



# **SWORD HEALTH**

## USER MANUAL





**SPONSOR**

SWORD Health, SA

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This manual applies to SWORD Phoenix®

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## TABLE OF CONTENTS

<b>Getting to know SWORD Phoenix</b>	<b>9</b>
1 - Introduction	10
2 - Indications, Contraindications and Adverse Events	11
3 - Candidate Selection	12
4 - Components	13
5 - Digital Therapist Kits	14
6 - Setup	19
7 - Motion Trackers	21
8 - Patient's Card	22
9 - Straps	27
<b>Phoenix Portal</b>	<b>28</b>
10 - Create a User Account	29
11 - Accessing the Portal	31
12 - Getting to Know the Portal	32
13 - Patient List	34
14 - Add a New Patient	35
15 - Patient Screen	38
16 - Prescription	39
17 - Prescribe a Session	40
18 - Set Exercise Difficulty Level	46
19 - Patient Results	47
20 - Patient Profile	51
21 - Overview	52
22 - Daily Summary	53
23 - Send Messages	55
24 - Settings	56
<b>Digital Therapist</b>	<b>57</b>
25 - Turn On the Digital Therapist	58

26 - First Configuration	59
27 - Performing the Sessions	72
28 - Updates	93
29 - Calibrate Motion Trackers	96
30 - Place Motion Trackers on Body	98
31 - Settings	103
<b>Glossary</b>	<b>105</b>
32 - Exercise Categories	106
33 - Metrics and Definitions	107
<b>Support</b>	<b>109</b>
<b>Technical specifications</b>	<b>111</b>
34. Service and inspections	112
35. Regulatory Statements	114

## **ABOUT THIS MANUAL**

This User Manual provides detailed technical and operational information on the medical device SWORD Phoenix.



**Warning:** No modification of this equipment is allowed.

**Caution:** Do not use SWORD Phoenix before reading this manual.

### Explanation of the pictograms on this manual and on the label

Pictogram	Description
	General warning sign according to IEC 60601-1 (2005)
	Type BF applied part sign specified in standard IEC 60601-1 (2005)
	Operating instructions sign according to IEC 60601-1 (2005)
	Refer to instruction manual/booklet according to IEC 60601-1 (2005)
	Protective earth (ground) sign according to IEC 60601-1 (2005)
	CE marking symbol. Complies with MDD93/42/EEC Requirements
	Symbol for the marking of electrical and electronic equipment according to Directive 2002/96/EC. Protecting the environment. When disposing of this unit, or the batteries it uses, do so in an environmentally friendly way.
	Manufacturer symbol sign according to NP EN 980 (2008)

## **GETTING TO KNOW SWORD PHOENIX**

## 1 - INTRODUCTION



**Caution:** The medical device is not to be used by people with visual difficulties.

SWORD Phoenix is a medical device with a measuring function.

At **SWORD Health**, we focus on finding technological solutions for some of the most important problems in healthcare systems. By identifying common needs across different problems, we are maximizing our impact on people's lives. This is why we have focused on physical rehabilitation.

Current rehabilitation models are based on a one-to-one interaction between therapist and patient. However, high economic costs and heavy logistics represent major impediments in a day-to-day setting. Moreover, tools for communication within and between clinical teams are inefficient and process accountability is low.

We believe that the solution for this problem is a wise combination of novel science-driven therapeutic methods and effective technologies that facilitate dissemination of care, communication and the use of all the knowledge produced in the rehabilitation process of each patient.

Pursuing this vision, we have developed SWORD Phoenix. SWORD Phoenix is a medical device designed to measure and evaluate the movement of body parts through a motion quantification system based on inertial motion trackers. The information gathered is used to give real-time feedback on patient performance during motor tasks. This feedback, presented in a mobile app, allows the patient to improve the movement in terms of range of motion and motor control.

SWORD Phoenix also includes a web-based portal with a clinical database, prescription and result analysis tools, allowing the clinical team to control and monitor different aspects of the rehabilitation process.

SWORD Phoenix is composed of third-party hardware and proprietary software combined into a medical device intended as a non-invasive physical therapy tool.

## **2 - INDICATIONS, CONTRAINDICATIONS AND ADVERSE EVENTS**

### **Indications**

SWORD Phoenix is indicated in the recovery process of musculoskeletal diseases to improve range of motion, muscle strength, motor control and/or movement pattern.

### **Contraindications**

The device has the following contraindications:

- Hemodynamic instability or other serious medical condition limiting physical rehabilitation;
- Hyper-acute stroke patients;
- Pain or deformity limiting the movement of target joints;
- Respiratory and/or cardiovascular disease contraindicating mild to moderate exercise;
- Skin lesions or any continuity solution in the area where the motion trackers would need to be placed.

### **Adverse effects**

SWORD Health has exercised great diligence in selecting the materials for SWORD Phoenix, in particular, those that will be in direct contact with the patient. These materials have been assessed for their biological compatibility and are continuously monitored by the manufacturer. Nevertheless, there is always a small chance that some materials may lead to allergic reactions in individuals under exceptional circumstances.

### 3 - CANDIDATE SELECTION

SWORD Phoenix can be used both in patients capable of active collaboration (**patient paced tasks**) and in patients unable to collaborate (**professional paced or passive tasks**).

In order for **patient paced tasks** to be performed, the following criteria must be met:

1. The patient must be able to understand both simple and complex motor commands. This implies that the patient does not have global aphasia or severe receptive aphasia; overt dementia (based on clinical judgment and/or MMSE score); psychosis or other condition interfering with patient compliance.
2. Ability to perform active movement either of the targeted limb or at least involving the targeted joint(s) (e.g. the patient may be a candidate for upper-limb rehabilitation using SWORD Phoenix even if unable to produce fine finger movement). For this purpose, a grade of at least 2 in 5 in the Medical Research Council Scale for Muscle Strength is necessary (ability to move joint without gravity resistance).

## 4 - COMPONENTS

SWORD Phoenix is composed of the following interconnected parts:

### **Motion Trackers**

Lightweight, high precision sensors that acquire and digitize patient motion and communicate wirelessly with the Digital Therapist.

### **Straps**

The straps are suitable for the majority of the adult population and must be placed on top of the clothing. It is advisable to wear relatively tight-fitting clothes.



**Caution:** Do not use straps directly on skin. Always use the straps over clothes.

The Straps can be reused after appropriate cleaning practices.

### **Digital Therapist**

The Digital Therapist guides the patient through each rehabilitation session with human grade real-time feedback, ensuring exercises are performed correctly.

### **Portal**

The Portal is a web cloud-based platform that enables clinical teams to perform an in-depth analysis of each patient's evolution and adapt rehabilitation programs remotely based on objective data, maximizing their efficacy.

## 5 - DIGITAL THERAPIST KITS

**SWORD Phoenix contains four different kits:**



Every kit is different and contains a different number of components. Make sure you have the correct kit, that it contains every component, and that every component is in perfect condition.

### **How can I make sure this is my kit?**

On the front of the box, there is a sticker identifying your kit.





## LOWER LIMB



## UPPER LIMB





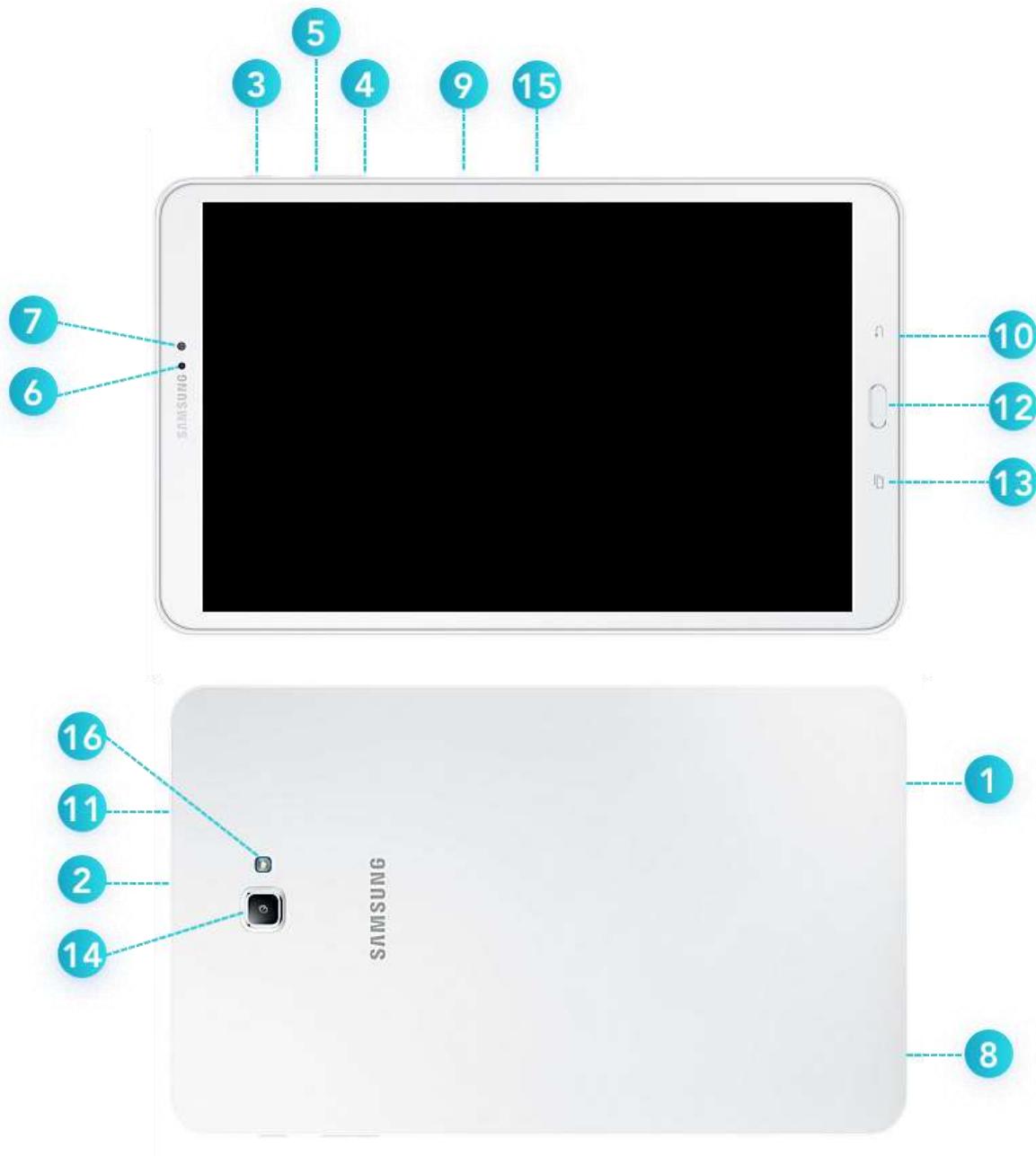
## LOW BACK



## NECK



## Samsung Galaxy Tab 10.1" (SM T585 Model)



**1.** Speaker 1

**2.** Headset jack

**3.** Power button

**4.** Volume button (-)

**5.** Volume button (+)

**6.** Light tracker

**7.** Front camera

**8.** Speaker 2

**9.** Memory card slot

**10.** Back button

**11.** Charger/Accessory port

**12.** Home button

**13.** Recent apps button

**14.** Back camera

**15.** SIM Card slot

**16.** Flash camera

## **Motion Tracker**



**The motion tracker is composed by:**

1. Micro USB port
2. RGB Led
3. Sticker with a colored letter

## 6 - SETUP

After unpacking and before the first use, ensure that all devices are fully charged.

### Step 1 - Charging the Tablet



#### **To charge the tablet you must:**

1. Plug micro USB cable connector into Tablet USB port.
2. Plug the USB cable into Samsung Charger/Accessory port.
3. Plug the charger into the power supply

## Step 2 - Charging the Motion Trackers



### **To charge the Motion Trackers you must:**

1. Plug the micro USB cable end-point into the micro USB port of each Motion Tracker.
2. Plug the USB cable into the charger.
3. Plug the charger into the power supply.

## 7 - MOTION TRACKERS

The motion trackers provide 3D angular velocity (by using gyroscopes), 3D acceleration (by using accelerometers) and 3D earth magnetic field (by using magnetometers). These are integrated using sensor fusion algorithms to provide 3D special orientation of limb segments.

These motion trackers were specifically designed to be used in a clinical or ambulatory setting with a minimum need of calibration procedures.

### Operating conditions

The recommended operating temperature of the motion trackers is between -10°C and +50°C. If operated outside this temperature range, performance may decrease or the motion trackers might be damaged. Fast transient temperature fluctuations may cause significant temperature gradients across the device.

The Motion Trackers contain the absolute possible minimum amount of ferromagnetic materials. Nonetheless, some minor components can be magnetized permanently by exposure to strong magnetic fields. This will render the calibration of the magnetometers useless. Therefore, it is necessary to prevent exposure of the motion trackers to strong magnetic fields, such as close proximity to permanent magnets, speakers, electro motors, among others. It is also advisable to ensure that measurements, in particular calibration steps, are conducted in an area free of or with minimal magnetic distortions.

The Motion Trackers should be protected from electrostatic discharges or sources of radiation, as exposure to such sources will damage the internal electronics. The Motion Trackers should be protected from violent handling such as drops on hard surfaces. Excessive shocks or violent handling may damage the Motion Trackers.

The Motion Trackers, cables and tablet must be kept dry at all times. Condensation and water may damage the internal electronics.



- Do not expose the Motion Trackers to strong magnetic fields or electrostatic discharges
- Do not expose the Motion Trackers, charger or power supply to water or

liquids.

- Do not open the charger or power supply case; there are no user serviceable parts inside.
- Do not cover the fan exhaust or obstruct the airflow, this will cause overheating.
- Use only the manufacturer's power supply and observe terminal polarity.
- Place the charger in a cool spot, away from external heat sources.
- Caution - during charging the charger may become warm.

## Motion Trackers States

Color	LED State	Motion Tracker State
Blue	Steady blue light	Waiting to connect to tablet
Green	Steady green light	Connected to tablet
Red	Pulsing red light	Low battery
	Steady white light	Starting
Orange	Pulsing orange light	Charging battery
Green	Pulsing green light	Full battery
Purple	Steady purple light	Waiting for a firmware update
Pink	Pink	Updating firmware

## 8 - PATIENT'S CARD

### Sealed Card

The card is sealed inside SWORD Phoenix's box. In that seal, you can see the Card Number and CVV.



## Open package

To use the card, open the package and in the center you will find the Card's Security PIN code. This code is used to start your sessions with the Digital Therapist after you present your card. Never share your personal PIN code with anyone; if you do that, you might put your clinical and personal data at stake.



## Card

The card's size and format are the same as those of a credit card. This card belongs to the patient and must never be shared or reused by another person. Once you finish your treatment, you must keep the card.



- 1. QR Code** - A QR code is used to identify the patient.
- 2. Card Number** - This is a unique, six-digit number to identify the card.
- 3. CVV** - Card Verification Value, a three-digit number used as a safety procedure to ensure the card is authentic.

## How to use the card

Patients use their cards to start their sessions with the Digital Therapist.



- To make sure the card is promptly read, ensure you have good lighting in the room.
- During the reading of the card, keep it at least 8 inches (20 cm) away from the tablet's front camera.
- **During the reading, keep your fingers away from the QR code, otherwise, the Digital Therapist won't be able to read the card.**

## 9 - STRAPS



**Caution:** Do not use straps directly on skin. Always use the straps over clothing.

The straps are suitable for the majority of the adult population. They must be placed over clothing for comfort purposes. It is advisable to wear relatively tight-fitting clothes.

### Strap cleaning and care

Do not put the straps on the washing machine or dryer, since that might damage the material. Wash the straps by hand with tepid water. Use a neutral detergent if they are dirty. Rinse well. Squeeze gently to remove the excess water. Dry it naturally, with the foam side up, on the **stand** or on a towel or hang it to dry. It is preferable to wash it regularly to keep the material clean and free from body salts, oils, etc.. This will help the material last longer.

# PHOENIX PORTAL

## 10 - CREATE A USER ACCOUNT

To access the Portal, you need a user account. User accounts can only be created with an invitation from SWORD Health.

Here is how you can create an account, step by step.

### **Step 1 - Invitation Email**

After the initial contact with SWORD Health's team, you will get an email inviting you to create a user account.

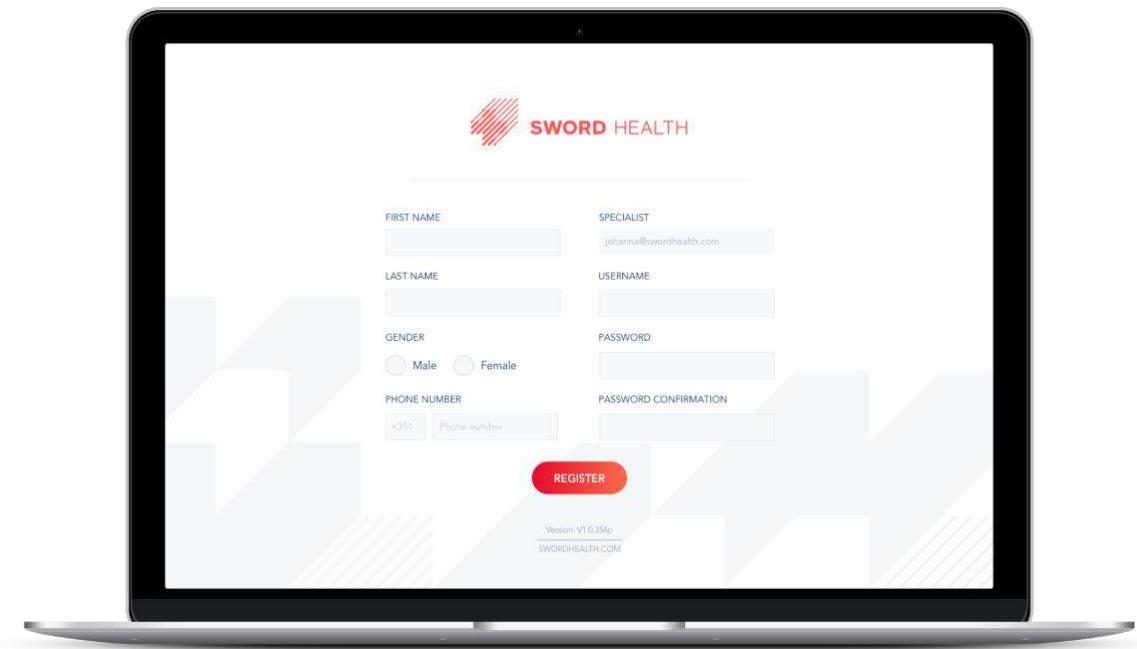
If you don't get the email, please make sure it is not in your Spam box. If it's not in the Spam box, please contact [help@swordhealth.com](mailto:help@swordhealth.com) to help you solve the problem.

### **Step 2 - Click the link**

The email we sent you contains a link you must click. By clicking it, you will be redirected to Phoenix Portal to start creating your account.

### Step 3 - Create a User Account

In this step, you must fill out every required field.

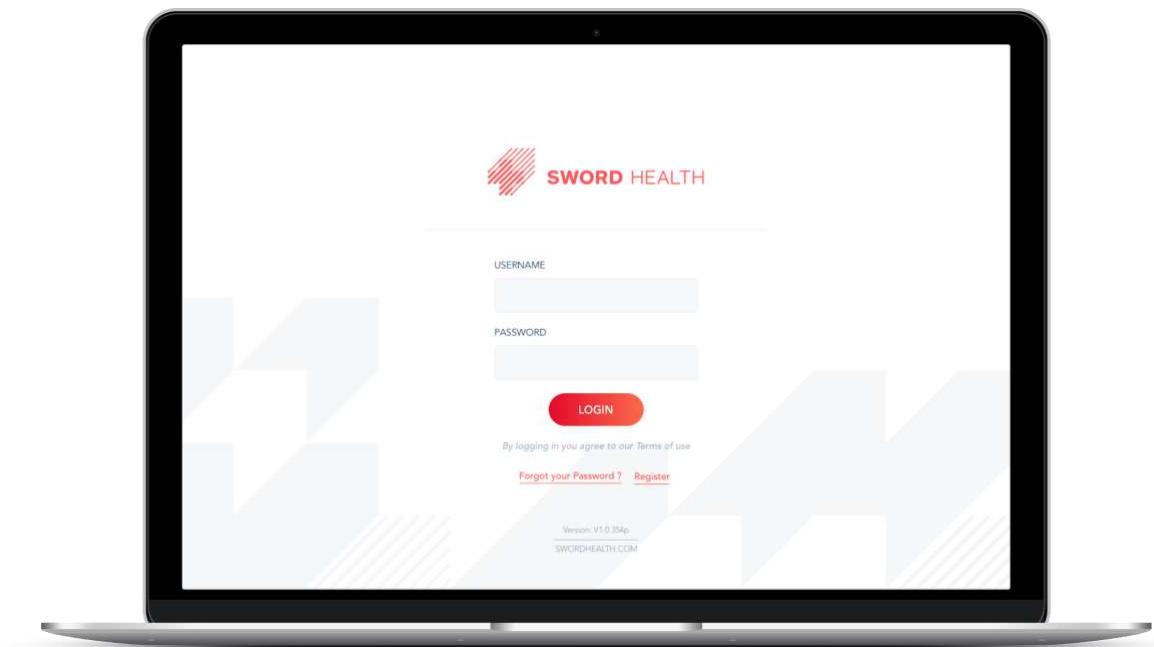


### Step 4 - Verification Email

After you have finished creating your account, you will receive a verification email. As soon as you get it, you're ready to [access the Portal](#).

## 11 - ACCESSING THE PORTAL

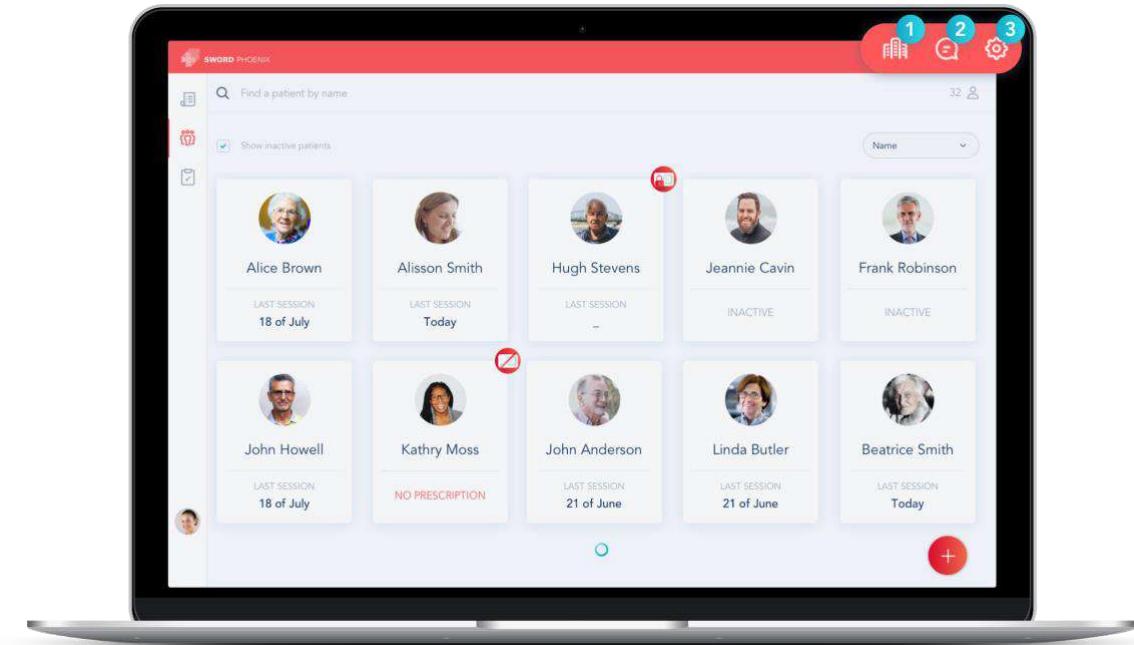
Use your credentials (Username and Password) to access the portal.



