STAPPONE REHAB

USER MANUAL

V1.1.0

English Version

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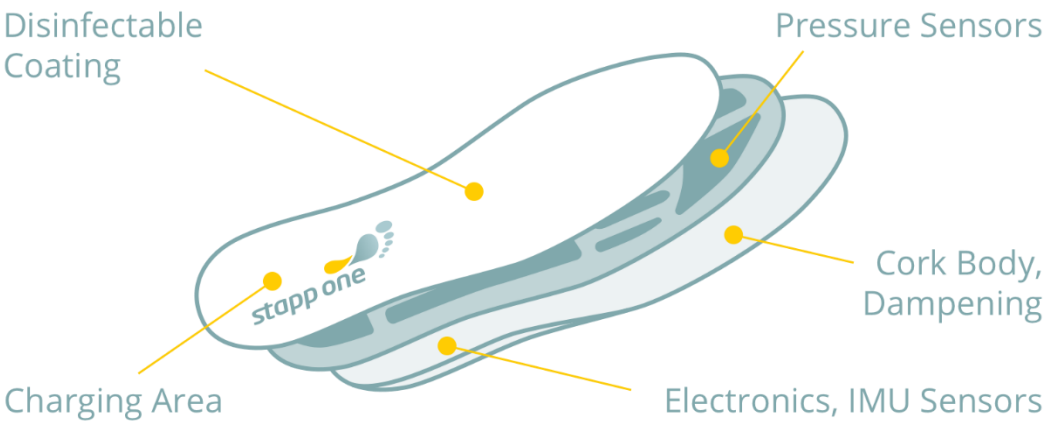
1. DEVICE DESCRIPTION

STAPPONE REHAB APPLICATION

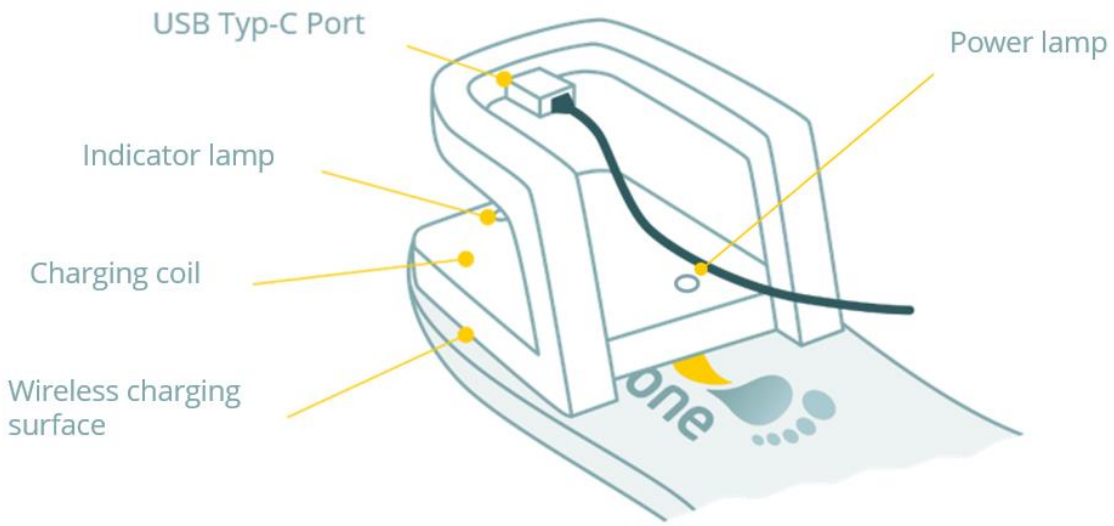
The STAPPONE Rehab application for mobile devices is used to visualize the data collected by the sensor soles and thus supports treatment and rehabilitation with partial loading.

TWO SENSOR SOLES

This device is a sensor-based shoe insole, which measures movements relatively with a combination of pressure sensors and IMU sensors.



TWO WIRELESS CHARGERS + TWO USB-C CABLES



In this manual the terms **STAPPONE sensor insoles** and **device** refer to a pair of one left and one right sensor insole.

- The STAPPONE sensor insoles are a medical device class I.
- For using this device no special qualification is needed, besides basic IT skills.
- This device is designed for 500 uses, or 1 million steps per device. One use is defined as one therapy unit.
- This device is designed for indoor- and outdoor-use in combination with closed shoes.
- This device is designed for Home Healthcare Environment & Professional Healthcare.
- The STAPPONE sensor insoles are the applied part of the medical product.

	Expected service life
Applied parts	
STAPPONE sensor insoles	1 year
Accessories	
STAPPONE wireless charger	1 year
USB-C Cable	1 year

2. STAPPONE QUICK START

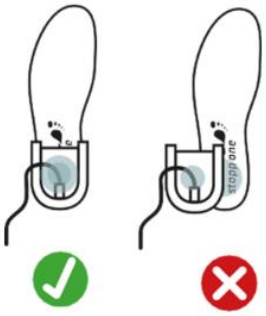
This process is a small overview of the key functionalities of the STAPPONE system. Further information is available in the next chapters.

Download the STAPPONE Rehab application

Download the STAPPONE Rehab application in the Google Play Store.
Currently the application is only available for Android mobile devices.

- Please note: To run the application successfully your Android device must support at least Android version 7.0.

Charging the insoles



To connect the insoles with the rehab application, they need to be active and charged.

For charging, put the charger centric on the insole's heel area until the blue light appears.

- Please note: On page 20 the wireless charging process is explained in detail.

Find out sole ID

On the product label of your insoles, the sole ID is presented. The sole ID of the **right** insole is required to connect the insoles to the mobile device.

Insert Insoles into your shoe

If possible, remove the soles of the shoes you want to use the STAPPONE sensor insoles with. Afterwards put the STAPPONE sensor soles into your shoe.

Connect Insoles with your mobile device

Connect your mobile device to the insoles. Make sure that Bluetooth on your mobile device is activated.

- Shake both insoles or give them a slight tap before connecting to ensure they are activated

Start your rehab activities

Once your mobile device is connected to the insoles you can start doing rehab activities. Follow the instructions given in the application.

