SUBLIMED

actiTENS
INSTRUCTIONS FOR USE

The actiTENS device is a transcutaneous electrical nerve stimulator to be used to ease pain in people ages 22 and older. The stimulator is set on a self-adhesive strip, directly on the body. Thanks to the flexible design, it fits your body shape and can be discreetly used during your daily activities.

It is operated through a smartphone app that allows you to choose from a wide number of stimulation programs and to save all the information recorded from the stimulation treatment sessions.

To get the most out of your actiTENS, a healthcare professional will instruct you how to correctly position the electrodes and to select an appropriate stimulation program for your specific needs.

Table of content

1. INTENDED USE / INDICATIONS FOR USE

actiTENS 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 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 electrodes placement.
- Allodynia.
- Allergy to electrodes.
- Pregnant women.
- Children (under 22).

3. WARNINGS AND PRECAUTIONS FOR USE


Help

- This guide is continuously being updated; to view the latest version, go to the “Help” menu in the actiTENS app.
- 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, 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 stimulator 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).
- Do not use the stimulator 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 stimulator.
- 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 neurostimulator and the charging case - there is a risk of electric shock.
- Do not use the actiTENS neurostimulator and the charging case 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 and the charging case 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 neurostimulator and the charging case away from water and other liquids.

- Do not use the device in a flammable environment (ex: gas station).
- Do not use the actiTENS device in emergency medical services.
- We recommend that you do not use the actiTENS 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 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.
- **The stimulator should be used only with actiTENS accessories listed in section 21.** The use of other accessories may lead to a deficient operation.
- Warnings about the electrodes used with actiTENS stimulator:
  - 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.
  - Before removing the electrodes from the skin, turn off the stimulator by stopping the session from the application or by pressing the ON/OFF button. If an electrode comes off, turn off or pause the stimulator before touching the electrode. Electrical pulses to the fingers from the stimulator are unpleasant, but not harmful in any way. See page 26 “Stopping a stimulation session”.
  - Do not superimpose electrodes.
  - It is recommended to not use conducting gel with the electrodes.

- Use of the stimulator can irritate the skin or cause inflammation, allergy or burns at the electrode sites.
- For hygiene reasons, each set of electrodes should be used for only one patient.
- Please only use electrodes supply by Sublimed with references mentioned in the section 21
- For replacing your electrodes by new ones, contact the supplier who supplied you the actiTENS Standard kit.
- Do not use electrodes beyond their intended lifetime for safety reasons.

- Always keep the actiTENS stimulator and its accessories out of the reach of children under 22, pets, and people with intellectual limitations (risk of strangulation, mild electric shock...).
- The use of actiTENS can in some cases causes hyperalgesia. We recommend that you stop using the device and tell your doctor.
- Precautions for the use of the self-adhesive strip with the actiTENS:
  - Do not place the self-adhesive strip 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.
- Do not disconnect the cables connected to the electrodes or the actiTENS stimulator by pulling on the cables. This action may cause a cable rupture.
- Handle the connectors with care, and in particular pay attention to the direction of insertion of the micro-USB connector of the power supply in the charging case.
- Do not use the stimulator during physical activities that may involve collision or impact.
- If you drop the actiTENS or the charging case, 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 stimulator or its accessories if it is malfunctioning or any part is damaged. Always check the system before using.
- actiTENS stimulator must be charged inside a room (ambient temperature).

- The actiTENS neurostimulator must only be recharged using the power cable supplied with the device.
- Do not use the stimulator while it is charging.
- When plugging in the AC charger during device use, ensure that the mains plug (disconnecting device) remains accessible.
- Keep your applications and devices up to date.
- Do not store the actiTENS 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.

4. THERAPY

4.1. 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 choice is based on how each patient feels. Do not hesitate in contacting your healthcare professional.

4.2. 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 in contacting your healthcare professional.

5. DEVICE OVERVIEW

actiTENS Standard kit:

- **1 actiTENS (stimulator)**

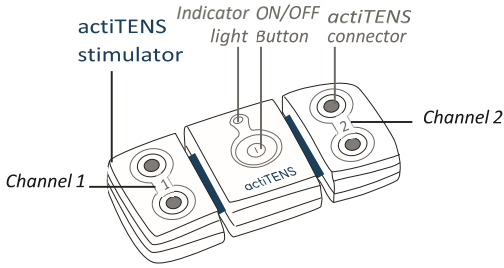
To place the device on the body:

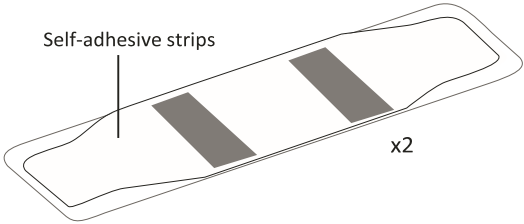
- **1 pack of 2 self-adhesive strips**
  (which corresponds to 2 weeks of treatment)
- **2 packs of 2 medium 40 cm**
- **1 Pack of 4 UltraStim® snap Electrodes 50 x 50 mm**
  These electrodes are FDA cleared under K130987, manufactured by Axelgaard Co., Ltd.