## 12 - GETTING TO KNOW THE PORTAL

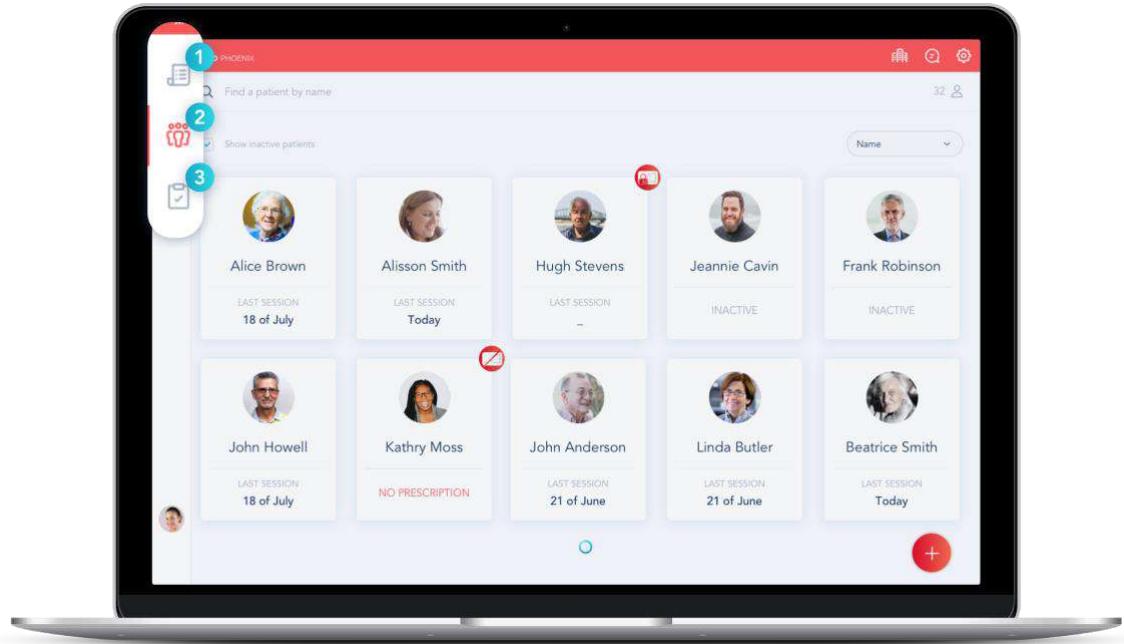
The portal has two navigation bars, one on the left side and one on top. In these bars, you can find different features.

### Top Navigation Bar



- 1. Institutions** - If your user account has access to several institutions with different patients, you can change your view by institution.
- 2. Messages** - By clicking this button, you can send messages to the patients.
- 3. Setting** - By clicking this button, you will open the Portal's [settings](#).

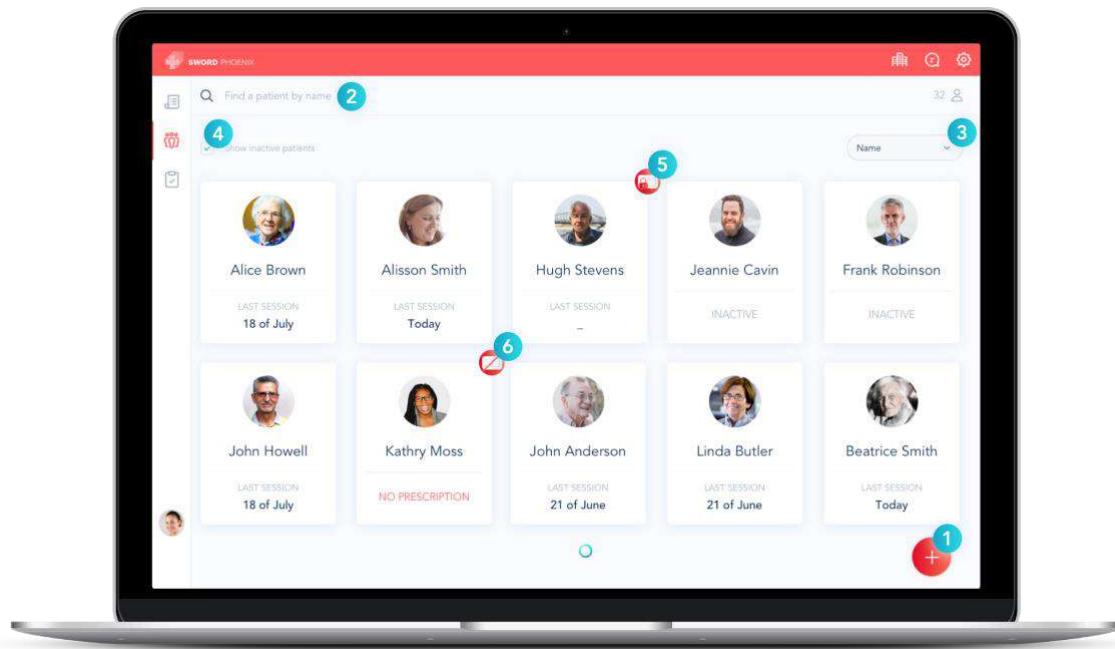
## Lateral Navigation Bar



- 1. Daily Summary** - By clicking this tab, you will access the patients' current day and former sessions' summary.
- 2. Patient List** - By clicking this tab, you will access your list of patients.
- 3. Overview** - By clicking this tab, you will get an overview of your patients by week or month.

## 13 - PATIENT LIST

The patient list is the starting point for the entire portal; this is where you can access all your active and inactive patients and where you can add new patients.



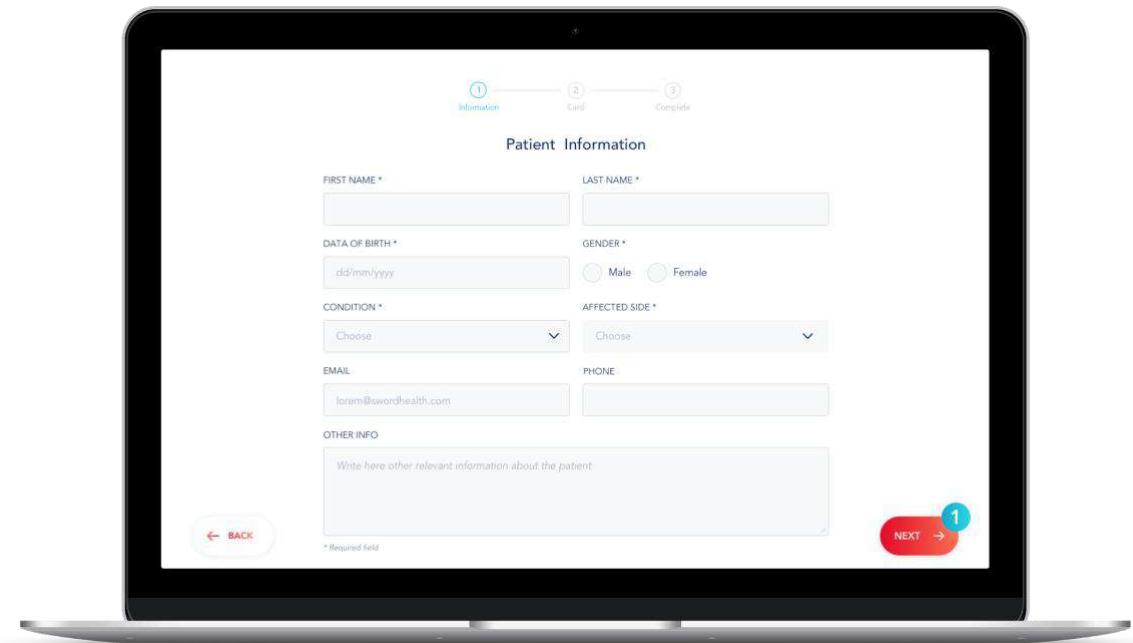
- 1. Add** - By clicking this button you can [add a new patient](#).
- 2. Search** - The search bar allows you to look for a patient by name.
- 3. Sort by** - Here, you can sort the patients by Name or Last Session.
- 4. Show Inactive Patients** - This will show you all your inactive patients.
- 5. Unblock Patient Card** - When a patient blocks his card by typing the wrong PIN code five consecutive times, this notification will show up for you to unblock the card. To do so, just click it and a confirmation window will pop up.
- 6. Associate a Card with a Patient** - When you add a new patient and the associate card step is ignored, this notification will appear until a card is associated with the patient. By clicking the notification, you can associate a [card](#) with the patient.

## 14 - ADD A NEW PATIENT

To add a new patient, three consecutive steps must be followed.

### Step 1 - Fill out patient information

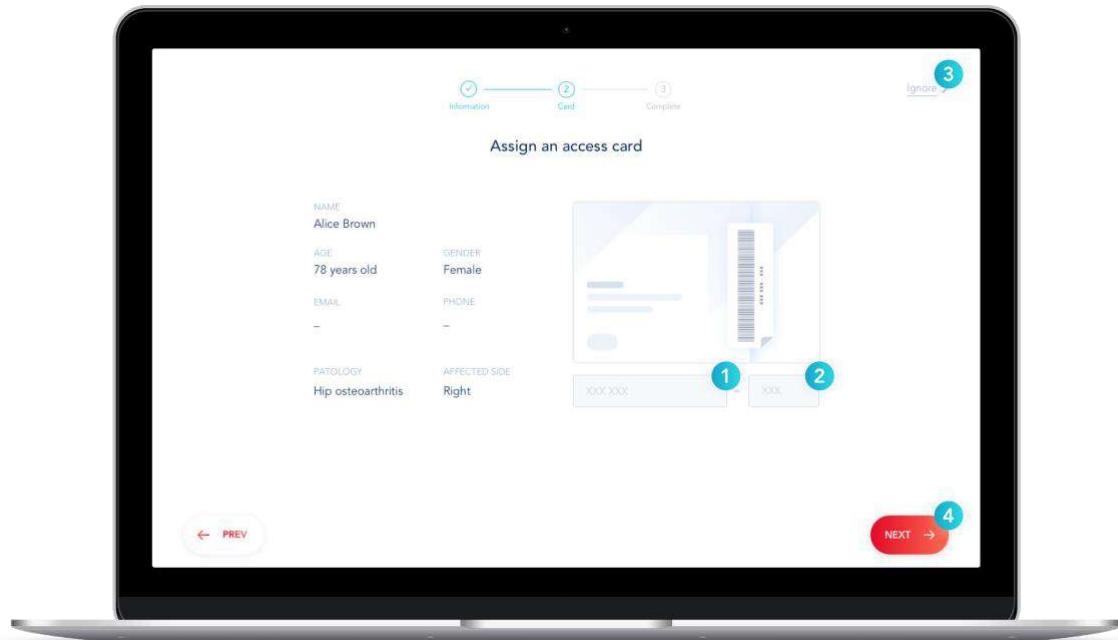
In this step, you must fill out every field with the patient information.



1. **Next** - After you finish filling out the fields, click this button to go to the next step (Step 2).

## Step 2 - Associate a card with a patient

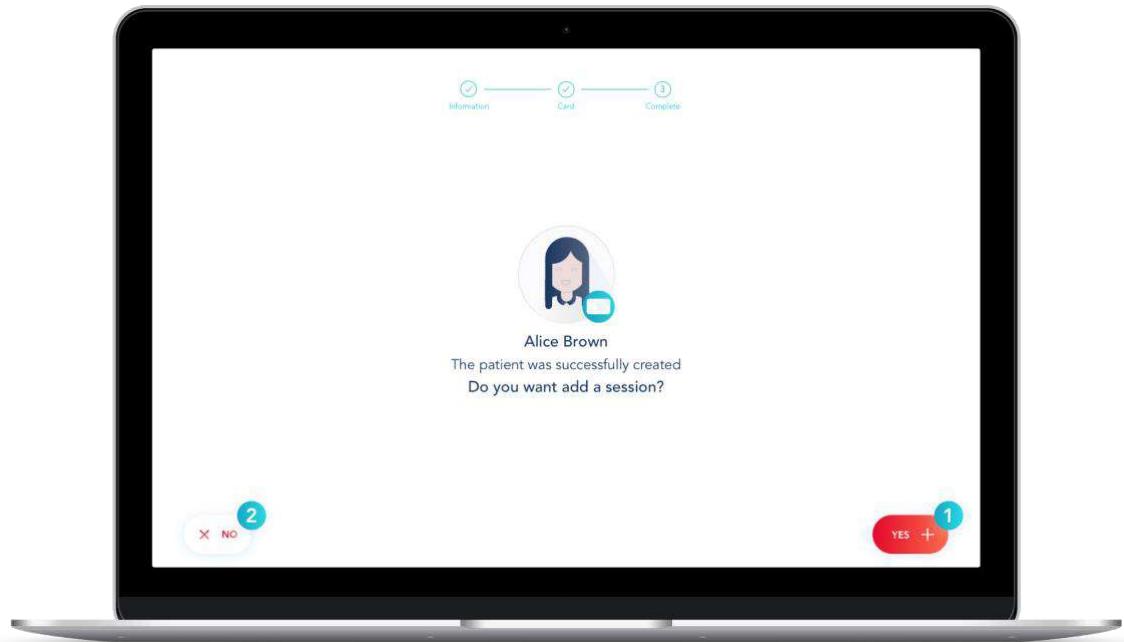
In this step, ensure all the fields you filled out about the patient are correct and associate a card with the patient.



- 1. Card number** - Insert the 6-digit card number in this field.
- 2. CVV** - Insert the three-digit card's CVV in this field.
- 3. Ignore** - In case you don't have a card readily available, ignore this step and associate a card later on.
- 4. Next** - After you finish filling out the fields, click this button to go to the next step (Step 3).

### Step 3 - Patient successfully added

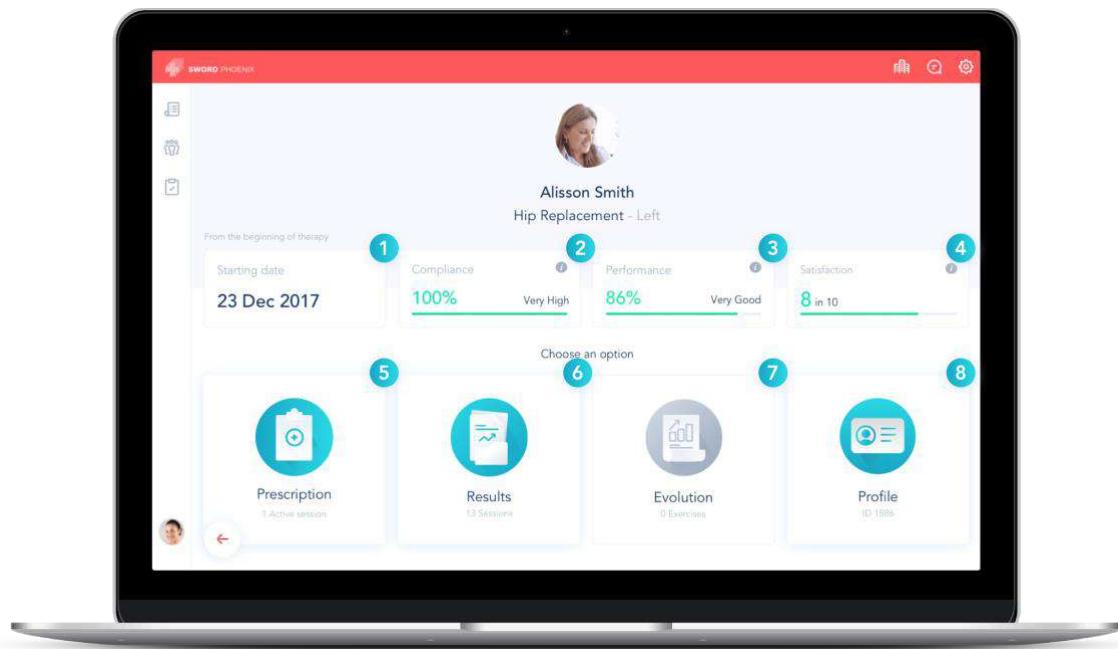
For the next step, you will get a notification saying the patient was successfully added and you can now prescribe your first session.



- 1. Yes** - If you choose this option, you will prescribe a session to a patient.
- 2. No** - If you choose this option, you will be redirected to the patient's page.

## 15 - PATIENT SCREEN

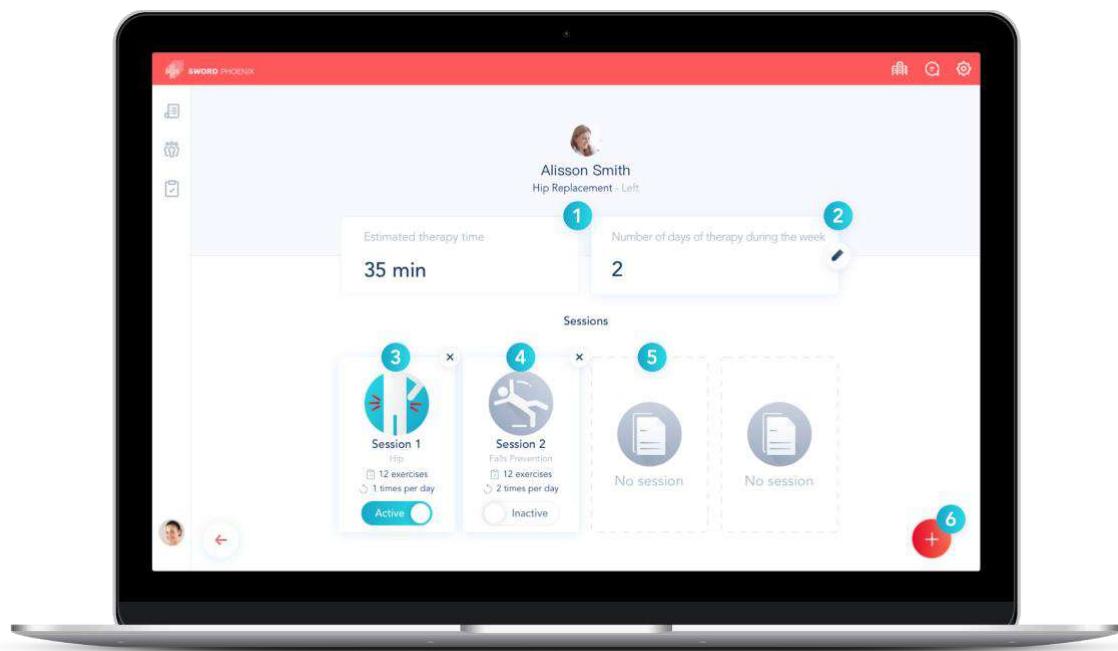
In this page, you can access all the information about a patient, as well as other features.



- 1. Starting date** - The date the treatment started, i. e., the date the patient had his first session.
- 2. Compliance** - Compliance of the patient from the starting date to today.
- 3. Performance** - Performance of the patient from the starting date to today.
- 4. Satisfaction** - Satisfaction of the patient regarding the treatment.
- 5. Prescription** - By clicking here, you can access the patient's current prescription, edit it or create new prescriptions.
- 6. Results** - By clicking here, you will access the patient's results since the beginning of the treatment.
- 7. Progress** - **This feature is not active at the moment.**
- 8. Profile** - By clicking here, you can access the patient's profile and other features.

## 16 - PRESCRIPTION

In this page, you can access the patient's prescription.



**1. Estimated therapy time** - This is an approximate value calculated based on the prescribed sessions.

**2. Number of therapy days during the week** - The days that show up were set during the patient's first session prescription. This is where you can edit that value.

**3. Active Session** - Active Session the patient must perform every day he adheres to the therapy.

In this session card, you can find the following information:

- Name of the session
- Chosen therapy
- Number of exercises for the session
- Number of times per day the patient should perform the session
- Activate/Deactivate session button
- Remove session button

**4. Inactive Session** - This session will not be shown to the patient. To reactivate it, click the button.

**5. No session** - Indicating that the patient doesn't have any prescribed session in its slot. The patient can have up to four different sessions happening at the same time.

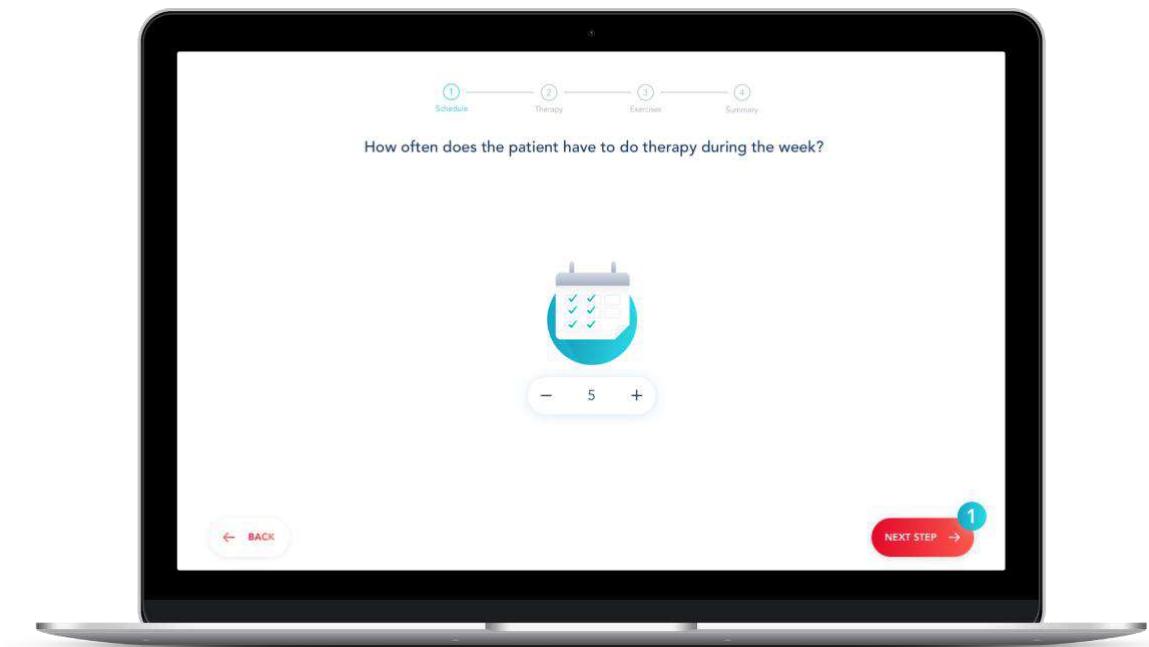
**6. Add a new session** - In case there are empty slots available for new sessions, just click this button to prescribe a new session.

**Important:** All the active sessions are used to calculate Performance, so it's important that, from the moment a patient adheres to the therapy, he attends all his or her active sessions, in the number of times they are prescribed.

## 17 - PRESCRIBE A SESSION

### Step 1 - Set the number of therapy days per week

In this step, you must set the number of days the patient should have therapy per week. This step will only show up the first time you prescribe a session to the patient. To change this value, go to the Prescription page.

