MADE IN FRANCE

NOTICE actiTENS

USER GUIDE / GEBRAUCHSANLEITUNG
ISTRUZIONI / HANDLEIDING

SUBLIMED

actiTENS USER GUIDE

The actiTENS is a connected medical device for transcutaneous electrical neurostimulation intended to treat pain in adults and intended for persons over 18 years of age with unimpaired intellectual abilities.

The actiTENS is fixed directly on to the body using a self-adhesive strip or textile accessory. It adapts to the shape of your body with its flexible design. The actiTENS can be used discreetly 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, we recommend that a healthcare professional instruct you how to correctly position the electrodes and to select an appropriate stimulation programme for your specific needs.

actiTENS is a medical device for hire or sale.

These instructions may be modified and you can consult the latest version through the actiTENS mobile app in the "Help" menu.

Help

SUMMARY

1. INTENDED USE AND PATIENT TARGET GROUP

The actiTENS is a connected medical device for transcutaneous electrical neurostimulation designed to treat pain in adults. The actiTENS also has a non-medical muscle stimulation programme for strengthening muscles. The intended patient population for actiTENS medical device is adult patients (persons over 18 years of age with unimpaired intellectual abilities) suffering from pain, and being mentally and physically capable of placing the electrodes and adjusting the intensity, or capable of expressing pain or wishes regarding treatment modifications or treatment termination.

2. CONTRAINDICATIONS

The actiTENS should not be used on the following patients without medical advice:

- **Patients with pacemakers, implantable cardioverter defibrillators, or other similar electronic implantable devices.**
- **Patients at risk of heart problems.**
- **Patients with epilepsy.**
- **Patients with decreased or impaired sensation or sensibility on the area to be treated, for example patients suffering from allodynia (pain triggered by a normally painless stimulus).**
- **actiTENS should not be used on pregnant women without medical advice. The electrodes must not be placed on the abdomen of a pregnant woman.**

Failure to respect these contraindications may have serious consequences and be harmful to the patient.

3. RESIDUAL RISKS AND UNDESIRABLE SIDE EFFECTS

- Use of the actiTENS may in certain 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 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 20).
- Using the actiTENS may cause temporary muscular pain or involuntary muscular contractions. It is recommended to consult a healthcare professional before using the device.
- Certain accessories (cables, AC charger and textile accessories) may present a risk of strangulation.

All serious incidents related to the use of the device must be declared to the manufacturer at the address contact@subli-med.com and the competent authority of the member state where the user lives (cf list on the back of the instructions).

4. WARNINGS

- Always keep the actiTENS and its accessories out of reach of children, animals and persons of impaired intellectual ability.
- 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 place the electrodes on either side of the heart. Putting the electrodes near the thorax may increase the risk of cardiac fibrillation.
- Do not use the neurostimulator for transcranian stimulation (electrodes on either side of the head), the 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 neurostimulator when the patient is connected to high frequency surgical equipment (e.g. an electrical scalpel). The simultaneous use may cause burns under the electrodes and the neurostimulator may be damaged.
- 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 actiCHARGE charging case - there is a risk of electric shock.
- Do not use the actiTENS neurostimulator and the actiCHARGE 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 actiCHARGE 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 actiCHARGE charging case away from water and any other liquids as this may cause unpredictable current flows and damage the product.
- Do not use the actiTENS in an explosive environment (e.g. a filling station).
- Do not use the actiTENS device in emergency medical services.
- We recommend that you do not use the actiTENS neurostimulateur 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 actiTENS neurostimulators simultaneously on the same person.

5. PRECAUTIONS FOR USE

- The neurostimulator must only be used with accessories from the actiTENS range. The use of other accessories may lead to a deficient operation.
- Precautions for the use of electrodes with the actiTENS

  - Do not place the electrodes on damaged or irritated skin, and especially not on an open wound or in proximity to cancerous lesions. In the event of rash or skin irritation, remove the device. This rash generally disappears after a few hours. If the irritation persists, consult a healthcare professional.
  - Always place the electrodes on clean dry skin.
  - Before removing the electrodes from the skin, stop the session from the app ( ) or by pressing the ON/OFF button. If an electrode comes unstuck, switch off the neurostimulator or put it on pause before touching the electrode. Pulses of current on the fingers from the neurostimulator are unpleasant but are not, however, dangerous. See section 15 "Stopping a stimulation session".
  - Do not superpose the electrodes.
  - It is not recommended to use conducting gel with the electrodes.

- Precautions for the use of the self-adhesive strip and textile accessories with the actiTENS:
  - 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 tighten the armband too much so as not to cut off blood circulation in the limb concerned.
- Do not disconnect the cables connected to the electrodes or to the actiTENS by pulling on the cable wire so as not to damage it.
- Handle the connectors with care, and in particular pay attention to the direction of insertion of the micro USB connector of the AC charger into the actiCHARGE charging case.
- Do not use the actiTENS neurostimulator during physical activities where there is a risk of damage from shocks or impacts.
- If you drop the actiTENS or the actiCHARGE 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 the actiTENS and its accessories if it is not working correctly, or if part of it is damaged. Always check that the device is not damaged and is functioning correctly before use.
- The actiTENS neurostimulator must be recharged indoors at ambient temperature.
- The actiTENS neurostimulator must only be recharged using the power cable supplied with the device.
- When charging the device, make sure that the mains plug remains accessible at all times so that disconnection from the mains supply is possible quickly if necessary.
- 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 stimlation 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.

6. CLINICAL BENEFITS AND CLINICAL SAFETY

The use of actiTENS is intended to reduce the patient's pain.

Using actiTENS helps reducing medication in patients suffering from chronic pain.

Besides, it has minimal and limited side effects. Fewer and especially less severe than the side effects of a drug treatment, they allow for a better tolerance of the therapy.

7. HOW TENS THERAPY WORKS

Transcutaneous Electric Nerve Stimulation, commonly known as TENS, is a drug-free method of pain relief. It consists in sending low intensity electrical pulses close to the area of pain through electrodes placed on the skin.

7.1. Mechanisms of action

TENS involves two main mechanisms:

- (1) **Gate Control**
- (2) **Endorphinic stimulation**

(1) **Gate control** is based on the principle of inhibiting the pain signal. While using the TENS, this signal is replaced by a tingling sensation. This sensation short-circuits the pain signal at the spinal cord and prevents it reaching the brain.

(2) **Endorphinic stimulation** promotes an increased production of endorphins. Endorphins are pain-killers that are naturally secreted in the body. This increa se in endorphins causes a general analgesic effect. TENS in endorphinic mode produces a sensation of small beats.

The TENS programmes offer one or other of these action mechanisms or a combination of both.

The choice is based on how the patient feels. Do not hesitate to consult a healthcare professional.

7.2. Placement of the 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.

You should follow the advice given by a healthcare professional in choosing programmes, duration and intensity of stimulation and positioning of the electrodes of the actiTENS neurostimulator.

7.3. Controlling the intensity

The stimulation intensity should be adjusted for a balance between 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 consult a healthcare professional.

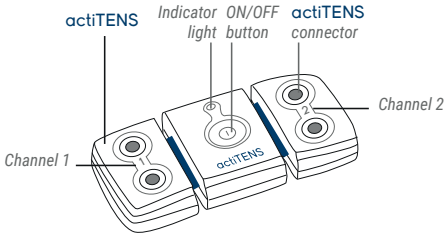
8. DEVICE OVERVIEW

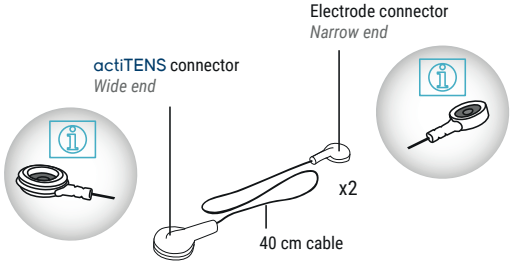
actiTENS Standard kit:

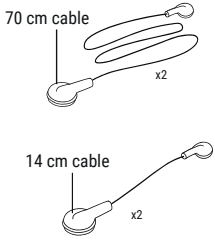
- 1 actiTENS (neurostimulator)
- To place the device on the body:
  - 1 standard size actiTENS armband
- 1 pack of 2 x 40 cm actiTENS cables
- 1 pack of 2 x 14 cm actiTENS cables
- 1 pack of 2 x 70 cm actiTENS cables
- 4 actiTENS electrodes 50 mm x 50 mm providing 20 successive uses
- For charging the device:
  - 1 actiCHARGE charging case
  - 1 AC charger
- 1 user guide

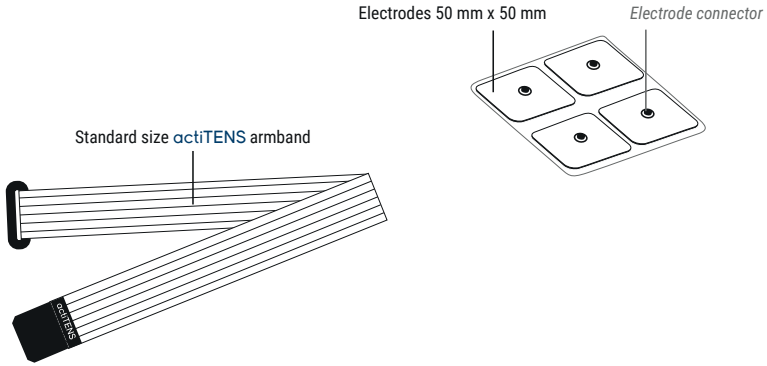
Remember

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









To charge the device

9. INDICATOR LIGHTS: MEANING

MODE	INDICATOR	MEANING
While charging	 Flashing green medium frequency (1.4 times per second)	Battery charging
	 Permanent green	Battery is charged
	 Flashing red	actiTENS error
	 Flashing blue high frequency (2.8 times per second)	actiTENS is updating. It is important to complete the updating to be able to use actiTENS. For more details see section 18.
In use	 Flashing green low frequency (0.8 times per second)	actiTENS turned on with no session started or paused
	 Flashing green high frequency (2.8 times per second)	actiTENS paused
	Permanent yellow	Session running, following automatic placement check
	 Flashing red	actiTENS error
	 Flashing blue high frequency (2.8 times per second)	actiTENS is updating. It is important to complete the updating to be able to use actiTENS. For more details see section 18.

