

re.flex  
recovery made simple

## User Manual

EN English



**Subject to technical changes. You can find the current user manual on the Internet at [www.reflex.help](http://www.reflex.help)**

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## CHAPTER 1: APPLICATION NOTES

### GENERAL NOTES

Dear patient,


Please read the enclosed instructions for use carefully. If you have any questions, please contact the doctor treating you, your nearest specialist shop or contact us directly.


### MEDICAL PURPOSE

**re.flex** is a therapeutic training programme for knee osteoarthritis patients and post ligamental surgery patients, consisting of an app and two movement sensors, which supports the patient, doctor and physiotherapist in the course of the therapy.

A detailed and predefined training programme offers the possibility for the patient to train independently and to document the training activity, the course of pain and an overview of the perceived exertion of the individual exercises.

By means of the movement sensors, **re.flex** is able to give the patient clear instructions and immediate live feedback on correct and incorrect execution of the exercise, both acoustically and visually in 3D.

 Before use, a doctor should have confirmed that **re.flex** is suitable for you and your health situation

 **re.flex** does not provide a medical or therapeutic diagnosis, recommendation or medical treatment.

## INDICATIONS

The use of **re.flex** is intended for patients with the following diagnoses (indications according to ICD-10):

- M17.0 Bilateral primary osteoarthritis of the knee
- M17.1 Unilateral primary osteoarthritis of the knee
- M17.2 Bilateral post-traumatic osteoarthritis of the knee
- M17.3 Unilateral post-traumatic osteoarthritis of the knee
- M17.4 Other bilateral secondary osteoarthritis of knee
- M17.5 Other unilateral secondary osteoarthritis of knee
- M17.9 Osteoarthritis of knee, unspecified
- M22 Disorder of patella

- S83 Dislocation and sprain of joints and ligaments of knee

## CONTRAINDICATIONS

**re.flex** must not be used for the following diagnoses (contraindications according to ICD-10):

- Z96.64 Presence of a hip joint prosthesis (< 6 months after surgery).
- Z96.65 Presence of a knee joint prosthesis (< 6 months after surgery)
- M51.0 Lumbar and other disc damage with myelopathy
- M51.1 Lumbar and other intervertebral disc damage with radiculopathy
- R27 Other coordination disorders
- R20 Sensitivity disorder of the skin
- I89.00 Lymphoedema of upper and lower limb(s), stage I
- I89.01 Lymphoedema of upper and lower limb(s), stage II
- I89.02 Lymphoedema of upper and lower limb(s), stage III
- T13.1 Open wound of lower limb, height unspecified

The decision as to whether or not therapy with re.flex is indicated is always the responsibility of the treating physician.


**re.flex** is not intended to replace the expertise or experience of a medical professional.


If you are unsure whether you have a contraindication, you should first consult your treating physician.

## SIDE EFFECTS

Side effects are undesirable effects that can occur when the product is used as intended. The following side effects may occur with the use of **re.flex**:


- temporary, slight pain due to overuse of joints, muscles and tendons;
- tiredness;
- swelling;
- skin irritation.


 If you experience undesirable effects when using **re.flex**, pause the training and contact your attending physician.


 Check yourself regularly for possible skin irritation or signs of allergic reactions. If a skin complication occurs due to the straps, pause your training and consult your attending physician.




## IMPORTANT NOTES


 In principle, the indication and duration of wear should be discussed with the attending physician, especially in the presence of subsequent medical conditions.


 Check the function of the product together with your doctor or specialised retailer.


 The sensors are intended to be supplied to one patient.


 Do not wear the sensors on open wounds.

 It is permissible to bring the product into contact with splash water.

 In the event of serious incidents during the use of **re.flex**, contact your doctor, your medical supply store or **re.flex** directly at: [info@reflex.help](mailto:info@reflex.help) immediately to report the incident.

 Improper modifications to the product and/or use of **re.flex** for other than the intended purpose exclude any product liability on the part of the manufacturer.

 The product contains metallic objects. We recommend that you do not bring them into contact with electromagnetic interference.

 Possible mutual health risks or other disadvantages with certain treatments that may arise in connection with the use of **re.flex** must be discussed with the attending physician.