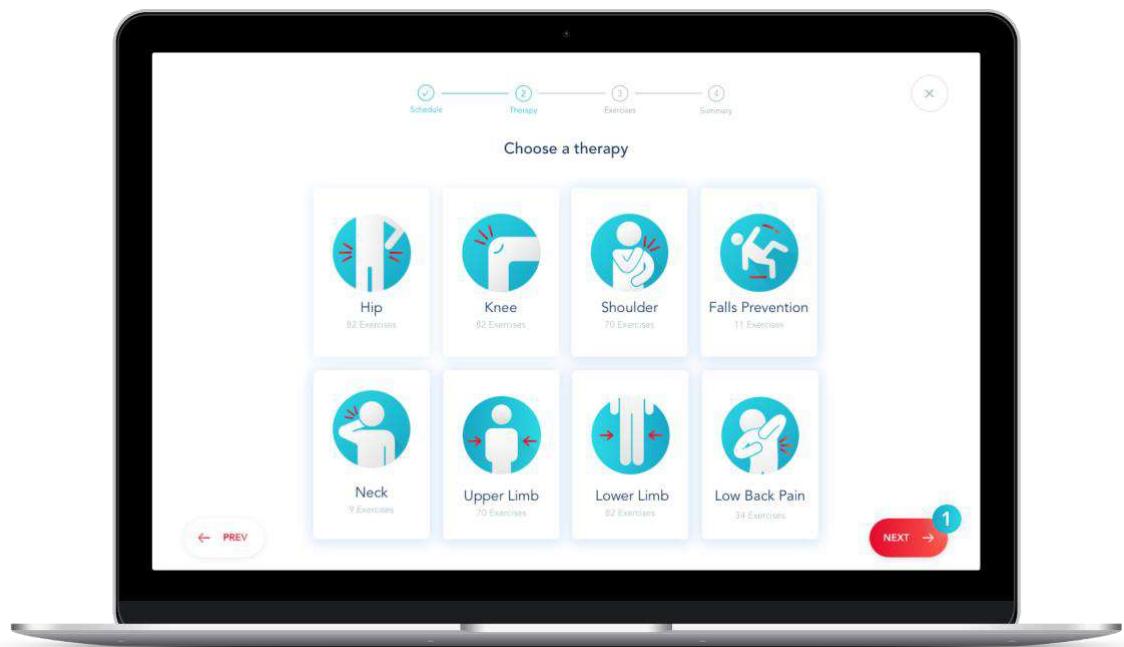


**1. Next** - After you set the number of days a patient should adhere to therapy, click here to go to the next step (Step 2).

**Important** - *To calculate Compliance, the number of days a patient should adhere to the therapy is taken into account. Please set these values wisely and communicate them to the patient, since it will affect Compliance values.*

## Step 2 - Choose the therapy

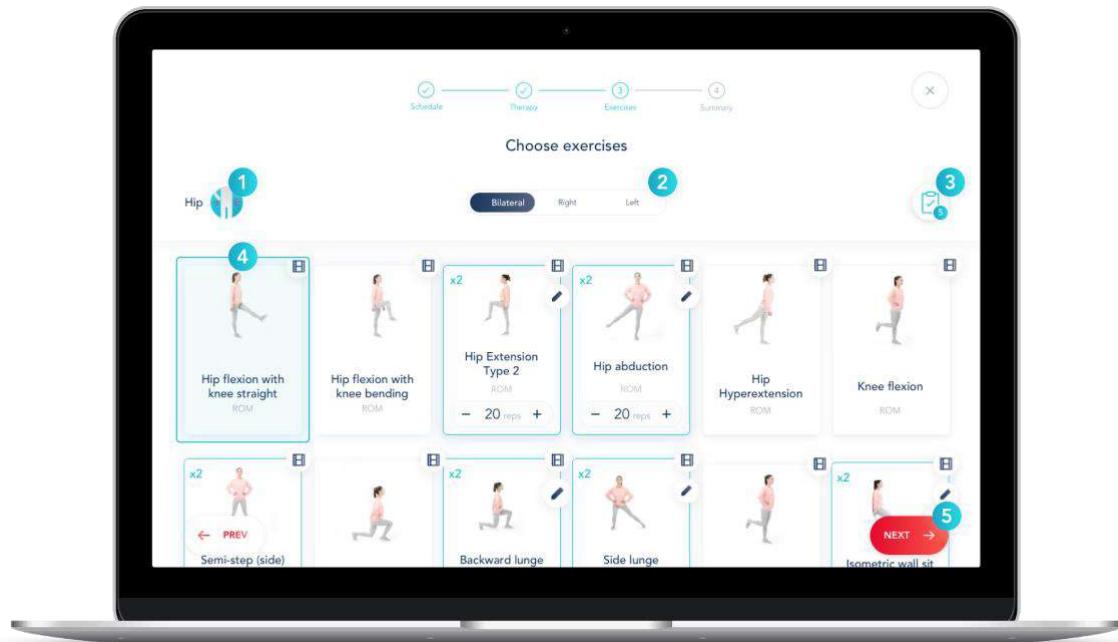
In this step, you have to choose the kind of therapy you want to prescribe to the patient.



**1. Next** - After you set the therapy, click here to go to the next step (Step 3).

## Step 3 - Choose the exercises

In this step, you can choose the exercises that will compose the session.



**1. Therapy** - Here you can see the therapy you have chosen before (**Step 2**).

**2. Sides** - These filters indicate the different sides for which you can prescribe an exercise. The list of exercises will change according to the sides you choose.

**3. List of exercises chosen** - By clicking this, a list containing the exercises you selected to compose the session will show up. You can remove exercises from this list.

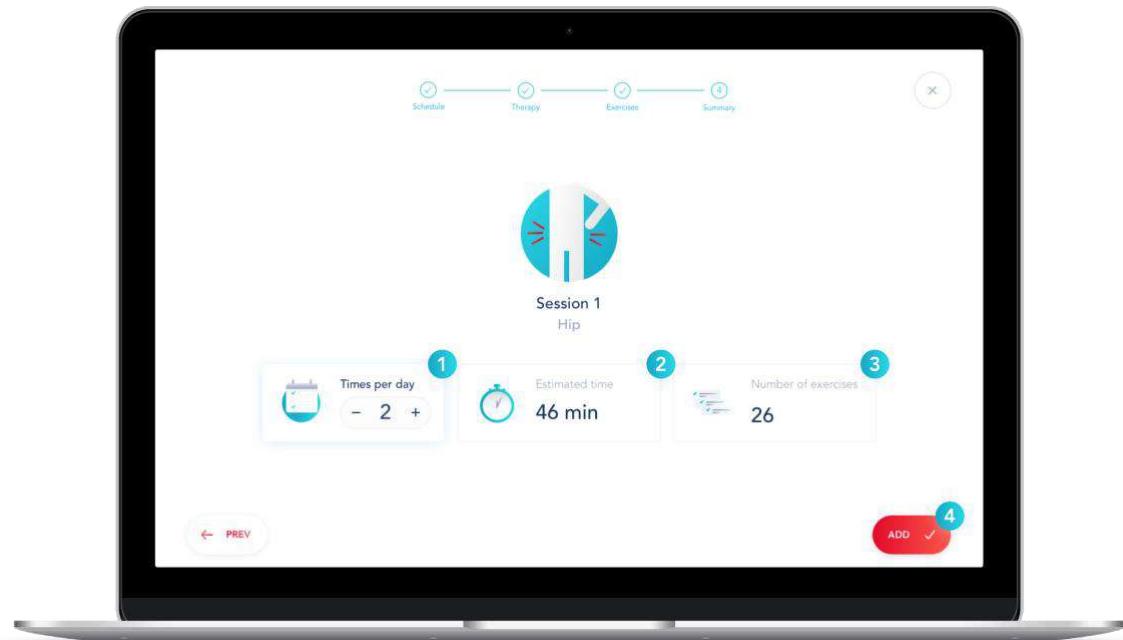
**4. Exercises** - To select the exercises that will compose the session or add a series of the same exercise, just click the exercise card.

- **Video** - You can see a video of the exercise
- **Repetitions** - Choose the number of repetitions/correct movements the patient should perform during the exercise
- **Set difficulty level** - Here you can set the goal (difficulty level) the patient should reach during his or her movements.

**5. Next** - After you set the exercises that will compose a session, click here to go to the next step (Step 4).

## Step 4 - Session summary

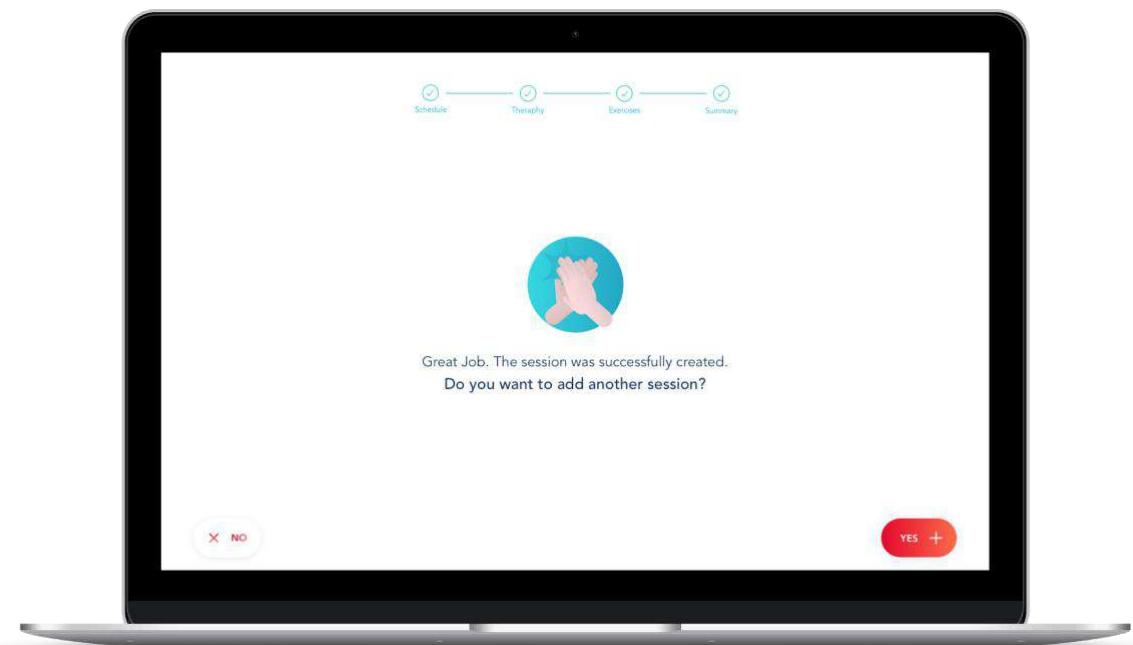
In this step, you will see a summary of the session.



- 1. Number of times per day** - This is where you must set how many times a day the patient must perform a session.
- 2. Estimated time** - A time estimate is made based on the number of exercises selected and the number of repetitions for each exercise.
- 3. Number of exercises** - Number of exercises selected to compose the session.
- 4. Next** - Click here to finish the session prescription (Step 5).

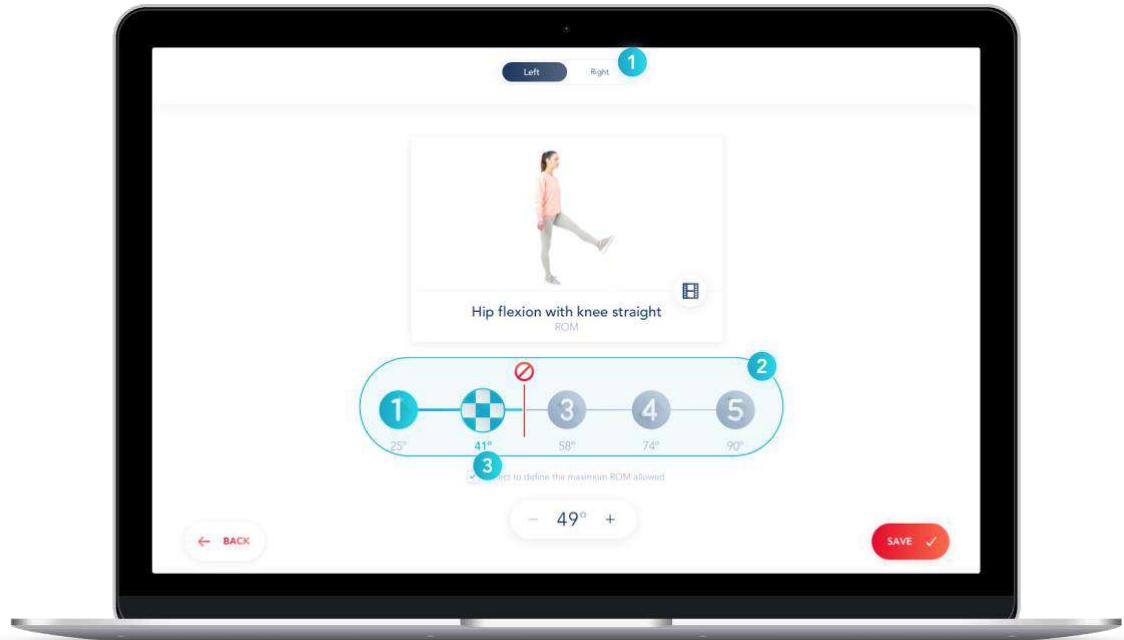
## Step 5 - Session prescribed successfully

In this step, you will get a notification that the session was successfully prescribed and you have the chance to make another prescription, in case you need one. At this point, the session is now active for the patient to see. The next time he/she begins a daily therapy session, this session will be available for him/her to perform.



## 18 - SET EXERCISE DIFFICULTY LEVEL

Difficulty levels can be set depending on the exercise category: Range of Motion (degrees of motion), Time (in seconds) or Difficulty (Very Easy, Easy, Medium, Hard, Very Hard).



- 1. Sides/Directions** - If an exercise is to be performed on both sides, you will have to specify the difficulty for each side.
- 2. Difficulty Levels** - Here you can see the exercise's difficulty level and set the intended goal.
- 3. Range of Motion Limit** - In Range of Motion (RoM) exercises, you can set the maximum RoM allowed. If the patient surpasses that limit, the repetition/movement will be considered incorrect.

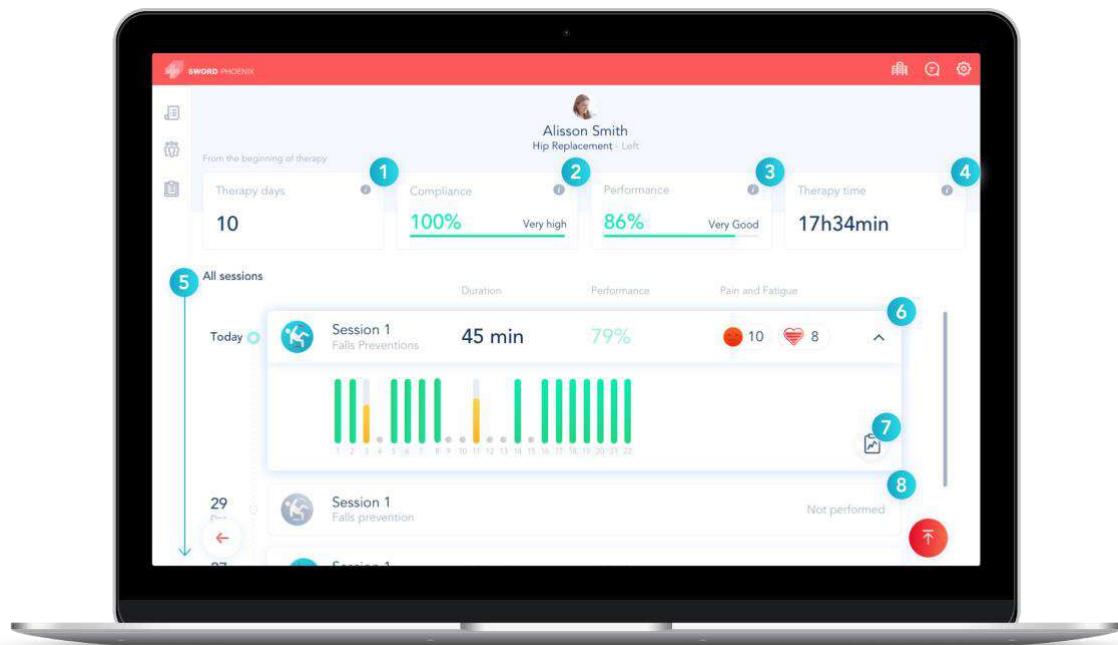
**Important:** The level you set is an indicative goal, but it is not mandatory for validating a repetition as correct.

## 19 - PATIENT RESULTS

This feature allows the therapist to check on the results of every session the patient has performed, from the starting date to present day. There are many levels of information a therapist can access, from an overview of the sessions the patient performed to the specific results of a given exercise on a given session.

### Overview of patient's results

In this screen, you can check various patient's metrics since the beginning of the treatment, as well as get a general overview of all the sessions performed by the patient throughout the treatment.



**1. Therapy days** - This date represents the number of days since the beginning of therapy. Depending on the patient's state (Active/Inactive), results may change:

- **Active** - Number of days from the beginning of therapy until the current day.
- **Inactive** - Number of days from the beginning of therapy until the day the patient was deactivated.

**2. Compliance** - Patient compliance from the beginning of treatment until today.

**3. Performance** - Patient performance since the beginning of treatment regarding goals and prescribed sessions.

**4. Therapy time** - Total therapy time, adding up the time from every session the patient performed.

**5. Sessions Timeframe** - In this section, you can see all the sessions that were performed or not performed by the patient in the days he adhered to the treatment in a chronological order.

**6. Performed Session** - Here you can have an overview of how the patient's session went. You can also access further information about the session:

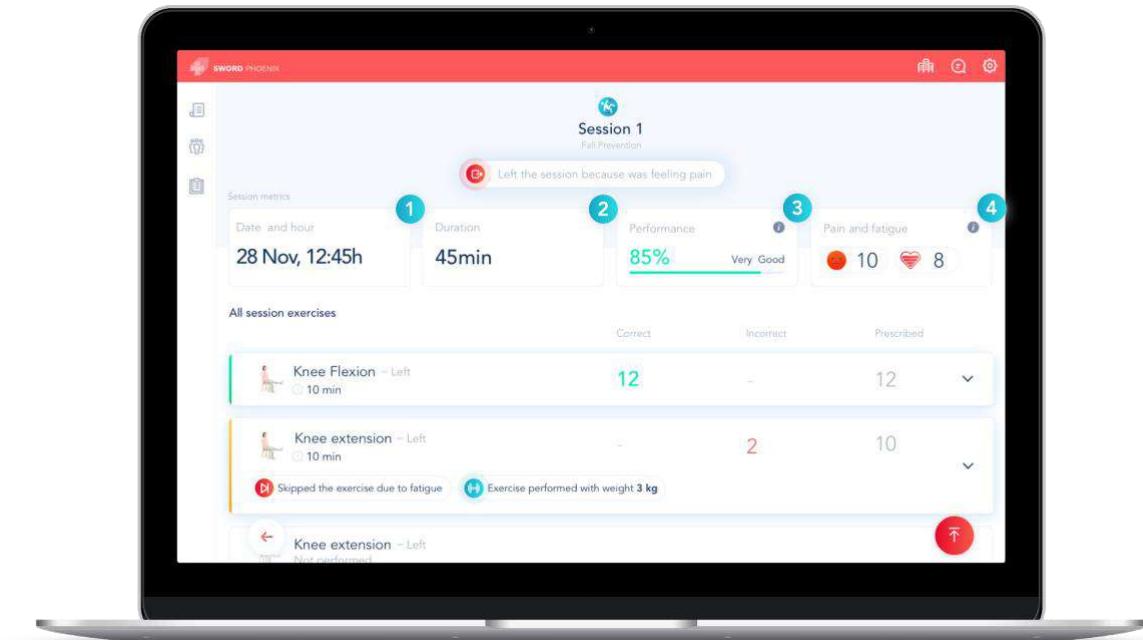
- Session Duration
- Pain and Fatigue reported by the patient in this session
- Patient Performance in the session

**7. See session results** - By clicking here you can access detailed results regarding this session (12.9.2).

**8. Session Not Performed** - This tells you that the patient adhered to the therapy in that specific day but didn't perform the session that was prescribed.

## Detailed session results

In this screen, you can see the patient's results for a specific session with maximum detail, as well as have a general overview of how the exercises went.



- 1. Date and Time** - Date and Time the patient began the session.
- 2. Session Duration** - Session duration from the beginning of the first exercise to the conclusion of the last one.
- 3. Performance** - Patient Performance for this session.
- 4. Pain and Fatigue** - Pain and Fatigue reported by the patient at the end of the session.

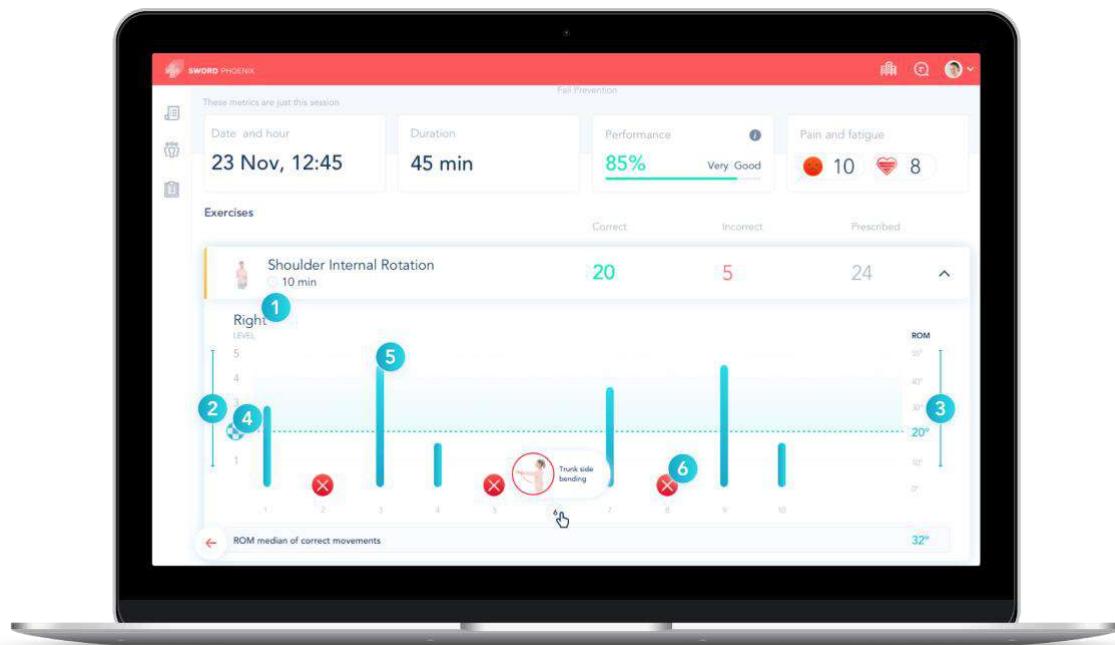
In the lower part of the page, you can see all the exercises that were performed or not performed by the patient. You can get a macro vision of how each exercise went via the following information:

- Exercise duration
- Number of **Correct** Repetitions/Movements performed by the patient
- Number of **Incorrect** Repetitions/Movements performed by the patient
- Number of **Prescribed** Repetitions/Movements
- Lets you know when a patient abandoned the exercise due to:
  - Pain
  - Fatigue
  - Any other reason the patient didn't specify
- Sidebar with a color representing:
  - **Green** - The patient performed every repetition/movement correctly
  - **Yellow** - The patient was unable to perform every repetition/movement correctly
  - **Grey** - The patient didn't perform any movement correctly.

By clicking a specific exercise, you have access to the detailed results of the exercise.

## Detailed result of an exercise

When you access the detailed results of an exercise you see a graphic containing detailed information regarding each repetition/movement the patient made. In this graphic, you can see every mistake made and goal achieved by the patient during the exercise in detail.



