Stimuplex® HNS 12

Nerve Stimulator
for Peripheral Regional Anesthesia

GB User Manual

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The Stimuplex® HNS 12 may only be used in applications for which this product is intended.
Federal (US) law restricts this device to sale by or on the order of a physician.

Contents

1.	Principles of Peripheral Electrical Nerve Stimulation	7
1.1.	Area of Application	7
1.2.	Intended Use	9
1.3.	Indications	9
1.4.	Contraindications	9
1.5.	Warnings	10
1.6.	Constant voltage or constant current	17
2.	Description of the Device	18
2.1.	Checks before Start-up	20
2.2.	Technical Description	23
2.2.1.	Plug Connections	24
2.2.2.	Current regulator (dial) and keys	24
2.2.3.	Sound	26
2.2.4.	LED	26
2.2.5.	Display modes	27
2.2.6.	Menu structure	29
3.	Operation of the Stimuplex® HNS 12	32
3.1.	Stand-by	32
3.2.	Selecting the current adjustment range	33
3.3.	Selecting the stimulation current	34
3.4.	Selecting the stimulus duration	34
3.5.	Selecting the stimulation frequency	37
3.6.	Current threshold display	37
3.7.	Checking the battery voltage	38
3.8.	Additional information – Menu info	38
4.	Setting parameters and options for future switch-on procedures	39
4.1.	Setting switch-on values for stimulation parameters	39

4.1.1. Current adjustment range 39
4.1.2. Stimulus duration 40
4.1.3. Frequency 40
4.1.4. Current threshold display 40
4.2. Setup 41
4.2.1. Tone 41
4.2.2. Dial turns 41
4.2.3. Contrast on the LCD display 42
4.2.4. Automatic switch off 42
4.2.5. Date and time 42
4.2.6. Language 43
4.2.7. Options 43

5. Initial setup, maintenance and notes 46
5.1. Testing the Stimuplex® HNS 12 46
5.2. Special technical features 47
5.3. Technical data 48
5.4. Battery 49
5.5. Cleaning and disinfecting the Stimuplex® HNS 12 50
5.6. Maintenance and safety checks 50
5.7. Equipment logbook (Specific requirement for use on German market) 51
5.8. Notices 51
5.9. Error messages 52
5.10. Instruments and accessories 56

6. References 60

7. Appendix 61

8. Symbols on Stimuplex® HNS 12 67

9. Electromagnetic compatibility (EMC) 70

10. Specific requirements for the US market 75
10.1. Addition to Section “5.6. Maintenance and safety checks” of the Manual 75

Preface

With your purchase of the Stimuplex® HNS 12 nerve stimulator, you have acquired a device that is easy to operate and provides you with a straightforward array of all the functions you need to perform peripheral nerve blocks.

The following chapters describe the operation of Stimuplex® HNS 12.

The use of the stimulation needles required for performing stimulation is described in the instructions for use accompanying the needles, which are not part of this user manual.

Chapter 1 describes the basic functions of unipolar nerve stimulation including a discussion of the principle of constant current stimulation.

For your study of its operational fundamentals, we recommend that you have a Stimuplex® HNS 12 with all of its accessories at hand and functional so that you can learn about the functions in practical exercises.

It is helpful to simulate the patient with a wet paper tissue or a small sponge soaked in saltwater. The saline solution is required to produce electrical conductivity.

The device may only be operated in compliance with the user manual.

The device may only be used in professional environments (e.g. hospital).

If you have further questions, the people at B. Braun Melsungen AG and STOCKERT GmbH are happy to be at your service.

Yours,

B. Braun Melsungen AG

STOCKERT GmbH

1. Principles of Peripheral Electrical Nerve Stimulation

1.1. Area of Application

Peripheral nerve stimulation facilitates the performance of peripheral nerve and plexus blocks. The user no longer needs to rely on feedback from the patient about paresthetic sensations. The danger of mechanical nerve lesions is mostly eliminated.

When the stimulation needle is placed sufficiently close to the target nerve, predefined electrical pulses generate muscle contractions at motor efferent fibers and electrically elicited paresthesias at sensory afferent fibers. During this procedure, direct contact of the injection needle with the nerve is intentionally avoided.

The Stimuplex® HNS 12 nerve stimulator shall be used only by medical personnel trained and experienced in the techniques of peripheral nerve stimulation and only in the clinical environment (not in home care environment).

⚠ **Since peripheral electrical nerve stimulation (PNS) is no substitute for the anatomical knowledge required to perform regional anesthesia, accurate knowledge of the topography and nerve distribution area is a prerequisite.**

Advantages of nerve stimulation:

- Objective muscle response is obtained without the user having to rely on information or cooperation from the patient
- No direct needle-nerve contact, no painful paresthesias, no mechanical nerve lesions, and no intraneural injections.

Permissible and possible options:

- Sedation and analgesia prior to blockade depending upon the patient's needs
- General anesthesia prior to blockade
- Blockades distal to the previous site of a regional anesthesia procedure in anesthetized or partially anesthetized regions
- Extension of the indication spectrum
- Enhancement of safety standards

The resting potential at the nerve membrane is around 80 mV. The cell's interior is negatively charged compared to the surrounding medium. Sufficiently large ion movement reduces the membrane potential to 55 mV, making the membrane freely permeable and generating an action potential.

The various types of nerve fiber differ with regard to their sensitivity to electrical stimulation. The A-alpha motor fibers have the shortest chronaxia (50-100 µs). The afferent fibers that transmit pain sensation (Aδ and C-fibers) require a longer pulse (150 and/or 400 µs) at a minimum current. Mixed peripheral nerves can be localized using short pulses (0.10 ms) without triggering pain sensations. For pure sensory nerves, a longer pulse is recommended (0.30 ms, 0.50 ms or 1.00 ms).

When unipolar needles (insulated and with conductive tip) are used, the current necessary to trigger muscular contractions (= pulse amplitude) correlates with the distance from the tip of the needle to the nerve. The lower the current, the more accurately the target nerve can be localized. This allows quicker onset and ensures a more reliable success of the blockade.

⚠ **Nevertheless, it is important to observe and stay within the predefined threshold currents so as to avoid a too close proximity to the nerve and prevent nerve damage.**

The shorter the electrical pulse (= pulse width), the faster is the rise in current to the nerve. This allows better discrimination by the physician as to whether the needle tip is sufficiently close to the nerve. The stimulation needle should always be connected to the negative pole. If the needle is connected to the positive pole, higher currents are required.

The conductive tip of the stimulation needle affects the geometry of the electrical field. The smaller the emission site of the electrons at the tip of the needle, the higher is the current density at this point and the lower the threshold level once the nerve has been localized exactly.

Special attention must be paid as the current density at needle tip can exceed 2 mA/cm^2 depending on stimulation settings.

The Stimuplex® HNS 12 is meant for long-term usage.

1.2. Intended Use

The nerve stimulator is intended for localisation of nerves in peripheral regional anesthesia.

Under no circumstances may it be used on a patient undergoing surgery.

1.3. Indications

- Surgical interventions on the upper and lower extremity
- Patients with high aspiration risk
- Hemodynamically unstable patients
- Postoperative analgesia to allow early mobilization and physical therapy
- Replantation surgery
- Diagnostic and therapeutic blockades

1.4. Contraindications

- Refusal of regional anesthesia by the patient
- Infection at the puncture site
- Preoperatively known neurological dysfunctions
- Anatomical abnormalities
- Severe coagulation disorders
- Insufficient liver function

1.5. Warnings

Warnings and Precautionary Measures

General Precautionary Measures

1. The connecting socket of the stimulation needle may only be connected to the counter plug of the connecting cable. The connecting cable plug may only be connected to the nerve stimulator and the clip may only be connected to the skin electrode on the skin of the patient. Under no circumstances should you allow these plugs/connections to come in contact with voltage channeling components (e.g. electrical outlets) or metallic objects.
2. To prevent anesthesia gases from exploding or flammable liquids from igniting, Stimuplex® HNS 12 may not be used in hazardous areas. To avoid injury to the patient, all ported equipment in the vicinity of the patient must comply with the applicable rules and regulations. All equipment and accessories must show compliance with EN 60601-1, EN 60601-1-1 as well as the applicable collateral standards. The user should be aware that, even when all rules are complied with for each piece of equipment, under worst circumstances, all leakage currents or auxiliary patient-coupled currents can add up and produce unacceptably high levels that can endanger the patient. The user must therefore check in advance whether the interconnected equipment might exceed allowable limits under certain circumstances. Devices and equipment (system building) assembled improperly can cause life-threatening injury to the patient.
3. The patients themselves should not come into contact with metallic objects that are grounded or produce an electrical conductive connection with other equipment and/or enable capacitive coupling. On these grounds, we recommend that an adequately insulated, antistatic pad be placed on the operating table.
4. Unauthorized persons opening or attempting to repair Stimuplex® HNS 12 can create a dangerous situation and will cause all warranty claims to be null and void.

No modification of the Stimuplex® HNS 12 is permitted.

Warnings and Precautionary Measures for Stimuplex® HNS 12

⚠ **Under no circumstance should the device be operated with accessories other than those released and supplied by the manufacturer or listed in Section 5.10, "Instruments and accessories". These accessories are EMC tested and approved. Any other accessories can lead to serious impairment of the device and system properties and cause permanent injury to the patient, user or device.**

5. Whenever high frequency surgical equipment is used simultaneously, there is an acute danger of severe burns occurring at the Stimuplex® HNS 12 connection ports, the connecting cable, the tip of the needle and at the skin electrode. It is therefore imperative to disconnect all connections to Stimuplex® HNS 12 before using high frequency surgical equipment and to also remove the stimulation needle from the tissue. The stimulation needle with its connecting cable acts like an antenna for high-frequency energy; this can generate very high current densities at the needle tip and cause irreversible destruction to the nerve fibers in this proximity. At the same time, the ported stimulator can rectify the high frequency energy, which leads to extremely high direct currents and voltage potentials at the electrodes. The direct current stimulation generated as a result can be very painful and strong, and trigger irreversible electrophysiological reactions.
6. To prevent poor contact of the skin electrode (red clip) from leading to a malpositioning of the stimulation needle, the user must make sure that the skin electrode, which functions like a neutral electrode here, shows sufficiently safe contact with low tissue impedance. Fatty tissue, hair, dirt, repeatedly used skin electrodes and electrodes of poorer quality can negatively impact tissue impedance, thereby incurring the risk of neural damage. It is therefore recommended to select the contact surface carefully in well-vasculated muscular areas only. Clean, shave and degrease the skin. At the same time, do not position the skin electrode too far away from the puncture site. However, thoracic application of the skin electrode is to be avoided.
7. The skin electrodes must not be applied to areas of injury.

8. Only use high-grade, commercially available, CE-marked ECG single-use skin electrodes with silver/silver chloride sensors precoated with gel. For non EU countries, CE marking is not required on ECG skin electrodes. To achieve optimum nerve stimulation always make sure the electrodes are undamaged and not dried out.
9. The nerve stimulator should not be used on patients with implanted electrical devices (e.g. cardiac pacemakers) without prior consultation with an appropriate medical specialist. The stimulation current may cause interference with the implanted devices and thereby put the patient at risk.
10. The perithoracic application of electrodes (around the ribcage, heart) can increase the risk of cardiac fibrillation.
11. Stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.
12. The stimulation current should not drop below a specific value. By activating the option "Current threshold" (see Section 3.6.), the Stimuplex® HNS 12 alerts you with an optical and acoustic warning whenever the target stimulation current is set below this value.
13. If the stimulator shows a direct current or an offset direct current at the outlet, the stimulator should not be used and must be returned to the manufacturer for repair. These failures can be detected by performing a simple functional test with the testing resistor (see Section 5.1. Testing the Stimuplex® HNS 12).
14. The special precautionary measures specified by the EMC standard apply to electrical medical devices. Portable and mobile RF communication devices can affect Stimuplex® HNS 12 which can lead to functional failure of the device and/or system.
15. Dynamic electrical and dynamic magnetic interference fields can cause interactions between device and system to occur which can impact the actual stimulation current measurement and, in extreme cases, lead to error messages and possibly to the activation of a safety shut-off on the device. Do not use Stimuplex® HNS 12 in the proximity of equipment that produces strong electromagnetic fields such as cordless phones, high frequency surgical equipment, shortwave or microwave medical equipment. The stimulation needle may pick-up high frequency currents, which could cause damage to nerves. (See Table 4 Recommended separation distances between portable and mobile RF telecommunication devices and Stimuplex® HNS 12.)

16. Do not connect Stimuplex® HNS 12 to other devices (except for instruments and accessories, see section 5.10). If Stimuplex® HNS 12 is operated near another device, the user must monitor the equipment or system and check that the configuration used in this way is operated properly and as intended.
17. Other devices can interfere with Stimuplex® HNS 12 or the system, even if they show compliance with the applicable CISPR emission requirements. Interference impulses can be picked up by the stimulation current detector and thereby trigger an error display and, possibly, a safety shutoff.
18. Operation of other devices or systems with Stimuplex® HNS 12 accessories can increase emissions or reduce immunity to interference on devices or systems. Observe the supplied EMC instructions concerning installation, initial setup and operation of the device or system (see Section 9. Electromagnetic compatibility (EMC)).
19. Do not use the device after ingress of liquids. Ingress of liquids or humidity can cause an electronic failure.
20. To avoid damage to the connecting cable and the device, do not hold or carry the device by its connecting cables and/or its accessories. Do not wrap the cable around the device or around other equipment.
21. Wrapping the connecting cable during normal operation of the stimulator generates inductive components and, at very short stimulation pulses, can lead to a reduction in stimulation efficacy and/or false measurements of the actual stimulation current. False interpretations of the indicated values can be the result.
22. For safety reasons, never operate Stimuplex® HNS 12 if the battery is leaking, but return it to the manufacturer for proper cleaning. The same applies if any liquid soaks through!
23. Do not continue to operate the device if repeated error messages appear. The device must be returned to the manufacturer for proper repair.
24. Known undesirable side effects: Hematoma at puncture site

25. Avoid contamination at the connections. Water and dirt impair the contact properties of the plug connections and lead to undesired short circuits or leakage currents. This can lead in part or even fully to channeling of the stimulation currents, which impairs or even cancels out the stimulation effect completely. In this event, the device can no longer properly indicate the actual current flowing to the patient.
26. To prevent damage to the device and its accessories, never use aggressive cleaning agents. For further details, see Section 5.5. “Cleaning and disinfecting the Stimuplex® HNS 12”. All accessories have to be visually inspected at regular intervals. The insulation for cable and plug connections must not exhibit any damage.
27. The user must follow the instructions for use when operating Stimuplex® HNS 12 and its corresponding accessories. Avoid any inadvertent contact of the stimulation needle with bone, since this could irreversibly damage the needle and consequently traumatize the tissue.
28. Keep accessories and device away from voltage-conducting objects. The electrostatic and electromagnetic fields they radiate can impact the stimulation outcome and, under certain circumstances, may lead to adverse stimulation effects in the tissue.
29. Before and during use, the device, the connecting cable and their plugs must be kept completely clean and dry. Moisture and contamination will impair the function of the nerve stimulator and/or the stimulation outcome.
30. Be aware of the position of metallic implants in the tissue (e.g. plates or electrode cables), which may potentially channel stimulation signals to other sites where it can cause damaging effects. Implanted electronic equipment can be impaired by the stimulation current, which, in turn, will lead to malfunctions of the implants or even destroy them.
31. To avoid malfunctions of Stimuplex® HNS 12, check all functions prior to the intervention and make sure that the accessories are in functional order. The accessories must meet safety class type BF. Inspect all parts for any visible damage or manipulations. Never use any damaged or manipulated parts!
32. To protect the patient from electrophysiological shocks through electrostatic discharges (ESD), it is necessary for them to wear the appropriate clothing and to move around in an appropriately secured environment. An electrostatic discharge (ESD) at the tip of the needle can cause extremely high current densities to occur which can damage the surrounding tissue.