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


actiTENS

10. CHARGING YOUR actiTENS

Charge your actiTENS before each use. Initial charging of the actiTENS takes about two and a half hours.

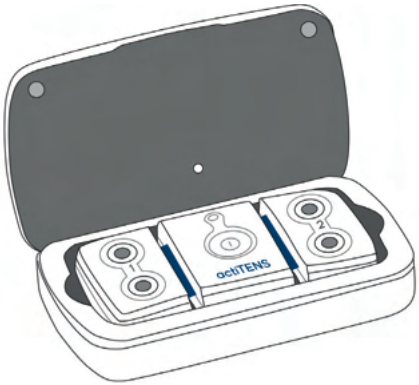
NB: the battery operating time depends on how the machine is used (type of programme and intensity), the skin resistance of the patient and the surroundings.

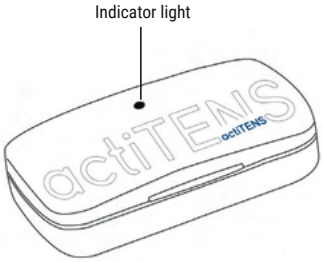
NB: as with all similar devices, the operating time of the battery will decrease with use.

NB: to ensure the performance and safety of the machine, it is essential to use the AC charger provided with the actiTENS. Using other AC chargers invalidates the actiTENS guarantee.

How to charge your actiTENS

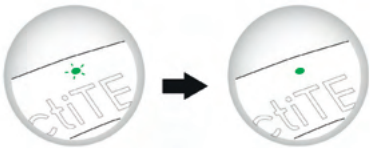
- Place the actiTENS into its charging case and close the lid. See the illustration below for the correct way to place the device in the case.





- Carefully insert the micro-USB cable of the AC charger into the micro-USB socket on the actiCHARGE charging case in the correct direction.

- Connect the other end of the AC charger to the mains.
- When the light on the actiTENS changes from flashing green (battery charging) to permanent green (battery charged), unplug the AC charger and disconnect the micro USB from the charging case actiCHARGE.



How to check how much charge your actiTENS has left

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

actiTENS

11. DOWNLOADING THE actiTENS APP

The actiTENS app is essential for starting and adjusting the settings for your stimulation session.

You need to be connected to a mobile network or Wi-Fi to download the app.

Downloading the actiTENS app:

From the App Store (iOS):

Download on the App Store

Or Google Play (Android):

GET IT ON Google Play

The actiTENS application is only available on Google Play and App Store, any download of actiTENS 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.

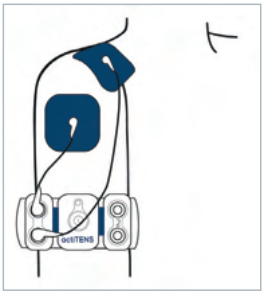
IMPORTANT: although we try to make sure our device is up to date, some telephones may not be compatible with our app. This incompatibility may be temporary and can sometimes be resolved by updating your phone and/or the actiTENS app. For more information visit our website www.subli-med.com to see the list of incompatible telephones or contact our customer care department (details also available on our website).

12. PLACING THE DEVICE

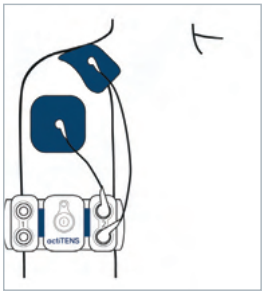
- **Preliminary step:**
  - Choose the number of electrodes based on the area to be stimulated: 2 or 4.
  - Use the same number of cables as electrodes.

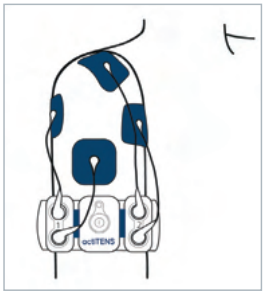
  For two electrodes, only one channel on the actiTENS will be active. With four electrodes, both channels on the actiTENS will be active.

Remember



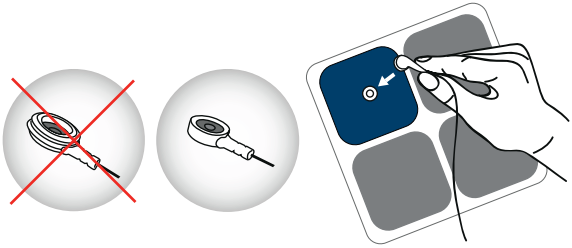
2 electrodes = 2 cables
Channel 1 or Channel 2





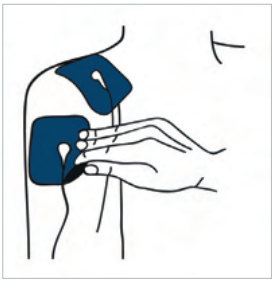
4 electrodes = 4 cables
Channel 1 and Channel 2

- **Step 1:** clip the narrow end of the cables to the electrodes.



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

  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.



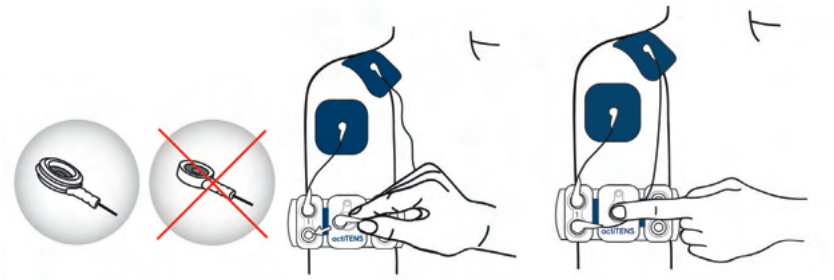
Illustrative example with two electrodes

- **Step 3**: Place the textile accessory on the desired area of the body, then position the actiTENS directly on the textile accessory.

  If you are using a self-adhesive strip, attach the actiTENS to the self-adhesive strip then stick the self-adhesive strip attached to the actiTENS near to the electrodes.

Illustrative example with two electrodes

- **Step 4:** clip the wide end of the cables on to the channels of the actiTENS neurostimulator.



- **Step 5** : turn on the actiTENS by pressing the ON/OFF button. The indicator light will flash green. Your device is ready for your stimulation session. When you want to start a session, follow the instructions for **Launching a programme** (section 14).

Remember

The actiTENS will automatically turn off after 10 minutes if a session is not launched.

13. HOW TO USE THE actiTENS APP

- When you launch the app for the first time, a start-up screen is displayed. The second screen reminds you of the contraindications. This start-up screen includes links to the latest version of the user guide, the privacy policy and general terms and conditions for the use of 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 application 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 application.
- Your telephone will communicate with the actiTENS via Bluetooth to control the stimulation programmes. You do not need to be connected to a mobile network or internet to use the actiTENS. Once the stimulation programme is launched, the app continues to run in the background and you can use your telephone as normal without interrupting your session. The actiTENS app will ask you to activate Bluetooth, which also requires access to your location (on Android).

  You can also manage Bluetooth activation and access to the location via the "**Settings**" menu on your telephone.

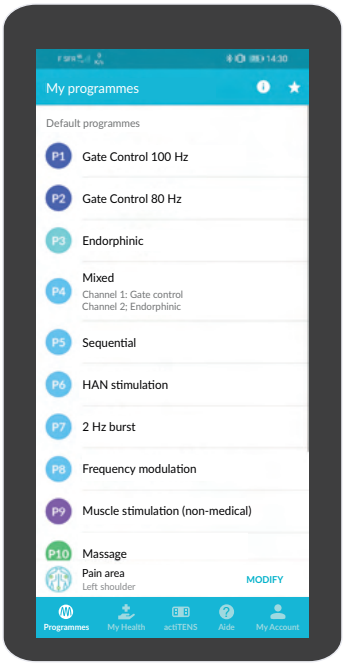
  We recommend that you find a quiet and calm location when connected.

- **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.

