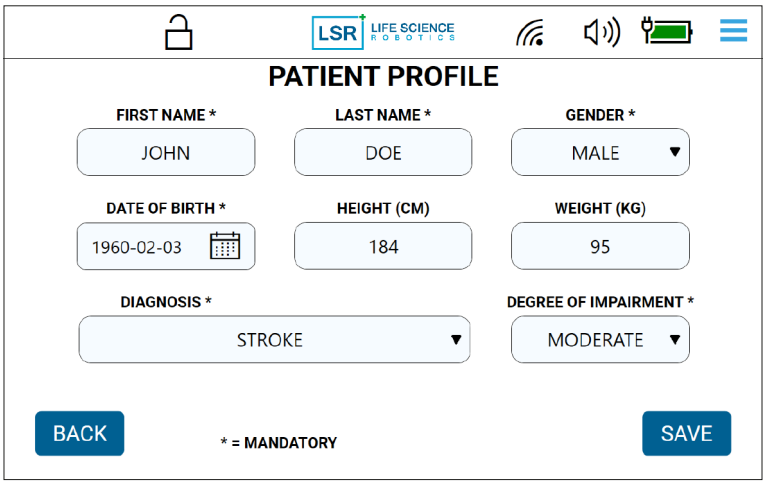


Figure 40: New patient setup

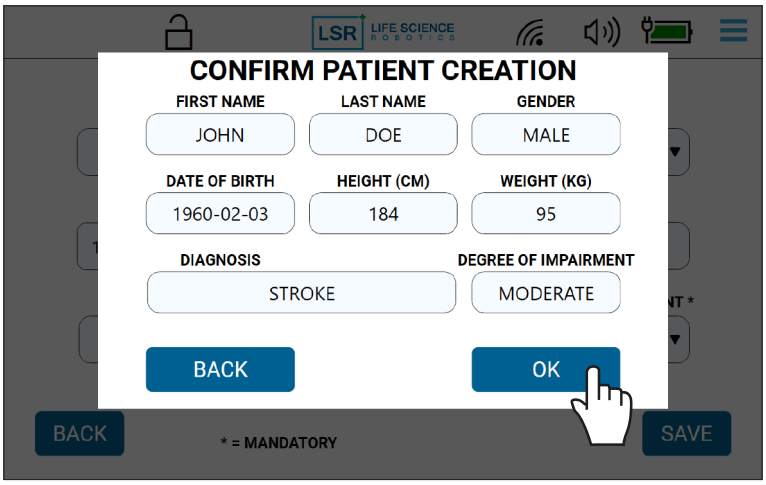


Figure 41: Confirm patient creation

2. Once signed in with the patient and if it is an existing patient, you can either review patient journal and/ or recall previous training setup.

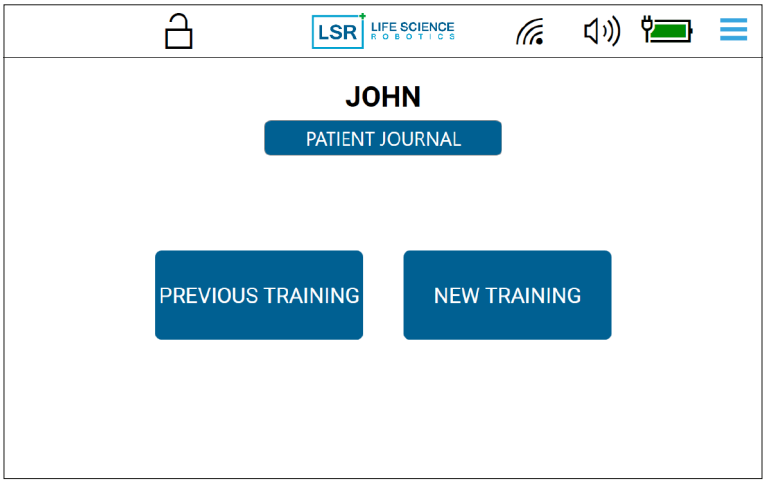


Figure 42: Patient training options

2a. “Patient journal” provides an overview of historic training data, e.g., progression in number of repetitions within a specific exercise type, as well as resistance and force measures for comparison. Select a period of data and press “view” (Figure 43). Hereafter, you can view different exercise data, depending on point of interest (Figure 44). If data is exported (only available with Data Export Module installed), data will be password protected. Password is the serial number of the device in the format “SNXXXXX”.

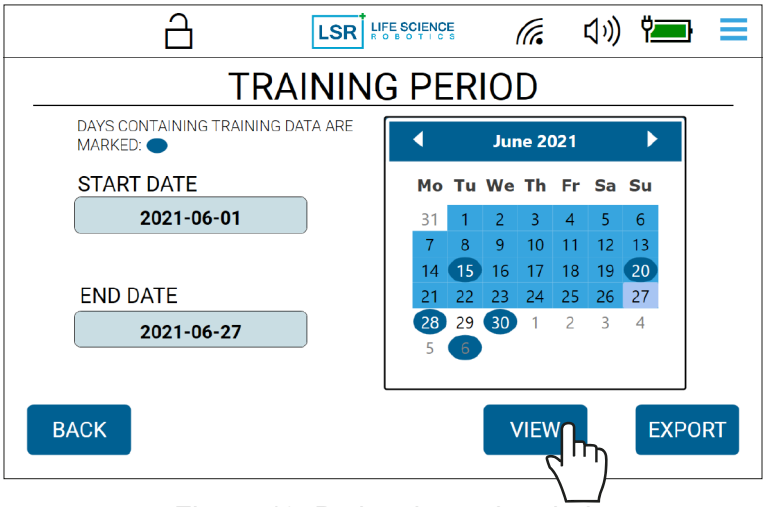


Figure 43: Patient journal period

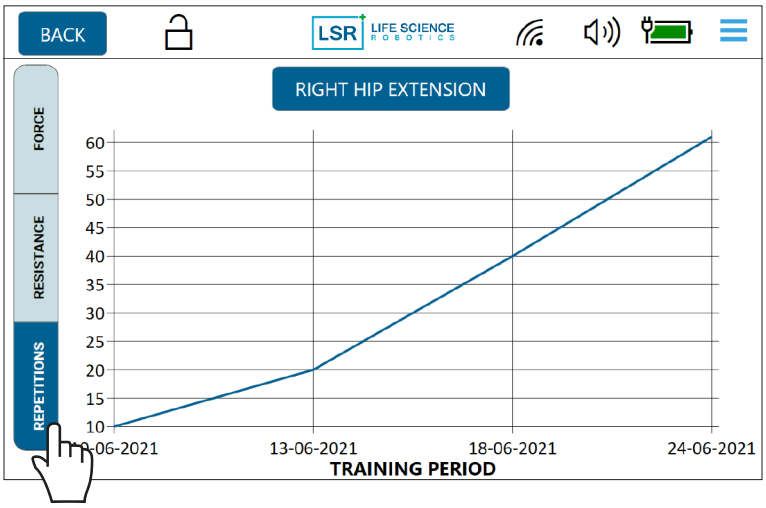


Figure 44: Progression data of the period of choice, example: Number of repetitions

2b. “Previous training” allows you to recall previous training setups. Scroll the previous training record(s) and select the wanted setup. Please note, that selecting a previous setup will only recall the parameters i.e., exercise type, number and type of sets, repetition number etc. within the motion setups. The recording of the exercise path must be performed uniquely per motion.

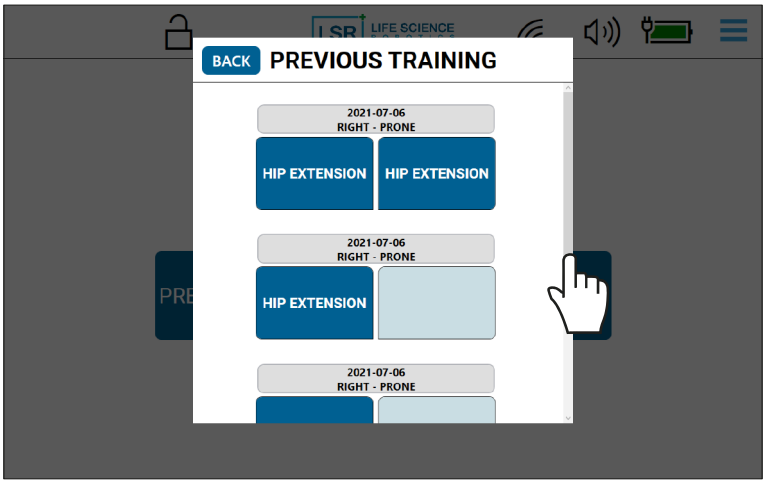


Figure 45: Previous patient training

2c. “New training” brings you to the actual setup of motion(s) as detailed in the following sections. Select this option if this is the first time a patient is using ROBERT® and/or if you want to setup a new set of exercise motion for an existing patient.

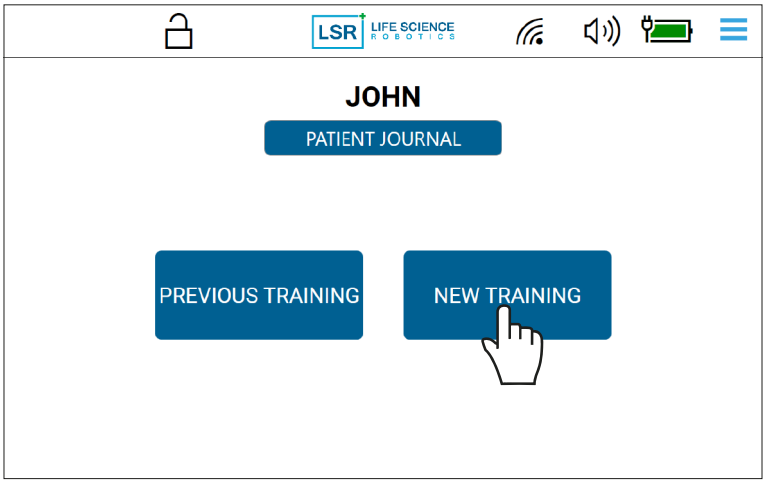


Figure 46: New training

6.5 Connect ROBERT® to the patient

1. Grab the linkage and hold down the “attach” button on the linkage when moving the robot arm (Figure 47).

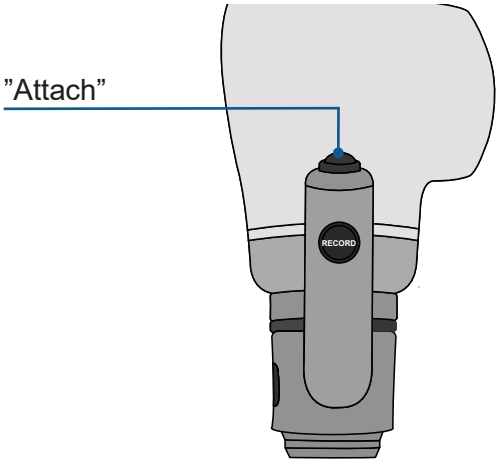


Figure 47: Linkage “attach” button

2. Move the robot arm to the accessory on the patient’s lower leg and connect the two parts by pressing them together while pressing the “attach” and “quick release” buttons. A small rotation of the linkage may be nessesary. The “quick release” button will fall into place when attached correctly (Figure 48).

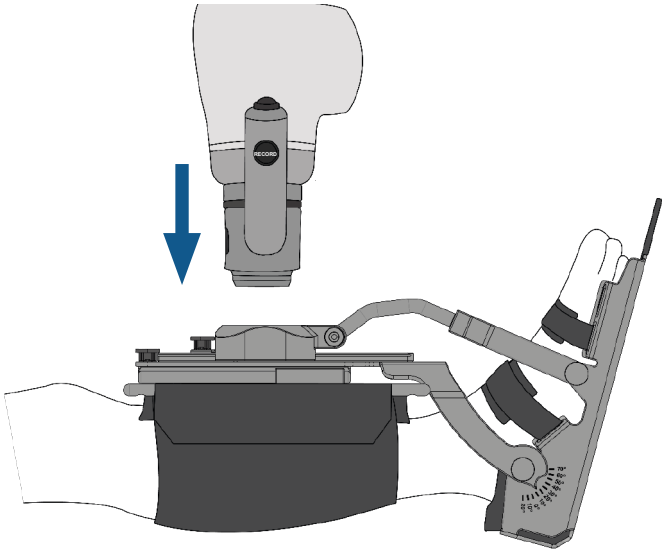


Figure 48: Connecting the linkage to the accessory

6.6 ROBERT® detects the weight of the patient's leg

1. Press the "record" button on the linkage briefly (1-2 sec.) (Figure 49). The robot arm moves vertically upwards, thus lifting the patient's leg free of the mattress and into starting position (Figure 50).

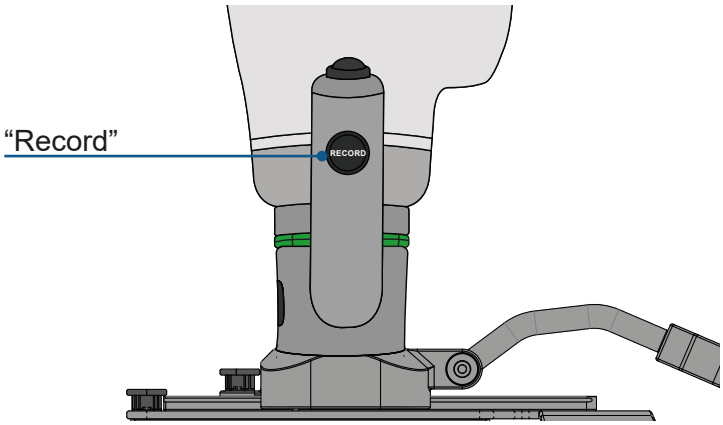


Figure 49: Linkage "record" button

2. ROBERT® assesses the weight of the patient's leg while lifting it free of the mattress and the light indicator on the linkage turns green. If the leg is too heavy, the light indicator will light up yellow and the robot arm will not be able to perform exercises. Be careful to position the ROBERT® linkage vertically, as this will allow the device to lift as large a load as possible.