Conformity with the following standards:

DIN EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
DIN EN 1041	Information supplied by the manufacturer with medical devices
93/42/EEC and MPG	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices - Annex I (Essential Requirements); Annex II (without section (4))
Directive 2006/66/EC and ElectroG (German Battery Law)	Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators
Directive 2011/65/EU	Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II)
Directive 2012/19/EU	Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)
FDA 21 CFR 21 Part 801	FDA - Code of Federal Regulations Title 21 Part 801 - Subpart A - Labeling
FDA 21 CFR 21 Part 820	FDA - Code of Federal Regulations Title 21 Part 820 - QS regulation - Subpart K - Labeling and Packaging Control
FDA 21 CFR 21 Part 830	FDA - Code of Federal Regulations Title 21 Part 830 - Unique device identification
IEC 60601-1	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility - Requirements and tests (applicable to Ed. 3 and 4)
IEC 60601-1-4	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable Electrical Medical Systems

IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability
IEC 60601-1-9	Medical electrical equipment – Part 1-9: General requirement for basic safety and essential performance - Collateral standard: Requirements for the reduction of environmental impacts.
IEC 60601-2-10	Medical electrical equipment – Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
IEC 60812	Analysis Techniques for System Reliability – Procedure for Failure Mode and Effects Analysis (FMEA)
IEC 62304	Medical device software - Software life-cycle processes
IEC 62353	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
IEC 62366	Medical devices - Application of usability engineering to medical devices
ISO 13485	Medical devices – Quality Management Systems – Requirements for regulatory purposes
ISO 14971	Medical devices – Application of risk management to medical devices
ISO 15223-1	Medical devices - Symbols to be used with medical device label, labelling and information to be supplied - Part 1: General requirements
Regulation (EC) 1907/2006	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
UL 60601-1	Medical electrical equipment - Part 1: General requirements for safety

1.6. Constant voltage or constant current

According to Ohm's Law I ~ U it is possible to use both voltage as well as current to measure the intensity (amplitude) of the electrical stimulation. One speaks of constant voltage or constant current devices.

The electrical resistance (impedance) in the circuit of a stimulation, which comprises the sum of skin, tissue, needle, electrode cable resistance, etc., fluctuates within a large range. It can move between < 1 kΩ and infinity. Factors such as skin moisture, conductivity of the skin and tissue and the potential resistance of the skin electrode can hardly be influenced.

If voltage (V) is selected as a measure of the intensity of the stimulation pulse, currents can flow during treatment that differ greatly depending on the impedance and in accordance with Ohm's Law.

Therefore, it is better to use a nerve stimulator that allows the user to select the desired current (mA) exactly between the two electrodes - skin electrode (anode) and stimulation needle (cathode).

Nevertheless, a stimulator with constant current settings must be equipped with a very high output impedance - ideally infinity - to reduce the resistances possible in the external circuit to negligible levels and to display the actually flowing current accurately. In recent years, constant current devices, which allow selection of the desired current (mA) for the stimulation pulse, have become established.

On the Stimuplex® HNS 12, the external load resistance can be up to 12 kΩ. If this load resistance is exceeded, the nominal current flowing to the patient (actual stimulation current) may be less than the set target stimulation current. In this case, the target stimulation current and the actual stimulation current are displayed separately, and optical and acoustic warning messages are set off. Moreover, the applied impedance is calculated constantly and indicated in the LCD display.

2. Description of the Device

Stimuplex® HNS 12 is a precision instrument for localizing neuronal pathways in the human body. It was specifically designed to stimulate nerve fibers in living organisms with special nerve stimulation needles that conventionally show a very high contact impedance with the aim of determining their spatial position relative to the tip of the needle. The stimulation needles are constructed in such a way that a local anesthetic can be injected near the nerve fiber, which reversibly interrupts stimulus conductance.

The Stimuplex® HNS 12 nerve stimulator should only be used by a physician with an appropriate knowledge in peripheral nerve blocks. The physician is responsible for the correct usage of the nerve stimulator.

The functions of Stimuplex® HNS 12, Stimuplex® and Contiplex® stimulation needles as well as the connecting cable by B. Braun are designed to work in perfect harmony. Only in this way can an optimum of precision and reliability be achieved.

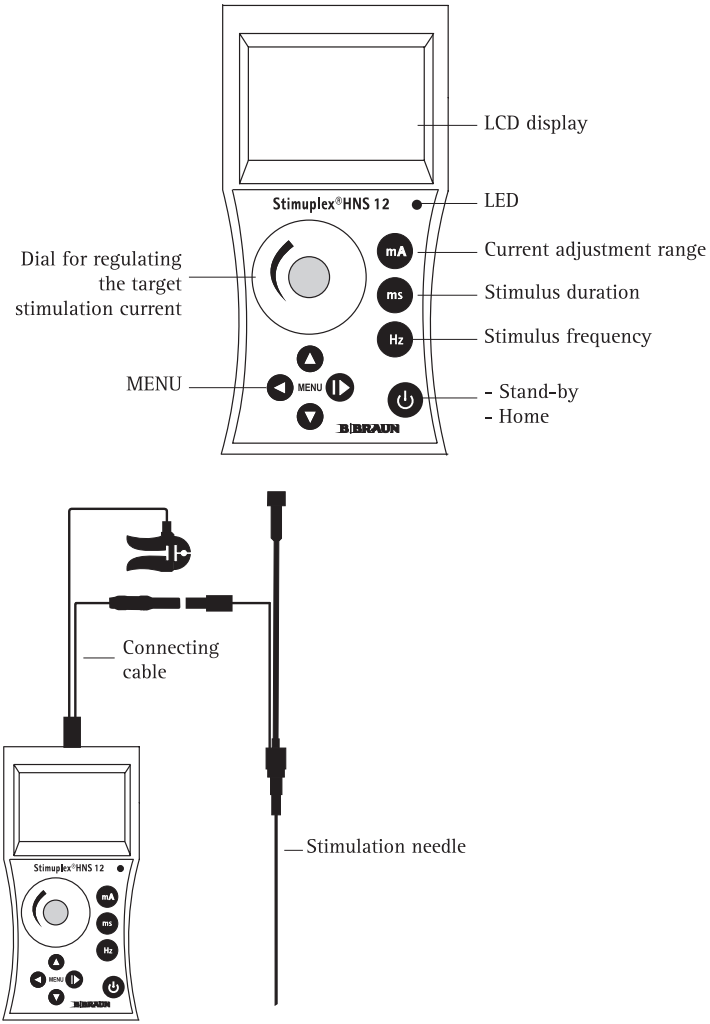
For more in-depth knowledge about the use of this device, its risks and side effects we recommend studying in detail the relevant literature cited in the „References“ Section.

Stimuplex® HNS 12 is supplied with the following basic equipment:

- Stimuplex® HNS 12 nerve stimulator
- 9-volt block battery
- Cable for connecting B. Braun stimulation needles (cable length 1.25 m)
- 10 kΩ test resistance
- User manual (this document)
- CD-ROM with user manuals in different languages (PDF files)
- Brief instructions for use
- Technical Service Manual
- Storage case for keeping Stimuplex® HNS 12 and accessories

The special knob and the Stimuplex® Pen can be purchased separately as accessories and kept safely in the storage case in the intended compartments.

Overview of the Stimuplex HNS 12 Nerve Stimulator



Manufacturer's factory settings configured on delivery (preset in the menu).

Max. desired current	- 5.00 mA
Stimulus duration/Frequency	- SENSe (see Section 2.2.)
Impedance	- kΩ (is calculated automatically)
Range (not displayed)	- 1 turn (can only be changed in the menu)

2.1. Checks before Start-up

The Stimuplex® HNS 12 is a class IIa medical device according to Council Directive 93/42/EEC. The device should not be used until it has been subjected to an on-site function test and the persons responsible for operating the device are instructed how to use the device with the aid of the user manual.

Before putting the Stimuplex® HNS 12 into operation, carry out the following tests.

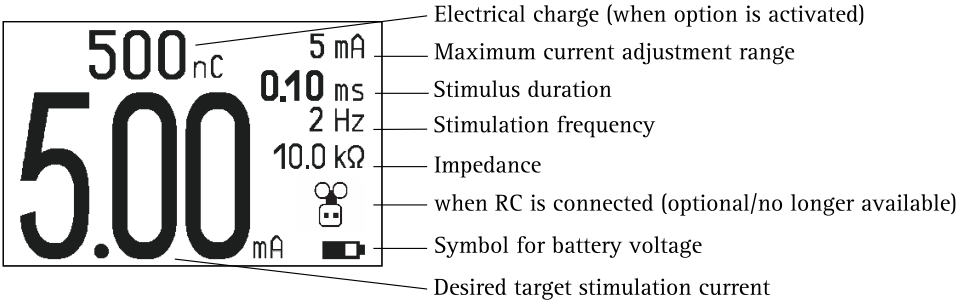
1. Carry out a visual inspection of the electrode cable. Damaged cables must not be used. Connect the electrode cable for connection with the stimulation needle to the front of the nerve stimulator (to the middle 4-polar plug). The plug connector configuration prevents wrong polarity connection.
2. Check if the battery is installed.
3. Press the "Stand-by" key to switch on the Stimuplex® HNS 12. While you are holding down the "Stand-by" key to switch on Stimuplex® HNS 12, important equipment parameters are indicated in the unit's display. After releasing the key, the device automatically runs a self-test. If the self-test detects a defective function, an error code will appear in the LCD display that switches off automatically after 8 seconds.
4. A battery symbol appears in the right lower corner of the LCD display that allows a check of the battery voltage. The symbol flashes when the battery voltage drops below 7 V. The device automatically shuts off when the battery voltage reaches < 6 V.

   If no display appears when the Stimuplex® HNS 12 is switched on, change the battery immediately (refer to Section 5.4. „Battery").

Whenever the battery symbol is flashing, a new 9 V alkaline block battery must be installed immediately to avoid having to abort a stimulator treatment.

5. Connect the red clip for the skin electrode and the insulated 2-mm male plug for the stimulation needle with the 10 kΩ test resistance (included in the equipment supplied).

   The LCD display shows the current operating conditions:



After switching on Stimuplex® HNS 12, the target stimulation current is zero; in other words, no stimulation pulse is generated and the LED is not flashing. If the target stimulation current is > 0.00 mA and the actual stimulation current flowing does not deviate by more than 0.04 mA from the target stimulation current, the green LED lights up (or yellow, if the optionally adjustable current threshold has been undershot) and a stimulation frequency sound becomes audible. The actual current is indicated automatically and only indicated as a warning when it deviates from the target current. In this state, the LED will light up red and a higher-pitch warning signal will be sounded.

6. Use the dial to set the maximum current of 5.00 mA. No error message should appear at a load resistance of 10 kΩ (see accessories). The LED flashes green at the selected stimulation frequency. The sound is dependent on the preselected stimulation current, when “sound variable” has been configured in the sound-menu.
7. Now release the connection between clip and male plug. The warning message „actual current is less than target current“ appears, both stimulation currents are displayed (see Section 2.2.5.), the LED flashes red because no current is flowing, and the click or beep sound starts ticking louder at a higher pitch.
8. To switch off the nerve stimulator, hold down the ”Stand-by” key until the display disappears (switch off time = 1 second). If the key is released during this switch-off phase, the device switches back to „ON“ status. Refer specifically to the Section „Warning and Safety information“ before using the Stimuplex® HNS 12 on a patient. If the device does not behave as previously described, it must not be put into operation. Please contact the manufacturer or distributor listed.

Maintenance on medical equipment may only be performed by the manufacturer or persons explicitly authorized by the manufacturer.
Stimuplex® HNS 12 is designed for regional anesthesia to optimally localize peripheral nerves.

2.2. Technical Description

Stimuplex® HNS 12 generates square pulses with selectable stimulus duration and continuously adjustable stimulation current.

The range of adjustment of the pulse current from 0.00 to 5.00 mA peak-to-peak can be reduced to 0.00 to 1.00 mA with the "mA" button. This 1 mA range allows extremely precise adjustments of the stimulation current. The stimulation frequency and stimulus duration can be varied for different applications. The Stimuplex® HNS 12 nerve stimulator features the option of selecting a frequency of either 1 Hz, 2 Hz or 3 Hz for SENSe and a stimulus duration of 0.05 ms - 0.10 ms - 0.30 ms – 0.50 ms - 1.00 ms.

The Stimuplex® HNS 12 measures the tissue impedance and displays it in kΩ. This measurement allows for a quick check and visualization of the current state of the circuits.

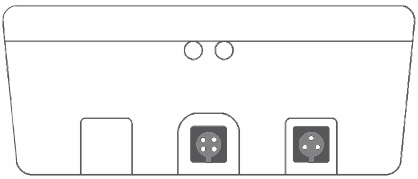
Sequential electrical nerve stimulation (SENSe) technique utilizes an alternating sequenced stream or series of three electrical pulses of varying pulse duration at any given amperage. The two accurate 0.1 ms pulses are sequenced with a pulse of longer duration (e.g. 0.3 ms). A longer duration pulse elicits motor responses at greater distance at lower frequency, increasing sensitivity. The shorter pulses maintain the accuracy underlying successful nerve location, whereas the longer duration pulse enables stimulation at a greater distance. Therefore, SENSe maintains specificity and accuracy, while increasing sensitivity. Clinically, this translates into more motor response information at distance from the nerve. Moving the needle toward the nerve increases the strength or frequency of the motor response. In the clinical setting, SENSe gives more continuous feedback and markedly diminishes the disappearance of motor responses once they are encountered. Therefore, SENSe automatically increases visual clues and feedback during nerve location by needle movement alone with less necessity to adjust the amperage control of the nerve stimulator.

SENSe mode can be activated in the "Options" menu.

SENSe is valid for software version 1.003.x or newer only.

2.2.1. Plug Connections

Two polarized plug connections are located on the front of the nerve stimulator:



– 3-polar plug for connecting single-handed remote control (Stimuplex® Remote Control is no longer available). For continuing use of a remaining remote control, please see instructions for use of remote control
– 4-polar plug for connecting the electrode cable to the stimulation needle and skin electrode or the Stimuplex® Switch (no longer available, for continuing use of a remaining Stimuplex® Switch, please see instructions for use of Stimuplex® Switch).

2.2.2. Current regulator (dial) and keys

Current regulator (dial):
The current regulator (dial) is used to adjust the target stimulation current. The dial can be turned infinitely, but is graduated. The maximum currents (5 or 1 mA) can be achieved either with 2 turns, or 1 turn (factory setting).