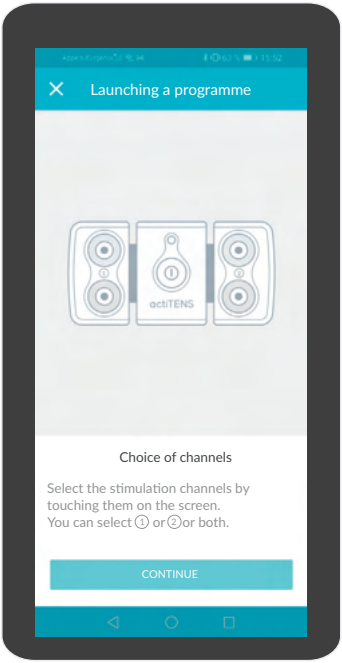
Programmes	**Programmes**: ▪ Select and launch a stimulation programme
My Health	**My Health:** ▪ Stimulation session history ▪ History of pain levels recorded before and after the sessions ▪ Medical questionnaires and monitoring the impact of pain on your daily life
actiTENS	actiTENS : ▪ If the actiTENS is not connected: connect button ▪ If the actiTENS is connected: actiTENS battery level ▪ If a programme is running: access to the remote control
Help	**Help:** ▪ Contraindications and key precautions for use ▪ Starting up ▪ Contact your local dealer ▪ actiTENS instructions for use ▪ Quick-start guide ▪ Positioning the electrodes
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

14. LAUNCHING A PROGRAMME

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



- Choose a programme from the suggested list (the list of programmes and their descriptions are available in section 23 of this guide).



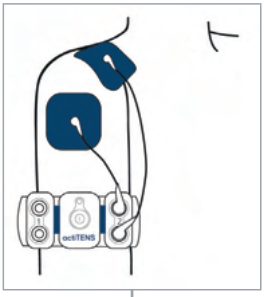
- Choose the channel or channels that you want to use.

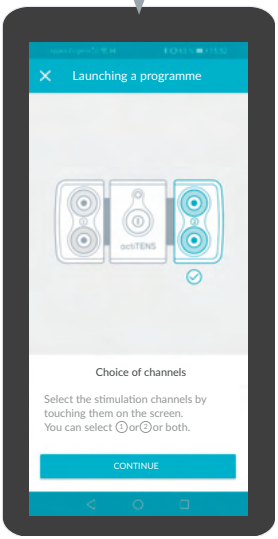
Remember

2 electrodes = 2 cables
Channel 1 or Channel 2

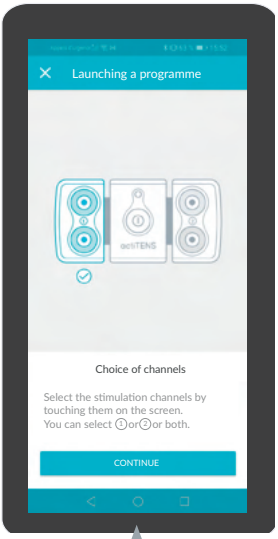
4 electrodes = 4 cables
Channel 1 and Channel 2

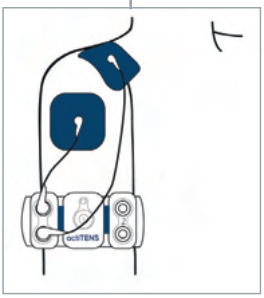
• 1 channel:



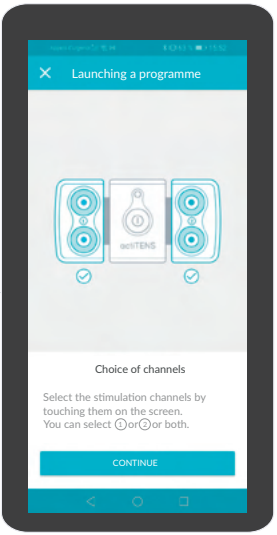


OR

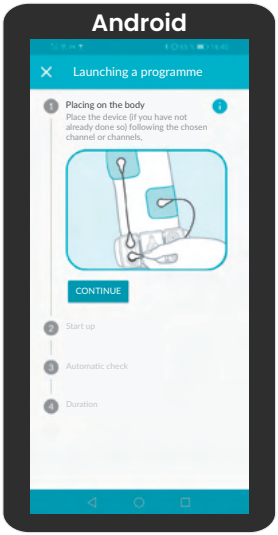




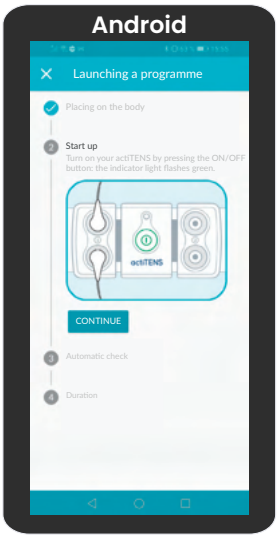
• 2 channels:

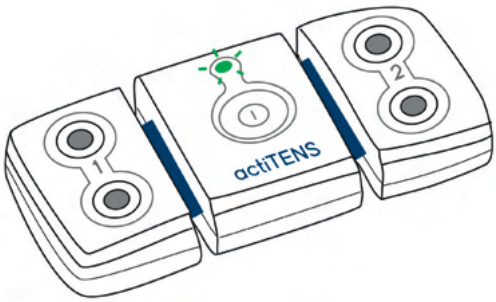


- Place the device on your body (if you have not already done so). For help, go to the "**Placing the device**" section (section 12).



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



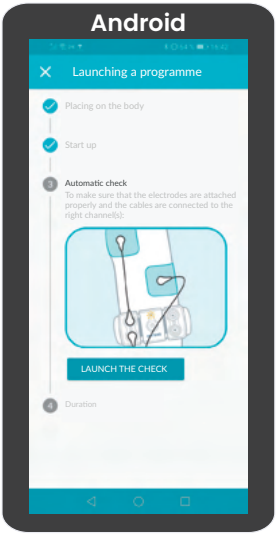


Remember

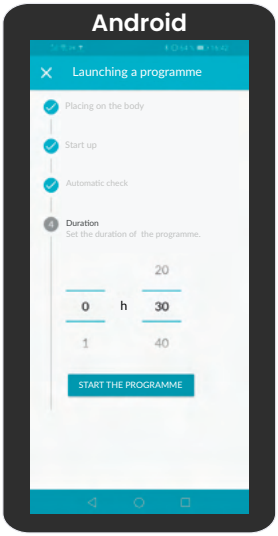
Once turned on, if a programme is not launched the actiTENS will automatically turn off after 10 minutes.

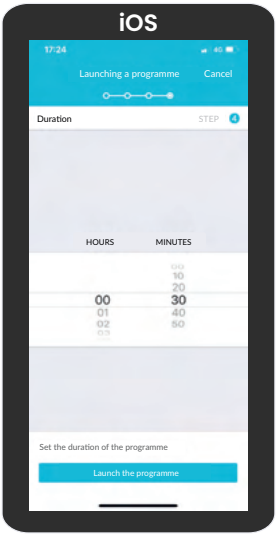
- Launch the automatic placement check. This step ensures that all the connections between the actiTENS, the cables, the electrodes and your body are working correctly and checks that there is good adhesion of the electrodes to the skin.

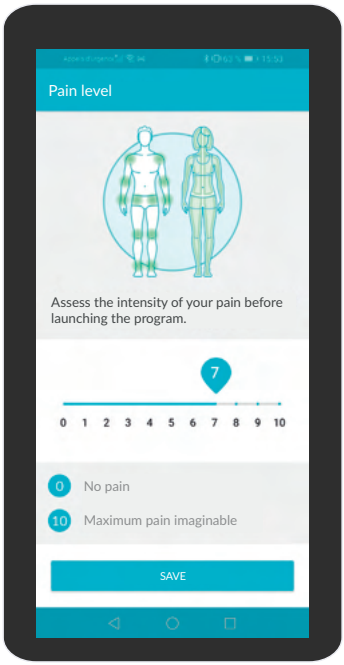
  NB: if there is an error, manually check the connections, cables and electrodes and repeat the automatic check.



- Set the duration of the programme. The app allows you to choose between 10 minutes and 12 hours of stimulation. Each programme type is automatically set to a default duration, summarized in section 23 “**Description of the programmes**”.





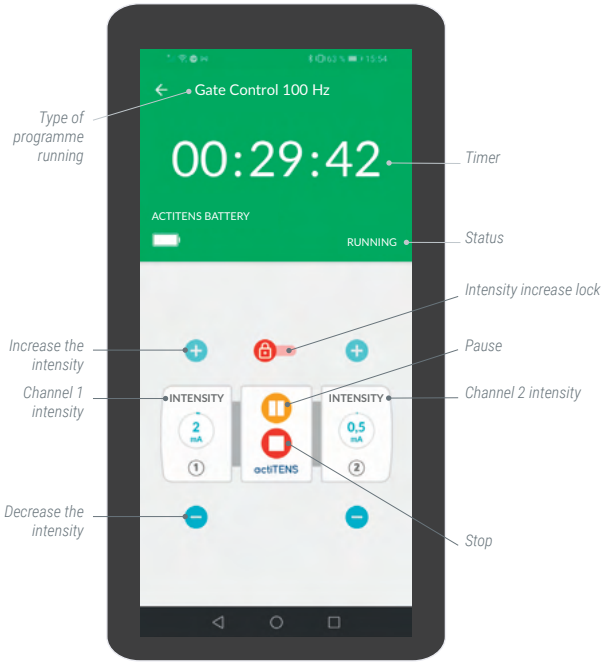


- Enter your pain level (an option that can be deactivated via the “**My Account**” menu and non-applicable for the P9 muscle stimulation programme) before your stimulation session. Historical data can be accessed via the "**My Heatlh**" menu (see section 17).

