actiTENS Mini

INSTRUCTIONS FOR USE

Instruction for use - actiTENS mini

The **actiTENS mini** is a connected medical device for transcutaneous electrical nerve stimulation (TENS) intended to treat pain in adults. It also contains an electrical muscle strengthening (EMS) program. It is intended for people over 22 years of age with unimpaired intellectual abilities. The **actiTENS mini** is fixed directly on the body using a fastening accessory. It adapts to the shape of the body with its flexible design. The **actiTENS mini** can be used discreetly during daily activities.
The EIG (electrical impulse generator) generates electrical impulses that are diffused in the body through skin electrodes connected to one or two channels via cables available in various lengths. Managing the EIG is done by means of the **actiTENS** Mobile App that allows users to control the stimulation session by choosing: a stimulation program, the number of channels used, the stimulation intensity for each channel and the stimulation duration.
It is intended to be used by the patient at home and also for therapeutic application by medical professionals.

This guide is continuously being updated; to view the latest version, go to the “Help” menu in the **actiTENS mini** app.

Table of content

1. INTENDED USE / INDICATIONS FOR USE

actiTENS mini is intended to be used as:

Transcutaneous Electrical Nerve Stimulator (TENS), used for the following indications:

- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities
- Relief of pain associated with arthritis

Electrical Muscle Stimulation (EMS), used for the following indications:

- Temporary relaxation of muscle spasms
- Prevent or retard disuse atrophy
- Increase of local blood flow in the treatment area
- Re-educate muscles
- Maintain or increase the range of motion
- Prevention of venous thrombosis of the calf muscles immediately after surgery

2. CONTRAINDICATIONS

The **actiTENS mini** is contraindicated for the following:

- Patients with pacemakers, implantable cardioverter defibrillators, or other similar active implantable devices.
- Heart-risk patients.
- Patients with epilepsy.
- People with dermatological conditions in the area of the electrode's placement.
- Allodynia.
- Allergy to electrodes.
- Pregnant women.
- Children (under 22).

3. RESIDUAL RISKS AND UNDESIRABLE SIDE EFFECTS

- The use of **actiTENS mini** can in some cases cause hyperalgesia. (abnormally amplified pain caused by a painful stimulus). It is recommended to stop using the device and to consult a healthcare professional.
- Use of the **actiTENS mini** may in certain cases cause erythema (redness), skin irritation, inflammation, allergy or burns in the area where the electrodes are placed or the area where textile accessories are fixed. In case of skin irritation after a stimulation session, you should stop the treatment temporarily and consult a healthcare professional.
- If the electrodes start to peel off, this may cause a slight electric shock. Make sure you change your electrodes regularly to limit peeling off (see section 11).
- Using the **actiTENS mini** may cause temporary muscular pain or involuntary muscular contractions. It is recommended to consult a healthcare professional before using the device and stop using it if these effects happen.
- Some accessories (cables, AC charger and textile accessories) may present a risk of strangulation.

4. WARNINGS

- Always keep the **actiTENS mini** neurostimulator and its accessories out of the reach of children under 22, pets, and people with intellectual limitations to avoid any risk to them or damage to the equipment.
- Do not position the electrode and the neurostimulator on the front of the neck (especially the carotid sinus) as this may cause adverse effects on heart rate or blood pressure or cause severe muscle spasms resulting in airway closure and difficulty breathing.
- Do not position the electrode on the chest on either side of the heart. Placement of the electrodes near the thorax can increase the risk of cardiac fibrillation.
- Do not use the neurostimulator for transcranial stimulation (electrodes on either side of the head), effects of transcranial stimulation on the brain are unknown.
- Do not place the electrodes directly over the spinal column.
- Do not place the electrodes on a pathological limb (active phlebitis). Never place the electrodes inside body openings; they are designed solely for external application. Do not apply stimulation directly to the eyeballs or mouth.
- For hygiene reasons, the electrodes must only be used by a single patient.
- Do not attempt to open or modify the **actiTENS mini** - there is a risk of electric shock.

- Do not use the neurostimulator if the patient is connected to high-frequency surgical equipment (e.g., electric scalpel). Simultaneous use can cause burns underneath the electrodes and damage to the neurostimulator.
- Do not use the **actiTENS mini** neurostimulator in the immediate vicinity (e.g. 1 m) of shortwave or microwave devices. The output power of the device may be affected, which may turn into painful reactions.
- Do not use the neurostimulator near electronic surveillance equipment (e.g. cardiac monitors, ECG, EEG), as there is a risk they may not work properly whilst the neurostimulator is being used.
- Keep the **actiTENS mini** neurostimulator away from water and other liquids.
- Do not use the device in a flammable environment (ex: gas station).
- Do not use the **actiTENS mini** device in emergency medical services.
- We recommend that you do not use the **actiTENS mini** neurostimulator while driving a vehicle or handling dangerous equipment (saw, lawnmower...) because of the risk of uncontrolled muscle contractions if the intensity is too high. An accidental change in stimulation could divert attention and cause a dangerous situation.
- We recommend not to use the **actiTENS mini** neurostimulator while sleeping, as pain may be felt too late.
- Caution should be taken in the case of patients with psychological disorders or electrophobia.
- Do not use several stimulators at the same time on the same person.

5. PRECAUTIONS FOR USE

- The use of other accessories than those provided by SUBLIMED may lead to a deficient operation.
- Warnings about the electrodes used with **actiTENS mini** neurostimulator:
  - Do not place the electrodes on injured or irritated skin, and particularly not on open wounds or in proximity to cancerous lesions. If skin irritation occurs after stimulation, the session should be suspended. If irritation persists, consult your doctor.
  - Always place the electrodes on clean dry skin. It is recommended to not use conducting gel with the electrodes.
  - Do not superimpose electrodes.
  - Before removing the electrodes from the skin, turn off the neurostimulator by stopping the session from the application or by pressing the ON/OFF button (⏻) If an electrode comes off, turn off or pause the neurostimulator before touching the electrode. Electrical pulses to the fingers from the

neurostimulator are unpleasant, but not harmful in any way. See section 9 “Stopping a stimulation session”.

- Please only use electrodes supplied by SUBLIMED with references mentioned in section 15.
- For replacing your electrodes by new ones, contact the supplier who supplied you the **actiTENS mini** kit.
- Do not use electrodes beyond their intended lifetime for safety reasons.

