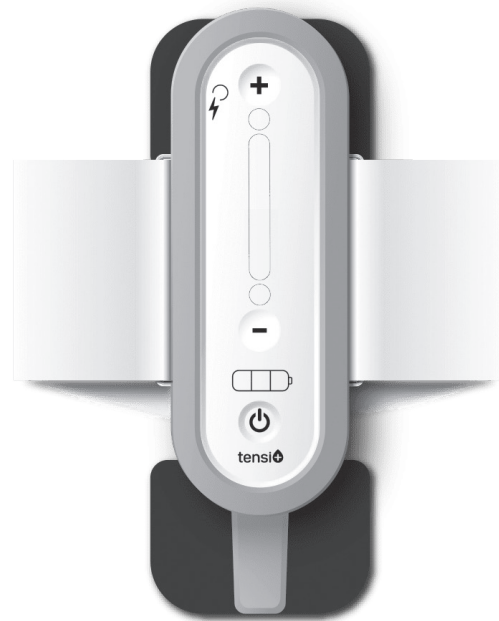




tensi+

tensi+

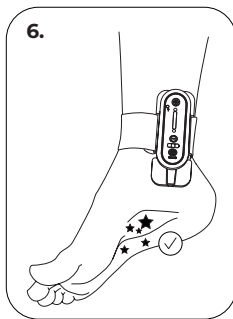
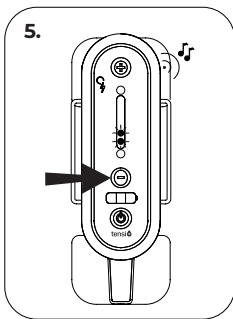
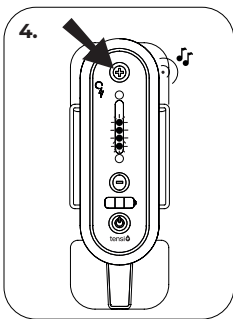
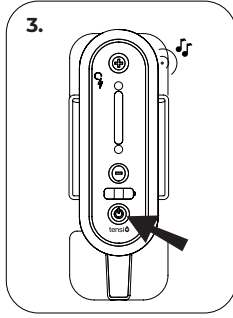
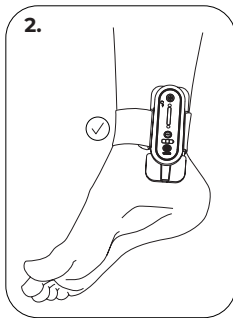
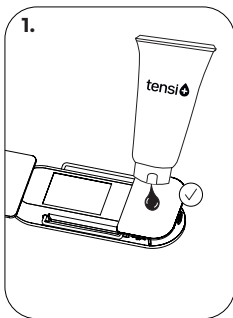


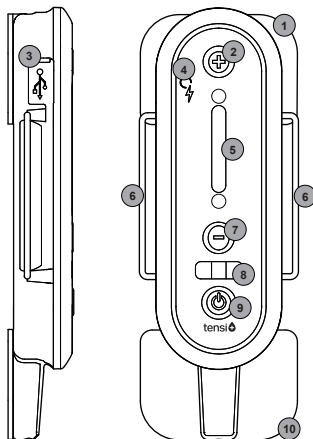
 Stimuli Technology
20 bis rue Barthélémy Danjou
92100 Boulogne-Billancourt
France
www.tensiplus.com
PID 12899



FUI-PF0001-01/05-2024

CE
2797





DEVICE DESCRIPTION

Tensi+ was designed to stimulate the posterior tibial nerve.