The settings 1 or 2 dial turns are configured in the „Setup“ menu, „Dial turns“. For maximum accuracy, select the two turn configuration and use the intermediate steps between the stops.

1 Dial turn

5.00 mA range	- Resolution = 0.02 mA from 0.00 mA to 0.50 mA
	- Resolution = 0.10 mA from 0.50 mA to 2.00 mA
	- Resolution = 0.25 mA from 2.00 mA to 5.00 mA
1.00 mA range	- Resolution = 0.01 mA from 0.00 mA to 0.06 mA
	- Resolution = 0.02 mA from 0.06 mA to 1.00 mA

2 Dial turns

5.00 mA range	- Resolution = 0.01 mA from 0.00 mA to 0.55 mA
	- Resolution = 0.05 mA from 0.55 mA to 0.60 mA
	- Resolution = 0.10 mA from 0.60 mA to 5.00 mA
1.00 mA range	- Resolution = 0.01 mA from 0.00 mA to 1.00 mA

Keys:

"mA" key:	Sets the desired stimulation current range.
"ms" key:	Sets the desired stimulus duration.
"Hz" key:	Sets the desired stimulation frequency.
"Stand-by" key:	On and off switch for the Stimuplex® HNS 12.
Briefly press the "Stand-by" key:	To jump from the menu mode to the normal stimulation mode or to immediately delete a potentially existing marking in the stimulation mode (e.g. 5.00 mA).
MENU arrow keys:	For navigation and settings in the menu.

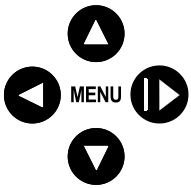
The Stimuplex® HNS 12 is very user friendly in its handling. It features a menu structure with "Main Menu" and "Setup" with which the user can configure user settings, such as switch-on settings, volume and tone pitch, dial resolution, display contrast, automatic switch-off time, date, time and language as well as further options. Navigation through these menus is done with the arrow keys.

Right arrow:
Is used to activate the Main Menu or submenus and select or confirm an option.

Up and down arrows (Up and down keys):
Are used to select a menu item or option and/or to change values.

Fast selection or change by holding down the up/down key.

Left arrow:
Is used to jump back one menu level



2.2.3. Sound

Each stimulation pulse (preset stimulation current is flowing) generates a clear click or beep sound. The sound pitch increases from a low pitch during maximum stimulus current to a high pitch when the current threshold is being approached. However, changes in sound pitch can also be turned off in the „Setup“ menu, „Tone“, „Variable tone“ so that the same sound is always heard regardless of the respective stimulation current.

The type of sound can be selected in the „Setup“ menu, „Tone“, „Mode“. The user can choose between a click and a beep sound. When warnings (actual stimulation current < target stimulation current, target stimulation current < current threshold, automatic switch off, EEPROM) and errors are signaled, the click or beep changes to a louder and higher signal pitch. Whenever any key is operated, a short, clear beep is audible. The volume can be adjusted in the „Setup“ menu, „Tone“, „Volume“ at settings ranging from 0 (a very quiet ticking sound in the stimulus frequency; warning signals remain) to 8 (max. volume).

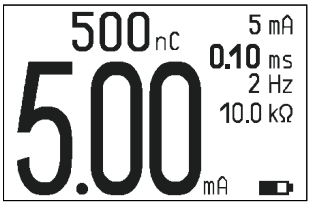
2.2.4. LED

Green LED:	Actual stimulation current = target stimulation current
Yellow LED:	Actual stimulation current = target stimulation current, below the threshold current (if current threshold activated is, see Section 3.6.)
Red LED:	deviation, actual stimulation current < target stimulation current (starting from a deviation of - 0.04 mA), errors.

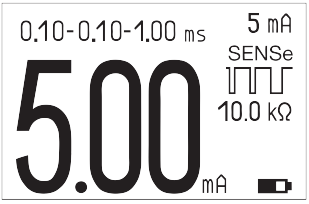
2.2.5. Display modes

The Stimuplex® HNS 12 has 4 basic display modes:

1. **Stimulation mode**
   – With or without electrical charge (nC) display

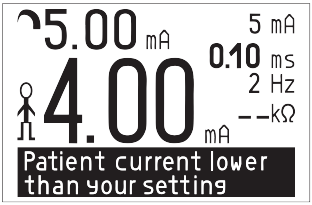


   – when in SENSe mode, the stimulus duration of the three stimulus impulses generated per second is shown instead of the electrical charge (nC)



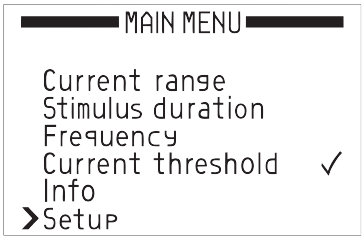
2. **Stimulation mode with warning**

(Actual stimulation current less than target stimulation current)



3. Menu mode

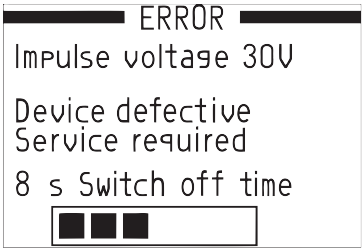
In the menu mode, various submenus and options can be selected by using the up and down arrows. The checkmark (✓) symbolizes the selected value and/or the selected option. Each selection (displayed by a ”>”) can be changed by using the up and down arrow keys and must be confirmed by pressing the right arrow key, if applicable. The checkmark (✓) then appears at the corresponding position.



4. Error display mode

(For example, indicating that the stimulation voltage is too low.)

If an error message appears in the LCD display, the device is automatically switched off within 8 seconds. During this process, the target stimulation current is set to zero and the stimulation voltage is turned off.



2.2.6. Menu structure

Main Menu (arrow keys MENU)

Current range:	0.00 - 5.00 mA
	0.00 - 1.00 mA
Stimulus duration:	1.00 ms
	0.50 ms (optional)
	0.30 ms
	0.10 ms
	0.05 ms (optional)
Frequency:	2 Hz
	1 Hz
	SENSe (3 Hz)
Current threshold:	On (√) or Off (no √)
Info:	Battery level, date, serial no., version
	Distributor
	Manufacturer
	USER INFO (future option, currently not available)
	Activate infrared interface (future option, currently not available)

Setup:	Tone:	Volume:	from 0 to 8
		Mode:	(click or beep)
		Variable tone:	On (√) or Off (no √)
	Dial turns:	1 or 2	
	Contrast:	0 to 8	
	Automatic switch off:	0 to 10 min. (in min. increments)	
		15 to 30 min. (in 5 min. increments)	
	Date	HH:MM - YYYY.MM.DD	
	Language	GB – English	
		D – German	
		F – French	
		E – Spanish	
		I – Italian	
		P – Portuguese	
		S – Swedish	
		NL – Dutch	

Setup:	Language	DK – Danish
		N – Norwegian
		FIN – Finnish
		GR – Greek
		RUS – Russian
		H – Hungarian
		RO – Romanian
		CZ – Czech
		SK – Slovak
		SLO – Slowenian
		PL – Polish
		TR – Turkish
		EST – Estonian
		LV – Latvian
		LT – Lithuanian
		BG – Bulgarian
		CN – Chinese
		J – Japanese
Options:	Factory standard:	Yes (Y?)
		Confirm using the right arrow key
	El. charge nC:	On (✓) or Off (no ✓)
	Auto adjust current:	On (✓) or Off (no ✓)
	Add. stimulus duration:	On (✓) or Off (no ✓)
	SENSe:	On (✓) or Off (no ✓)

3. Operation of the Stimuplex® HNS 12

The device is configured with the following factory settings on delivery:

Maximum current:	**5.00**	**mA**
Stimulus duration:	**SENSe**	(two impulses at 0.1 ms, third impulse varies with current strength from 0.15 ms to 1.0 ms)
Stimulation frequency:	**3**	**Hz**
Impedance:		**kΩ (is calculated)**
Scale range (not displayed):	**1**	**turn (can only be changed in the menu)**
Auto switch off:	**20**	**min. (can only be changed in the menu)**
Current threshold:	**Off**	(changes only possible in the menu, is not reset by the option "Factory setting")
Language:	**English**	(can only be changed in the menu, is not reset by the "Factory setting" option) If a language nor comprehensible to user should accidentally be set, please follow Setup-Language menu to reset to your country language.

3.1. Stand-by

Switch on: 

Press the "Stand-by" key. After the key is released a self-test (not displayed) is run, the stimulation mode is displayed and the device is ready for operation.

or:

Hold down the "Stand-by" key – the equipment data are displayed. After the key is released, a self-test is run as described above and the device is ready for operation.

Switch off: 

Hold down the "Stand-by" key (for approx. 1 sec.). After the display of a progress bar is completed, the display disappears. The device is switched off.

⚠ **Please do not replace the battery if the patient is connected to the device. Please do not replace the battery while the device is turned on as this can damage the LCD display.**

If the key is released within the 1-second switch-off phase, the device remains turned on and switches into the stimulation mode (home function).

If neither the dial nor the keys are operated for a period of 20 minutes, the stimulator switches off automatically. An audible warning signal will sound (4 Hz rhythm) during the last minute. In the "Setup" menu, "Auto switch off", the automatic switch-off time can be set to between 0 and 30 minutes using the up and down keys.

3.2. Selecting the current adjustment range

Factory setting on delivery:	0.00 to 5.00 mA max.
The two ranges are selectable:	- 0.00 to 5.00 mA
	- 0.00 to 1.00 mA

The current range can be changed in two ways:

1. **Selecting the current range for future switch-on procedures:**

   Switch on the device. Activate the Main Menu using the right arrow key and activate "Current range" using the right arrow key. Select the desired range using the up or down key (indicated by > on the left) and confirm with the right arrow key (✓ appears on the right next to the selection). Switch off the device. The current range now selected will be configured when the device is switched on the next time.

2. **Changing the current range during the application:**

   Press the mA key (the displayed value is highlighted by a border) and press the mA key again immediately (the second possible value is set and highlighted). This value is now activated for this application (the border disappears after approx. 3 sec.). If the mA key is pressed repeatedly while the border is activated, each of the other current ranges is set.

   If the current range is changed during the application and a target current has been set, the target current may be reduced slightly automatically for technical reasons.

3.3. Selecting the stimulation current

The amplitude of the stimulation current (desired current) is set using the dial.

The resolution of the regulator increments is dependent on whether one or two dial turns have been set in the „Setup“ menu (see Section 2.2.2.).

3.4. Selecting the stimulus duration

Factory setting on delivery: SENSe (ca. 3 Hz: 3 impulses in 1 s: 350 ms – 350 ms – 300 ms; first two impulses fixed at 0.10 ms while third impulse varies with target current from 0.15 ms to 1 ms).

Stimulus duration values can be selected from three numerical series:

- The first series includes 0.10 ms, 0.30 ms and 1.00 ms (these values are equivalent to those on Stimuplex® HNS 11).
  If these 3 values are not sufficient for your application, you can activate the menu item „Add. stimulus duration“ in the menu „Setup“, „Options“ (✓ appears next to „Add. stimulus duration“ on the right). You can then choose between the values from the second series (below).
- The second series includes 0.05 ms, 0.10 ms, 0.30 ms, 0.50 ms and 1.00 ms.
- The third series conforms to the SENSe mode. SENSe can be enabled in the „Frequency“ menu if the option SENSe is already enabled in the „Options“ menu (✓ appears on the right) and selected with the Hz key. In SENSe mode the ms key is deactivated, as the stimulus duration values are determined by the current set; the stimulus duration value is selected automatically when the current is changed.

Stimulation current:	Stimulus duration:
0.00 - 0.19 mA	0.10 - 0.10 - 0.15 ms
0.20 - 0.29 mA	0.10 - 0.10 - 0.17 ms
0.30 - 0.39 mA	0.10 - 0.10 - 0.20 ms
0.40 - 0.49 mA	0.10 - 0.10 - 0.23 ms
0.50 - 0.59 mA	0.10 - 0.10 - 0.26 ms
0.60 - 0.69 mA	0.10 - 0.10 - 0.30 ms
0.70 - 0.79 mA	0.10 - 0.10 - 0.33 ms
0.80 - 0.89 mA	0.10 - 0.10 - 0.36 ms
0.90 - 0.99 mA	0.10 - 0.10 - 0.39 ms
1.00 - 1.09 mA	0.10 - 0.10 - 0.42 ms
1.10 - 1.19 mA	0.10 - 0.10 - 0.46 ms
1.20 - 1.29 mA	0.10 - 0.10 - 0.49 ms
1.30 - 1.39 mA	0.10 - 0.10 - 0.52 ms
1.40 - 1.49 mA	0.10 - 0.10 - 0.55 ms
1.50 - 1.59 mA	0.10 - 0.10 - 0.58 ms
1.60 - 1.69 mA	0.10 - 0.10 - 0.62 ms
1.70 - 1.79 mA	0.10 - 0.10 - 0.65 ms
1.80 - 1.89 mA	0.10 - 0.10 - 0.68 ms
1.90 - 1.99 mA	0.10 - 0.10 - 0.76 ms
2.00 - 2.24 mA	0.10 - 0.10 - 0.84 ms
2.25 - 2.49 mA	0.10 - 0.10 - 0.92 ms
2.50 - 5.00 mA	0.10 - 0.10 - 1.00 ms

The stimulus duration setting can be changed in three ways:

1. Changing the stimulus duration for future switch-on processes:

Switch on the device and activate the Main Menu using the right arrow key. Use the down key to select "Stimulus duration" and activate the menu page using the right arrow key. Use the up or down key to highlight the desired ms value; select and confirm using the right arrow key (✓ appears on the right). Switch off the stimulator. The value now selected will be set when device is switched on the next time. This is valid except with the SENSe mode.

2. Changing the configured setting during an application (only ms key):

Press the ms key. The current value is highlighted by a border. By repeatedly pressing the ms key, the next higher value appears from the numerical series selected above. Repeatedly press the ms key switch on all values consecutively. The displayed value is immediately active. The border disappears after approx. 3 seconds.

3. Changing the configured setting during an application (ms and up/down arrow keys):

Press the ms key. The current value is highlighted by a border. The stimulus duration can be extended or shortened with the up or down arrow keys in accordance with numerical series selected above. The new value is immediately active. The highlighting disappears after 3 seconds or when the ms key is pressed again or the Stand-by key is pressed briefly.

3.5. Selecting the stimulation frequency

Factory setting on delivery: SENSe (3 Hz)

The selectable options are 2 Hz, 1 Hz or SENSe.

Two setting options are available to change the stimulation frequency:

1. Changing the stimulation frequency for future switch-on processes:

Switch on the device and activate the Main Menu using the right arrow key. Use the down key to highlight "Frequency" and activate the menu page using the right arrow key. Select the desired Hz setting or SENSe (if the option SENSe is already enabled in the „Options" menu) using the up or down arrow keys and confirm it using the right arrow key (✓ appears on the right). The value now selected will be set when device is switched on the next time.

2. Changing the configured setting during an application:

Press the Hz key. The set value is highlighted by a border. By repeatedly pressing the Hz key, the other value appears. Repeatedly pressing the Hz key switches on the values alternately. The displayed value is now active for this application, the highlighting disappears after approx. 3 seconds.

3.6. Current threshold display

Highlight the option "Current threshold" in the "Main Menu" and confirm using the right arrow key (✓ appears on the right).