- Precautions for the use of self-adhesive strip and textile accessories with the **actiTENS mini**:
  - Do not place these accessories on damaged or irritated skin, and especially not on an open wound. In the event of rash or skin irritation, remove the device. If the irritation persists, consult a healthcare professional.
  - For hygiene reasons, the self-adhesive strip must only be used by a single patient.
  - It is recommended not to overtighten the armband so as not to interrupt blood circulation in the limb concerned.
- Do not disconnect the cables connected to the electrodes or the **actiTENS mini** neurostimulator by pulling on the cables. This action may cause a cable rupture.
- Do not use the neurostimulator during physical activities that may involve collision or impact.
- If you drop the **actiTENS mini**, check the condition of the device before use. If the device is damaged, there is a risk of electric shock during use.
- Do not use **actiTENS mini** neurostimulator or its accessories if it is malfunctioning or any part is damaged. Always check the system before using.
- The **actiTENS mini** neurostimulator must be charged inside a room (ambient temperature). For your safety, remove the device, cables and electrodes from your body before recharging your **actiTENS mini** with the charger supplied. The mains plug (disconnecting device) must remain accessible during charging, so that you can quickly disconnect the device from the mains if necessary.
- Do not store the **actiTENS mini** neurostimulator for a long time without using it to avoid deep discharge of the batteries.
- We recommend that the phone is locked (manually or automatically) after a stimulation is initiated or when not in use, and that a security feature is required when unlocking.
- When creating a user account, it's important to use a password with sufficient security. Do not share your password with anyone else, do not write it down on a piece of paper near your phone or tablet and do not reuse your password for different accounts.
- The **actiTENS mini** should be used with caution for undiagnosed pain syndromes where etiology has not been established.

6. TENS THERAPY

- Transcutaneous electrical nerve stimulation is not effective for pain of central origin, as compared to pain of peripheral origin.
- Transcutaneous electrical nerve stimulation is of no known curative value.

Placement of electrodes

To relieve pain, the electrodes must be placed along the pathway of the nerve or around the area where the pain is located. Several configurations should be tried to determine the ideal one. The anatomical location for the placement of the electrodes is mentioned in Section 14.

The choice is based on how each patient feels. Do not hesitate to contact your healthcare professional.

Controlling intensity

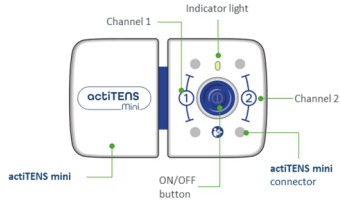
The stimulation intensity should be adjusted to balance a tolerable sensation with a decrease in pain. A high intensity is not necessarily more effective than a moderate intensity and can even cause discomfort.

The choice is based on how each patient feels. Do not hesitate to contact your healthcare professional.

7. DEVICE OVERVIEW

The **actiTENS mini** kit:

- 1 **actiTENS mini** (neurostimulator)
- 1 **actiTENS** armband - 70cm
- 3 packs of 2 **actiTENS mini** cables (14 cm / 40 cm / 70 cm)
- 1 pack of 4 **actiTENS** electrodes 50 mm x 50 mm providing 20 successive uses These electrodes are FDA cleared under K160138, manufactured by GMDASZ Manufacturing Co.
- 1 **actiTENS mini** AC charger
- 1 **actiTENS mini** instruction for use



8. PROGRAM OVERVIEW

Action Mode	Programmes
TENS	
Inhibits pain signals	P1, P2, P10, P11, P12
Stimulates the muscles for a general pain-relieving effect	P3, P13
Combined action: • Inhibits pain signals. • Stimulates the muscles for a general pain-relieving effect	P4, P5, P6, P7 P8
EMS	
Muscle strengthening	P9

P1 100 HZ

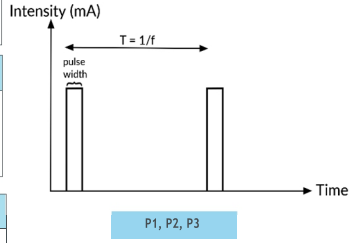
Frequency: 100 Hz
Pulse width:200 µs
Default duration: 30 min

P2 80 HZ

Frequency: 80 Hz
Pulse width:150 µs
Default duration: 30 min

P3 2 Hz

Frequency: 2 Hz
Pulse width: 250 µs
Default duration: 30 min



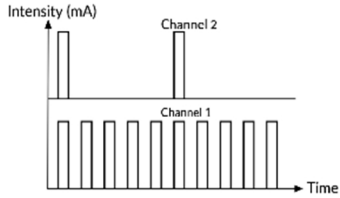
P1, P2, P3

P4 MIXED

Channel 1: 100 Hz
Frequency: 100 Hz
Pulse width: 200 µs

Channel 2: 2 Hz
Frequency: 2 Hz
Pulse width: 200 µs

Default duration: 30 min



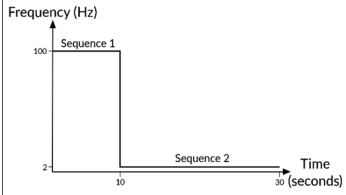
P4

P5 SEQUENTIAL

1st sequence (1/3 of the time, so by default: 10 minutes): Program 100Hz
Frequency: 100 Hz
Pulse width: 150 µs

2nd sequence (2/3 of the time, so by default: 20 minutes): Program 2Hz
Frequency: 2 Hz
Pulse width: 200 µs

Default duration: 30 min



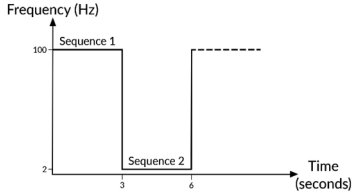
P5

P6 HAN STIMULATION

1st sequence (duration: 3 seconds) Program 100Hz
Frequency: 100 Hz
Pulse width: 150 µs

2nd sequence (duration: 3 seconds): Program 2Hz
Frequency: 2 Hz
Pulse width: 200 µs
These sequences alternate every 3 seconds

Default duration: 30 min



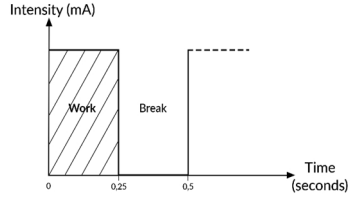
P6

P7 BURST 2 HZ

1st sequence (duration: 0.25 seconds): Program 100Hz.
Frequency: 100 Hz
Pulse width: 150 µs

2nd sequence (duration: 0.25 seconds): No pulse
These sequences alternate every 0.25 seconds

Default duration: 30 min



P7

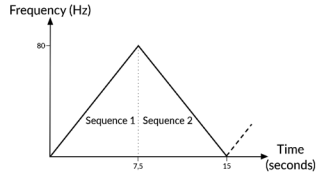
P8 FREQUENCY MODULATION

1st sequence (duration: 7.5 seconds):
Increasing frequency: 2 Hz to 80 Hz
Decreasing pulse width: 200 µs to 100 µs

2nd sequence (duration: 7.5 seconds):
Decreasing frequency: 80 Hz to 2 Hz
Increasing pulse width: 100 µs to 200 µs

These sequences alternate every 7.5 seconds

Default duration: 30 minutes

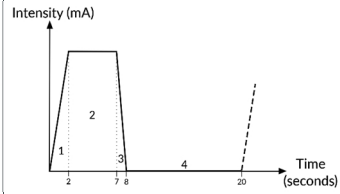


P8

P9 MUSCLE STIMULATION

Frequency: 50 Hz
Pulse width: 250 µs
1st sequence (2 seconds): Increasing intensity: 0mA to desired intensity
2nd sequence (5 seconds): Constant intensity (desired intensity)
3rd sequence (1 second): Decreasing intensity: desired intensity to 0mA
4th sequence (12 seconds): No pulse
These sequences alternate throughout the program.