- 1. Positive electrode**
- 2. Button (+)** to increase the intensity of the stimulation
- 3. Charging port**
- 4. Charge indicator**
- 5. LEDs** showing the stimulation intensity
- 6. Loop** to insert the retention strap
- 7. Button (-)** to reduce the intensity of the stimulation
- 8. Battery charge level indicator**
- 9. On/Off button:** holding down the button for 1 second turns the device on or off
- 10. Negative electrode**



INSTRUCTION MANUAL

1. Important safety instructions.....	26
2. Purpose.....	26
3. Information about TENS technology	28
4. Technical description	28
5. Using the Tensi+ device.....	29
6. Cleaning and maintenance	34
7. Environmental conditions.....	35
8. Disposal of the device parts.....	36
9. Warranty.....	36
10. Troubleshooting	36
11. Technical data	39
12. Electromagnetic sensitivity	40

Dear User, these instructions on the use of the Tensi+ device are intended for the patient or carer.

1. IMPORTANT SAFETY INSTRUCTIONS – Warnings

- Read the manual carefully before using the device and always follow the treatment instructions.
- Always use this device as intended and as described in this manual. Store the device in a dry place and at room temperature (between -10°C (14°F) and 40°C (104°F)).
- This device is not waterproof. Except the electrodes when they are disassembled from the device, keep away from water and any other liquid.
- Protect this device from electric shocks.
- Do not drop the device.
- Follow the maintenance instructions in this manual.
- Never alter the device or try to open it. If there is a problem, contact the manufacturer.
- This is a medical device. Keep it out of the reach of children. Stop using the device if there is an anomaly or malfunction.
- If the charging port cover is lost or if the device casing is damaged, the device may no longer provide IP22 protection.

2. PURPOSE

Indications

Tensi+ was designed to stimulate the posterior tibial nerve. It is indicated for the treatment of an idiopathic or neurogenic overactive bladder involving urinary urgency, urge incontinence, nocturia or pollakiuria. It is intended for adult patients (from the age of 18) without contraindications.

Contraindications – Do not use the device

- If you have a pacemaker, a defibrillator, or any other implanted electronic device as any use could cause an electric shock, interference, burns or a malfunction of the pacemaker;
- If you have a metal implant near to the area stimulated as any use may cause burning or interference with Tensi+;
- If you have joint problems in your ankles, ankle oedema or dermatological oedema in the area where the electrodes need to be placed;
- On injured skin;
- If you are pregnant;
- If you have a cognitive deficiency.

If in doubt, ask your doctor.

Precautions for use

Tensi+ must only be used with the original accessories: charging cable (part no.: AC0203), retention strap, graphite silicone electrodes. Replacement accessories are available separately. The device must always be placed along the posterior tibial nerve on the inner side of the (right or left) ankle. The device must never be placed in another area. Place the device on clean skin, facing the right way, with the on/off button at the bottom. The device should not be charged while it is being worn by the patient.

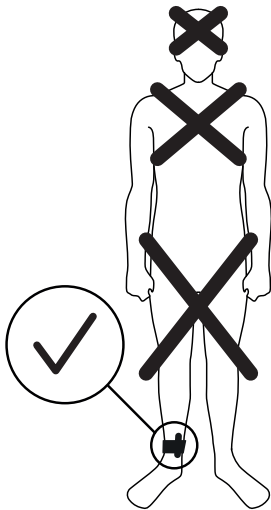
Warnings

Do not use Tensi+ for other indications. Simultaneous use with a high-frequency surgical device may cause burns under the Tensi+ electrodes.

Tensi+ is a medical electronic device requiring special precautions for electromechanical compatibility. This device should not be used in an environment with strong electromagnetic interference. Using Tensi+ near (around 1 m/3 ft. from) a microwave, short-wave or ultra-short-wave device (microwave oven, Wi-Fi terminals or modules, mobile phones, Bluetooth systems, etc.) may alter the stimulation settings.

Undesirable effects

If you experience pain or discomfort, stop using the product and contact your doctor. Use maximum intensity treatments with caution. Do not exceed your comfort level.