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

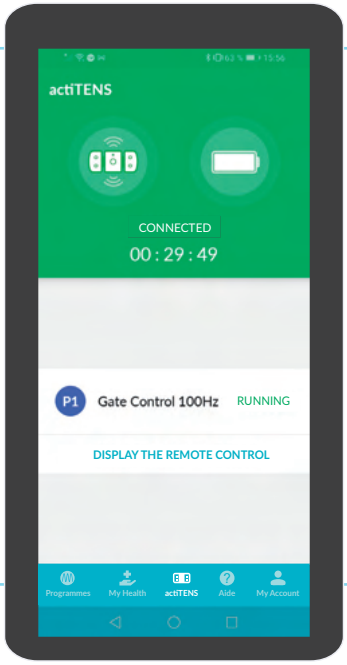
- The actiTENS control screen is displayed. The timer automatically starts when you start adjusting the intensity. You need to adjust the stimulation intensity.

The stimulation intensity should be adjusted to balance a tolerable sensation with a decrease in pain.



Remember

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 quit the actiTENS app screen and use your telephone as usual.

Just press the actiTENS icon ( ) again to return to the app.

To return to the control screen, touch the actiTENS icon , then the programme that is 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 5 "**Precautions for use**"). To adjust the positioning of the electrodes during a session, use the "Pause" mode ( ). The session will then be paused and the electrodes can be handled safely.

Relaunch the programme ( ), when you have re-positioned the electrodes and set a new intensity.

Remember

When you use Pause mode ( ), then on relaunching the programme you have to reset the intensity level again.

15. STOPPING THE STIMULATION SESSION

- Stopping at the end of a session: the stimulation session is automatically stopped at the end of the programmed duration. A message is displayed confirming the end of the session.
- Stopping during a session:
  - A session that is running can be stopped temporarily or definitively.

    To stop temporarily, use the Pause button ( ).

    To stop definitively, use the Stop button ( ). In the latter case, a message is displayed confirming the end of the session.
  - You can also stop a session by pressing the actiTENS ON/OFF button. This option is not recommended because records of the session running will be incomplete.

16. REMOVING THE DEVICE

Before removing the device, make sure that no session is running. The indicator light should be flashing green or off.

INDICATOR LIGHT	MEANING	ACTION
 Flashing green	actiTENS on without any session running or on pause.	You can remove it.
Permanent yellow	Session running	Pause or stop the session before removing. The indicator light changes to flashing green.

Carefully peel off the electrodes and place them on their plastic film before putting them in their bag.

The cables can be removed from the actiTENS together with the electrode by carefully unclipping the connectors (do not pull on the cables).

17. 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.

This information can be shared with your healthcare professional during follow-up consultations so

that your treatment can be analysed and adapted if necessary.

18. UPDATING THE actiTENS

18.1. General remark

We strongly recommend that you keep your telephone and applications updated, both for security reasons and to ensure compatibility or enhanced user experience. Updates are available for:

- The actiTENS mobile app
- The actiTENS neurostimulateur

18.2. Updating the actiTENS app

You can use Google Play or App Store to check whether a new version of the app is available. There is also a link in the "**My Account**" menu of the app.

18.3. Updating the actiTENS neurostimulator

- **Step 1:** Download the latest version of the mobile app.
- **Step 2:** The app itself will tell you whether the actiTENS can be updated. You can also update the actiTENS from the "**Programmes**" menus, "actiTENS" and "**My Account**".
- **Step 3:** Make sure that the actiTENS and your telephone are sufficiently charged (at least 50%).
- **Step 4:** Make sure the Bluetooth connection between your telephone and the actiTENS is maintained right the way through the operation so that you don't have to start all over again. To ensure the connection, keep the telephone,with Bluetooth on, close to the actiTENS while updating.
- **Step 5:** Follow the instructions sent by the app. The indicator light turns flashing blue until the update is finished, when it will change to flashing green. Once launched, the update must be allowed to continue to the end for normal use afterwards.

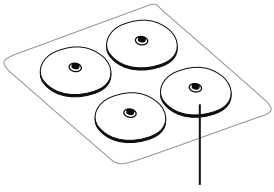
IMPORTANT INFORMATION: You cannot turn off the actiTENS when the indicator light is flashing blue. If it does turn off because the battery is discharged, just put it on charge (the indicator light will be flashing blue) to resume the updating.

19. OPTIONAL ACCESSORIES

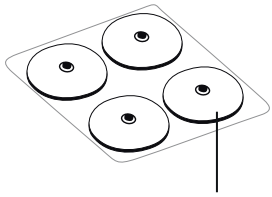
19.1. Optional actiTENS accessories (to order separately)

For a full list, go to our website: www.subli-med.com

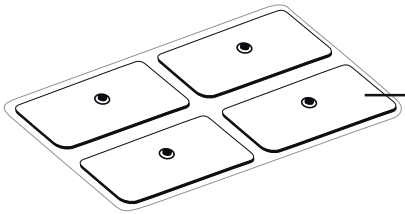
- actiTENS electrodes diameter 32 mm
- actiTENS electrodes diameter 50 mm
- actiTENS electrodes 50 mm x 90 mm
- Mixed actiTENS electrodes 50 mm x 50 mm and 50 mm x 90 mm
- actiTENS multisite electrode
- actiTENS low back electrode (preferably for use with 4 cables of 14 cm)
- 100 cm actiTENS cables
- actiTENS self-adhesive strip
- actiTENS armband XS size
- actiTENS armband XL size
- actiTENS belt / bra accessory



Electrode Ø 32 mm

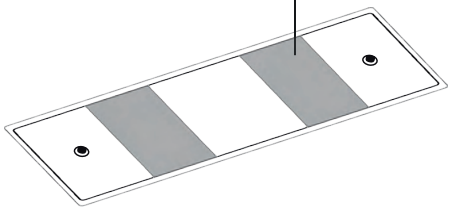


Electrode Ø 50 mm

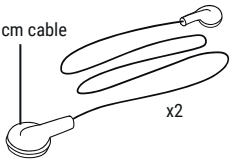


Electrode 50 mm x 90 mm

Multisite electrode

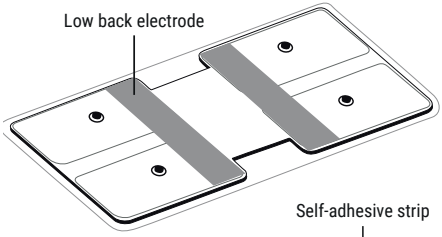


100 cm cable

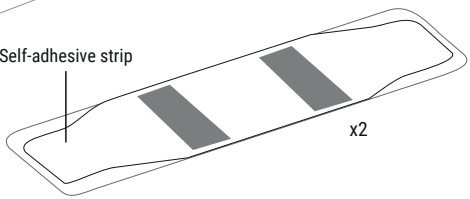


x2

Low back electrode

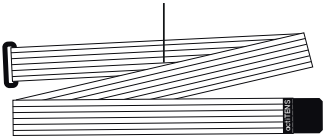


Self-adhesive strip

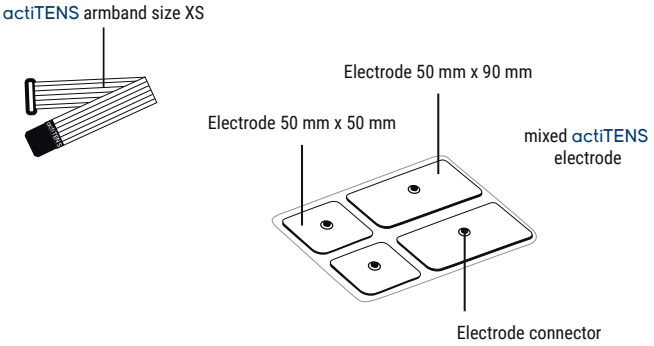


x2

actiTENS armband size XL



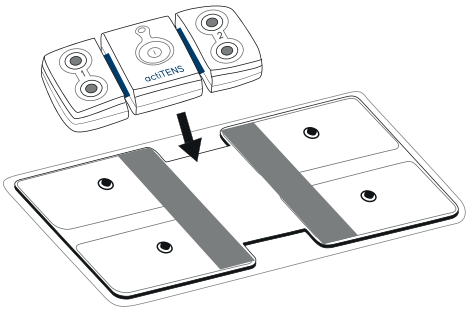
actiTENS belt / bra accessory



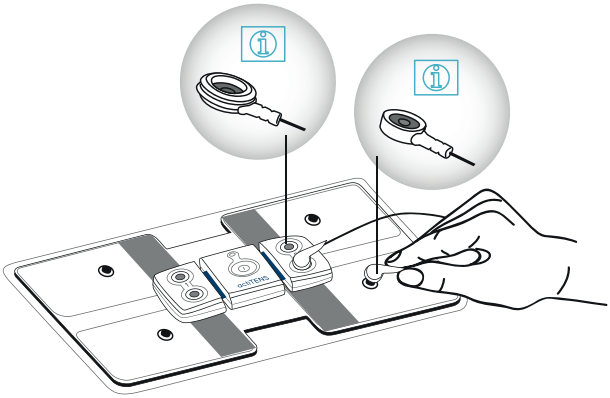
19.2 Using the low back electrode

- **First of all: prepare 4 cables.** When using the low back electrode, it is preferable to have 4 short 14 cm cables (to order separately) **Both actiTENS channels are active**.