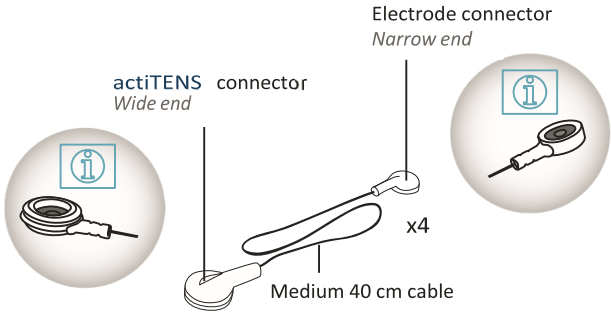
For charging the device:

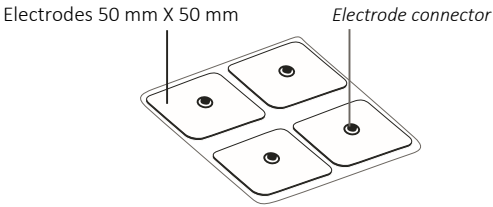
- **1 Charging case**
- **1 AC charger**
- **1 instruction for use**
- **1 Quick-start guide**

Remember: the two ends of the cable are different. Make sure you clip the wide end to the actiTENS and the narrow end to an electrode.

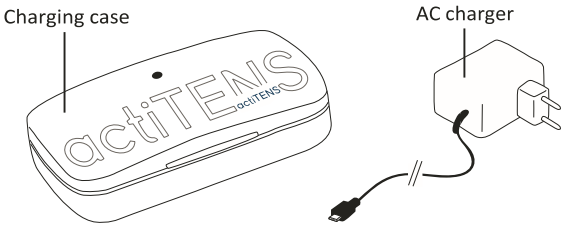








For charging the device



6. INDICATOR LIGHT : MEANING

Mode	Light	Meaning
When charging	 Blinking green Medium frequency (1.4 times per second)	Battery charging
	 Permanent green	Battery is charged
	 Blinking red	actiTENS stimulator error
	 Blinking blue High frequency (2.8 times per second)	actiTENS is updating. It is important to complete the update to be able to use actiTENS. For more details see chapter 15
During use	 Blinking green Low frequency (0.8 times per second)	actiTENS turned on with no session started or paused
	 Blinking green High frequency (2.8 times per second)	actiTENS stimulator paused
	Permanent yellow	Session running, following automatic placement check
	 Blinking red	actiTENS stimulator error
	 Blinking blue High frequency (2.8 times per second)	actiTENS is updating. It is important to complete the update to be able to use actiTENS. For more details see chapter 15

All of this information, plus the actiTENS *stimulator battery level indicator are also available via the app in the* actiTENS *menu at the bottom of the screen.*

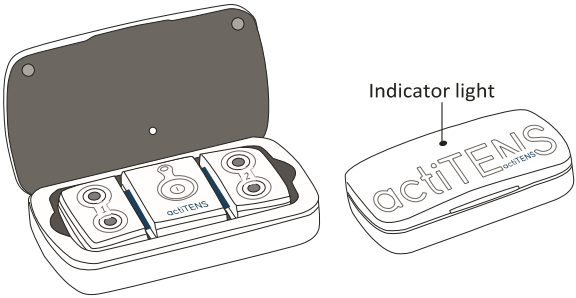
7. CHARGING YOUR actiTENS

Charge your actiTENS stimulator 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.

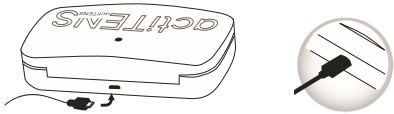
NB: to ensure the performance and safety of the machine, the AC charger (SBM1AF211) provided with the actiTENS must be used at all times. Using other AC charger invalidates the actiTENS guarantee.

How to charge your actiTENS?

- Place the actiTENS stimulator into its charging case and close the cover. See the illustration below for the correct way to place the device in the case.

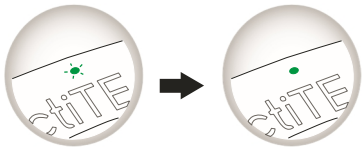


- Carefully insert the micro-USB cable into the micro-USB socket in the charging case in the correct direction.



- Connect the other end of the AC charger to the mains.

- When the light on the stimulator changes from blinking green (battery charging) to permanent green (battery charged), unplug the AC charger and disconnect the micro-USB from the charging case.



How to check how much charge your actiTENS **stimulator has?**

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

actiTENS

8. 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).

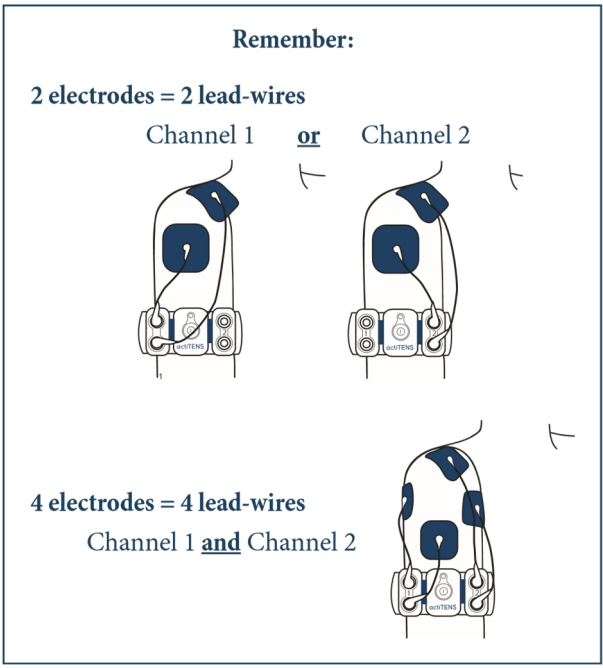
The app is only available on Google Play and App Store, any download of the app from another source is strongly discouraged.
This app has been developed to work with Android or iOS smartphones or tablets compatible with Bluetooth Low Energy 4.2. The Android and iOS versions supported may change with time. A major release of the mobile app comes with 3 years of support for the 4 latest versions of Android and iOS available.

