Operating Instructions

CE 0197

451600-0161
V01

Prof. HAN stim

Dual-channel transcutaneous nerve stimulator

REF 104 009

schwa-medico
MEDICAL EQUIPMENT & SUPPLIES

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CE0197
Version 0
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schwa·medico
MEDICAL EQUIPMENT & SUPPLIES

Contents

The Prof. HAN stim

Purpose

The **Prof. HAN** stim device was designed for transcutaneous nerve electrostimulation. Please do not use this device for any other purpose.

Important safety instructions

Please read the **„operating instructions"** carefully before using the device.

To ensure safe use of the device
- Only use the **Prof. HAN** stim with original accessories.
- Keep the **Prof. HAN** stim away from water or other fluids.
- Do not drop the **Prof. HAN** stim, handle it incorrectly or expose it to extreme temperatures or high humidity (only use at temperatures between 10 °C and 40 °C and at a relative humidity below 90 %).
- Never use the **Prof. HAN** stim when it is not functioning properly or when it is damaged in any way.
- Store the **Prof. HAN** stim in its original packaging after use to protect it from damage and contamination.

Precautions

Patients with an implanted electronic device (e. g. pacemaker) should not undergo electrotherapy with the **Prof. HAN** stim before consulting a doctor. The **Prof. HAN** stim may only be connected to one person at a time.

Warning

Connecting the patient at the same time to a high-frequency surgical unit may cause burning under the electrodes.
Operation near (e. g. 1 m from) a short-wave or microwave device may cause fluctuations in the baseline values of the electrotherapy device.
The minimum area of the electrodes should not be less than 2 cm^2.

Device description

The **Prof. HAN** stim was designed to stimulate human nerves. The keys may be used to make all adjustments necessary. The display shows the different operating modes.

1. display
2. menu keys
3. modification keys
4. ON / OFF key
5. battery compartment
6. sockets

Explanation of symbols

Caution: Please read the **„operating instructions“**!

CE 0197 — Conform with directive 93/42/EEC of 14 June 1993 concerning medical devices

BF type application part

SN — Serial n° of the device

REF — Article n°

Year of construction

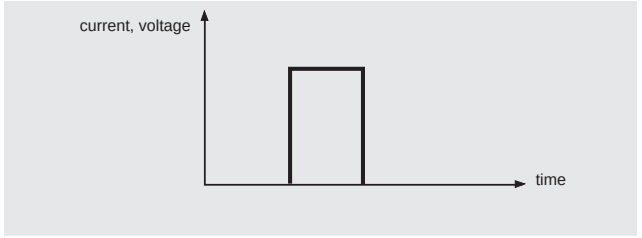
Specifications

Dual-channel nerve stimulator with electrically insulated channels, constant current characteristic, output short circuit control element (AKS) and 3 integrated programmes.

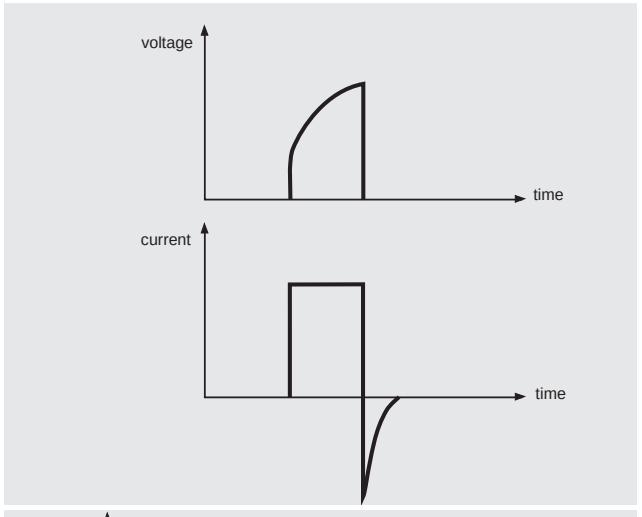
Output current with 1kΩ load real	70 mA, infinitely variable
Frequencies	2 – 120 Hz
Pulse width	60 – 300µs
Pulse shape	positive rectangular wave with negative component
Current consumption	approx. 6 mA (without load)
Current supply	9 V compound battery
Dimensions	11,4 x 5,9 x 2,7 cm
Weight	approx. 170 g

Pulse forms

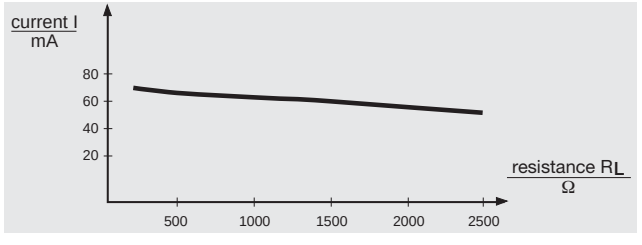
with 1kΩ load real



with ANSI / AAMI standard load



Change in output current depending on load



Operating the Prof. HAN stim

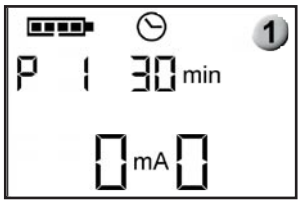
Switching on the device

Switch on the device using the key.
The **Prof. HAN** stim starts with the programme number which was active when the device was last switched off (Fig. 1). If locking (please refer to section entitled “Locking the device“) is active, the key symbol appears in the upper right-hand corner of the display.