- **Step 1:** attach the actiTENS to the low back electrode.



Step 2: clip the 4 cables on to the low back electrode and on to the actiTENS, making sure that the ends are compatible (narrow end on the electrode side, wide end on the actiTENS side).

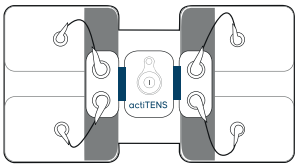


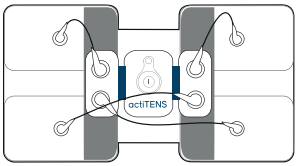
Remember

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

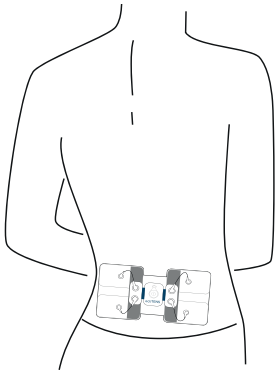
Remember

There are two possible configurations.





- **Step 3:** place the strip on the area of stimulation.



- **Step 4** : turn on the actiTENS by pressing the ON/OFF button. The indicator light will flash green. Your device is ready for your stimulation session. When you want to start a session, follow the instructions for **Launching a programme** (section 14).

20. STORING, CLEANING AND SCRAPPING

- Storing and using consumables (electrodes, self-adhesive strips and textile accessories):
  - Storing electrodes and self-adhesive strips: it is important to put electrodes and the self-adhesive strip on their plastic film and put them in their protective bag. Close the bag completely to prevent dust from entering.
  - Store in a dry place. Avoid extreme heat and direct exposure to the sun.
  - The electrodes, the self-adhesive strip and the actiTENS textile accessories can be used several times. The number of uses depends on the type of skin, the climate and the precautions taken during use and storage.
  - The electrodes have been tested for 20 peel-offs. However, it is recommended to change the electrodes every 2 weeks.
  - The self-adhesive strips have been tested for 7 peel-offs. When you have several stimulation sessions during the day, it is recommended to keep the self-adhesive strip on the skin between two sessions for longer life. It is recommended to change your self-adhesive strip every week.

- Storing the actiTENS neurostimulator and the actiCHARGE charging case:
  - Keep the devices away from water or other liquids.
  - Do not store at too high a temperature or humidity. The storage conditions for the actiTENS and accessories are given on the labels and in section 26.
  - Replace the device in its original package after use to prevent any damage.

- Cleaning:
  Make sure the actiTENS neurostimulator is switched off and the charging case unplugged before cleaning them.
  - Never immerse the actiTENS neurostimulator or the actiCHARGE charging case in water and do not rinse them. Never immerse consumables in water. Do not use any other cleaning products than those given below. They may cause serious damage to the equipment.
  - To remove dirt, use a damp cloth and mild detergent (e.g. washing up liquid), to clean the actiTENS, the cables, the AC charger and the actiCHARGE charging case. You can also use 70% isopropyl alcohol (IPA) to clean the actiTENS and the actiCHARGE charging case.
  - If the electrodes are dirty, put a drop of water on your finger and carefully remove the dirt from the surface. Neither soap nor alcohol may be used to clean electrodes.
  - It is recommended to machine wash the textile accessories at 40°C using a mild detergent before the first use and then every 3 weeks.

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

21. DEVICES LIFETIME

COMPONENT	LIFETIME
actiTENS neurostimulator	5 years
Charging case	5 years
Cables	6 months
Electrodes	2 weeks of treatment See the precautions for use and storage
Self-adhesive strip	1 week of treatment See the precautions for use and storage
Textile accessories	24 months See the cleaning precautions

22. CUSTOMER CARE SERVICE

- Errors encountered:
  - Flashing red indicator light.

POSSIBLE CAUSE	SOLUTION
actiTENS error	Switch off the equipment immediately, leave it for about fifteen minutes, then switch it back on. If the error recurs, contact Customer care.

NB: If you use the actiTENS at its maximum setting for several hours, it may overheat and go into error mode for safety. If this happens, wait for the device to cool completely. It is normal for the device to become warm during a session, but the heat will not cause injury or damage. Under normal conditions, the actiTENS can reach a temperature of 42.3°C.

• The actiTENS will not start.

POSSIBLE CAUSE	SOLUTION
1- The battery is discharged	Recharge the device.
2. actiTENS error	Contact Customer care.

• The stimulation seems different or less agreeable than before.

POSSIBLE CAUSE	SOLUTION
1- The electrodes are not correctly positioned	Change the position of the electrodes while not in a session by putting your session on Pause from the app.
2- The intensity is wrong	Set the intensity from the app so that the sensation is not disagreeable. The intensity necessary can vary from one session to another.
3- The electrodes are damaged	Check the condition of the electrodes: wear, cleanliness, expiry date. Replace or clean them.

• Slight discharge on touching the electrodes.

POSSIBLE CAUSE	SOLUTION
A session was in progress when you touched the electrodes	Always end or pause a session before handling the electrodes.

• The actiTENS becomes disconnected.

• Once the programme is launched, disconnection does not affect the running of the actiTENS. The Bluetooth signal range may be affected by the charge level of your telephone or your actiTENS. Some telephones are designed to cut the connection more quickly to save the battery. To reconnect your actiTENS, go to the actiTENS menu and press "**Detect an actiTENS**".

For the actiTENS to function correctly, it must not be paired or manually associated with the telephone; the connection must always be made from the actiTENS app. If you have connection problems, check whether the actiTENS is among the devices listed in the Bluetooth menu and dissociate them.

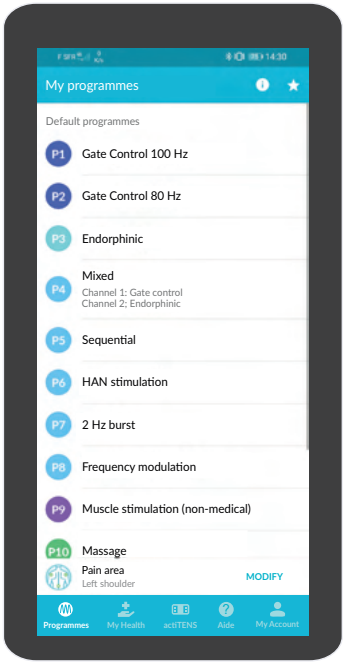
- The neurostimulator and its components are guaranteed under normal conditions of use.

COMPONENT	DURATION OF THE GUARANTEE
actiTENS neurostimulator	2 years
actiCHARGE charging case and AC charger	2 years
Cables	Not guaranteed
Electrodes, self-adhesive strip, textile accessories	Consumables not guaranteed: see the precautions for use and storage

- Outside the guarantee, there is no maintenance on the device and its components. Do not try to modify the device or the guarantee will no longer be valid. Under normal conditions of use, the actiTENS is designed to have a lifetime of at least 5 years.
- Contact your local dealer:
  - if you need help in installing or using the device.
  - to report abnormal functioning or events.

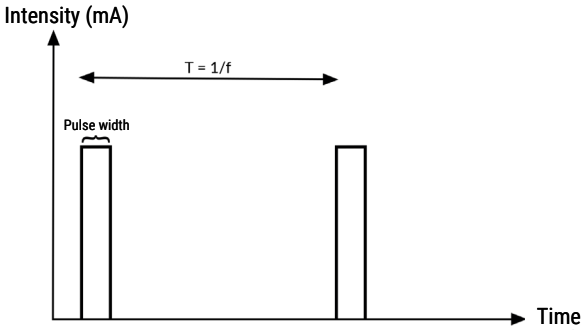
  For a full list, go to our website: www.subli-med.com

23. DESCRIPTION OF THE PROGRAMMES



P1 GATE CONTROL 100 HZ

Technical specifications	Frequency: 100 Hz Pulse width: 200 µs Default duration: 30 min
Mode of action	Inhibition of pain signal



P2 GATE CONTROL 80 HZ

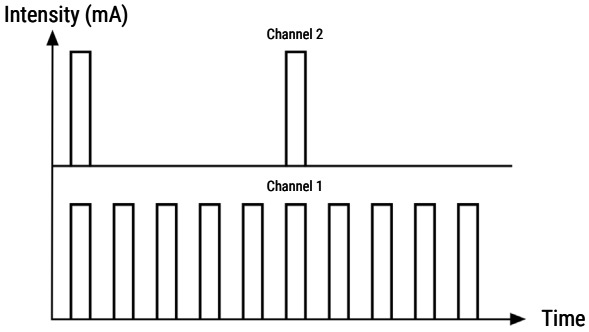
Technical specifications	Frequency: 80 Hz Pulse width: 150 µs Default duration: 30 min
Mode of action	Inhibition of pain signal