3. INFORMATION ABOUT TENS TECHNOLOGY

Transcutaneous Electrical Nerve Stimulation, more commonly known as TENS, is a non-medicinal, non-invasive technique. It uses electrodes on the skin to deliver electrical pulses close to an innervated area to affect nerve transmission. Tensi+ targets the posterior tibial nerve, part of which originates close to the nerve fibres controlling the bladder. Stimulating this nerve modulates messages sent between the bladder and the brain, improving the central nervous control of urination. Clinical studies have shown that treatment lasting 20 minutes once a day can reduce* the symptoms of overactive bladder (urinary urgency: irrepressible and urgent urge; urge incontinence: inability to avoid urinating; nocturia: need to urinate at least once a night; pollakiuria: urge to urinate more than eight times a day) and improve the quality of life.

**A decrease in symptoms was observed from 1 month of treatment. It is recommended to continue treatment for at least 2 months.*

Ammi M, Chautard C, Brassart E, Culty T, Azzouzi AR, Bigot P (2014) Transcutaneous posterior tibial nerve stimulation: evaluation of a therapeutic option in the management of anticholinergic refractory overactive bladder - The International Urogynecological Association

4. TECHNICAL DESCRIPTION

Tensi+ is a Transcutaneous Electrical Nerve Stimulator (TENS) of the posterior tibial nerve that delivers pulses of an adjustable intensity through electrodes placed on the skin.

The Tensi+ device has a lifespan of 2 years according to IEC 60601-1-11.

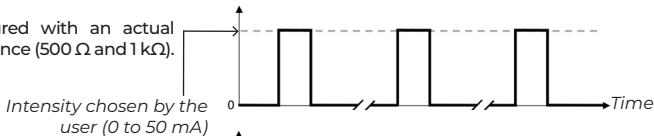
Technical characteristics:

Output current	0 to 50mA (+/- 10%)
Frequency	10Hz (+/- 20%)
Pulse width	200 µS (+/- 20%)
Rated current	15 mA

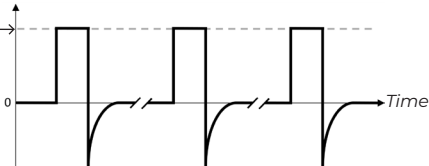
The values are valid under resistances of 500 Ohm and 1000 Ohm +/- 10%.

Pulse shape:

Measured with an actual resistance (500 Ω and 1 k Ω).



Measured using an ANSI/AAMI-standard model.



5. USING THE TENSİ+ DEVICE

a. Precautions before each use

- Take care not to damage the electrodes by bending them;
- Do not allow the electrodes to touch metal objects when using the device.
- You may use the device when dressed. Simply place the device under your clothes. Keep the electrodes in contact with your skin by adjusting the retention strap. Tensi+ is used with the electrodes directly on the skin. However, it is advisable to place a small amount of conductive gel (*TENS*) *conductive gel for electrodes*) between each electrode and your skin for greater comfort.

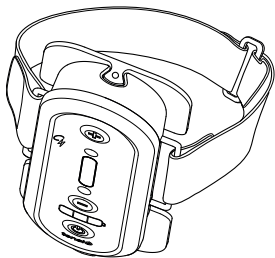
It is recommended to use gel in the following situations:

- On dry skin and areas covered with body hair, if you experience tingling, or if you have trouble making good contact with the skin which will cause the device to switch itself off (the LEDs showing the level of intensity will flash and the device will emit sound signals).
- If using conductive gel, only use the conductive gel recommended by the manufacturer: (*TENS*) *conductive gel for electrodes*.

b. Assembling the device

One retention strap and 2 pre-assembled electrodes are provided with the device. To adjust the device at the ankle, pull on the long part of the retention strap. If the pre-assembled device is too loose, remove the short part of the strap and only use the long part. The strap keeps the device comfortably in place for use. Position the plastic buckle of the short part of the strap on either the inner or outer side of your ankle – whichever you prefer. Make sure the electrodes are installed correctly (see section 6.a) before using the device.