IMPORTANT: although we try to make sure our device is up to date, it is possible that some smartphones are not compatible with our app. This incompatibility may be temporary and can sometimes be resolved by updating your phone and/or the actiTENS app.

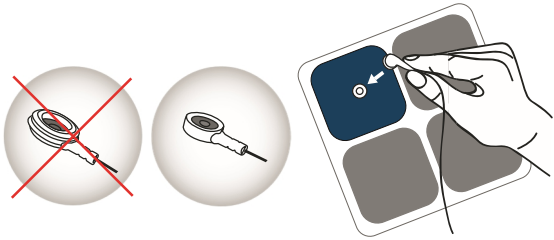
9. PLACING THE DEVICE

- 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 stimulator will be active. For four electrodes, both channels on the stimulator will be active.

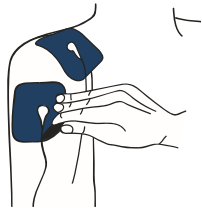


- Step 1: clip the narrow end of the cables to either 2 or 4 electrodes.



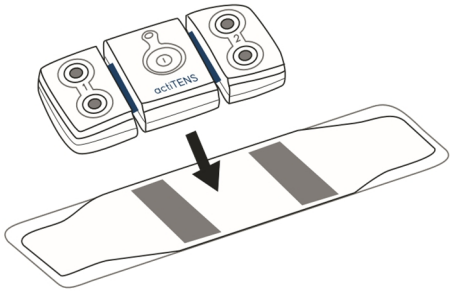
- **Step 2**: stick the electrodes to the area to be stimulated.

  Example using two electrodes



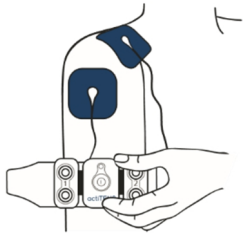
To get the most out of your treatment, do not hesitate to contact a healthcare professional who can help you to correctly position the electrodes.

- **Step 3**: attach the actiTENS stimulator to the self-adhesive strip.

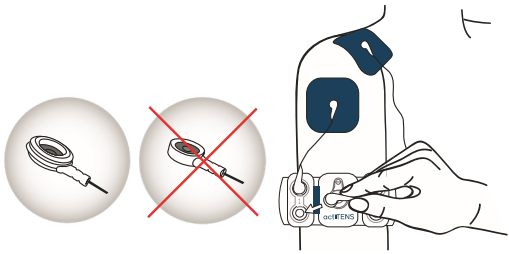


- **Step 4**: stick the self-adhesive strip attached to the actiTENS near to the electrodes.

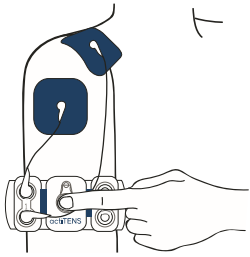
  Example using two electrodes



- **Step 5**: clip the cables (wide end) to the actiTENS stimulator.



- **Step 6**: turn on the stimulator by pressing the ON/OFF button. The indicator light will blink green.



Your device is ready for your stimulation session. When you want to start a session, follow the instructions for "**Launching a program**" (section 11).

Remember : the stimulator will automatically turn off after 10 minutes if a session is not launched.

10. GETTING TO KNOW THE actiTENS APP

- When you launch the app for the first time, a **start-up screen** is displayed to remind you of contraindications. This start-up screen includes links to the latest version of the instruction for use, the privacy policy and general terms and conditions for the app. You will need to accept these conditions to be able to use the actiTENS.

The user guide and contraindications can be found at all times in the "Help" menu.

- The actiTENS mobile app offers you to create a user account. This user account is optional for the use of your actiTENS but will give you 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 stimulator via Bluetooth to control the stimulation program. 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. actiTENS app will ask you to activate Bluetooth, which also requires access to your location. You can also manage Bluetooth activation and location access via the "**Settings**" menu on your telephone.

  It is recommended to find a quiet and calm location when connected.

- **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.

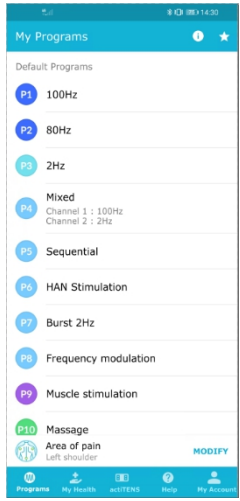
 Programs	**Programs**: o Select and launch a stimulation program
 My Health	**My Health**: o Stimulation session history o History of pain levels registered before and after sessions

	o Medical questionnaires and monitoring the impact of pain on your daily life
 actiTENS	actiTENS: o If the stimulator is not connected: connection button o If the stimulator is connected: actiTENS battery level o If a program is running: access to the remote control
 Help	Help: o Contraindications and key precautions for use o Start-up screen o Sublimed support Contact o actiTENS instructions for use
 My Account	My Account: o Contains options for creating or managing an account o Contains the account profile if it has been created o Contains the application settings

11. LAUNCHING A PROGRAM

- Select the "**Programs**" menu from the navigation bar at the bottom of the screen.