P3 ENDORPHINIC

Technical specifications	Frequency: 2 Hz Pulse width: 250 µs Default duration: 30 min
Mode of action	Stimulation of endorphin secretion for a general analgesic effect

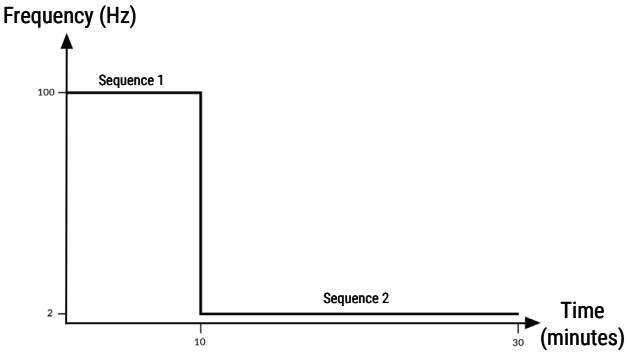
P4 MIXED

Technical specifications	▪ **Channel 1: Gate Control** Frequency: 100 Hz Pulse width: 200 µs ▪ **Channel 2: Endorphinic** Frequency: 2 Hz Pulse width: 200 µs ▪ Default duration: 30 min
Mode of action	Combined action: ▪ Inhibition of pain signal ▪ Stimulation of endorphin secretion for a general analgesic effect



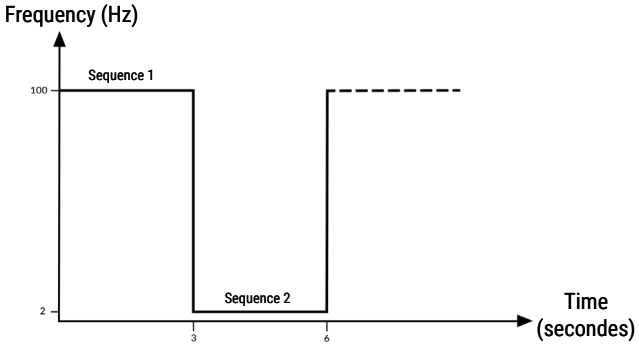
P5 SEQUENTIAL

Technical specifications	▪ **1st sequence (1/3 of the duration, hence by default: 10 min): Gate Control** Frequency: 100 Hz Pulse width: 150 µs ▪ **2nd sequence (2/3 of the duration, hence by default: 20 min): Endorphinic** Frequency: 2 Hz Pulse width: 200 µs ▪ Default duration: 30 min
Mode of action	Combined action: ▪ Inhibition of pain signal ▪ Stimulation of endorphin secretion for a general analgesic effect



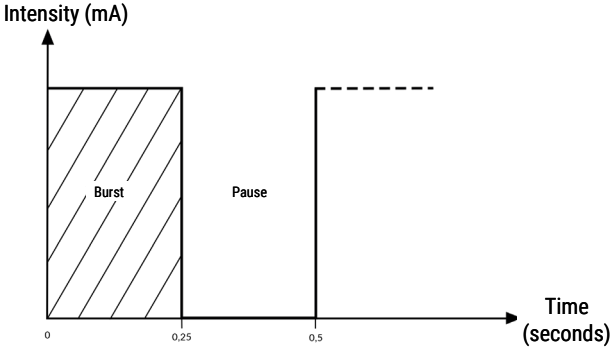
P6 HAN STIMULATION

Technical specifications	▪ **1st sequence (duration: 3 s): Gate control** Frequency: 100 Hz Pulse width: 150 µs ▪ **2nd sequence (duration: 3 s): Endorphinic** Frequency: 2 Hz Pulse width: 200 µs ▪ These two sequences are alternated every 3 s. ▪ Default duration: 30 min
Mode of action	Combined action: ▪ Inhibition of pain signal ▪ Stimulation of endorphin secretion for a general analgesic effect



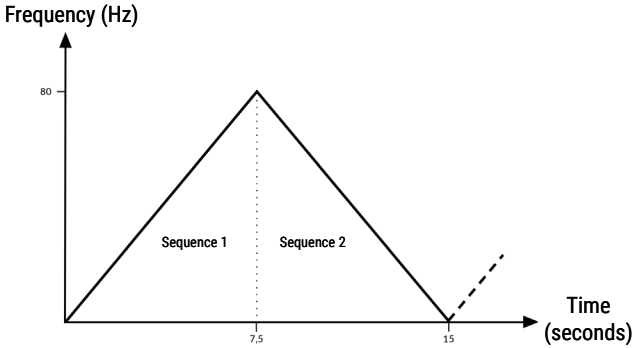
P7 2 HZ BURST

Technical specifications	▪ **1st sequence (duration: 0.25 s): Gate Control** Frequency: 100 Hz Pulse width: 150 µs ▪ **2nd sequence (duration: 0.25 s): No pulse** ▪ These two sequences are alternated every 0.25 s. ▪ Default duration: 30 min
Mode of action	Inhibition of pain signal



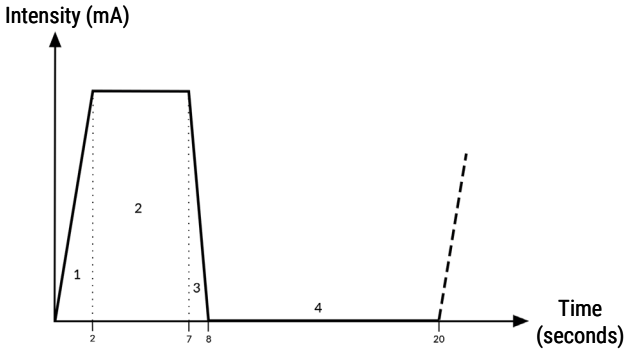
P8 FREQUENCY MODULATION

Technical specifications	▪ **1st sequence (duration: 7.5 s):** Rising frequency: 2 Hz to 80 Hz Falling pulse width: 200 µs to 100 µs ▪ **2nd sequence (duration: 7.5 s):** Falling frequency: 80 Hz to 2 Hz Rising pulse width: 100 µs to 200 µs ▪ These two sequences are alternated every 7.5 s. ▪ Default duration: 30 min
Mode of action	Combined action: ▪ Inhibition of pain signal ▪ Stimulation of endorphin secretion for a general analgesic effect



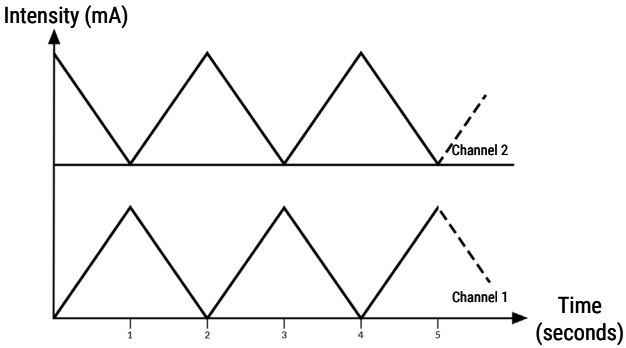
P9 MUSCLE STIMULATION (NON-MEDICAL)

Technical specifications	Frequency: 50 Hz Pulse width: 250 µs ▪ **1st sequence (2 s):** Increasing intensity: 0 mA to the set intensity ▪ **2nd sequence (5 s):** constant intensity (set intensity) ▪ **3rd sequence (1 s):** Decreasing intensity set intensity to 0 mA ▪ **4th sequence (12 s):** No pulse ▪ The sequences are alternated for the duration of the programme ▪ Default duration: 30 min
Mode of action	Muscle strengthening (non-medical programme, not covered by the BSI certificate)



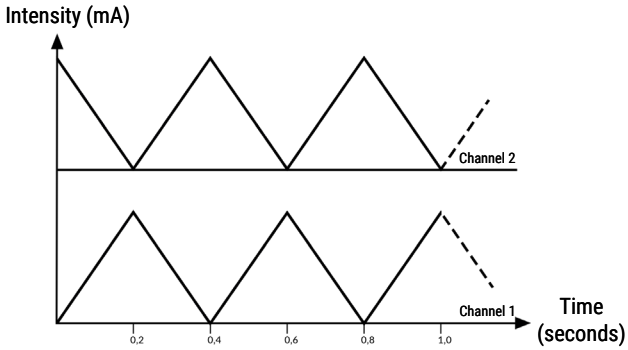
P10 MASSAGE

Technical specifications	Frequency: 80 Hz Pulse width: 150 µs ▪ **Channel 1:** • **1st sequence (1 s)**: Increasing intensity from 0 mA to the value set • **2nd sequence (1 s):** Decreasing intensity from the value set to 0 mA ▪ **Channel 2:** • **1st sequence (1 s):** Decreasing intensity from the value set to 0 mA • **2nd sequence (1 s)**: Increasing intensity from 0 mA to the value set ▪ Default duration: 30 min
Mode of action	Inhibition of pain signal