3. DEVICE SPECIFICATIONS

Sensors	12 pressure sensors per sole 2 acceleration sensors per sole 1 gyroscope per sole 1 magnet sensor per sole
Battery	Li-Ion battery cell with a capacity of 0.36 Ah per sole 10 hours running time
Charging	Wireless charging
Sizes	EU unisex shoe sizes from 36 to 47

Requirements for the mobile device

STAPPONE Rehab is only available for Android devices. An application for iOS devices is currently not provided. To use the STAPPONE Rehab application on your mobile device it needs to meet the following **minimum requirements**:

- **Android version 7.0.**
- **Android API 24**

The usage of mobile devices with versions older than 7.0 is **not supported**.

Bluetooth specifications

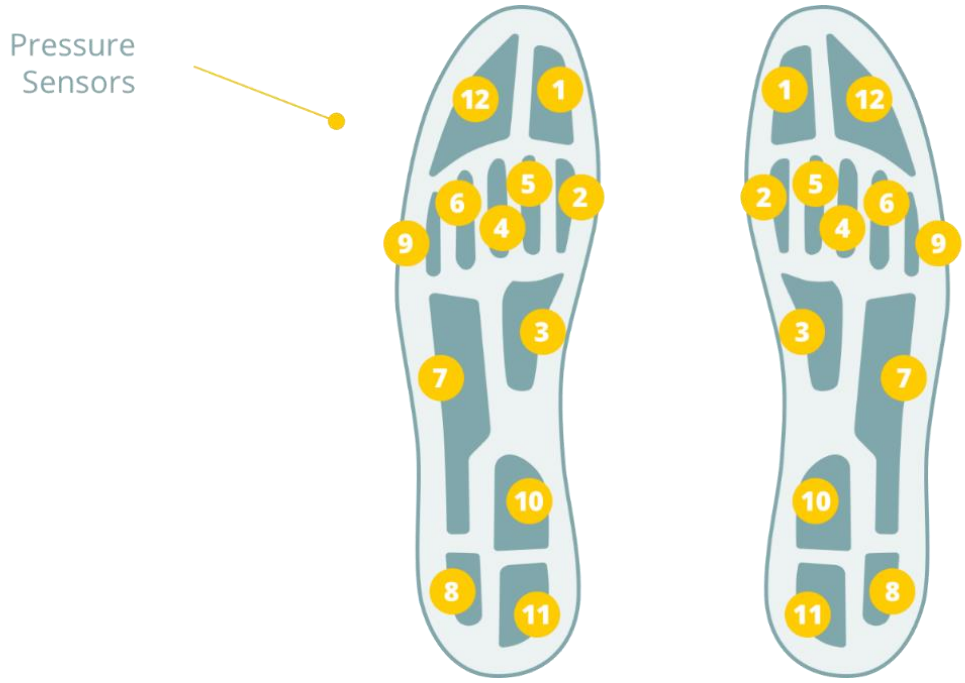
Frequency band	2.4GHz ISM Band (2.402 – 2.480 GHz utilized)
Channels	40 channels with 2 MHz spacing (3 advertising channels/37 data channels)
Max Tx Power	Class 2: 2.5 mW (+4 dBm)
Range	approx. 10 meters
Standard	Bluetooth Low Energy v4.2

Resolution

Pressure values: 0 - 1023 (relative pressure) – 10 Bit.
Accelerometer values: -4000 to +4000 mg – 10Bit
Time resolution: 4 milliseconds

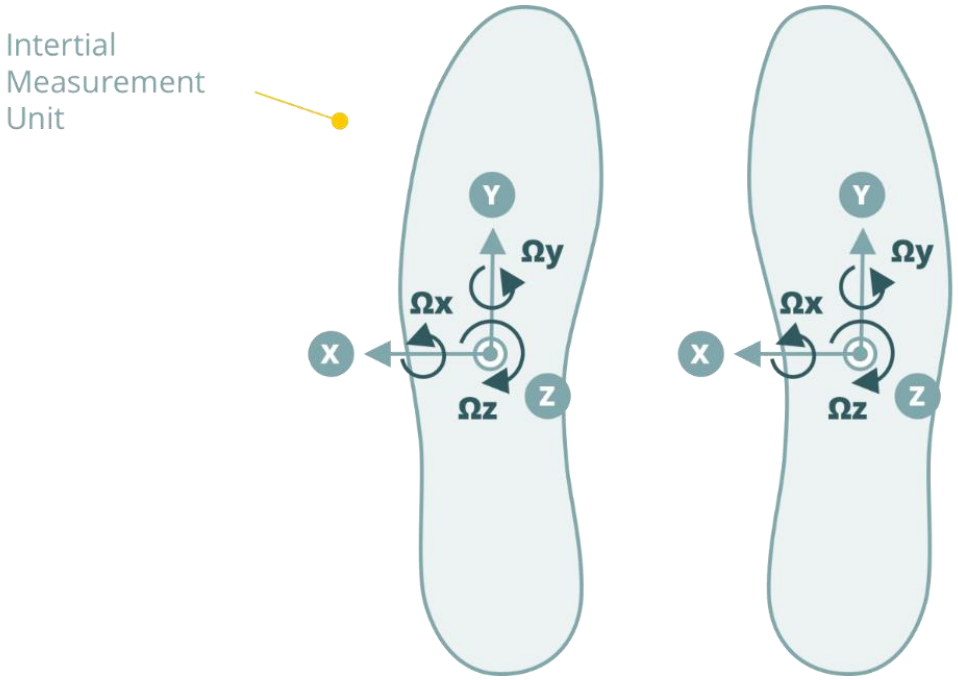
Pressure sensor position

Every insole has 12 integrated pressure sensors. The graphic below shows the position of every sensor. In the graphic the visualizations are equal to the left and right insoles.



IMU Sensor Orientation

X, Y and Z defines the orientation of the accelerometer and the magnet sensor.
Ωx, Ωy and Ωz defines the orientation of the gyroscope.
In the graphic the left visualization is equal to left insole.



Sole dimensions

Sole size EUR	Length [mm]	Width [mm]
36	228,9	87,17
37	236,9	87,17
38	248,6	87,17
39	248,7	89,3
40	256,7	89,3
41	270,0	89,3
42	271,3	98,3
43	279,4	98,3
44	288,6	98,3
45	290,1	103,1
46	298,2	103,1
47	307,2	103,1

4. SYMBOLS AND LABELING

The label is located on the bottom side of both insoles as well as on the packaging.

