Shoulder Pacemaker®

USER MANUAL

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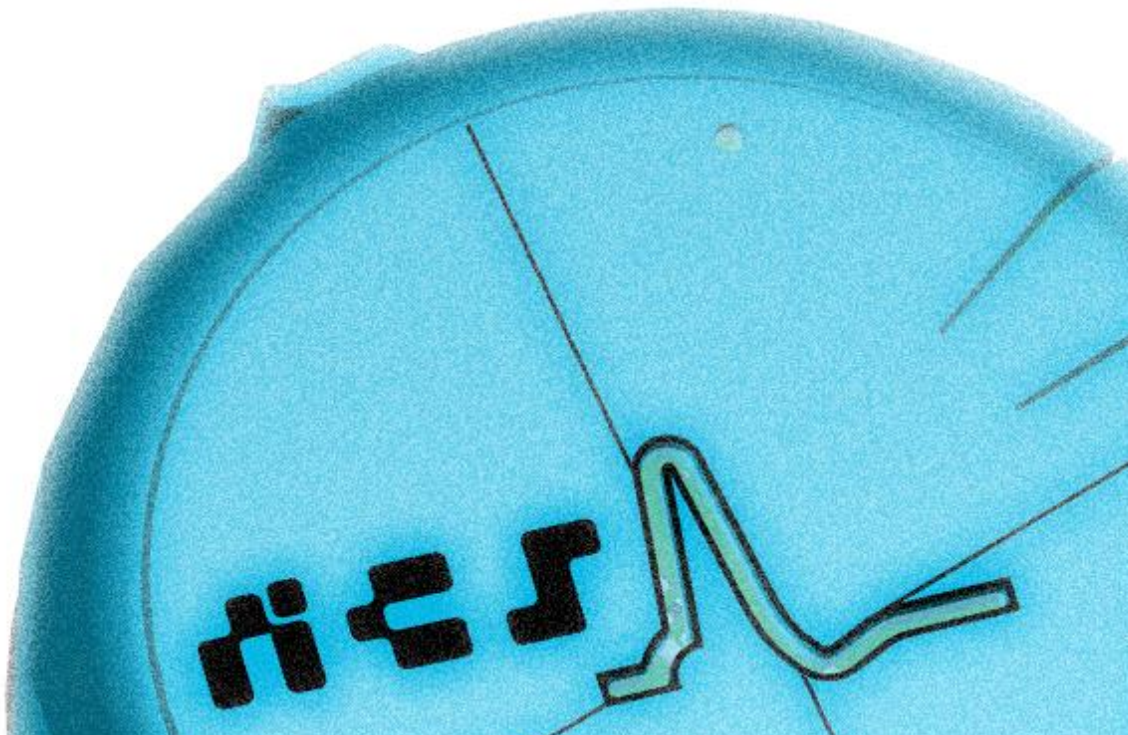
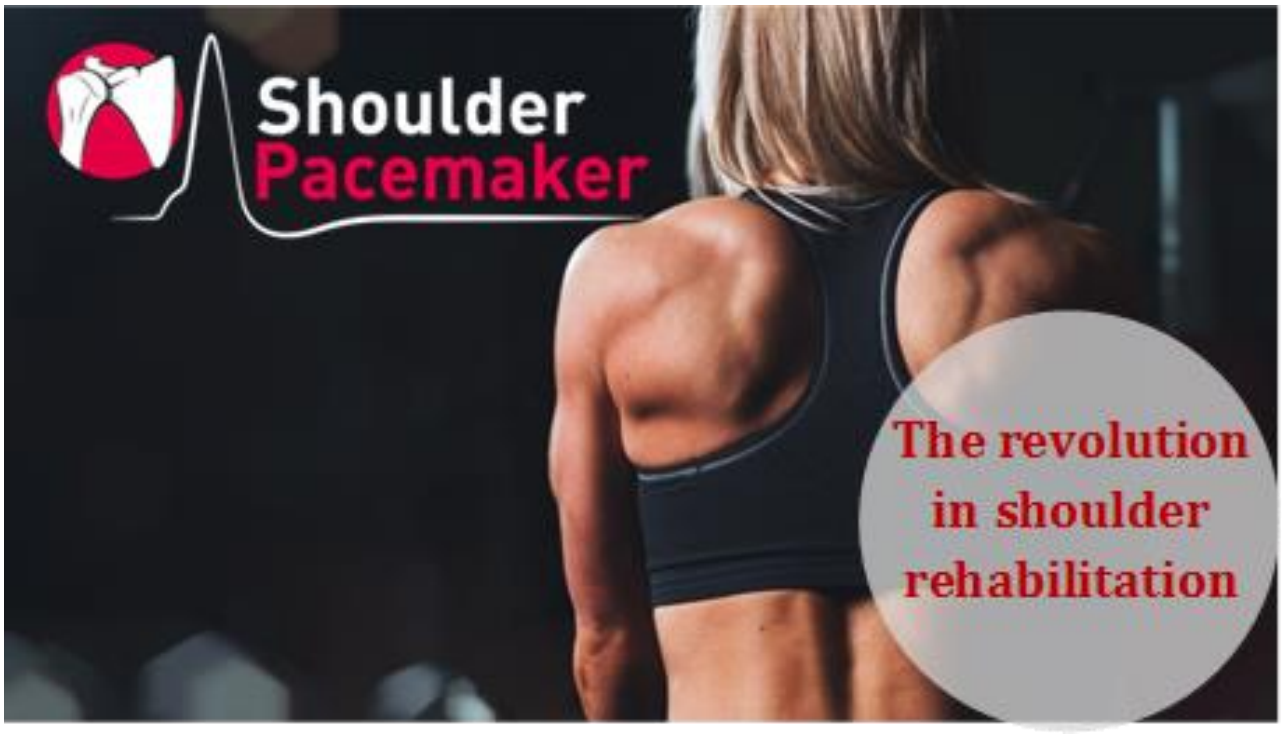
COMBINED SOLUTIONS FOR INDUSTRY



SUMMARY

THE FUTURE OF STIMULATION

Welcome to the future and thank you for choosing Shoulder Pacemaker™.
Shoulder Pacemaker™ is the most innovative product for the stimulation of scapular muscles.
Shoulder Pacemaker™ is a wearable neuromuscular stimulator.
Shoulder Pacemaker™ brings electrical stimulation of the scapular muscles to a new level of rehabilitation.



DISCLAIMER

Please read this manual carefully before using the device Shoulder Pacemaker™.

This manual is an informative document and not an independent training text for the use of the product.
For proper training, please contact our support and assistance team at the following address**: info@shoulderpacemaker.com**
Technical assistance is provided by our team. Any problem encountered must be reported to the address provided above. Our team will provide technical assistance regarding all aspects of the device supplied, including the replacement of any damaged parts of the device as indicated in the "Replaceable parts" section of the manual. These replacements can only be made through our service center.