P11 FRICTION

Technical specifications	Frequency: 80 Hz Pulse width 150 µs ▪ **Channel 1:** • 1st sequence (0.2 s): Increasing intensity from 0 mA to the value set • 2nd sequence (0.2 s): Decreasing intensity: value set to 0 mA ▪ **Channel 2:** • 1st sequence (0.2 s): Decreasing intensity: from the value set to 0 mA • 2nd sequence (0.2 s): Increasing intensity from 0 mA to the value set ▪ Default duration: 30 min
Mode of action	Inhibition of pain signal



P12 SENSITIVE AREAS

Technical specifications	Frequency: 80 Hz Pulse width: 60 µs Default duration: 30 min
Mode of action	Inhibition of pain signal

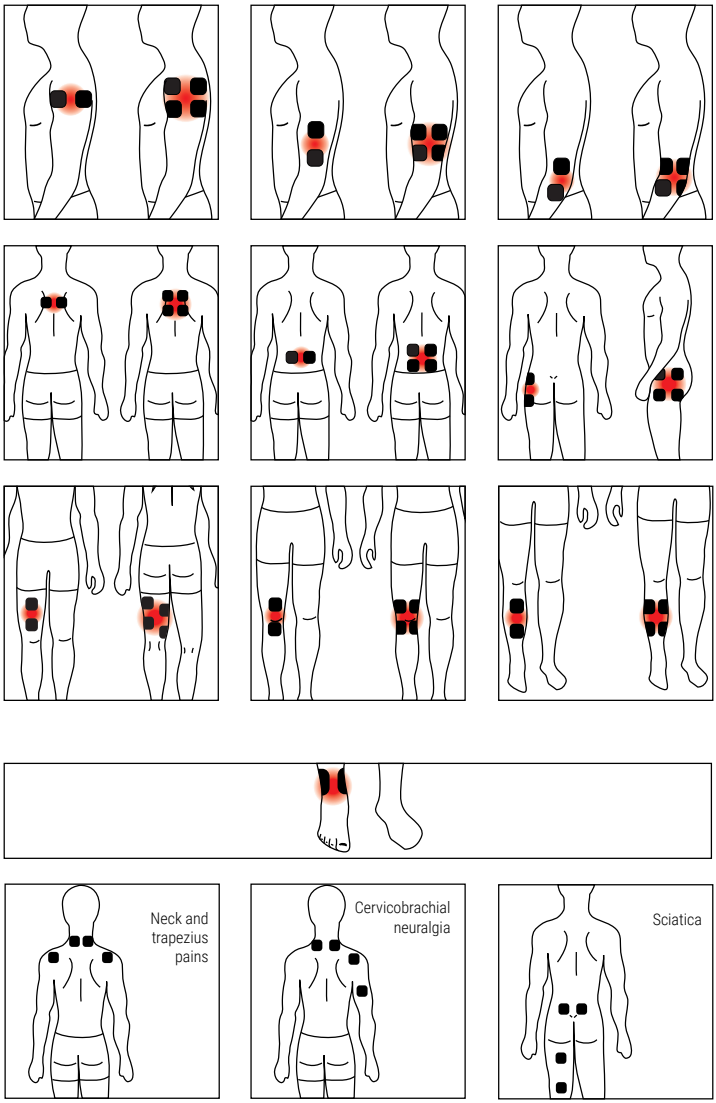
The type of treatment and choice of programme should be decided with your doctor according to your pathology.

24. POSITIONING THE ELECTRODES

The electrodes can be positioned according to the painful area to be stimulated, using either 2 electrodes or 4 electrodes. We remind you that it is strongly recommended to consult a health professional to test the positioning of the electrodes for the best possible pain relief.

During this test, to find the optimum position for you we recommend that you choose an initial position of the electrodes and launch a programme. To adjust the positioning, you can use the "Pause" mode ( ). The session is then suspended and the electrodes can be handled safely. Relaunch the programme after re-positioning the electrodes and readjust the intensity.

Examples of electrode positioning:



25. CATALOGUE REFERENCES

actiTENS **standard Kit** **SBM1AA008**

- 1 actiTENS (neurostimulator) **SBM1AA100**
- 1 Standard size actiTENS armband **SBM1AG301**
- 1 pack of 2 x 40 cm actiTENS cables **SBM1AE001**
- 1 pack of 2 x 14 cm actiTENS cables **SBM1AE002**
- 1 pack of 2 x 70 cm actiTENS cables **SBM1AE004**
- 4 actiTENS electrodes 50 mm x 50 mm **SBM1AC003**
- To charge the device:
  - 1 actiCHARGE charging case **SBM1AF100**
  - 1 AC charger **SBM1AF200**
- 1 user guide **SBM1AL001**

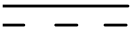
Optional actiTENS **accessories (to order separately):**
For a full list, go to our website: www.subli-med.com

- actiTENS electrodes diameter 32 mm **SBM1AC001**
- actiTENS electrodes diameter 50 mm **SBM1AC002**
- actiTENS electrodes 50 mm x 90 mm **SBM1AC004**
- Mixed actiTENS electrodes 50 mm x 50 mm et 50 mm x 90 mm **SBM1AC005**
- actiTENS low back electrode (preferably for use with 4 cables of 14 cm) **SBM1AD002**
- actiTENS multisite electrode **SBM1AN001**
- 100 cm actiTENS cables **SBM1AE003**
- actiTENS self-adhesive strip **SBM1AB001**
- actiTENS armband XS size **SBM1AG300**
- actiTENS armband XL size **SBM1AG302**
- actiTENS belt / bra accessory **SBM1AG400**

26. TECHNICAL DATA SHEET

TECHNICAL SPECIFICATIONS	
Intended operator	Final users (patients), caregivers or expert users. All users must be persons over 18 years of age with unimpaired intellectual abilities.
Channels	2 independent channels
Programmes	12 programmes including: ▪ Gate control: 80-100 Hz, pulse width 150-200 µs ▪ Endorphinic: 2 Hz, pulse width 250 µs ▪ Mixed programmes ▪ EMS programme (electrical muscle stimulation) Current delivered: from 1 mA to 60 mA ± 10% (1000 Ω) in steps of 0.5 mA
Battery	Li-ion
actiTENS output voltage and intensity	max 60 mA ± 10% (1000 Ω) / max 60 V ± 10%
Essential performance of the actiTENS	Does not deliver a current > 60 mA ± 10% or a voltage > 60 V ± 10%
AC charger input voltage and intensity	100-240 V AC 0.1-0.2 A
Frequency of supply network	50-60 Hz
Input and output voltage and intensity of the actiCHARGE charging case	5 V DC – 1 A
Conditions of use of the actiTENS, the actiCHARGE charging case and the AC charger	From 10°C to 40°C with relative humidity from 15% to 93% Atmospheric pressure from 700 hPa to 1060 hPa
Charging conditions of the actiTENS	Ambient temperature
actiTENS standard kit storage conditions	From 5°C to 35°C with relative humidity from 30 % to 80 % Temperature between 15°C and 25°C are best suited to preserve the battery's capacity
actiTENS storage conditions	From -10°C to 45°C with max. relative humidity of 93% Temperature between 15°C and 25°C are best suited to preserve the battery's capacity
actiCHARGE charging case storage conditions	From -20°C to 60°C
AC charger storage conditions	From -40°C to 85°C
Warm-up time of the device when it has been stored at -10°C for it to be ready for use at ambient temperature (20°C)	5 minutes minimum

TECHNICAL SPECIFICATIONS (CONT)	
Cooling time of the device when it has been stored at 45°C for it to be ready for use at ambient temperature (20°C)	10 minutes minimum
actiTENS dimensions	108 mm x 53.5 mm x 17 mm
Weight of actiTENS	~ 65 g
actiCHARGE charging case dimensions	133.8 mm x 79 mm x 34 mm
actiCHARGE charging case weight	~ 115 g
actiTENS IP classification	IP22: protection against solid bodies greater than 12.5 mm, protection against dripping water up to 15° from the vertical
actiCHARGE charging case IP classification	IP21: protection against solid bodies greater than 12.5 mm, protection against vertically dripping water
Waveform	Compensated asymmetric two-phase waves
Pulse width	50-400 µs ± 5 µs
Frequency	1-120 Hz ± 10%
Sessions length	10 min-12 h adjustable with the mobile app
Electrode	Any electrode in which the current density exceeds 2 mA/cm^2 requires special attention; stimulation should never be painful.
actiTENS electrode storage conditions	From 5°C to 35°C with relative humidity from 30 % to 80 %
actiTENS self-adhesive strip storage conditions	From 0°C to 40°C
Composition actiTENS self-adhesive strip	Medical grade silicone
Composition actiTENS textile accessories	Main fabric: Polyamide 58%, Polyester 30%, Elastane 12% Label: Polyamide 90%, Elastane 10% Buckle and Velcro: Polyamide
Composition of the low back and multisite electrodes	Biocompatible hydrogel conductor (High polymer material, Glycerin, Water, Salt), conducting part: vinyl carbon; insulating base material: non-woven PET 25 microns, Velcro: Velour 3165, snap connector: stainless steel 316
Composition of the standard electrode	Biocompatible hydrogel conductor (High polymer material, Glycerin, Water, Salt), conducting part: carbon + PE; insulating base material: non-woven PET fibre, snap connector: stainless steel

SYMBOLS	DESCRIPTION OF THE SYMBOLS USED
	This device includes a radio frequency emitter and emits non-ionising radiation. The device is connected to the mobile application through low energy Bluetooth communication. Frequency range: [2,400 – 2,483.5] MHz Modulation: DSSS EIRP: -9.8 dBm
	Read the user guide carefully before use.
	Device with a degree of protection against electric shocks in compliance with standard IEC 60601-1 The entire actiTENS envelope is a type BF applied part.
	Designed solely for use INDOORS. This is only applies when the device is connected to the mains.
	The device, its accessories and packaging must be recycled appropriately at the end of use. Please follow the local regulations.
	Manufacturer's name and address.
CE 2797	EC marking.
SN	Device serial number.
REF	Device reference number.
	N.B. Read the user guide carefully before use.
	State of the actiTENS battery.
	Electrical input.
	Electrical output.
	Direct current.
	Alternating current.
	Class II equipment.