- Choose a program from the suggested list. (the list of programs and their descriptions are available in section 17 of these instructions for use)

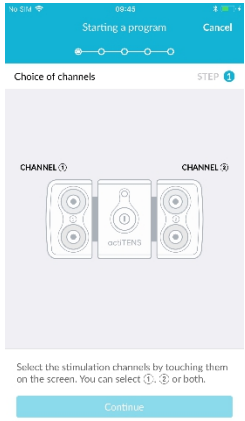


- Choose the channel or channels that you want to use.

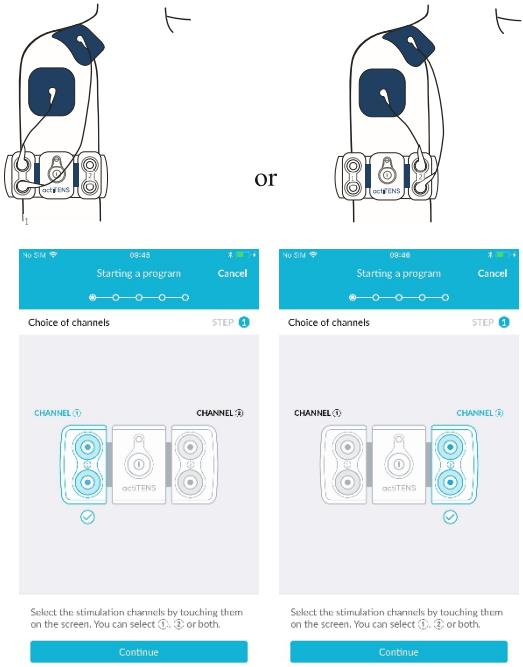
Remember:

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

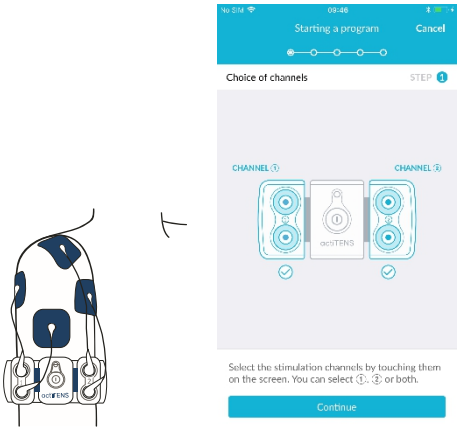
4 electrodes = 4 cables
Channel 1 **and** Channel 2



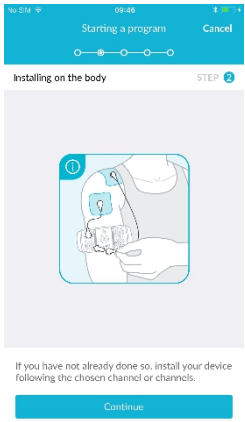
o 1 channel:



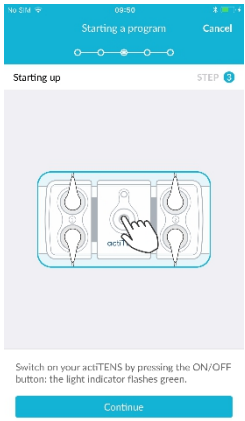
o 2 channels:

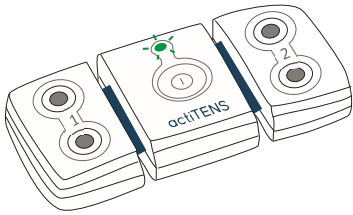


- Place the device on your body (if you have not already done so). For help, go to the "**Placing the device**" section (section 9).



- Turn on the stimulator by pressing the ON/OFF button (if you have not already done so). The indicator light will blink green.

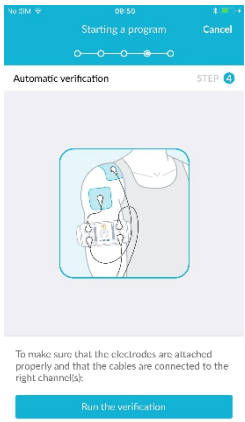




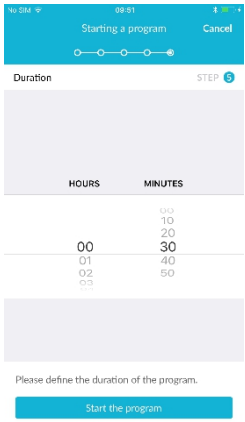
Remember: once turned on, if a program is not launched the stimulator will automatically turn off after 10 minutes.

- Launch the automatic placement check. This step ensures that all the connections between the actiTENS stimulator, 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.

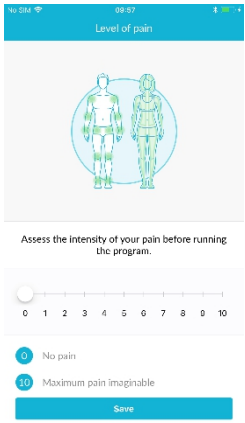


- Define the program length. The app allows you to choose between 10 minutes and 12 hours of stimulation. Each program type is automatically set to a default length, summarized in section 18 “Program overview”.