Symbol	Definition
	This device is a medical device class I
	CE certificated
	Device serial Number
	Manual must be read before using this device
	The symbol on the device or its packaging signifies that this device must be disposed separately from ordinary household wastes at its end of life because it contains a battery and is electronic equipment. Ensure that you dispose of your STAPPONE device at a recycling centre.
	One patient – multiple use
	To identify a type BF applied part complying with IEC 60601-1
	CLASS II equipment complying with IEC 60601-1
	Direct current

	Prohibited: situations that could cause injury to yourself or others or damage your devices or other equipment.
	Warning: situations that could cause injury to yourself or others or damage your devices or other equipment.
	Mandatory: situations that could cause injury to yourself or others or damage your devices or other equipment.
	Name and address of the manufacturer

5. INTENDED USE

- The following section is a simplified summary of the medical purpose statement.

This device is a sensor-based shoe insole, which measures the movements of our clients (patients or healthy persons) relatively with a combination of pressure sensors, acceleration sensors, gyroscopes and magnet sensors for diagnosis, therapy, and prevention. These relative data can be used for warning our clients if a pre-adjusted pressure limit is exceeded. The intended operators are clients and people with special education in health studies. Both intended operator groups can safely use all functions explained in this manual.

6. CONTRAINDICATIONS

The following conditions are absolute contraindications for using the device:

- open wounds on the foot, irritated or otherwise unhealthy foot skin
- severe gait impairments where the device might increase the risk of fall
- inability of the client to wear closed shoes in combination with the STAPPONE sensor insoles
- body weight over 135 kg

When instructing a client to use the sensor soles for more than one day, the user applying the device to the client must ensure that the wearer will not encounter negative orthopaedic long-term effects from wearing the device and must instruct the client to report discomfort and pain due to wearing the device, and to stop wearing the sensor insole in such case.

7. IMPORTANT SAFETY AND DEVICE INFORMATION

Prohibited Action:

- Do not use the application without prior consultation with your attending doctor or physiotherapist.
- Do not proceed unassisted without the consent of your attending doctor or physiotherapist.
- Do not change the parameters set by your doctor or physiotherapist in the application yourself. Acting unassisted without consulting your treating medical staff may reduce or prevent the success of the therapy.
- Do not wear your STAPPONE device while charging it.
- Do not charge your STAPPONE device while it is wet.
- Do not dispose of your STAPPONE device in a fire. The battery could explode.
- Do not use your STAPPONE device in a sauna or steam room.
- Do not use abrasive cleaners to clean your STAPPONE device.
- Do not expose your STAPPONE device to extremely high or low temperatures.
- Do not attempt to replace the battery or disassemble your STAPPONE device. Doing so will void the warranty and can result in a safety hazard.
- Do not use your STAPPONE device if the carbon plate on the bottom is damaged or dissolving from the cork.
- Do not modify this equipment without authorization of the manufacturer.

Safety critical warning:

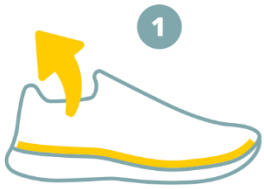
- The device may cause skin irritation.
- Prolonged contact may contribute to skin irritation or allergies in some users. To reduce irritation, follow three simple wear and care tips: (1) Keep it clean; (2) keep it dry; (3) let it breath.
- Only use this device when you can wear it properly in your shoes without any restrictions in movement, developing pressure marks or any other pain or numbness. Only wear the insoles if they fit completely in the shoe.
- This device cannot be used by persons (including children aged 8 and above) with reduced physical, sensory or mental capabilities or lack of experience and knowledge, unless they have been given supervision or instruction concerning use of the appliance by a person responsible for their safety and understand the resulting dangers.
- Consult your doctor before beginning or modifying any exercise program.
- Consult your doctor before use if you have any pre-existing conditions that might be affected by your use of this STAPPONE device.
- This device is not a toy. Do not allow children or pets to play with your STAPPONE device. The device contains small components that can be a choking hazard.
- Substances in this device and its battery may harm the environment or cause injury if handled and disposed of improperly.
- This device is not designed for Emergency Medical Service or use in critical environments (Emergency rooms, ICU etc.).
- When using this product take note of the information in section 10 regarding stacking and location to other equipment.

Mandatory action:

- Only use this device with socks.
- The device contains electrical equipment that could cause injury if not handled properly.
- Remove your STAPPONE device if it feels unusually warm or hot.
- Charge the battery in accordance with the instructions provided during setup. Only use a computer, powered hub or power supply that is verified by a recognized testing laboratory and an authorized STAPPONE charging device.
- STAPPONE rehab requires an active Bluetooth connection for the correct use. STAPPONE rehab utilizes the location data for connecting the insoles. Without an active Bluetooth connection, the use of STAPPONE rehab is not possible.
- STAPPONE rehab requires the mobile device's location data. STAPPONE rehab utilizes the location data for connecting the insoles. Without the permission for using the mobile device's location, the use of STAPPONE rehab is not possible.
- The use of STAPPONE Rehab does not automatically guarantee a shortened or complication-free rehabilitation.
- At no time during the use of STAPPONE Rehab is a diagnosis made or a therapy suggestion given. The design of the therapy and rehabilitation is furthermore the responsibility of the treating medical staff.
- STAPPONE Rehab guarantees 20% around the calibration point a maximum deviation of 5%. This must be considered by the treating medical staff when selecting the weight limits. If a larger deviation occurs, calibration must be repeated and, if necessary, stappone support must be contacted.
- The sensor soles allow accurate data according to the above point up to 4 hours of use (wearing the sensor soles). After 4 hours (continuous or not), the soles must be recalibrated.
- Do not rely solely on STAPPONE Rehab - if pain occurs with certain loads, load according to your pain threshold and consult with treating medical personnel.

We urge everyone to see a doctor immediately if your health issues include back pain and additionally two of the following cases:
Bad general condition, known tumour disease, adequate trauma, osteoporosis, pronounced neurological deficits (loss of power or skin sensibility...), fever, night pain, uncontrolled departure of urine or stool, unintentional weight loss.