Default duration: 30 minutes



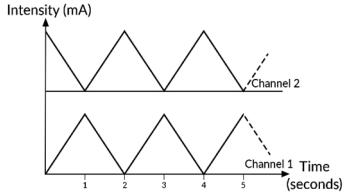
P9

P10 MASSAGE

Frequency: 80 Hz
Pulse width: 150 µs
Channel 1:
1st sequence (1 second): Increasing intensity from 0mA to the desired value
2nd sequence (1 second): Decreasing intensity from the desired value to 0 mA

Channel 2:
1st sequence (1 second): Decreasing intensity from the desired value to 0 mA
2nd sequence (1 second): Increasing intensity from 0mA to the desired value

Default duration: 30 minutes



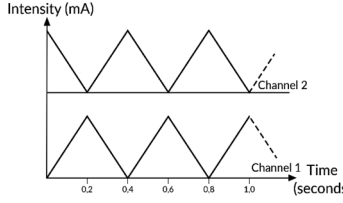
P10

P11 RUBBING

Frequency: 80 Hz
Pulse width: 150 µs.
Channel 1:
1st sequence (0.2 seconds): Increasing intensity from 0 mA to the desired value
2nd sequence (0.2 seconds): Decreasing intensity from the desired value to 0 mA

Channel 2:
1st sequence (0.2 seconds): Decreasing intensity from the desired value to 0 mA
2nd sequence (0.2 seconds): Increasing intensity from 0 mA to the desired value

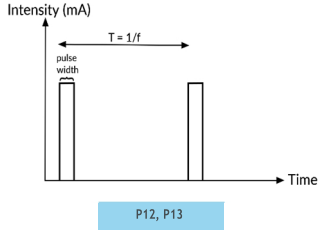
Default duration: 30 minutes



P11

P12 SENSITIVE AREAS TREATMENT
Frequency: 80 Hz Pulse width: 60 µs Default duration: 30 min

P13 10 HZ
Frequency: 10 Hz Pulse width: 180 µs Default duration: 30 min



Treatment type and choice of program to be determined with your doctor based on your disease.

9. USING THE actiTENS mini DEVICE

actiTENS mini AC Charger

An AC Charger is provided in the **actiTENS mini** KIT. You must use it, or at least, an AC Charger fulfilling the requirement (Cf specifications below) in order to guarantee the performance and safety of the device. Otherwise, the **actiTENS mini** warranty will no longer apply.

If the AC Charger is lost or damaged, contact your reseller or SUBLIMED so that you can obtain a new one.

If you use a power supply other than the one provided, it is your responsibility to ensure that it is compatible with the **actiTENS mini** and complies with medical safety requirements:

Criteria to check before using another power supply:

Comply with the following standards:
- IEC 60601-1 (with 2 MOPP),
- IEC 60601-1-2,
- FCC certified,

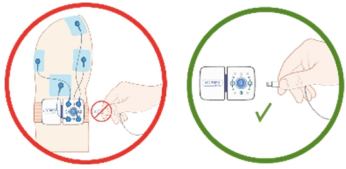
And its technical characteristics are:
- USB-C Connector
- Input voltage: 100-240 V, AC
- Input frequency: 50-60Hz
- Output voltage: 5V DC

Charging your actiTENS mini

Charge your **actiTENS mini** neurostimulator before each use. The charging time lasts around two and a half hours.

NB: The battery operating time depends on how the machine is used (type of program and intensity), the skin resistance of the patient and the surroundings.
NB: As with all similar devices, battery life performance diminishes over time.

Note: For your security, please take off the device, the cables and the electrodes of your body before charging your **actiTENS mini** with the AC charger provided.



- Carefully insert the USB-C cable into the USB-C socket in the **actiTENS mini**
- Connect the other end of the AC charger to the mains.
- When the light on the neurostimulator changes from blinking green (battery charging) to permanent green (battery charged), unplug the AC charger.

The charge level can be checked via the app, in the actiTENS menu.

Downloading the **actiTENS** app

There is an **actiTENS** app available that allows you to start and change the settings for your stimulation sessions.

You need to be connected to a mobile network or Wi-Fi to be able to download the app.
Download the **actiTENS** app from the App Store (iOS) or Google Play (Android). The app is only available on Google Play and App Store, any download of the app from another source is strongly discouraged.

From App Store (iOS) :

Télécharger dans l'App Store

From Google Play (Andoid) :

DISPONIBLE SUR Google Play

This app has been developed to work with Android or iOS smartphones or tablets compatible with Bluetooth Low Energy 5.2. Scan the QR code to see if you have access to the mobile app.

The Android and iOS versions supported may change with time. A major release of the mobile app comes with 3 years of support for the 4 latest versions of Android and iOS available. Contact our customer support for more information.

Getting to know the **actiTENS** app

- When you launch the app for the first time, a start-up screen is displayed. You will need to accept general terms and conditions to be able to use the actiTENS mini.
- You can create an optional user account to have access to more functionalities related to your health monitoring. A user account is necessary to keep your data in case you change phone or uninstall the app. You need to be connected to an internet network via mobile or Wi-Fi to be able to create your account.
- Your smartphone will communicate with the actiTENS mini neurostimulator via Bluetooth to control the stimulation program. actiTENS app will ask you to activate

Bluetooth. You can also manage Bluetooth activation via the “Settings” menu on your telephone.
You do not need to be connected to a mobile network or Wi-Fi to be able to use the actiTENS. Once the stimulation program is launched, the app continues to run in the background, and you can use your telephone as normal without interrupting your session.

Navigating within the actiTENS app.

At the bottom of the screen there is a navigation bar, with several icons that enable you to navigate within the app.

 Programs	**Programs :** • Select and launch a stimulation program
 My Health	**My Health:** • Stimulation session history • History of pain levels registered before and after sessions • Medical questionnaires and monitoring the impact of pain on your daily life
 actiTENS mini	**actiTENS mini :** • If the neurostimulator is not connected: connection button • If the neurostimulator is connected: **actiTENS mini** battery level • If a program is running, access to the remote control
 Help	**Help:** • Contraindications and key precautions for use • Start-up screen • SUBLIMED support Contact • **actiTENS mini** instructions for use
 My Account	**My Account:** • Contains options for creating or managing an account • Contains the account profile if it has been created • Contains the application settings

Pairing your actiTENS mini

Before installing the device, make sure it is connected to your mobile device. To do this, check the status (connected or not connected) of your **actiTENS mini** in the “actiTENS” menu of the mobile application.