INTRODUCTION

The shoulder is a very complex joint, mainly stabilized by the coordinated activation of several muscles that keep the joint in position. If this control system fails, severe dyskinesia, functional restrictions, and instability can occur.

The Shoulder Pacemaker™ device is an electrical muscle stimulator, internally powered and used for medical purposes. The device induces muscle contractions by means of passage of electric current through conductive electrodes positioned on the body areas of interest. The Shoulder Pacemaker™ device can be used to stimulate the shoulder and periscapular musculature in patients with non-physiological muscle-activation pattern.

Electrostimulation in general is an effective training method for muscles. The Shoulder Pacemaker™ is primarily designed to re-educate patients in terms of their muscle activation pattern. Focus group is rapresented by posterior shoulder instability patients without any structural defects to bone, tendons, muscles or nerves that merely suffer from a malcoordination of their muscle activation leading to severe instability symptoms. In this particular patient group preliminary results have been very encouraging (1,2). Furthermore, the Shoulder Pacemaker™ device can as well be used in other pathologies including but not limited to preoperative and postoperative muscle strengthening for different types of shoulder surgery. There is evidence that electrical muscle stimulation treatment has a positive effect on infraspinatus and shoulder external rotation force production after rotator cuff repair surgery (3) or infraspinatus strength in a non-operative setting as well (4). Even in reverse shoulder prosthesis preoperative and postoperative muscle strangthening has been shown to improve the clinical outcome (5) making the application of electrical muscle stimulation in these patients feasible. It would seem that in neurological patients, the benefits of the electrostimulation could be lower than in the orthopaedic patients as nerve lesions lead to muscle disactivation, atrophy and fatty infiltration with partial or complete loss of function that can be irreversible. Nonetheless, research has shown that even in patients with hemiparetic or hemiplegic shoulder pain, subluxation and loss of function due to stroke, electrical muscle stimulation treatment can improve muscle activation, reduce pain and improve function (6,7,8).

It should be emphasized that not all shoulder disorders can be treated by muscle electrostimulation; the competent doctor is responsible for selecting the correct indication and treatment based on the extent of the injury and the patient's medical history.

Conventional electrical muscle stimulation imposes a pre-defined rhythm on the users/patients as they need to adapt the speed and timing of intervals of their motion to the electrical impulse. This limitation is overcome by the Shoulder Pacemaker™ device thanks to the fact that the movements performed by the subject's arm are identified by sensors placed inside the device, and the stimulation is automatically adapted to the patients motion thus greatly improving the applicability during a dedicated exercise program. The training performed with the Shoulder Pacemaker™ device aimes at automated activation of hypoactive muscle groups during motion with the goal to help the users/patients to retrain their muscle activation pattern by means of a feed-forward mechanism.

(1) Moroder et al, Use of shoulder pacemaker for treatment of functional shoulder instability, Obere Extremität (2017), 12(2): 103-108

(2)Moroder et al, Shoulder-Pacemaker Treatment Concept for Posterior Positional Functional Shoulder Instability,The American Journal of Sports Medicine (2020), 48(9): 2097-2104

(3) Reinold et al, The effect of neuromuscular electrical stimulation of the infraspinatus on shoulder external rotation force production after rotator cuff repair surgery, The American Journal of Sports Medicine (2008), 36(12): 2317-2321

(4) Yanase et al, Electrical Stimulation to the Infraspinatus on Hypertrophy and Strenght of the Shoulder, International Journal of Sports Medicine (2018), 39(11): 828-834

(5) Uschok et al, Reverse shoulder arthroplasty: the role of physical therapy on the clinical outcome in the mid-term to long-term follow-up, Archives of Orthopaedic and Trauma Surgery (2018), 138(12): 1647-1652

(6) Jeon et al, The effects of electromyography-triggered electrical stimulation on shoulder subluxation, muscle activation, pain, and function in persons with stroke: A pilot study, Neurorehabilitation (2017), 40(1): 69-75

(7) Chuang et al, Effect of EMG-triggered neuromuscular electrical stimulation with bilateral arm training on hemiplegic shoulder pain and arm function after stroke: a randomized controlled trial, Journal of NeuroEngineering and Rehabilitation (2017), 14(1):122

(8) Wilson et al, The effect of Peripheral Nerve Stimulation on Shoulder Biomechanics: A Randomized Controlled Trial in Comparison to Physical Therapy, American Journal of Physical Medicine & Rehabilitation (2017), 96 (3): 191-198

MAIN FEATURES

What is Shoulder Pacemaker™? Shoulder Pacemaker™ is a muscle stimulator, powered by an internal battery, used for rehabilitation/physiotherapy purposes to produce muscle contraction through the passage of electric current by means of conductive electrodes positioned on the body area of interest.

Why and when is it useful? Shoulder Pacemaker™ can be used to stimulate the periscapular musculature that is no longer properly recruited in patients suffering from alterations of the scapulohumeral rhythm.

How does it work? The device automatically detects the elevation angle of the humerus and based on that information it can modulate the electrical stimulation.

Why choosing this product? Shoulder Pacemaker™ training is an effective treatment option for scapulohumeral rhythm alterations that do not respond to conventional physiotherapy. The device must be used under the supervision of a therapist.

The innovative features of Shoulder Pacemaker™ compared to other systems available on the market are:

- No invasiveness
- Wearable
- Progressive and personalized therapeutic approach
- Easy to use
- Interaction with the motor task
- App monitored
- Domestic use

INTENDED USE

NOTE: This manual is to be considered as an accessory to the device and therefore must always be in support of the same. Please read the entire manual carefully before using the device.
The instructions provided below are related to the intended use, the functionality of the device and the safety specifications of the patient who uses it. The device must be used by a properly trained healthcare professional.

- Shoulder Pacemaker™ is a wearable electrostimulation device used on patients with abnormal scapulohumeral rhythm. The Shoulder Pacemaker™ product is intended to be used as a periscapular muscle stimulation tool to reduce and eliminate dyskinesia.
- The user must receive adequate training before using the device for the first time.
- A maximum of 30 minutes of device use is required to complete a stimulation session based on Shoulder Pacemaker™technology.

PERSON DESIGNATED AS THE SUBJECT OF THE TREATMENT

The person designated to be rehabilitated with the Shoulder Pacemaker™ device is a person who can express himself, understand and execute instructions at all stages of the procedure.

WARNING: Do not use the device in the case of people with pacemakers or similar devices, or who suffer from epilepsy or heart disease.
Do not use the device if the subject has skin sensitivity problems.
Do not use the device on pregnant patients.
Do not use the device for prolonged periods without first consulting your doctor or therapist.

USED MATERIAL

The use of the product requires the combined use of the Shoulder Pacemaker™ device with the proper conductive electrodes.

The use of the product requires the combined use of the Shoulder Pacemaker™ device with protective skin protection devices.

Optional features of the product can require the combined use of the Shoulder Pacemaker™ device with the mobile application MySPM or MySPM@Home.

