EMP 2 PRO

Dual-channel transcutaneous nerve stimulator



Operating Instruction Art. No. 100846



schwa-medico Operating Instruction - EMP 2 PRO

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Purpose

The EMP 2 PRO device is designed for transcutaneous muscle and nerve electrostimulation. Please do not use this device for any other purpose.

Important safety instructions

Please read the "Operating Instruction" carefully before using the device.

To ensure safe use of the device

- Only use the EMP 2 PRO with original accessories.
- Keep the EMP 2 PRO away from water or other fluids.
- Do not drop the EMP 2 PRO, 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 EMP 2 PRO when it is not functioning properly or when it is damaged in any way.
- Store the EMP 2 PRO 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 EMP 2 PRO before consulting a doctor. The EMP 2 PRO 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 burns under the electrodes.

Operation near (e. g. 1 m) from a short-wave, mobile phones 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 cm².

Explanation of symbols

 \triangle

Attention: Read Operation Instructions!



BF type application part. Protection against electric shock.



The year of construction of the product follows this symbol.

REF The article or order number of the product follows this symbol.

SN The serial number of the product follows this symbol.



This equipment is marked with the recycling symbol. It means that at the end of the life of the equipment you must dispose of it separately at an appropriate collection point and not place it in the normal domestic unsorted waste stream. This will benefit the environment for all.



Conform with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Device description

The EMP 2 PRO was designed to stimulate human nerves and muscles. The keys may be used to make all adjustments necessary. The display shows the different operating modes.

- 1. Display
- 2. Programme key
- Key for visualisation of the parameters, pause and edit mode
- Modification keys (these keys may be used to alter intensity during stimulation and to alter parameters in the editing mode)
- 5. ON/OFF key
- 6. Battery compartment
- 7. OUT hubs
- 8. 230-V transformation socket



Operating the EMP 2 PRO

Switching on the device

Switch on the device using the key. The EMP 2 PRO starts with the programme number which was active when the device was last switched off.

Using the 230-Volt mains supply (optional)

After having connected the transformer to your 230-Volt socket, connect the cable to the central supply socket in the front face of the appliance between the channel outlets 1 and 2. It should be noted that when the machine is connected to the transformer connected to the 230-Volt mains supply it will operate from the mains supply and not the battery.

Activating the editing mode

Only if you switch on the EMP 2 PRO pressing the key, you can activate the standard programmes (please refer to section entitled "Activating the 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 key pressed down while switching on the device (please refer to section entitled "Resetting the operating parameters").

Programme selection



Use the P key to change to the next standard or user programme. However, this is only possible with an unlocked device. The standard programmes 1 to 20 marked with a "P" run initially, followed by the user programmes marked with an "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 modification key, or the key increase the intensity (Fig. 2), the two keys may be used to start stimulation. In

the display on the right hand-side you find two vertical lines. This means: with the key both channels will be increased at the same time.

Setting the intensity

You can use the modification keys or the key 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 0-100 mA. Intermediate values are clearly marked by a dash behind the digit. If the electrodes are not correctly connected to the device, the intensity is returned to zero starting from a current of 4 mA. If you are in the run-down or pause phase in muscle stimulation programmes and you press one of the modification keys, the working phase is started directly from the build-up phase.

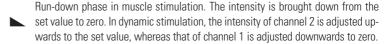
Symbols on the display

During stimulation, the current intensity status is shown in the middle of the display by four symbols:

Continuous stimulation or work phase in muscle stimulation. Stimulation is performed at the set intensity.



from zero. In dynamic stimulation, the intensity of channel 1 is adjusted upwards to the set value, whereas that of channel 2 is adjusted downwards to zero.



Pause phase in muscle stimulation. Stimulation is performed with 75 % of the set intensity at a frequency of 3 Hz.

Pause the stimulation



When the sequence number is not flashing, the key may be used to interrupt stimulation. The word "PAUSE" appears on the display. If the pause key is pressed again, the last intensity set for both channels is restored via a build-up ramp.

Stopping stimulation

Use the P key or modulation keys to stop stimulation at any time. Stimulation stops automatically at the end of a programme.

Locking the programmme



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

Locking the intensity

Choose the programme desired for the patient using the key (please refer to section entitled "Description of the programmes"). The EMP 2 PRO will be locked automatically after 10 sec. without increasing or decreasing the intensity. On the display in the right corner the "P" symbol will be showed. To unlock the EMP 2 PRO you have to decrease the intensity.

Activating the editing mode



Please switch on the device while pressing the key. An "E" on the right-hand side of the display indicates the editing mode. Then use the key to select the standard or user programme (Fig. 6) that you wish to edit.

The 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".

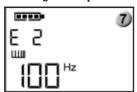
Editing standard or user programmes

The parameters of each programme are used as the starting value. Press the 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.