The first time you use your **actiTENS mini**, you'll need to pair it with your phone:

- Open the **actiTENS** application and go to the “actiTENS” menu. Your **actiTENS mini** will appear not connected.
- Switch on your **actiTENS mini** (green light flashing)
- Press the central button for 3 seconds (blue light flashing).
- On the **actiTENS mini** menu in your mobile app, click on "Find your actiTENS".
- Accept the association between the two devices. Your mobile app is now connected to your **actiTENS mini**.

NB: If the association request does not work, check that your device's Bluetooth is activated. You can also pair your **actiTENS mini** from your phone's Bluetooth settings.

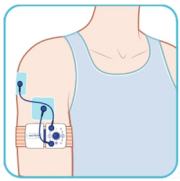
For future sessions, simply switch on your **actiTENS mini** and click on "Find your actiTENS". It will automatically connect to your phone.

Placing the device

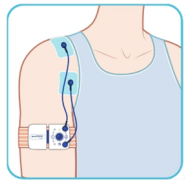
Preliminary step:

- Choose the number of electrodes based on the area to be stimulated: 2 or 4.
- Use as many cables as there are electrodes.

For two electrodes, only one channel on the neurostimulator will be active. For four electrodes, both channels on the neurostimulator will be active.

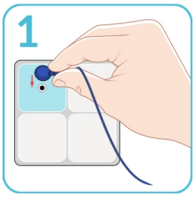


2 electrodes = 2 **cables**
Channel 1 **or** Channel

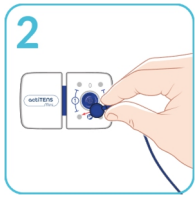


4 electrodes = 4 **cables**
Channel 1 **and** Channel

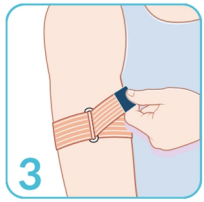
Installation steps:



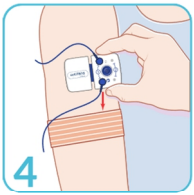
Clip the cables on the electrodes.



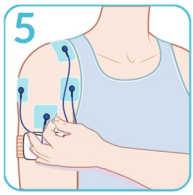
Clip the cables to the **actiTENS mini** stimulator.



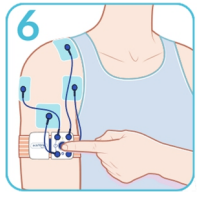
Install the armband on the desired body area[1].



Install the **actiTENS mini** neurostimulator.



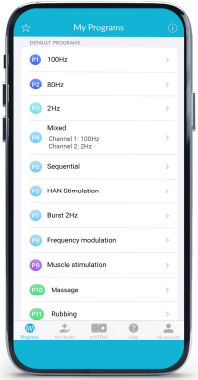
Stick the electrodes to the area to be stimulated.



Turn on the **actiTENS mini** [2] by pressing the ON/OFF button. The indicator light will blink green.

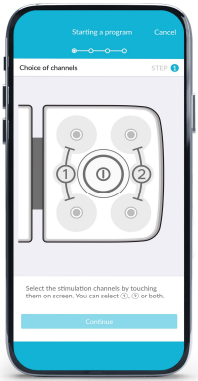
1. Depending on the textile accessory used, it can be worn on the arm, leg, chest, belt or bra.
2. If you have not previously switched it on.

Launching a program



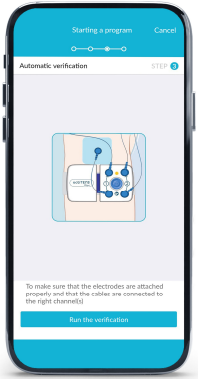
Step 1: Select the “Programs” menu from the navigation bar at the bottom of the screen

Step 2: Choose a program from the suggested list. (the list of programs and their descriptions are available in section 8 of these instructions for use)



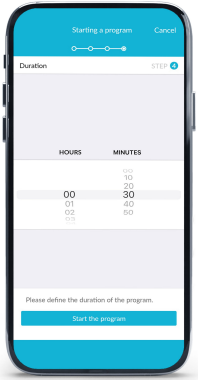
Step 3: Choose the channel or channels that you want to use.
Place the device on your body (if you have not already done so). For help, go to the “Placing the device” section (section 9). Turn on the neurostimulator by pressing the ON/OFF button. The indicator light will blink green.

Remember: Once turned on, if a program is not launched the neurostimulator will automatically turn off after 10 minutes.



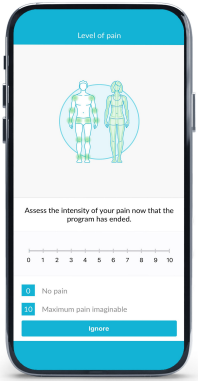
Step 4: Launch the automatic placement check. This step ensures that all the connections between the **actiTENS mini** neurostimulator, the cables, the electrodes and your body are working correctly.

NB: if there is an error, manually check the connections, cables and electrodes and repeat the automatic check.



Step 5: Define the program length. The app allows you to choose between 10 minutes and 12 hours of stimulation.

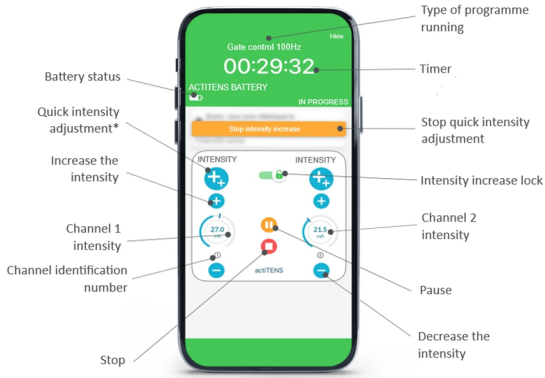
Each program type is automatically set to a default length, summarized in section 8 “Program overview”.



Step 6: Enter your pain level (an option that can be deactivated via the “My Account” menu) before your stimulation session. Historical data can be accessed via the “My Health” menu (see section 9).

NB: at the end of a session, you will be asked your pain level again.

The **actiTENS mini** control screen is displayed. The timer automatically starts when you start adjusting the intensity. You need to adjust the stimulation intensity.



The stimulation intensity should be adjusted to balance a tolerable sensation with a decrease in pain. A high intensity is not necessarily more effective than a moderate intensity and can even cause discomfort.

*The quick intensity adjustment function allows you to select the intensity level wanted. Once the intensity is selected, the device gradually increases the intensity automatically until the set value is reached. This function can be accessed after a few stimulation sessions.
To stop the automatic increase, simply press the button or the dedicated button: "Stop intensity increase" (Stop intensity increase).

A lock is automatically applied after 10 seconds to prevent any unwanted change in intensity level. To unlock the setting, press on the padlock. Even if the lock is activated, it is possible to reduce the intensity.

Note: You can adjust the position of the electrodes using the “Pause” mode. The session is suspended, and the electrodes can be handled safely. Restart the program after repositioning the electrodes, and set the intensity again.