Activating the editing mode
Only if you switch on the **Prof. HAN** stim pressing the E key, you can activate the standard programmes (please refer to section entitled “Editing mode“) and make copies of them in the form of user programmes. However, this function is only available if the device was not locked beforehand.

Resetting the operating parameters and deleting the user programmes
If you wish to delete the user programmes and return the operating time meter, the cycle meter and the mean stimulation intensity to zero, keep the key on the left and the P key pressed down while switching on the device (please refer to section entitled “Operating parameters“).

Mode of stimulation



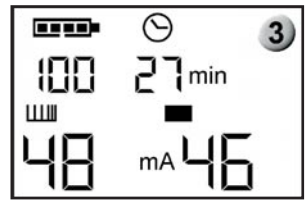
Programme selection
Use the P key to change to the next standard or user programme (Fig. 1). However, this is only possible with an unlocked device. The standard programmes 1 to 3 marked with a „P“ run initially, followed by the user programmes marked with a U, if present. When the last programme has been reached, pressing the key again returns the setting to Programme 1 (P1).

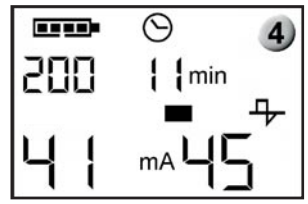
Starting stimulation
First, position the electrodes at the desired points of the body and connect the electrode cables to the electrodes and the device. When the desired programme has been selected using the P key, or the locked device has been started directly with the desired programme (Fig. 1), the two keys may be used to start stimulation.

Setting the intensity
You can use the modification keys to set the intensity of both channels to a pleasant value at any time. The display shows the strength of current for both channels, which may be varied from 0 to 70 mA. Intermediate values are clearly marked by a dash behind the digit (Fig. 2). If the electrodes are not correctly connected to the device, the intensity is returned to zero starting from a current of 4 mA.

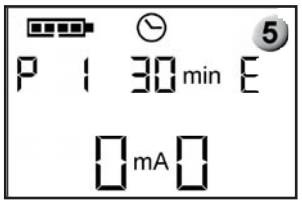
Displaying the stimulation parameters
Press the E key to display the programme parameters in the upper left-hand corner of the display during stimulation. The first value to appear is frequency (Fig. 3) and then pulse width (Fig. 4) if you press the key once more. The programme number is then displayed again (Fig. 2). The remaining stimulation time in minutes is shown in the middle of the display.

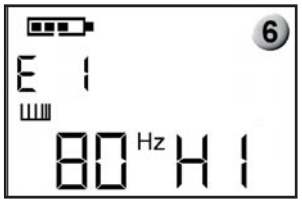
Stopping stimulation
Use the P or keys to stop stimulation at any time. Stimulation stops automatically at the end of a programme. This is confirmed by a double beep from the device.

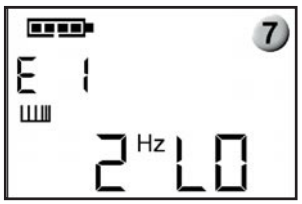


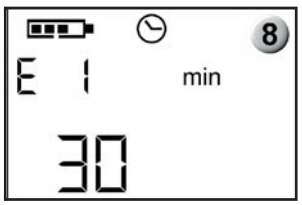


The editing mode









Activating the editing mode
Please switch on the device while pressing the **E** key. An E in the upper right-hand corner of the display indicates the editing mode. However, this only works if the device was not locked beforehand. Then use the **P** key to select the standard or user programme that you wish to edit. The **E** key is then used to start editing the currently active standard or user programme. This is shown by the fact that the P or U symbol before the programme number changes to an E (Fig. 6).

Editing standard or user programmes
The parameters of each programme are used as the starting value. Use the ▲ ▼ modification keys to adjust the values. If you keep the keys pressed down, counting up or down of the parameter is automatically continued. Press the **E** key to jump to the next parameter or to save the values. Use the **P** key to interrupt the editing process at any time without saving the altered parameters.

In case that „OFF“ is adjusted for the total run time, the internal timer is deactivated during operation, i. e. stimulation has to be stopped manually.