Assembly with two parts of the strap (long part + short part)



Assembly with one part of the strap (long part)



c. Positioning the device

Step 1: Clean your skin

Always use the device on clean skin. Any oil, cream, lotion, dust or other substance on the skin could affect the electrical pulses.

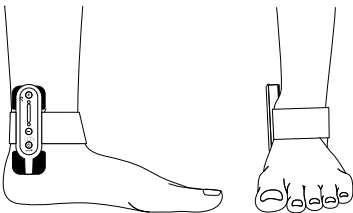
Clean the area to be treated (inner side of your ankle and Achilles tendon) with a damp cloth. Using the device on hydrated skin improves the electrical pulses.

Step 2: Add gel to the electrodes (recommended)

Place a small drop of gel on each electrode, just before applying Tensi+ to the site indicated in the next section.

Step 3: Place the device on the ankle

Install the device with the power off on either your right or left ankle, as shown below.

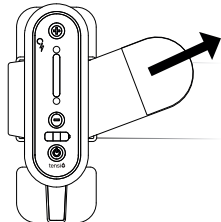


1. The lower electrode is placed below and behind the medial malleolus (inner side of the ankle).

2. The device is then placed along your leg, with the on/off button at the bottom.

Once the device is in place, pass the free end of the strap through the plastic buckle and tighten to adjust to your ankle.

For your comfort, do not pull too tight.



d. Operating the device

Step 1: Switch the device on

Press the on/off button for 1 second to turn on the device. You will hear a long, soft beep to indicate that the device is now on.

Step 2: Initiate the treatment

Press the (+) button (short or long press) to start the programme. LED 1, indicating the lowest treatment intensity, will light up and you will hear a short, soft beep.

Pressing the (+) or (-) button increases or decreases the intensity of the treatment by 0.5 mA. You will hear a short beep for each increment.

	(+)	
LED +	●	
LED 6	●	
LED 5	●	
LED 4	●	
LED 3	●	
LED 2	●	
LED 1	●	
LED -	●	
	(-)	

>25,0 mA	LED 1 to 6
[20-24,5] mA	LED 1 to 5
[15-19,5] mA	LED 1 to 4
[10-14,5] mA	LED 1 to 3
[5,5-9,5] mA	LED 1 to 2
[0,5-5] mA	LED 1

Step 3: Comfort level adjustment

You will need to adjust the comfort level every time you use the device:

Tensi+ stimulates the posterior tibial nerve which passes between the inner side of the ankle and the Achilles tendon. When used correctly, the treatment should not cause any pain or discomfort.

Find your comfort level as follows:

1. Gradually increase the intensity by pressing the (+) button until you feel a slight tingling on the bottom of your foot.

This means that the signal is being transmitted to the nerve.

2. Decrease the intensity by pressing the (-) button until you no longer feel discomfort due to the tingling. The LEDs show your comfort range.

If no tingling is felt on the bottom of the foot, this does not in any way mean that the device is not working. The sensation can vary from one individual to the next.



Please note:

- It is entirely possible to position Tensi+ on the ankle after turning it on. However, the intensity should only be regulated after positioning it on the ankle.
- The device will tell you if you exceed 10 mA by emitting 2 short beeps. This is simply for information purposes.
- To ensure that the device is positioned correctly on the tibial nerve, you can increase the intensity until your big toe contracts.
- En cas de déconnexion de l'appareil avec la peau de plus d'une seconde, l'intensité si le device is detached from the skin for more than one second, the stimulation level immediately drops to zero to keep the user safe and all 6 LEDs will flash. Ensure that the two electrodes are in contact with the skin, then press the (+) or (-) button to restart the adjustment.
- If you feel tingling under any of the electrodes, it means that the electrode is not properly in contact with your skin. Check that it is touching the skin, adding a small amount of conductive gel to the electrodes if necessary.

Step 4: Treatment

Once the device has been adjusted, you can move around, but depending on the morphology of the user's ankle the device may lose contact with the skin and disconnect (the LEDs showing the level of intensity will flash and the device will emit sound signals).