## REPORTING OF ADVERSE EFFECTS

If you experience any undesirable effects, e.g. changes in your state of health, when using **re.flex**, please send us a message directly in the app or by email to [info@reflex.help](mailto:info@reflex.help). In addition, you can contact your attending physician.

## TRANSPORT AND STORAGE CONDITIONS

Please ensure that the product is stored in a dry place and protected from moisture and sunlight. Store the product at usual temperature and humidity. The storage period should not exceed two years without loading the sensors.



## QUALITY MANAGEMENT SYSTEM

All Kineto Tech Rehab SRL products are subject to product testing within our quality management system. Should you nevertheless have any complaints about our product, please contact your specialist shop. You can find an online version of the instructions for use on our homepage at <https://www.reflex.help/>




## CHARGING THE SENSORS


To charge the sensors, insert the magnetic charging plugs into the charging pads on the back of the sensors. The magnets facilitate correct positioning of the charging plugs in the charging pads. Connect the USB connector of the cable to a socket adapter or a laptop / PC. Refer to the specifications of the motion sensors on page 60-61.


The sensors are equipped with three LED lights. While the sensors are charging, all sensor LEDs light up blue. When fully charged, all LEDs will turn off.


The sensors are automatically switched off when the battery is low and cannot be used while charging. The battery charging time is approximately one hour.

Important note about charging:

 Make sure you connect the charger to the back of the sensors with the magnetic charging plug first to avoid a possible short circuit

 Do not attach the magnetic charging plugs of the charging cable to any other metal.

 When the positioning process is complete, first remove the cable from the charging plug

 The sensors should be charged for 30-60 minutes before each training session to ensure that the battery is sufficient for the entire training session.


## CARE AND RETURN

If the sensors are dirty, wipe them with a damp cloth.

Do not clean the sensors with chemical cleaning agents. If the sensors are dirty, wipe them with a damp cloth.

You can wash the elastic straps by hand or in the washing machine if they are dirty.

Maintenance of the units should not be carried out by anyone other than the manufacturer.


 Do not throw the sensors in the household waste at the end of their useful life, but return them to Kineto Tech Rehab SRL for processing.



## THE MOBILE DEVICE

Training with **re.flex** requires a mobile device. Update the operating system of your mobile end device regularly.

The **re.flex** application only stores a minimum of information. This includes the therapeutic training programme and the exercises, of the current and the coming three training days. The associated videos and thumbnails are thus saved for offline use.









 The application currently only works on iOS operating systems. An Android version will soon be available.

## INTERNET CONNECTION

To download and configure the **re.flex** app, you need an active internet connection. Once you have downloaded the necessary components such as the training programme and videos, you can train without an internet connection for the current day and the following three days.

However, in offline mode you will not be able to view your progress reports or send and receive messages. For this reason, we recommend that you use the app with a permanent Wi-Fi connection to get the most out of all the features.

## SAFETY REGULATIONS

-  All warning messages must be heeded.
-  If the sensors are swallowed, they may pose a choking hazard. Therefore, keep out of the reach of children and pets.
-  Do not use **re.flex** if any of the components are damaged or altered.
-  If the sensors are damaged or no longer work, please contact your specialist dealer or send us a message directly in the app or by e-mail to [hello@reflex.help](mailto:hello@reflex.help). Do not try to open the device or repair it yourself.
-  Make sure that the straps are not too tight to allow normal blood flow.
-  Operation in the immediate vicinity of shortwave or microwave therapy devices can lead to instabilities in the data transmission of the sensors.
-  Radiated high-frequency electromagnetic fields can lead to a loss of performance in the accuracy of **re.flex**.
-  Do not modify this unit without the manufacturer's approval.

## Chapter 2: Training structure


### FIRST TRAINING SESSION

Make sure the sensors are charged, your mobile device has sufficient battery, the latest version of the app is installed, there is a Wi-Fi connection and the sensors and bands are present.

The sensors are always on and go into a power-saving mode when not in use. Make sure to charge the sensors sufficiently before the first training session.

### PREPARATION OF THE TRAINING ROOM

Make sure you have enough space to exercise safely. Make sure that no useless objects hinder you from performing the exercises correctly.

 Disconnect your mobile device from the charging cable for training.

### THE TRAINING PROGRAMME

While using **re.flex**, you benefit from a predefined exercise programme specifically for your diagnostic, which was created



by medical professionals based on the guidelines for sports and exercise therapy.