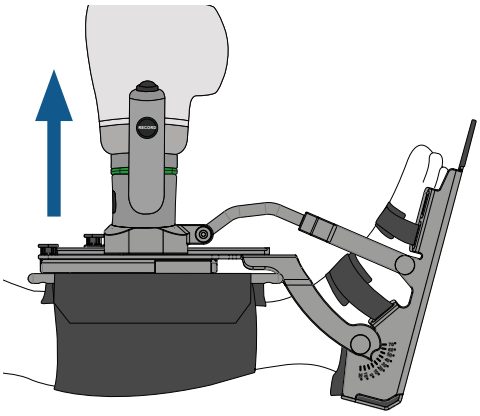


Figure 50: ROBERT® lifts and weighs the patient's leg

3. ROBERT® is ready to record the first motion. During recording an exercise motion, the robot arm will support lifting the patient leg by 80% of the registered weight.

6.7 Programming and execution of a motion

When programming a motion, distinction is made between guided and active modes, see section "5.9 Touchscreen" for further description. These modes will appear on the touchscreen within the motion setup when a motion has been recorded. The programming of motions and the setting up of modes is described in the following. It is recommended to record one motion at a time and in accordance with the normal movements of the hip, knee and ankle joint, e.g., recording a hip abduction in one motion and a hip adduction in another motion, and not a hip abduction and adduction in the same motion recording. For active mode, the robot arm offers different levels of resistance to the motion from the start and finish positions of the programmed motion, e.g., if the Operator wants to programme an exercise with resistance to a hip abduction, the start position of the hip must be in an adducted position and the end position of the hip must be in an abducted position.

6.7.1 Setting up motion(s)

1. Press and hold down the “record” button (Figure 51) while moving the patient’s leg to the start position of the motion. Release the “record” button with the patient’s leg in this position. Press and hold down the “record” button while moving the patient’s leg to the end position of the desired motion. After completing the desired motion, release the “record” button again. The programming of a motion is finalized. If you are unsatisfied with the motion, then repeat step 1 before proceeding to the next step.

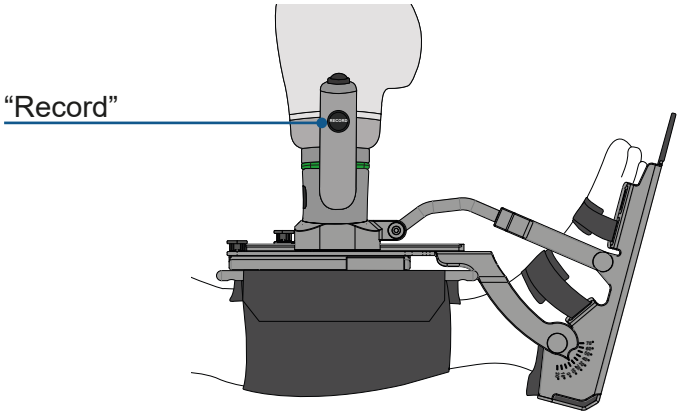


Figure 51: Record button

2. Press Motion 1 on the touchscreen (Figure 52).

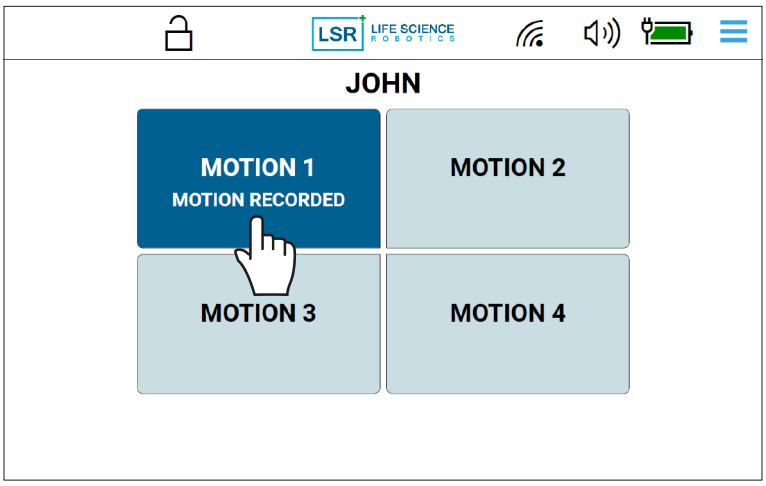


Figure 52: Selecting Motion 1

3. Within the motion setup menu, you firstly must set the prerequisites of the motion. This will allow you to later compare and evaluate the different training exercises, and also provide an overview after completion of the training session. When done selecting the prerequisites, press “confirm” to continue motion setup (Figure 53).

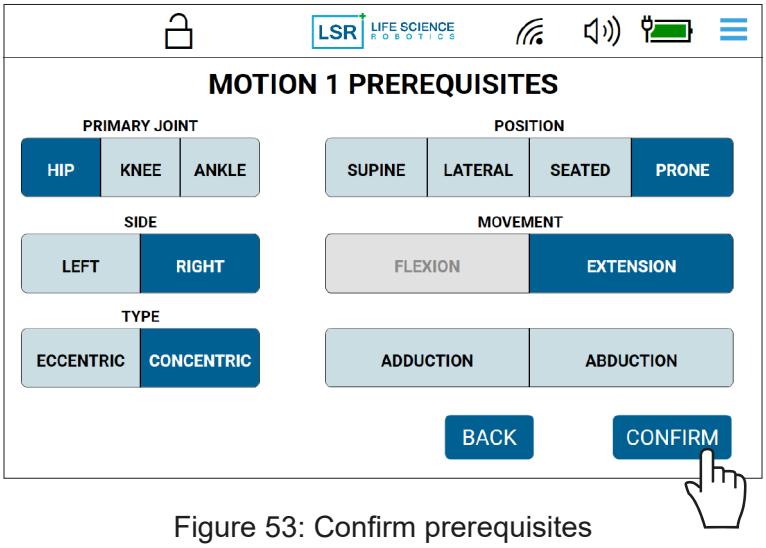


Figure 53: Confirm prerequisites

4. Secondly you have the option to add up to 8 sets of the recorded motion. Set the number of sets you want ROBERT® to perform for motion 1 by pressing "+" on the touchscreen (Figure 54). If you want to remove a set, press the "-".

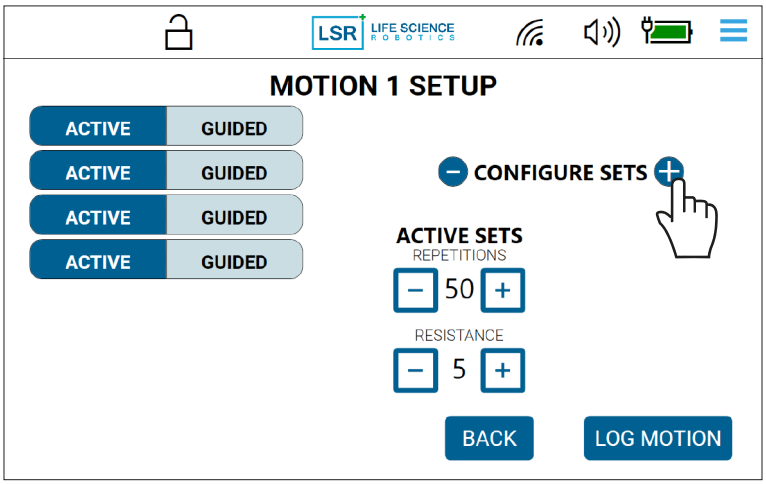


Figure 54: Adding number of sets

5. For each set you can select the mode (guided or active) (Figure 55). The chosen mode will be highlighted.

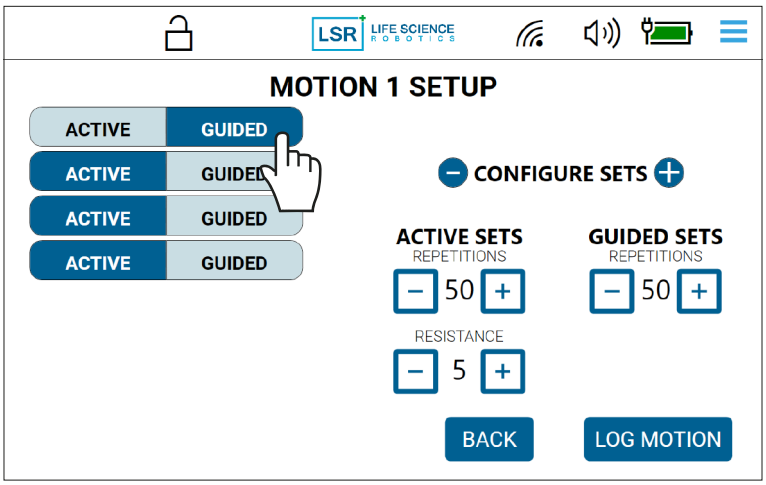


Figure 55: Selecting exercise mode

6. Set the number of repetitions you want ROBERT® to perform for each set by pressing “+” or “-“ on the touchscreen (Figure 56).

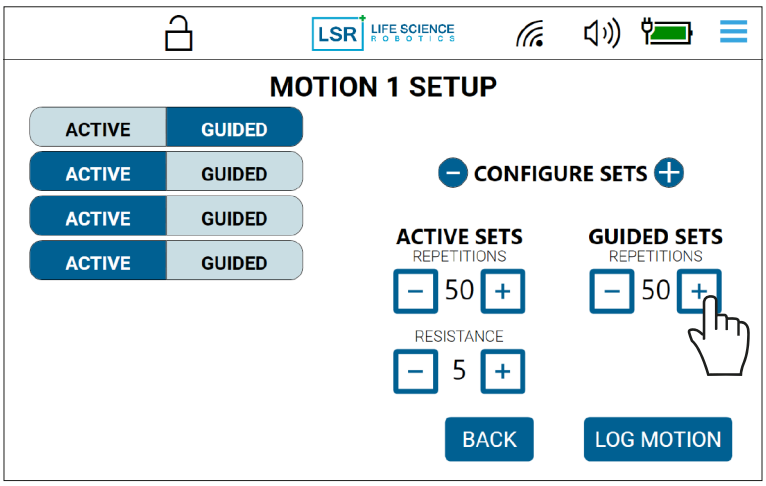


Figure 56: Selecting number of repetitions

7. For sets in active mode the level of resistance can be configured. Set the level of resistance you want ROBERT® to apply by pressing “+” or “-“ on the touchscreen (Figure 57). Level 1 has the lowest level of resistance and level 10 has the highest level of resistance.

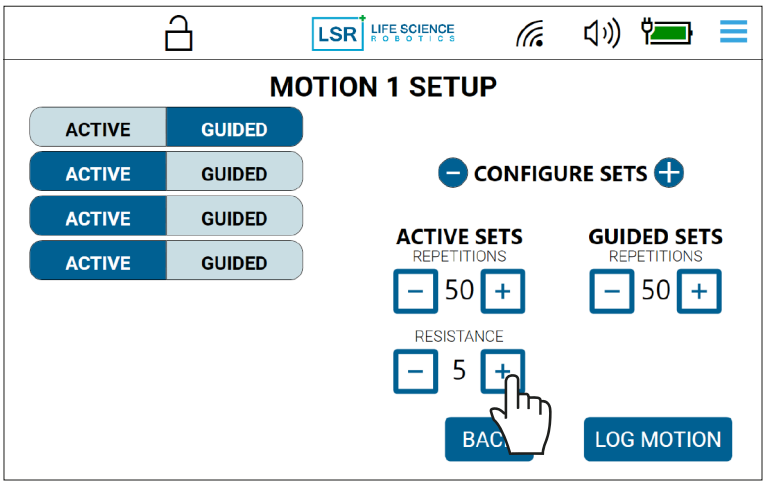


Figure 57: Setting level of resistance

8. The default settings (Figure 58), i.e., number of repetitions in guided mode, break time between sets etc. can be adjusted in the settings menu at any time during motion setup, see section ”5.9 Touchscreen”. Once the motion(s) has been started any adjustment to the “default” parameters will not be effectuated until motion completion.

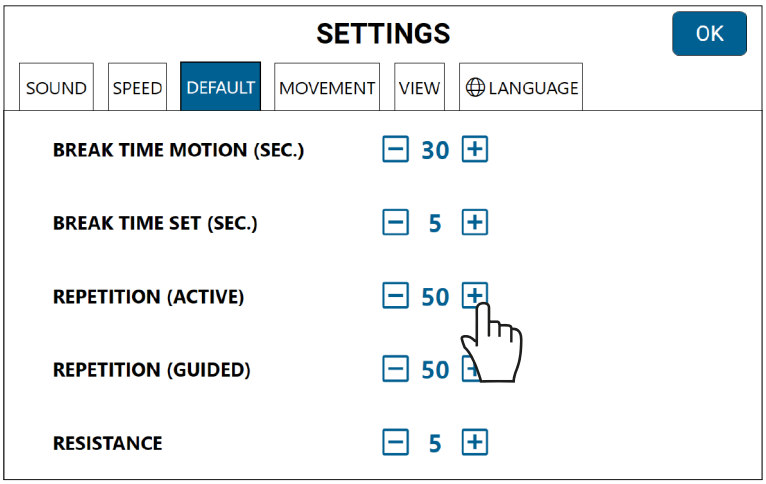


Figure 58: Default motion parameters

9. When Motion 1 setup is complete, press “log motion” on the touchscreen (Figure 59) and ROBERT® will log the forces backwards though the motion, while the light indicator flashes green. When the robot arm has returned to the starting position and the light indicator stops flashing green, the motion has been fully logged. If ROBERT® encounters forces or resistances that are too great during the first motion, the light indicator will be lit up yellow and the robot arm will stop and not be able to perform the motion. Try to record a new motion. When doing so the previous recording will be deleted.