This option can be used to visually and acoustically indicate when the target stimulation current is falling below the stimulus duration-dependent current threshold.

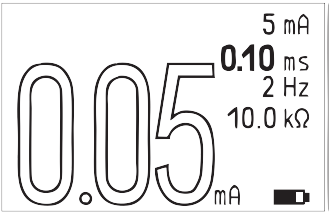
- Visual warning:

  The full digits of the target current display are converted to contoured digits when the current threshold drops below the preset level.

  The LED flashes yellow (instead of green).

- Acoustic warning:

  A warning signal is additionally sounded.



Stimulus duration ms	0.05	0.10	0.30	0.50	1.00
Current threshold mA	0.50	0.30	0.20	0.15	0.10

3.7. Checking the battery voltage

The battery level is displayed as a symbol in the stimulation mode on the bottom right of the LCD display. The filling level of the symbol indicates the battery's remaining capacity. The battery's remaining capacity is additionally indicated in the menu under the item "Info" (see below) in volt and percent.

Press the right arrow key to activate the menu. Navigate with the up/down keys until the highlighting arrow ">" is in front of the menu item "Info". Press the right arrow key to open the "Info" menu. In the upper row, the battery's remaining capacity is indicated in % and volt.

3.8. Additional information – Menu info

The menu "Info" has 5 pages. With the up/down keys you can scroll through these pages.

The version number format has the following meaning:

Version 1.003.x

1 = hardware revision number

003 = software revision number

x = language module revision number

In addition to the equipment data, distribution and manufacturer information is displayed.

4. Setting parameters and options for future switch-on procedures

The parameters and options desired by the user, which should be available when the device is switched on, can be configured via the menu.

The arrow keys up/down and right/left are used for navigating through the menu structure.

These keys have the following functions:

Left arrow key:	Go back one menu level
Right arrow key:	Go down one menu level or select/confirm the highlighted value
Up key:	Jump to the upper menu items or increase the highlighted value
Down key:	Jump to the lower menu items or reduce the highlighted value

Please keep in mind that the desired and set values are immediately saved with the checkmark (✓). If you forget this and Stimuplex® HNS 12 meanwhile switches off automatically, the previous values remain configured.

4.1. Setting switch-on values for stimulation parameters

Press the right arrow key MENU to activate the Main Menu.

4.1.1. Current adjustment range

The desired switch-on value for the current range can be set under the menu item "Current range".

Navigate with the up/down keys until the marking arrow (>) is in front of the menu item "Current range". Press the right arrow key to confirm the menu item, thereby the desired switch-on value is activated for the current range. The switch-on value is indicated by a checkmark (✓).

Changing this menu item during an application has no impact on the previously set values. The changes will not be active until Stimuplex® HNS 12 has been switched off and restarted.

4.1.2. Stimulus duration

The desired switch-on value for the stimulus duration can be set under the menu item "Stimulus duration".

Navigate with the arrow up/down keys until the marking arrow (>) is in front of the menu item "Stimulus Duration". Press the right arrow key to confirm the menu item and thereby activate the adjustable stimulus duration values. Using the arrow up/down keys you can now select the desired switch-on value for the stimulus duration. Confirm your selection with the right arrow key. The switch-on value is now indicated by a checkmark (✓).

Changes to the stimulus duration values in the menu item "Stimulus Duration" will not be active until Stimuplex® HNS 12 has been switched off and restarted. Changing this menu item during an application has no impact on the currently set values.

4.1.3. Frequency

The desired switch-on value for the stimulation frequency can be set under the menu item "Frequency".

Navigate with the up/down keys until the marking arrow (>) is in front of the menu item "Frequency". Press the right arrow key to confirm the menu item, thereby activating the desired switch-on value for the stimulation frequency. The switch-on value is indicated by a checkmark (✓). Changing this menu item during an application has no impact on the current settings. The changes will not be active until Stimuplex® HNS 12 has been switched off and restarted.

4.1.4. Current threshold display

The desired current threshold warning (visual and acoustical) can be activated or deactivated under "Main Menu" "Current threshold".

Highlight "Current threshold" using the arrow up/down keys and confirm and activate (✓ appears on the right) or deactivate (✓disappears) with the right arrow key.

4.2. Setup

Press the right menu arrow key to go to the Main Menu.

Using the up/down keys, choose ”Setup”.

With the right arrow key, open the ”Setup“ menu and you can select from the following menu items:

Tone – Dial turns – Contrast – Auto switch off – Date – Language – Options.

4.2.1. Tone

The desired volume, the sound mode and the dependency of the tone pitch on the target stimulation current can be set in this menu. On the menu page ”Tone”, use the up/down keys to highlight the submenu item ”Volume” by opening it with the right arrow key. With the up/down keys, the volume can be set between 0 (lowest volume) and 8 (loudest volume). The setting is immediately active. Additional confirmation is not required.

In the submenu ”Mode”, the type of sound, i.e. click or beep, can be set with the up/down keys. Additional confirmation is not required here.

Use the option ”Variable tone” to set whether the tone pitch should be dependent on the target stimulation current, or whether you desire a consistent stimulation tone over the entire setting range. Activate this option with the right arrow key (✓ appears on the right) or inactivate it (✓ disappears). The setting is active immediately.

4.2.2. Dial turns

The setting accuracy can be adjusted to suit to your needs by configuring the number of dial turns (one or two turns) for the entire current range of 0.00 mA or 5.00 mA. For maximum accuracy, select the two turn configuration and use the intermediate steps between the stops.

In the Main Menu, select the item ”Setup” and open it with the right arrow key. Highlight the option ”Dial turns” and open it with the right arrow key. With the up or down key, select 1 or 2 turns and activate this selection at the same time. Additional confirmation is not required. For safety reasons, the stimulation current is always reset to zero during this procedure.

4.2.3. Contrast on the LCD display

The contrast on the LCD display can be changed under the menu item ”Contrast”.

Open the ”Setup” menu, select ”Contrast” and open with the right arrow key. The contrast can be set from 0 to 8. The factory setting is 5.

When you change the value with the up or down keys, you can see the changes in the display contrast by checking the B|BRAUN logo. The displayed value is immediately activated and remains set after you have exited the menu.

4.2.4. Automatic switch off

The set time interval for the automatic switch off applies from the last time the stimulator has been operated. It is factory set to 20 minutes on delivery. The switch-off time can be set to between 0 and 30 minutes. If the value is set to 0, the device does not switch off automatically.

Open the ”Setup” menu, select the option ”Auto switch off” and open it with the right arrow key.

Using the up or down key, set the desired automatic switch-off time. The increment is 1 minute between 1 and 10 minutes; above this the increment is 5 minutes. Each setting is immediately activated.

4.2.5. Date and time

After every battery replacement, the date and time must be reset.

Open the ”Setup” menu, highlight ”Date” and open with the right arrow key.

Order for the setting:

00 : 00 0000 . 00 . 00

Hour

Set the hour using the Up/down keys.

With the right arrow key, move the cursor (underline) to the next position.

The minutes are displayed. Set the minutes with the arrow up/down keys.

With the cursor over the right arrow key, go to the next position "Year" and set it with the up/down keys.

Afterwards, set month and day as described above.

The changes are immediately active.

4.2.6. Language

The desired language for menus and warning messages can be configured under the menu item "Language".

With the right arrow key, activate "Main Menu", highlight the "Setup" menu with the down key and open with the right arrow key. With the up or down key, highlight the menu "Language" and open with the right arrow key. Now, you have the option of highlighting the desired language with the up or down key and activating your selection with the right arrow key (✓appears on the right).

When switching to another language than English, the English terms for Setup and Language menus are always additionally displayed behind the terms for the selected language to enable the user to reset the language when he unintentionally changed it.

4.2.7. Options

This menu page offers the following options:

1. Factory standard restores factory settings.
2. Electrical charge nC – additional display of the amount of electricity to be given off in nanocoulomb.
3. Auto current adjustment – the current is adjusted automatically when the stimulus duration is changed.
4. Add. stimulus duration – additional stimulus duration parameters.
5. SENSe - SENSe option can be enabled / disabled

Use the right arrow key to activate (✓ appears on the right) or deactivate these options (✓ not visible).

4.2.7.1. Factory standard

Activation of this menu item resets all of the parameters back to the manufacturer's declared factory settings on delivery (see Section 3.). However, this does not change the language setting or the current threshold display.

In the "Setup" menu, open the "Options" submenu. The "Factory standard" option is automatically highlighted and can be activated with the right arrow key. First, Y? appears to ask the user whether they really want to activate the factory settings. The factory standard are not reset until the right arrow key is pressed once more and ✓ appears on the right. Now, the following parameters are immediately activated:

Current range:	5.00 mA	Dial turns:	1
Stimulus duration:	SENSe	Contrast:	5
	(0.10ms, 0.10ms, 0.15ms-1.0ms)	Autom. switch off:	20 Min.
Frequency:	SENSe (3 Hz)	El. charge nC:	Off
Tone:	Beep	Auto adjust current:	On
Volume:	5	Add. stimulus duration:	Off
Variable tone:	On	SENSe:	On

4.2.7.2. Displaying the electrical charge of the stimulation pulse (electrical charge nC)

By activating this menu item, the electrical charge to be given off per stimulation pulse in nC is additionally displayed in the upper line on the LCD display (el. Charge in Nanocoulomb [nC] = current [µA] x stimulus duration [ms], 1 nC = 10^{-9} As).

When in SENSe mode, the stimulus duration of the three stimulus impulses generated per second is shown instead of the electrical charge (nC), even if this option has been activated in the menu.

In the "Setup" menu, open "Options", highlight "El. charge nC" and activate with the right arrow key (✓ appears on the right).

4.2.7.3. Current adjustment

This option allows automatic adjustment of the set stimulation current to the new settings when the stimulus duration is increased **during an application**. This prevents the set stimulation current from suddenly being given off for too long when the stimulus duration is increased without the stimulation current having been turned back to 0.00 mA.

When in SENSe mode, there is no automatic current adjustment, since the stimulus duration is fixed and can not be changed via the quick access button for impulse duration „ms".

⚠ **When the stimulus duration is lowered with the ms key and then increased again without the dial being operated in the interim, the target stimulation current is turned up to the old value again.**

In the "Setup" menu, open "Options", highlight "Auto adjust current" and activate (✓) or deactivate with the right arrow key.

4.2.7.4. Additional stimulus duration

With this option, you can add the stimulus durations 0.05 ms and 0.50 ms to the selection series (see Section 3.4). In "Setup", open "Options", highlight "Add. stimulus duration" and activate (✓) or deactivate with the right arrow key.

4.2.7.5. SENSe option

With this option enabled, you can add the SENSe stimulation mode (see Section 2.2.) to the 2 Hz/1 Hz series. In „Setup", open „Options", highlight „SENSe" and activate (✓) or deactivate with the right arrow key.

5. Initial setup, maintenance and notes

5.1. Testing the Stimuplex® HNS 12

A device check may be conducted as follows:

1. Switch on the Stimuplex® HNS 12. After the "Stand-by" key has been released and the self-test successfully completed, the device is ready for operation.
2. With the stimulus duration set at 0.30 ms and the current adjustment range at 5.00 mA and the circuit open, check that the actual current equals zero over the entire adjustment range from 0.10 to 5.00 mA. (The warning "Patient current lower than your setting" must appear in the display, the warning signal must be audible and the LED in the stimulation frequency must light up red).
3. Now, connect the electrodes (clip and plugs) using the 10 kΩ resistance supplied as an accessory. At this time, recheck the entire adjustment range to make sure that no warning is displayed, the LED lights up green or yellow, if applicable, and the sound is audible at the pitch of the selected stimulation frequency.

   If the user wants to perform a safety check we recommend yearly maintenance by following the test instructions in the Technical Service Manual.

5.2. Special technical features

The electrode connection is configured to prevent the electrode cable for the stimulation needles from being plugged in incorrectly and thereby creating the wrong polarity.

This reliable plug connection system ensures the correct polarity of the stimulation needle (negative) and skin electrode (positive).

As a result of the high peak stimulation voltage, the working spectrum is extremely broad, even when extremely small stimulation electrodes are used (fully insulated needles with pinpoint electrode). The Stimuplex® HNS 12 generates a negative, current-stabilized square pulse. Unlike conventional instruments of this type, the pulse of Stimuplex® HNS 12 is shaped by extremely fast active pulse drivers at both slopes.

An output amplifier specially designed for this application has an extraordinarily wide dynamic range and generates reproducible settings even below 0.10 mA.

The latest microcomputer technology has made it possible to integrate performance features into the Stimuplex® HNS 12 that – until now – could only be provided by large and expensive systems. Some examples of the integrated features include the exact measurement of actual current and battery voltage, display of tissue impedance, menu structure and error messages available in various languages, configuration of user-specific options, the infrared interface, and the large high-contrast and userfriendly graphic display.

The internal quartz time base ensures precise stimulus durations and stimulus frequencies.

5.3. Technical data

Type:	Stimuplex® HNS 12
Instrument type:	BF
Battery:	9V (alkaline, max. 1000mAh)
Power consumption:	6 mA (8 mA max.)
Stimulation current:	Î = 5 mA (max.) (0 – 12 kΩ)
Stimulation voltage:	Û = 95 V (max.)
Stimulation frequency:	1 Hz / 2 Hz ±1% / SENSe (ca. 3 Hz: 3 impulses in 1 s: 350 ms – 350 ms – 300 ms)
Stimulus duration:	0.05 ms – 0.10 ms – 0.30 ms – 0.50 ms – 1.00 ms ±1% SENSe (0.10 ms - 0.10 ms - 0.15 ms to 1.0 ms)
Allowable load impedance:	0 kΩ – 12 kΩ
Current measuring accuracy:	+/-5 % or +/-0.04 mA which one is greater, in a 0.5 kΩ to 12 kΩ load
Impedance measuring range:	1 kΩ – 90 kΩ for target stimulation current > 0.5 mA
Impedance measuring accuracy:	±10% / ±20% for target stimulation current > 1 mA / <= 1 mA
Sound pressure level:	51 dB / 54 dB / 63 dB for stimulation / warning / error
Weight:	250 g
IP protection class:	IPX0

Operational Environmental Conditions:

Temperature:	0°C to +40°C
Relative humidity:	max. 90%, no condensation
Atmospheric pressure:	700 mbar to 1060 mbar

Storage and Shipping Conditions:

Temperature:	0°C to +40°C
Relative humidity:	up to 90%, no condensation
Atmospheric pressure:	500 mbar to 1060 mbar

5.4. Battery

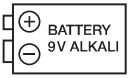
The battery charge status must be checked regularly. The battery must be replaced immediately whenever the battery symbol is flashing.

⚠ **Do not replace the battery if the patient is connected to the device. Please do not replace the battery while the device is turned on as otherwise the LCD display can become damaged.**

When the battery voltage drops below 6 V, the nerve stimulator stops operating and issues an error message. Change the battery. While not performing a stimulation, you can save battery power by setting the stimulation current to 0.00 mA.

Periodic inspection of the battery must be performed to avoid leakage.

If the Stimuplex® HNS 12 nerve stimulator is not intended to be used for a long period of time, the battery must be removed to prevent leakage.