Parameters
1. high frequency: 80 Hz up to 120 Hz (Fig. 6)
2. low frequency: 2 Hz up to 10 Hz (Fig. 7)
3. total run time: „OFF“ up to 99 min. (Fig. 8)

Deleting the user programmes
To delete all user programmes, keep the **P** key and the ▼ key on the left pressed down when switching on the device. This will also return all operating parameters to zero.

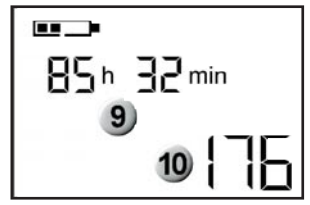
Description of parameters
These values are used to check the patient's stimulation behaviour. The following information are recorded by the **Prof. HAN** stim:
The **stimulation time** (Fig. 9) is the total time during which stimulation was carried out with the device.
The **cycles** (Fig. 10) mark how often the device was switched on and concomitantly used for stimulation.
The **mean stimulation intensity** (Fig. 11) is the mean value of all values for current set by the patient. This information is registered separately for the two channels. The values are updated every minute during stimulation. However, only intensities above 4 mA are considered.

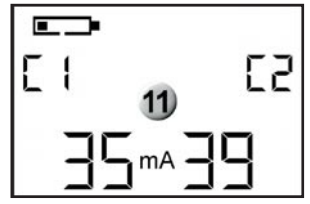
Calling up the parameters
Press the ▼ key on the left and the **E** key at the same time. The stimulation time in hours and minutes is first shown in the upper part of the display. The number of cycles is shown in the lower part of the display.
After pressing the **E** key, the mean stimulation intensity for channel 1 is shown in the lower left part of the display, that for channel 2 in the lower right part.

Resetting the operating parameters
To reset all the described values to zero, keep the **P** key and the ▼ key on the left pressed down when switching on the device. Please be aware that all user programmes are also deleted.

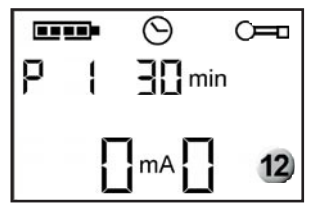
Choose the programme desired for the patient using the **P** key. Lock the device by then pressing the ▼ key on the left and also the **P** key. A key appears in the upper right-hand corner of the display (Fig. 12). All device functions apart from stimulation with the selected programme are now no longer available. Use the same key combination to unlock the device.
Attention: A locked device cannot be started in the editing mode.

Operating parameters





Locking the device



Switching off the device

Use the key to switch off the device. If the battery voltage has fallen below a critical value, or if no key is pressed for two minutes outside stimulation, the device switches itself off automatically. This is signalled by a beep.

Changing the battery

The voltage of the battery in the device is displayed during operation by the segments within the battery symbol. If the voltage falls below a critical value, the **Prof. HAN** stim switches itself off automatically and cannot be switched back on again. You then need to insert a new battery into the device.

- Switch off the device.
- Take off the lid of the battery compartment.
- Remove the used battery from the compartment.
- Insert a new battery into the compartment.
  (Check polarity when connecting the new battery).
- Put the lid of the battery compartment back on.

Always remove the battery when not using the device for a long time.
Battery type: 9V compound battery (e. g. type 6 LR 61).

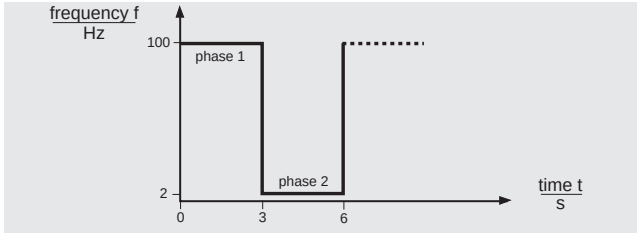
Please dispose of used batteries correctly.

Please observe the instructions accompanying the battery charger, if rechargeable batteries are used.

Programmes

Description of the programmes

The device stimulates alternately with a high frequency and a relatively low pulse width (phase 1) respectively with a low frequency and a relatively high pulse width (phase 2). The duration of the phases depends on the programme number.