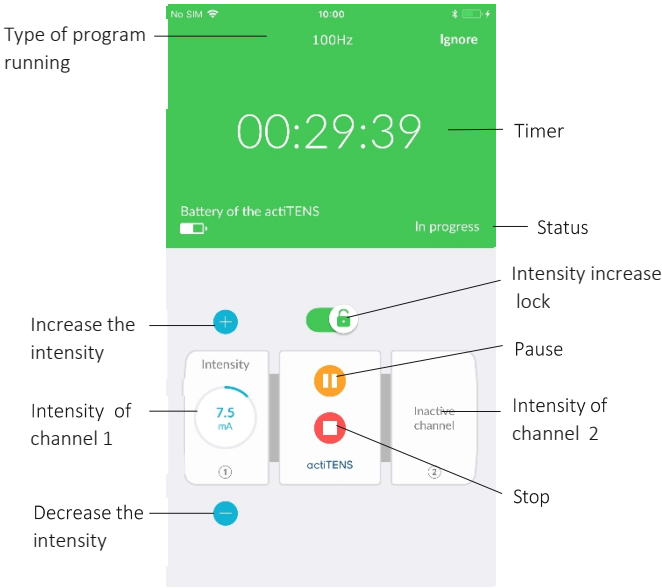


- Enter your pain level (an option that can be deactivated via the "**My Account**" menu) before your stimulation session. Historical data can be accessed via the "**My Health**" menu (*see section 14.2. "**Pain level history**"*).

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



- The actiTENS 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 reach a balance between a tolerable sensation and pain relief.



Adjust the electrical stimulation intensity to between 0.5 and 60 mA for each active channel.

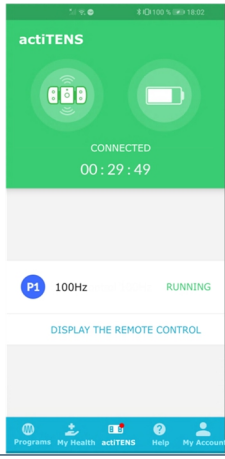
Remember: just after an adjustment is made, a lock is automatically applied after 10 seconds to prevent any unwanted change in intensity level. To unlock the setting, press on the padlock

Remember during treatment, you can leave the actiTENS app screen and use your telephone as usual.

To return to the app, touch the actiTENS icon.

To return to the control screen, touch the actiTENS icon, then the program running.

actiTENS



- How to adjust the position of the electrodes during a session ?

The electrodes should not be removed or moved during stimulation (*see section 3 "Precautions for use"*). To adjust the position of the electrodes during a session, 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.

Remember: after being in Pause mode , when you re-start the program you will need to re-adjust the intensity level again.

12. 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 stimulator. This option is not recommended as this will mean the session recordings will be incomplete.

13. 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.

Light	Meaning	Action
 Flashing green	Stimulator turned on with no session started or paused.	The device can be taken off.
Permanent yellow	Session running.	Pause or suspend the session before taking off the device. The light will change to flashing green.

Carefully unstick the electrodes and the self-adhesive strip 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).

14. 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.

15. actiTENS UPDATES

15.1. Generality

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 also for security reasons. Updates will be available for:

- actiTENS the mobile app
- actiTENS the stimulator

15.2. 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.

15.3. Updating the actiTENS stimulator

- **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 stimulator actiTENS.
- **Step 3:** The actiTENS and your smartphone must have over 50% remaining battery to proceed with the update.
- **Step 4:** A steady Bluetooth connection must be maintained during the whole update process. Thus, you need to keep your phone close to the actiTENS with the Bluetooth switched ON.
- **Step 5:** Follow the onscreen instructions. The light indicator blinks blue during the update and become blinking green when it is finished.

IMPORTANT: While the actiTENS indicator light blinks blue, you will not be able to switch it ON nor OFF. If the actiTENS battery is emptied, it first has to be charged to resume the update.

16. STORAGE CONDITIONS AND CLEANING

- **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.
  - Your self-adhesive strips should be changed every week.

For replacing your electrodes by new ones, contact the supplier who supplied you the actiTENS Standard kit. Please only use electrodes supply by Sublimed with references mentioned in the section 21.

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

- **Cleaning**

  Make sure that the actiTENS stimulator is turned off and the charging case is not being powered (disconnected) before cleaning them.
  - Never immerse or rinse the actiTENS stimulator 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 stimulator, its cable and the charging case. 70° isopropyl alcohol (IPA) can also be used.
- 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.

17. CUSTOMER SUPPORT

- **Errors seen:**

  - Indicator light flashing red

Possible cause	Solution
actiTENS 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 Care Department.

NB: If you use the actiTENS stimulator 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 can reach a maximum temperature of 42.3 °C [108.1 °F].

  - The actiTENS stimulator no longer turns on

Possible cause	Solution
1- The battery is not charged	Charge the device.

2- actiTENS error	Turn off the device off for fifteen minutes then turn it back on again. If the error has not cleared, contact the Customer Care Department.

- Stimulation seems to be different or less pleasant than before

Possible cause	Solution
1- The electrodes are not positioned correctly	Change the position of the electrodes when a session is not running or pause your session from the app.
2- The intensity is not right	Adjust the intensity from the app; the sensation should not be unpleasant. The intensity required may vary from session to session.
3- The electrodes are damaged	Check the condition of the electrodes: wear and tear, cleanliness, expiry date. Replace or clean them.