Stopping a stimulation session

Stopping at the end of a session:

- The stimulation session stops automatically at the end of the time set. A notification appears to confirm the end of the session.

Stopping during a session:

A session can be stopped temporarily or permanently while it is running.

- To stop it temporarily, use the Pause button ( ).
- To stop it permanently, use the Stop button ( ). If the session is permanently stopped, a notification appears to confirm the end of the session.
  It is also possible to stop a session by pressing the ON/OFF button on the neurostimulator. This option is not recommended as this will mean the session recordings will be incomplete.

Taking off the device

Before taking off the device, make sure that a session is not running: the light should be blinking green or off.
Carefully unstick the electrodes and put them back on their plastic film before placing them in their bag.

The cables can be detached from the actiTENS stimulator and the electrodes by carefully unpluggging the connectors (do not pull on the cables).

Following-up your treatment

In the "My Health" menu you can consult or enter various data related to your health and your treatment. The application saves this data on your phone and in your user account so that it can be retrieved if you change phones or uninstall the application.

You can view and share this data with your healthcare professional to potentially adapt your treatment.

actiTENS mini updates

It is highly recommended to keep your phone and mobile app up to date, to get the best user experience your device has to offer, and for security reasons. Updates will be available for:

- **actiTENS** the mobile app
- **actiTENS mini** the neurostimulator

Updating the actiTENS mobile app

Use App Store to check on available updates. A link to the application store is available via the “Settings” menu in the app.

Updating the actiTENS mini neurostimulator

Step 1: Install the last version of the mobile app.
Step 2: The mobile app will warn you in the event of an available update of the neurostimulator **actiTENS mini**. The **actiTENS mini** can also be updated via the “Programs”, “**actiTENS mini**” and “My Account” menus.
Step 3: Make sure that the **actiTENS mini** and your phone are sufficiently charged (at least 50%) and that you maintain the Bluetooth connection between your phone and the **actiTENS mini** throughout the operation.
Step 4: Follow the onscreen instructions. The light indicator blinks white during the update and becomes blinking green when it is finished.

10. INDICATOR LIGHT: MEANING

MODE	LIGHT		MEANING
When charging		Blinking green Medium frequency (1.4 times per second)	Battery charging ongoing
		Permanent green	Battery is charged
		Blinking pink	**actiTENS mini** neurostimulator error
During use		Blinking green Low frequency (0.8 times per second)	**actiTENS mini** turned on with no session started
		Blinking blue Medium frequency (1.4 times per second)	**actiTENS mini** is ready for Bluetooth pairing
		Blinking green High frequency (2.8 times per second)	On Pause
		Permanent yellow	Session running, following automatic placement check
		Blinking pink	**actiTENS mini** neurostimulator error
		Blinking white High frequency (2.8 times per second)	**actiTENS mini** is updating. For further details, please refer to section 9.

11. STORAGE CONDITIONS, CLEANING AND DISPOSAL

Storing consumables (electrodes and self-adhesive strips)

- Storing the electrodes and the self-adhesive strips: it is important to replace the plastic film back on the electrodes and the self-adhesive strips and return them to their protective bag. To prevent them from getting dusty, close the bag entirely. Store them in a dry place. Avoid extremes of heat and exposure to direct sunlight.

- Electrodes, self-adhesive strips and textile accessories can be reused several times. The number of uses depends on skin type, climate, and precautions taken during use and storage.
- The electrodes have been tested for 20 sticking/unsticking operations. It is nevertheless advisable to change the electrodes every 2 weeks, or as soon as signs of degradation appear.
- Self-adhesive strips were tested for 7 sticking/unsticking operations. For several stimulation sessions a day, we recommend keeping the adhesive backing stuck to the skin between sessions, to improve its longevity. We recommend changing your adhesive backing every week.

For replacing your electrodes by new ones, contact the supplier who supplied you the actiTENS mini kit. Please only use electrodes supply by SUBLIMED with references mentioned in section 15.

Storing the neurostimulator

- Keep the device away from water and other liquids.
- Avoid storing at high temperatures and humidity. How to store the **actiTENS mini** neurostimulator and its accessories are stated on the labels and in section 16.
- After use, return the device to its original packaging to prevent it from getting damaged.

Cleaning

- Make sure that the **actiTENS mini** neurostimulator is turned off disconnected from the AC Charger before cleaning it.
- Never immerse or rinse the **actiTENS mini** neurostimulator in water. Never place the consumables in water. Do not use any other cleaning materials than the ones listed below. They could seriously damage the device.
- Using a damp cloth and mild detergent (e.g., washing up liquid), clean the **actiTENS mini** neurostimulator, its cables and the AC charger. 70° isopropyl alcohol (IPA) can also be used to clean the **actiTENS mini** neurostimulator.
- If the electrodes are dirty, moisten your finger with a few drops of water and carefully remove the dust from the surface. Under no circumstances should soap or alcohol be used to clean the electrodes.
- Textile accessories should be machine-washed at 40°C with a mild detergent before first use, and every 3 weeks thereafter.

Disposal

- Plastic packaging and instruction leaflets are recyclable.
- The electrodes and self-adhesive strips can be placed with household waste.
- Waste electrical and electronic equipment (WEEE), namely the neurostimulator, the AC charger and the cables must be recycled in accordance with the regulations in each country.

12. SERVICE LIFE AND GUARANTEE

Part	Length of guarantee	Service life
actiTENS mini neurostimulator	2 years	5 years
Cables	Not guaranteed	1 year
Electrodes and self-adhesive strips	Consumables are not guaranteed: refer to the use and storage instructions	2 weeks of treatment
Textile accessories	Not guaranteed	24 months

Consult the cleaning and storing precautions.

The neurostimulator and its parts are guaranteed under normal conditions of use.

- After the guarantee period, no maintenance of the device and its parts is included.
- Do not attempt to modify the device, as this invalidates the guarantee.
- Under normal conditions of use, **actiTENS mini** neurostimulator is designed for a service life of at least 5 years.
- Contact your reseller or SUBLIMED:
  - For help in placing or using the device, if needed
  - To report unexpected operations or events.

13. CUSTOMER SUPPORT

Errors seen:

- Indicator light flashing pink

Possible cause	Solution
actiTENS mini error	Turn off the device immediately and leave it for fifteen minutes then turn it back on again. If the error has not cleared, contact the Customer support.

NB: If you use the **actiTENS mini** neurostimulator at the maximum setting for several hours, the device may overheat and display an error as a safety precaution. If this is the case, wait for the machine to fully cool down. It is normal for the device to get hot during a session, however this heat is not harmful and will not damage the device. Under normal conditions, the **actiTENS mini** can reach a maximum temperature of 42.3 °C [108.1 °F].