The battery compartment is located in the base of the nerve stimulator. Open the compartment. Change the battery - **ensuring correct polarity**. Then, close the compartment. When inserting the battery, please insure that polarity is correct and that there is a firm connection between the battery and the contacts.

Use only 9 V alkaline manganese batteries (e.g. VARTA 4922, DURACELL MN 1604). These will provide you with an optimum operating time. Rechargeable batteries must not be used as they may cause the device to malfunction. External power supply must not be use.

⚠ **If the battery is leaking, the Stimuplex® HNS 12 should no longer be operated on the grounds of safety. Acid penetrating the inside of the instrument can damage or impair essential circuitry. It must be returned to the manufacturer for correct cleaning and a safety check.**

5.5. Cleaning and disinfecting the Stimuplex® HNS 12

The Stimuplex® HNS 12 must be regularly cleaned and disinfected before and/or after each use.

Use only soft, damp cloths to clean, wipe and disinfect the Stimuplex® HNS 12 and the accessories, e.g. electrode cable. Water or soap are particularly suitable for this purpose. Ensure that no moisture penetrates the Stimuplex® HNS 12.

Use only wipe disinfection, no spray disinfection! Avoid condensation!

White spirit or commercially available methanol-free disinfectant in an ethyl alcohol base can be used for disinfection. Meliseptol® or white spirit can be used for wipe disinfection.

⚠ **The following substances must not be used: trichloroethylene, acetone, butanone, benzene methyl ethyl ketone, benzene, methanol, cellulose thinner, 2-propanol or any other organic solvents, acids and sodium hydroxide solution. Disinfectants containing iodine or dyes can discolor the housing and should not be used.**

5.6. Maintenance and safety checks

Check the serviceable condition of the Stimuplex® HNS 12 and accessories on each occasion before use. A defective instrument must not be used. Electromedical equipment may only be repaired by the manufacturer or by an organization expressly authorized by the manufacturer. An order for repairs must be accompanied by a detailed description of the fault.

The measuring function of the Stimuplex® HNS 12 is the measurement of the actual stimulation current with the accuracy defined in Chapter 5.3. “Technical Data”.

Stimuplex® HNS 12 conducts integrated self-tests during stimulation including tests of the actual stimulation current measurement. A safety check every second year or yearly maintenance by following the test instructions in the Technical Service Manual is recommended.

➢ **Refer to Section 10 for Specific requirements for the US market.**

5.7. Equipment logbook (Specific requirement for use on German market)

1. The operator is required to keep an equipment logbook on medical-technical devices according to the German Medical Devices Operator Ordinance (MPBetreibV).
2. Mandatory entries in the logbook include:

   2.1. Designation and other information for identification of the device

   2.2. Certification about the function testing performed and instructions given in accordance with the German Medical Devices Operator Ordinance (MPBetreibV).

   2.3. Name of the officer authorized in accordance with the MPBetreibV, time of instructional training and the name of the instructed persons.

   2.4. Deadlines and dates for performing prescribed safety checks and mechanical inspections and their results and the date of maintenance work including the name of the person or company responsible for carrying out these measures.

5.8. Notices

General notes

The cables of the nerve stimulator Stimuplex® HNS 12 should be positioned in such a way that they do not contact either the patient or other cables.

All accessories have to be visually inspected at regular time intervals. The insulation of the cables and plug connections must not exhibit any damage.

Only stimulation needles and Stimuplex® HNS 12 Accessories offered by B. Braun and labeled with B. Braun logos should be utilized with this nerve stimulator.

➢ **Refer to Section 5.10. for Instruments and accessories**

All electrical and electronic equipment provided with systems released after 13 August 2005, are marked with a symbol indicating that this equipment must undergo separate collection for disposal.

In order to ensure an appropriate disposal of the device you have the possibility to give your device back to your B. Braun contact person or to return the device to Stockert GmbH free of charge.

Please decontaminate the device before shipping (see Section 5.5.).

5.9. Error messages

Stimuplex® HNS 12 checks the battery voltage periodically. If the voltage is less than 6.00 V, an error message will be displayed and the device will switch off automatically. The used battery must be replaced immediately.

⚠ **An empty battery can leak, damaging the device and making it unusable. If the device is not used for a longer period of time, it is imperative that the battery is removed. Any damage caused by a leaking battery is not covered under the warranty.**

Stimuplex® HNS 12 conducts safety checks periodically.

In the event of the following malfunctions, the device switches off automatically within 8 seconds.

During this time, the cause of the error is displayed (see Section 2.2.5., display mode 4: “Error display mode“).

1. Actual stimulation current > target stimulation current + tolerance
   tolerance = 0.10 mA in the target current range = 0.00 – 0.49 mA
   tolerance = 0.20 mA in the target current range = 0.50 – 1.99 mA
   tolerance = 0.50 mA in the target current range = 2.00 – 5.00 mA
2. Max. stimulation voltage of the stimulation pulse less than 50 V
3. RAM (memory) error
4. CPU (computer) error
5. ROM (program memory) error
6. ADC (analog digital converter) error
7. Frequency error

Signal Specification

All specification values have 10% tolerance.

Stimulation	Information Signals		Reset Action
	Tone (variable)	LED	
	Pattern Frequency Repetition	On Color Repetition	
1 Hz Stimulation	ti 2 kHz (to 0.925 kHz) 1 s	0.05 s green 1 s	---
2 Hz Stimulation	ti 2 kHz (to 0.925 kHz) 0.5 s	0.05 s green 0.5 s	---
SENSe (ca.3 Hz Stimulation: 3 impulses in 1 s: 350 ms – 350 ms – 300 ms)	ti 2 kHz (to 0.925 kHz) 1 s	0.05 s green 1 s	---

Warnings	Information Signals		Reset Action
	Tone	LED	
	Pattern Frequency Repetition	On Color Repetition	
Current threshold 1 Hz Stimulation	tiTii 2 kHz / 1.2 kHz 1 s	0.05 s yellow 1 s	---
Current threshold 2 Hz Stimulation	tiTii 2 kHz / 1.2 kHz 0.5 s	0.05 s yellow 0.5 s	---
Current threshold SENSe (ca.3 Hz Stimulation: 3 impulses in 1 s: 350 ms – 350 ms – 300 ms)	tiTii 2 kHz / 1.2 kHz 1 s	0.05 s yellow 1 s	---
Patient current lower than your setting 1 Hz Stimulation	tiTii 2.7 kHz / 1.4 kHz 1 s	0.05 s red 1 s	---
Patient current lower than your setting 2 Hz Stimulation	tiTii 2.7 kHz / 1.4 kHz 0.5 s	0.05 s red 0.5 s	---
Patient current lower than your setting SENSe (ca.3 Hz Stimulation: 3 impulses in 1 s: 350 ms – 350 ms – 300 ms)	tiTii 2.7 kHz / 1.4 kHz 1 s	0.05 s red 1 s	---

Errors	Information Signals		Reset Action
	Tone	LED	
	Pattern Frequency Repetition	On Color Repetition	
Patient current Device defective Service required 8s Switch off time	ti 2.7 kHz 0.25 s - 0.25 s - 0.5 s	0.05 s Red 0.25 s - 0.25 s - 0.5 s	---
Impulse voltage Device defective Service required 8s Switch off time	ti 2.7 kHz 0.25 s - 0.25 s - 0.5 s	0.05 s Red 0.25 s - 0.25 s - 0.5 s	---
RAM ERROR Device defective Service required 8s Switch off time	ti 2.7 kHz 0.25 s - 0.25 s - 0.5 s	0.05 s Red 0.25 s - 0.25 s - 0.5 s	---
CPU ERROR Device defective Service required 8s Switch off time	ti 2.7 kHz 0.25 s - 0.25 s - 0.5 s	0.05 s Red 0.25 s - 0.25 s - 0.5 s	---
ROM ERROR Device defective Service required 8s Switch off time	ti 2.7 kHz 0.25 s - 0.25 s - 0.5 s	0.05 s Red 0.25 s - 0.25 s - 0.5 s	---
ADC ERROR Device defective Service required 8s Switch off time	ti 2.7 kHz 0.25 s - 0.25 s - 0.5 s	0.05 s Red 0.25 s - 0.25 s - 0.5 s	---
Frequency ERROR	ti 2.7 kHz 0.25 s - 0.25 s - 0.5 s	0.05 s Red 0.25 s - 0.25 s - 0.5 s	---

If any such error occurs, the device must not be used any longer and must be sent in for repair.

In the event of malfunctions that have no impact on the functional safety of the device, e.g. a deviation between internal parameters, Stimuplex® HNS 12 will first try to reconstruct these parameters. During this procedure, the message "EEPROM" Correction" appears. This message automatically disappears after the error has been corrected successfully and the device is again ready for operation. If the error cannot be corrected, the factory set default values are used. The error message "K(U) EEPROM INIT" then appears during every switch-on procedure. In this case, the device might run at slightly changed stimulation settings. Please send in the device immediately to the manufacturer or distributor for repairs or testing.

Loading a language

If an error occurs when changing the language, the device will automatically switch back to English.

During this procedure, the LCD may briefly go blank.

5.10. Instruments and accessories

The Stimuplex® HNS 12 should only be operated with the accessories and instruments referred to in this user manual. The accessories must meet safety class type BF.

Before every use check the accessories and instruments to make sure they are in serviceable condition and follow the care and disinfection instructions supplied (see Section 5.5.).

Stimuplex® HNS 12 and Accessories, Spare parts, Stimuplex® and Contiplex® needles

Product	Designation
Product Description	Ø x length
Battery cover for Stimuplex® HNS 12	
Carrying case for Stimuplex® HNS 12	
Test resistor for Stimuplex® HNS 12	
Replacement electrode cable for Stimuplex® HNS 12	1.25 m (including cable)
Stimuplex® D needles, 15° bevel	
25 G x 1 1/3“	0.5 x 35 mm
25 G x 2 1/8“	0.5 x 55 mm
23 G x 1 1/2“	0.6 x 40 mm
23 G x 2 3/4“	0.6 x 70 mm
22 G x 2“	0.7 x 50 mm
22 G x 3 1/8“	0.7 x 80 mm
22 G x 4 3/4“	0.7 x 120 mm
20 G x 6“	0.9 x 150 mm
Stimuplex® D needles, 30° bevel	
22 G x 1 1/2“	0.7 x 40 mm
22 G x 2“	0.7 x 50 mm
22 G x 3 1/8“	0.7 x 80 mm
Stimuplex® A needles, 30° bevel	
24 G x 1“	0.55 x 25 mm
22 G x 1“	0.70 x 25 mm
22 G x 1 3/8“	0.70 x 35 mm
22 G x 2“	0.70 x 50 mm
21 G x 2“	0.80 x 50 mm
21 G x 4“	0.80 x 100 mm
20 G x 6“	0.90 x 150 mm
Contiplex® D needles, 15° bevel	
18 G x 2 1/8“	1.3 x 55 mm
18 G x 4 3/8“	1.3 x 110 mm
Contiplex® D needles, 30° bevel	
18 G x 2 1/8“	1.3 x 55 mm
Contiplex® D catheter set	
- Contiplex® catheter	0.41 x 0.71 x 400 mm
with 20G Contiplex® D cannula, 15° bevel	1.1 x 33 mm
with 20G Contiplex® D cannula, 15° bevel	1.1 x 55 mm
- Contiplex® catheter	0.45 x 0.85 x 400 mm
with 18G Contiplex® D cannula, 15° bevel	1.3 x 55 mm
with 18G Contiplex® D cannula, 30° bevel	1.3 x 55 mm
- Contiplex® catheter	0.45 x 0.85 x 1000 mm
with 18G Contiplex® D cannula, 15° bevel	1.3 x 80 mm
with 18G Contiplex® D cannula, 15° bevel	1.3 x 110 mm
Contiplex® Tuohy	
Needles with Tuohy bevel	
With Contiplex® catheter	
0.45 x 0.85 x 500 mm and sideport	
18 G x 1 1/2“	1.3 x 40 mm
18 G x 2“	1.3 x 50 mm
18 G x 4“	1.3 x 100 mm
0.45 x 0.85 x 1000 mm and sideport	
with 18 G Contiplex® Tuohy cannula	1.3 x 150 mm

Contiplex® Tuohy Ultra	
Needles with Tuohy bevel	
with Contiplex® catheter	0.45 x 0.85 x 400 mm
18 G x 1 1/2"	1.3 x 40 mm
18 G x 2"	1.3 x 50 mm
18 G x 4"	1.3 x 100 mm
with Contiplex® catheter	0.45 x 0.85 x 1000 mm
18 G x 6"	1.3 x 150 mm
Contiplex® Tuohy Ultra 360®	
Needles with Tuohy bevel	
18G x 1 1/2"	1.3 x 40 mm
18G x 2"	1.3 x 50 mm
18G x 4"	1.3 x 100 mm
18G x 6"	1.3 x 150 mm
Contiplex® Tuohy 360 (only for China)	
Needles with Tuohy bevel	
18G x 1 1/2"	1.3 x 40 mm
18G x 2"	1.3 x 50 mm
18G x 4"	1.3 x 100 mm
18G x 6"	1.3 x 150 mm
Contiplex® S	
Needles with 20°bevel	
with Contiplex® catheter	0.45 x 0.85 x 500 mm
18 G x 2"	1.3 x 50 mm
18 G x 4"	1.3 x 100 mm
18 G x 6"	1.3 x 150 mm
Contiplex® S Ultra	
Needles with 20°bevel	
with Contiplex® catheter	0.45 x 0.85 x 1000 mm
18 G x 2"	1.3 x 50 mm
18 G x 4"	1.3 x 100 mm
18 G x 6"	1.3 x 150 mm
Contiplex® S Ultra 360®	
Needles with 20°bevel	
18 G x 2"	1.3 x 50 mm
18 G x 4"	1.3 x 100 mm
18 G x 6"	1.3 x 150 mm
Contiplex® S 360 (only for China)	
Needles with 20°bevel	
18 G x 2"	1.3 x 50 mm
18 G x 4"	1.3 x 100 mm
18 G x 6"	1.3 x 150 mm
Contiplex® C	
with Contiplex® catheter	1.05 x 187 mm / 19 G
Needles with 15° bevel	
25 G x 7 1/2"	0.53 x 190 mm
Needles with 30° bevel	
25 G x 7 1/2"	0.53 x 190 mm
Stimuplex® D Ultra	
Needles with 15° bevel	
22G x 1 1/3"	0.7 x 35 mm
22G x 2"	0.7 x 50 mm