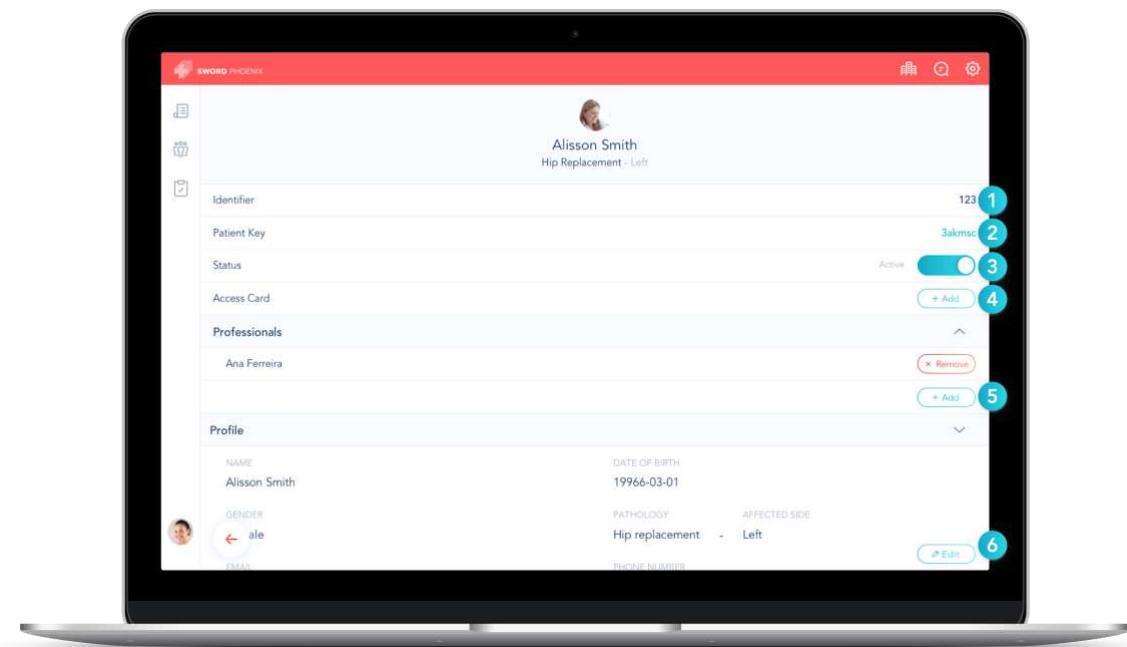
- 1. Side/Direction** - Side or Direction of the movements
- 2. Difficulty Levels** - You can find the difficulty levels on the left side of the graphic.
- 3. Values for each level** - On the right side of the graphic you can find the values for each level. These values vary depending on the exercise category.
- 4. Goal** - Level the patient should reach during his/her movement.
- 5. Correct Repetition/Movement** - Blue bars represent correct movements. By moving the mouse over the bar, you can see the level and value the patient reached during the movement
- 6. Incorrect Repetition/Movement** - This symbol represents incorrect movements. By moving the mouse over the bar, you can see detailed information about the mistake the patient made.
- 7. Range of Motion Limitation** - Here you can see the range of motion you assigned to the patient during the exercise prescription.

**Important** - Depending on the category, side and directions of the exercise, the information on the graphics may vary.

## 20 - PATIENT PROFILE

By accessing the patient profile you can:

- Activate or Deactivate Patient
- Associate or Remove access card
- Share patient
- See and Edit patient profile

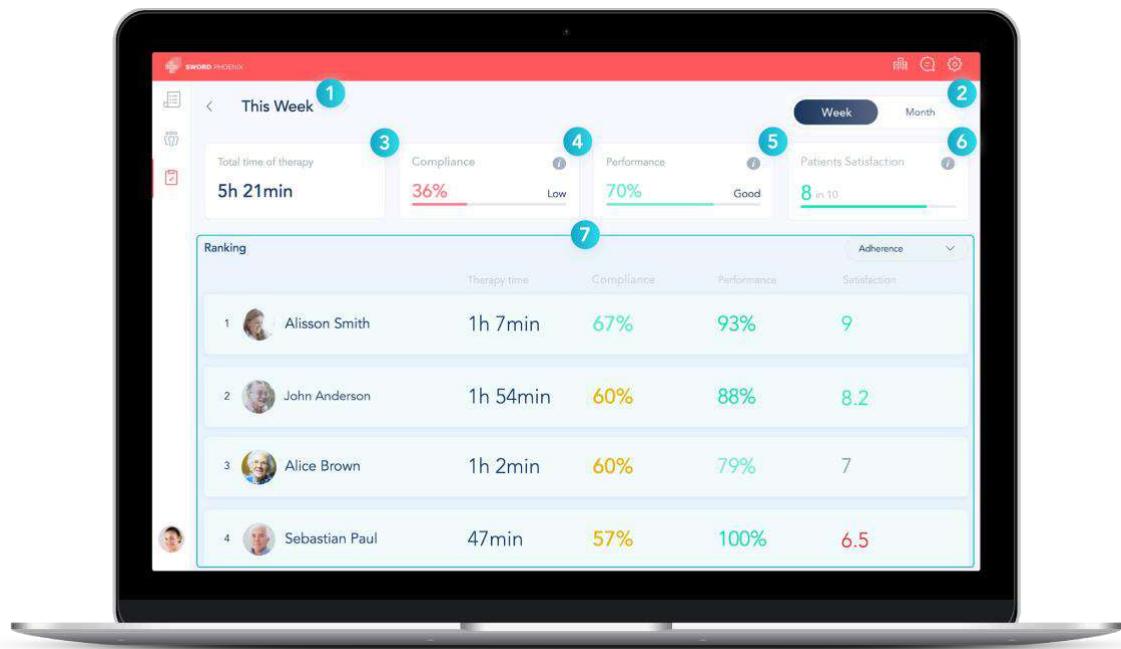


- 1. ID Number (ID)** - This number is automatically generated when the patient is created and must be used to identify the patient if you need to contact SWORD Health's support team.
- 2. Patient Key** - The key was discontinued and must not be used.
- 3. Status** - Here you can see if the patient is active or inactive; you can change that status here.
- 4. Access Card** - Here you can see the patient's card, remove it or associate a new one.
- 5. Share Patient** - This feature allows you to share the patient with other therapists working in the same institution and who are able to access SWORD Phoenix.
- 6. Edit Profile** - This is where you can see/edit the patient's personal and clinical information.

**Important** - By sharing a patient with another therapist, you are also sharing all the personal and clinical information in the Portal regarding that patient, as well as the possibility to edit that patient's information and prescriptions. Furthermore, when a patient is shared, all his/her metrics (compliance, performance, satisfaction) will influence/change the general metrics of every professional he/she is attributed to.

## 21 - OVERVIEW

This feature gives you an overview of all the patients that were active at a given week or month.



You can choose the time frame you want to see on the top of the page, numbers **1** and **2**.

**3. Total therapy time** - The total therapy time is the sum of the therapy for all the patients in the timeframe you defined.

**4. Compliance** - Compliance is the average compliance of all the patients in the timeframe you established.

**5. Performance** - Performance is the average performance of all the patients in the timeframe you set.

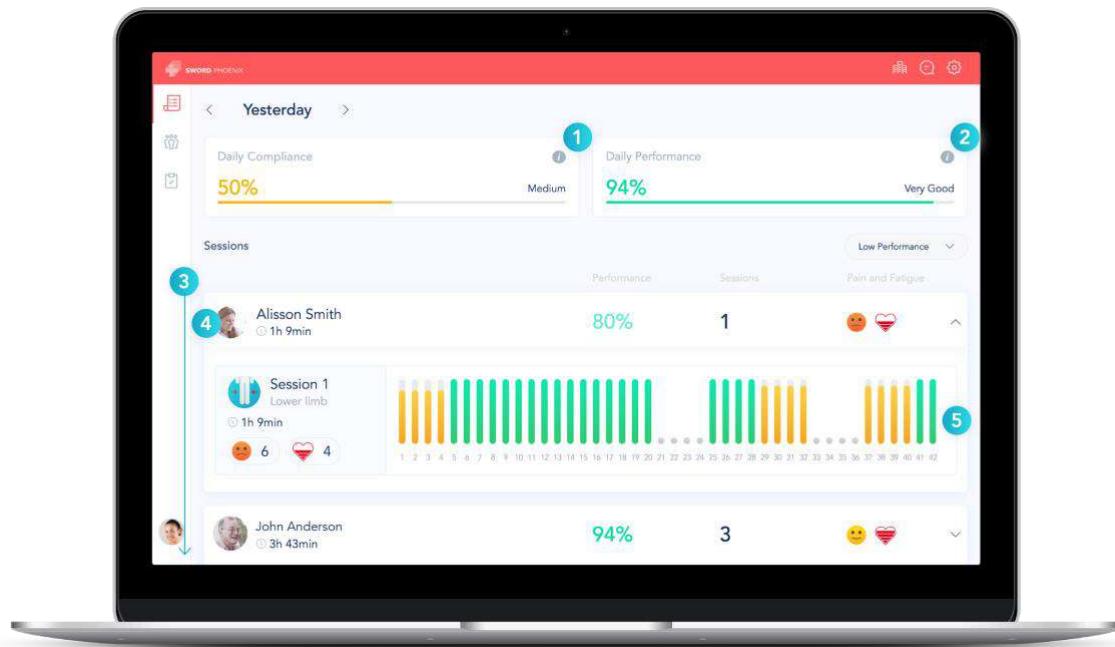
**6. Satisfaction** - Satisfaction is the average satisfaction of all the patients in the timeframe you defined.

**7. Ranking** - Patient ranking refers to the timeframe you specified and can be ordered by:

- Therapy time
- Compliance
- Performance
- Satisfaction

## 22 - DAILY SUMMARY

Every day, you can see all your patients' activity and have an overview of how sessions are going. As you enter this page, a summary of the present day appears by default, but you can also see the summary of previous days.



**1. Daily compliance** - Daily compliance tells you the percentage of patients that adhered to therapy out of all the patients that had prescriptions/active sessions and could have had sessions that day.

**2. Daily performance** - Average performance of every patient that adhered to therapy.

**3. Patient list** - Here you can see all the patients that adhered to therapy.

**4. Patient** - You can see, for every patient:

- Therapy time.
- Average performance of every session he/she underwent.
- The number of sessions the patient overwent.
- The worst Pain and Fatigue value the patient reported during every session of the day.

**5. Overview of how the sessions went** - By clicking a specific patient, you will have an overview of how each session went. For every session, you can see:

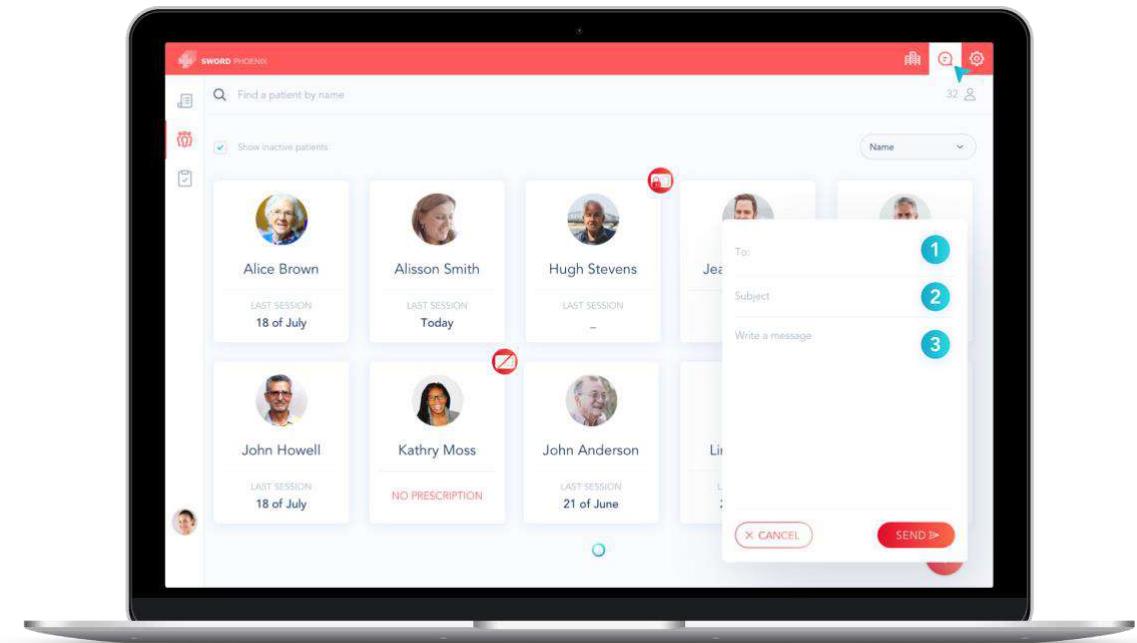
- Session name
- Session duration
- Pain and Fatigue reported by the patient in that session
- Color-coded Bars representing each exercise of a given session:
  - **Green** - The patient completed every assigned repetition/movement correctly
  - **Yellow** - The patient was unable to perform every repetition/movement correctly

- **Grey** - The patient was unable to perform any movement of the exercise correctly or skipped the entire exercise.
- On mouse-over in the exercise bar, you can access the following information:
  - Name of the exercise
  - Correct vs. Prescribed Repetitions/Movements

**Important** - *Patient session results may not be readily available for consultation.*

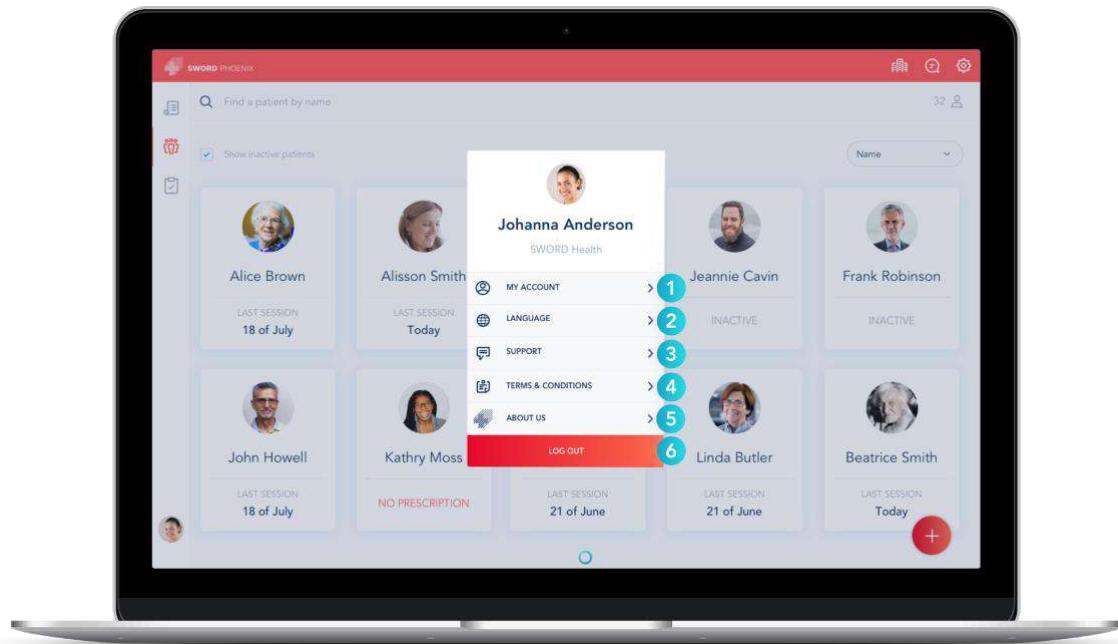
## 23 - SEND MESSAGES

This feature allows you to send messages to your patients. The patient cannot answer via the same channel.



- 1. To** - Here you must choose the patient you want to message
- 2. Subject** - Fill out the message subject
- 3. Message Body** - Write the message to the patient here.

## 24 - SETTINGS



- 1. My Account** - By accessing this field you can change your password and your profile information.
- 2. Language** - You can change the Portal's language.
- 3. Support** - This is where you can find our User Manual and support contacts.
- 4. Terms and Conditions** - Here you can read SWORD Phoenix's terms and conditions.
- 5. About Us** - This will redirect you to our website, where you can find more information on SWORD Health.
- 6. End Session** - By clicking here will end your session in the Portal.

**DIGITAL THERAPIST**

## 25 - TURN ON THE DIGITAL THERAPIST

To turn on the Digital Therapist, press the “on” button continuously.

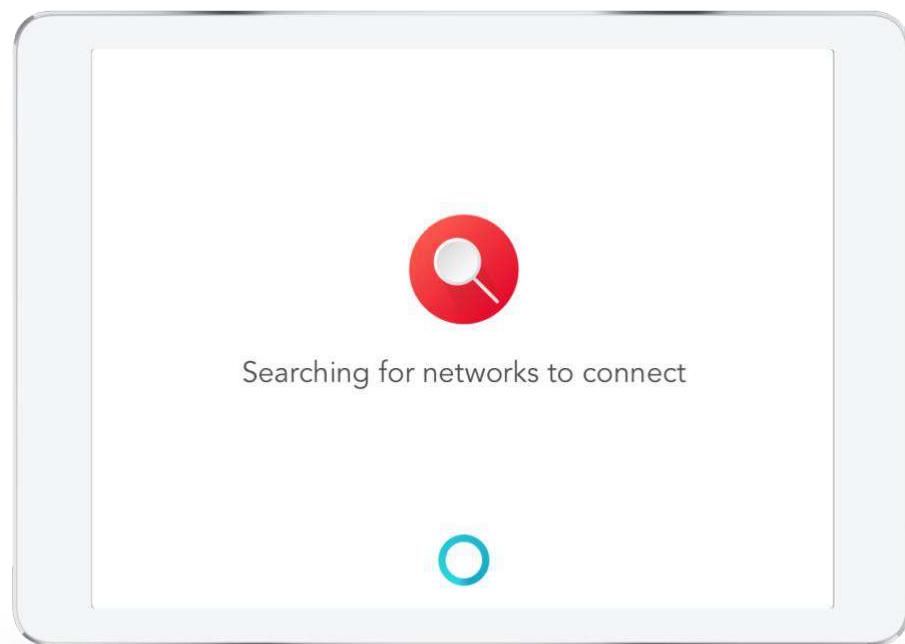


## 26 - FIRST CONFIGURATION

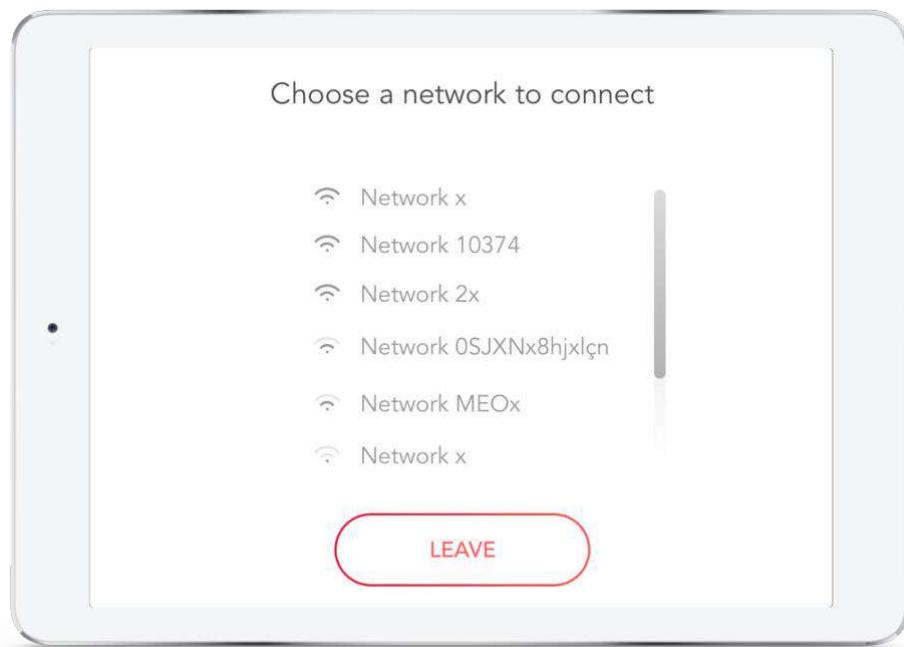
### Step 1 - Connect to the Internet

If the device doesn't have a SIM card with 4G mobile access, a Wi-Fi connection is required.

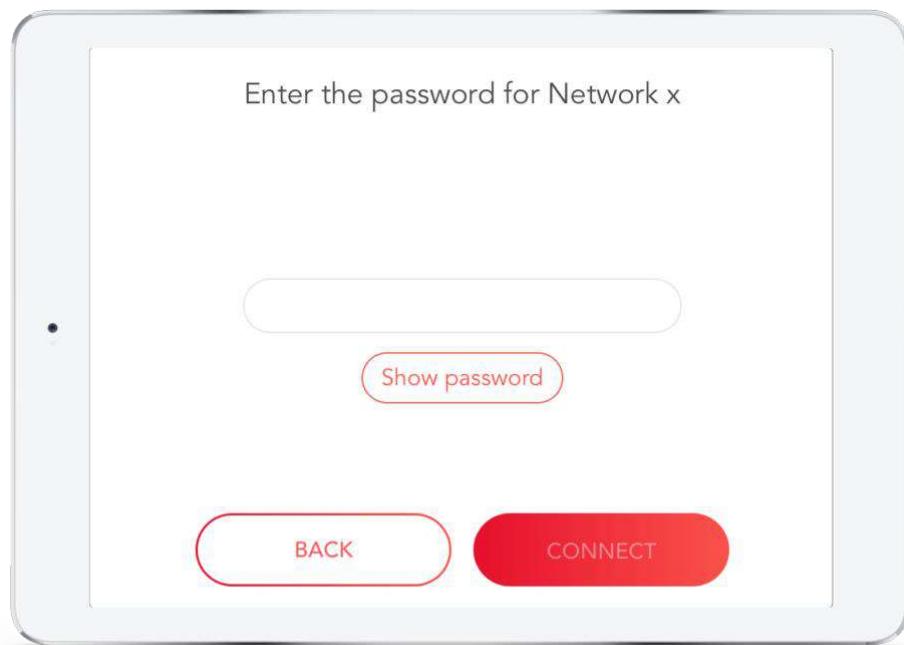
**1st** The system will automatically look for available networks to connect.



**2nd** A list of available networks will show up, choose the one you want to connect to.



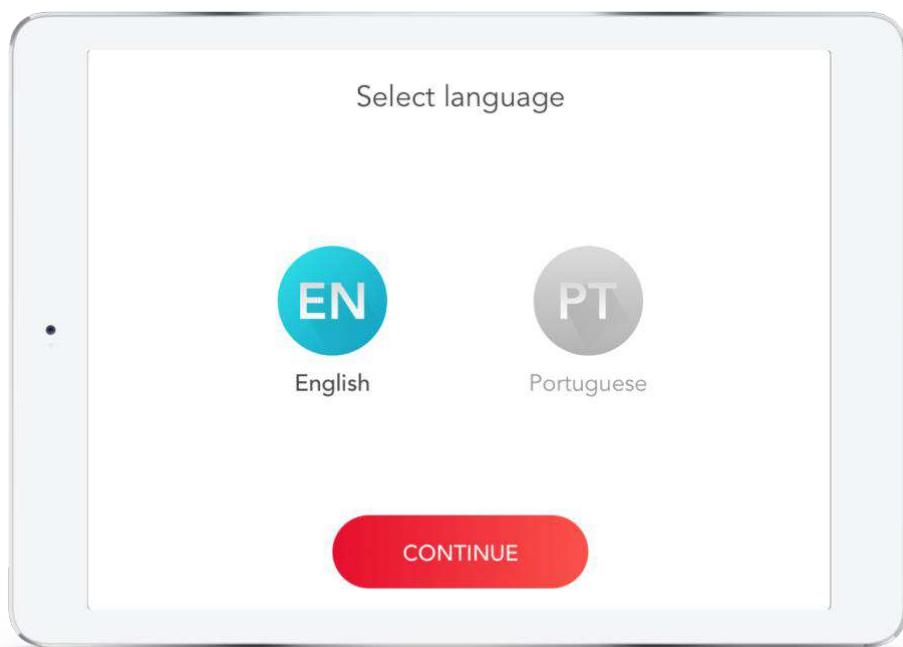
**3rd** Insert the network's password and click "Connect".