8. HANDLING INSTRUCIONS OF THE INSOLES



If possible, remove the soles of your shoes you want to use the STAPPONE sensor insoles with.

Find out the sole ID of the **right** insole you want to use (device label on the bottom side of the soles).

Put the STAPPONE sensor insoles into your shoe.

Make sure you put the STAPPONE sensor insoles in your shoes correctly (you are still able to see the STAPPONE logo).

Check if the STAPPONE sensor insoles are in full contact with the shoes.

Check if the STAPPONE sensor insoles match the size of your shoes (if not try another size).

Put on your shoes.

Make sure the shoes with the STAPPONE sensor insoles match your feet and you have a stable stance in it.

Take off your shoes.

To remove the STAPPONE sensor insoles, lift sensor insole in medial mid foot area.

Pull on the heel area of the STAPPONE sensor insoles to remove it from your shoe.

9. WIRELESS CHARGING

Warnings:

- Do not place foreign materials, such as metal objects, magnets, and magnetic stripe cards, between the insole and the wireless charger or the STAPPONE
- STAPPONE suitcase. The insole may not charge properly or may be damaged due to overheating.
- Do not use the wireless charger or STAPPONE suitcase with other devices than your STAPPONE sensor insoles. Do not try to recharge non-rechargeable batteries.
- Do not touch insoles longer than 1 minute while charging.
- Do not touch charger longer than 10 seconds while charging.
- The charger or the STAPPONE suitcase MUST be placed outside the patient's environment (minimum distance of 1.5 meters), even when the device is not charging.
- Wait 10 minutes after charging, to cool down your insoles, before using them.
- While charging you may lose the Bluetooth connection to your insoles.

Indicator Light definition

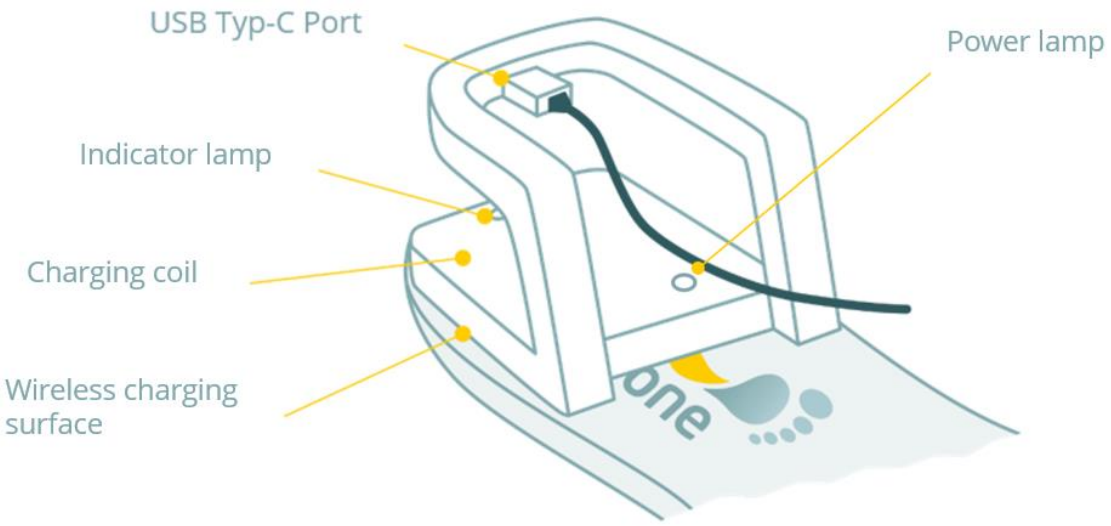
A constant blue light indicates the correct alignment and the ongoing charging process.

A blinking blue light indicates that charging is going on – but due to too low energy income slower than usual.

A constant red indication light signals that the charger has stopped charging due to high temperature and is cooling down. It is not necessary to remove the charger. This is a safety mechanism and no cause of concern.

A blinking red indication light signals an error in the process. Please remove the wireless charger from the insole and ensure that there are no obstacles between the wireless charger and the insole. Afterwards realign the wireless charger as before and continue the charging process.

Charging process charger



Warnings:

- Only connect the USB charger to a properly installed grounded socket-outlet. The socket-outlet shall be installed near to the equipment and shall be accessible easily.
- Use only USB chargers with an output voltage of 5V and a minimum of 1 A output current (SELV – Safe Extra Low Voltage).
- Use only IEC 60601-1 certificated chargers.

1. For a full usage, both batteries (left and right insole) must be charged
2. To charge your STAPPONE sensor insoles, you do not necessarily have to remove them from your shoes
3. Connect a USB C cable to the wireless charger
4. Place the wireless charger on a STAPPONE sensor insoles so that the centre of the charger is aligned with the heel of the insole
5. Move the charger slowly from the heel towards the toe area until the blue indication light starts to blink

Additional charging information:

If the indicator light does not work as described, disconnect the USB cable from the wireless charger and reconnect it.

To save energy, unplug the USB charger when not in usage. The wireless charger does not have a power switch, so you must unplug the USB charger from the electric socket when not in use to avoid wasting power. The USB charger should remain closely to the electric socket and easily accessible while charging.

If you have any technical problems, do not hesitate to contact us on our email support@STAPPONE.com.

10. ENVIRONMENT

Warnings:

- The sensor insole must not be used in environments where radio emissions at 2.4 GHz are potentially harmful or forbidden by law.
- Disadvantageous radio performance may occur if used in an environment with other devices operating at 2.4 GHz (e.g. WiFi, Bluetooth). In this case, stop using the sensor insole in this environment.

Environment Specifications	
Operation humidity range	15 – 90 [%rH], noncondensing
Storage and transportation humidity range	5 – 90 [%rH], noncondensing
Air pressure range for operation	< 3000m (> 690hPa)
Air pressure range for storage	< 13000m (> 190hPa)
Operation temperature	5 – 40 C°
Storage and transportation temperature	-25 – 70 C°
Time required for ME (medical electrical) equipment to warm from the minimum storage temperature between uses until it is ready for intended use	1 hour (room temperature)
Time required for me equipment to cool from the maximum storage temperature between uses until it is ready for intended use	1 hour (room temperature)
Degree of protection (IEC 60529)	IP52 (Full protection against contact, protection against interior injurious dust deposit and protection against diagonal water drips)

11. RADIATION AND SAFETY DISTANCE

Warnings:

- Other cables and accessories may negatively affect EMC performance.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the medical, including cables specified by the manufacturer.