22G x 3 1/8"	0.7 x 80 mm
22G x 4 3/4"	0.7 x 120 mm
Needles with 30° bevel	
22G x 2"	0.7 x 50 mm
Stimuplex® Ultra	
Needles with 30° bevel	
22G x 1 3/8"	0.7 x 35 mm
22G x 2"	0.7 x 50 mm
22G x 3 1/8"	0.7 x 80 mm
22G x 4"	0.7 x 100 mm
20G x 6"	0.9 x 150 mm
Stimuplex® Ultra 360®	
Needles with 30° bevel	
22G x 1 1/3"	0.7 x 35 mm
22G x 2"	0.7 x 50 mm
22G x 3 1/8"	0.7 x 80 mm
20G x 4"	0.9 x 100 mm
20G x 6"	0.9 x 150 mm
Stimuplex® 360 (only for China)	
Needles with 30° bevel	
22G x 1 1/3"	0.7 x 35 mm
22G x 2"	0.7 x 50 mm
22G x 3 1/8"	0.7 x 80 mm
20G x 4"	0.9 x 100 mm
20G x 6"	0.9 x 150 mm
Stimuplex® Onvision®	
22G x 2"	0.7 x 50 mm
22G x 3 1/8"	0.7 x 80 mm
20G x 4"	0.9 x 100 mm
22G x 4 3/4"	0.9 x 120 mm
20G x 6"	0.9 x 150 mm
Stimuplex® Pen	Pen for stimulation of nerves through skin, for the purposes of nerve mapping before nerve block application.
And also covering all different Hub-, NRFit® variations and Onvision® system cable. Dimensions: Cannulas: OD x length / Gauge x length Contiplex Catheter: ID x OD x length Contiplex C Catheter: OD x length / Gauge	

6. References

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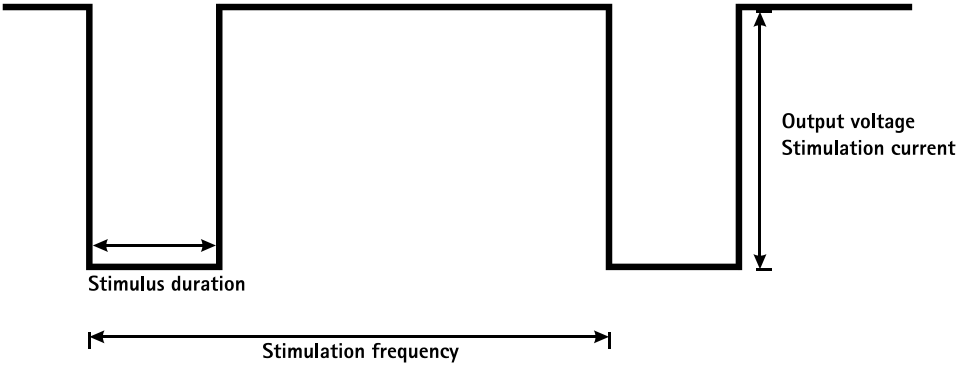
7. Appendix

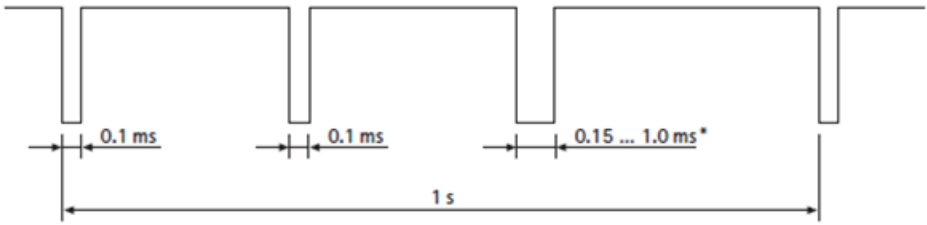
Appendix A (according to IEC 60601-2-10):

Output curve shape: rectangle negative, constant current



where	Stimulus duration =	0.05 ms or 0.10 ms or 0.30 ms or 0.50 ms or 1.00 ms
	Stimulation frequency =	1 Hz, 2 Hz or SENSe
	Output voltage Û =	95 V (without load, open)
	Output impulse current Î =	maximal 1.00 mA or 5.00 mA (short circuit)

SENSe



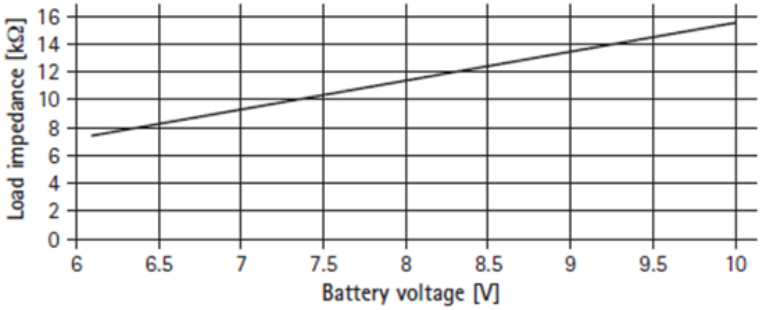
Ca. 3 Hz: 3 impulses in 1 s: 350 ms – 350 ms – 300 ms

* see Section 3.4. “Selecting the stimulus duration” for more details

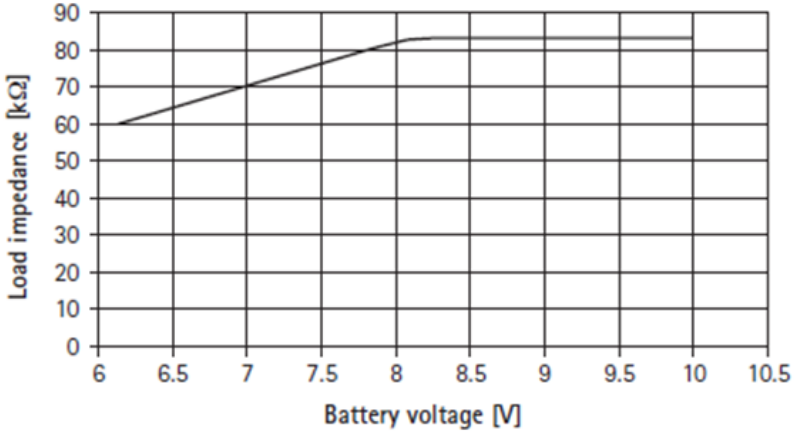
Conversion table: stimulation current [mA] and pulse width [ms] in charge (nanocoulomb, nC)

Amplitude	Pulse Width	Charge	Pulse Width	Charge	Pulse Width	Charge
mA	ms	nC	ms	nC	ms	nC
0.1	0.1	10	0.3	30	1.0	100
0.2	0.1	20	0.3	60	1.0	200
0.3	0.1	30	0.3	90	1.0	300
0.4	0.1	40	0.3	120	1.0	400
0.5	0.1	50	0.3	150	1.0	500
0.6	0.1	60	0.3	180	1.0	600
0.7	0.1	70	0.3	210	1.0	700
0.8	0.1	80	0.3	240	1.0	800
0.9	0.1	90	0.3	270	1.0	900
1.0	0.1	100	0.3	300	1.0	1000
1.2	0.1	120	0.3	360	1.0	1200
1.6	0.1	160	0.3	480	1.0	1600
1.8	0.1	180	0.3	540	1.0	1800
2.0	0.1	200	0.3	600	1.0	2000
2.5	0.1	250	0.3	750	1.0	2500
3.0	0.1	300	0.3	900	1.0	3000
3.5	0.1	350	0.3	1050	1.0	3500
4.0	0.1	400	0.3	1200	1.0	4000
4.5	0.1	450	0.3	1350	1.0	4500
5.0	0.1	500	0.3	1500	1.0	5000

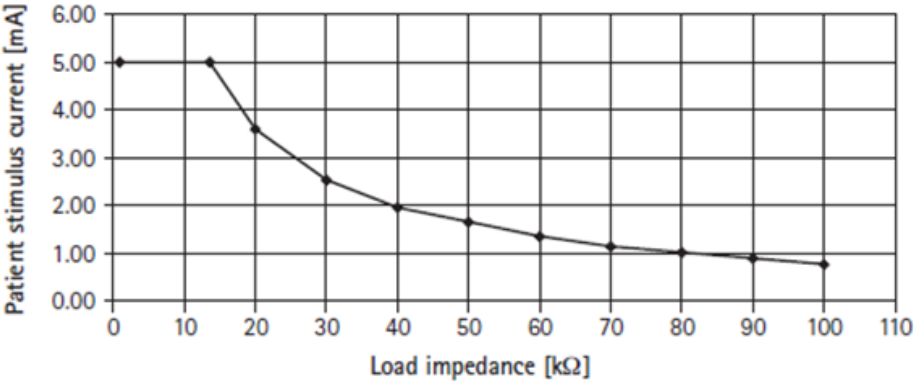
Appendix B (according to IEC 60601-2-10):
Load impedance as a function of battery voltage
Setting: stimulation current = 5.00 mA



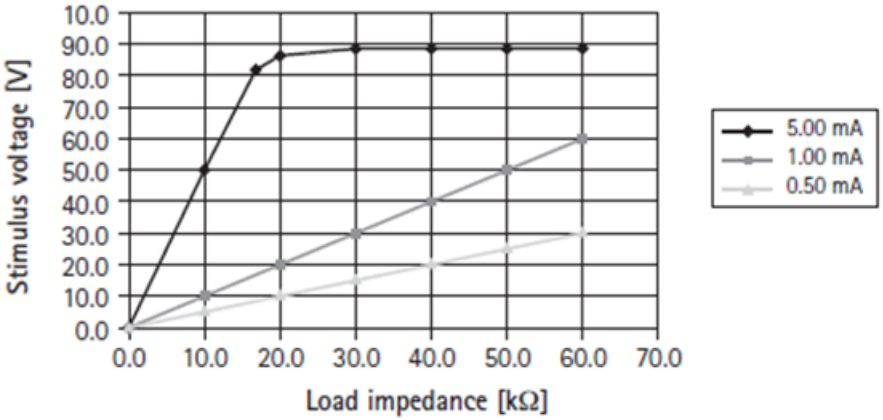
Load impedance as a function of battery voltage
Setting: stimulation current = 1.00 mA



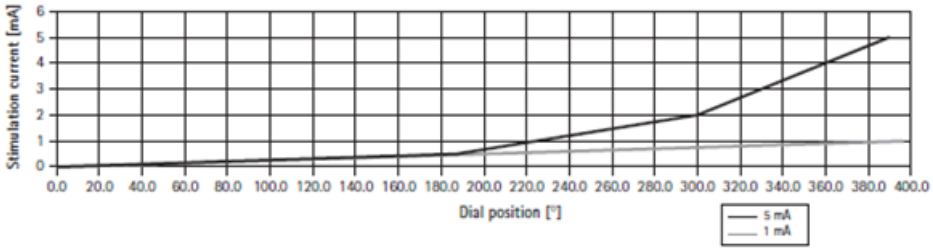
Actual stimulation current as a function of load impedance
Setting: target stimulation current = 5.00 mA, battery voltage = 9.0 V



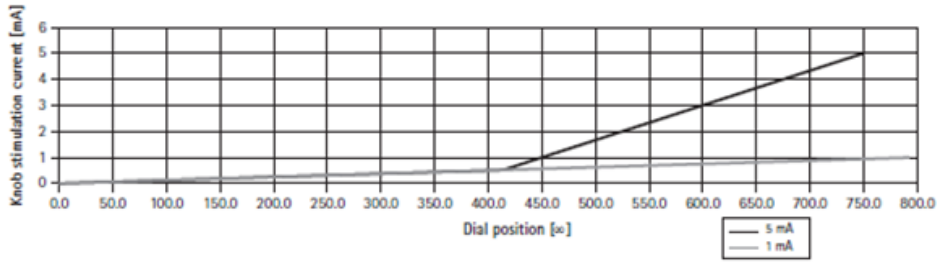
Output voltage as a function of load impedance



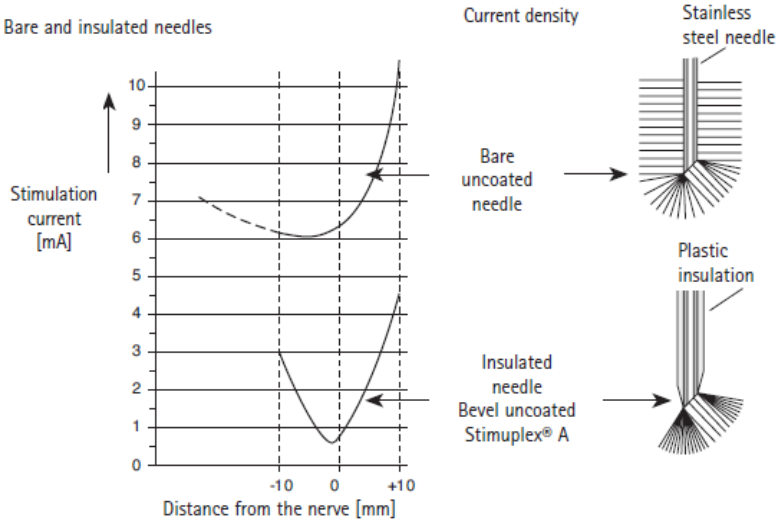
Target stimulation current as a function of adjustment control setting (relative to 0°)

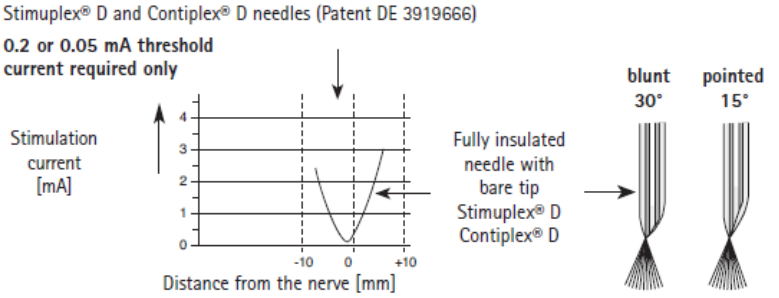


Setting: 2 turns



Appendix C (according to IEC 60601-2-10):





8. Symbols on Stimuplex® HNS 12

Symbol	Description
	Status of the battery voltage
	Target stimulation current
	Actual stimulation current
	Stimulus duration
	1 Hz
	2 Hz
	SENSe (description see Section 2.2. “Technical Description”)
	Infrared transmission (for service only)
	Volume
	Shut-off procedure
	Remote control active (Single-handed remote control active; The Remote Control is no longer available.)
	Remote control inactive (Single-handed remote control inactive; The Remote Control is no longer available.)
	Patient-coupled circuit open
	Type BF applied part
	Caution
	Remote Control Connector (Single-handed remote control; The Remote Control is no longer available.)

	Stimulation current instrument (needle)
	Battery
	Date of manufacture
	Manufacturer
	Consult instructions for use
	MEDICAL — APPLIED CURRENT/ENERGY EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES 60601-1: 2005 + A1:2012; CAN/CSA-C22.2 No.60601-1:2014; IEC 60601-1-6:2010 + A1:2013; IEC 60601-2-10:2012 + A1:2016 Control No.: E352559
	Separate collection for electrical and electronic equipment (currently applicable to EU community only)
CE 0297	CE marking with number of the notified body
	Distributor
REF	Catalogue number
LOT	Batch number
SN	Serial number
	Humidity limitation (storage and shipping conditions)
	Atmospheric pressure limitation (storage and shipping conditions)

	Temperature limits (storage and shipping conditions)
	Follow operating instructions
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	Russian GOST certification
	Ukraine conformity assessment body sign and number
	Keep dry
	The electrical and electronic product contains some hazardous substances which can be safely used during their environment-friendly use period; after their environment-friendly use period expires, they shall be put into the recycling system.