These accessories are supplied by the manufacturer in the sales kit.

WARNING:
Never apply the electrodes:

- near the head
- on the front and side of the neck
- in a contralateral position (i.e. with the two poles placed on opposite segments of the body)
- on or near injuries of any kind (sores, edemas, burns, irritations, eczema, tumor lesions, etc.)
- on parts of the body not directly visible without help
- near implanted devices such as cochlear implants, cardiac stimulators, implantable cardiac defibrillators, implantable neurostimulators, implants with skeletal anchoring or with electrical components

Use only the electrodes supplied by NCS Lab (Carpi, Italy). Other electrodes may have inadequate electrical properties or they may damage the Shoulder Pacemaker™ device. For reasons of hygiene, each user must have his own set of electrodes. Do not use the same electrodes on different people. Never use a set of adhesive electrodes for more than 5 sessions, as the quality of the contact between the electrode and the skin, which is essential for the comfort and effectiveness of the stimulation, progressively decreases. Consult the instructions for use and storage directly on the electrode package.

Other precautions related to the use of electrodes:

- Move or remove the electrodes ensuring that the device is switched off or the stimulation cables are not connected to the electrodes
- Do not immerse the electrodes in water
- Do not apply any type of solvent to the electrodes
- Wash and clean the skin before treatment to remove any traces of grease and dry it before placing the electrodes on it
- Apply the electrodes so that the entire surface is in contact with the skin
- Do not reuse the electrodes on the same patient for more than 5 use cycles

Some people, whose skin is particularly sensitive, may have redness under the electrodes after a session. This redness is completely normal and usually disappears after 10-20min. However, do not start another stimulation session on the same area if the redness is still visible.

Do not use the Shoulder Pacemaker™ device directly in contact with the skin but exclusively interposing a protective skin-protection device between the stimulator and the arm. The sales kit system has a certified medical device protection system inside.

ENVIRONMENTAL REQUIREMENTS

- Do not use the Shoulder Pacemaker™ device in water or in damp environments (sauna, hydrotherapy, etc.)
- Do not use the Shoulder Pacemaker™ device in an oxygen-rich atmosphere
- Do not use the Shoulder Pacemaker™ device at an altitude higher than 3000 meters
- Do not use the Shoulder Pacemaker™ device in potentially explosive areas
- Do not use the Shoulder Pacemaker™ device less than 30 cm away from short-wave or microwave equipment as they may modify the current generated by the stimulator
- Do not use the Shoulder Pacemaker™ device in areas where unprotected equipment is present for the emission of electromagnetic radiation. Portable communication devices can interfere with electro-medical devices

In case of doubt about the use of the stimulator near another medical device, contact the manufacturer of the device in question or the doctor.

The recommended operating temperature is between -0 °C and + 40 °C, with a relative humidity of 30% to 75% and atmospheric pressure from 700 hPa to 1060 hPa. If you work outside this temperature range, the performance may decrease, or the devices may be damaged. Sudden temperature variations can cause condensation to accumulate inside the stimulator.

The device must be stored and transported inside the packaging provided in the kit respecting the temperature range from -20 °C to + 45 °C, a relative humidity of 75%, and atmospheric pressure from 700 hPa to 1060 hPa.

SECURITY MEASURES

WARNING: Do not modify this device without the manufacturer's authorization
It is not permitted to modify or open the device

WARNING: The use of accessories, transducers and cables other than those specified or supplied by the manufacturer of this equipment could lead to greater electromagnetic emissions or a decrease in the level of electromagnetic immunity of this device, resulting in incorrect operation.

- Do not apply stimulation near metal parts
- Do not perform the first stimulation session on a standing person. For the first few minutes always carry out stimulation on a person sitting or lying down because the first stimulation can cause a feeling of weakness in people who are very nervous or afraid of stimulation
- The Shoulder Pacemaker™ device is not compatible with high-frequency surgical equipment. Do not use the Shoulder Pacemaker™ device if you are connected to a high-frequency surgical device, as this may cause skin irritation or burns under the electrodes

- During the stimulation session, do not disconnect any part of the device in tension. You must first turn off the device
- To recharge the device always use the cable supplied by the manufacturer
- Do not use the Shoulder Pacemaker™ device or the charging cable if they are damaged or open. There is a risk of electrical discharge
- Immediately disconnect the power supply in case of temperature increase or abnormal odors, or if smoke comes from the adapter or from the appliance
- Do not place the device in the recharging area in a confined space. There is a risk of electrocution
- Keep the Shoulder Pacemaker™ device out of reach of children and animals
- Do not allow any foreign body (earth, water, metal, etc.) to enter the device
- Do not apply stimulation during sleep
- Do not use the stimulator while driving or operating machinery
- Do not use the device directly in contact with the patient's arm, place a medical device certified skin-saving adhesive layer

REGULATIONS

To guarantee the safety of users, the Shoulder Pacemaker™ device was designed, manufactured and distributed in compliance with the amended European directive 93/42/EEC concerning medical devices.

The Shoulder Pacemaker™ device also complies with the IEC 60601-1 standard relating to the general safety requirements for electromedical equipment, to the IEC 60601-2 standard on electromagnetic compatibility, to the IEC 60601-2-10 standard on particular safety rules for neuromuscular stimulators and to the CEI EN 60601-1-11 on the home use of electro-medical equipment..

The Shoulder Pacemaker™ device also complies with the European Directive 2012/19/EU on Waste Management from Electrical and Electronic Equipment (WEEE). All products bearing the WEEE mark must be separated from household waste and sent to special collection and recycling stations. It is mandatory to follow the common procedures adopted within your own hospital, clinic and home, in order to properly dispose of it.

INFORMATION TO THE USER

1. For devices approved under Part 15, the user's manual or instruction manual for an intentional or unintentional radiator shall caution the user about changes or modifications to the device (Section 15.21).

2. For Class A and Class B digital devices, information to the user is required to include the following statements (Section 15.105):

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

RF RADIATOR EXPOSURE STATEMENT

The device Shoulder Pacemaker should be installed and operated with minimum distance of 5 mm between the radiator and your body. The case of the device guarantees the fulfillment of this requirement and therefore allows its direct application on the body by means of elastic bands.

PRODUCT DESCRIPTION

MATERIAL AND ACCESSORIES SUPPLIED

READ CAREFULLY – A user manual is provided together with the device. It serves as the main reference for both hardware and software use. It is essential that the user and all personnel involved in using the product fully understand the contents of the manual and follow the instructions provided during all phases of the implemented protocol.

The Shoulder Pacemaker™ product can be used in **stand-alone mode** or in **wireless mode**. In the wireless mode the device is provided in combination with an usb receiver and a dedicated control software executed on a pc/laptop or with a mobile phone/tablet application according to the sales kit.