**Important** - You won't be able to use SWORD Phoenix unless you have an internet connection.

## Step 2 - Choose Language

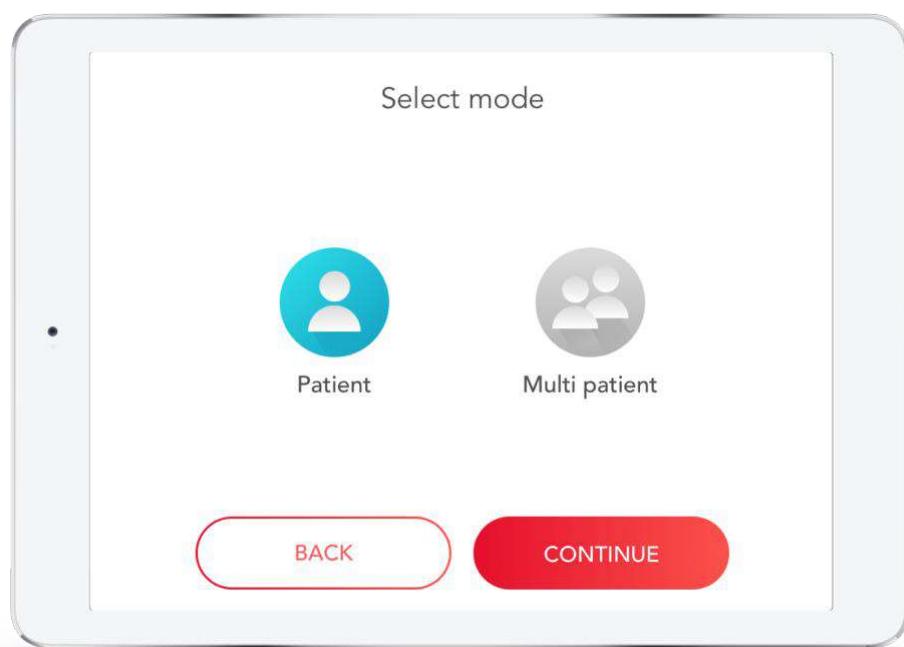
In this step, you must choose the Digital Therapist's language.



### Step 3 - Select User Mode

In this step, you must choose the Digital Therapist's user mode. There are two different modes available:

- **Patient** - The Digital Therapist will be configured and used by only one patient. This is the recommended mode for patients having therapy at home.
- **Multi-Patient** - The Digital Therapist will be configured and used by several patients. This is the recommended mode for clinics where several patients access the same digital therapist.

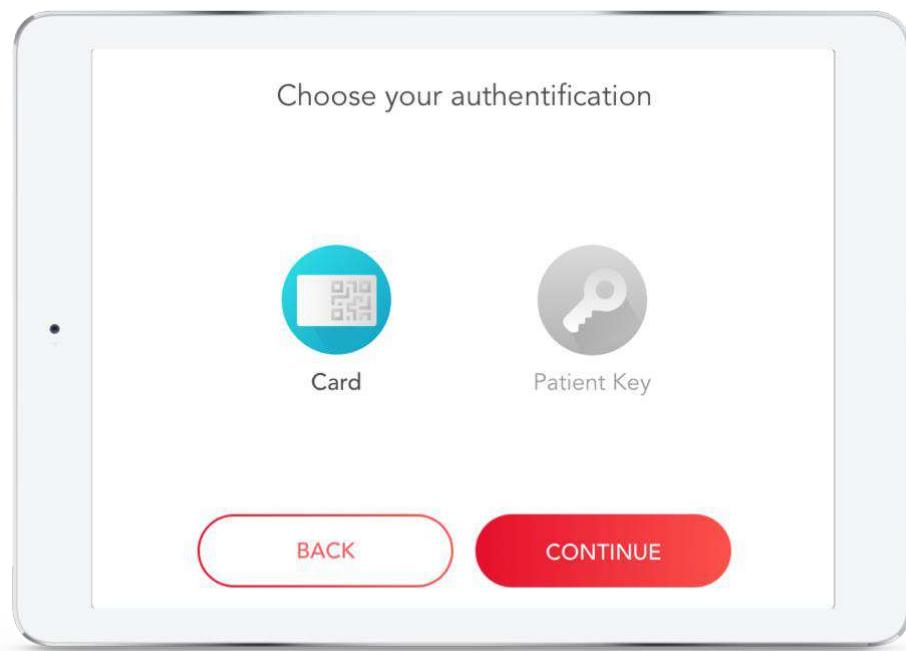


## Step 4 - Choose a type of patient authentication

If you chose the Patient user mode, you're required to choose the way the patient will authenticate himself. If you chose the Multi-Patient user mode, you can automatically skip to **Step 8**.

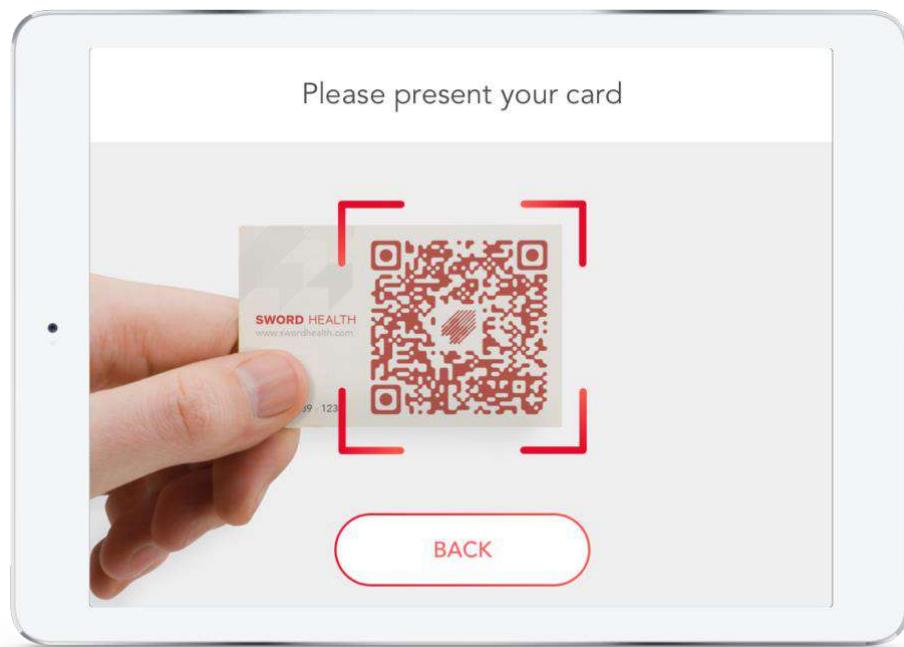
There are two ways to authenticate a patient:

- **Card** - The patient will use a card to log into the system.
- **Patient Key** - This type of authentication was discontinued, therefore it must not be used.



## Step 5 - Present card

In this step, you must present your card. Pay attention to all the instructions we give you to avoid card reading problems.

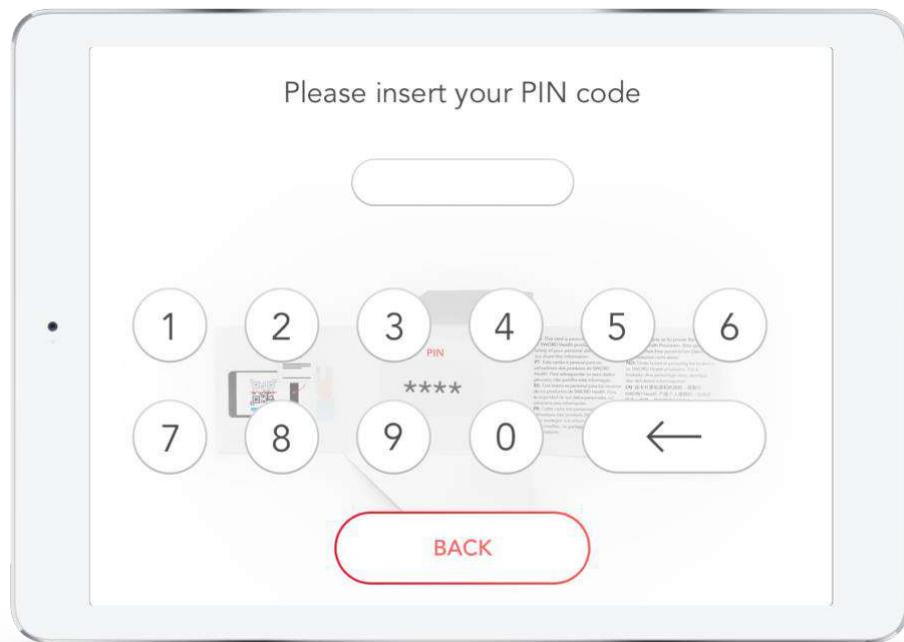


### How to use the card:

- To make the card reading easier, make sure there is good lighting in the room.
- During the card reading, please keep it at an 8 inches (20 centimeters) distance from the tablet's front camera.
- **During the reading process, never put your fingers in front of the QR code; if you do that, the Digital Therapist won't be able to read the card.**

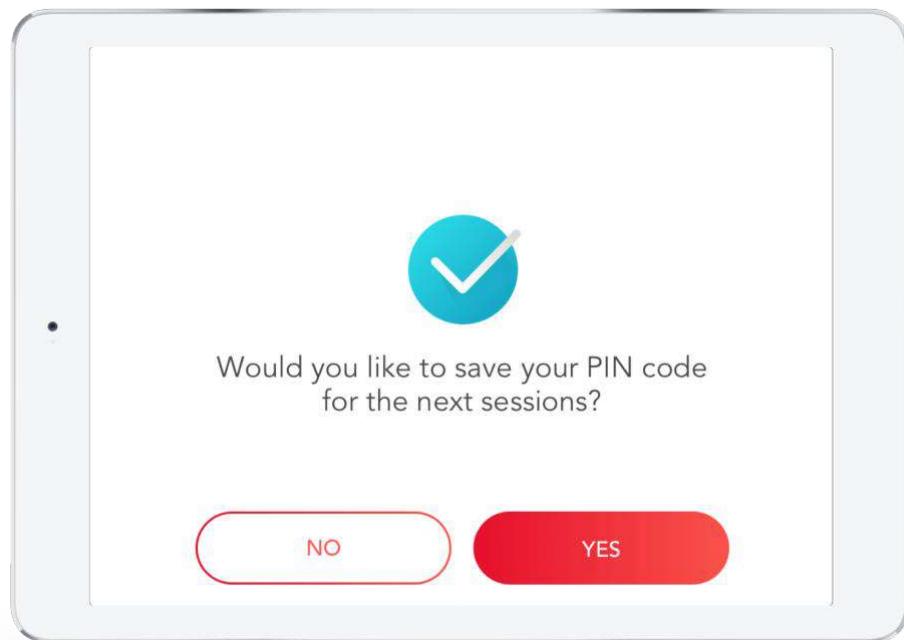
## Step 6 - Insert PIN Code

In this step, you are required to insert the card's PIN code. This code can be found inside the card's box.



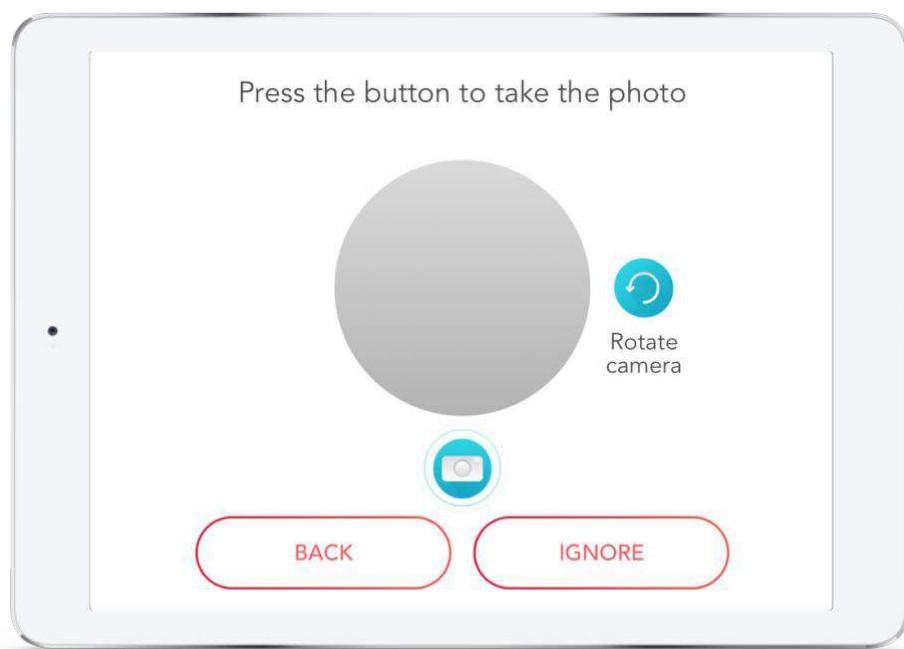
## Step 7 - Save PIN Code

In this step, the system will ask you if you want to save the PIN Code. If you accept to save it, you won't be required to insert the PIN code ever again when accessing your Digital Therapist.



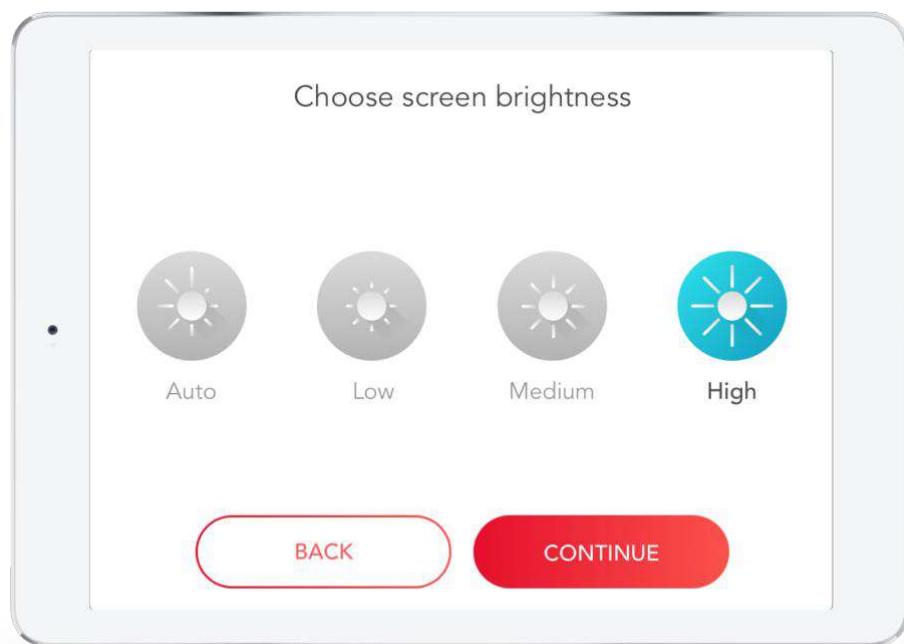
## Step 8 - Take a photo

This is the step where you get to take your picture. It is important to have a patient's picture so your therapist can easily identify you and access your data. You can ignore this step, if you don't want to take a picture.



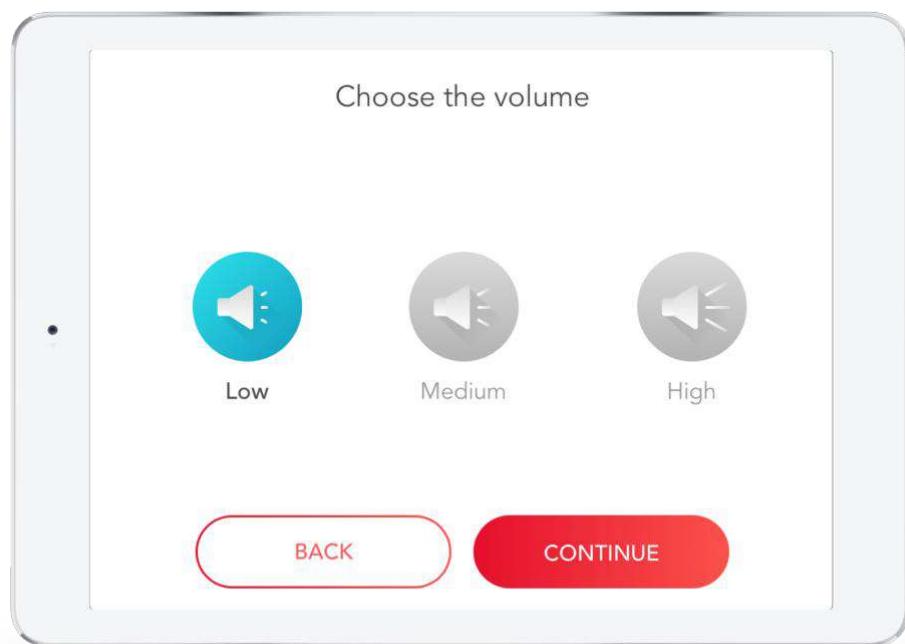
## Step 9 - Screen Brightness

In this step, you can choose the screen brightness to however you feel comfortable.



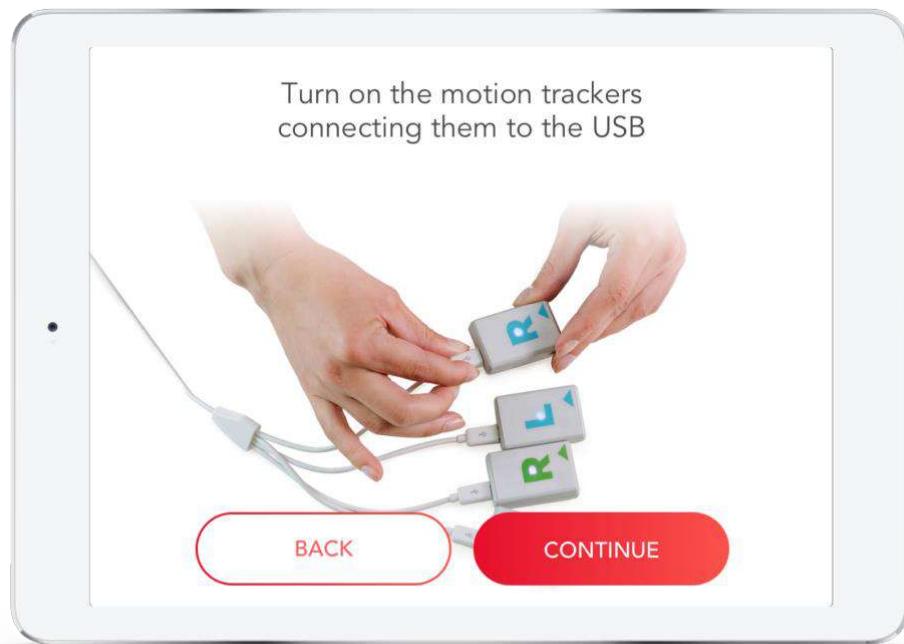
## Step 10 - Volume

In this step, you can set a comfortable sound volume.



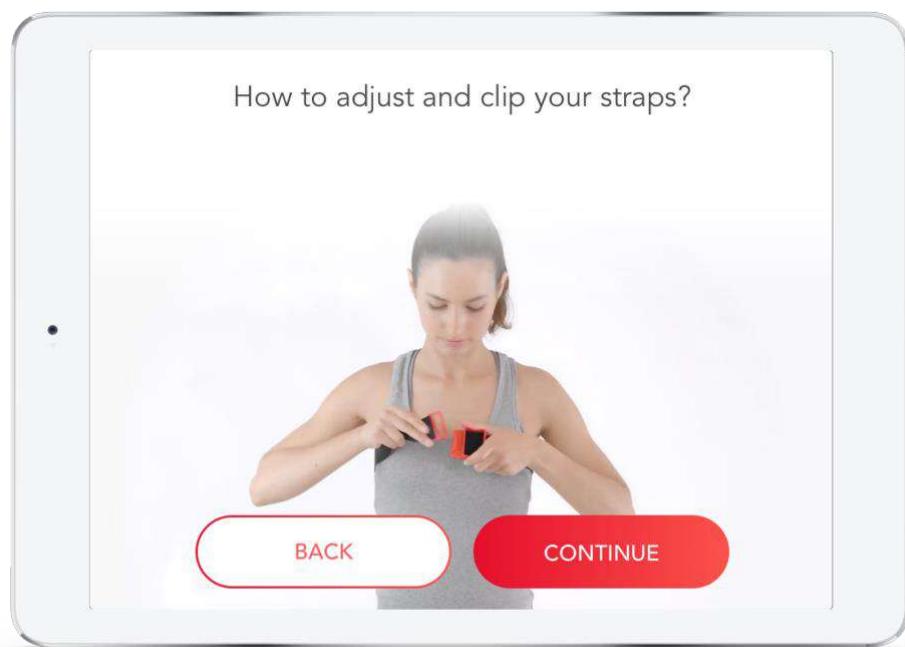
## Step 11 - Plug in the Motion Tracker

When you get your SWORD Phoenix kit, the motion trackers are turned off and you must turn them on for the first time. To do that, just plug them into the socket and make sure they all show a blue light.



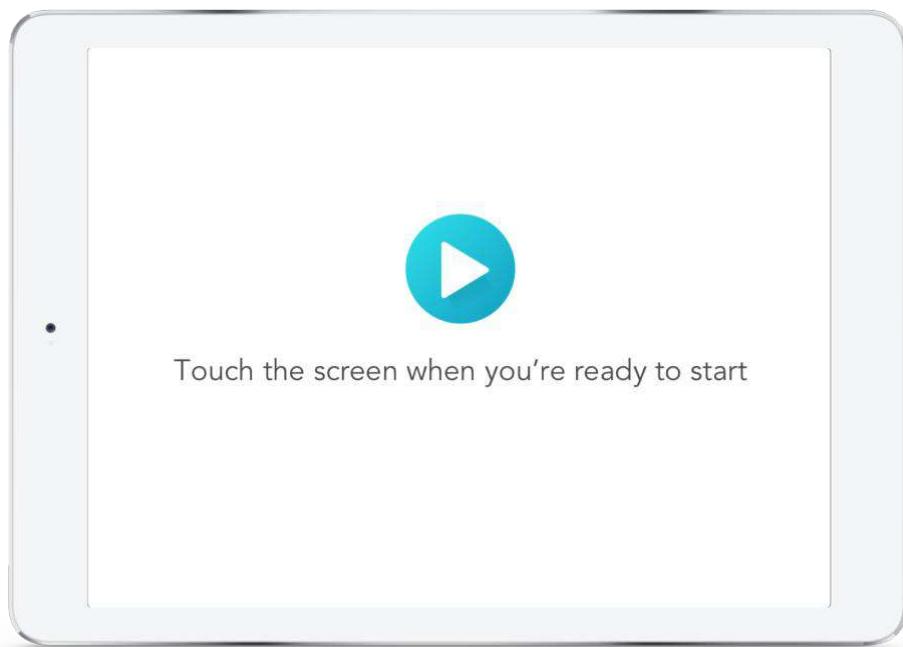
## Step 12 - Adjust and clip the straps

To finish the Digital Therapist's setup, a small instructional video will show up telling you how to adjust and clip the straps to your body.



## Step 13 - Setup Finished

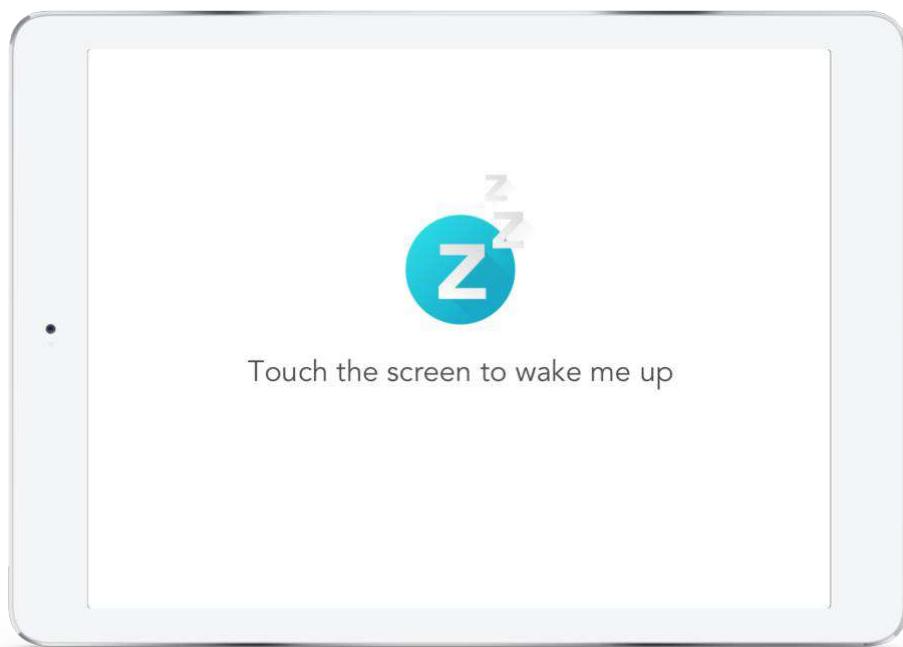
After you complete every step correctly, the Digital Therapist is set up and ready to be used.