Auto-lock: 30 seconds after the last press of a button, the stimulation level increase function will lock to prevent an accidental increase. Press the (-) button to unlock the device. Then press the (+) button to increase the intensity and the (-) button to decrease the intensity. Then let the programme run until it is complete. The programme lasts 20 minutes. Once the programme has run for 20 minutes, the device will turn itself off automatically, the LEDs will turn themselves off and the device will emit a long beep.

Step 5: Stop the device

The device can be switched off at any time by pressing and holding down the on/off button.

Do not remove the device from your skin during the treatment. Always turn off the device before removing it.

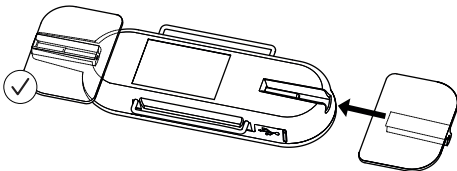
Step 6: Clean the device then put it away.

6. CLEANING AND MAINTENANCE

a. Installing and changing the electrodes

To remove the electrodes, gently pull lengthwise while applying a little pressure. Insert the electrodes the other way to reinstall them. The electrodes should be inserted all the way in to the end of the groove.

Ensure the electrodes are facing the right way (rounded tip pointing outwards).



Please note:

- It is recommended not to remove the electrodes each time they are used to avoid damaging them.
- Only use the electrodes supplied by the manufacturer.
- When the product is used daily, it is advisable to change the electrodes every year.
- The lifespan of the electrodes can vary depending on how often they are washed, the condition of the skin and the storage conditions.
- Replace the electrodes with new ones if they are damaged or if you start to feel discomfort during the stimulation.

b. Changing the retention strap

Replace the retention strap with a new one if it is damaged or if you feel it does not stay in place properly during treatment.

c. Cleaning

The device must be switched off and unplugged for maintenance and cleaning.

Cleaning the electro-stimulator: Clean the device with a soft, smooth, dry cloth.

Cleaning the electrodes: After each use, it is advisable to wipe the electrodes with a damp cloth to remove any remaining gel.

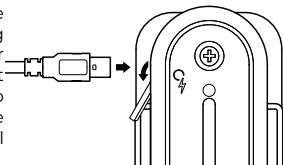
Furthermore, we recommend cleaning the electrodes at least once a week as follows: remove the electrodes from the Tensi+ and then wash them with clean, lukewarm water. Make sure they are clean and dry before repositioning them on the device.

Cleaning the retention strap: Once it has been removed from the device, the retention strap can be cleaned by hand. Avoid machine washing the retention strap.

d. Charging the device

To charge the device, connect the charging cable provided (part no.: AC0203) to the device charging port and the other end of the cable to a power source (5V continuous current) at least overnight (8 hrs). This source must be certified according to the IEC-62368-1 or IEC-60601-1 standard. A charge indicator will turn on (next to the (+) button) and will turn off once the battery is full.

We advise you to fully charge it at least once every three months to ensure an optimal battery service life.



7. ENVIRONMENTAL CONDITIONS

a. Storage

The device must be stored in an environment with a temperature of between -10°C (+14°F) and +40°C (+104°F) with a relative humidity up to 90%, with no condensation.

b. Use

The device must be used in an environment with a temperature between +5 °C (+41°F) and +40°C (+104°F) with a relative humidity between 15% and 90%, with no condensation, and an atmospheric pressure between 700 hPa and 1060 hPa.

8. DISPOSAL OF THE DEVICE PARTS

Dispose of the device in accordance with Directive 2012/19/EU on waste electrical and electronic equipment (WEEE). Contact your local waste disposal authorities if in doubt. Electrodes and straps: these parts are not hazardous waste and can be disposed of with household waste.