- Slight discharge when touching the electrodes

Possible cause	Solution
A session was still running when the electrodes were handled	Always end or pause a session before handling the electrodes.

- The actiTENS has disconnected

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

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

Part	Length of guarantee
actiTENS stimulator	2 years
Charging case and AC charger	2 years
Cables	Not guaranteed
Electrodes and self-adhesive strips	Consumables are not guaranteed: refer to the use and storage instructions

- 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 stimulator is designed for a service life of at least 5 years.

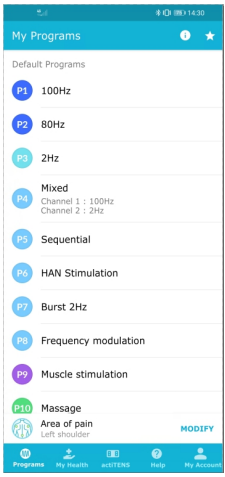
- Contact your reseller or SUBLIMED:

  ▪ *For help in placing or using the device, if needed*

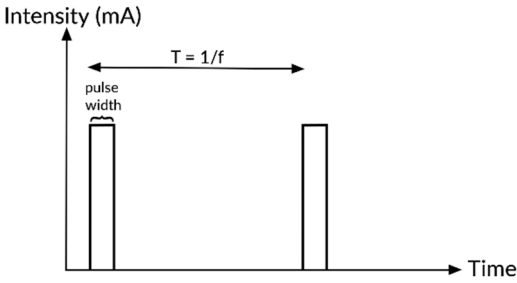
  ▪ *To report unexpected operations or events.*

18. PROGRAM OVERVIEW

Programs P1, P2, P3, P4, P5, P6, P7, P8, P10, P11, P12 and P13 correspond to TENS mode.
Program P9 corresponds to EMS mode.



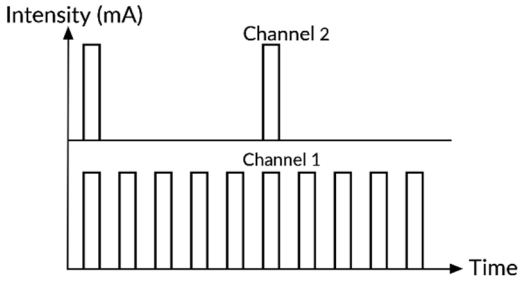
P1 100Hz	
Technical information	Frequency: 100 Hz Pulse width: 200 µs Default duration: 30 minutes
Mode of action	Inhibits pain signals



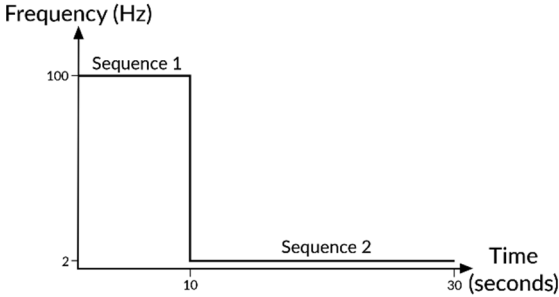
P2 80Hz	
Technical information	Frequency: 80 Hz Pulse width: 150 µs Default duration: 30 minutes
Mode of action	Inhibits pain signals

P3 2Hz	
Technical information	Frequency: 2 Hz Pulse width: 250 µs Default duration: 30 minutes
Mode of action	Stimulates the muscles for a general pain-relieving effect

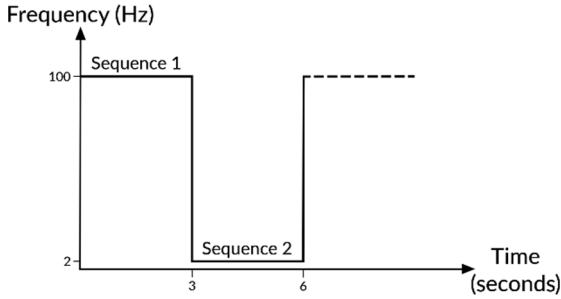
P4 Mixed	
Technical information	**Channel 1: 100Hz** Frequency: 100 Hz Pulse width: 200 µs **Channel 2: 2Hz** Frequency: 2 Hz Pulse width: 200 µs Default duration: 30 minutes
Mode of action	Combined action: Inhibits pain signals Stimulates the muscles for a general pain-relieving effect



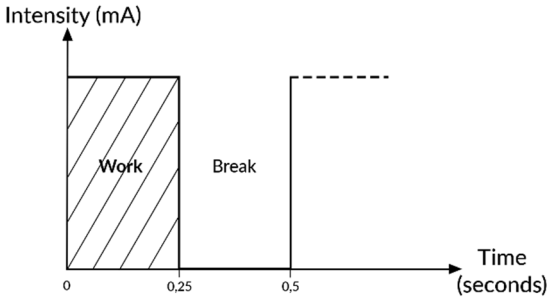
P5 Sequential	
Technical information	1st sequence (1/3 of the time, so by default: 10 minutes): Program 100Hz Frequency: 100 Hz Pulse width: 150 µs 2nd sequence (2/3 of the time, so by default: 20 minutes): Program 2Hz Frequency: 2 Hz Pulse width: 200 µs Default duration: 30 minutes
Mode of action	Combined action: Inhibits pain signals Stimulates the muscles for a general pain-relieving effect