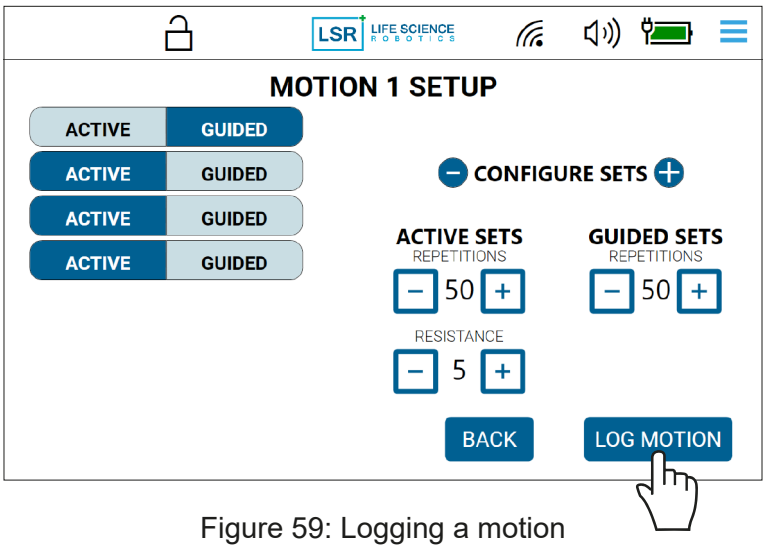


Figure 59: Logging a motion

Note: At any time during this step, the logging can be paused by pressing “pause” on the touchscreen (Figure 60) and logging resumed by pressing “play” on the touchscreen (Figure 61).

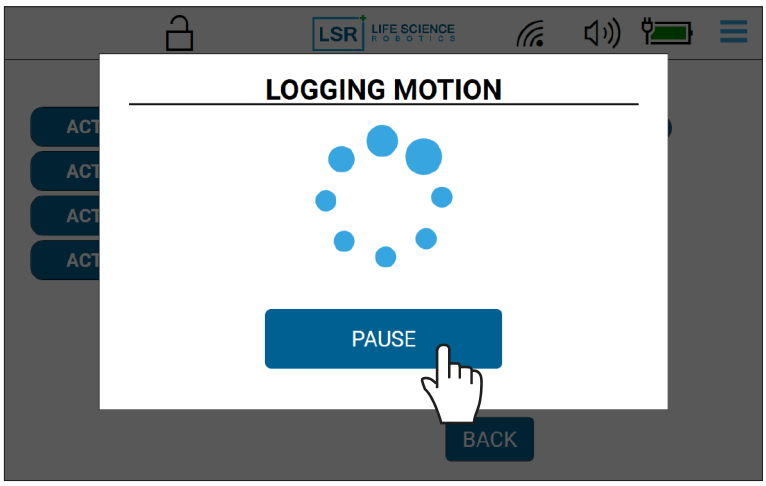


Figure 60: Pausing the logging of a motion

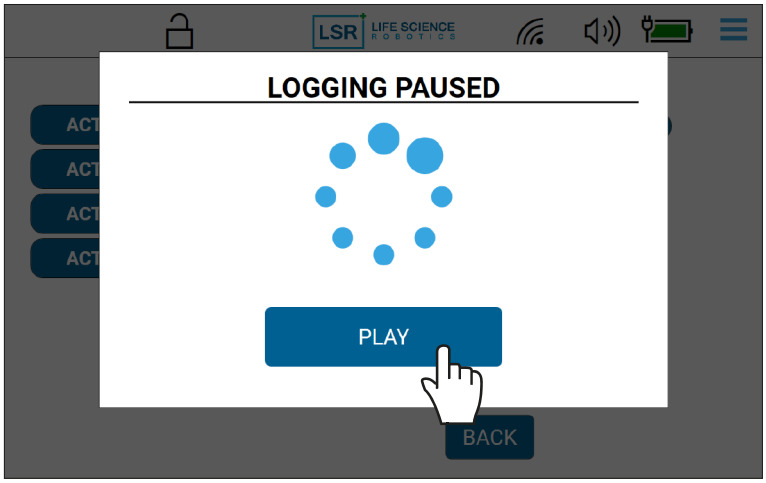


Figure 61: Resuming the logging of a motion

10. If you want to add another motion, the system will allow you to record a new motion by illustrating the next motion is ready (Figure 62). It is possible to record a total of 4 motions that each contain up to 8 sets.

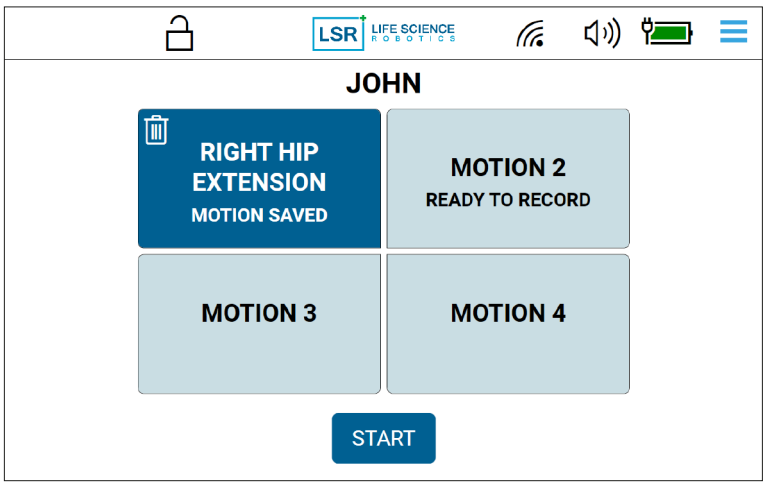


Figure 62: New motion ready for recording

11. Repeat step 1. When finished recording the new motion, selected the motion setting (Figure 63) and follow the steps, 3 to 9. Otherwise proceed to the next step.

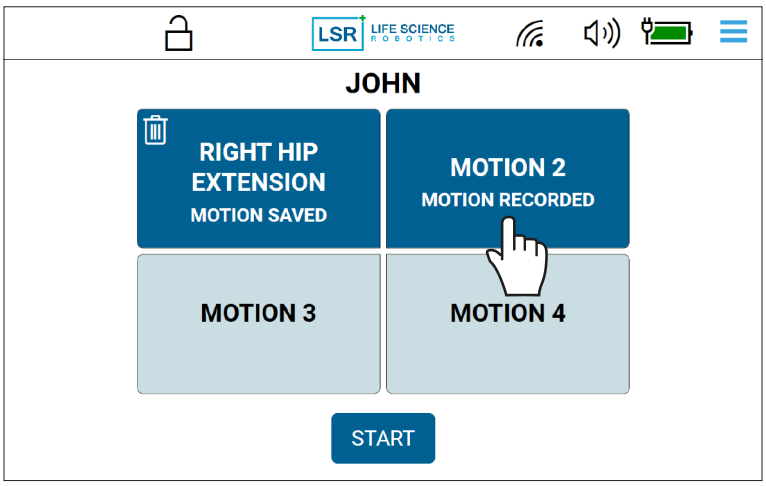


Figure 63: Selecting the next motion settings

12. When all motions are saved, press “start” on the touchscreen to start the exercise(s) (Figure 64).

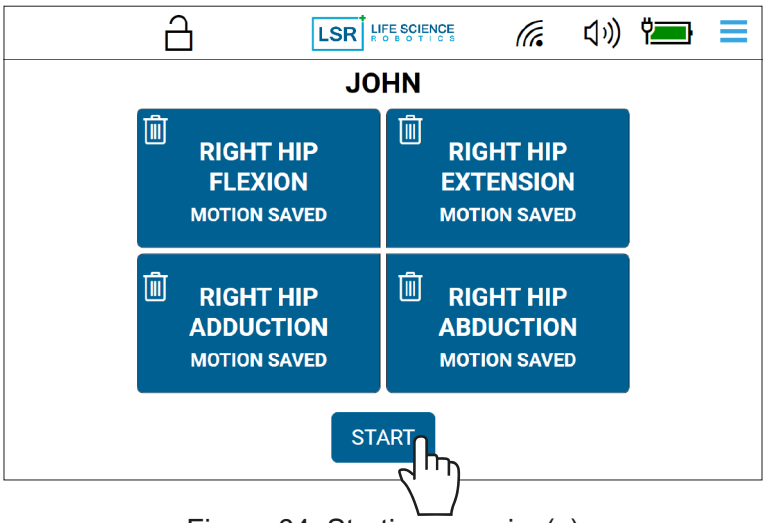


Figure 64: Starting exercise(s)

6.7.2 Executing motion(s)

Note: Be aware that ROBERT® moves in a straight trajectory from the end to start positions, both between and after motion recordings. It is recommended that the Operator is present during the execution of this part.

Note: At any time, when a motion is not active, It is possible to press the ”attach” or ”record” button at any time to allow the free movement of the robot arm. If “attach” is pressed, all previous motions will be deleted and a new motion must be recorded. If the ”attach” button is pressed make sure to support the patient’s leg during movement as the weight detection is also deleted after ”attach” button is pressed.

1. The exercise(s) will be performed in the sequence programmed by the Operator when pressing “start”, unless the exercise(s) are ended or paused by the Operator or patient. During the exercise the linkage light indicator will be green. The number of repetitions, sets and resistance can be adjusted throughout the exercises (Figure 65). The adjustment of resistance is activated at the subsequent repetition when the patient briefly halts the exercise.

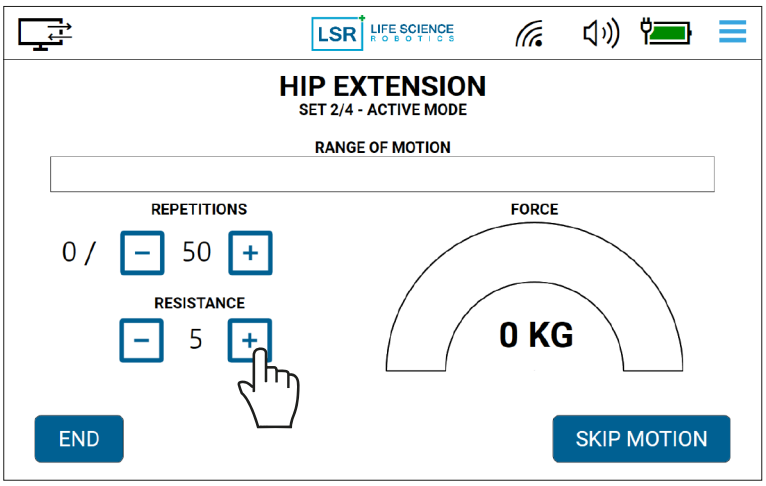


Figure 65: Adjusting motion parameters while performing exercise(s)

2. During exercise motion a progress bar illustrates the completion ratio per exercise repetition (Figure 66). The length of the bar is a representation of the exercise motion from start point to end point and the blue progress bar illustrates the exercise movement conducted by the patient. For active sets, a force measure graph illustrates live the amount of force the patient applies during each exercise.

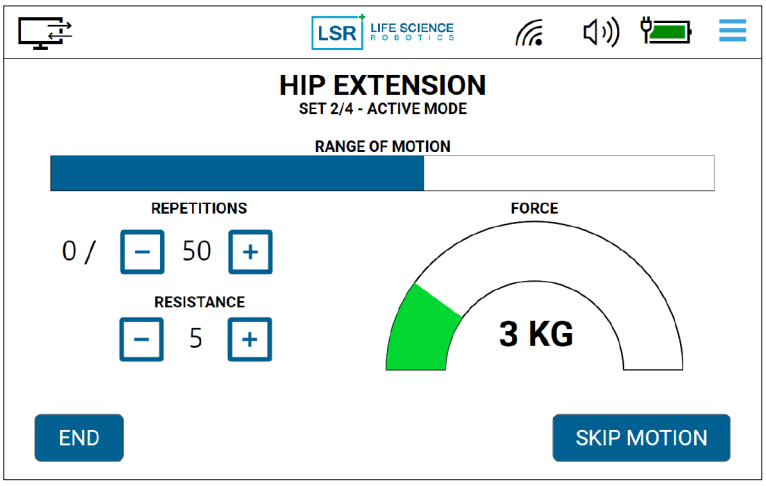


Figure 66: Progress bar and force measure during active mode

3. For guided sets, two force measure graph illustrates live the amount of force the patient can produce in relation to the exercise motion, along or against the movement (Figure 67). The red area indicates when safety is engaged (force limit exceeded, motion will be paused).

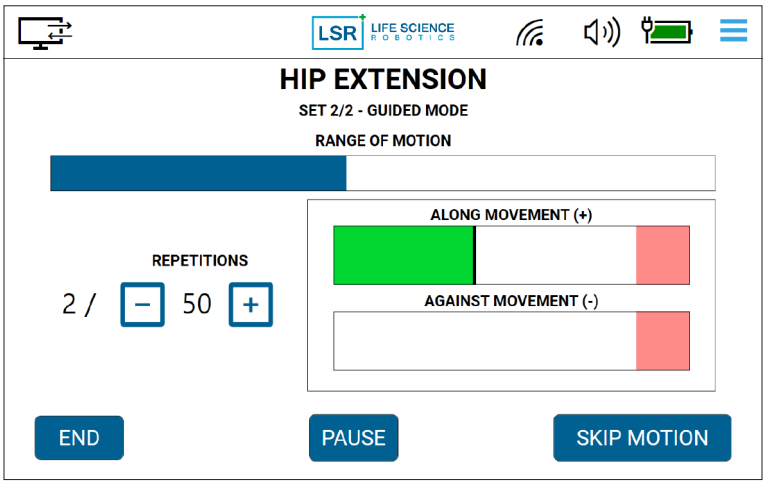


Figure 67: Progress bar and force measure during guided mode

4. If wanting to skip the current motion and moving on to the next motion you can do so by pressing the ”skip motion” button. This will prompt a confirmation to stop the current motion (Figure 68). Upon acceptance, the current motion will end. Hereafter the screen will count down to the next motion before moving the robot arm to the start position of the next exercise motion.