For safety reasons, the following tables must be observed with regard to EMC (Electromagnetic Compatibility). They are part of the certification according to the standard EN 60601-1-2 and taken from it accordingly.
Portable and mobile RF communications equipment (radios) should not be used closer to any part of the 'STAPPONE medical' product than the recommended safety distance specified in the tables below. In the following tables ME device is used for 'Medical electrical device' and describes the device 'STAPPONE medical'

Accessories	**Type**	**Cable length**
2x USB Cable	C	150 cm
2x STAPPONE wireless charger	UNIQT-0004	N/A
STAPPONE suitcase	N/A	N/A

Electromagnetic emissions: manufacturer's declaration and guidelines

(Table according to EN60601-1-2)

Guidance and manufacturer's declaration - electromagnetic emissions		
The ME device is intended for use in an electromagnetic environment as specified below. The user of the ME device should ensure that he is operating in such an environment.		
EMI measurements	**Conformity**	**Electromagnetic environment – guidelines**
RF emissions to CISPR 11	Group 1	The ME device uses RF energy only for its internal function. Therefore, its RF transmission is very low and it is unlikely that neighbouring electronic devices will be disturbed.
RF emissions to CISPR 11	Class B	The ME device is suitable for use in facilities other than residential and those directly connected to the public utility network that also supplies buildings used for residential purposes.
Transmission of harmonics according to IEC 61000-3-2	N/A	
Transmission of voltage fluctuations / flicker according to IEC 61000-3-2	N/A	

Electromagnetic immunity: manufacturer's declaration and guidelines

(Table according to EN 60601-1-2)

Guidance and manufacturer's declaration - electromagnetic immunity			
The ME device is intended for use in an electromagnetic environment as specified below. The user of the ME device should ensure that he is operating in such an environment.			
Immunity	IEC 60601-1-2:4th Edition	Matching level	Electromagnetic environment - guidelines
Static electricity discharge (ESD) according to IEC 6100-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be wood, concrete, or ceramic tile. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
EFT/Burst according to IEC 61000-4-4	± 2 kV - AC Mains 100 kHz PRF	N/A	The quality of the supply voltage should be that of atypical business or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV Voltage outer conductor to outer conductor	N/A	The quality of the supply voltage should be that of a typical business or hospital environment.
Voltage dips, short-term interruptions and fluctuations in the supply voltage according to IEC 6100-4-11	UT = 0%, 0.5 cycle (0, 45,90, 135, 180, 225, 270 and 315°) UT = 0 %; 1 cycle UT = 70%; 25/30 cycles (@ 0 degrees) UT = 0%; 250/300 cycle	N/A	The quality of the supply voltage should be that of atypical business or hospital environment. If the user of the ME device requires continued operation even in the event of power interruptions, it is recommended that the foot scanner be powered from an uninterruptible power supply or a battery.
Magnetic field at the supply frequency (50 / 60Hz) according IEC 61000-4-8	30 A/m	30 A/m	Mains frequency magnetic fields should be the typical value found in the business and hospital environment.
Note: U_T is the mains AC voltage before the application of the test levels.			

Electromagnetic Immunity: Manufacturer's Declaration and Guidelines for Non-Life-Causing ME Equipment

(Table according to EN 60601-1-2)

Guidance and manufacturer's declaration - electromagnetic immunity			
The ME device is intended for use in an electromagnetic environment as specified below. The user of the ME device should ensure that he is operating in such an environment.			
Immunity	**IEC 60601 test level**	**Matching level**	**Electromagnetic environment - guidelines**
Conducted RF interference according to IEC 61000-4-6 Radiated RF interference according to IEC 61000-4-3	3V 150kHz to 80MHz ISM Bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz 10V/m 80MHz to 2,7GHz 80% AM at 1 kHz	N/A 10V/m 80MHz to 2,7GHz 80% AM at 1 kHz	Portable and mobile radios should be used no closer to the ME device, including the wires, than the recommended safe distance calculated using the equation applicable to the transmit frequency. Recommended safety distance in meters: $d=(3,5/3)*\sqrt{P}$ $d=(3,5/3)*\sqrt{P}$80MHz to 800MHz $d=(7/3)*\sqrt{P}$ 800MHz to 2,5GHz with P as the nominal power of the transmitter in watts (W) according to the transmitter manufacturer and d as the recommended safety distance in meters (m). The field strength of stationary radio transmitters should be lower than the compliance level at all frequencies according to an onsite survey. In the vicinity of devices bearing the following icon, interference is possible.
Proximity Field from Wireless Transmitters	9 V/m to 28 V/m 15 specific frequencies	28 V/m	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the STAPPONE medical including cables specified by the manufacturer.
Electrical Transients – Vehicle 12 Volt Powered	ISO 7637-2 Pulses – 600V max.	N/A	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not be applicable in all cases. The spread of electromagnetic quantities is influenced by absorption and reflection of buildings, objects, and people.
a The field strength of stationary transmitters, e.g. Base stations of radio telephones and land mobile radios, amateur radio stations, AM and FM radio and television stations cannot be theoretically accurately predicted. To determine the electromagnetic environment with respect to the stationary transmitters, a study of the electromagnetic phenomena of the location should be considered. If the measured field strength at the location where the ME device is used exceeds the above compliance levels, the ME device should be observed to verify its intended function. If unusual performance is observed, additional measures may be required, such as: a changed orientation or another location of the ME device. b Over the frequency range of 150kHz to 80MHz the field strength should be less than 3V / m.

Recommended separation distances between portable and mobile HF telecommunications equipment and the ME device

(Table according to EN 60601-1-2)

Recommended safety distances between portable and mobile HF telecommunications equipment and the ME device			
The ME device is intended for operation in an electromagnetic environment in which the RF disturbances are controlled. The user of the ME device may thereby help to avoid electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the ME equipment, depending on the output power of the communication equipment as indicated below.			
Rated power P of the transmitter *W*	**Guard distance, depending on the transmission frequency *m***		
	150kHz to 80MHz $d=(3,5/3)*\sqrt{P}$	80 MHz to 800MHz $d=(3,5/3)*\sqrt{P}$	800MHz to 2,5GHz $d=(7/3)*\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33
For transmitters whose maximum rated power is not specified in the table above, the recommended guard distance d in meters (m) can be obtained using the equation associated with each column, where P is the transmitter maximum power rating in watts (W) as specified of the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not be applicable in all cases. The spread of electromagnetic quantities is influenced by absorption and reflection of buildings, objects, and people.			