9. Electromagnetic compatibility (EMC)

Guidelines and manufacturer's declaration concerning electromagnetic emissions		
Stimuplex® HNS12 is intended for use in an environment as stated below. The customer or user of Stimuplex® HNS 12 should ensure that the device is operated in this type of environment.		
Emitted interference	**Compliance**	**Electromagnetic environment guidelines**
RF emissions according to CISPR 11	Group 1	The Stimuplex® HNS 12 utilizes RF energy for its internal function exclusively. Therefore, its RF emissions are very low and are unlikely to interfere with electronic equipment in the proximity.
RF emissions according to CISPR 11	Class A	The Stimuplex® HNS 12 is suitable for use in other facilities than the residential environments and such facilities that are directly connected to a public mains network that also supplies buildings used for domestic purposes.
Harmonic current emissions according to IEC 61000-3-2	Not applicable	
Voltage fluctuations, flicker emissions according to IEC 61000-3-3	Not applicable	

Guidelines and manufacturer's declaration concerning electromagnetic immunity to interference			
Stimuplex® HNS12 is intended for use in an environment as stated below. The customer or user of Stimuplex® HNS 12 should ensure that the device is operated in this type of environment.			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	±8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	The floors should be made of wood or cement or paved with ceramic tiles. If the floor is made of synthetic material, the relative humidity must be a minimum of 30 %.
Fast transient electrical disturbances /bursts according to IEC 61000-4-4	±2 kV for mains power lines ±1 kV for in and output lines 100 kHz repetition frequency	Not applicable	Not applicable
Surges according to IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV	Not applicable	Not applicable

Voltage dips and interruptions according to IEC 61000-4-11	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles	Not applicable	Not applicable
Power frequency magnetic fields (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should correspond to the values typical to those found in commercial and hospital environments.

Remark: U_T is the mains alternating currents prior to application of the test level.

Guidelines and manufacturer's declaration concerning electromagnetic immunity to interference

Stimuplex® HNS12 is intended for use in an environment as stated below. The customer or user of Stimuplex® HNS 12 should ensure that the device is operated in this type of environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment guidelines
RF conducted disturbances according to (W) IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Mobile and portable radio frequency communication equipment should not be used at a lesser distance to Stimuplex® HNS 12 including its lines than the recommended separation distance which is calculated according to the equation applicable to the modulation frequency. **Recommended separation distances:** d = not applicable for 150 kHz to 80 MHz $d = 1.17\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ for 800 MHz to 2.7 GHz With P as rated power of the transmitters in watts according to the transmitter manufacturer's information and d as recommended separation distance in meters (m). The field strength of stationary radio transmitters should be less than the compliance level at all frequencies based on on-site[a] testing[b]. Malfunctions are possible in the environment of equipment that bears this symbol.
RF radiated-disturbances according to IEC 61000-4-3 test methods	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	

Remark 1: The higher frequency range is applicable at 80 MHz and 800 MHz.

Remark 2: These regulations may not apply in all cases. The distribution of electromagnetic fields is affected by absorptions and reflections of buildings, objects and persons.

a	The field strength of stationary transmitters, such as base stations for mobile phones and mobile land (radio) telephones, amateur radio stations, AM and FM radio broadcasting and television transmitters, can in theory not be exactly determined beforehand. An inspection of the location should be considered to determine whether there are any stationary transmitters creating an electromagnetic environment. If the measured field strength at the location where Stimuplex® HNS 12 is operated exceeds the above-stated compliance level, Stimuplex® HNS 12 should be monitored to verify that it functions properly. If abnormal performance features are observed, additional measures may be required, such as changing the orientation of Stimuplex® HNS 12 or moving it to another location.
b	The field strength should be less than 3 V/m over the frequency range of 0.15 MHz to 80 MHz.

Recommended separation distances between portable and mobile RF telecommunication devices and Stimuplex® HNS 12		
Stimuplex® HNS12 is intended for operation in an electromagnetic environment in which RF disturbances are controlled. The user of the Stimuplex® HNS 12 can help prevent electromagnetic malfunctions by maintaining a minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the Stimuplex® HNS 12, dependent on the output power of the communications equipment as listed below.		
Rated power of the transmitter (W)	**Separation distance as a function of modulation frequency (m)**	
	80 MHz to 800 MHz	**800 MHz to 2.7 GHz**
	$d = 1.17 \sqrt{P}$	$d = 2.33 \sqrt{P}$
0.01	0.12	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.69	7.38
100	11.67	23.33
For transmitters whose maximal rated power is not listed in the table above, the recommended separation distance d in meters (m) can be calculated by applying the equation that belongs to each column, where P is the maximum rated power of the transmitter in watts (W) as stated in the transmitter 's information.		
Remark 1: At 800 MHz, the separation distance for the higher frequency range applies. **Remark 2:** These guidelines may not apply in all cases. The distribution of electromagnetic fields is affected by absorptions and reflections of buildings, objects and persons		

10. Specific requirements for the US market

To U.S.A Customers:
The User Manual packaged with the nerve stimulator includes all the procedures and requirements for operation the Stimuplex® HNS 12 Nerve Stimulator. Please heed all warnings and recommendations presented in the manual. For our US customers only, the following revisions and/or additions should be used in place or in conjunction with the information provided within the manual.

Thank you.

B. Braun Medical Inc.

10.1. Addition to Section "5.6. Maintenance and safety checks" of the Manual

Service and Technical Support:

If, during the initial warranty period, the Stimuplex® HNS 12 fails to respond to the operating or troubleshooting procedures listed in this manual and the cause cannot be determined, discontinue using the unit and contact B. Braun Medical Customer Service for further instruction regarding Warranty Service Support and Repair:

B. Braun Medical Inc.

824 Twelfth Avenue

Bethlehem, PA 18018-3524, USA

Ph: 1-800-227-2862

Should it be necessary to return the unit for repair, Customer Service will provide a Returned Goods Authorization (RGA) number and instruction for the return. Carefully package the unit (preferably in the original case), mark it with the RGA number and ship according to Customer Service instruction.

B. Braun Medical cannot assume any responsibility for loss and damage to returned units while they are in transit.

Please contact B. Braun Medical Clinical and Technical Support with product function complaints:

B. Braun Medical Inc.

Clinical and Technical Support

824 Twelfth Avenue

Bethlehem, PA 18018-3524, USA

Ph: 1-800-854-6851

Fax: 1-610-758-9020

You will be asked to provide the following information with each complaint:

1. Unit Serial Number
2. Verification of last battery replacement date
3. Verification of completion of unit Short Test
4. contact name, address, phone number and e-mail address
5. Account name and /or number
6. Any information which might aid in the investigation of the complaint

Also please note that no Inspection Sheet has been included with this unit as it does not contain any pertinent information to our U.S.A. customers.

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13615K

CE 0297

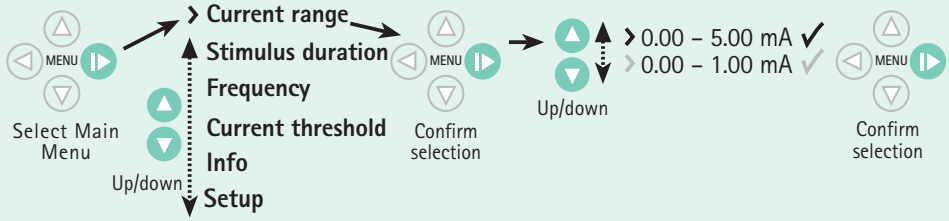
REF 6043570 - valid for software version 1.003.x

0819

Brief Instructions for Use: Stimuplex® HNS 12

Configuring the basic settings for current range (example):

-> Switch on: Display: 0.00, Basic settings.
-> Press right menu key, select current range (with up-down menu key),
-> Confirm current range with right menu key,
-> Select desired value with up/down key › confirm with right menu key ✓.



Menu structure:

Current range

0.00 – 5.00 mA; 0.00 – 1.00 mA

Stimulus duration

1.00 ms, 0.50 ms (optional), 0.30 ms, 0.10 ms, 0.05 ms (optional)

Frequency

2 Hz, 1 Hz, SENSe (3Hz)

Current threshold on/off

Info

Battery, Date, Serial No., Version, Distributor, Manufacturer, User Info Infrared

Setup

- Tone: Volume (0-8), mode (click, beep), variable tone
- Dial Turns: 1,2
- Contrast: 0 – 8
- Auto Switch-off: 0 – 30
- Date: Hour, minute, ...
- Language: English, German, ...
- Options: Factory standard, El. charge nC, Auto adjust current, Add. stimulus duration, SENSe

Left key: One step back
Right key: Select menu, confirm
Up/down key: Select desired value

mA key: Set current range

ms key: Set stimulus duration

Hz key: Set stimulation frequency

Stand-by key

Factory settings on delivery:

Maximum current	5 mA
Stimulus duration:	SENSe (0.10ms - 0.10ms - 0.15ms to 1.0ms)
Stimulation frequency:	SENSe (3Hz)
Scale range:	1 turn
Auto shut-off:	After 20 Min.

Battery 9 V alkaline

If the stimulus duration-dependent current threshold is out of tolerance, the target current is displayed as contoured digits and the yellow LED blinks.
A warning signal is additionally sounded.

For procedure refer to reverse page.

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The physician is responsible for ensuring that Stimuplex® HNS 12 is used properly.

1. **Apply skin electrode.**
2. **Plug electrode cable into the stimulator and connect skin electrodes.**
3. Switch on Stimuplex® HNS 12. Display: **0.00**; the basic settings are displayed in the upper right.
4. **Changing the settings during use:**
   (Only framed values can be changed and are immediately active.)

4.1 Change maximum current (mA key): 5 mA / 1 mA possible

Press mA | 5 mA | immediately press mA again | 1 mA |

4.2 Change stimulus duration for 1Hz/2Hz (ms key): 0.10 ms / 0.30 ms / 1.00 ms for stimulation frequency 1 Hz and 2 Hz. When using SENSe the pre-defined impulse sequence is 0.10 ms - 0.10 ms - 0.15 to 1.0 ms

Press ms | 0.10 ms | press ms again | 0.30 ms | –> ms | 1.00 ms |

Additional stimulation duration values (ms key): 0.05 ms / 0.10 ms / 0.30 ms / 0.50ms / 1.00ms

Menu: Setup –> Options –> Set Extra stimulus duration ✓.

Press ms | 0.05ms | press ms immediately again | 0.10ms | –> ms | 0.30ms | –> | 0.50ms | –> | .... |

Alternatively: Select the values with the up/down menu keys ms –> ▲ ▼

4.3 Changing the frequency (Hz key): 2 Hz / 1Hz / SENSe (if SENSe option enabled)

Press Hz | 2Hz | press | 1Hz | again –> Hz | ⎍⎍⎍ | (for SENSe)

5. Plug electrode cable into stimulation needle.
6. Set the stimulation current to the desired value by turning dial.
   Red LED blinks; clear warning pitch, warning message: Patient current 0.00
7. Perform puncture with stimulation needle. Warning message disappears. Green LED, Tone sounds at stimulation frequency.
8. Advance the needle until you observe the desired muscle contractions.
9. When the desired current is reached, turn the dial to reduce the stimulation current until weak contractions are noticeable.
   Use CAUTION in the lower stimulus current range.
10. Inject test dose. Motor responses disappear. Set stimulation current back to maximum. (no motor responses should be observed) Inject remaining dose.
11. Switch-off: Hold down key for 1 second (the last basic menu settings are reactivated). Stimulator switches off.

Note:
If the circuit is interrupted or the impedance too high: Red light, warning pitch, warning message appear.
Please check: Is skin electrode dry? – Loose? Stimulation needle plugged in? Cable defective?

Rx only

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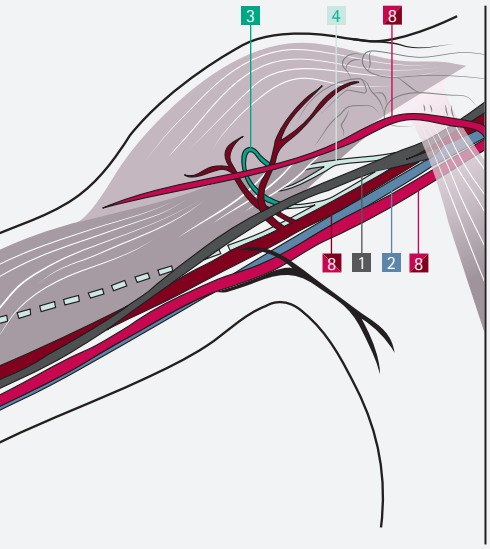
W. 01.01.08/8 6043571 0115 Date of last revision: January 2015

B|BRAUN
SHARING EXPERTISE

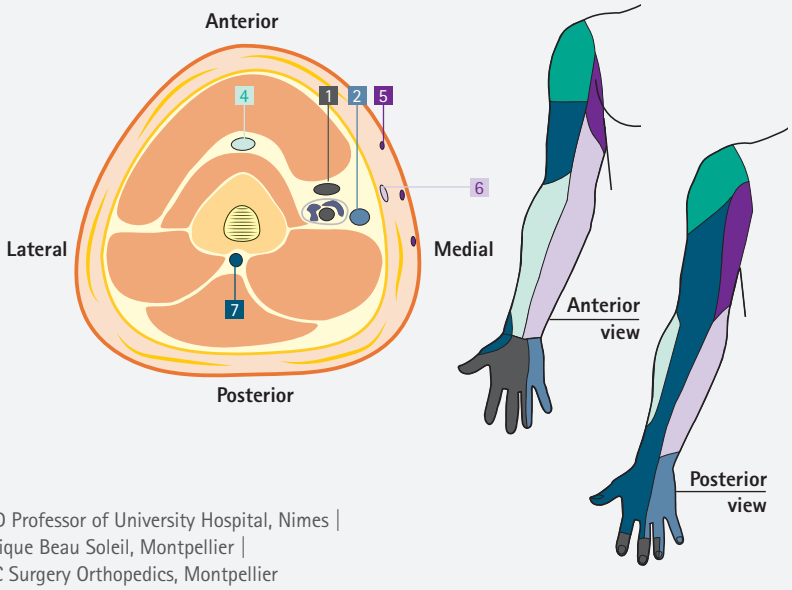
Regional Anesthesia Upper Extremity

Axillary approach

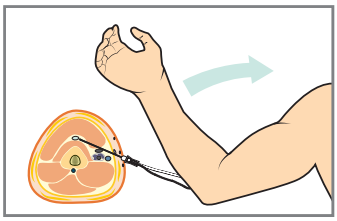


Transverse section of axillary canal

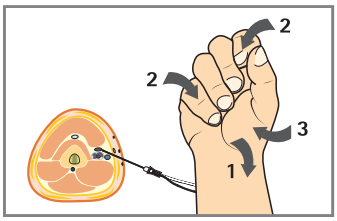
1 Median nerve
2 Ulnar nerve
3 Axillary nerve
4 Musculocutaneous nerve
5 Medial cutaneous nerve of arm
6 Medial cutaneous nerve of forearm
7 Radial nerve
8 Artery/Vein



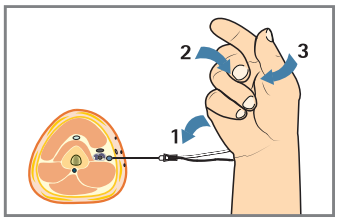
Reference
J.-J. Eledjam: M.D.; PH.D Professor of University Hospital, Nimes |
Dr. B. Bassoul: MD; Clinique Beau Soleil, Montpellier |
Dr. J. Teissier: MD; DESC Surgery Orthopedics, Montpellier