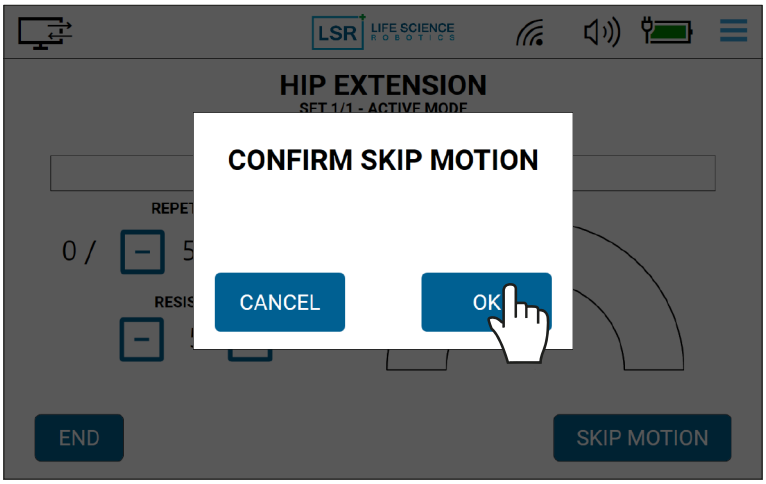


Figure 68: Skip and move to next motion

5. When the exercise is completed, the robot arm will position the lower extremity in the end position, and an overview of all exercises will be shown on the touchscreen (Figure 69).

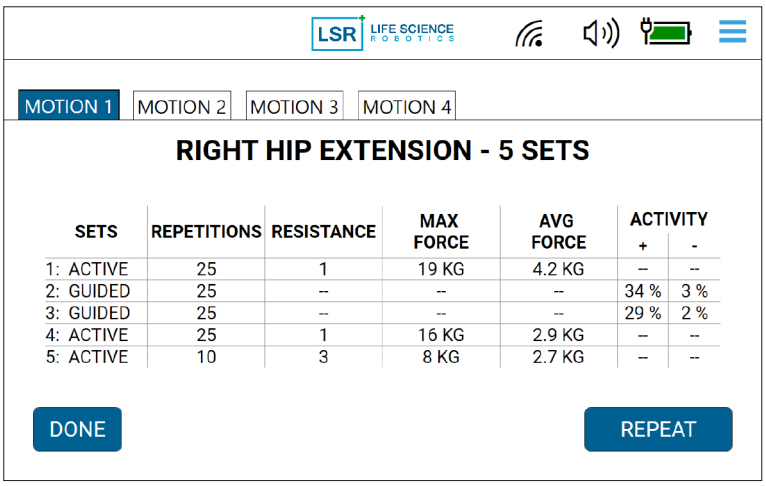


Figure 69: Example of overview of exercises

6. Press “done” on the touchscreen to remove the overview and the touchscreen then goes to home screen (Figure 70). If wanting to repeat the same set of motions press the “repeat” button. Pressing the “repeat” button will also bring you to the home screen where adjustments can be made before starting the motion(s) again.

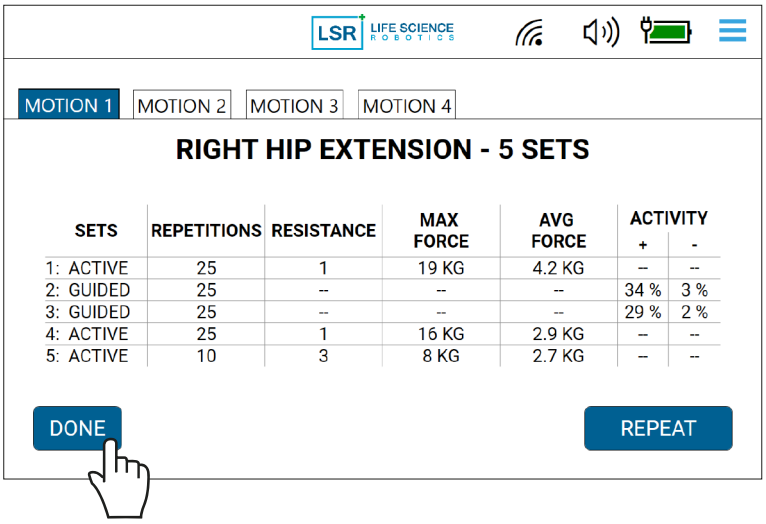


Figure 70: Going to home screen from overview of exercise(s)

6.7.3 Patient view

During exercises, the touchscreen can be rotated towards the patient and the patient view can be engaged by pressing the “change view” icon on the touchscreen (Figure 71).

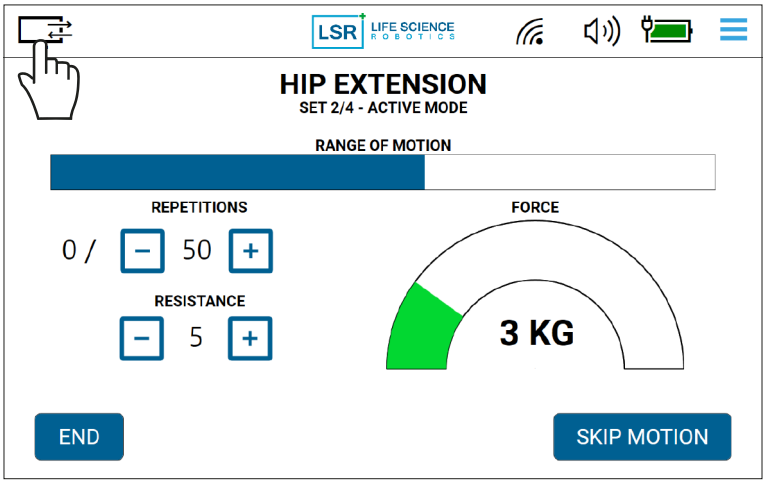


Figure 71: Engaging patient view

From the patient view, the patient can keep track of the exercise, as the screen shows the number of repetitions remaining, the sets the patient has performed and how many that still need to be performed to end the motion (Figure 72). The screen will also show the level of resistance for the active exercises.

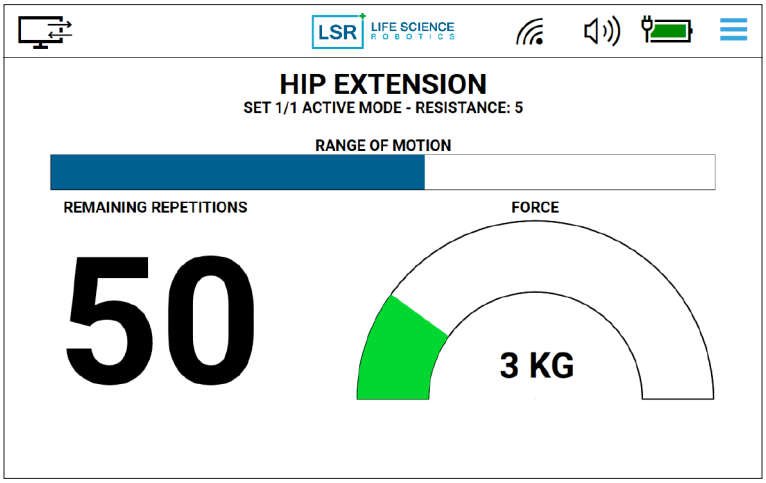


Figure 72: Patient view during exercises in active mode

If a more simplified patient view is desired, this can be selected from the settings menu for guided and active mode respectively, see also section ”5.9 Touchscreen” (Figure 73).

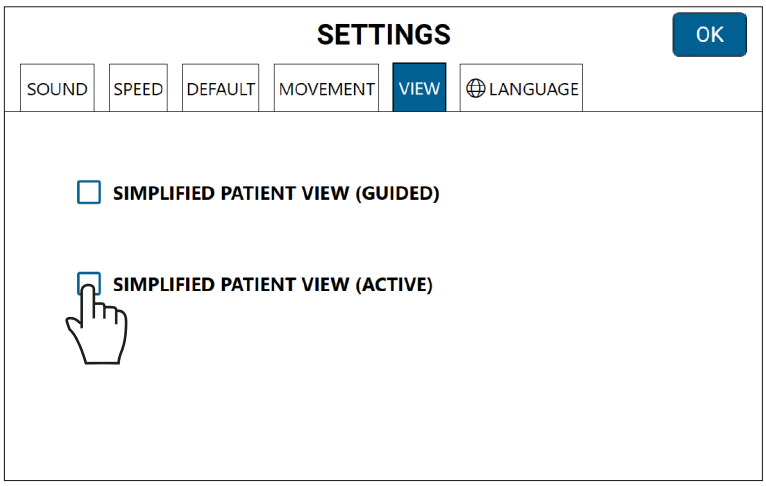


Figure 73: Setting the detail level of patient view

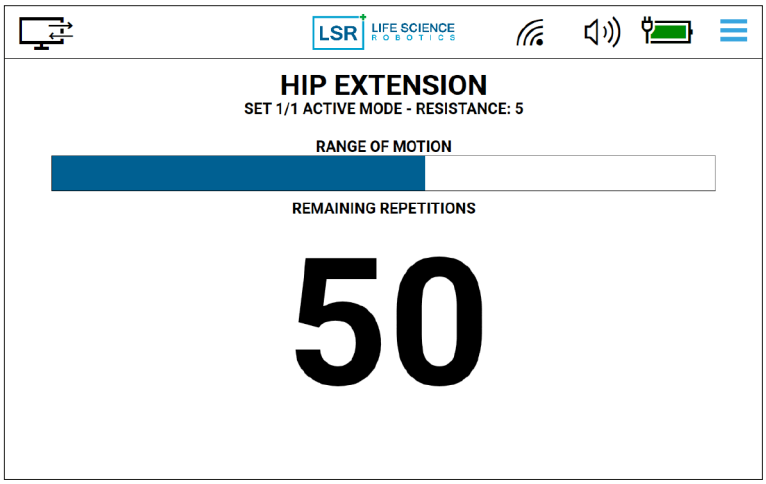


Figure 74: Simplified patient view example with less graphs

When all repetitions for a set have been performed, the touchscreen will turn green to indicate that the exercise is done (Figure 75).

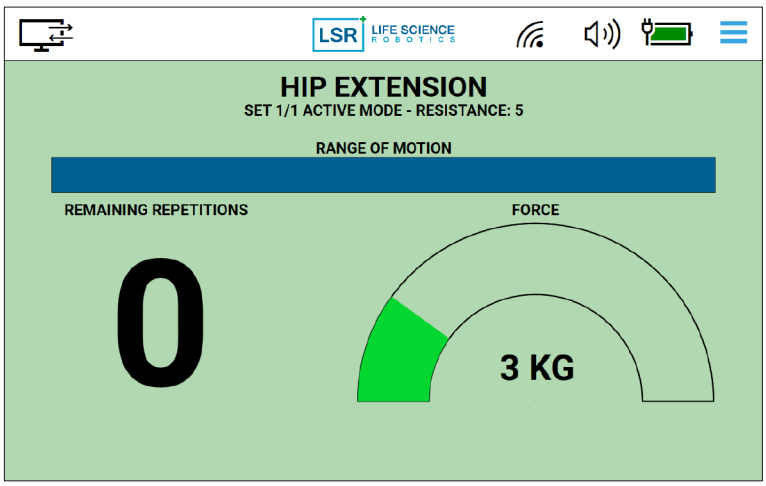


Figure 75: Green screen in patient view when finishing a set

If more exercises have been programmed, the screen will count down to the next exercise before moving the robot arm to the start position of the next exercise (Figure 76).

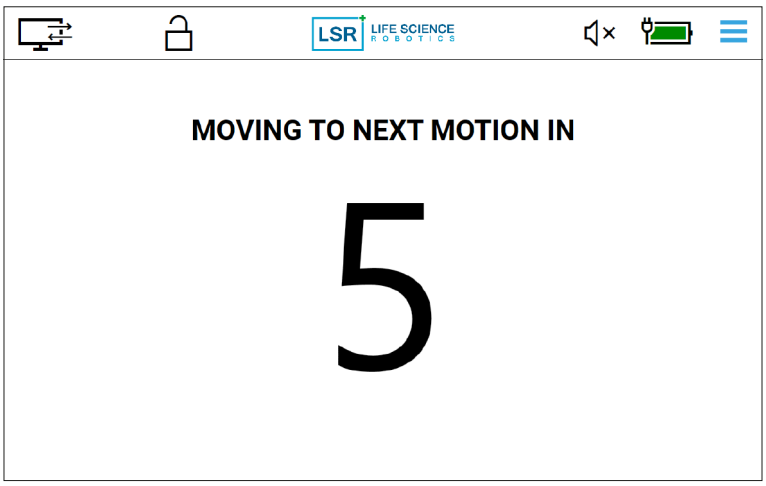


Figure 76: Counting down to the next exercise

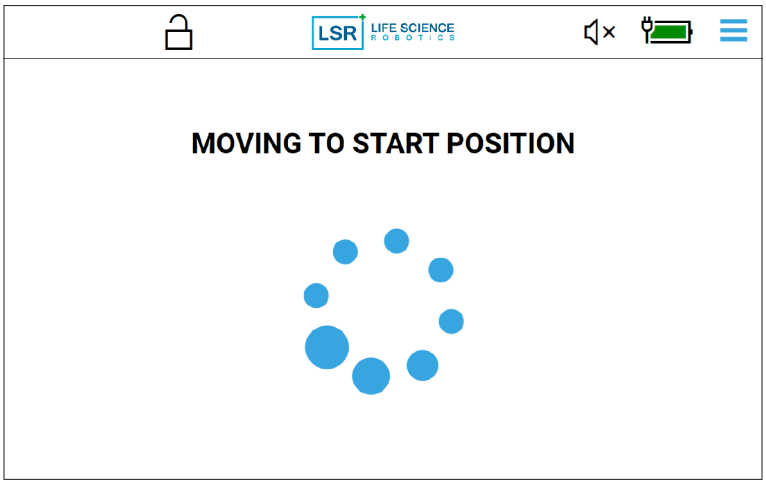


Figure 77: Patient view when the robot arm moves to the next exercise

To engage the interactive touchscreen functions, press the ”change view” icon again (Figure 78).