12. REPROCESSING

Warnings:

- The sensor soles are intended exclusively for the use of one user.

- The sensor soles are not sterile.
- The sensor soles cannot be disinfected.
- Wipe off coarse soiling of the sensor soles with a dry cloth. Do not use any liquids!

- The sensor soles may only be worn by one user because they cannot be disinfected.
- The use of the sensor soles by several users is prohibited.

For more detailed information you will find the corresponding hygiene certificate in the appendix section. If you have any problems, do not hesitate to contact us on our email **support@STAPPONE.com**

13. STAPPONE REHAB APPLICATION

Warning:

- The software visualizes sensor data and notifies users when their weight exceeds or falls below a pre-set weight limit specified by the attending medical staff.
  At no time is a diagnosis made or therapy suggestions made!

General information and symbols

Symbols

Symbol	Where	Definition
	Main Menu / Header	Button that leads you to the help page
	Overview	Battery status insoles
	Overview	Choose something out of the menu
	Activity	Changing the activity settings
	Report	Sharing the report via messenger application

Instructions for use

In the following section, the use of the sensor soles in combination with the STAPPONE rehab application is explained in a step-by-step guide.

DOWNLOAD THE APP

Download the STAPPONE Rehab application in the Google Play Store.
Currently the application is only available for Android mobile devices.

- Please note: To run the application successfully your Android device must support at least Android version 7.0.

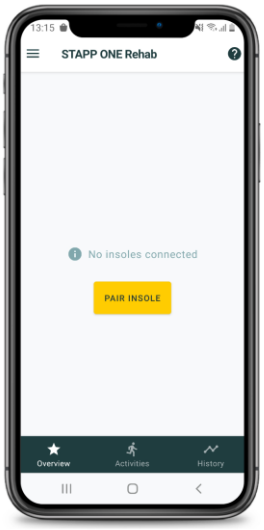
CONNECT YOUR INSOLES

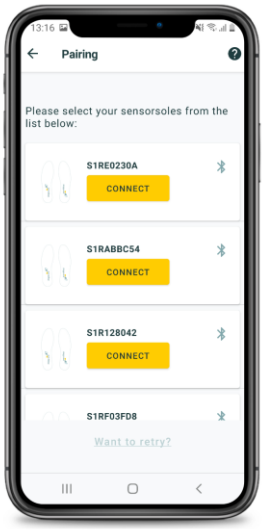
Find out the sole ID

On the product label of your insoles, you find the Sole ID. You need the Sole ID of the **right** insole to connect the insoles with the electronic device.

- Both Insoles must be charged and activated for a connection to be able to be established

Couple your insole with the application





To connect the insoles to the STAPPONE Rehab app, click **CONNECT**. When the pair of insoles you are using is displayed, click **CONNECT** to connect the insoles to your mobile device. If a connection could not be established, click **TRY AGAIN**.

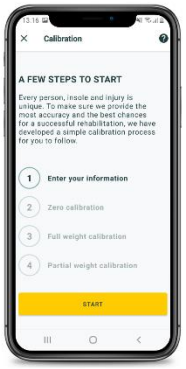
- Make sure Bluetooth on your mobile device is activated.
- Insoles should be within 5 meters of the mobile device to ensure reasonable connectivity.
- Shake both insoles or give them a slight tap before connecting to ensure they are active

CALIBRATE THE SENSOR SOLES

In this step, the soles will be calibrated. To do this, click on **CALIBRATE**. Before you start the calibration, you must enter your user data and your partial load prescription. After that, the calibration steps **Zero calibration** (no feet on the ground), **Full weight calibration** (standing on the healthy side) and **Partial weight calibration** (standing on the injured side with the partial load prescription) will be performed. Before each calibration step, you will receive a 3-second countdown before the **2-second measurement** begins.

Enter information

The first step is to enter the body weight and the prescribed partial load.
If it is not possible to reach the maximum limit for the calibration (for example, due to pain), you can enter a weight lower than the prescribed partial load under "Loadable with (kg)".



- The entered weight must be at least 15kg.

Zero calibration

In the next step, the sensor soles must be calibrated to a base value - without load. To do this, both legs must be lifted from the floor and **START** pressed.

- The sensor sole should be as free as possible from additional pressure during this calibration.

Full weight calibration

In the next step, the sole which is fully loaded – using the healthy leg - is calibrated. For this purpose, the corresponding sensor sole must be loaded with the full body weight. Stand on your healthy leg and press **START**.

- The sensor sole should be loaded as evenly as possible - avoid loads exclusively in the heel or forefoot area.

Partial weight calibration

In the last step, the sole which is partially loaded - injured leg - is calibrated. For this purpose, the corresponding sensor sole must be loaded with the corresponding pre-set weight. Use an analogue scale to load the injured leg accordingly and press **START**.