SYMBOLS	DESCRIPTION OF THE SYMBOLS USED
	Symbol of the actiTENS ON/OFF button for switching the neurostimulator on and off.
	Humidity range to which the device may be exposed during storage.
	Minimum and maximum temperatures to which the medical device may be exposed during storage.
	Date beyond which the device must not be used.
	Device batch number.
	Quantity of products.
	Name and address of the authorised representative in the European Community.
	Name and address of the importer.
	Medical Device.
	Recyclable user guide and plastic packaging in France.
	Medical device for use several times on a single patient.
	Consult the user guide.
	Maximum washing temperature 40°C.
	Do not iron.
	Do not bleach.
	Do not dry clean.
	Do not machine dry.

27. ELECTROMAGNETIC COMPATIBILITY

actiTENS medical device is intended to be used in a home healthcare environment (for example at home, in the street or at the restaurant) or in a professional healthcare facility environment, while considering the precautions for use and the conditions described in this chapter.

The actiTENS kit is designed for use in an electromagnetic environment specified below.

The actiTENS user must ensure that it is used in such an environment.

WARNINGS

- Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the actiTENS, including its cables. Otherwise, degradation of the performance of the actiTENS and these devices could result. See table 2 for further details on the appliances tested.
- Use of the actiTENS adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the actiTENS and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided with the actiTENS could result in increased electromagnetic emissions or decreased electromagnetic immunity of the actiTENS and result in improper operation.

Table 1: Manufacturer's directives and declaration – Electromagnetic emissions

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – DIRECTIVES
CISPR RF emissions 11	Group 1	The actiTENS only uses RF power for its internal functions. Therefore its RF emissions are very low and are not likely to cause interference with a nearby appliance.
CISPR RF emissions 11	Class B	The actiTENS is suitable for use in all places, including in the home and in places directly connected to the low voltage mains for domestic buildings.
Harmonic emissions IEC 61000-3.-2.	Class A	
Voltage fluctuations / flicker IEC 61000-3-3	Compliant	

Table 2 : Manufacturer's directives and declaration – Electromagnetic immunity

IMMUNITY TESTS	TEST LEVEL IEC 60601-1-2	LEVEL OF COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – DIRECTIVES
Electrostatic discharges (DES) IEC 61000-4-2	± 8 kV on contact ± 2, 4, 6, 8 and 15 kV in the air	± 8 kV on contact ± 2, 4, 6, 8 and 15 kV in the air	Stimulation should not be launched until the appliance has been set up according to the procedure described in §11. Floors should be of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity of the floor should be at least 30%.
Repeated fast transients IEC 61000-4-4	± 2 kV for electricity power lines ± 1 kV for input/ output lines Repetition frequency 100 kHz	± 2 kV for electricity power lines ± 1 kV for input/ output lines Repetition frequency 100 kHz	The quality of the mains power supply should be that of a typical commercial or hospital environment.
Transitory over-voltage IEC 61000-4.-5	± 0.5, ± 1 kV between phases ± 0.5, ± 1, ± 2kV between phase and earth	± 0.5, ± 1 kV between phases ± 0.5, ± 1, ± 2 kV between phase and earth	The quality of the mains power supply should be that of a typical commercial or hospital environment.
Voltage dips, brief cut-offs and voltage variations on electrical power input lines IEC 61000-4-11	0% Ut for a duration of 0.5 cycles 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% for a duration of 250/300 cycles at 0°	0% Ut for a duration of 0.5 cycles 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% for a duration of 250/300 cycles at 0°	The quality of the mains power supply should be that of a typical commercial or hospital environment. If the actiTENS user requires continuous running during power cuts, they are recommended to power the actiTENS with an uninterruptible power supply or a battery.

IMMUNITY TESTS	TEST LEVEL IEC 60601-1-2	LEVEL OF COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT
Magnetic field at mains frequency	30 A/m 50 and 60 Hz	30 A/m 50 and 60 Hz	Magnetic fields at mains frequency should have levels of representative locations typical for commercial or hospital environments.
Conducted RF Disturbances IEC 61000-4-6	3 Vrms from 150 kHz to 80 MHz 6 V in ISM bands	3 Vrms from 150 kHz to 80 MHz 6 V in ISM bands	IPortable and mobile RF communication equipment must not be used closer to any part of the actiTENS, including cables, than the recommended separation distance, from the equation applicable to the frequency of the emitter.of the app. Recommended separation distance d=1.2 √P
Radiated RF disturbances IEC 61000-4-3	10 V/m from 80 MHz to 2.7 GHz	10 V/m from 80 MHz at 2.7 GHz	d=1.2 √P for a frequency between 80 MHz and 800 MHz d=2.3 √P for a frequency between 800 MHz and 2.7 GHz where P is the transient maximum output power of the emitter in watts (W) according to the manufacturer of the emitter and is the recommended separation distance in metres (m). The field intensities of fixed RF emitters, determined by an on-site[a] electromagnetic investigation, should be lower than the level of compliance in each range of frequencies[b]. Disturbances may be produced near appliances marked with the following symbol: 

IMMUNITY TESTS	TEST LEVEL IEC 60601–1–2	LEVEL OF COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT– DIRECTIVES
Near field emitted by RF wireless communications equipment. IEC 610004-3	The equipment must not be used at a distance of <30 cm from another electronic device 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 compliance with the levels required by standard 60601-1.-2.	The equipment must not be used at a distance of <30 cm from another Service electronic device: 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 compliance with the levels required by standard 60601-1-2.	The actiTENS has been tested and found compatible in the corresponding environments.
Proximity magnetic fields IEC 61000-4-39	134.2 kHz / Pulse modulation 2.1 kHz / 65A/m 13.56 MHz / Pulse modulation 50 kHz / 7.5A/m 30 kHz / CW / 8A/m	134.2 kHz / Pulse modulation 2.1 kHz / 65A/m 13.56 MHz / Pulse modulation 50 kHz / 7.5A/m 30 kHz / CW / 8A/m	The actiTENS has been tested and found compatible in the corresponding environments.

NOTE 1: At 80 MHz and 800 MHz, the highest frequency range applies.

NOTE 2: These directives may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection form structures, objects and people.

[a] The field intensities of fixed emitters, such as telephone base stations (cellular/cordless) and terrestrial mobile radios, amateur radio, AM and FM transmission and TV transmission cannot be predicted theoretically with any accuracy. To assess the electromagnetic environment due to fixed RF emitters, an on-site electromagnetic investigation should be carried out. If the field intensity, measured at the location where the actiTENS is used, exceeds the applicable RF compliance level above, the actiTENS should be observed to make sure that functioning is normal. If abnormal performance is observed, extra measures may be required such as reorienting or repositioning the actiTENS.

[b] Over the reference range of frequencies from 150 kHz to 80 MHz, field intensities should be lower than 3 V/m and 6 V/m for the ISM bands.

Table 3: Recommended separation distances between portable and mobile RF communications

MAXIMUM RATED OUTPUT POWER OF THE EMITTER W	SEPARATION DISTANCE ACCORDING TO EMITTER FEQUENCY M		
	FROM 150 KHZ TO 80 MHZ D=1.2 √P	FROM 80 MHZ TO 800 MHZ D=1.2 √P	FROM 800 MHZ TO 2.7 GHZ 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 for which the maximum rated output power is not given above, the recommended separation distance d in metres (m) can be determined from the equation applicable to the emitter frequency, where P is the transient maximum output power of the emitter in watts (W) according to the manufacturer.

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

NOTE 2: These directives may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection form structures, objects and people.

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Customers located outside of France, contact your local dealer.
Kunden außerhalb von Frankreich, wenden Sie sich an den Fachhandel.
Clienti che abitano fuori dalla Francia, contattare il rivenditore locale.
Afnemers die buiten Frankrijk gevestigd zijn, contact op met uw plaatselijke dealer.

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SBM1AL001

actiTENS
CE 2797

Premier marquage obtenu en janvier 2018
First marking obtained in 2018
CE-Kennzeichnung erstmals im Januar 2018 erhalten
Primo marchio ricevuto in gennaio 2018
Eerste markering verkregen in januari 2018