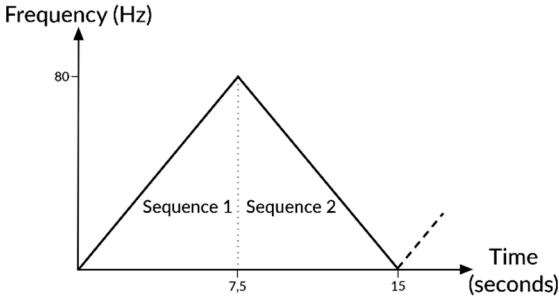
P6 HAN Stimulation	
Technical information	**1st sequence (duration: 3 seconds): Program 100Hz** Frequency: 100 Hz Pulse width: 150 µs **2nd sequence (duration: 3 seconds): Program 2Hz** Frequency: 2 Hz Pulse width: 200 µs These sequences alternate every 3 seconds Default duration: 30 minutes
Mode of action	Combined action: Inhibits pain signals Stimulates the muscles for a general pain-relieving effect



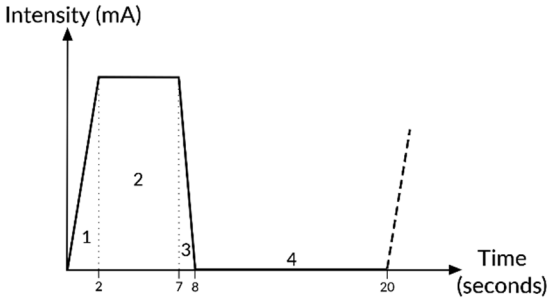
P7 Burst 2 Hz	
Technical information	1st sequence (duration: 0.25 seconds): Program 100Hz Frequency: 100 Hz Pulse width: 150 µs 2nd sequence (duration: 0.25 seconds): no pulse These sequences alternate every 0.25 seconds Default duration: 30 minutes
Mode of action	Combined action: Inhibits pain signals Stimulates the muscles for a general pain-relieving effect



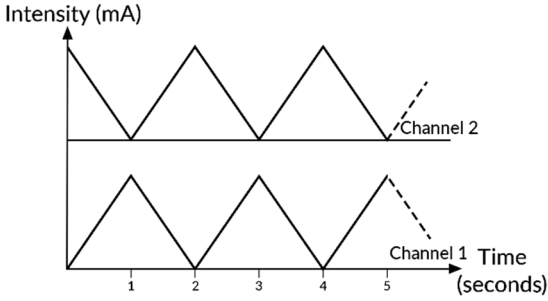
P8 Frequency modulation	
Technical information	**1st sequence (duration: 7.5 seconds):** Increasing frequency: 2 Hz to 80 Hz Decreasing pulse width: 200 µs to 100 µs **2nd sequence (duration: 7.5 seconds):** Decreasing frequency: 80 Hz to 2 Hz Increasing pulse width: 100 µs to 200 µs These sequences alternate every 7.5 seconds Default duration: 30 minutes
Mode of action	Combined action: Inhibits pain signals Stimulates the muscles for a general pain-relieving effect



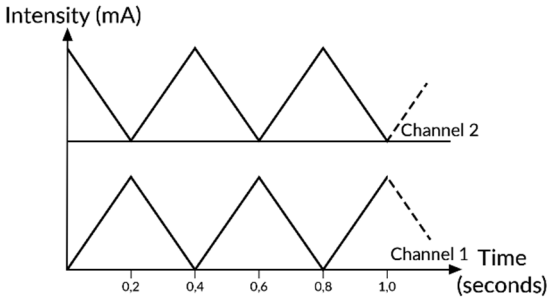
P9 Muscle Stimulation	
Technical information	Frequency: 50 Hz Pulse width: 250 µs **1st sequence (2 seconds):** Increasing intensity: 0mA to desired intensity **2nd sequence (5 seconds):** Constant intensity (desired intensity) **3rd sequence (1 second):** Decreasing intensity: desired intensity to 0mA **4th sequence (12 seconds):** No pulse These sequences alternate throughout the program Default duration: 30 minutes
Mode of action	Muscle strengthening



P10 Massage	
Technical information	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
Mode of action	Comfort



P11 Rubbing	
Technical information	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
Mode of action	Comfort



P12 Sensitive areas treatment	
Technical information	Frequency: 80 Hz Pulse width: 60 µs Default duration: 30 minutes
Mode of action	Inhibits pain signals

P13 Nausea	
Technical information	Frequency: 10 Hz Pulse width: 180 µs Default duration: 30 minutes
Mode of action	Stimulates the muscles for a general pain-relieving effect

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

19. 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.