## 27 - PERFORMING THE SESSIONS

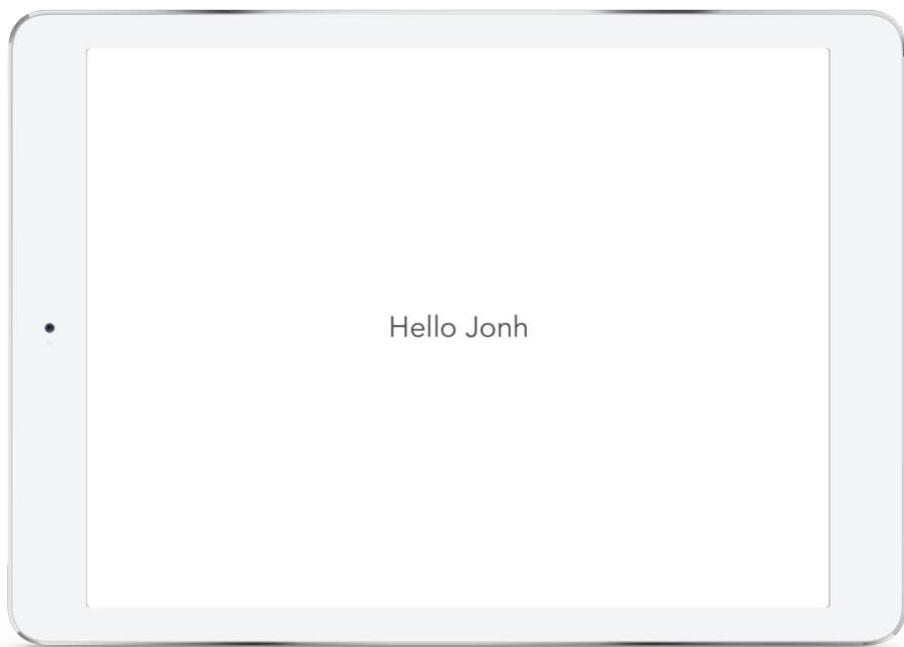
### Step 1 - Waking up

The first thing you have to do is wake up the Digital Therapist: to do that, just touch the screen.



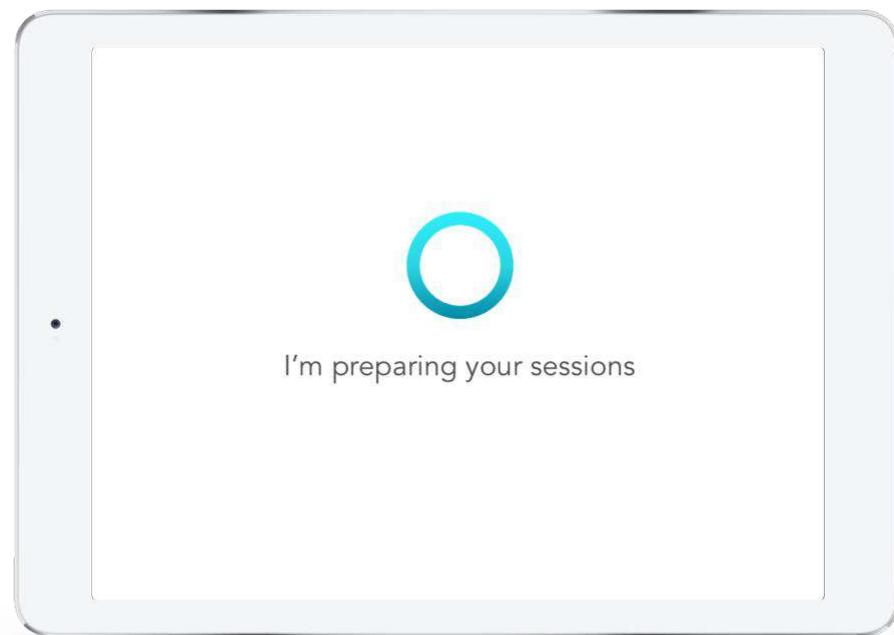
## Step 2 - Hello

After waking up, the Digital Therapist will greet you with "Hello".



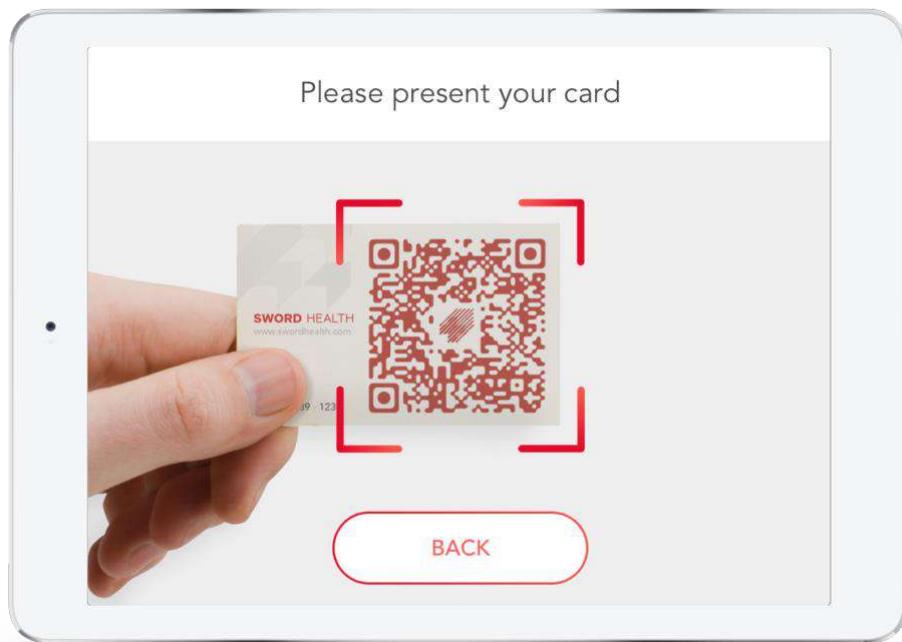
## Step 3 - Wait

The Digital Therapist is communicating with the server, please wait.



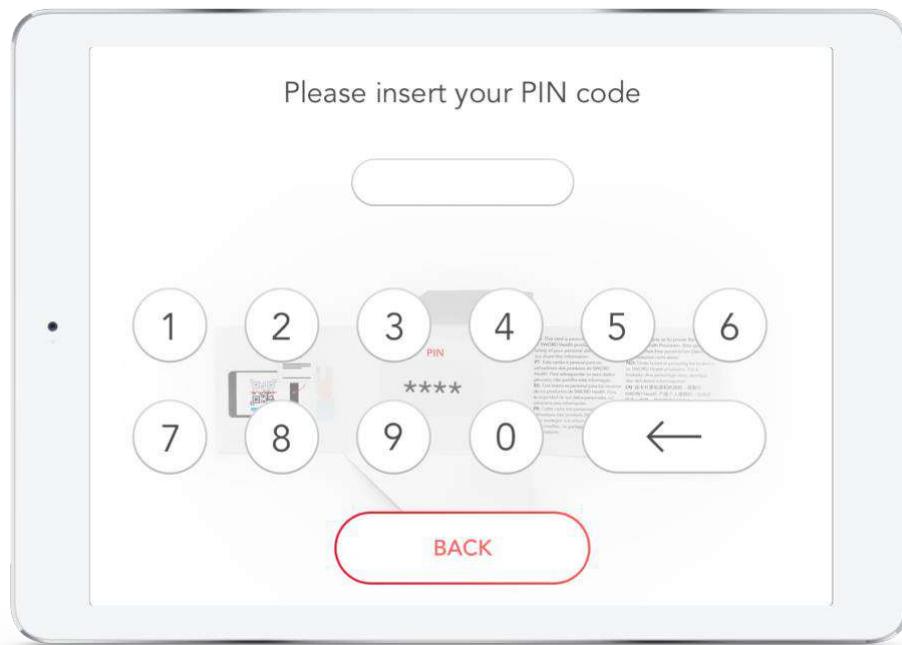
## Step 4 - Present Card

If the last time you showed your ID card to the Digital Therapist was more than 24 hours ago, you will have to do it again. If you showed the card less than 24 hours ago, this screen will be skipped.



## Step 5 - Introduce PIN Code

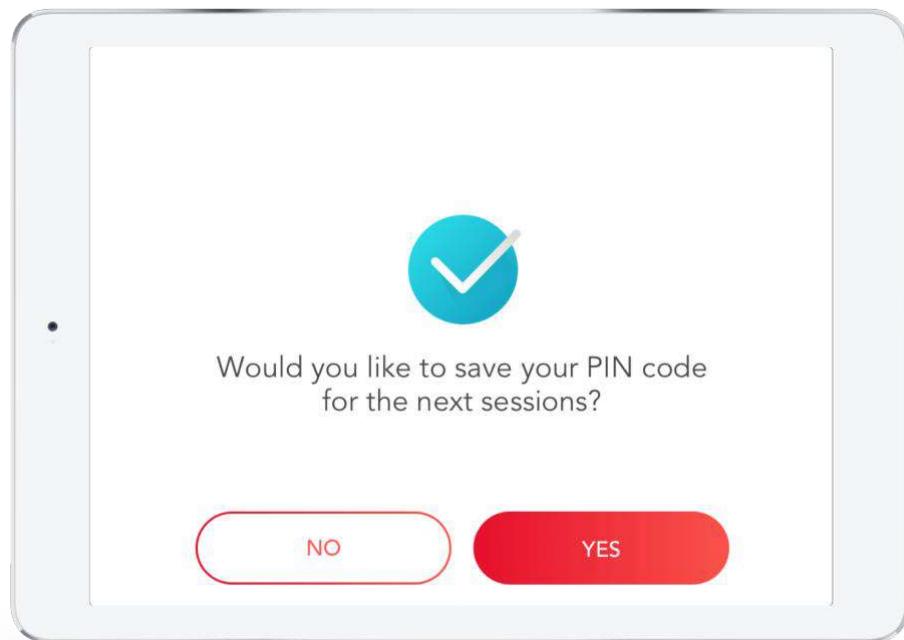
If you didn't choose the save the PIN Code for the following sessions option during setup, you will have to introduce your PIN Code.



**Important** - If you enter the wrong PIN Code more than 5 consecutive times, the card will be blocked and you will have to reach out to the physical therapist in charge of your therapy for him or her to unlock the Portal.

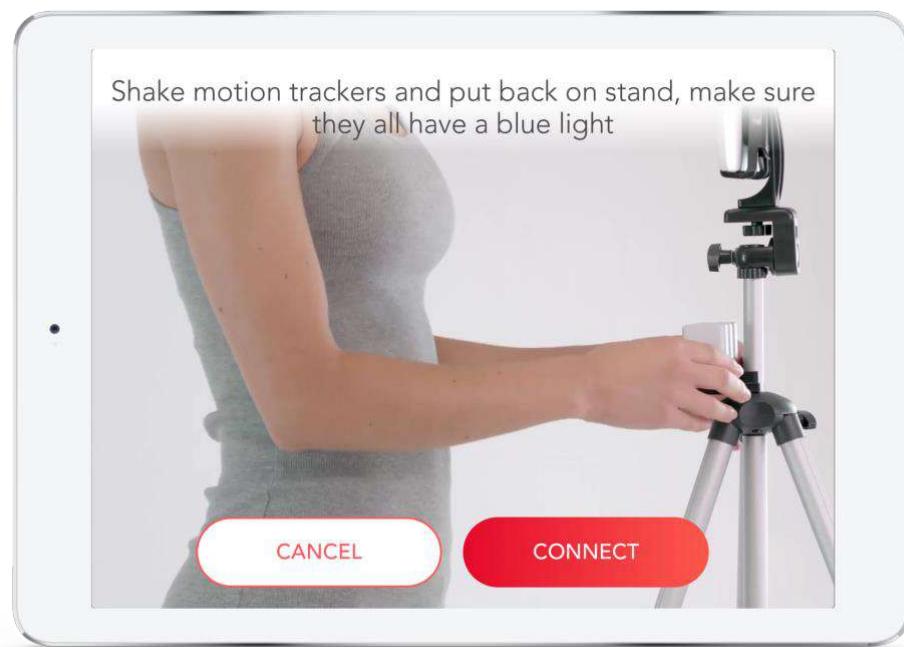
## Step 6 - Save PIN Code

If you didn't choose to save your PIN Code during Setup, you will always be asked if you want to do that after step 5.



## Step 7 - Waking up the motion trackers

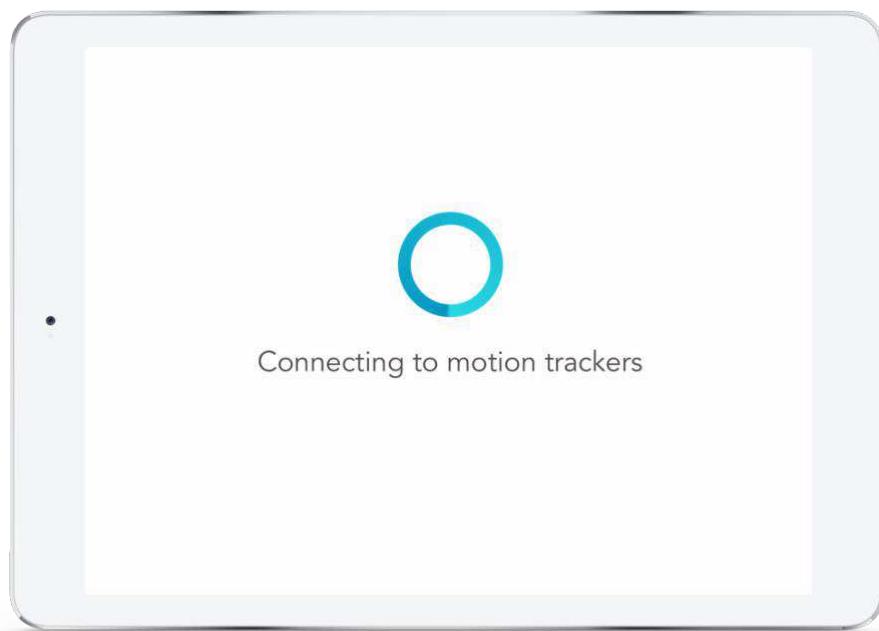
In this step, the Digital Therapist will ask you to shake the motion trackers to wake them up. Please shake them and make sure a blue light shows up in all of them. Upon checking if there is a blue light on in every tracker, click the "Connect" button.



**Important** - To keep the motion trackers calibrated, please keep them at the dock with the plug turned upwards during this process.

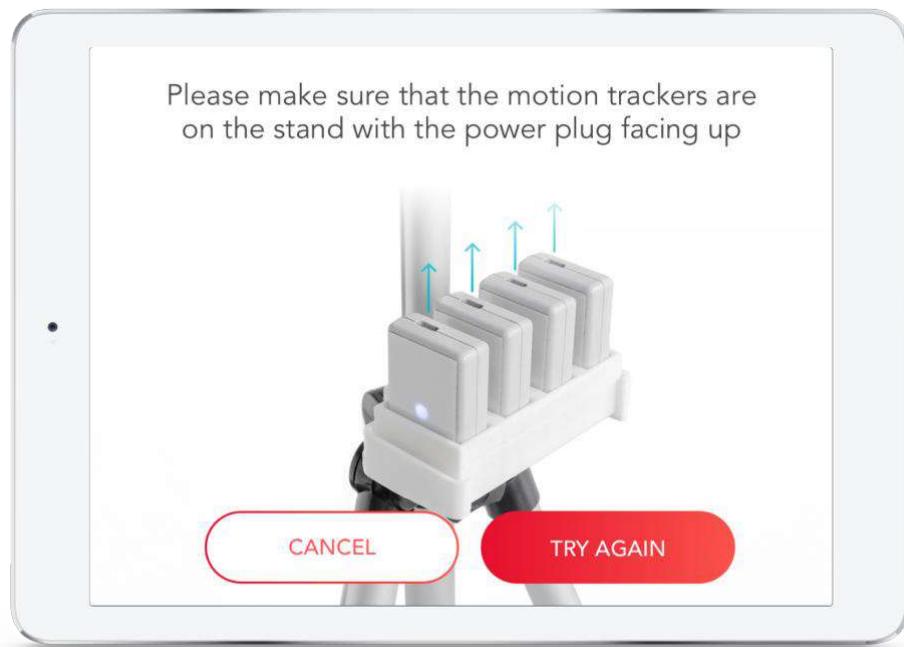
## Step 8 - Connecting to the Motion Trackers

In this step, you must wait while the Digital Therapist connects to the motion trackers. If by any reason the Digital Therapist has difficulties connecting to the trackers, go back to step 7, shake them and click the “Connect” button. If the connection is successful, a green light will appear on the motion trackers.



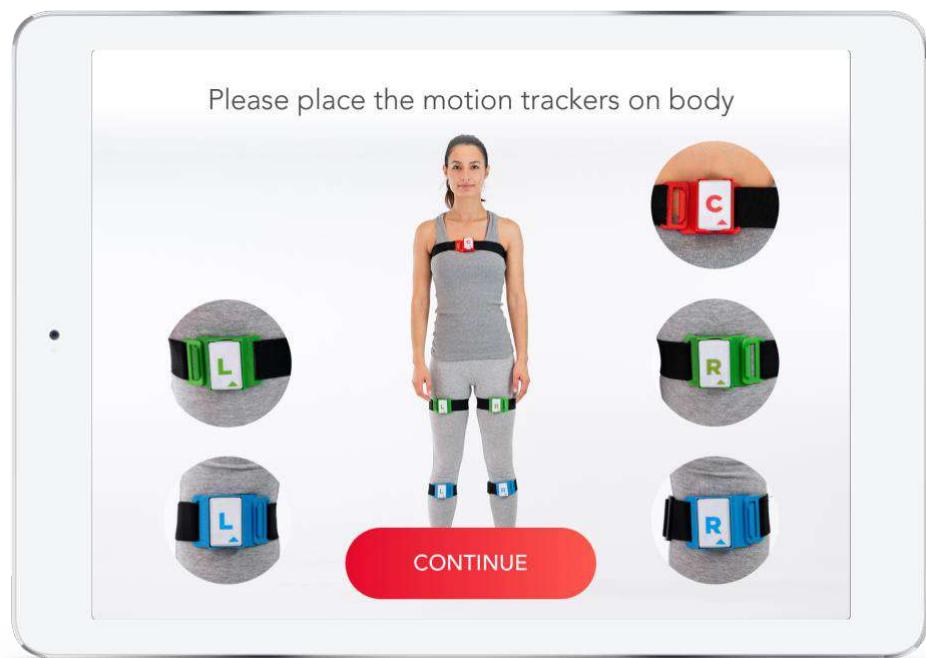
## Step 9 - Checking the Motion Trackers

In this step, the Digital Therapist will check whether the motion trackers are aligned and correctly adjusted to the dock, as requested in step 7. If the Digital Therapists detects an anomaly, you will be notified to correct it.



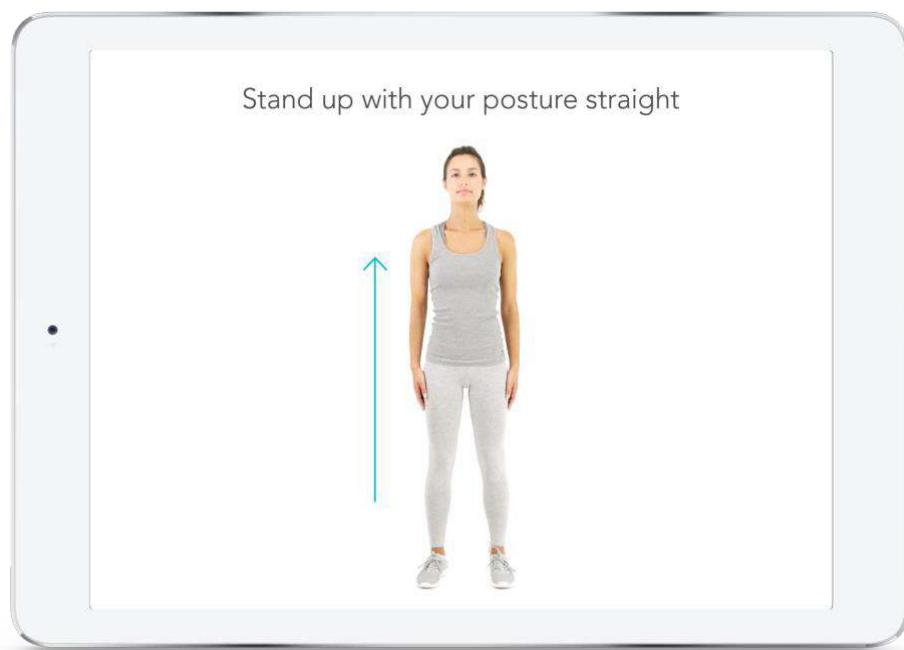
## Step 10 - Place the motion trackers on the body

In this step, the Digital Therapist will ask you to put on the straps and the trackers on your body as shown in the image. Depending on the kind of therapy you're doing, the number of trackers and the place to put them on may vary, so pay attention to the instructions you're given, so as to avoid placing them wrong.



## Step 11 - Calibrating the trackers on your body

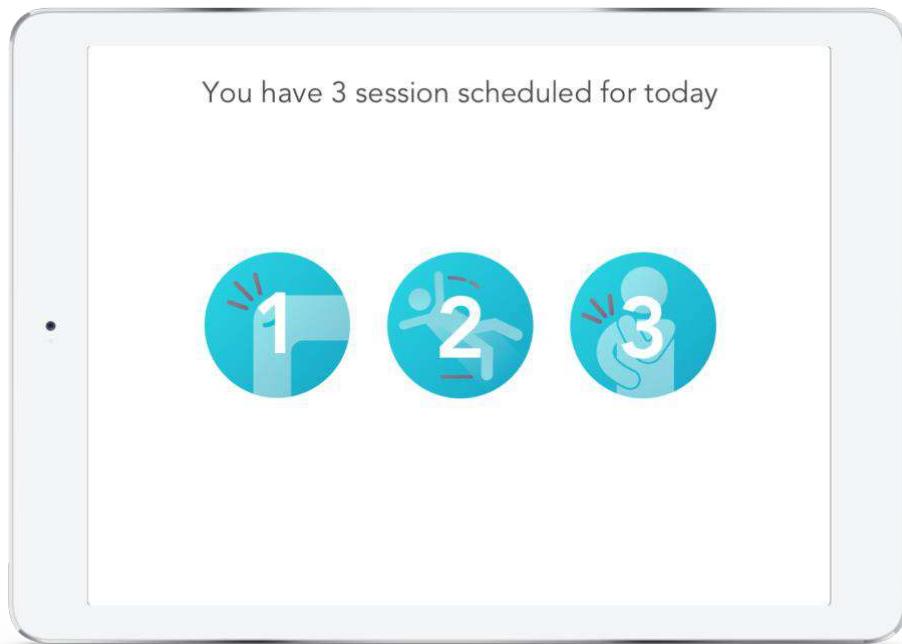
In this step, the Digital Therapist will give you different instructions to calibrate the motion trackers on your body. Please pay attention to every instruction so that the calibration is successful.