For only stand-alone mode version, the content of the SPM01K1 kit is:

- 1 electrostimulator (REF: SPM01);
- 1 elastic band;
- 1 pair of conductor cables (code SPM-S);
- 1 charging cable (code SPM-C);
- 2 bags of pre-sealed electrodes for electrostimulation with standard clip coupling with 4mm head and conductive surface not less than 5cm2 (Medical device according to Directive 93/24/EEC);
- 1 pack of protective skin protection system (Medical device according to Directive 93/24/EEC).

For wireless mode feature, it is necessary to use a laptop on which the Shoulder Pacemaker Control software 1.1.2.0 is installed or an Android mobile phone/tablet on which the MySPM or MySPM@Home applications is installed.

The Shoulder Pacemaker Control 1.1.2.0 software must be installed on a computer with one of the following operating systems: MS Windows 7, MS Windows 8, MS Windows 8.1, MS Windows 10. The executable software must be installed on a computer with at least 4GB of RAM, with a processor equal to or greater than i3 and with at least 100MB of free disk space to allow installation and saving of files.

In this case, the product configuration is SPM01K2 kit, which contains:

- 1 electrostimulator (REF: SPM02);
- 1 receiver (REF: GTWY02);
- Software Shoulder Pacemaker control 1.1.2.0;
- accessories and consumable material as in the SPM01K1 kit with stand-alone operation.

The MySPM and MySPM@Home applications must be installed on a mobile phone/tablet compatible with BLE communication and that runs on the Android operating system version 6.0 onwards and with at least 100MB of free disk space to allow installation and saving files..

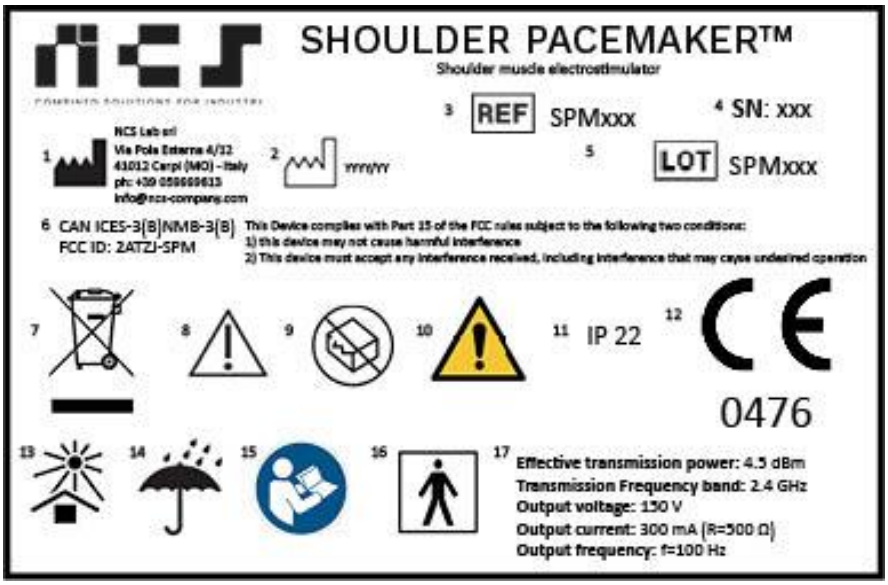
The SPM01K3 kit configuration contains:

- 1 electrostimulator (REF: SPM01);
- MySPM application (REF: SPM01A1 Medical device according to Directive 93/24/EEC)
- accessories and consumable material as in the SPM01K1 kit with stand-alone operation.

The SPM01K4 kit configuration contains:

- 1 electrostimulator (REF: SPM01);
- MySPM@Home application (REF: SPM01A2 Medical device according to Directive 93/24/EEC)
- accessories and consumable material as in the SPM01K1 kit with stand-alone operation.

LABEL



1. Manufacturer
2. Date of manufacture
3. Catalogue number
4. Serial number
5. Batch code
6. FCC Data
7. WEEE symbol: Waste electrical and electronic equipment
8. Caution
9. Do not use if package is damaged
10. General warning sign
11. Degree of protection
12. CE Marking
13. Keep away from sunlight
14. Keep away from rain
15. Refer to instruction manual/booklet
16. Type BF applied part
17. Technical data

The device has a degree of protection for the casings of electrical equipment equal to IP 22 (protected against solid bodies greater than 12mm in diameter, protected from falling drops of water with a maximum tilt of 15°).

The FCC ID of the Shoulder Pacemaker™ is 2ATZJ-SPM and it is affixed in the back side of the device as show in the figures.

This Device complies with Part 15 of the FCC rules subject to the following two conditions:

1) This device may not cause harmful interference

2) This device must accept any interference received, including interference that may cause undesired operation

TECHNICAL FEATURES

General information

Battery. The Shoulder Pacemaker™ device is equipped with a rechargeable Li-ion battery with a capacity of 550 mAh. Fully charged, its operating time is about 2 hours, depending on the intensity of stimulation. The charging time is approximately 1 hour at room temperature. Do not exceed the temperature range between 0 ° C to +35 ° C in the charging environment. Typical battery life under the conditions of use is 2 years.

Adapter: Use an adapter capable of providing 5V charging voltage and current of at least 275mA, compliant with IEC 60601-1.

Neurostimulation

All electrical specifications are provided for a minimum impedance of 500 ohms per channel and may present tolerances no greater than 10% with respect to the indicated value.

Outputs: two channels electrically isolated from each other

Shape of the pulses: compensated biphasic wave, in order to exclude any component of direct current and avoid residual polarizations on the skin

Maximum pulse intensity (instantaneous value): 300 mA

Maximum intensity of the pulses (intended as an effective value mediated on 1s): <10 mA

Duration of a pulse: 10 to 200 µs

Maximum amount of electricity for one pulse: 10.2 microcoulombs

Pulse frequency: from 1 to 100 Hz

Appendix A shows the tables with the electrical reference values for the stimulation signals when the load parameters and stimulation intensity vary in the typical scenarios of operation.

RF data

Emission and reception frequency band: 2.4 [GHz] ISM (2.4-2.4835 GHz)

Characteristics of the modulation type and frequency: FSK / GFSK and 0-QPSK

Effective emission power: 4.5 [dBm] at -40 ° C, 3.5 [dBm] at 25 ° C, 2.1 [dBm] at 105 °C.

Date related to electromagnetic compatibility (EMC)

The Shoulder Pacemaker™ device is designed for the use in authorized environments in compliance with the safety standard for EMC EN 60601-1-2. The Shoulder Pacemaker™device emits very weak levels in the radiofrequency (RF) range and should therefore not interfere with nearby electronic equipment (radios, computers, telephones, etc.).

The Shoulder Pacemaker™device is designed to overcome the predictable disturbances caused by electrostatic discharges, magnetic fields of the main power supply or radio frequency emitters. Nevertheless, it is not possible to guarantee that the stimulator will not be influenced by powerful RF (radio frequency) fields from other sources. For more detailed information on electromagnetic emission and immunity, contact the manufacturer.