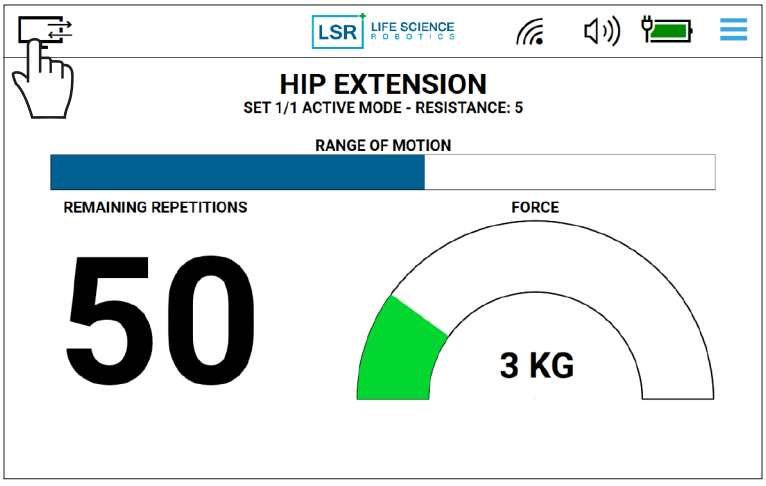


Figure 78: Engaging interactive touchscreen from patient view

6.7.4 Pausing and resuming a motion

This function is accessible for both the Operator and the patient. In order for the patient to activate the patient “play/pause” button, the Operator must pass the patient “play/pause” button to the patient.

1. Press “pause” on the touchscreen (Figure 79) or press the patient “play/pause” button once (Figure 80) and ROBERT® stops at the current position of the motion. The light indicator on the linkage flashes green during pause.

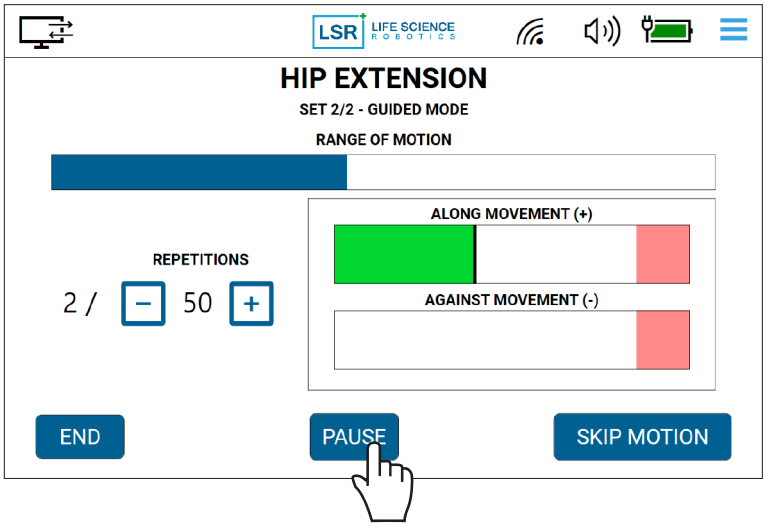


Figure 79: Pressing “pause” on the touchscreen

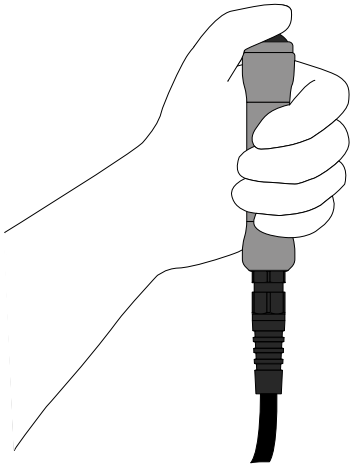


Figure 80: Pressing the patient button for “pausing” the exercise

2. Press the “play” button on the touchscreen (Figure 81) or the patient “play/pause” button once (Figure 82) and ROBERT® continues from the current position of the motion.

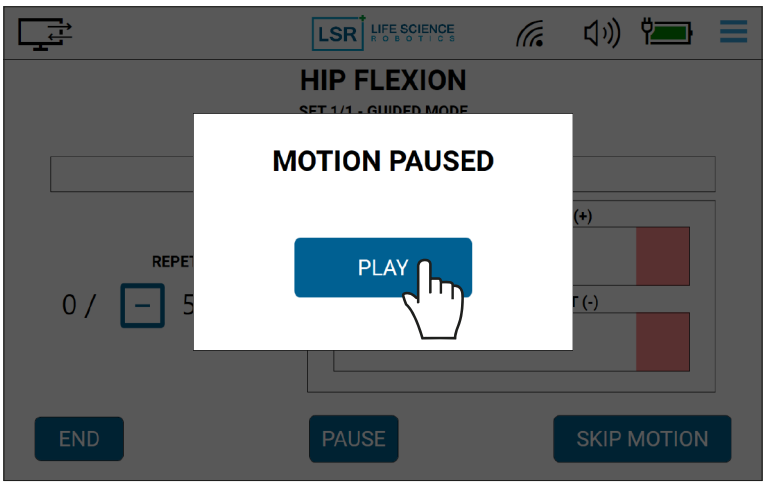


Figure 81: Pressing “play” on the touchscreen

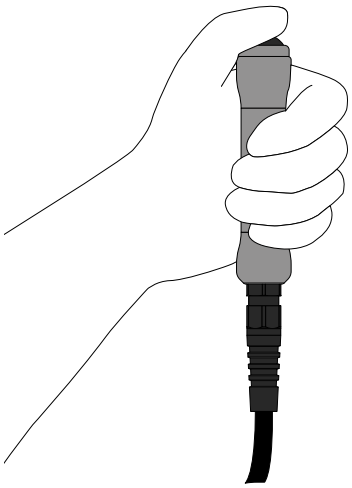


Figure 82: Pressing the patient ”play/pause” button to resume the exercise

6.7.5 Ending the exercise

If you want to end an exercise before completing the planned set of exercises, you can do so. Be aware that this process deletes all programmed motions.

1. Press “end” on the touchscreen (Figure 83) and then press “OK” on the touchscreen to confirm if you want to end the exercise (Figure 84). ROBERT® stops the exercise at the current position, deletes all programmed motions, goes to home screen and switches off the light indicator on the linkage.

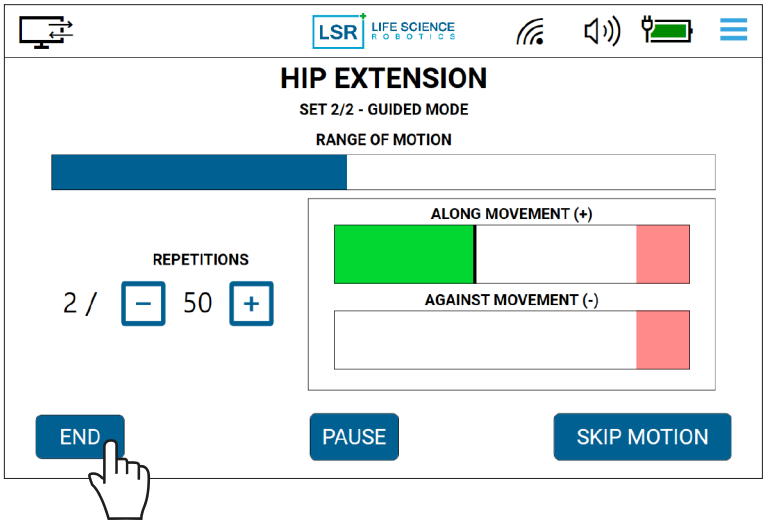


Figure 83: Pressing “end” on the touchscreen

Figure 84: Pressing “ok” to confirm ending of exercise

2. Program new motion(s) or disconnect the patient.

6.8 Disconnect the patient

When exercise(s) are finalized the patient must be released from ROBERT®.

1. Press “record” on the linkage while you support the patient’s leg while moving it down to the mattress (Figure 85).

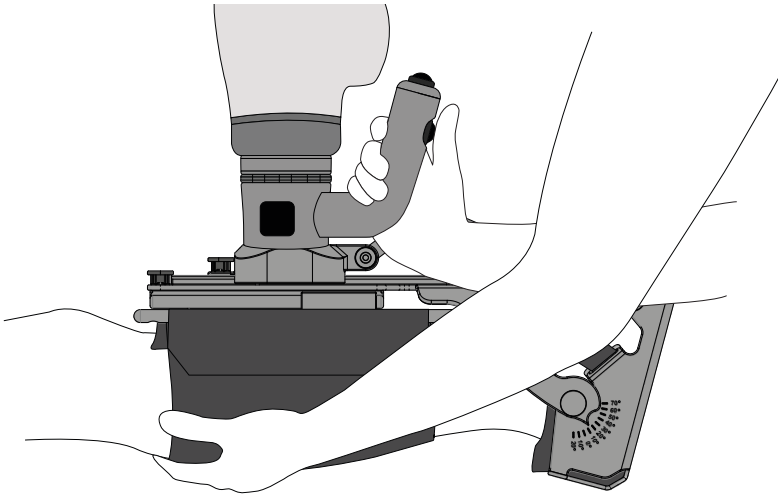


Figure 85: Pressing “record” and support the patient’s leg to the mattress

2. Disconnect the accessory from the robot arm by pressing both the ”quick release” button and the “attach” button on the linkage (Figure 86). Move the robot arm away from the patient, while pressing the ”attach” button.

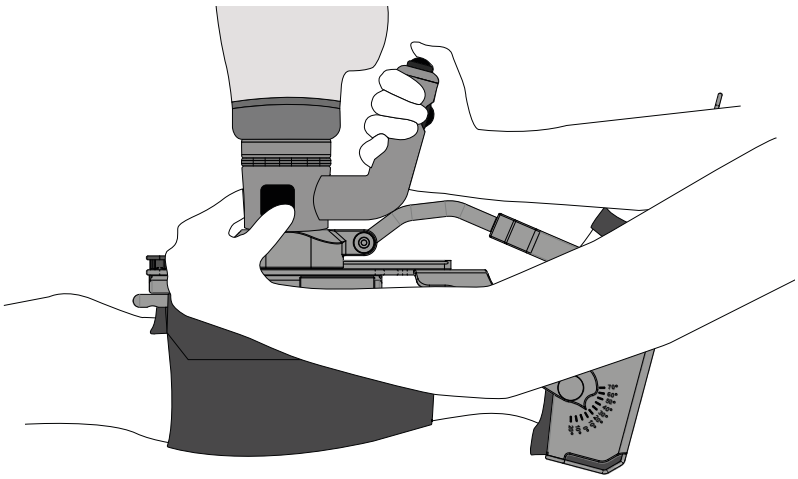


Figure 86: Pressing the ”quick release” and the “attach” button on the linkage

3. Depending on the accessory used:

3a. ROBERT® Brace: Remove the brace from the patient‘s leg by releasing the sheet (Figure 87).

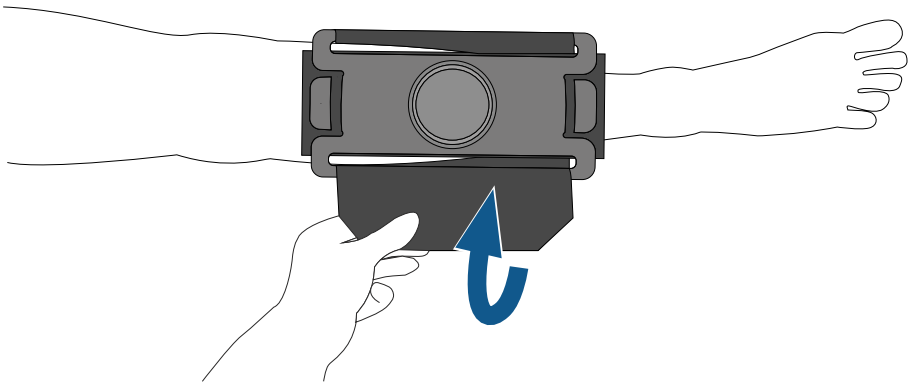


Figure 87: Remove the brace from the patient’s leg

3b. ROBERT® Fixture no.1: Remove the fixture from the patient by releasing the sheet and the foot straps (Figure 88).