Each movement is shown in a video before the exercise begins and is additionally described in the text. In addition, the movement within the exercise is demonstrated exactly in the extent of movement, speed and execution by a virtual leg (shadow leg). Make sure that you imitate the movement exactly. This minimises the risk of incorrect movements and resulting injuries.

## Chapter 3: re.flex application

### FIRST TIME INSTALLATION

The app is installed via the Apple App Store.

On your mobile device, click on the App Store and search for **re.flex** app and install it.

Open the **re.flex** app once it is installed.

To set up your account, you will receive an activation code from your health insurance company.

### LOGIN SCREEN

On the login screen, the patient has the following items:

1. you can "**create account**" with the activation code. To do this, enter the code and your data. An activation link will be sent to your email address. (Fig. 1 - 5)  
or
2. you can log in to your "**existing account**". In case of incorrect login data, you will be informed by an error message. (Fig. 6)

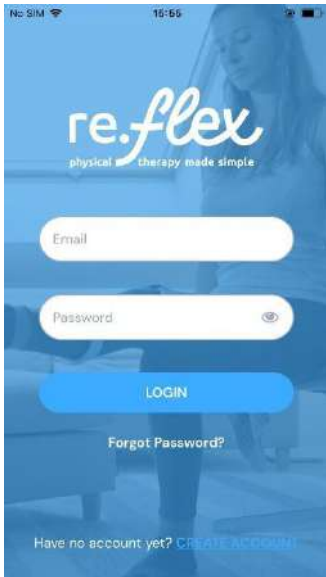


Figure 1: re.flex application login screen

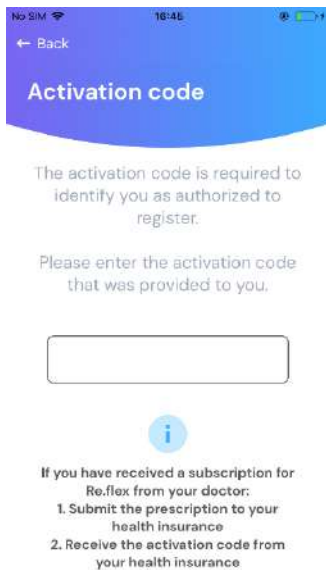


Figure 2: Entering the activation code



re.flex is committed to protecting and respecting your privacy. As a principle, we collect as little of your data as possible and secure it with the latest technology. This data protection declaration



First name

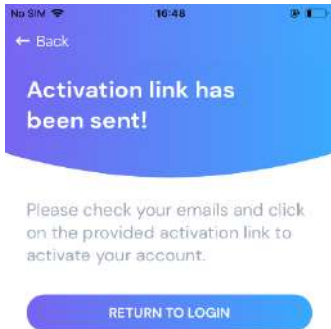


Figure 5:

Sending activation link

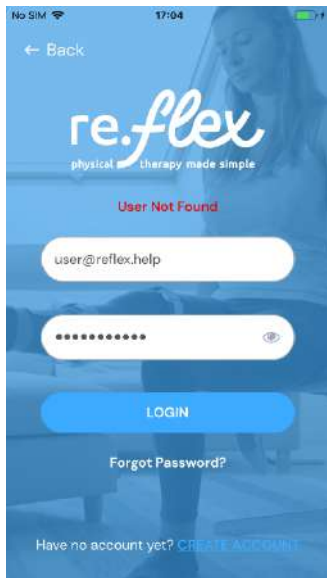
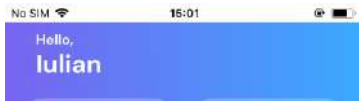


Figure 6: Error message in case of incorrect login

## HOME SCREEN



There are the following elements in the home screen:

<p><b>Support</b></p>	<p>In the support area you will come to a chat function where you can contact a member of staff directly about technical difficulties.</p>
<p><b>Settings</b></p>	<p>Here you can make the settings for the audio and video support, the training reminder. You can disconnect and reconnect the sensors, log out or delete your account, change the password.</p>
<p><b>Connect sensors now</b></p>	<p>Allows the sensors to be connected before training</p>
<p><b>Progress</b></p>	<p>Contains information on the weekly progress of the entire training programme</p>
<p><b>Completed exercises</b></p>	<p>Shows how many exercises have been completed or skipped.</p>

<p><b>Form</b></p>	<p>Displays the last recorded form value The form value is the grade of each movement from 0 – 10. The better the movement, the higher the grade</p>
<p><b>All statistics</b></p>	<p>Provides information about the adherence, the pain level, the perceived effort as well as the execution accuracy</p>
<p><b>View exercise plan</b></p>	<p>Displays the complete training programme</p>

## TRAINING PLAN

After pressing "[View exercise plan](#)" on the home screen, you will be taken to the application calendar, which shows your current week and the exercises available for the current and future days.