- The sensor sole should be loaded as evenly as possible - avoid loads

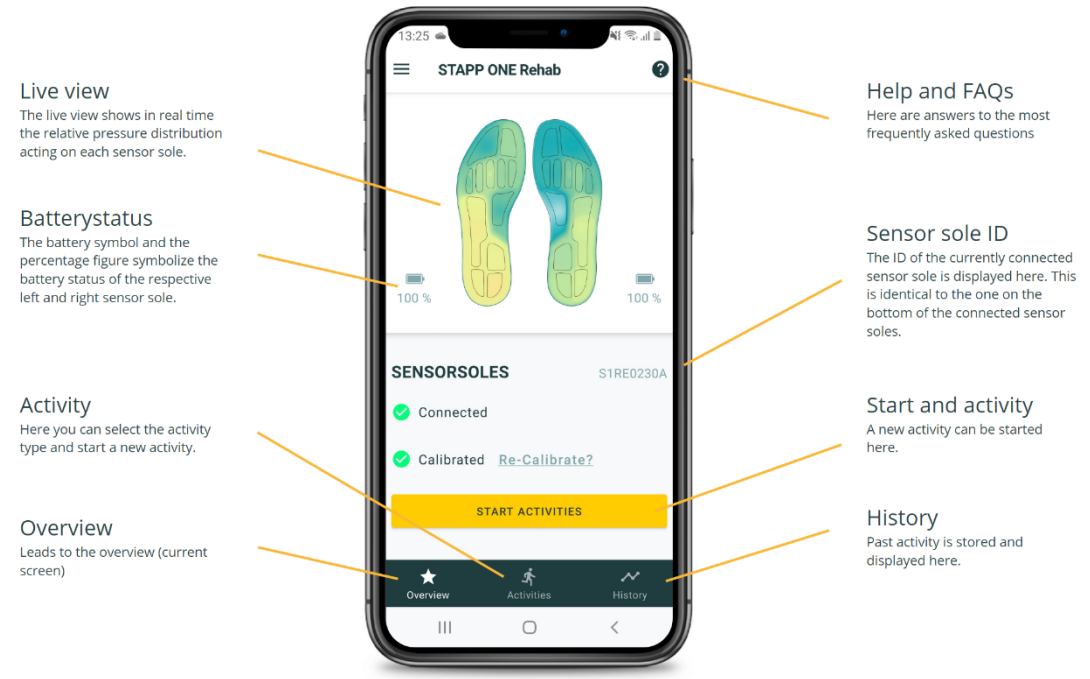
exclusively in the heel or forefoot area.

Note the following safety instructions regarding calibration:

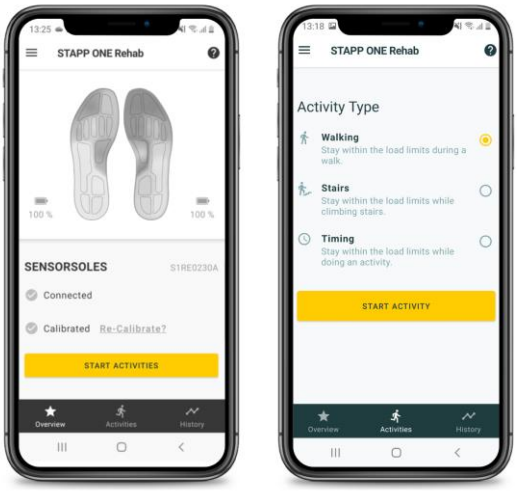
- Calibration is important for the accuracy of your measurement.
- After each calibration, check in an activity whether the calibration was successful.
- The sensor sole is not a scale! The sensor soles provide an accuracy at 20% around the calibration point a maximum deviation of 5% if the calibration was successful.
- The sensor soles allow accurate data according to the above point up to 4 hours of use (wearing the sensor soles). After 4 hours (continuous or not), the soles must be recalibrated.
- We recommend using the sensor soles exclusively in a pair of shoes and not removing the sensor soles from them. Doing so can extend the life of a calibration

HOME SCREEN - OVERVIEW

After successful connection and calibration of the sensor soles with the mobile device, a live visualization of the pressure distribution is displayed in the overview (home screen). If no live view is displayed, then decouple and pair your sensor soles with the mobile device again.



START A NEW ACTIVITY



To start a new recording, please click on **START ACTIVITY**.
If you click on Activity, you will get to the activity settings.

In the activity settings you can select the type of your activity. You can choose between:

- Walking
- Climbing stairs
- Timing

To start a new activity, please press **START**

During an activity

During an activity, the application signals overloads, and underloads based on the pre-set limits. Exceeding or falling below these limits is indicated visually (on the screen), acoustically (by beep) and haptically (by vibration). The notification type can be set in the **ACTIVITY SETTINGS** directly in the activity or in the menu.

In this way, overloads or underloads are signaled by the app:

Overloading

When a pre-set maximum limit (the maximum partial load limit) is exceeded, the bar in the app turns red. In addition, a continuous high-pitched signal tone appears, and the smartphone vibrates in a pulsating manner. If the load on the sole is reduced and the load is again below the maximum limit, the bar appears green again and the signal tone and vibration end.

Loading within the limits

When the load is within the limits, the bar is displayed in green. In addition, neither the signal tone nor the vibration appears.

Underloading

Your treating medical staff can also set a lower load limit to avoid underloading. If the injured side is permanently underloaded (activity type walking or climbing steps: after 2 steps / activity type timing: after 5 seconds of permanent underload), the bar appears in orange. In addition, a deep signal tone will appear, and the smartphone will vibrate constantly. If the load is increased so that it is above the minimum limit, the notification ends.

Changing activity settings during an activity

It is possible to change specific settings during an activity. Under the icon ⚙, the activity settings can be changed directly while the activity is running. The notification type (sound/vibration) and the unit can be changed from kg to % of body weight. In addition, a timer can be displayed and hidden.

Warning:

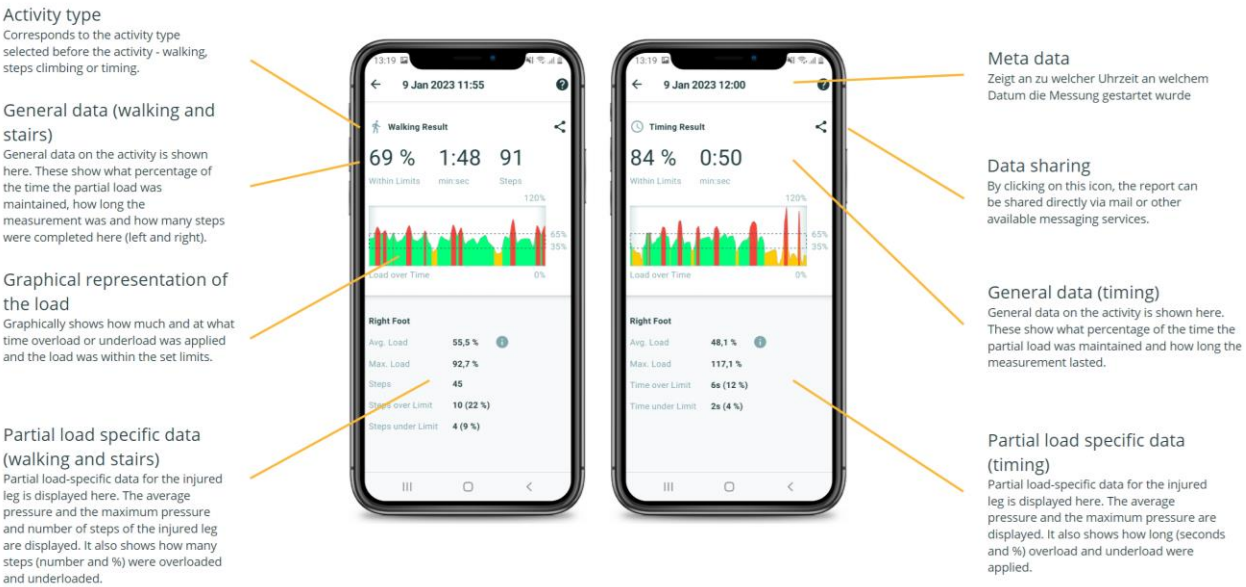
- During the entire recording, the mobile device and the insoles must be connected via Bluetooth. The recording will be interrupted, and your data will be saved automatically.