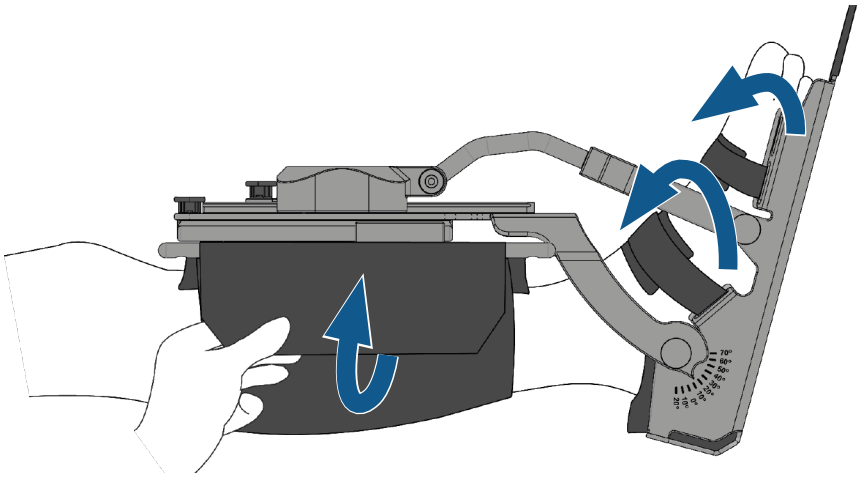


Figure 88: Remove the fixture no.1 from the patient’s leg

3c. ROBERT® Fixture no.2: Remove the fixture from the patient by releasing the sheet and the foot straps (Figure 89).

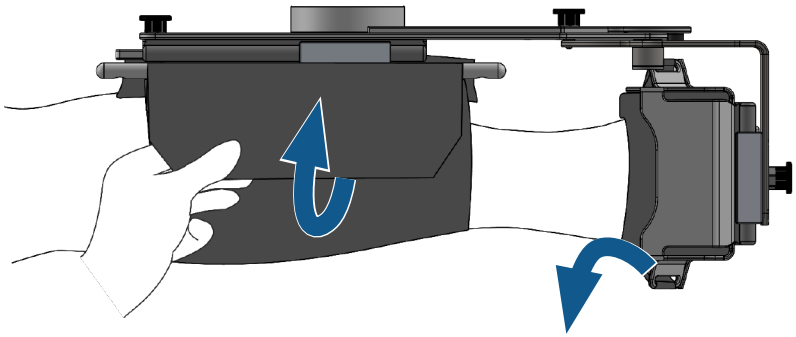


Figure 89: Remove the fixture no.2 from the patient’s leg

4. The textile sheets and foot straps shall be washed according to the indicated washing instructions, before using them on a different patient.
5. The brace, fixtures, pillow, insole and heel pillows must be wiped with disinfectant according to standard hospital precedures for disinfection before using on another patient (Figure 90).

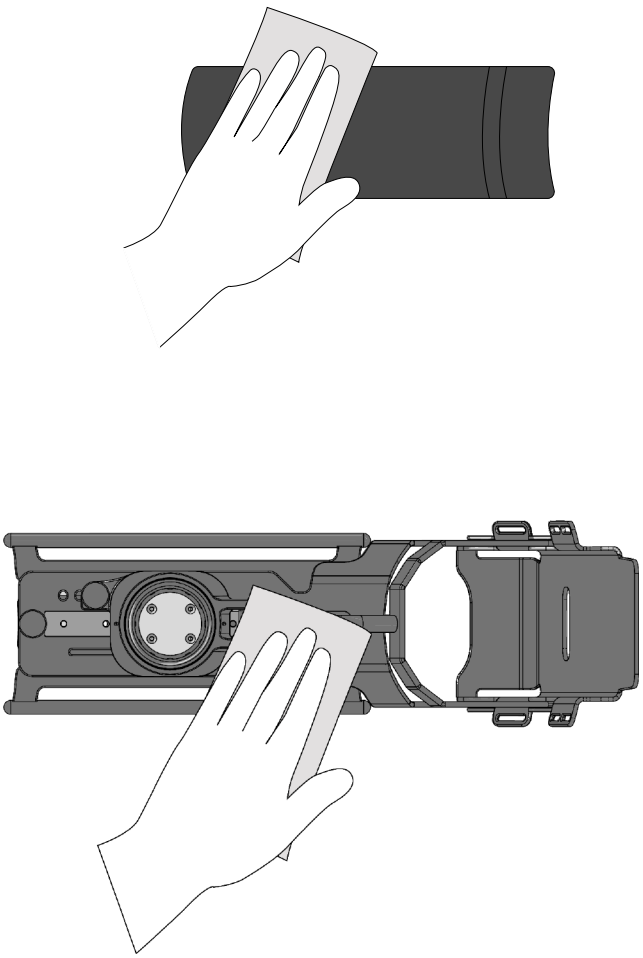


Figure 90: Cleaning brace, insole, fixtures and pillows with disinfectant

7. HANDLING MODES OTHER THAN ”NORMAL” OPERATING MODE

7.1 Power loss during exercise

If the power supply cord is disconnected whilst the device is turned on (see section ”5.4 Power supply”), ROBERT® is supplied by a battery to avoid restarting ROBERT® when moving it over shorter distances. However, if ROBERT® is unintentionally disconnected from the power supply while the battery is discharged during exercises, the robot arm stops immediately.

The patient and the accessories must be disconnected from the robot arm and the device must be turned away from the patient/bed before ROBERT® is reconnected to the power outlet!

To continue exercises:

1. Disconnect the patient from the robot arm by releasing the “quick release” button on the linkage (Figure 91) OR unmount the patient from the accessory by releasing foot straps and/or sheet (Figure 92).

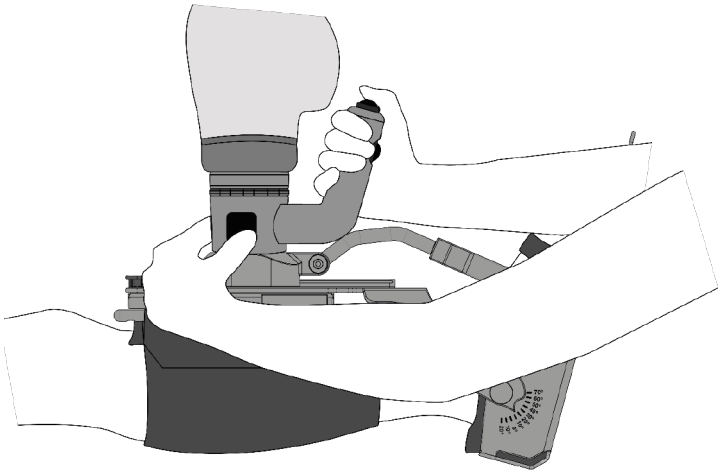


Figure 91: Pressing “quick release” to disconnect the patient

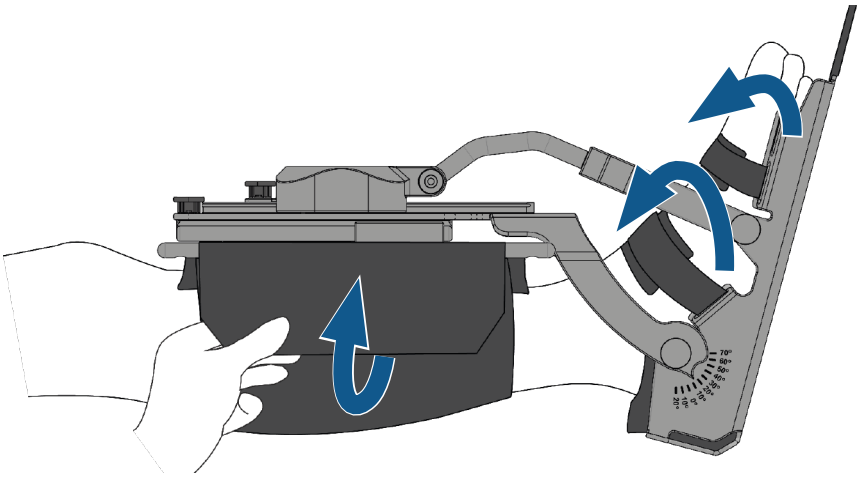


Figure 92: Releasing the patient from the accessory by releasing the sheet and/or foot straps

2. Plug in the power supply cord and wait at least 10 seconds before switching ROBERT® back on at the power switch (Figure 93).

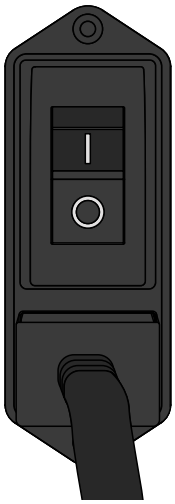


Figure 93: ROBERT® Power switch

3. Before reconnecting the patient to ROBERT® the robot arm must perform a system check (see section ”6.2 Prepare ROBERT® for exercises”).

4. To continue exercising, follow the steps from section ”6.5 Connect ROBERT® to the patient”.

7.2 Emergency situation

In the event of a sudden aggravation of the patient’s condition, e.g. in the event of a heart attack or severe pain, the patient must be promptly released from ROBERT®:

1. Press the “emergency” button on the back of the body of ROBERT®, the “pause” button on the touchscreen or the patient “play/pause” button to stop the robot arm in its current position. If the emergency button is used, the programmed exercise will be deleted.

2. Detach the patient from the robot arm by pressing the “quick release” button, OR by releasing the sheet and the additional straps and support the patient’s leg back to the mattress.

3. Release the brakes and pull ROBERT® away from the patient.

After the “emergency” button has been pressed, it must be released to use ROBERT® again (Figure 94):

1. Make sure the patient is not connected to ROBERT® before releasing the “emergency” button.

> **Make sure the patient is released from ROBERT® before releasing the “emergency” button**

Figure 94: Emergency button has been pressed

2. Release the “emergency” button by turning the button clockwise.
3. When the emergency button has been released, press “resume” on the touchscreen (Figure 95).

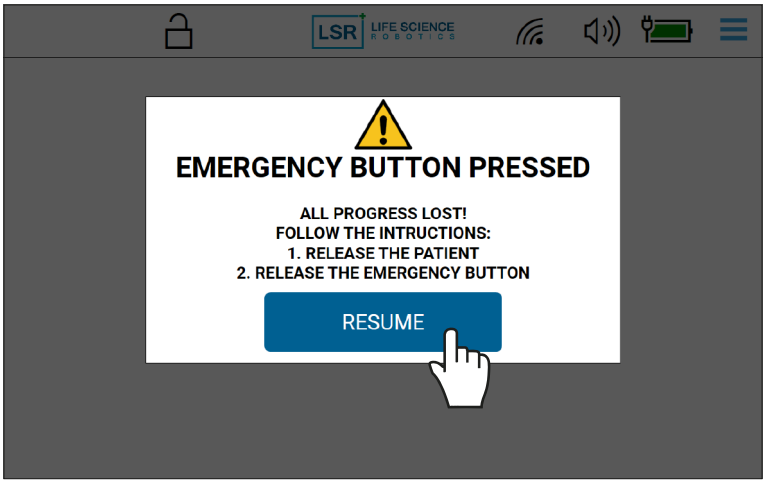


Figure 95: Pressing “resume” on the touchscreen after releasing the emergency button

The touchscreen then goes to the home screen, and it is possible to move the robot arm by pressing the “attach” button. ROBERT® is ready for use again.

7.3 System check

System check is a standard routine and part of the start-up (see section ”6.3 Start-up ROBERT®”). A system check will, in some cases, be required during use, e.g. if the robot arm has been subjected to forces which are too great. In which case, the following will happen:

1. The light indicator will flash yellow.
2. A pop-up message will appear on the touchscreen stating: “System check needed. Release the patient.” (Figure 96).

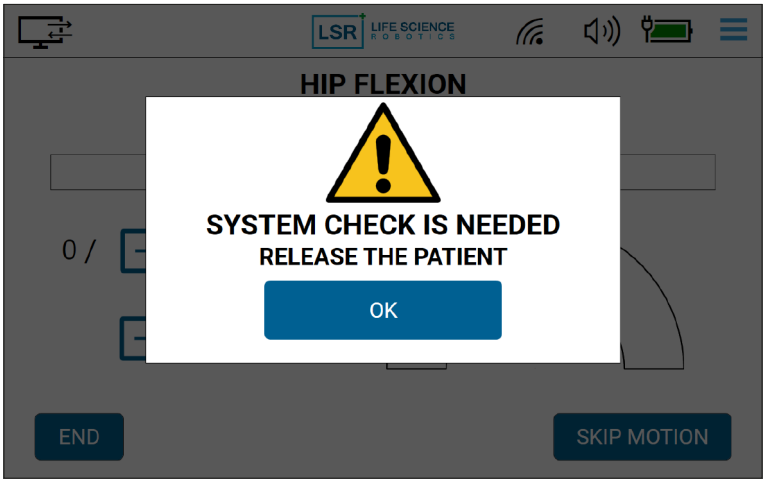


Figure 96: System check needed. Release the patient

3. Disconnect the patient from the robot arm, and move ROBERT® so that the robotarm is not placed over the patient, see section ”6.8 Disconnect the patient”. Press ”OK” on the touchscreen.

Before system check and/or restart, the patient and any of the accessories must be detached from the robot arm, and the device must be turned away from the patient/bed!