You can scroll through the calendar to see which exercises follow.

If there are no exercises scheduled for a day in your training programme, you will see the message "[Rest day](#)". (Fig. 9)



Figure 9: A day without planned exercises

The exercises with a golden circle are completed for the day, while the exercises with a grey circle still have unfinished repetitions. Every single repetition and exercise counts towards higher adherence. You can scroll down through the exercises on a day to see all the exercises. (Fig. 10)

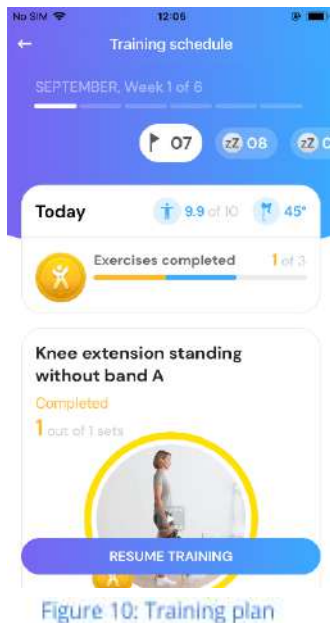


Figure 10: Training plan

When you tap on an exercise, you get a video tutorial of the exercise, as well as a textual description. These ensure the correct and safe execution of the exercise. (Fig. 11)



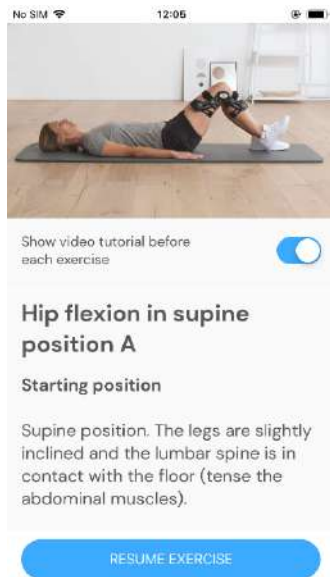


Figure 11: Detailed information about the exercise

## ACTIVATION & CALIBRATION

Calibration of the sensors is required each time you start the training session. This is done just before the start of the

training session after you have pressed "**Connect sensors now**" in the Dashboard.


The next step is to activate the sensors:

Hold the phone/tablet with the back as close as possible to the sensor. The sensors will now automatically connect to the phone/tablet. You can speed up the connection process by pressing the "Connect sensor now" button.

When prompted, bring the mobile device close to the upper (thigh) sensor. Wait until the upper sensor flashes and vibrates. Then select the upper sensor. (Fig. 12)

Then perform the same procedure with the lower (lower leg) sensor.

If neither sensor flashes and vibrates, select "**No sensor is blinking or vibrating**". (Fig. 13)

 Make sure that you are close to the upper sensor with the mobile device when you start this procedure. It is very important to connect the upper sensor first and only switch to the lower sensor after connecting it, so that you avoid errors and incorrect readings on the screen.

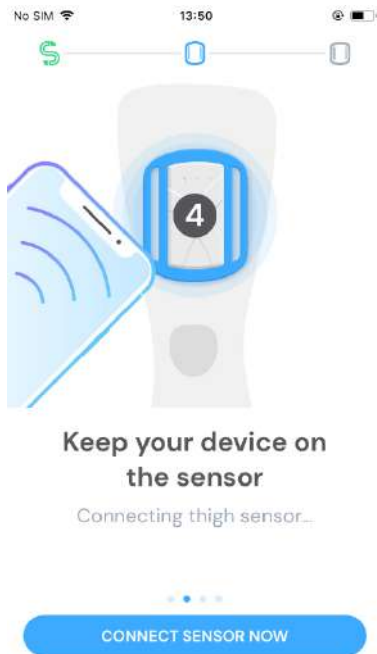


Figure 12: Connecting the thigh sensor



Figure 13: Selection of the thigh sensor

After the sensors are ready, you must now carry out the actual calibration. To do this, you must press "**I am in straight**

**position**" in the first step while standing normally and stretching your leg. (Fig. 14)



No SIM

12:01



## Calibration



### Stand up straight

Stand upright and keep your legs together as straight as possible.