Symbols on the display:
phase 1: ▬
phase 2: ▬

Programme 1

Name:	HAN 1 - STANDARD
	Total run time = 30 min
Parameter Phase 1:	Frequency = 100 Hz
	Pulse width = 200 µs
	Duration: 3 s
Parameter Phase 2:	Frequency = 2 Hz
	Pulse width = 300 µs
	Duration = 3 s

Programme 2

Name:	HAN 2 - ALLODYNIA
	Total run time = 30 min
Parameter Phase 1:	Frequency = 100 Hz
	Pulse width = 200 µs
	Duration: 2 s
Parameter Phase 2:	Frequency = 2 Hz
	Pulse width = 300 µs
	Duration = 4 s

Programme 3

Name:	HAN 3 - MUSCULAR SPASMS
	Total run time = 30 min
Parameter Phase 1:	Frequency = 100 Hz
	Pulse width = 200 µs
	Duration: 4 s
Parameter Phase 2:	Frequency = 2 Hz
	Pulse width = 300 µs
	Duration = 2 s

General

Readjustments, alterations and repairs

The manufacturer is only responsible for the safety and performance of the **Prof. HAN** stim device when readjustments, alterations and repairs are carried out by authorised individuals and when the **Prof. HAN** stim is used in accordance with the operating instructions.

Circuit diagrams, spare parts list and setting instructions

Qualified technicians who are familiar with the technical features of the device can be provided with circuit diagrams, spare parts list and setting instructions by the manufacturer.

Warranty

We give a guarantee of 1 year from the date of purchase on the **Prof. HAN** stim device. This guarantee does not cover cables and electrodes.

Cleaning and care of the device

No special cleaning or care agents are required for the **Prof. HAN** stim.
Clean the **Prof. HAN** stim with a soft, dust-free cloth.
Please ensure that no moisture gets into the device.
If moisture does enter the device, a technical check must be carried out before using the device again.

Technical checks

Technical checks on the device should be performed every 24 months.

These include:

1. Checking to see whether the operating instructions and the medical device book are included in the accompanying documentation.
2. Checking the equipment for completeness.
3. Visual check:
   – for mechanical damage
   – for damage to all cables and connections
4. Functional safety
   – Checking the output signals with a load resistance of 1 kΩ real (current and voltage)
   – Checking the frequency
   – Checking the pulse width.

These technical checks may only be performed by individuals with appropriate training. The results must be noted in the medical device book along with the date and name of the person carrying out the check.

Classification

In accordance with the Law on Medical Devices, the **Prof. HAN** stim device is classified as a Class IIa medical product.

Combination

The **Prof. HAN** stim may be used together with all accessories mentioned in the chapters „Scpoe of supply“ and „Optional accessoiries“.

Scope of supply

1	**Prof. HAN** stim	REF 104 009
1	Kabel Typ 5.15 (black)	REF 106 351
1	Kabel Typ 5.16 (grey)	REF 106 352
1	Self-adhering electrodes 50 x 50mm	REF 283 400
1	Battery	REF 601 000
1	Transportation box	REF 450 980-0050

Accessories

Technical Data

Compound:	conductive and bonding material
Durability:	80-150 treatments
Colour:	grey
Manufacturer:	Pierenkemper GmbH Hörnsheimer Eck 19 D-35578 Wetzlar

Self-adhering electrodes

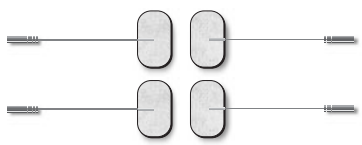
Application
Place self-adhering electrodes directly on appropriate skin treatment area.
Do not apply to demaged skin!

Electrode maintenance
For hygienical reasons, self-adhering electrodes are for single patient use only. After every treatment session, return electrodes to their original foil and store them in their plastic bag. To increase longevity, store in cool area (i. e. refrigerator). With appropriate use and proper care the electrodes are applicable 80-150 times.
To renew adhesion of electrodes, place 2-3 drops of water on the electrodes adhesive surface and air dry a couple of seconds before placing on treatment area.

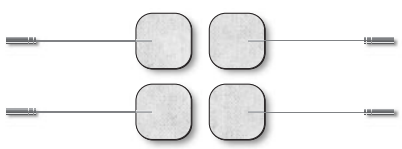
Art. No.	Size	Quantity
281000	stimex, round 32 mm Ø	4

282 000	stimex, round 50 mm Ø	4

283 300	stimex, 50 x 30 mm	4



283 400	stimex, 50 x 50 mm	4



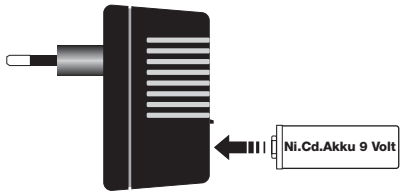
283 600	stimex, 50 x 90 mm	2

283 000	stimex, 50 x 130 mm	2

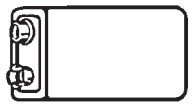
283 100	stimex, 80 x 130 mm	2

Article N°	Description	Quantity
106 351	Electrode cable Typ 5.15, black	1 pc.
106 352	Electrode cable Typ 5.16, grey	1 pc.

603 110	Rechargeable battery 9 V NiCd	1 pc.
603 000	Charger for 9 V rechargeable batteries	1 pc.



601 000	9 V compound battery	1 pc.



Optional accessories