- A connection error has been detected

Possible cause	Solution
1- Channels not correctly selected when starting a program	Check that the channel(s) selected when starting the program corresponds to the configuration set up on the **actiTENS mini**.
2- Cables not properly connected	Check that the cables are properly connected to the **actiTENS mini** and the electrodes.
3 - The cables are defective	Check the condition of the cables. Test cables 2 by 2, running a program on a single channel to identify any faulty cables.
4- Electrodes not correctly installed	Check that the electrodes are correctly installed on the skin and not too worn.

- The **actiTENS mini** does not switch on

Possible cause	Solution
1- The battery is not charged	Charge the **actiTENS mini.**
2- **actiTENS mini** error	Turn off the device immediately and leave it for fifteen minutes then turn it back on again. If the error has not cleared, contact the Customer support.

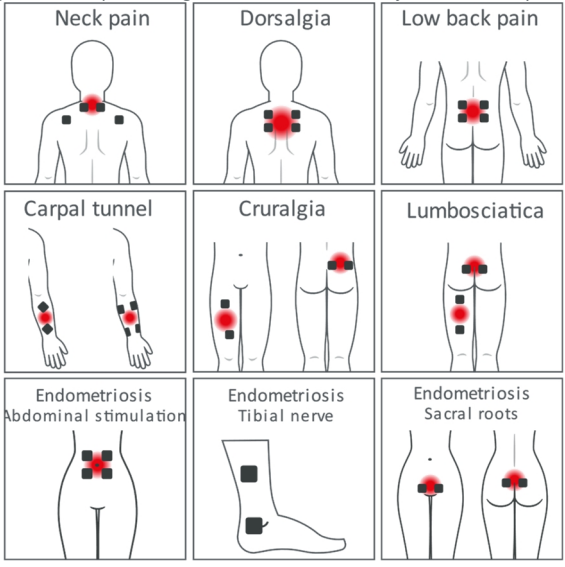
- The **actiTENS mini** has disconnected

Once a program has been launched, disconnection does not affect the operation of the **actiTENS mini**. The strength of the Bluetooth signal can vary depending on how much charge your phone or the **actiTENS mini** features. Some telephones are designed to disconnect more quickly to save battery charge. To reconnect your **actiTENS mini**, go to the **actiTENS mini** menu and touch “Detect an **actiTENS**”.

14. POSITIONING THE ELECTRODES

The electrodes can be positioned depending on the area of pain to be stimulated, by either using 2 or 4 electrodes. It is highly recommended that you make an appointment to see a healthcare professional to test the positioning of the electrodes, to get the best pain relief from your device.

When testing to determine the optimal placement, select an initial electrode positioning and launch a program. To adjust the positioning, use the “Pause” mode (⏸). The session is then suspended, and the electrodes can be handled safely. Re-start the program after repositioning the electrodes and re-adjust the intensity.



15. CATALOGUE REFERENCES

actiTENS mini Kit..... SBM7AA011

- actiTENS (neurostimulator)..... SBM7AA100
- 1 pack of 2 **actiTENS mini** 40 cm cables..... SBM7AE001
- 1 pack of 2 **actiTENS mini** 14 cm cables..... SBM7AE002
- 1 pack of 2 **actiTENS mini** 70 cm cables..... SBM7AE004
- 1 actiTENS armband – 70 cm..... SBM1AG301
- 1 pack of 4 actiTENS electrodes 50 mm x 50 mm..... SBM1AC003
  (Manufactured by GMDASZ Manufacturing Co, FDA cleared K160138)
- 1 **actiTENS mini** AC Charger..... SBM7AF210
- 1 **actiTENS mini** instruction for use..... SBM7AL110
- 1 **actiTENS mini** transport case..... SBM7AH100

Optional accessories (to order separately):

- Pack of 4 actiTENS electrodes diameter 32 mm..... SBM1AC001
  (Manufactured by GMDASZ Manufacturing Co, FDA cleared K160138)
- Pack of 4 actiTENS electrodes diameter 50 mm SBM1AC002
  (Manufactured by GMDASZ Manufacturing Co, FDA cleared K160138)
- Pack of 4 actiTENS electrodes 50 mm x 90 mm..... SBM1AC004
  (Manufactured by GMDASZ Manufacturing Co, FDA cleared K160138)
- Pack of 4 mixed actiTENS electrodes 50 mm x 50 mm and 50 mm x 90 mm..SBM1AC005
  (Manufactured by GMDASZ Manufacturing Co, FDA cleared K160138)
- Pack of 8 actiTENS electrodes 50 mm x 50 mm SBM1AC008
  (Manufactured by GMDASZ Manufacturing Co, FDA cleared K160138)
- Pack of 2 actiTENS multisite electrodes..... SBM1AN001
  (Manufactured by GMDASZ Manufacturing Co, FDA cleared K160138)
- Pack of 2 actiTENS low back electrodes..... SBM1AD002
  (Manufactured by GMDASZ Manufacturing Co, FDA cleared K160138)
- Pack of 4 UltraStim® snap Electrodes sensitive skin 50 x 50 mm.....SBM1AC006
  (Manufactured by Axelgaard Co., FDA cleared under K130987)
- Pack of 4 UltraStim® snap Electrodes 50 x 50 mm.....SN2020
  (Manufactured by Axelgaard Co., FDA cleared under K130987)
- Pack of 2 actiTENS 100 cm cables..... SBM1AE003
- actiTENS self-adhesive strip..... SBM1AB011
- actiTENS armband – 40 cm..... SBM1AG300
- actiTENS armband – 130 cm..... SBM1AG302
- actiTENS belt/bra accessory..... SBM1AG400

16. TECHNICAL DATA SHEET

Technical information	
System	The combination of power supply and neurostimulator forms an electro-mechanical system.
Intended operator	Lay users (patients and caregivers) and healthcare professionals. All users must be over 22 years of age and have undiminished intellectual capacity.
Channels	2 separate channels
Programs	13 programs, including: - Programs 80 and 100 Hz, pulse width 150-200 µs - Program 2 Hz, pulse width 250 µs - Combined programs - EMS (Electric Muscle Stimulation) program Current delivered: from 1 mA to 60 mA ± 10% with a 0.5 mA step
Battery	Li-Ion
Output voltage and intensity of the **actiTENS mini** neurostimulator	max 60 mA ± 10% (1000 Ω) / max 60 V ± 10%
Essential performance of **actiTENS mini** neurostimulator	Does not deliver a current > 60 mA ± 10% or a voltage > 60 V ± 10%
Input AC charger voltage, intensity	100-240 V AC 0.1-0.2 A
Power supply frequency	50-60 Hz
Conditions of use for the **actiTENS mini** neurostimulator	From 10°C to 40°C (50°F to 104°F) with a relative humidity from 15% to 93% Atmospheric pressure700 hPa to 1060 hPa
Conditions of use for the AC charger	From 0°C to 40°C (32°F to 104°F) with a relative humidity from 10% to 90%
Charging conditions	Ambient temperature
Storage conditions for the **actiTENS mini** kit	From 5°C to 35°C (41°F to 95°F) with a relative humidity from 30% to 80% Temperature between 15°C and 23°C (59°F and 73.4°F) are best suited to preserve the battery's capacity