If you have undergone surgery, try to stretch the operated leg completely.


I AM IN STRAIGHT POSITION

Figure 14: Screen: Knee is straight

The calibration can be done both in the standing and supine position. In both cases you have to stretch your knee and click on the "**I am in straight position**" button.

After you have pressed "**I am in straight position**", you will have to re-confirm the position. Afterwards, the sensors vibrate and you have to bend your knee a few times in an interval of 15 seconds up to the maximum possible bending in the direction of your upper body and put it down on the floor again stretched.

 Try to do at least two bends.

 Avoid wobbling or holding in flexion.

If the calibration is successful, you can start training.

If the calibration failed, please repeat the calibration process.  
(Fig. 15)

## Calibration Failed



It seems that your knee was not extended at the beginning of the calibration. At the beginning of the calibration, your leg must be extended.

Please restart the calibration and follow the instructions

RETRY CALIBRATION

Figure 15: Display of a faulty calibration

If the app is closed for more than 2 minutes, or the sensors have been removed for more than 2 minutes, the sensors will go into standby mode and will need to be rebooted and recalibrated when used again. (Fig. 16)



### Sensors are initializing

While the sensors are being initialized, you can have a look at your training plan for today before the training starts.

PREVIEW EXERCISES



If your Bluetooth is not switched on, the application will prompt you to switch it on. (Fig. 17)

Figure 1: Bluetooth activation notification


No SIM 


14:47




There are two types of calibration:

- Standing (Fig. 18)
- Supine (Fig. 19)

 If a standing exercise follows a supine exercise, you will receive a prompt to recalibrate. The same applies to a standing exercise that follows a supine exercise.

 While lying on your back, make sure you bend your knee while keeping your heel on the floor. Do not lift the heel in the air while bending. These rules do not apply when calibrating while standing.

 Make sure that you keep your legs parallel during calibration and that you do not turn your body.



### Stand up straight

Stand upright and keep your legs together as straight as possible.

If you have undergone surgery, try to stretch the operated leg completely.

I AM IN STRAIGHT POSITION

Figure 1: Calibration in standing position



### Go into supine position

Lie down on your back and maintain your legs as straight as possible.

If you have undergone surgery, try to stretch the operated leg completely.

I AM IN STRAIGHT POSITION

Figure 1: Calibration while lying down (Supine)

## START TRAINING

After successful completion of the calibration process, you can now start your training.

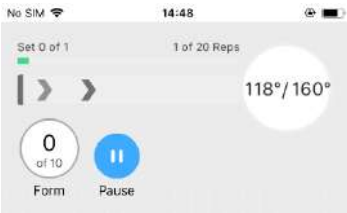
If you now start with an exercise, the live view opens. The live view consists of the following components:

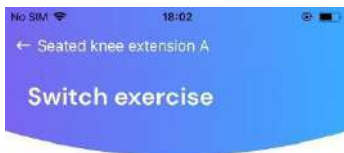
- Number of sets and repetitions (Fig. 20);
- Progress bar of the movement execution including target angle (Fig. 20);
- Form: Grading of each movement from 0 - 10. The better the movement, the higher the grade (Fig. 20);
- Live 3D display of the Avatar (active leg, blue) (fig. 20);
- Shadow leg: the leg that indicates the movement (grey/orange) (Fig. 20);

- Pause function (fig. 25) containing the following:
- Video tutorial (fig. 21);
- Possibility to skip or switch the exercise (Fig. 22 - 23);
- Sensors: to check the connectivity and battery power of the sensors and also recalibrate or disconnect them (fig. 24).

⚠ Be careful not to overtrain. Generally, overtraining means that you exercise more or more intensely than your body can reasonably recover from.