**Important** - If the motion trackers are not calibrated properly, significant mistakes might occur during the exercises.

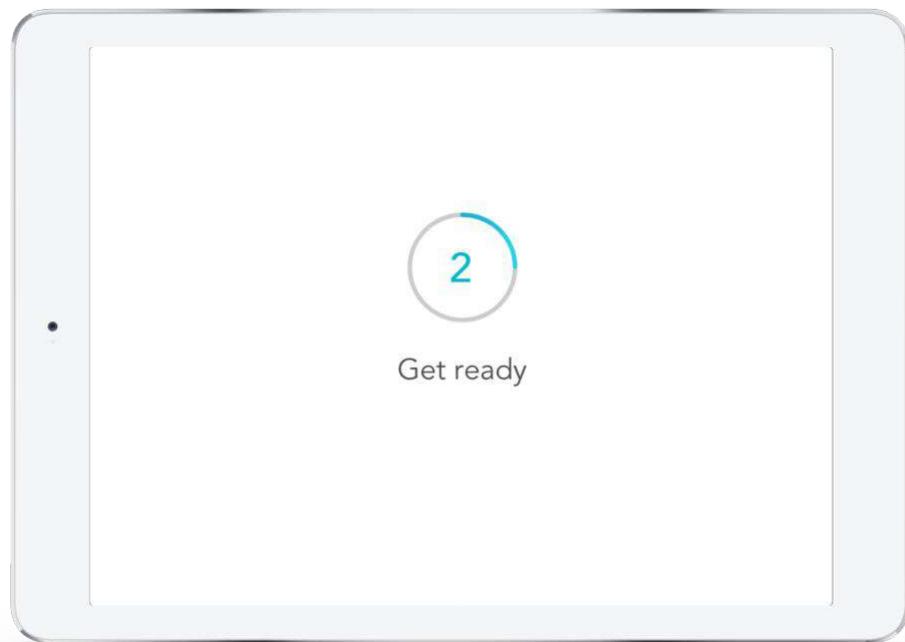
## Step 12 - Session Presentation

In this step, the Digital Therapist will show you the sessions you have prescribed for the day. Good treatment results depend on performing the sessions prescribed by your therapist as well as possible.



## Step 13 - Starting a Session

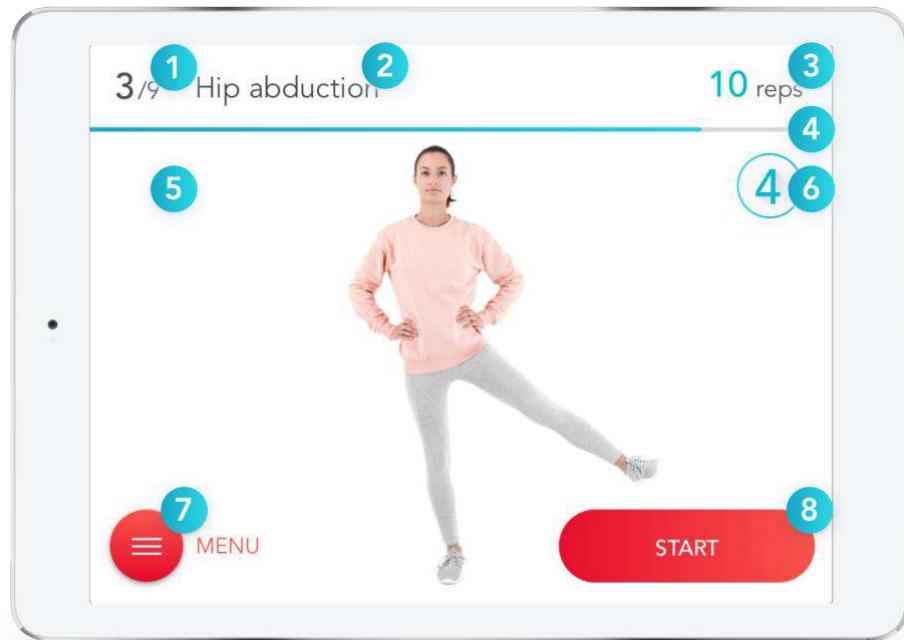
After the Digital Therapist shows you the sessions for the day, the first session will automatically start.



**Important** - Sessions are automatically chosen using an algorithm that optimizes therapy results and reduces treatment time.

## Step 14 - Exercise Instructions

In this step, the Digital Therapist will give you audio and video indications of how to perform the exercise. Always pay attention to every instruction to avoid mistakes.



**1. Exercise Number** - This is where you can see the number of the current exercise and the total number of exercises for this session.

**2. Name** - Name of the exercise.

**3. Repetitions** - Number of repetitions prescribed for this exercise.

**4. Time** - This bar allows you to listen to every instruction and rest in between exercises. When the bar completely full, the exercise will automatically start.

**5. Video** - At the screen center, there is a video containing all the instructions for the exercise.

**6. Level** - Here you can see the level your therapist set for this exercise.

**7. Menu** - In this menu, you can:

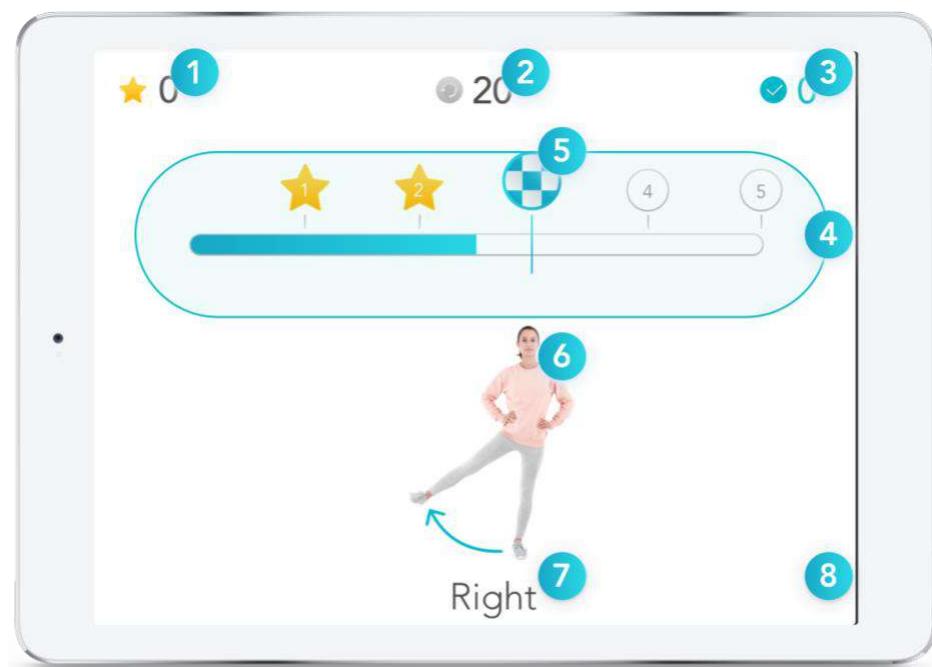
- Pause the instructions and time until the beginning of the exercise.
- Skip this exercise and move on to the next one.
- Leave this session.

**8. Start** - if you already know this exercise and think you have rested enough, you can tap this button to start the next exercise.

## Step 15 - Performing the exercise

After being given every instruction to perform the exercise (step 14), you are ready to start. Throughout the exercise, the Digital Therapist will give you real-time instructions as to how to perform the movements. These are:

- Instructions to stand correctly before you start the exercise.
- Feedback when the movement was performed correctly.
- Feedback when the exercise was performed incorrectly and which was the mistake made so you can correct it next time.



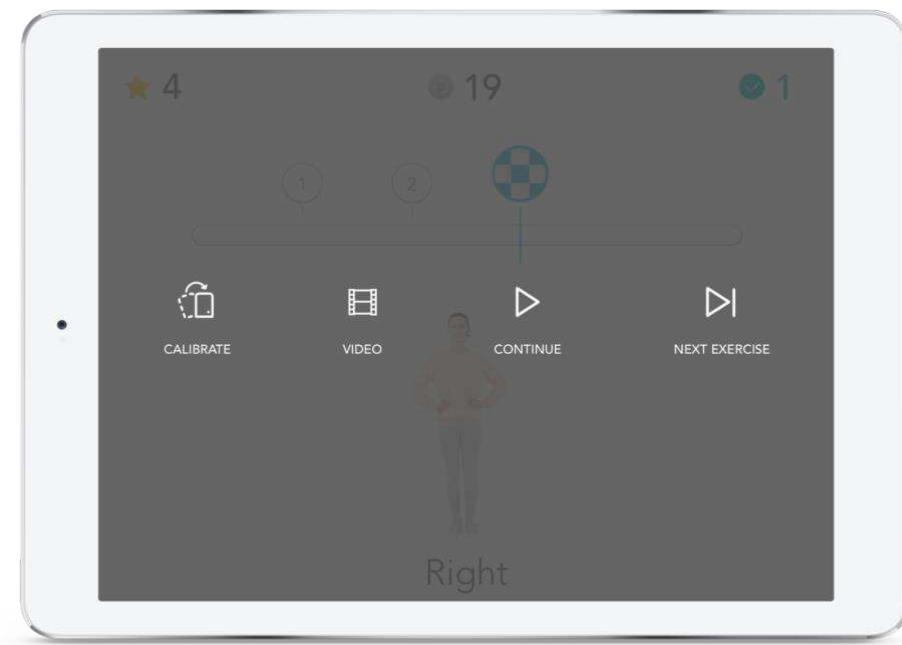
During the exercise, you can also access other information:

- 1. Stars** - Here you can see all the stars you earned during the exercise.
- 2. Repetitions left** - Here you can see all the repetitions/movements you have to do until the exercise ends.
- 3. Correct Repetitions** - Here you can see all the correct repetitions/movements you made.
- 4. Movement Bar** - A bar that progresses with the movement you are making, which is composed of 5 difficulty levels. As you reach a new level, you get a new star. This bar might change according to the type of exercise you're doing.
- 5. Goal** - This is the goal your therapist set, you are expected to meet it during the movement.
- 6. Movement Video** - During the exercise, a video will help you through every movement, showcasing the side and the movement you must perform.
- 7. Instructions** - Text instructions will show up here to help you with each movement.
- 8. Pause** - If you want to pause the exercise, just click anywhere on the screen.

## Step 15.1 - Pause (Optional)

When you stop the exercise, you can see different options:

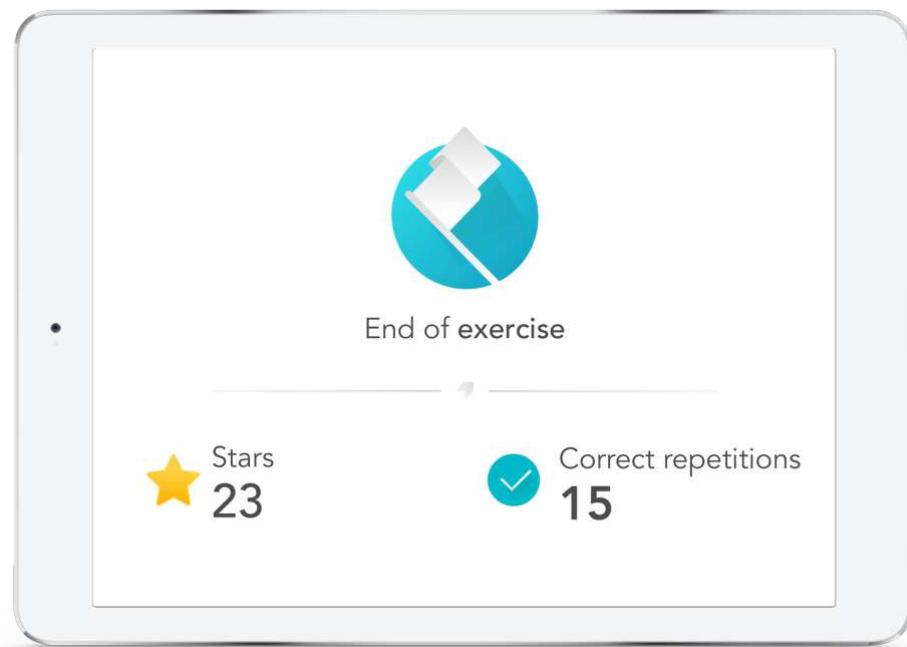
- Calibrate the motion trackers
- Watch a video with the exercise instructions
- Continue the exercise
- Leave the exercise



## Step 16 - End of Exercise

Once you complete every prescribed repetition/movement, the exercise will automatically end. A summary of the exercise will show up on the screen where you can see:

- How many stars you earned during the exercise
- How many correct repetitions you made

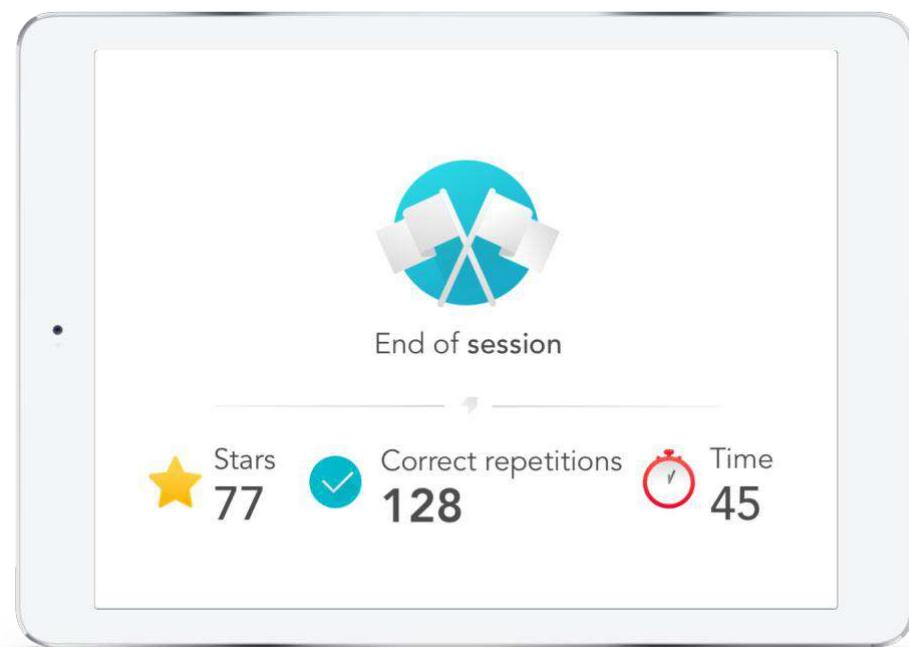


When an exercise finishes, if any exercises are left undone, you will go back to step 14, where instructions for the next exercise will be given, followed by the performance of those exercises (Step 15). If you have completed every exercise, you will move on to the End of Exercise screen (Step 17).

## Step 17 - End of Session

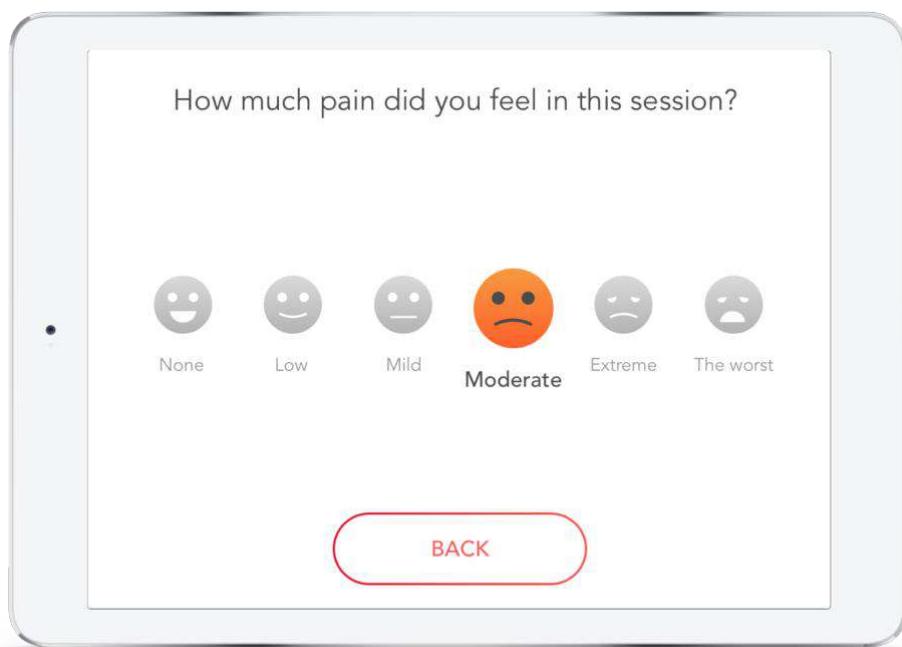
Once you finish the session, a summary containing the following information will show up:

- How many stars you earned during the session
- How many movements/repetitions you performed correctly during the session
- How long the session lasted



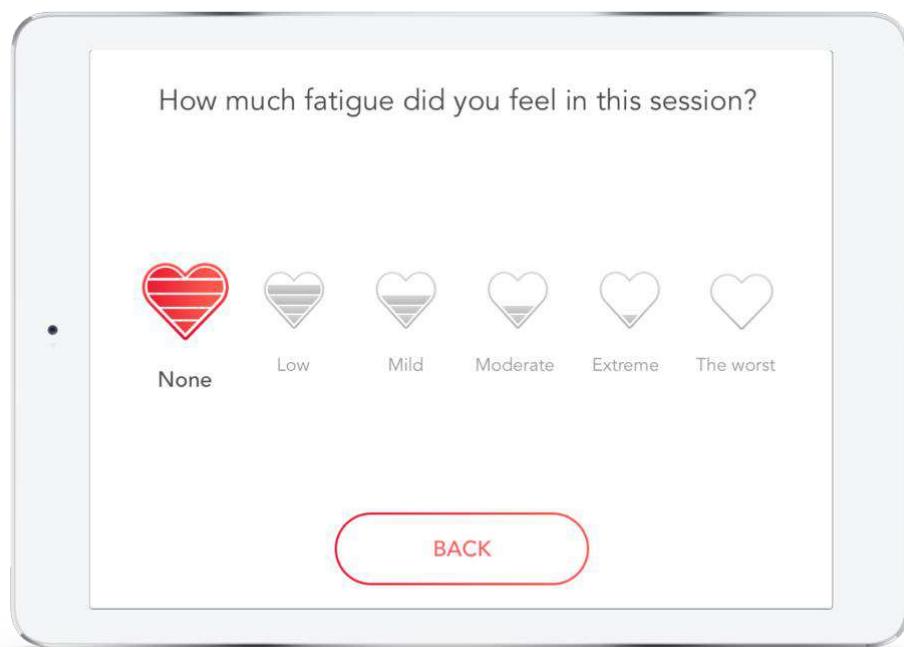
## Step 18 - Pain

In this step, you will have to indicate the amount of pain you felt during the session.



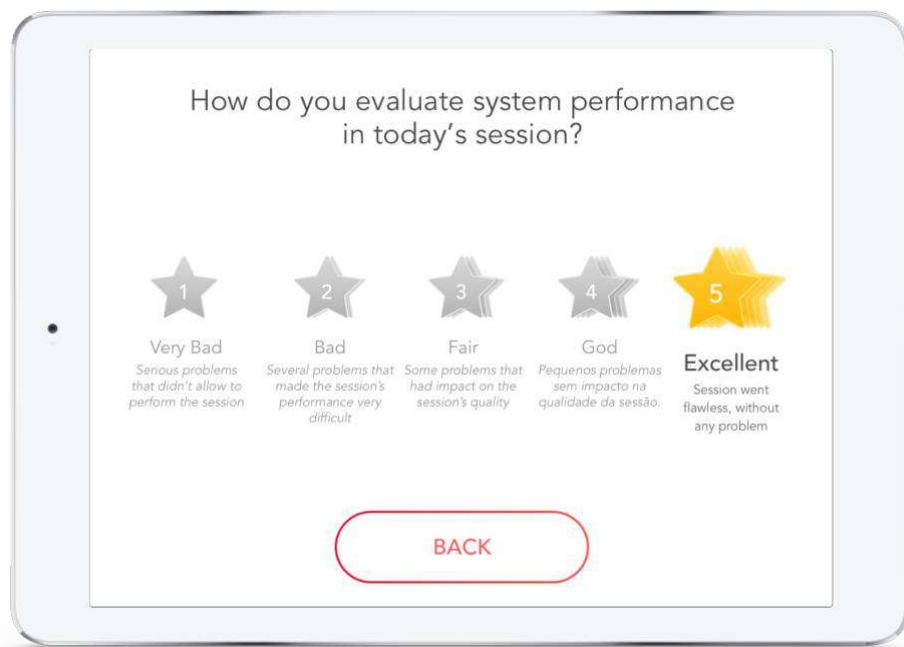
## Step 19 - Fatigue

In this step, you will have to indicate how fatigued you felt during the session.



## Step 20 - System Performance

In this step, you will have to evaluate the Digital Therapist's performance during the session. Your evaluation is very important because it allows SWORD Health's team to keep improving the Digital Therapist, correcting every problem that might have occurred during the exercises.

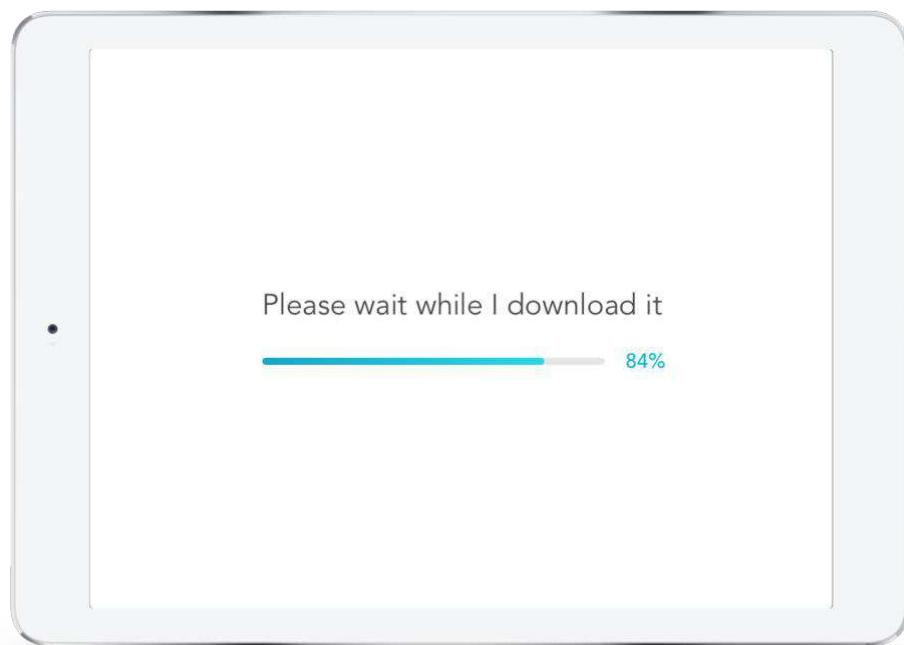


## 28 - UPDATES

Throughout your therapy, your Digital Therapist might have to perform updates. These updates are meant to bring you new features and correct any problems the Digital Therapist might have. Whenever a new update is available, please install it as soon as possible.