Storage conditions for the **actiTENS mini** neurostimulator	From -10°C to 45°C (14°F to 113°F), with a maximum relative humidity of 93% Temperature between 17°C and 23°C (62.6°F and 73.4°F) are best suited to preserve the battery's capacity
Storage conditions for the AC charger	From -20°C to 85°C (-4°F to 185°F)
Warm up time before start when stocked at -10°C to ambient temperature (20°C)	5 minutes maximum
Cool down time before start when stocked at 45°C to ambient temperature (20°C)	10 minutes maximum
Dimensions of the neurostimulator	92 mm x 56 mm x 13 mm
Weight of **actiTENS mini** neurostimulator	~ 60 g
IP classification of the **actiTENS mini** neurostimulator	IP22: protection from touch by fingers and objects greater than 12.5 mm, protection from water spray up to 15° from vertical
Waveform	Compensated asymmetrical biphasic waves
Pulse width	50-400 µs ± 5 µs
Frequency	1-120 Hz ± 10%
Treatment time	Session duration:10 min-12 h, adjustable via the mobile app.
Electrodes	Any electrode for which the density of current exceeds 2 mA/cm² requires special attention, stimulation should never be painful
Electrodes storage conditions	From 5°C to 35°C (41°F to 95°F) with a relative humidity of 30% to 80 %
Sensitive skin électrodes storage conditions	From 5°C to 27°C
Storage conditions for the self-adhesive strips	From 0°C to 40°C (32°F to 104°F)
Composition of the actiTENS textile accessories	Main fabric: 58% polyamide, 30% polyester, 12% elastane Label: 90% Polyamide, 10% Elastane Buckle and Velcro: Polyamide

Composition of the multisite and low back electrodes	Conductive biocompatible hydrogel (High polymer material, Glycerin, Water, Salt), conductive part: vinyl carbon, insulating base material: 25-micron PET non-woven, Velours: polyamide, snap connector: 316 stainless steel.
Composition of the electrodes in the kit	Biocompatible hydrogel conductor (High polymer material, Glycerin, Water, Salt), conducting part: carbon + PE; insulating base material: non-woven PET fiber, snap connector: stainless steel
Composition of sensitive skin electrodes	Biocompatible hydrogel conductor formulated for sensitive skin, conducting part: silver, insulating base material: water repellent fabric, snap connector: stainless steel

General information on battery :

The battery is not replaceable by a lay user, only the **actiTENS mini** manufacturer can replace the battery.

Manufacturer's name	JUHEYUAN SCIENCE & TECHNOLOGY CO., LTD.
Company name or registered trademark	Alium
Adress	No. 47, Longfeng Road, Xinsheng Community, Longgang Street, Longgang District, Shenzhen .
Website	www.jhypower.com
E-mail	kai.zhong@changhong.com
Battery category	Portable rechargeable battery, non-replaceable
Model	ABI-H653034
Weight	14 g
Capacity	700mA/h
Chemical characteristics	Lithium-ion polymere (LIP)
Suitable extinguishing agents	Powder extinguishers
Raw materials	Lithium Cobalt Oxide, Polyvinylidene Fluoride (PVDF), Aluminum, Graphite, Styrene-Butadiene Rubber (SBR), Carboxymethylcellulose, Copper, Nickel, Lithium Hexafluorophosphate, Polyethylene, Nylon, Polypropylene

Symbols	Description of symbols used
	This device includes a Radio Frequency transmitter and emits non-ionizing radiation. The device is connected to a mobile app via Low Energy Bluetooth. Frequency range: [2400 – 2483.5] MHz Modulation: DSSS EIRP: -9.8dBm
	Read the instructions for use closely before using.
	Read the instructions for use thoroughly before use.
	Design for INTERIOR use only. This is only valuable when the **actiTENS mini** is charging (connected to the main)
	Disposed in accordance with EU WEEE Directive (UE only).
	Electrical input.
	Electrical output.
	Direct current.
	Alternating current.
	Importer’s name and address.
	Distributor’s name and address.
	Manufacturer’s name and address.
	Medical device
	Humidity range the device can be exposed to.
	Minimum and maximum temperatures the medical device can be exposed to.
	Read the instructions for use
	Class II device.
	Device with a degree of protection against electric shocks, conform to the standard IEC 60601-1. Any shell for the **actiTENS mini** is a BF type applied part. This is the only applied part of the **actiTENS mini**.

Symbols	Description of symbols used
	Expiration date.
	Reference of the device.
	Batch number of the device.
	Serial number of the device.
	Quantity of product
	Name and address of authorized representative in the European Community.
	Name and address of Swiss agent's registered office.
	Status of the neurostimulator battery.
	Medical device that can be used several times on a single patient.
	Maximum wash temperature 40°C (105°F).
	Do not iron.
	Do not bleach.
	Do not dry clean.
	Do not tumble dry.
	Leaflets and plastic packaging recyclable in France.
	The electromagnetic interference from the device is under limits approved by the Federal Communications Commission.
	**actiTENS mini** is MR Unsafe
	CE marked (UE only).
	ON/OFF button symbol for turning the stimulator on and off.

17. ELECTROMAGNETIC COMPATIBILITY

The **actiTENS mini** is intended for clinical use and home use.
The **actiTENS mini** is intended to be used in the electromagnetic environment specified below. The user of the **actiTENS mini** must ensure that it is used in such an environment.

WARNINGS

- Do not use portable Radio-Frequency communication equipment (including peripherals such as antenna cables and external antenna) less than 30 cm (12 inches) from the **actiTENS mini** neurostimulator. Otherwise, the performance of the **actiTENS mini** neurostimulator and these devices may be affected. Go to Table 2 for more details about the equipment tested.
- The **actiTENS mini** neurostimulator should not be used next to other electronic devices or stacked with them. This could cause a malfunction. If this use is necessary, the operation of the **actiTENS mini** neurostimulator and other devices should be observed to ensure that they operate normally.
- The use of accessories and cables other than those supplied with the **actiTENS mini** neurostimulator or mentioned in this guide is not permitted. Using other accessories or cables may result in an increase in electromagnetic emissions, reduce immunity and cause a malfunction of the **actiTENS mini**.