⚠ If the exercise requires a movement that is beyond your capabilities, you can skip the exercise





Choose an alternative exercise



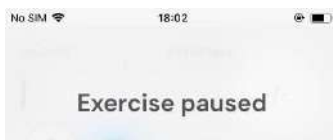
Figure 2: Switch exercise



Are you sure you want to skip the current exercise now?



Figure 2: Skip exercise



**⚠** The abduction button only appears for exercises that involve abduction (moving the leg to the side). The button is available on the right side of your screen.

The button helps you to re-centre the model and the camera if you turn your body with the sensors on during an abduction exercise. To do this, move to your neutral standing position and click "**Reset avatar**". The model, camera and degrees will be re-centred and you can perform the exercise correctly. (Fig. 26 - 27)

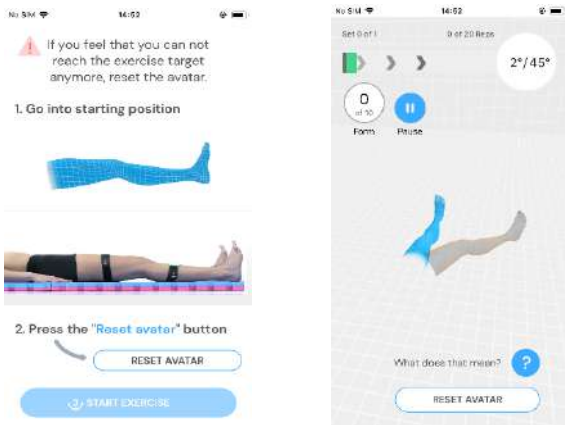


Figure 2 - 2: Abduction screen and button



## EXERCISE DETAILS

In order to count a repetition, the exercise must be performed correctly. To do this, the movements must be performed using the video tutorials, the exercise descriptions and the given shadow leg.

Each repetition has 3 steps to be counted. 1:

1. get into the indicated starting position.
2. bend, extend or abduct the specified joint (knee or hip) to the value indicated by the shadow and the repetition progress bar.
3. return to the starting position after reaching the maximum movement. For isometric exercises, remain in this position for the specified number of seconds.

When you have successfully completed all repetitions of an exercise, you automatically move to the next exercise.

After you have completed all the required repetitions with the sensor leg, you will be prompted to perform the same number of repetitions with the other leg. This is to ensure that you maintain good functionality on both legs and that no muscular imbalance occurs. (Fig. 28)

After you have finished the repetitions, confirm manually to continue with the next exercise. (Fig. 29)

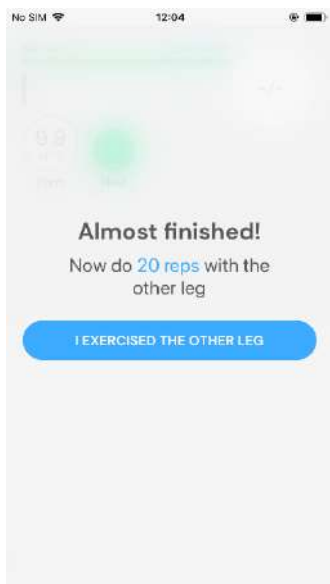


Figure 2 - 2: Prompt to move the other leg and finish the exercise

## CALIBRATION BETWEEN TWO EXERCISES

During certain training sessions, there is a change from exercises that require calibration from a standing position to exercises that require calibration in a supine position. In this

case you will be asked to straighten your leg and click "**I am in straight position**". (Fig. 30)

No SIM

12:04



## Calibration



Figure : Re-calibration after exercise change

### Go into supine position

Lie down on your back and maintain your legs as straight as possible.

If you have undergone surgery, try to stretch the operated leg completely.

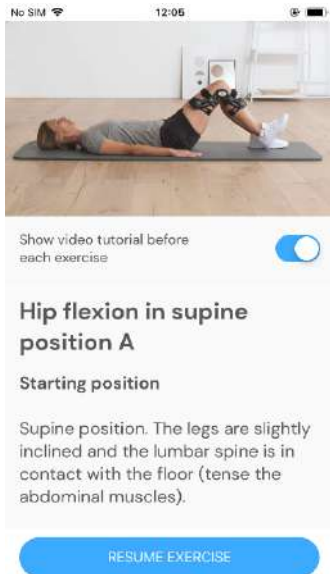
I AM IN STRAIGHT POSITION

## VIDEO SUPPORT

The video support can be accessed at any time from the live view by pressing the **“Pause”** button, followed by the **“Video tutorial”** button.