Guidance and manufacturer's declaration - electromagnetic emissions		
Shoulder Pacemaker™ is designed to operate in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment
CISPR 11 RF emission	Group 1	Shoulder Pacemaker™ uses RF energy only for its internal operation. As a result, RF emissions are very low and are unlikely to cause any interference in nearby electronic devices
CISPR 11 emission	Class B	Shoulder Pacemaker™ is suitable for the use in all environments, including those directly connected to a public low-voltage grid supply.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Table 1: electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic immunity			
Shoulder Pacemaker™ is designed to operate in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment			
Proof of Immunity	Test level of IEC 60601	Level of compliance	Electromagnetic field
Electrostatic discharge (ESD) IEC 61000-4-2	in contact +- 8kV	In contact +- 8kV	Floors must be wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
	in air +- 2;4;8;15kV	in air +- 2;4;8;15kV	
High frequency magnetic field (50/60Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should have characteristic levels of a typical location in a commercial or hospital environment.

Table 2: electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity				
Shoulder Pacemaker™ is designed to operate in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment. Portable and mobile RF communications equipment should not be used closer to any part of the device, including cables, than the recommended separation distance calculated with the equation applicable to the transmitter frequency.				
Proof of Immunity	Test level of IEC 60601		Level of compliance	Recommended separation distance d:
RF Irradiate IEC 61000-4-3	10 V/m da 80 MHz a 2,7 GHz		10 V/m	d= 30 cm
Proximity field immunity from IEC 61000-4-3 RF wireless communication devices	TETRA 400 380 – 390 MHz	27 V/m	27 V/m	d= 30 cm
	GMRS 460 FRS 460 430 – 470 MHz	28 V/m	28 V/m	
	LTE Band 13, 17 704 – 787 MHz	9 V/m	9 V/m	
	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 800 - 960 MHz	28 V/m	28 V/m	
	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 5 1700 – 1990 MHz	28 V/m	28 V/m	
	Bluetooth, WLAN, 802.11 b/g/n, RIFD 2450, LTE Band 70 2400 – 2570 MHz	28 V/m	28 V/m	
	WLAN 802.11 a/n 5100 – 5800 MHz	9 V/m	9 V/m	

Table 3: electromagnetic immunity

INSTRUCTIONS FOR USE

We strongly recommend that you carefully read the contraindications and safety measures described in the "Intended Use" chapter of this manual.

WARNING: Use this device only with cables, electrodes and accessories recommended by NCS Lab.

Preliminary checks

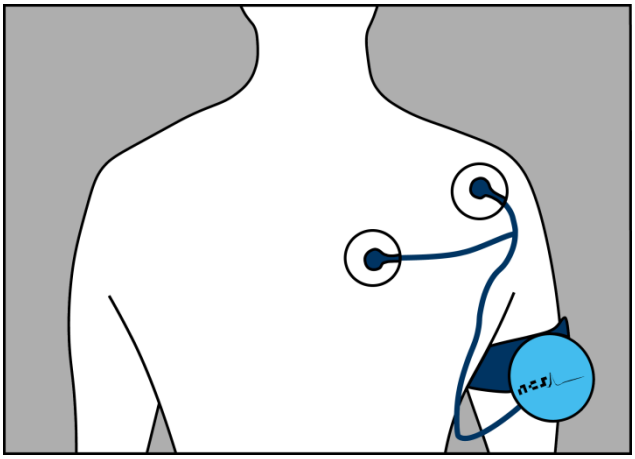
- Make sure the stimulator battery is fully charged before each use session.
- Make sure that at least 2 electrodes are available to stimulate the muscles of interest.
- Check that the environmental and safety requirements described above are met.

Positioning of the electrodes

It is important to use the electrodes provided in the kit and to position them correctly on the muscle group you wish to stimulate in order to ensure the effectiveness of the treatment. Always follow the positioning instructions shown in the following figures, except in the case of specific medical indications.

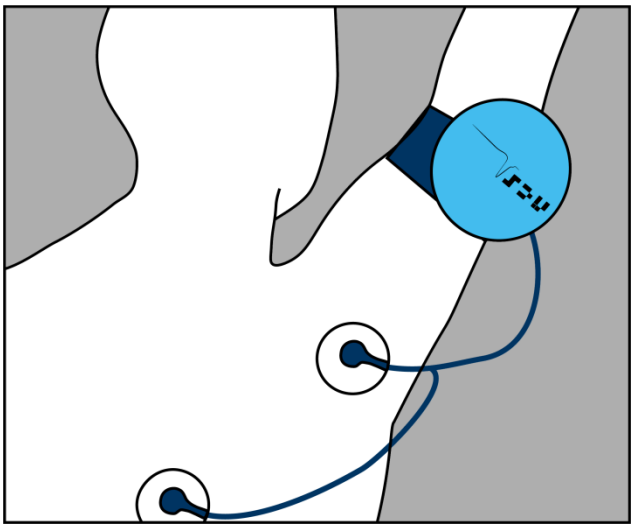
Remark: an approximate positioning of the electrodes makes the session less effective, but it does not constitute a danger, except for the contraindications described in this manual.

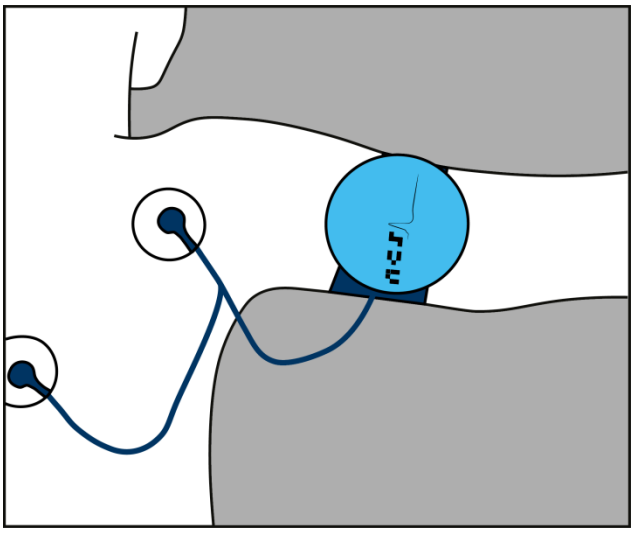
The electrode is positioned in the area of the nerve supplying the hypoactive muscles. Simultaneous stimulation of agonist and antagonist should be avoided because of the resulting movement restriction. One electrode is placed inferior to the spina scapulae to stimulate the external rotators (M. infraspinatus, M. teres minor). The second electrode is placed medially to the margo medialis scapulae to stimulate the scapula retractors (M. trapezius pars transversa, Mm. rhomboidei).