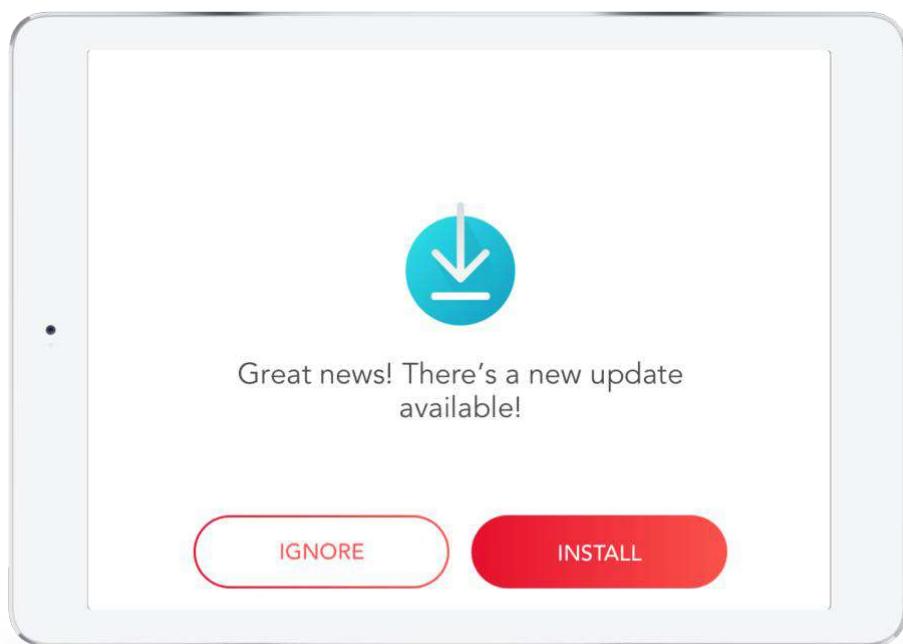
### Step 1 - Download Update

In this step, the update will be downloaded (you might have to wait a few minutes).



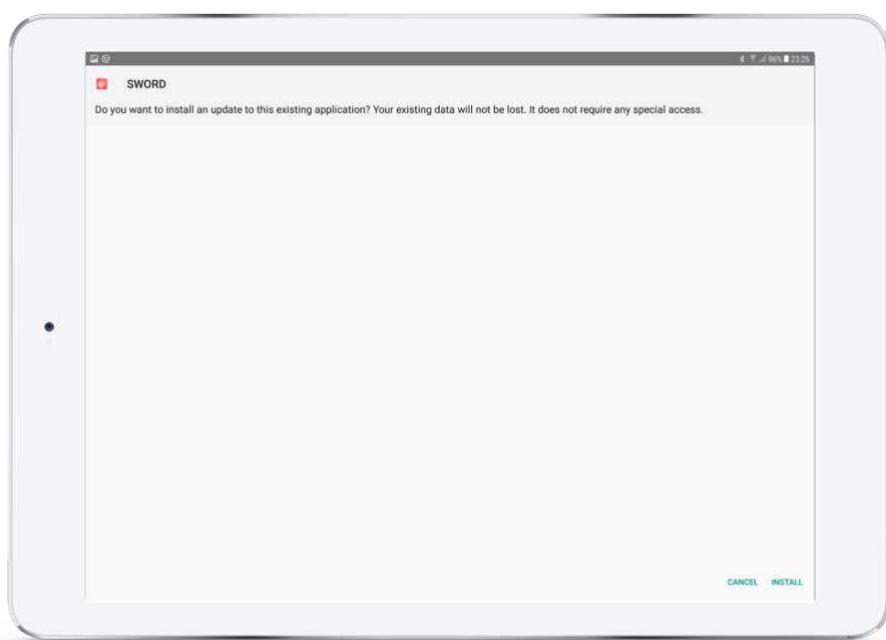
## Step 2 - Choose "Install"

After the download, the Digital Therapist will ask you if you want to update straight away.



### Step 3 - Install

Confirm that you want to install the update by clicking “Install” at the bottom right corner of the screen.

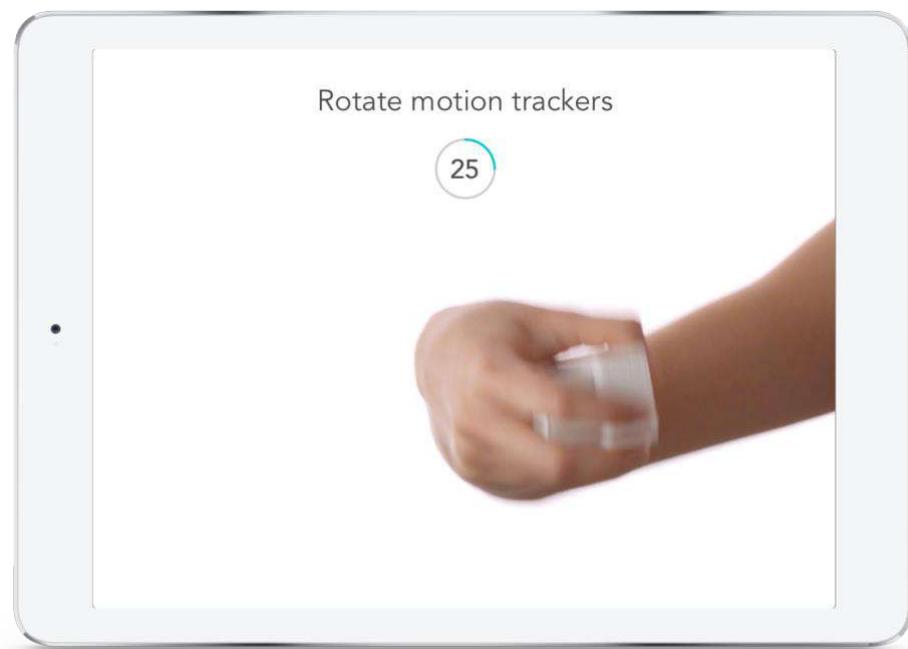


## 29 - CALIBRATE MOTION TRACKERS

You will have to calibrate the Motion Trackers approximately every two weeks.

### Step 1 - Rotate the Motion Trackers for approximately 30 seconds

After you turn the motions trackers on and before you start your session, the system will ask you to rotate the trackers at the bottom for 30 seconds. Rotate them continuously and make sure you stay away from metallic objects that might interfere with the calibration.



## Step 2 - Put the trackers in your hand

After you rotate the motion trackers continuously for 30 seconds, you must place them horizontally in hour hand and stand still for 3 seconds. After you finish this process, the motion trackers are calibrated and ready to be used for the next few weeks.



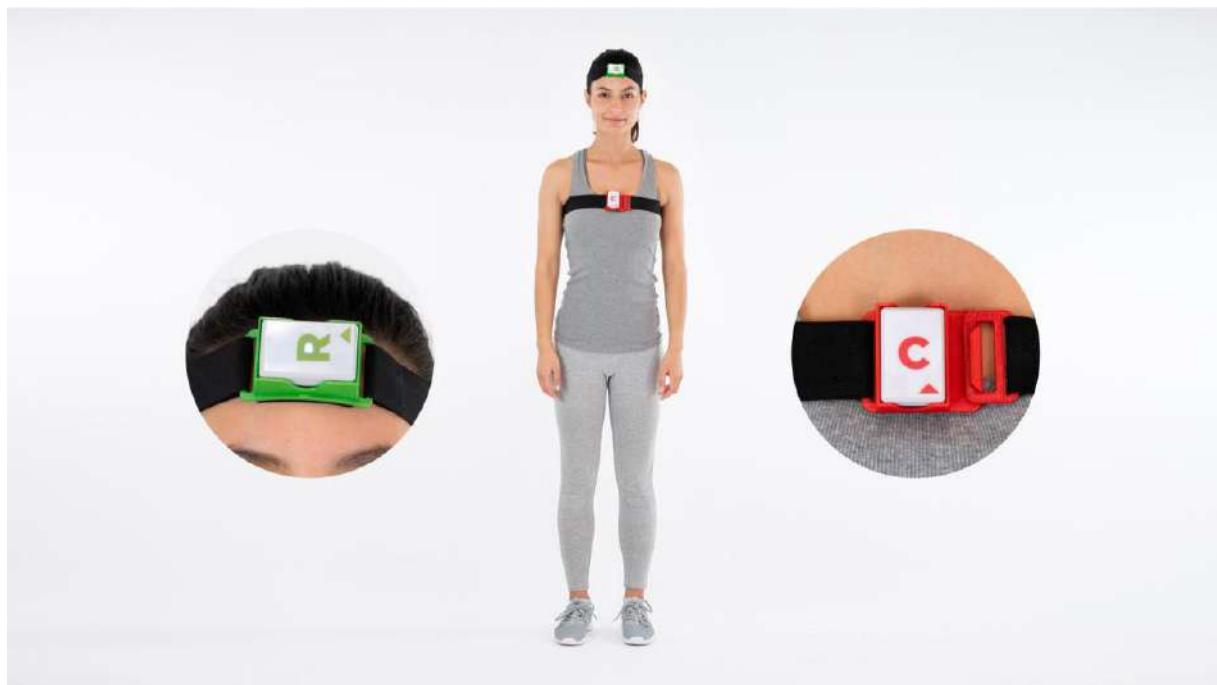
## 30 - PLACE MOTION TRACKERS ON BODY

Depending on the type of therapy you are performing, the motion trackers must be placed in strategic locations on your body.

Placing the motion trackers correctly prevents problem during the exercises, so it is very important that you pay attention to the instructions during this phase.

Where should you place the motion trackers for each different kind of therapy?

### Head



Tracker	Where to place it?
C	Chest
R	Forehead

**Important** - In this image, the straps are placed directly on the skin to exemplify the perfect placement and orientation of the trackers on the body. As told in section 9, the straps must always be worn over clothing, not directly on the skin.

## Left Arm



Tracker	Where to place it?
C	Chest
L	External part of the arm, above the elbow
L	Slightly above the wrist

**Important** - In this image, the straps are placed directly on the skin to exemplify the perfect placement and orientation of the trackers on the body. As told in section 9, the straps must always be worn over clothing, not directly on the skin.

## Right Arm



Tracker	Where to place it?
C	Chest
L	External part of the arm, above the elbow
R	Slightly above the wrist

**Important** - In this image, the straps are placed directly on the skin to exemplify the perfect placement and orientation of the trackers on the body. As told in section 9, the straps must always be worn over clothing, not directly on the skin.

## Legs



Tracker	Where to place it?
C	Chest
R	Right Thigh, center
R	Right Shin, center, just below the knee
L	Left Thigh, center
L	Left Shin, center, just below the knee

## Back



Tracker	Where to place it?
<b>C</b>	Back
<b>R</b>	Low back

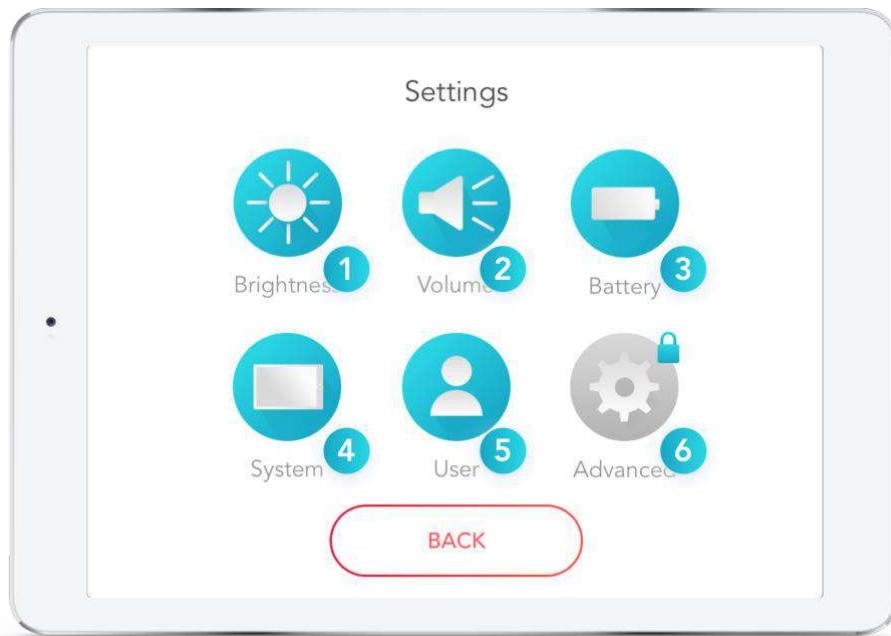
## 31 - SETTINGS

### Step 1 - Access Settings

While you're using the Digital Therapist, you can access the Settings by continuously pressing the *Back* button on your tablet.



## Step 2 - Settings



**1. Brightness** - Go here to adjust the screen brightness.

**2. Volume** - Go here to adjust volume.

**3. Battery** - Go here to:

- Check the motion trackers' battery
- Check the tablet's battery.

**4. System** - Go here to:

- Restart the Digital Therapist.
- Reset the Digital Therapist to configure a new user (patient).

**5. User** - Go here to:

- Take a profile picture
- End the session on your tablet.

**6. Advanced** - You must only access this menu if a member of SWORD Health's technical team is helping you solve problems with your device.

## **GLOSSARY**

## 32 - EXERCISE CATEGORIES

Category	Description
<b>Range of Motion (RoM)</b>	<p>These exercises evaluate the range of motion of a single joint and are divided into 5 difficulty levels. Its unit of measurement is degrees (°).</p> <p>Example of difficulty levels for these exercises:</p> <ul style="list-style-type: none"><li>• Level 1 - 10°</li><li>• Level 2 - 20°</li><li>• Level 3 - 30°</li><li>• Level 4 - 40°</li><li>• Level 5 - 50°</li></ul>
<b>Time</b>	<p>These exercises evaluate the patient's ability to hold a specific position for a given period of time. These exercises have 5 difficulty levels and its unit of measurement is seconds (s).</p> <p>Example of difficulty levels for these exercises:</p> <ul style="list-style-type: none"><li>• Level 1 - 5s</li><li>• Level 2 - 10s</li><li>• Level 3 - 15s</li><li>• Level 4 - 20s</li><li>• Level 5 - 25s</li></ul>
<b>Difficulty</b>	<p>These exercises evaluate a patient's ability to perform a movement with a combination of multiple joints. The difficulty of these exercises is evaluated through the measurement of the range of various joints in the different phases of movement.</p> <p>There are 5 different difficulty levels:</p> <ul style="list-style-type: none"><li>• Very easy</li><li>• Easy</li><li>• Medium</li><li>• Hard</li><li>• Very hard</li></ul>
<b>Rep No/Rep</b>	<p>These exercises evaluate a patient's capacity to reach a given position. These exercises don't have difficulty levels.</p>
<b>March</b>	<p>These exercises evaluate a patient's ability to give a few steps or walk in different directions. These exercises don't have difficulty levels.</p>

## 33 - METRICS AND DEFINITIONS

Metrics and Definitions	Description
<b>Compliance</b>	<p>Compliance is assessed with the number of days a patient adheres to therapy divided by the number of prescribed days. This metric is presented as a percentage.</p> <p>Ranking:</p> <ul style="list-style-type: none"> <li>• Very low (0 - 20%)</li> <li>• Low (21- 40%)</li> <li>• Medium (41 - 60%)</li> <li>• High (61 - 85%)</li> <li>• Very High (=&gt; 86%)</li> </ul>
<b>Performance</b>	<p>Performance is assessed with the number of correct repetitions of a given exercise divided by the total number of repetitions prescribed. This metric is presented as a percentage.</p> <p>Ranking:</p> <ul style="list-style-type: none"> <li>• Very bad (0 - 25%)</li> <li>• Bad (26- 49%)</li> <li>• Fair (50 - 69%)</li> <li>• Good (70 - 85%)</li> <li>• Very good (86 - 100%)</li> </ul>
<b>Satisfaction</b>	<p>Satisfaction is the last score the patient attributed to the treatment's quality. This question is asked every 10 days and it is ranked from 1 to 10.</p> <p>Ranking:</p> <ul style="list-style-type: none"> <li>• Negative (0 - 6.9)</li> <li>• Neutral (7- 7.9)</li> <li>• Positive (8 - 10)</li> </ul>
<b>Pain</b>	<p>At the end of each session, the patient is required to indicate how much pain he or she felt during the exercises. The patient can answer:</p> <ul style="list-style-type: none"> <li>• No pain (0)</li> <li>• Discomfort (2)</li> <li>• Moderate (4)</li> <li>• Intense (6)</li> <li>• Very intense (8)</li> <li>• The worst possible pain (10)</li> </ul>
<b>Fatigue</b>	<p>At the end of each session, the patient is required to indicate how much fatigue he or she felt during the exercises. The patient can answer:</p> <ul style="list-style-type: none"> <li>• No fatigue (0)</li> <li>• A little fatigued (2)</li> <li>• Somewhat fatigued (4)</li> <li>• Fatigued (6)</li> <li>• Extremely fatigued (8)</li> <li>• Exhausted (10)</li> </ul>
<b>Date of therapy</b>	<p>Date of therapy start is the day the patient had his or her first session.</p>

<b>start</b>	
<b>Days of therapy</b>	The number of days from the date of therapy start until the current day or until the day the patient was deactivated.
<b>Time of therapy</b>	The total amount of time of every session a patient performed.
<b>Therapy</b>	The therapy is a set of exercises for a given pathology or anatomical location.
<b>Prescription</b>	The prescription is a set of exercises and its specifications which are determined by the therapist/clinician.
<b>Session</b>	A session is a set of exercises a patient must perform one or several times a day throughout its treatment.
<b>Repetitions</b>	The total number of prescribed movements a patient must correctly perform during the exercise.
<b>Correct Movement</b>	A movement performed within the predefined parameters, that doesn't violate the postural restrictions nor includes forbidden movements.
<b>Incorrect movement</b>	A movement that violates the pre-established restrictions, be them postural mistakes or forbidden movements.
<b>End of time</b>	The predefined time for performing a movement was exceeded.

**SUPPORT**

## **1 - REPORTING ADVERSE EVENTS AND PROBLEMS WITH SWORD PHOENIX**

If you detect any adverse events or functioning problems while using Sword Phoenix, please contact SWORD Health's Support teams via an email to [help@swordhealth.com](mailto:help@swordhealth.com)

To make it so our team can give you an answer quickly with a prior analysis, make sure the following information can be found on your email:

**Subject:** Help

**Message body:**

- Name
- Telephone Number (optional)
- Problem Description
- Date and Time the problem occurred
- If the problem is in regard to the Digital Therapist, please let us know the Motion Trackers' number.

After you send your email, SWORD Health's teams will contact you as soon as possible.

## **TECHNICAL SPECIFICATIONS**

## 34. SERVICE AND INSPECTIONS

### Cleaning

General rules when cleaning the outside of SWORD Phoenix and its components:

#### **Digital Therapist (Tablet):**

- Make sure SWORD Phoenix is unplugged from the power supply before cleaning.
- Do not use alcohol (methyl, ethyl or isopropyl) or any strong dissolvent. Do not use thinner or benzene, abrasive cleaners or compressed air.
- To clean the tablet, use a cloth lightly dampened with a mild detergent.
- Avoid getting liquids inside the touchscreen. If liquid does get inside, have a qualified service technician check it before you power it on again.
- Do not wipe the screen with a cloth or sponge that could scratch the surface.
- To clean the touchscreen, use window or glass cleaner on a clean cloth and wipe the touchscreen. Never apply the cleaner directly on the touchscreen.

#### **Motion Trackers:**

- Make sure the motion trackers are unplugged from the power supply before cleaning.
- Do not use alcohol (methyl, ethyl or isopropyl) or any strong dissolvent. Do not use thinner or benzene, abrasive cleaners or compressed air.
- To clean the trackers use a cloth lightly dampened with a mild detergent.
- Avoid getting liquids inside your touch monitor. If liquid does get inside, have a qualified service technician check it before you power it on again.

#### **SWORD Phoenix Straps cleaning and care**

Do not place in a washing machine or dryer as this may damage the material. Handwash with warm water. Use a mild detergent if soiled. Rinse well. Gently squeeze out excess water. Air dry, foam side up, on rack or towel or hang to dry. It is best to wash regularly to keep the material clean and free of body salts, oils, etc. This will help extend the material's life.

## Maintenance

SWORD Phoenix has an expected service life of 3 years. In order to guarantee a perfect and effective functioning of the equipment, an annual inspection by a service technician authorized by the manufacturer is recommended. SWORD Health has designed and tested a protocol to perform at each annual inspection - Metrologic Validation Protocol. The aim of the Protocol is to serve as a setup for product calibration, i.e., compare the Range of Motion measured with a goniometer (a standard clinical measurement tool) and the Range of Motion returned from SWORD Phoenix device.



Only authorized specialists can perform technical support and maintenance of SWORD Phoenix. Do not open the equipment. The opening of the equipment by unauthorized personnel will result in loss of warranty. In case of malfunction, contact the manufacturer.

## Disposal

This product consists of a device that may contain mercury, which must be recycled or disposed of in accordance with local, state, or federal laws.



Pay attention to the environment when disposing of SWORD Phoenix device. In this situation, you should contact the manufacturer.



The European Union Directive on waste electrical and electronic equipment (WEEE). This label indicates that this product should not be disposed of with household waste. It should be deposited at an appropriate facility to enable recovery and recycling. As an alternative, you can always contact the manufacturer.

## 35. REGULATORY STATEMENTS

### 1 - OWNERSHIP

SWORD Phoenix® including all the components and documents that are included in the kits, are the sole property of SWORD Health, S.A..

### 2 - INTENDED USE

SWORD Phoenix is a Medical Device intended to provide physical therapy. The information of the movement of body parts is gathered and used to give real time feedback on patient's performance. The physical therapy may be performed at home but must be oriented by a physical therapist.

### 3 - SIDEFFECTS AND CONTRAINDICATIONS

The device is contra-indicated for hemodynamic instability or other serious medical condition limiting physical rehabilitation; hyper-acute stroke patients; pain or deformity limiting the movement of target joints; respiratory and/or cardiovascular disease contraindicating mild to moderate exercise; skin lesions or any continuity solution in the area where the motion trackers would need to be placed. SWORD Health has exercised great diligence in selecting the materials for SWORD Phoenix. Nevertheless, there is always a small chance that some materials may lead to allergic reactions in individuals under exceptional circumstances.

### 4 - LIABILITY

In no event will SWORD Health be liable to the misuse or lack of the SWORD Phoenix, including negligence or any other use not described in this document. Whilst being a motor rehabilitation tool, the use of the SWORD Phoenix does not automatically guarantee patient improvement.

### 5 - WARRANTIES, RISKS, AND DAMAGE TO SWORD PHOENIX

SWORD Health, S.A. will be responsible for the deployment of SWORD Phoenix in the clinical facility. After the deployment, the responsibility of SWORD Health, S.A. is limited to the maintenance of the software and to the repair or replacement of equipment and/or non-conform components. SWORD Health, S.A. reserves the right to refuse warranty coverage, and will not be responsible for repairing or replacing any device or component nonconforming or defective under this warranty if any of the supplied parts is altered, tampered with, not maintained and/or not used as specified in the User Manual; or presents non-compliance or defect has resulted from any technical service or equipment maintenance executed by personnel not authorized by SWORD Health, S.A..

### 6 - INTELLECTUAL PROPERTY RIGHTS

The "intellectual property" rights are the exclusive property of SWORD Health, S.A.. These include all the intellectual property and/or industrial property rights/and or rights about software or hardware owned by SWORD Health, S.A. and/or related with the activity of SWORD Health, inter alia, relating to SWORD Phoenix or any other product, technological solution, technical

documentation, software, databases, feedbacks, documents and manuals, know-how, as well as all the studies and conclusions of any nature, including the ones connected with technics, business, process and commercialization, already existing and/or which are subsequently created and/or developed by SWORD Health, S.A. and/or by others.

## **7 - TERMINATION EFFECTS**

Upon termination of the agreement between SWORD Health, S.A. and the customer for use of SWORD Phoenix, all components of the system shall be returned to SWORD Health, S.A., including hardware, accessories and supporting documents.

## **8 - USER MANUAL**

The User Manual describes the system components, features, setup, and operability. The User Manual is not intended to replace and does not replace the need for appropriate training regarding the use of SWORD Phoenix.

## **9 - FCC Statement**

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.
- To assure continued compliance, any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. (Example - use only shielded interface cables when connecting to computer or peripheral devices).

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