End an activity

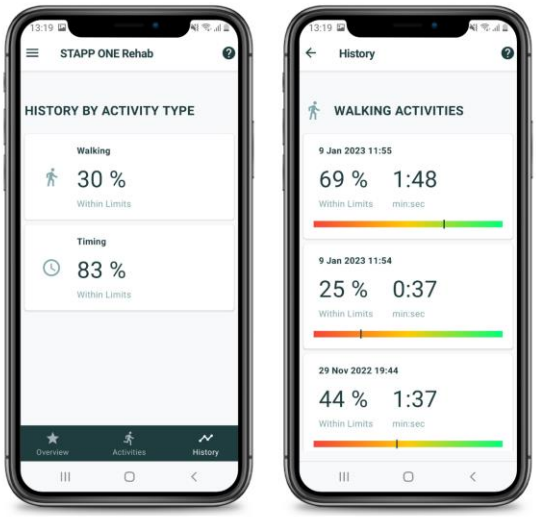
If you want to stop the activity, click **STOP**. After the activity is finished, the results of the recording are automatically displayed in **REPORT**.

REPORT

Once the exposure is completed by clicking **STOP**, all exposure results are automatically displayed and saved. In this area, various parameters are displayed that provide users and medical staff with information on how well the partial load was adhered to.



HISTORY – ACCESSING OLD REPORTS



In the **HISTORY** section, all previous activities are listed and saved.

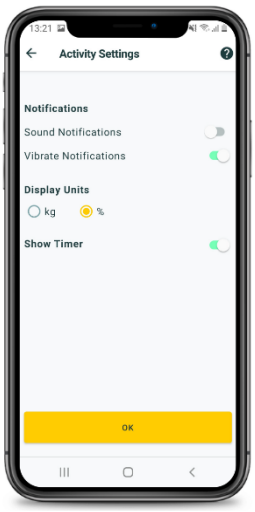
These are sorted by activity type - by clicking on the corresponding activity type, all previous reports of the activities are displayed in chronological order.

MENU AND SETTINGS

Activity settings

The following settings can be changed in the menu under ACTIVITY SETTINGS:

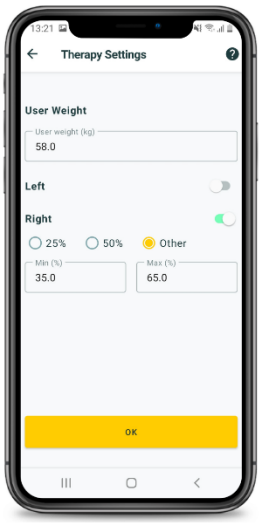
- Notification settings (sound and vibration on/off).
- Unit in which the weight values are displayed in the activity and report (kilogram and %)
- Time display (timer on/off)



Therapy settings

The following settings can be changed in the menu under THERAPY SETTINGS.

- Body weight of the user
- Side of the body to be partially loaded
- Limits of the respective side
    - 25%
    - 50%
    - Others: Individual limit



- Changing the body weight requires a new calibration
- Do not change therapy settings **WITHOUT** explicit instructions of the treating medical staff

Disconnect

By clicking DISCONNECT, the Bluetooth connection between the sensor soles and the smartphone can be disconnected.

Contact information

Clicking CONTACT INFORMATION in the menu, our contact information is displayed. In addition, a message can be sent to our support directly from the app.

- If you contact us via this way, we recommend to always submit the technical information during it (click the checkbox).

Privacy policy

Under **PRIVACY STATEMENT** in the menu, our privacy policy is displayed.

Version History

The version number of the application is displayed at the bottom.

HELP AND FAQs

Clicking on ❓ opens a collection of the most frequently asked questions. By clicking on a specific question, the content of that question and its answer will be displayed.
This page is accessible from almost all screens.

14. DISCLAIMER

- Do not use the application without prior consultation with your attending doctor or physiotherapist.
- Do not proceed unassisted without the consent of your attending doctor or physiotherapist.
- Do not change the parameters set by your doctor or physiotherapist in the application yourself. Acting unassisted without consulting your treating medical staff may reduce or prevent the success of the therapy.
- STAPPONE rehab requires an active Bluetooth connection for the correct use. STAPPONE rehab utilizes the location data for connecting the insoles. Without an active Bluetooth connection, the use of STAPPONE rehab is not possible.
- STAPPONE rehab requires the mobile device's location data. STAPPONE rehab utilizes the location data for connecting the insoles. Without the permission for using the mobile device's location, the use of STAPPONE rehab is not possible.
- The use of STAPPONE Rehab does not automatically guarantee a shortened or complication-free rehabilitation.
- At no time during the use of STAPPONE Rehab is a diagnosis made or a therapy suggestion given. The design of the therapy and rehabilitation is furthermore the responsibility of the treating medical staff.
- STAPPONE Rehab guarantees 20% around the calibration point a maximum deviation of 5%. This must be considered by the treating medical staff when selecting the weight limits. If a larger deviation occurs, calibration must be repeated and, if necessary, our support must be contacted.
- Do not rely solely on STAPPONE Rehab- if pain occurs with certain loads, load according to your pain threshold and consult with treating medical personnel.

15. INFORMATION ABOUT THE MANUFACTURER

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