The video support will always appear when you get to a new exercise, unless you deactivate the video support. (Fig. 31)

Figure 3: Video tutorial before each exercise



## PAIN & STRAIN FORM

The pain and strain form is automatically called up after each skipped or completed exercise.

Here you can indicate the pain and effort felt when performing the exercise. (Fig. 32)

The screenshot shows a mobile application interface for 'Exercise Feedback'. At the top, there is a blue header with the text 'Exercise Feedback'. Below the header, the question 'Did you feel any pain?' is displayed. There are six yellow smiley face icons in a row, representing different levels of pain. The first icon, which is a simple smile, is selected. Below the icons, there is a yellow button labeled 'no pain'. The next question is 'How strenuous did you find the exercise?'. Below this question is a slider control. The slider is currently set to '3: light', which is represented by a yellow speech bubble containing a smiley face and the text '3: light'. Below the slider is a blue button labeled 'CONTINUE'.

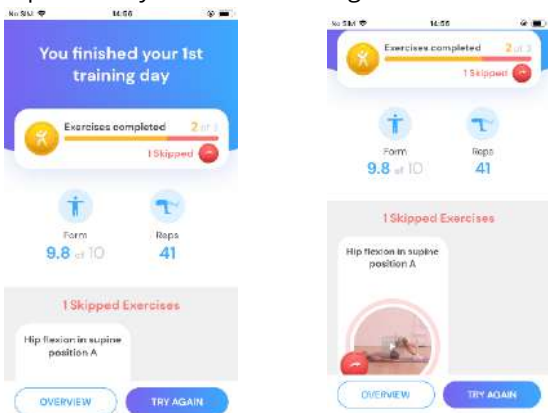
Figure 3: Pain form

## TRAINING COMPLETION

The training completion screen is displayed after the last repetition of the last exercise has been performed.

The exercise completion screen contains the following information: (Fig. 33 - 34)

- The current day of the exercise
- The form
- The number of repetitions
- Skipped or partially completed exercises include the option to try these exercises again



After finishing the training session, you can close the application process. It is not necessary to disconnect the

Figure 3 - 3: Training completion

sensors manually at the end of a training session.

## REPORTING

The "**All statistics**" area can be accessed from the Dashboard. (Fig. 35 - 36)

The following reports are stored here in graphic form about the progress of the therapy:

- Adherence;
- Pain;
- Knee flexibility;
- Exertion;
- Accuracy of execution.

The adherence shows the average number of repetitions you have performed per day.

The pain report represents the reported pain level.

The knee flexibility report represents how much the patient was able to bend his knee for the days he trained.

The exertion report represents the reported feeling of effort.

The accuracy of execution report represents the average movement scores of each repetition.

By swiping to the left and right, you can also view the reports from previous training weeks.



You can also send your data as a PDF or JSON export to your specified e-mail address.

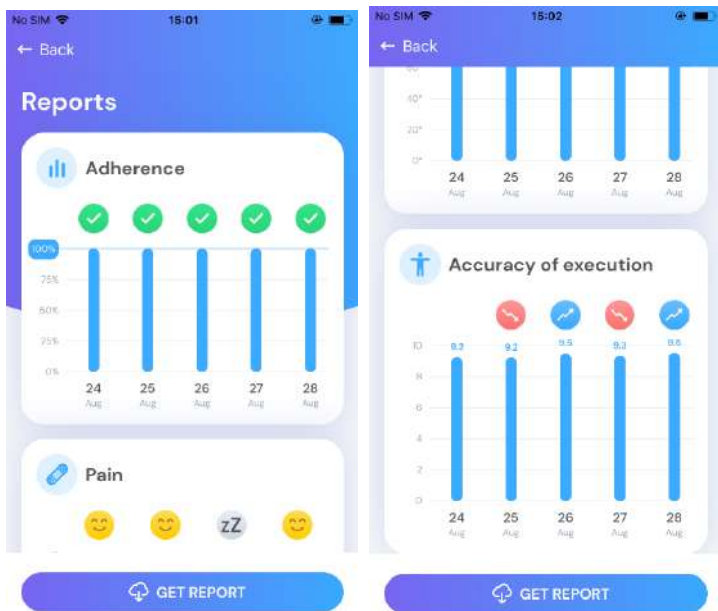
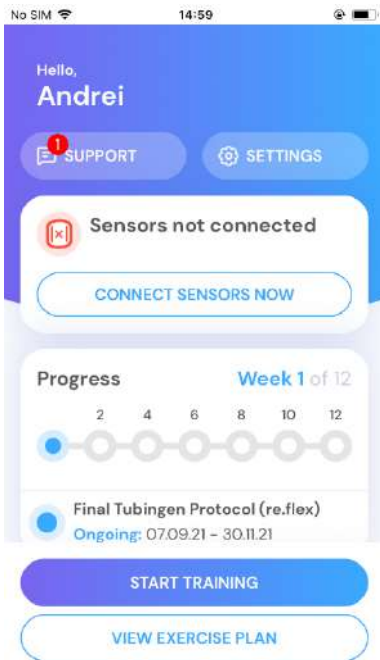