9. WARRANTY

The device is guaranteed for two years from the date of receipt. The warranty does not cover the charging cable, the electrodes, the retention strap or any breakage or failure when the device is not used as instructed in the manual. If you have any questions or comments about the device, contact your distributor or the manufacturer by email at service.client@stimuli-technology.com or by post at the following address: *Stimuli Technology, 20 bis rue Barthélémy Danjou, 92100 Boulogne-Billancourt, France*, or seek advice from a healthcare professional.

10. TROUBLESHOOTING

Situation	Possible causes	Solutions
The treatment seems to be different or more uncomfortable than before.	Electrodes are not in the right place.	Turn off the device and move the electrodes slightly.
	Intensity is too high or low.	Change the intensity using the intensity level buttons.

Situation	Possible causes	Solutions
The treatment seems to be different or more uncomfortable.	The electrodes are not in direct contact with the skin.	Switch off the device and remove the device from the skin. Add a drop of conductive gel to the electrodes and reposition the device so that it is in contact with the skin.
	The electrodes are too dirty.	Clean the electrodes (section 6.c). If the problem occurs again, replace the electrodes.
	The electrodes are worn out.	Remove the electrodes and replace them with new ones (section 6.a).
The device turns off or stops the stimulation during treatment.	The device turns off automatically if there is no activity or stimulation after 2 minutes.	This is normal: switch the device back on.
	The device turns off automatically after 20 minutes of treatment.	This is normal: the treatment is finished.
	The battery is flat.	Charge the device. You can use the device once it is charged.
	The device is no longer in contact with the skin or the device has come off.	Readjust the device.
The device will not turn on.	The battery is flat.	Charge the battery.
	The device is defective.	Contact customer service.

Beeping sound and/or LED indicator(s) on:

Situation	Possible causes	Solutions
LEDs 1 to 6 flash + regular beeping.	The electrodes are not in direct contact with the skin.	Reposition the device, add gel to the electrodes if necessary, then repeat the comfort level adjustment procedure.
The (-) button LED flashes after pressing on the (+) button.	The device locks automatically (after 30 seconds of inactivity).	Unlock the device by pressing on the (-) button.
2 short beeps.	The intensity level of 10 mA has been exceeded.	For information only; you can continue your treatment.
Battery charge level indicator flashing + beep.	Battery level low.	Charge the battery using the charging cable.
1 long beep + LEDs turn on and off.	When the device is turned on or off normally.	For information.
Continuous beep + LEDs off.	Device malfunction.	Do not use the device. Contact customer service.
The charge indicator does not turn off after 8 hrs of charging.	The battery is not fully charged.	Charge the device a bit longer.

11. TECHNICAL DATA

Type of device	Neuromuscular electrostimulator
Model	Tensi+
Classification	Ila according to Regulation (EU) 2017/745 on medical devices
CE marking	CE 2797
Manufacturer	Stimuli Technology, 20 B rue Barthélémy Danjou, 92100 Boulogne-Billancourt, France
Maximum intensity with resistance (500 Ω and 1000 Ω)	50 mA (+/- 10%)
Frequency	10 Hz (+/- 20%)
Pulse shape	Unidirectional pulsed current with a rectangular pulse shape
Pulse width	200 μ s (+/- 20%)
Programme duration	20 min
Power supply	Rechargeable 3.7 V lithium polymer battery
Dimensions	11 cm x 4 cm x 1.6 cm
Weight	65 g
Recommended electrode dimensions: part no. PF0105	28 mm x 40 mm

The values are correct under resistances of 500 Ohm and 1000 Ohm +/- 10%.

12. ELECTROMAGNETIC SENSITIVITY

This device complies with the requirements of standard EN 60601-1-2 describing electromagnetic compatibility (EMC) conditions for medical devices.

Tensi+ requires EMC precautions. Tensi+ must be installed and used in accordance with the EMC recommendations below.

Compliance with EMC standards does not mean that a device is totally immune. Tensi+ can be affected by portable or mobile RF communication equipment.