Positioning of the stimulator

Place a layer of skin protection in the area of the arm that will be in contact with the stimulation device. Ensure that the protective layer covers the skin and avoids direct contact between it and the stimulation device. The stimulator is posteriorly equipped with an elastic band to be positioned around the right or left arm based on the side of the pathology to be rehabilitated. Make sure Velcro fixing is stable on the arm. The device must be properly positioned in order to guarantee the correct connection of the cables to the electrodes. To check correct positioning, connect the conductor cables to the electrodes taking care to keep the device switched off. Try to raise the arm frontally and laterally and check that cables are not stressed and movements are comfortable for the subject.





Setting of stimulation energies

In a stimulated muscle, the number of fibers involved depends on the stimulation energy. For programs that induce powerful muscular contractions (tetanic contractions) it is absolutely necessary to use the maximum stimulation energies, within the subject's tolerance limits, in order to involve the greatest possible number of fibers. For other types of programs, which only induce muscle contraction, the stimulation energies must be progressively increased to obtain clearly visible muscle twitches.

It is important to use the maximum current intensity that the patient can comfortably tolerate, which generally increases during the course of the treatment, In general, it is not advisable to exceed the levels too quickly: the different levels correspond to a progressive advancement in training through electrostimulation.

The most correct procedure would be to start from a low level and then increase to a higher level when switching to a new electrostimulation cycle. At the end of a cycle you can start either a new cycle with the next higher level, or carry out a session maintenance training with the last level used.

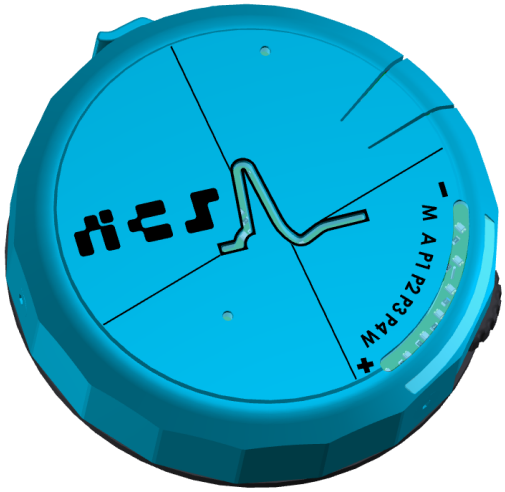
The maximum stimulation level delivered by the stimulator is 150V. In wireless operation mode, the software checks the selected voltage input value and it signals an error in the case of a value greater than 150V.

Usage protocol

The training performed with the Shoulder Pacemaker™ device involves the execution of a series of exercises that are completed during the stimulation of the muscle groups to keep the shoulder stable. Each treatment session lasts about 30 minutes and uses a stimulation frequency of 35 Hz. The protocol uses the device in 3 sessions a week for a period of six weeks. In any case, follow the therapeutic indications indicated by the competent doctor or therapist.

Stimulation programs

Shoulder Pacemaker™ has the following programs:



- Manual Operating mode **(M)**
- Automatic Operating mode **(A)**
- Training 5 seconds **(P1)**
- Training 7 seconds **(P2)**
- Training 9 seconds **(P3)**
- Training 11 seconds **(P4)**
- Only for the SPM01K2/SPM01K3/SPM01K4 kits - Wireless mode **(W)**

The **Manual Operating** program **(M)** is performed at the beginning of the usage session to let the patient familiarize with the muscle sensation induced by stimulation. The program allows the user to adjust the intensity of stimulation with a wheel, followed by a phase of discharge and relaxation.

The **Automatic Operating** program **(A)** implements an algorithm to activate/deactivate stimulation based on the angle of elevation of the arm.

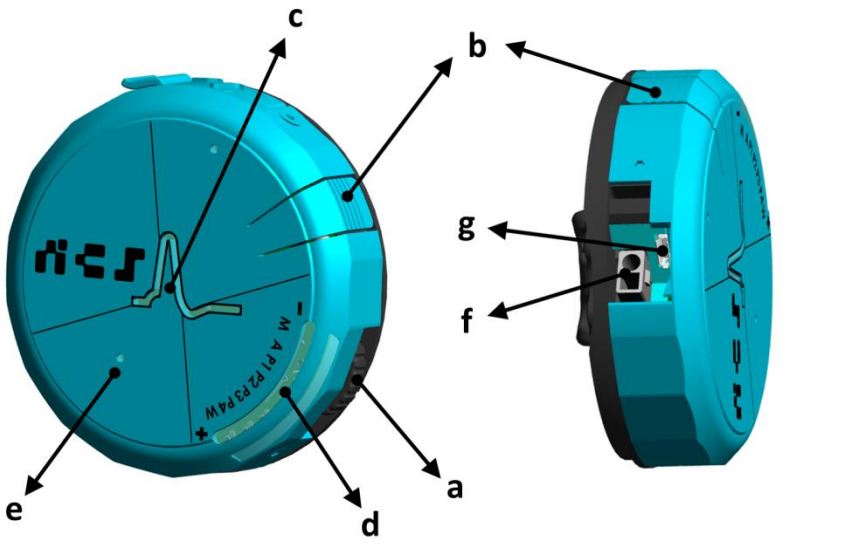
Training program are the real stimulation sessions in which the patient performs different types of exercises during the tetanic contraction phase. Each training program includes a sequence of loading phase and discharge phase. The device allows the user to run four possible training programs that differ in terms of loading phase duration **(P1-P2-P3-P4).**

The **Wireless** mode **(W)** allows the user to have a graphical aided control software allowing to set the stimulation training settings. In this operating mode it is also possible to inhibit stimulation based on the movement of the subject.

Please Note: The exercise session and the choice of the type of training must be agreed with the medical staff. The detailed description of the operation of each stimulation program is present in the next chapter.

FUNCTIONING OF THE DEVICE

DEVICE DESCRIPTION



The device is managed by rotating the wheel **(a)** and pressing the button **(b).** The status of the device (on, off, stimulation, charging) is indicated by the yellow led in the center of the device **(c)**. The management of the menu and the regulation of the intensity of the stimulation are revealed by the turning on, off or flashing of the band of the red leds **(d)**, that are switched on in sequence according to wheel rotation.

The alarm warning due to a low battery charge level is signaled through the lighting of a red led **(e)**, placed as shown in figure.

Along the lateral circumference, the device has an opening for the alternative insertion of either stimulation **(f)** or recharge **(g)** connector.

BASIC INSTRUCTIONS

BEGINNING OF A STIMULATION SESSION

Before using the device, be sure to recharge it for at least 30 minutes. In order to turn on the device and start a stimulation session, press the button for 2 seconds. When switched on, the lateral band of red leds and the central yellow led will light up. The number of lit and flashing red LEDs within the lateral band indicates the percentage of charge of the stimulator battery.

After 5 seconds, the device automatically enters the program selection mode in which the central yellow led will be on and flashing.

CHOICE OF THE PROGRAM

In the program selection phase, the central yellow led is on and flashing, while one of the lateral red leds lights up to indicate the actual selection of a program. At start-up, the first of the led sequence that corresponds to the first settable program will be illuminated. By rotating the wheel progressively one of the successive leds corresponding to one of the device programs will light up. The label of each program is shown on the stimulator case under each led. The program is selected by pressing the button.