Figure 3 – 3: Adherence and accuracy of execution reports

## COMMUNICATION

Via the **"Support"** function, it is possible to clarify questions and suggestions about specific problems in a chat. Each message contains information about the date on which the message was sent or received.



With this chat function you have the possibility to exchange information with trained specialists of **re.flex**.

When you receive a new message, you can see this by the red marking above the **"Support"** area (Fig. 37).

Figure 3: New message

## ENDING THE TRAINING SESSION

1. Close the app on your mobile device.
2. Remove the sensors from the leg.
3. Wipe the sensors clean.
4. Connect the sensors for charging.

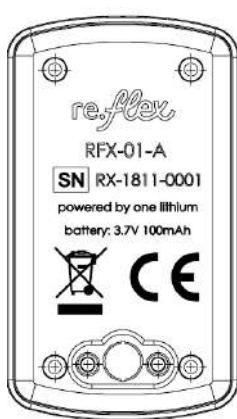
## Additional information

### PERFORMANCE PROBLEMS

If the device appears to be damaged or no longer works, please contact the medical staff or **re.flex** directly. Do not attempt to open the device or repair it yourself.

### EQUIPMENT LABELLING





The following markings can be found on the accessories of the product:

















The serial number for the sensors is printed on the back of each sensor and has the format RX-YYMM-XXXX.

## LEGAL INFORMATION

The following table shows the symbols and labels shown on the various components of **re.flex** and in this user manual.

Symbol	Definition
	Hand wash, Maximum temperature 40°C
	Do not bleach
	Do not iron
	No dry cleaning

	<p>Do not tumble dry</p>
	<p>CE marking</p>
	<p>Attention Read all warnings and precautions in the instructions for use</p>
	<p>User manual</p>
	<p>Protect from moisture</p>
	<p>Protect from sunlight</p>
	<p>Contains or presence of Natural rubber latex</p>
	<p>Patient information website</p>

	Do not dispose of in household waste (WEEE Directive 2012/19/EU)
	Manufacturer of the product
	Medical device
	Article number
	Production lot number, batch
	Serial number

## SPECIFICATION OF THE MOTION SENSORS

Characteristics	Description
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Model Name	RFX-01
Version	V01
Catalogue number	RFX-001-A
Power source	Rechargeable lithium battery 3.7V 100mAh
Number of battery charges	≥ 300 cycles
Battery life	>2 years
Charging	USB connection (type A), 5V / 1A
Charging cable	USB cable with two magnetic ends
Sensors	3-axis gyroscope, 3-axis accelerometer
Data recording	25Hz
Vibration motor	included
Size of the sensors (without frame)	(L x W x H) - 43 mm x 24 mm x 12 mm
Size of the sensors (with frame)	(L x W x H) - 48 mm x 40 mm x 6 mm
Weight	16 Grams (per Sensor)
Expected useful life	2 years



Wireless transmission frequency	2,4-GHz-Band (Bluetooth Low Energy)
Operating range	10 metres with a clear line of sight to the mobile device
Operating temperature	0 °C bis 40 °C
Operating humidity range	15% to 90% non-condensing
Atmospheric pressure range	700 hPa to 1060 hPa
Storage and transport temperature	-25 °C to 70 °C
Storage and transport humidity	5% to 90% non-condensing
IP protection factor	IP65