Various parameters may be processed, depending on the type of programme. If not indicated otherwise, the frequency and the pulse width apply for both channels. 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.

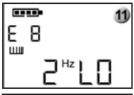
Programme parameters













Programme 1, 3, 4, 8, 9, 10, 11:

- 1. frequency: 20 Hz up to 120 Hz (Fig. 7)
- 2. pulse width: 70 µs up to 500 µs (Fig. 8)
- 3. total run time: 1 up to 99 min. (Fig. 12)

Programme 2, 5 (TENS):

channel 1 gate control + channel 2 endorphine release

- 1. frequency channel 1: 80 Hz. 90 Hz. 100 Hz. 110 Hz. 120 Hz (Fig. 9)
- 2. frequency channel 2: 0,5 Hz, 1 Hz, 2 Hz, 5 Hz, 10 Hz
- 3. pulse width: 60 µs up to 500 µs (Fig. 8)
- 4. total run time: 2 up to 99 min. (Fig. 12)

Programme 6:

1. total run time: 1 up to 99 min. (Fig. 12)

Programme 7:

Epicondylites modulation

- 1. max. frequency: 1 Hz up to 120 Hz (Fig. 10)
- 2. min. frequency: 0,5 Hz up to max. frequency -8 (Fig. 11)
- 3. pulse width: calculated according to the frequency
- 4. total run time: 1 up to 99 min. (Fig. 12)

Programme 12, 13, 14, 15, 16, 18, 19:

muscle stimulation

- 1. frequency: 20 Hz up to 120 Hz (Fig. 7)
- 2. pulse width: 70 µs up to 500 µs (Fig. 8)
- 3. Ramp up: 1 to 30 s
- 4. Ramp down: 1 to 30 s
- 5. Work time: 1 to 30 s
- 6. Total run time: 1 up to 99 min. (Fig. 12)

Programme 21:

muscle stimulation

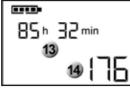
- 1. frequency: 20 Hz up to 120 Hz (Fig. 7)
- 2. pulse width: 60 µs up to 500 µs (Fig. 8)
- 3. Ramp up: 0,5 to 4 s
- 4. Ramp down: 0,5 to 2 s
- 5. Work time: 1 to 25 s
- 6. Total run time: 1 up to 99 min. (Fig. 12)

To save the new programme, press the key once more after processing the last parameter. An "U" symbol now appears before the programme number on the display.

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 reported by the EMP 2 PRO: The stimulation time (Fig. 13) is the total time during which stimulation was carried out with the device. The cycles (Fig. 14) mark how often the device was switched on and concomitantly used for stimulation. The mean stimulation intensity (Fig. 15) 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 very entire the left and the 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 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 key on the left and the key pressed down when switching on the device. Please be aware that all user programmes are also deleted.

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.

Description of the programmes

Programme 1 Lumbalgie gate control

Type of stimulation: Gate Control 80 Hz and dynamic stimulation

Parameters: Frequency channel 1 and 2 = 80 Hz

Pulse width = 150 μs Treatment time = 20 min

Symbol showing on display during stimulation:

Ramp up:
Ramp down:

Description: Both channels are continuously operated with the same frequency and pulse width.



Programme 2 Lombo-sciatalgie

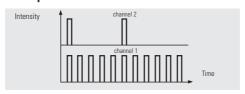
Type of stimulation: Gate Control 80 Hz (channel 1)

+ 2 Hz endorphin release (channel 2)

Parameters: Frequency channel 1 = 80 Hz

Frequency channel 2 = 2 Hz Pulse width = 200 μ s Treatment time = 20 min

Symbol showing on display during stimulation: Description:



Programme 3 Cervicobrachial nevralgia

Type of stimulation: Gate control 80 Hz stimulation fast dynamic movement

Parameters: Frequency = 80 Hz

Pulse width = 150 μ s Treatment time = 20 min Ramp up = 0,2 s

Ramp down = 0.2 s

Symbole showing on display during stimulation:

Ramp up:

Ramp down:

Description: Basically, the device works like in the muscle mode but without working and break times. During the build-up phase intensity is increased up to the set value. The run-down phase is following immediately, decreasing intensity back to zero. The channels of the EMP 2 PRO work alternately, i. e. when channel 1 has reached its maximum intensity; the intensity of channel 2 is zero and vice versa. There is a convenient massage effect owing to the dynamic stimulation when placing the electrodes next to each other on the painful area.