PROGRAM SELECTION

For safety reasons, stimulation does not start immediately after selecting the program. The selection of the program must be confirmed by pressing the button. As long as the choice is not confirmed, the red led, in correspondence of the selected program, is in flashing mode. If the program has been erroneously selected, do not confirm the selection with the button and turn the wheel to return to the program selection phase.

START OF STIMULATION

The start of the selected program causes the central yellow light to switch on in continuous mode. During the execution of the stimulation programs, the lateral red leds band represents the intensity of the stimulation (each led implies an intensity of 21 V). Refer to Appendix A for details.

STOP AND SWITCH OFF THE STIMULATOR

In order to end the program, the subject must press the button. The device returns to the program selection mode (with central yellow led flashing and one led of the lateral band switched on). A 10 seconds continuous pressure on the button causes the device to switch off.

In any case, for safety reasons, the device is automatically shut off after 120 minutes from power on.

BATTERY CHARGE STATUS AND STIMULATOR CHARGING PROCEDURE

During recharging, the central red led is on. The charging level is indicated by the lateral red led bar. When recharging, the led bar lights up with a cumulated ramp that indicates the current charging level. When the charge is completed the ramp will stop increasing and all the red leds on the bar will be lit and fixed.

During the device switching on phase, the current state of charge is represented by the number of lit red leds along the lateral bar. In fact, when the device is turned on, the number of flashing LEDs (in the first 5 seconds) is proportional to the state of charge of the device. For example, for charging over 90% all 7 leds in the band flash in sync. For charges between 50% and 90% 4 leds flash, for charging between 20% and 50% 2 leds flash and for the charge below 20% only the first led flashes. In case of low charge level (below 20%), the first led of the lateral bar will blink for 5 seconds while the red alarm, as described in (e), led will light up, flashing permanently.

ALARMS

Alarm activation is signaled by the lighting of the red led placed as described in (e).

For a low charge level, this red led lights up in permanent flashing mode to indicate to the user the battery status and therefore the need to stop stimulation. This led lights up when the battery charge level falls below a specific critical threshold value (20%) for the battery. The automatic shutdown of the device will take place for a threshold value (1%) of battery charge.

In Wireless mode, the software/application interface allows you to receive error messages through a log message window.

For example, if a parameter's value entered is out of the permitted range, an error message will appear with an explanation of the error type on the software application interface and no out-of-range parameter is accepted by the application and by the device.

For each stimulation session, any error messages will be automatically saved and inserted into a file saved locally on the user's computer or mobile phone. In the first case, make sure you have enough storage space for that archive, by checking file size and free space left on your disk (refer to you operative system manual for these standard computer maintenance procedures). Error and log messages contain important data, hence the Shoulder Pacemaker Control software does not provide any archive deletion feature. Do not manually delete error and log archive. External storage permission is required to use the MySPM and MySPM @ Home applications. The application reports if the battery level of the stimulation device and the tablet is below 20%. The application generates an alarm if the stimulation device disconnects and if the Internet connection is lost.

PROGRAMS

MANUAL MODE

The **Manual Operating** program **(M)** is performed at the beginning of the training program to get the patient's confidence with the stimulated muscle sensation. In this program the stimulation voltage intensity is increased/decreased manually by the operator by turning the wheel and it remains constant in the absence of wheel's movement. When the button is pressed, the program will set the recovery phase reaching one third of the selected threshold. Press the button again to exit the program and return to the selection menu.

AUTOMATIC MODE

The **Automatic Operating** program **(A)** implements an algorithm for activating/deactivating stimulation according to the arm angle. The subject's movement is detected by the MIMU (Magneto-Inertial Measurement Unit) technology which electrostimulation is equipped with. These sensors record the acceleration and angular velocity data of the device and allow to estimate the movement of the subject's arm. In this way you can choose to inhibit the stimulation in specific movement conditions/static phases, and then activate it again when these conditions are no longer verified.

To establish the level of stimulation, initially, the subject manually chooses the maximum tolerated stimulation value. Manual selection implies that the subject, by rotating the wheel, progressively increases the intensity of the stimulation. Once the maximum tolerated intensity level has been reached, the subject presses the button, the value of that intensity is recorded and the session begins.

In the range of elevation from 0° to 180°, stimulation occurs at different levels:

- from 0° to 20° at the recovery value (one third of the selected maximum value)
- from 20° to 70° linearly increasing as a function of the elevation angle up to reaching the selected maximum value
- from 70° to 180° at the selected maximum value.

TRAINING

The **Training** program is the heart of the stimulation session. During the tetanic muscle contraction, the patient can perform rehabilitative exercises, established and described by the reference medical staff.

Each training mode consists, primarily, of choosing the maximum contraction value and, then, repeating load cycles and unloading cycles. The manual selection of the threshold, must be performed on each use. Manual selection implies that the subject, by rotating the wheel, progressively increases the intensity of the stimulation. Once the maximum tolerated intensity level has been reached, the subject presses the button, the value of that intensity is recorded and the training session begins.

The four training methods differ for the duration of each phase:

- Training 5 seconds= loading phase 5 seconds, recovery phase 4 seconds **(P1)**
- Training 7 seconds= loading phase 7 seconds, recovery phase 4 seconds **(P2)**
- Training 9 seconds= loading phase 9 seconds, recovery phase 5 seconds **(P3)**
- Training 11 seconds= loading phase 11 seconds, recovery phase 6 seconds **(P4)**

The voltage value reached during the load phase is equal to the initially defined threshold value. The voltage value reached during the recovery phase is equal to one third of the stored threshold value.

The exercise session and the type of training must be agreed with the medical staff.

WIRELESS MODE

The SPM01K2/SPM01K3/SPM01K4 product configurations includes a stimulator with an operation program that can be set via wireless or Bluetooth® Low Energy (BLE), in addition to the previous stimulation programs that can be set manually as described above.

To use wireless controlled feature, you must use:

- a laptop running the Shoulder Pacemaker Control 1.1.2.0 software supplied by the manufacturer (SPM01K2 product configuration). Radio transmission with a laptop complies with the IEEE 802.15.4 PHY standard.
- or a mobile phone/tablet compatible with BLE communication running the MySPM or MySPM@Home application supplied by the manufacturer (SPM01K3/SPM01K4) product configuration) and available from Android 6.0 onwards.

In **Wireless mode (W)**, the user has a graphical interface that allows to set the stimulation training settings.

Refer to the specific user manuals on the management of the Shoulder Pacemaker Control Software 1.1.2.0 supplied with the SPM01K2 kit or on using the app MySPM supplied with the SPM01K3/SPM01K4 kit

The Basic Instructions described above remain valid even in wireless mode. The wireless mode requires the insertion of the receiver in the laptop, in case of SPM01K2 kit, or the activation of BLE connection, in case of SPM01K3/SPM01K4 kit and the launch of the installed software/application. Once the wireless program has started, the number of red LEDs on the bar corresponds to the current stimulation voltage level set and the central yellow LED is on and steady. Pressing the button the device returns to the program selection status. This specification allows the stimulation to be stopped immediately and is a safety measure with respect to any software anomalies.