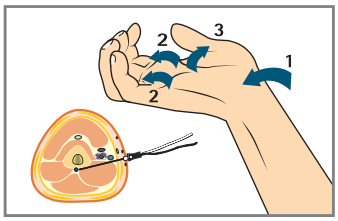
Motor response to musculocutaneous nerve stimulation



Motor response to median nerve stimulation
1 | Wrist flexion
2 | Fingers' flexion
3 | Thumb opposition

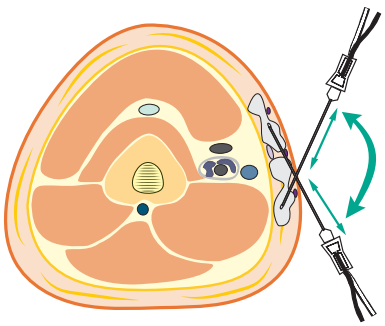


Motor response to ulnar nerve stimulation
1 | Ulnar deviation of the wrist
2 | Metacarpo-phalangeal flexion
3 | Thumb adduction



Motor response to radial nerve stimulation
1 | Wrist extension
2 | Metacarpo-phalangeal extension
3 | Thumb adduction

1 | Stimuplex® HNS 12
2 | Contiplex® S Ultra 360, Stimuplex® Ultra 360, Contiplex® Tuohy Ultra 360
3 | Stimuplex® Pen
4 | Stimuplex® HNS compact



Infiltration of the medial cutaneous nerve of the arm and the forearm

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Date of last revision: 12.2018

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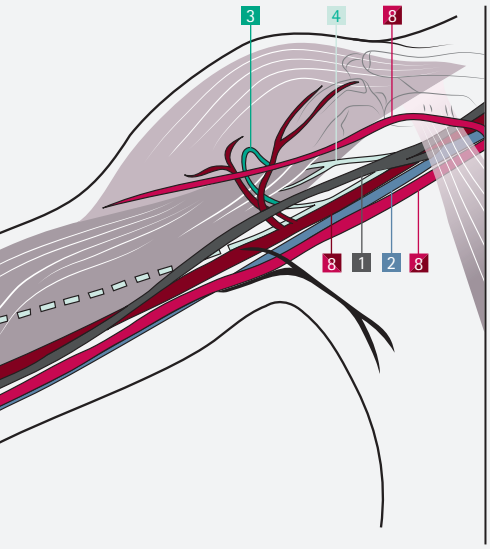
SHARING EXPERTISE

Regional Anesthesia Upper Extremity

Axillary approach



Transverse section of axillary canal

1 Median nerve
2 Ulnar nerve
3 Axillary nerve
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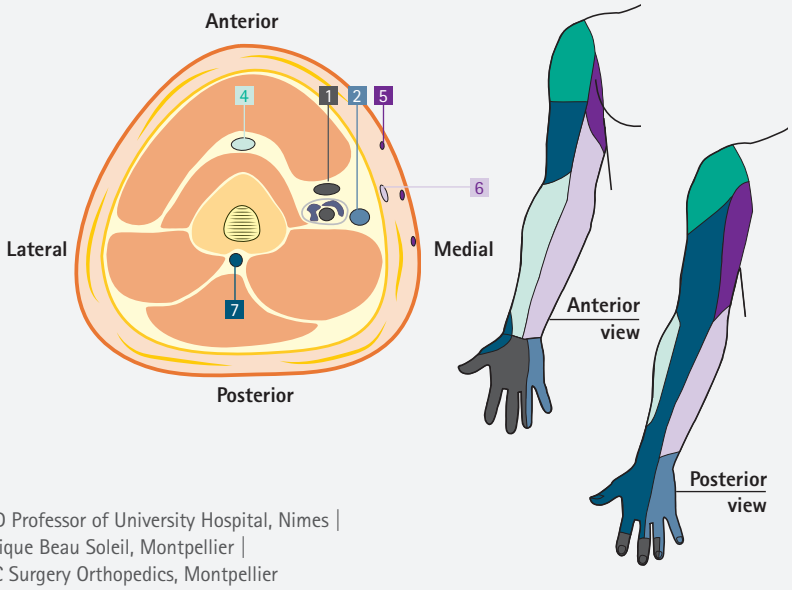
7 Radial nerve
8 Artery/Vein



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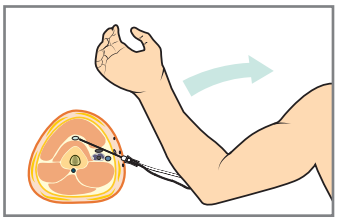
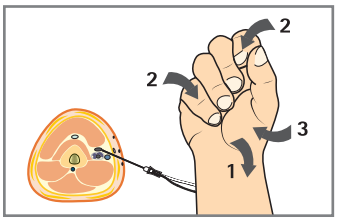
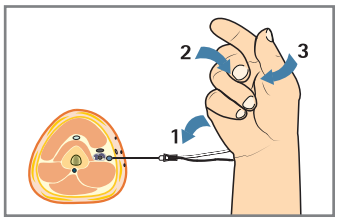


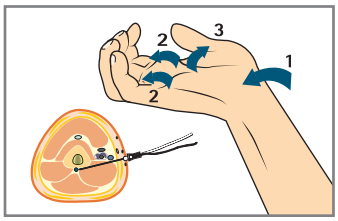
Motor response to musculocutaneous nerve stimulation



Motor response to median nerve stimulation
1 | Wrist flexion
2 | Fingers' flexion
3 | Thumb opposition



Motor response to ulnar nerve stimulation
1 | Ulnar deviation of the wrist
2 | Metacarpo-phalangeal flexion
3 | Thumb adduction



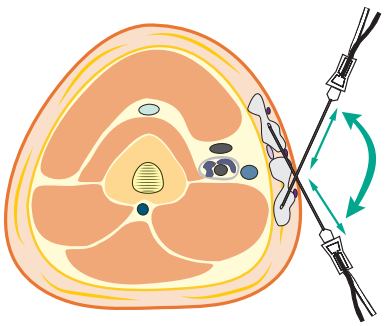
Motor response to radial nerve stimulation
1 | Wrist extension
2 | Metacarpo-phalangeal extension
3 | Thumb adduction

1

2

3

1 | Stimuplex® HNS 12
2 | Contiplex® S Ultra 360, Stimuplex® Ultra 360, Contiplex® Tuohy Ultra 360
3 | Stimuplex® Pen



Infiltration of the medial cutaneous nerve of the arm and the forearm

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Date of last revision: 12.2018

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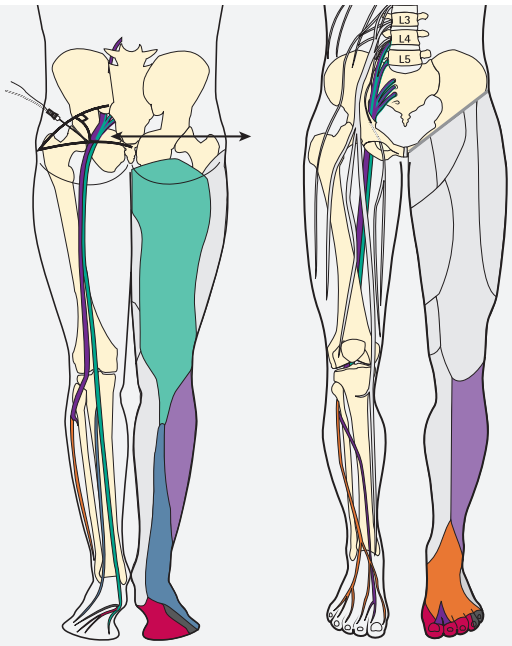
SHARING EXPERTISE

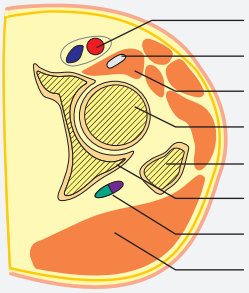
Regional Anesthesia Lower Extremity

Sciatic Nerve Block: Posterior Approach



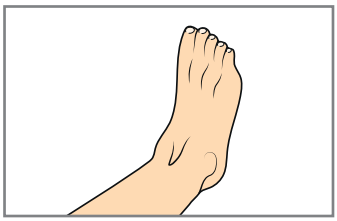
- Tibial nerve
- Posterior cutaneous nerve of thigh
- Medial plantar nerve
- Lateral plantar nerve
- Sural nerve
- Common peroneal nerve
- Lateral cutaneous nerve of calf
- Superficial peroneal nerve
- Deep peroneal nerve

Cross section of upper leg at level of head of femur

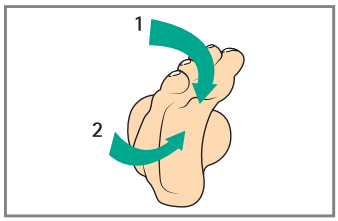


- Femoral vein and artery
- Femoral nerve
- Psoas muscle
- Head of femur
- Greater trochanter
- Acetabulum
- Sciatic nerve
- Gluteus maximus muscle

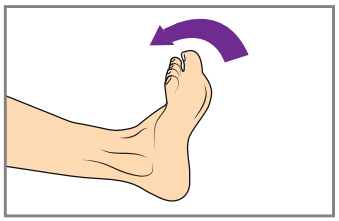
Reference
J.-J. Eledjam: M.D.; PH.D Professor of University Hospital, Nimes |
Dr. B. Bassoul: MD; Clinique Beau Soleil, Montpellier |
Dr. J. Teissier: MD; DESC Surgery Orthopedics, Montpellier



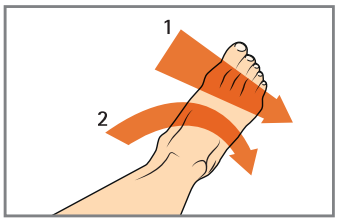
Foot in neutral position



Motor response to tibial nerve stimulation
1 | Plantar flexion of foot and toes
2 | Inversion of foot

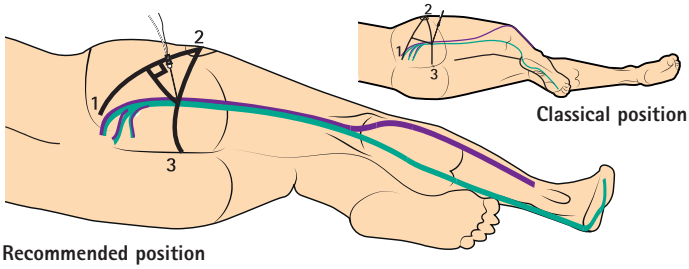


Motor response to deep peroneal nerve stimulation



Motor response to superficial peroneal nerve stimulation
1 | Abduction of foot
2 | Eversion of foot

1 | Stimuplex® HNS 12
2 | Contiplex® S Ultra 360, Stimuplex® Ultra 360, Contiplex® Tuohy Ultra 360
3 | Stimuplex® Pen
4 | Stimuplex® HNS compact



1 | Posterior superior iliac spine
2 | Greater trochanter
3 | Sacral hiatus

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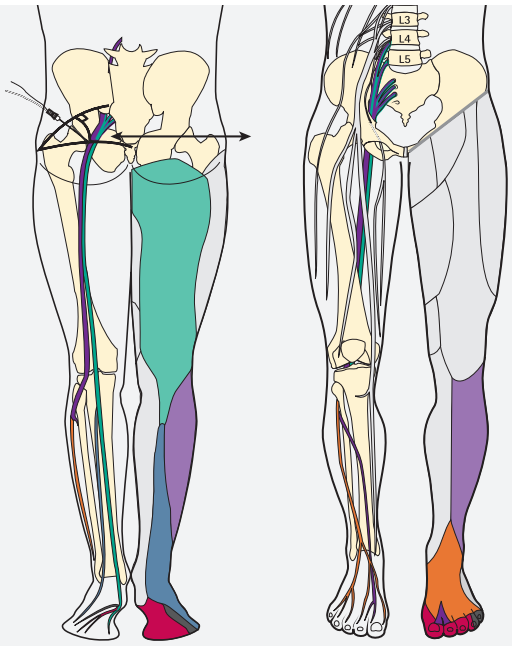
Date of last revision: 12.2018

B BRAUN
SHARING EXPERTISE

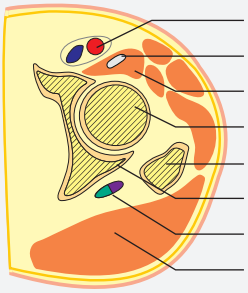
Regional Anesthesia Lower Extremity

Sciatic Nerve Block: Posterior Approach



- Tibial nerve
- Posterior cutaneous nerve of thigh
- Medial plantar nerve
- Lateral plantar nerve
- Sural nerve
- Common peroneal nerve
- Lateral cutaneous nerve of calf
- Superficial peroneal nerve
- Deep peroneal nerve

Cross section of upper leg at level of head of femur



- Femoral vein and artery
- Femoral nerve
- Psoas muscle
- Head of femur
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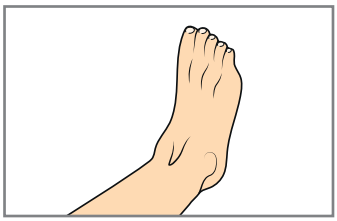
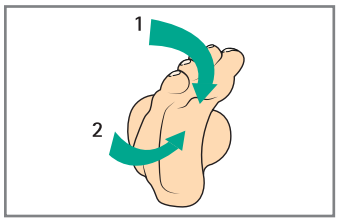
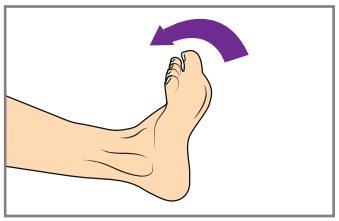


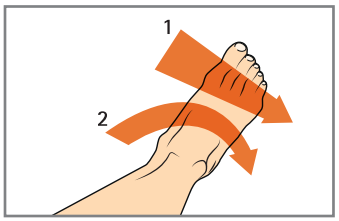
Foot in neutral position



Motor response to tibial nerve stimulation
1 | Plantar flexion of foot and toes
2 | Inversion of foot



Motor response to deep peroneal nerve stimulation



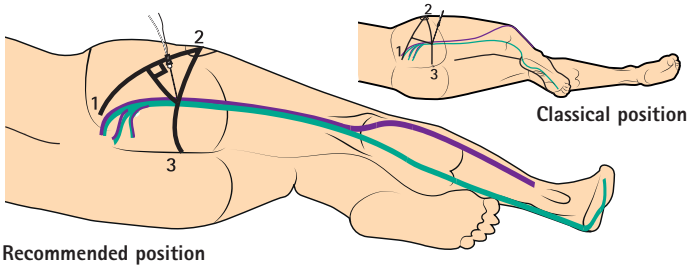
Motor response to superficial peroneal nerve stimulation
1 | Abduction of foot
2 | Eversion of foot

1

2

3

1 | Stimuplex® HNS 12
2 | Contiplex® S Ultra 360, Stimuplex® Ultra 360, Contiplex® Tuohy Ultra 360
3 | Stimuplex® Pen



Classical position

Recommended position

1 | Posterior superior iliac spine
2 | Greater trochanter
3 | Sacral hiatus

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