4. Press “start” on the touchscreen to perform system check (Figure 97).

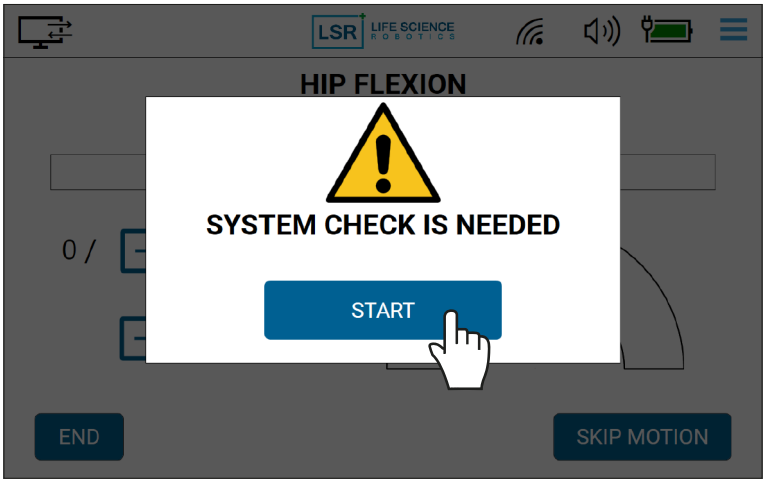


Figure 97: Pressing “start” to perform system check

5. The robot arm raises and slightly moves every joint while the light indicator flashes yellow on the linkage until the robot arm has returned to home position (Figure 98 and Figure 99).

Figure 98: Performing system check

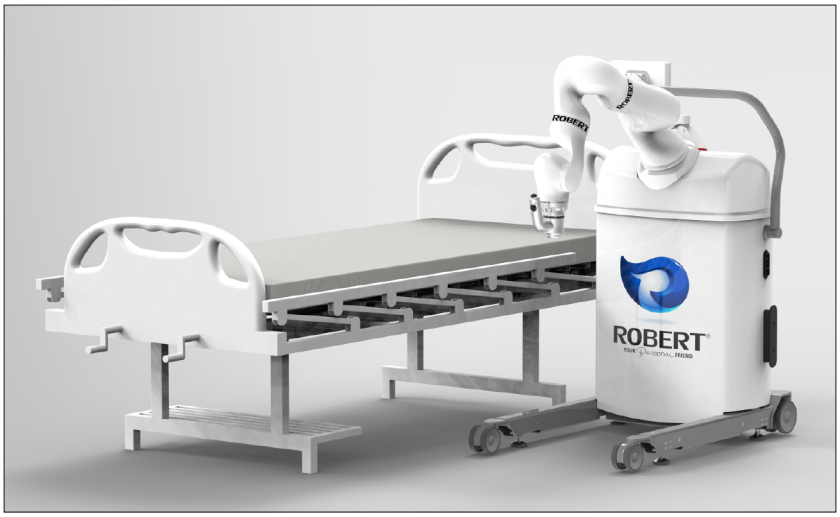


Figure 99: System check finished (home position)

6. The light indicator turns off to indicate that the system check is successfully completed. The device is now ready for use.

7.4 Unexpected patient behaviour

If the patient suddenly behaves or moves unexpectedly, e.g. due to cramps or because he/she wants to leave the bed, the robot detects the counteraction and stops the movement of the robot arm. The light indicator on the linkage flashes green, while the robot arm still allows for small movements to release stress from the patient's leg.

Assess the situation and perform one of following steps:

1. Press "play" on the touchscreen or the patient "play/pause" button to continue the exercise.

OR

2. Press "end" and "OK" to confirm the end of the exercise on the touchscreen and ROBERT® stops the exercise at the current position, deletes all programmed motions, goes to home screen and switches off the light indicator on the linkage.

OR

3. Press the "attach" button on the linkage and support the patient's leg back to the mattress. Detach the patient from the robot arm by pressing the "quick release" button and the "attach" button to move the robot arm away from the patient.

In cases where the robot arm is exposed to great force, it will stop short, before resuming the motion. If continuous force is applied, the robot arm will stop the motion and the light indicator will flash green. The robot arm will stay in the current position until action is taken.

Assess the situation and perform one of following steps:

4. Press “play” on the touchscreen to resume the exercise. If the light indicator on the linkage flashes yellow after end exercise, a system check is needed. This will be shown on the touchscreen, see section ”7.3 System check”.

OR

5. Detach the patient by following steps 2 or 3.

OR

6. Follow the guidance on the touchscreen, e.g. in cases where robot arm limits have been exceeded and a restart is necessary. In such an event a pop-up message will appear on the touchscreen (Figure 100).

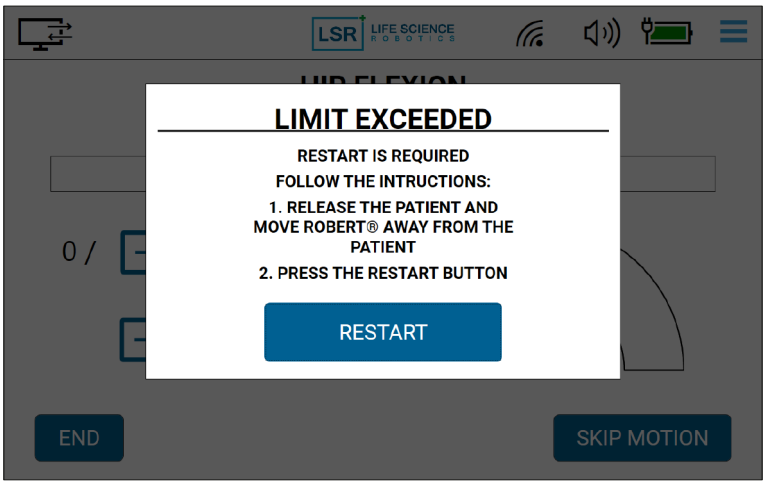
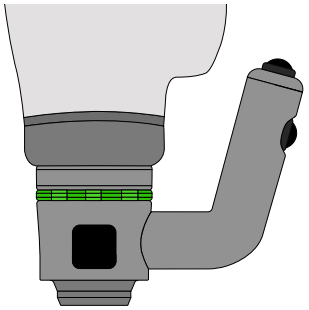
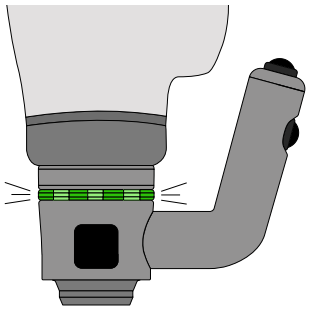
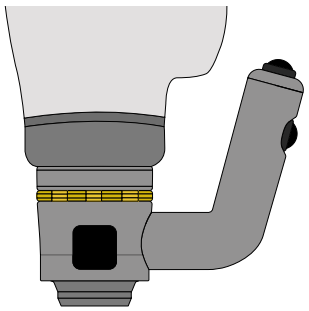
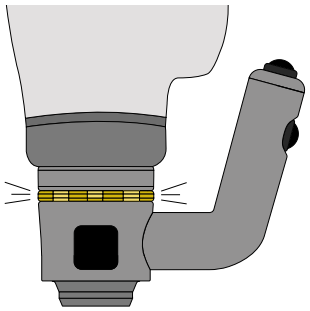
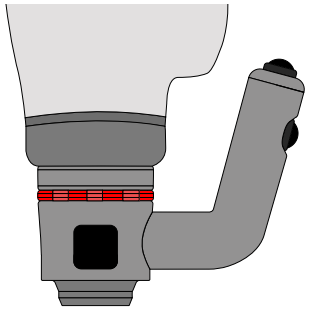


Figure 100: Robot arm limits exceeded, press “restart” to reboot the device

Before system check and/or restart, the patient and any of the accessories must be detached from the robot arm, and the device must be turned away from the patient/bed!

8. HOW TO INTERPRET THE LINKAGE AND BATTERY INDICATIONS

8.1 ROBERT® linkage indications

SITUATION	LIGHT INDICATOR
System start up	No indication
Software start up	No indication
Ready to record OR Performing exercises	 LIGHT IS GREEN
Logging first motion OR Pause OR Exercises interrupted due to unexpected force	 FLASHES GREEN
The weight of the patient's leg is too great OR The applied force is too great while logging motion	 LIGHT IS YELLOW
Need for system check OR Performing system check	 FLASHES YELLOW
Emergency button is activated	 LIGHT IS RED

8.2 ROBERT® battery indications

SITUATION	BATTERY INDICATOR
Battery high - You have battery for at least 25 % of usage (when fully charged, up to 20 minutes of usage).	
Battery low – You have battery for less than 25 % of usage. Charge device immediately to avoid motion stop.	
Powered by power cord and charging battery – It may take up to 4 hours for the battery to be fully charged when the battery has been fully discharged.	

9. TROUBLESHOOTING

Here you can find solutions to the most common difficulties, you might experience while using ROBERT®.

SITUATION	PROBABLE CAUSE	SOLUTION
ROBERT® does not start up when the “on/off” switch is turned on.	The battery is discharged, and the power supply is not connected.	Connect the cord to the power supply.
	Communication error between touchscreen and robot controller	Turn ROBERT® “off” on the power switch. Make sure to wait for at least 10 seconds before switching the power switch back on. Different types of errors can occur. Examples hereof are shown in Figure 101, Figure 102 and Figure 103.
ROBERT® is not movable.	Wheel brakes are locked.	Lift up the footswitch with your foot.
The robot arm stops during the first motion, while the light indicator flashes green.	You have activated “pause”, or the patient‘s “play/pause” button has been pressed.	Press “play” on the touchscreen to continue logging the motion.
The robot arm stops during an exercise.	The robot arm has been exposed to too great an external force.	If the light indicator flashes yellow, the robot arm needs a system check. Always disconnect the patient and the accessories from the robot arm before performing a system check.
	You have activated “pause” or the patient‘s “play/pause” button has been pressed.	If the light indicator flashes green, the exercise can be continued by pressing ”play” on the touchscreen or on the patient‘s “play/pause” button.
ROBERT® does not respond to activation of the buttons or the touchscreen and it is not possible to use ROBERT®.	ROBERT® has been switched on for more than 24 hours. OR The robot arm has been exposed to excessive external force.	Turn ROBERT® “off” on the power switch. Make sure to wait for at least 10 seconds before switching the power switch back on.

The light indicator is yellow and the robot arm is unable to lift the patient's leg before recording a motion.	The load is above the acceptable limit.	Detach the patient by pressing the "quick release" button or by removing the sheet from the patient's leg. ROBERT® cannot perform exercises on the patient due to the leg's excessive weight.
	The robot arm is placed too close to or too far from the ROBERT® body.	Press and hold the "attach" button and drag the patient's leg and robot arm away from or closer to the ROBERT® body.
After the interruption of an exercise or a hard collision, it is not possible to resume exercise.	The robot arm has been exposed to a great external force.	Reboot ROBERT® by pressing "restart" at the touchscreen at the dropdown menu. If it is not possible to access the "restart" feature, turn ROBERT® "off" on the power switch. Make sure to wait for at least 10 seconds before switching the power switch back on.
It is not possible to change the number of repetitions or resistance level while ROBERT® is executing the programmed exercises.	ROBERT® has reached the penultimate exercise, and it is no longer possible to change the number of repetitions and resistance level.	Wait for ROBERT® to finish the exercise, and program a new motion.

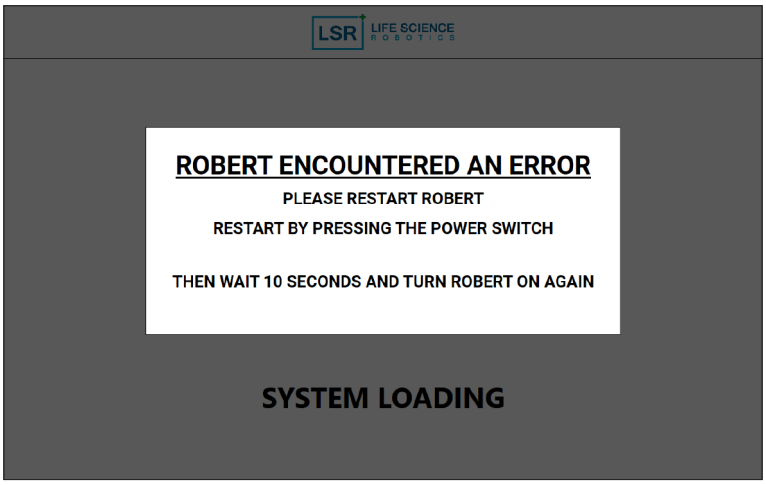


Figure 101: Error message, example 1 Turn off power, wait 10 sec. and turn on again

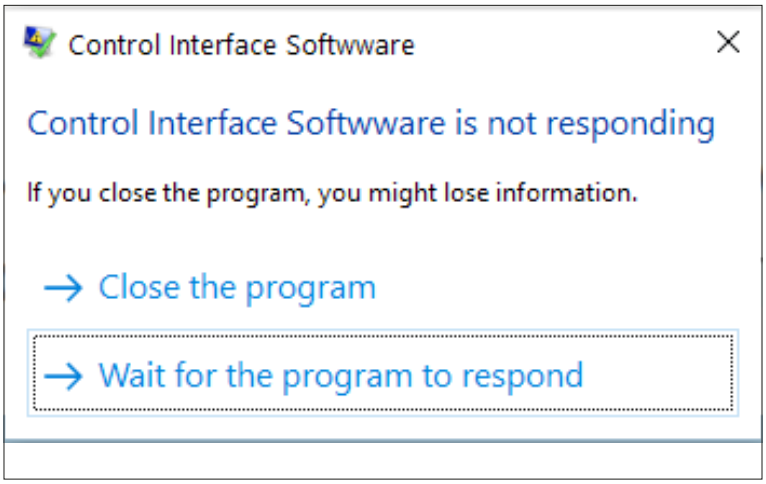


Figure 102: Error message, example 2. Turn off power, wait 10 sec. and turn on again

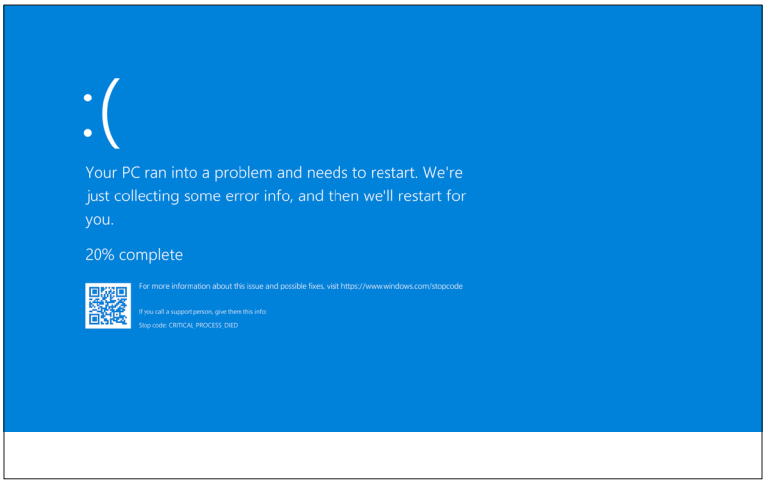


Figure 103: Error message, example 3. Turn off power, wait 10 sec. and turn on again

10. CLEANING ROBERT®

After using ROBERT® all parts in contact with the patient or the Operator must be cleaned according to the following rules:

The brace, fixtures, pillow, heel pillows, insole and linkage must be disinfected according to the standardized disinfection procedure for the place of usage. Commonly used disinfections like Ethyl alcohol are safe to use on ROBERT® and all the mentioned parts. It is recommended to wipe off all contact areas like the handle and the touchscreen on the ROBERT® body. Excessive amounts of liquid shall be avoided. ROBERT® is designed to withstand splashes of water and moisture, but cannot withstand large amounts of fluid.