Tensi+ should not be used near to or stacked with other devices. If this is not possible, monitor the device to check that it operates normally under these conditions.

Risk of interference: the use of accessories and leads other than those specified, with the exception of leads and accessories sold by the manufacturer as spare parts for internal components, may increase the device's emission levels or decrease its immunity levels.

See the electromagnetic emissions and immunity tables on the following pages.

Any serious incidents that occur in connection with the product must be reported by the patient and/or user to the manufacturer, Stimuli Technology: service.client@stimuli-technology.com or Stimuli Technology, 20 bis rue Barthélémy Danjou, 92100 Boulogne-Billancourt, France and to the local Competent Authority.

Guidance and manufacturer's declaration – electromagnetic emissions

Tensi+ is intended for use in the electromagnetic environment specified below. The patient or user should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – comments
Electromagnetic radiation disturbance (Radiated emissions) (CISPR 11)	Group 1	Home healthcare environment and professional healthcare facility.
Terminal disturbance voltage (conducted emissions) (CISPR 11)	Class B	

Guidance and manufacturer's declaration – electromagnetic immunity

Tensi+ is intended for use in the electromagnetic environment specified below. The patient or user should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 8 kV on contact ± 15 kV in air	± 8 kV on contact ± 15 kV in air	Home healthcare environment and professional healthcare facility.
Power-frequency magnetic field (IEC 61000-4-8)	30 A/m at 50/60Hz	30 A/m at 50/60Hz	Home healthcare environment and professional healthcare facility.

Guidance and manufacturer's declaration – electromagnetic immunity, radiofrequencies

Tensi+ is intended for use in the electromagnetic environment specified below. The patient or user should ensure that it is used in such an environment.

WARNING: Portable RF communication equipment (including peripherals such as antenna leads and external antennas) should not be used within 30 cm (12 inches) of any part of the TESTED DEVICE, including leads specified by the manufacturer. The performance of these devices could be impaired by such use.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
Radiated radiofrequency electromagnetic fields (IEC 61000-4-3)	3 V/m 80 MHz à 2.7 GHz 80 % MA à 1 kHz 10 V/m 80 MHz à 2.7 GHz 80 % MA à 1 kHz	3 V/m 80 MHz à 2.7 GHz 80 % MA à 1 kHz 10 V/m 80 MHz à 2.7 GHz 80 % MA à 1 kHz	Professional healthcare facility Home health-care environment
Proximity field emitted by wireless RF communication devices (IEC 61000-4-3 provisional method)	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	
Proximity magnetic fields (IEC 61000-4-39)	8 A/m 30 KHz CW 65 A/m at 134.2 KHz with Pulse 2.1 KHz modulation 7.5 A/m at 13.56 MHz with Pulse 50 KHz modulation	8 A/m 30 KHz CW 65 A/m at 134.2 KHz with Pulse 2.1 KHz modulation 7.5 A/m at 13.56 MHz with Pulse 50 KHz modulation	

Key to symbols

	This manual contains information related to your safety.
	CE marking. This device meets the regulatory requirements of European regulation 2017/745 on medical devices.
	Device with type BF protection against electric shocks.
	Device serial number
	Part number
	Protection against the penetration of foreign bodies > 12.5 mm. Water resistance: protection against dripping water (when tilted up to 15°).
	Name and address of manufacturer
	The device, its accessories and its packaging must be recycled appropriately when no longer used. Please follow local regulations.
	This product is a medical device.
	Read the user manual carefully before using the device.
	Do not use the product if either the product or packaging is damaged.
	Storage conditions: keep away from moisture and store at between -10°C and 40°C.
	Storage conditions: relative humidity 15 to 90%, pressure 700 to 1060 hPa
	Not to be used with a pacemaker/cardiac electrical stimulation device
	Unique device identification → (01): Identifier; (21): serial number
	Charging in continuous current (5V-2A)
	Swiss representative