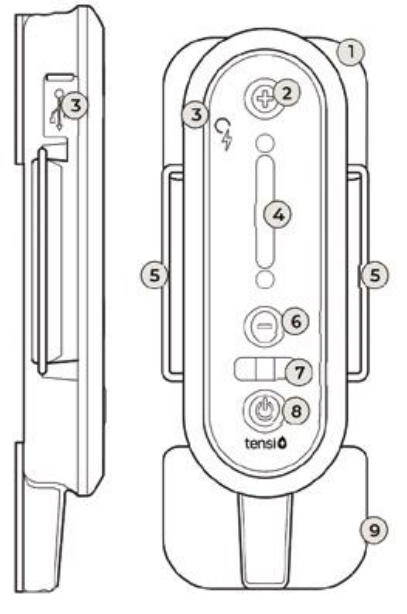
TECHNICAL DATA TENSI+

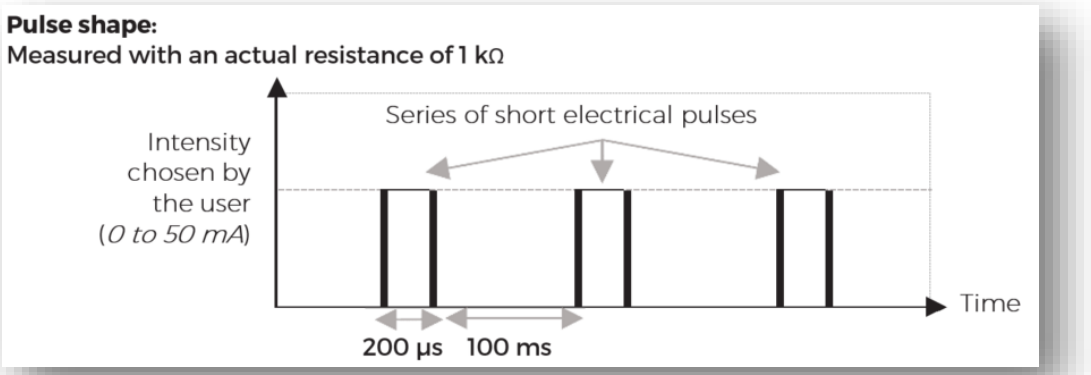
Tensi+ is a Transcutaneous Electrical Nerve Stimulator (TENS) placed directly on the posterior tibial nerve to deliver pulses of an adjustable intensity.
The Tensi+ device has a lifespan of 2 years according to IEC 60601-1-11.

1. **Positive electrode**
2. **(+) button**, to increase the stimulation intensity
3. **Micro-USB charging port** and charge indicator
4. LEDs showing the stimulation intensity
5. Retention strap loops
6. **(-) button,** to reduce the stimulation intensity
7. **Battery charge level indicator**
8. **On/Off button**: press and hold for 1 sec to switch the device on or off
9. **Negative electrode**



Type of device :	Neuromuscular electro-stimulator
Model :	Tensi+
Reference :	PF - 0001
Classification :	IIa 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 a resistance of 1,000 Ohm :	50 mA (+/- 10%)
Pulse shape :	Unidirectional pulsed current with a rectangular pulse shape
Programme duration :	20 min
Recommended electrode dimensions : reference PF0101	28 mm x 40 mm
Output current :	0 to 50mA (+/- 10%)
Frequency :	10Hz (+/- 20%)
Pulse width :	200 µS (+/- 20%)
Rated current :	15 mA
The values are valid under a resistance of :	1000 Ohm +/- 10%
Power supply :	Rechargeable 3.7 V lithium polymer battery
Charging time :	1 month, using 20 min per day, once a day
Dimensions :	11 cm x 4 cm x 1,6 cm

Weight :	65g
Operating temperature range :	5°C to 35°C / 41 °F to 95 °F
Storage conditions :	Store the device in a dry place and at room temperature (between -10°C and 40°C / 14°F to 104°F)
Storage conditions : relative humidity	15 to 90%
Storage conditions : Pressure	700 to 1060 hPa
Water resistance :	Protection against foreign objects >12.5 mm. Water resistance: protection against vertically falling water drops (when tilted up to 15°)
Lifespan :	2 years



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 electromagnetic emissions and immunity tables on the FUI-PF0001-01/02-2022.

ISO 13485-2016