PRODUCT MAINTENANCE

Depending on the intended use and on the conditions of use, storage and recharging of the product described in this manual, the expected lifetime span of the Shoulder Pacemaker™ device is 2 years.

WARNING: No modification of this product is permitted

CLEANING

Make sure that all the contents of the kit are placed in the proper packaging. If sweat is present on the device, use a soft dry cloth and a solvent-free detergent to remove them before use. All material must be placed in clean areas after use. In such areas there must not be great temperature changes or wet areas. Hygienize the elastic band after repeated use on the same patient. If the device is used on different people, sanitize the elastic band between use on different subjects.

RECHARGE

The stimulator contains a lithium battery that must be charged before each use.

Before recharging the device, make sure that the stimulator is switched off. Proceed by disconnecting the conductive cables from the stimulator and insert the USB charging cable in the space provided. Then connect the cable to a power supply capable of delivering 5V and at least 275mA.

Wait until the device has been recharged, signaled by the complete lighting of the red LED band.

REPLACEABLE PARTS

The replaceable parts of the system, which require the intervention of technical assistance, are listed: stimulator, conductive cable and charging cable.

In case of a malfunction, contact the technical assistance that will evaluate the replacement of one or more replaceable parts. Replacement of parts of the device can be done only through our service center.

TECHNICAL ASSISTANCE

Technical assistance is provided by our team. Any problem encountered must be reported to the following email: info@shoulderpacemaker.com

Our team will provide technical assistance regarding all aspects of the device and software supplied and will also take care of replacing any damaged parts of the device.

PRODUCT WARRANTY

The Shoulder Pacemaker™ device is covered by a warranty of 1 year, which comes into effect on the date of purchase of the device (proof of purchase is required). The warranty does not apply to the electrode pads and carry cases.

Within the warranty period, manufacturer will replace your faulty Shoulder Pacemaker™ device or accessories at no charge (except shipping & handling fees in some cases), provided that the product:

- Has been used for the intended purpose and in the manner described in this manual.
- Has not been connected to an unsuitable power source.
- Has not been subjected to misuse or neglect.
- Has not been modified or repaired.
- Has not been damaged further by shock.

Legal rights are not affected by this warranty.

WARNING: If for any reason water or liquids enter into the USB port of the device, immediately contact our customer service.

TROUBLESHOOTING

Stimulation does not produce the usual feeling

- Check that all settings are correct
- Check that the electrodes are positioned appropriately
- Change the position of the electrodes slightly

Stimulation causes discomfort

- The electrodes lose their adhesiveness and no longer provide adequate contact with the skin, then they must be replaced
- The electrodes are worn and must be replaced
- Change the position of the electrodes slightly

The device does not work

- Check that the device is charged
- If the device still does not work, contact our customer service

APPENDIX A

The following tables set out some relevant quantities calculated using a simplified stimulation circuit analysis for settable stimulation reference parameters. The following quantities are considered.

Name	Description	Units of measurement
V_{PEAK}	Peak voltage at the stimulation terminals, corresponding to the initial instant of stimulus obtained when the SWITCH is closed	Volt
V_{EFF_STIM}	Effective stimulus voltage (relative to the period during which the SWITCH is closed)	Volt
I_{EFF_CYCLE}	Effective current on a complete cycle (period between the initial peaks of two consecutive stimuli, equal to the inverse of the FSTIM stimulation frequency F_{STIM})	milliAmpere
E_{STIM}	Stimulus energy (relative to the period during which the SWITCH is closed)	milliJoule

Table 4: Electrical quantities calculated at the stimulation output terminals

The tables include different assessments for the stimulation parameters and possible load resistance values Z_{LOAD}.

Parameter	Selected values
V_{REF} [V]	25, 50, 75, 100, 125, 150 (maximum value)
F_{STIM} [Hz]	**35** (typical value)
T_{STIM}[µs]	**100** (typical value)
Z_{LOAD}[Ω]	500 (extreme precautionary value), **2000** (typical value), 5000

Table 5: Stimulation parameters and load resistances considered in the example tables

Z_{LOAD}=500 Ω T_{STIM}=100 µs F_{STIM}=35 Hz	V_{REF}					
	25	**50**	**75**	**100**	**125**	**150**
V_{PEAK} [V]	-24.43	-48.85	-73.28	-97.71	-122.13	-146.56
V_{EFF_STIM} [V]	-10.06	-20.11	-30.17	-40.23	-50.29	-60.34
I_{EFF_CYCLE} [mA]	1.19	2.38	3.58	4.77	5.96	7.15
E_{STIM} [mJ]	0.02	0.08	0.18	0.32	0.51	0.73

Table 6: Electrical levels at limit loading Z_{LOAD} = 500 Ω, T_{STIM} = 100 µs and F_{STIM}= 35 Hz

Z_{LOAD}=2000 Ω T_{STIM}=100 µs F_{STIM}=35 Hz	V_{REF}					
	25	**50**	**75**	**100**	**125**	**150**
V_{PEAK} [V]	-24.67	-49.33	-74.00	-98.66	-123.33	-147.99
V_{EFF_STIM} [V]	-17.85	-35.70	-53.55	-71.40	-89.25	-107.10
I_{EFF_CYCLE} [mA]	0.53	1.06	1.59	2.12	2.65	3.18
E_{STIM} [mJ]	0.02	0.06	0.14	0.25	0.40	0.57

Table 7: Electrical levels at limit loading Z_{LOAD} = 2000 Ω, T_{STIM} = 100 µs and F_{STIM}= 35 Hz

Z_{LOAD}=5000 Ω T_{STIM}=100 µs F_{STIM}=35 Hz	V_{REF}					
	25	**50**	**75**	**100**	**125**	**150**
V_{PEAK} [V]	-24.82	-49.64	-74.46	-99.27	-124.09	-148.91
V_{EFF_STIM} [V]	-21.58	-43.16	-64.74	-86.32	-107.89	-129.47
I_{EFF_CYCLE} [mA]	0.26	0.51	0.77	1.02	1.28	1.54
E_{STIM} [mJ]	0.01	0.04	0.08	0.15	0.23	0.34

Table 8: Electrical levels at limit loading Z_{LOAD} = 5000 Ω, T_{STIM} = 100 µs and F_{STIM}= 35 Hz

CONTACTS

For more information on software and system updates, and for software problems, troubleshooting during product use, contact the NCS Lab support team:

info@ncs-company.com
info@shoulderpacemaker.com
+39 059 669813
Via Pola Esterna 4/12, 41012 Carpi (MO)

The e-mails sent to the above address will be replied within 48 hours.

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