The textile sheet and foot straps of the accessories must be sent for cleaning to the designated facility for washing textiles and fabrics, before being used on a different patient. The textile sheet and foot straps can withstand washing at up to 60°C and can be dry cleaned. They must not be bleached or ironed and must be tumble dried at low heat. During washing, the velcro must be assembled.

11. STORING ROBERT®

When ROBERT® is not in use, it can be stored in a dry place at a temperature between 0°C and 45°C. It is recommended to store ROBERT® with the brakes locked in order to prevent unintentional movement or damage to ROBERT® and/or its surroundings. Furthermore, it is strongly recommended to set ROBERT® to charge, to make sure its batteries are fully charged for its next use.

12. DISPOSAL OF ROBERT®

ROBERT® contains electronics and batteries and must, therefore, be disposed according to national regulations for electronic and electrical waste. Contact the national authorities for further information about how and where to dispose of ROBERT®.

The accessories of ROBERT® i.e. the ROBERT® Brace, the ROBERT® Fixture No.1, the ROBERT® Fixture No.2, the ROBERT® Fixture Brace, the ROBERT® Pillow, the ROBERT® Heel Pillow Small, the ROBERT® Heel Pillow Large, the ROBERT® Sheets, ROBERT® Insole and the ROBERT® Foot Strap can be disposed of as household waste.

It is recommended to keep the original packaging in case ROBERT® must be returned for repair or service.

13. TECHNICAL SPECIFICATION

NAME	ROBERT®
Catalogue number	24-800-000
Expected lifetime	Minimum 2 years and/or 10,000 hours
Rated input	110 V / 230 V AC
Frequency	50/60 Hz ± 1 Hz
Rated power input	1 kVA
”Applied parts” type B according to EN 60601-1	ROBERT® Brace – 24-100-088 ROBERT® Fixture No.1 – 24-100-160 ROBERT® Fixture No.2 – 24-100-181 ROBERT® Fixture Brace – 24-100-184 ROBERT® Foot Strap – 24-100-141 ROBERT® Sheet – 24-600-000 (length 450mm – size XS) ROBERT® Sheet – 24-600-001 (length 500mm – size S) ROBERT® Sheet – 24-600-002 (length 550mm – size M) ROBERT® Sheet – 24-600-003 (length 600mm – size L) ROBERT® Sheet – 24-600-004 (length 650mm – size XL) ROBERT® Pillow – 24-300-001 ROBERT® Heel Pillow Small – 24-600-010 ROBERT® Heel Pillow Large – 24-600-011 ROBERT® Insole – 24-600-020
Operating temperature	5°C – 35°C
Storage temperature	0°C – 45°C
Atmospheric pressure	700 - 1060 hPa
Humidity	20% - 80% RH
Environment	Indoor usage
Ingress	IP21
Safe working load (SWL)	<11 kg
Sound level	67 dBA
Transmitter	Frequency: 2.4 / 5 GHz
Weight	165 kg
Dimensions	1069mm x 766mm x 1306mm

14. ELECTROMAGNETIC COMPATIBILITY

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim of preventing unsafe product situations, the IEC 60601-1-2 standard has been implemented. This standard defines the levels of immunity from electromagnetic interferences, as well as maximum levels of electromagnetic emissions for medical devices.

ROBERT® conforms to the IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- The use of cables other than those specified by Life Science Robotics ApS, may result in increased emission or decreased immunity from the device.
- ROBERT® should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, ROBERT® should be observed to verify normal operation in the configuration in which it will be used.
- Do not use mobile (cellular) telephones and other devices, which generate strong electrical or electromagnetic fields near ROBERT®. This may result in the incorrect operation of the device and may create a potentially unsafe situation. The recommendation is to keep a minimum distance of 30 cm (12 inches). ROBERT® is intended for use in electromagnetic environments in which radiated RF disturbances are controlled. The customer or the user of ROBERT® can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communication equipment (transmitters) and ROBERT®. Verify correct operation of the device if the distance is shorter.

14.1 Emissions

14.1.1 Guidance and manufacturer's declaration – electromagnetic emissions

ROBERT® is intended for use in the electromagnetic environment specified below. The customer or the user of ROBERT® must assure that it is used in such an environment.

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11.	Group 1	ROBERT® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR 11	Class B	ROBERT® is suitable for use in professional healthcare facility environments but not in home healthcare or special environments.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

14.2 Immunity (all devices)

14.2.1 Guidance and manufacturer's declaration – electromagnetic immunity

ROBERT® is intended for use in the electromagnetic environment specified below. The customer or the user of ROBERT® should assure that it is used in such an environment.

IMMUNITY TEST STANDARD	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT (0,5 cycle) at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT for 1 cycle 70% UT for 25 cycles 0% UT for 250 cycles (5s)	Mains power quality should be that of a typical commercial or hospital environment. If the patient requires continued operation during power interruptions, it can be done as long as the battery capacity allows. Be aware of the battery status. For further exercising, it is recommended that this is performed manually by the healthcare professional.
Note: UT is the AC mains voltage prior to application of the test level.		
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A / m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

14.3 Immunity (not life-supporting devices)

14.3.1 Guidance and manufacturer's declaration – electromagnetic immunity

ROBERT® is intended for use in the electromagnetic environments specified below. The customer or the user of ROBERT® should assure that it is used in such an environment.

14.3.2 Electromagnetic environment – guidance

Portable and mobile RF communication equipment should be used no closer to any part of ROBERT®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

IMMUNITY TEST STANDARD	COMPLIANCE LEVEL
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms for ISM band 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V / m 80 MHz to 2.7 GHz
IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3	28 V/m 450 MHz, ±5 kHz FM, 1 kHz sinus 810 MHz, 50% PM at 18 Hz 870 MHz, 50% PM at 18 Hz 930 MHz, 50% PM at 18 Hz 1720 MHz, 50% PM at 217 Hz 1845 MHz, 50% PM at 217 Hz 1970 MHz, 50% PM at 217 Hz 2450 MHz, 50% PM at 217 Hz 27 V/m 385 MHz, 50% PM at 18 Hz 9 V/m 710 MHz, 50% PM at 217 Hz 745 MHz, 50% PM at 217 Hz 780 MHz, 50% PM at 217 Hz 5240 MHz, 50% PM at 217 Hz 5500 MHz, 50% PM at 217 Hz 5785 MHz, 50% PM at 217 Hz

15. WARRANTY

Safe and effective use of ROBERT® requires that the product is transported, stored and used as intended, without modifications, following all the manufacturer´s recommendations. The product must be used in accordance with this manual.

The following parts of ROBERT® are consumables with reduced warranty:

- ROBERT® Sheets
- ROBERT® Foot Strap
- ROBERT® Pillow & ROBERT® Heel Pillows
- ROBERT® Insole

In accordance with European law, the following parts are covered by a 2-year warranty:

- ROBERT®
- ROBERT® Brace
- ROBERT® Fixture No.1
- ROBERT® Fixture No.2

16. SERVICE INFORMATION

16.1 Scope of delivery

The following articles are included in the scope of the delivery of a ROBERT®:

ITEM	CATALOGUE NUMBER
ROBERT®	24-800-000
ROBERT® Accessories	
ROBERT® Brace	24-100-088
ROBERT® Fixture No.1	24-100-160
ROBERT® Fixture No.2	24-100-181
ROBERT® Fixture Brace	24-100-184
ROBERT® Foot Strap	24-100-141
ROBERT® Sheet	24-600-000 (length 450mm – size XS) 24-600-001 (length 500mm – size S) 24-600-002 (length 550mm – size M) 24-600-003 (length 600mm – size L) 24-600-004 (length 650mm – size XL)
ROBERT® Pillow	24-300-001
ROBERT® Heel Pillow Small	24-600-010
ROBERT® Heel Pillow Large	24-600-011
ROBERT® Insole	24-600-020
ROBERT® User Manual	24-400-100=EN

16.2 Service and maintenance

ROBERT® must be set up and commissioned in accordance with the information provided in this manual. Check ROBERT® for any visual damage before every use. In the event of damage, malfunction or unexpected operation or events to any parts of the device, contact your local ROBERT® representative.

Contact your local ROBERT® representative for assistance, if needed, in setting up, using or maintaining ROBERT®.

Modification of ROBERT® or any of its accessories is not allowed. If the equipment is modified by an unauthorised person or organization, the responsibility and liability for the equipment is transferred to the person/organization modifying it.

Service and maintenance work must only be performed by authorized service personnel appointed by Life Science Robotics ApS. Maintenance work must be performed at the following maintenance intervals:

INTERVAL	ACTIVITY
Regular	Inspect wheels, brakes, robot arm and accessories. In the event of damage, parts must be replaced immediately.
1 year at the latest	Depending on the installation conditions and degree of fouling, the protective grill and fan of the controller cabinet must be cleaned with a brush.
2 years	The internal battery of the controller as well as the battery of the motherboard of the controller cabinet must be exchanged.

To reduce the risk of electrical shock, the equipment must only be connected to an earthed power outlet. Do not use the equipment if there is any doubt about the integrity of the power cord/power outlet. Ensure that the rating matches that specified on the equipment.

16.3 Receiving or returning ROBERT®

When receiving the device, all transport material must be stored, in case the device needs to be returned. When returning the device, the robot arm must be put in transport-mode prior to packaging. The device is put into transport-mode when the device is turned “on”. Press the menu icon at the upper right corner of the touchscreen and select the “service” icon (Figure 104). Upon conforming the setting, the robot arm will be positioned in transport-mode.

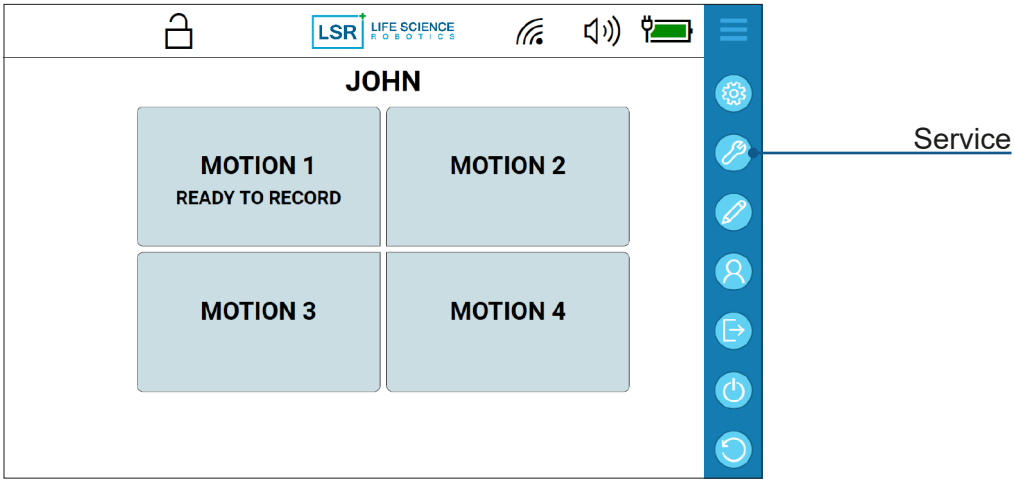


Figure 104: Service icon in drop-down menu

17. SYMBOLS AND MARKINGS

CE 0123	In compliance with the applicable European directives
	Emergency stop
IP21	Degrees of protection against liquids and particles
SN	Serial number
LOT	Batch Number
REF	Catalogue number
	Product contains electronics or batteries
	Type B Applied Part
	Manufacturer
	General Warning
	Temperature limitation
	Humidity
	Atmospheric pressure
	Keep dry
	Rough handling – This way up
	Wash at or below 60°C
	Do not iron
	Do not bleach
	Dry clean only (suitable for both dry cleaning and washing)
	Tumble dry, normal, low heat

	Date of manufacture
SWL	Safe working load
	Refer to instruction manual (consulting the manual is mandatory)
	The device includes RF transmitter

19. DECLARATION OF CONFORMITY

This device is a CE-marked medical device in accordance with the European Medical Devices Directive, 93/42/EEC, and registered with the FDA in accordance with 21 CFR Part 820.

Life Science Robotics ApS

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Life Science Robotics ApS has been certified by TÜV SÜD

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