Table 1: Directives and declaration by the manufacturer – Electromagnetic emissions

Emission test	Conformity	Electromagnetic environment - Directives
CISPR 11 RF Emissions	Group 1	The **actiTENS mini** only uses RF energy for its internal functions. As a result, its RF emissions are very low and are not likely to cause interferences with nearby electronic device.
CISPR 11 RF Emissions	Class B	The **actiTENS mini** is suitable for use in all premises, including domestic premises and those connected directly to the public low-voltage electricity power network supplying domestic use buildings.
IEC 61000-3-2 Harmonic current emissions	Class A	
IEC 61000-3-3 Voltage fluctuations / Flicker	Conform	

Table 2: Directives and declaration by the manufacturer - Electromagnetic immunity

Immunity test	IEC 60601-1-2 Test level	Level of conformity	Electromagnetic environment - Directives
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV at contact ± 2, 4, 6, 8 and 15kV in the air	± 8kV at contact ± 2, 4, 6, 8 and 15kV in the air	Stimulation should not be initiated until the device has been placed in accordance with the procedure described in §8. The floors should be made from wood, concrete or ceramic tiles. If the floors are covered with synthetic materials, it is recommended that the relative humidity is less than 30%.
IEC 61000-4-4 Electrical Fast Transient / Burst Immunity	± 2kV for electrical power lines ± 1kV for input/output lines Repetition frequency 100kHz	± 2kV for electrical power lines ± 1kV for input/output lines Repetition frequency 100kHz	The quality of the electrical power supply network should be either that of a typical commercial or hospital environment.
IEC 61000-4-5 Transient surge	± 0.5, ± 1 kV between phases ± 0.5, ± 1, ± 2 kV between phase and earth	± 0.5, ± 1 kV between phases ± 0.5, ± 1, ± 2 kV between phase and earth	The quality of the electrical power supply network should be either that of a typical commercial or hospital environment.
IEC 610004-11 Voltage dips, short interruptions and voltage variations on electrical power supply lines	0% UT for a duration of 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% Ut for a duration of 1 cycle, 70% for a duration of 25 / 30 cycles, both at 0 ° 0% Ut for a duration of 250/300 cycles at 0	0% Ut for a duration of 0.5 cycle at 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °, 315 ° 0% Ut for a duration of 1 cycle, 70% for a duration of 25 / 30 cycles, both at 0 ° 0% Ut for a duration of 250/300 cycles at 0	The quality of the electric power network should be that of a typical commercial or hospital environment. If the **actiTENS mini** user requires continuous functioning during cuts in the electric power supply, it is recommended to power the **actiTENS mini** using an energy source that does not experience cuts or a battery.

Immunity test	IEC 60601-1-2 Test level	Level of conformity	Electromagnetic environment - Directives
IEC 61000-4-8 Magnetic field at the frequency of the electric network (50/60Hz)	30A/m 50 and 60Hz	30A/m 50 and 60 Hz	The magnetic fields at the frequency of the electric network should have the characteristic levels of a representative place located in a typical commercial or hospital environment.
IEC 61000-4-6 Disturbances Conducted RF	3Vrms from 150kHz to 80MHz 6V in ISM bands	3Vrms from 150kHz to 80MHz 6V in ISM bands	RF portable and mobile communication devices should not be used closer to any part of the **actiTENS mini**, including the leadwires than the recommended separation distance calculated on the basis of the equation that applies to the emitter's frequency. Recommended separation distance d=1.2 √P
IEC 61000-4-3 Radiated RF disturbances	10V/m from 80MHz to 2.7GHz	10V/m from 80MHz to 2.7GHz	d=1.2 √P for a frequency between 80MHz and 800 MHz d=2.3 √P for a frequency between 800 MHz and 2.7 GMHz where P is the characteristic of the maximum output power of the emitter in Watts (W), according to the manufacturer of the emitter and d is the recommended separation distance in meters (m). The intensities of the fixed RF emitters, determined by an electromagnetic investigation on site[a], should be less than the level of conformity in each frequency range[b]. Interferences may occur near devices marked with the following symbol: 

Immunity test	IEC 60601-1-2 Test level	Level of conformity	Electromagnetic environment - Directives
IEC 610004-3 Proximity fields emitted by wireless RF communication equipment	The equipment must not be used within 30cm of other electronic devices. Services: TETRA 400, GMRS 460, FRS 460, LTE Band 13, 17, GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5, GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS, Bluetooth, WLAN, 820.11 b / g / n, RFID 2450, LTE Band 7, WLAN 802.11 a/n. In accordance with the levels expected by the IEC60601-1-2	The equipment must not be used within 30cm of other electronic devices. Services: TETRA 400, GMRS 460, FRS 460, LTE Band 13, 17, GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5, GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS, Bluetooth, WLAN, 820.11 b / g / n, RFID 2450, LTE Band 7, WLAN 802.11 a/n. In accordance with the levels expected by the IEC 60601-1-2	The **actiTENS mini** has been tested and found compatible in the corresponding environments.

NOTE 1: At 80MHz and 800MHz, the highest frequency range applies.
NOTE 2: These directives may not apply in all situations. Electromagnetic propagation is affected by the absorption and the reflection of structures, objects and people.

[a]The intensities of field of the fixed emitters, such as the base stations for radio-telephones (cellular/wireless) and mobile terrestrial radios, amateur radio, AM and FM radio diffusion, and TV diffusion, cannot, in theory, be predicted with precision. To evaluate the electromagnetic environment from fixed RF emitters, an electromagnetic investigation at the site should be considered. If the intensity of the field, measures at the place where the **actiTENS mini** is used, exceeds the level of RF conformity applicable above, the **actiTENS mini** should be observed to verify that it is working normally. If you observe abnormal performances, additional measures may be necessary, such as reorienting or repositioning the **actiTENS mini**

[b]On the frequency range from 150kHz to 80MHz, the intensities of the field should be less than 3V/mand 6V/m for ISM bands.

Table 3: Recommended separation distances between RF portable and mobile communication devices and the actiTENS mini

Maximum power output assigned to the emitter W	Separation distance according to the frequency of the emitter m		
	from 150kHz to 80MHz d=1.2 √P	From 80MHz to 800MHz d=1.2 √P	from 800MHz to 2.7GHz d=2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For emitters, the maximum output power of the assigned is not given above, the recommended separation distance d in meters (m) may be determined by using the equation that applies to the emitter's frequency, where P is the characteristic of the maximum emission power of the emitter in Watts (W), according to its manufacturer.

NOTE 1: At 80MHz and at 800MHz, the separation distance for the highest frequency range applies.

NOTE 2: These directives cannot apply in all situations. Electromagnetic propagation is affected by absorption and by the reflection of structures, objects and people.

18. FCC COMPLIANCE STATEMENT

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.
NOTE: The grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user's authority to operate the equipment.

NOTE: 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 or more 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.

As the device is in class B, which is more restrictive than class A, it can be used in a commercial environment, particularly in hospitals.

This portable equipment with it's antenna complies with FCC's radiation exposure limits set forth for an uncontrolled environment. To maintain compliance, follow the instructions below :

1. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. Avoid direct contact to the antenna, or keep contact to a minimum while using this equipment.

HVIN: A0
FCC ID: 2BALKSB7

INFORMATION:

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is not required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:
Report Online at
www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at
www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

Call FDA at 1-800-FDA-1088 to report by telephone.
Reporting Form FDA 3500 commonly used by health professionals. The form is available at
www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf

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