20. TECHNICAL DATA SHEET

Technical information	
Intended operator	User of device
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 stimulator	max 60 mA ± 10% (1000 Ω) / max 60 V ± 10%
Essential performance of actiTENS stimulator	Does not deliver a current > 60 mA ± 10% or a voltage > 60 V ± 10%
Input AC charger voltage, intensity and frequency	100-240 V AC 0.1-0.2 A 50-60 Hz
Input and output voltage and intensity of the charging case	5 V DC – 1 A
Conditions of use for the actiTENS stimulator and its charging case	From 10°C to 40°C (50°F to 104°F) with a relative humidity from 15% to 93% Atmospheric pressure 700 hPa to 1060 hPa
Charging conditions of the actiTENS	Ambient temperature

Storage conditions for the actiTENS standard kit	From 5°C to 27°C (41°F to 81°F) with a relative humidity from 5% to 93% Temperature between 15°C and 25°C (59°F and 77°F) are best suited to preserve the battery's capacity
Storage conditions for the actiTENS stimulator	From -10°C to 45°C (14°F to 113°F), with a maximum relative humidity of 93% Temperature between 15°C and 25°C (59°F and 77°F) are best suited to preserve the battery's capacity
Charging case storage conditions	From -20°C to 60°C (-4°F to 140°F)
AC charger storage conditions	From -40°C to 85°C (-40°F to 185°F) with relative humidity from 5% to 95%
Warm up time before start when stocked at -10°C to ambient temperature (20°C)	5 minutes (at least)
Cool down time before start when stocked at 45°C to ambient temperature (20°C)	10 minutes (at least)
Dimensions of the stimulator	108 mm x 53.5 mm x 17 mm
Weight of actiTENS stimulator	~ 65 g
Dimensions of the charging case	133.8 mm x 79 mm x 34 mm
Weight of charging case	~ 115 g

IP classification of the actiTENS stimulator	IP22: protection from touch by fingers and objects greater than 12.5 mm, protection from water spray up to 15° from vertical
IP classification for the charging case	IP21: protection from touch by fingers and objects greater than 12.5 mm, protection from vertical falling water droplets
Waveform	Compensated asymmetrical biphasic waves
Pulse width	50-400 µs ± 5 µs
Frequency	1-120 Hz ± 10%
Treatment time	10-12 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 27°C (41°F to 81°F)
Composition of the electrodes in the standard kit	Multistick patented hydrogel, conducting part: silver grid pattern and conductive film, insulating base material: woven fabric, snap connector: stainless steel

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
	The electromagnetic interference from the device is under limits approved by the Federal Communications Commission.
	Read the actiTENS instructions for use closely before using.
	Device with a degree of protection against electric shocks, conform to the standard IEC 60601-1. Any shell for the actiTENS is a BF type applied part.
	Design for INTERIOR use only. This is only valuable when the actiTENS is charging (connected to the main)
	Manufacturer's address.
	Serial number and date of manufacture of the device.
	Device reference number.
	Read the actiTENS instructions for use thoroughly before use.
	Status of the actiTENS stimulator battery.
	Electrical input.
	Electrical output.
	Direct current.
	Alternating current.
	Class II device.

	The actiTENS stimulator ON/OFF button symbol for turning the stimulator on and off.
	Humidity range the device can be exposed to.
	Minimum and maximum temperatures the medical device can be exposed to.
	Prescription-only device
	actiTENS is MR Unsafe

21. CATALOGUE REFERENCES

actiTENS Standard Kit **SBM1AA017**:

- actiTENS (stimulator) **SBM1AA110**
- 1 Pack of 2 Self-Adhesive strips **SBM1AB011**
- 2 Packs of 2 medium 40 cm cables **SBM1AE001**
- 1 Pack of 4 UltraStim® snap Electrodes 50 x 50 mm SN2020 (Manufactured by Axelgaard Co., FDA cleared under K130987)
- To charge the device:
  - 1 Charging Case **SBM1AF110**
  - 1 AC Charger **SBM1AF211**
- 1 Instruction For Use **SBM1AL011**
- 1 QuickStart **SBM1AL012**

Optional accessories (to order separately):

- Pack of 4 UltraStim® snap Electrodes 50 x 100 mm **SN2040** (Manufactured by Axelgaard Co., FDA cleared under K130987)
- Pack of 4 Sensitive Skin Electrodes 45 x 45 mm **BST11** (Manufactured by Pepin Mfg., FDA cleared K070807)
- Pack of 4 Sensitive Skin Electrodes 45 x 90 mm **BST13** (Manufactured by Pepin Mfg., FDA cleared K070807)
- Pack of 4 FlexStim® neurostimulation Electrodes 50 x 50 mm **S5050C2SC** (Manufactured by Medico Electrodes International Ltd., FDA cleared K161282)
- Pack of 4 FlexStim® neurostimulation Electrodes 50 x 100 mm **R50100C2SC** (Manufactured by Medico Electrodes International Ltd., FDA cleared K161282)

22. ELECTROMAGNETIC COMPATIBILITY

The actiTENS is intended for clinical use and home use.

The actiTENS is intended to be used in the electromagnetic environment specified below. The user of the actiTENS 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 stimulator. Otherwise, the performance of the actiTENS stimulator and these devices may be affected. Go to Table 2 for more details about the equipment tested.

- the actiTENS stimulator 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 stimulator 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 stimulator 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.

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

Emission test	Conformity	Electromagnetic environment - Directives
CISPR 11 RF Emissions	Group 1	The actiTENS 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 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.

Immunity test	IEC 60601-12 Test level	Level of conformity	Electromagnetic environment - Directives
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 user requires continuous functioning during cuts in the electric power supply, it is recommended to power the actiTENS using an energy source that does not experience cuts or a battery.
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, 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 800MHz d=2.3 √P for a frequency between 800MHz and 2.7GMHz 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 rangeb. 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 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 is used, exceeds the level of RF conformity applicable above, the actiTENS 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

[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

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.

23. 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.

HVIN : B8
FCC ID: 2BALKSBM

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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Caution: Federal law restricts this device to sale by or on the order of a physician.