Programme 4 Chronic pain

Type of stimulation: Endorphin release Burst 2 Hz

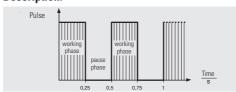
Parameters: Frequency = 80 Hz

Pulse width = 100 µs
Treatment time = 30 min
Work time = 0,25 s
Pause = 0,25 s

Symbol showing on display during stimulation:

Working time: Pause: —

Description:



Programme 5 Gate control + endorphin release

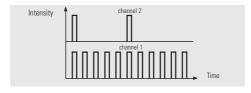
Parameters: Frequency channel 1 = 100 Hz

Frequency channel 2 = 2 HzPulse width = 200 μ s

Treatment time = 20 min

Symbol showing on display during stimulation:

Description: Channel 1 works continuously at a high frequency between 80 and 120 Hz, whereas channel 2 operates at a low frequency between 0,5 and 10 Hz.



Programme 6 Gonarthrosis-Coxarthrosis

Type of stimulation: HAN

Parameters Phase 1: Frequency = 100 Hz

Pulse width = 100 µs

Work time = 3 s

Parameters Phase 2: Frequency = 2 Hz

Pulse width = 200 us

Work time = 3 s

Treatment time = 20 min

Symbol showing on display during stimulation:

Phase 1: Phase 2:

Description: The device stimulates 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) alternately. The duration of the phases is 3 s each.



Programme 7 Epicondylites

Type of stimulation: Modulation

Parameters: Frequency minimal = 2 Hz => Pulse width = 200 µs

Frequency maximal = 80 Hz => Pulse width = 100 µs

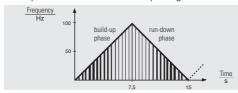
Treatment time during modulation = 7.5 s

Treatment time total = 30 min

Symbol showing on display during stimulation:

Ramp up: Ramp down:

Description: In the build-up phase, frequency is increased within a few seconds in individual steps, starting from minimum and reaching maximum frequency, the pulse width being adapted accordingly. This is followed by a rundown phase in which the intensity is regulated back down to the minimum.



Programme 8 Algodystrophy

Type of stimulation: Modulation

Parameters: Frequency minimum = 2 Hz => Pulse width = 148 μ s

Frequency maximum = 80 Hz => Pulse width = 70 µs

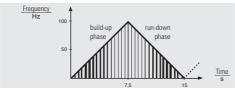
Treatment time during modulation = 7,5 s

Treatment time total = 20 min

Symbol showing on display during stimulation:

Ramp up: A Ramp down:

Description: In the build-up phase, frequency is increased within a few seconds in individual steps, starting from minimum and reaching maximum frequency, the pulse width being adapted accordingly. This is followed by a rundown phase in which the intensity is regulated back down to the minimum.



Programme 9 Gate control dynamic anti-adaptation

Type of stimulation: Gate control 80 Hz stimulation dynamic

Parameters: Frequency = 80 Hz

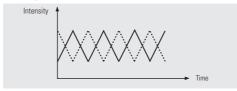
Pulse width = 150 μs Treatment time = 20 min

Ramp up = 0.5 sRamp down = 0.5 s

Symbol showing on display during stimulation:

Ramp up: Ramp down:

Description:



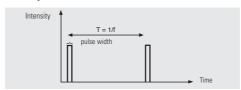
Programme 10 Gate control classic 80 Hz

Parameters: Frequency = 80 Hz

Pulse width = 150 μ s Treatment time = 20 min

Symbol showing on display during stimulation:

Description:



Programme 11 Treatment of contractures

Parameters: Frequency = 1 Hz

Pulse width = $150 \mu s$ Treatment time = 20 min

Symbol showing on display during stimulation: See programme 10

Muscle stimulation programmes (P12-P16 and P18-P19)

Ramp up:

Ramp down:

Pause:

Programme 12

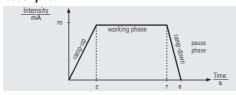
Type of stimulation: Atrophy upper extremities
Type of stimulation: Muscle strengthening
Parameters: Frequency = 35 Hz

Pulse width = 150 μs Ramp up = 2 s

Working period = 3 s

Pause = 9 s

Description:



Programme 13 Atrophy upper lower extremities

Type of stimulation: Muscle strengthening

Parameters: Frequency = 35 Hz

Pulse width = $300 \mu s$ Ramp up = 2 s

Working period = 3 s

Pause = 9 s

Programme 14 Muscle strengthening upper extremities

Type of stimulation: Muscle strengthening

Parameters: Frequency = 65 Hz

Pulse width = 250 µs Ramp up = 2 s Working period = 4 s

Pause = 8 s

Programme 15 Muscle strengthening lower extremities

Type of stimulation: Muscle strengthening

Parameters: Frequency = 65 Hz

Pulse width = 300 µs Ramp up = 2 s Working period = 4 s

Pause = 8 s

Programme 16 Venous reflux

Parameters: Frequency = 35 Hz

Pulse width = 250 µs Ramp up = 3 s Working period = 5 s Pause = 10 s

Programme 17 URO vesical instability

Parameters: Frequency = 10 Hz

Pulse width = $180 \mu s$ Treatment time = 20 min

Description: See Programme 10

Programme 18 URO incontinence mixed

Parameters: Frequency = 20 Hz

Pulse width = $180 \mu s$ Ramp up = 2 sWorking period = 4 s

Pause = 4 s

Programme 19 URO incontinence urge

Parameters: Frequency = 50 Hz

Pulse width = $180 \mu s$ Ramp up = 2 sWorking period = 3 s

Pause = 6 s

Programme 20 Relaxation and stimulation dynamic

Type of stimulation: Stimulation dynamic **Parameters:** Frequency = 120 Hz

Pulse width = 150 μs
Treatment time = 20 min

Ramp up = 2 sRamp down = 2 s

Symbol showing on display during stimulation:

Ramp up:

Ramp down:

Description:



Programme 21 Agonist/Antagonist

Type of stimulation: Stimulation dynamic - channnel 1, channel 2

Parameters: Frequency = 40 Hz

Pulse width = $300 \mu s$ Treatment time = 20 min

Ramp up = 2 sRamp down = 1 sWorking period = 3 s

Pause = 6 s

Description: First increase intensity channel 1 when the contraction is there you can increase channel 2 and when there is a contraction the treatment will start. When you want to increase channel 1 during stimulation channel 2 the intensity of channel 2 will go to zero and you can increase channel 1.

General information

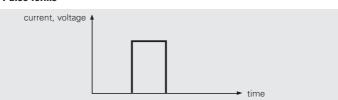
Specifications

Dual-channel nerve stimulator with electrically insulated channels, constant current characteristic, output short circuit control element (AKS) and 20 changeable integrated programmes.

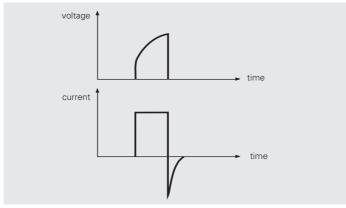
Output current	100 mA (with 1 k Ω real)
Frequencies	0,5-120 Hz
Pulse width	70-500 μs
Current consumption	12 mA
Current supply	3 x 1,5 V compound battery
Dimensions approx.	132 mm x 83 mm x 39 mm
Weight approx.	190 g (without accessories)

Pulse forms

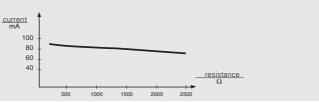
$\begin{array}{c} \text{Pulse form:} \\ \text{with 1k} \Omega \text{ load real} \end{array}$



With ANSI/AAMI standard load



Change in output current depending on load



Changing the battery

The voltage of the batteries in the device is displayed during operation by the segments within the battery symbol. If the voltage falls below a critical value, the EMP 2 PRO switches itself off automatically and cannot be switched back on again. You then need to insert new batteries into the device.

- Switch off the device
- Take off the lid of the battery compartment
- Remove the used batteries from the compartment
- Insert new batteries into the compartment

PLEASE DISPOSE OF USED BATTERIES CORRECTLY.

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

Readjustments, alterations and repairs

The manufacturer is only responsible for the safety and performance of the EMP 2 PRO device when readjustments, alterations and repairs are carried out by authorised individuals and when the EMP 2 PRO is used in accordance with the user instructions

Circuits 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 EMP 2 PRO 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 EMP 2 PRO. Clean the EMP 2 PRO with a soft, lint-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.

Classification

In accordance with the Law on Medical Devices, the EMP 2 PRO device is classified as being a Class Ila medical device. Technical checks on the device should be performed every 24 months.

Technical checks

These include:

- Checking to see whether the user instructions are included in the accompanying documentation.
- 2. Checking the equipment for completeness.
- Visual check:
 - a. for mechanical damage
 - b. for damage to all cables and connections
- 4. Functional safety
 - a. Checking the output signals with a load resistance of 1 k Ω real (current and voltage)
 - b. Checking the frequency
 - c. 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.

Combination

The EMP 2 PRO may be used together with all accessories mentioned in the chapter "Accessories".

Accessories

Rubber electrodes

Technical Data

Compound:	silicone-carbon
Durability:	approx. 12 months
Colour:	black
Manufacturer:	Pierenkemper GmbH, Germany

Application

Spread 2-3 drops of schwa-medico electrode gel evenly over the flat side of the electrode. The electrode gel improves the conductivity of the electrode. Place the electrodes on the relevant skin areas and secure the electrodes with a tape strip. Do not apply to broken skin!

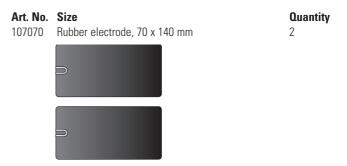
Because conductivity of the electrodes slowly decreases after approx. 6 months of use, replace electrodes after approx. 12 months of intensive use.

Cleaning

Clean electrode surface with water and soap or appropriate disinfectant (e. g. alcohol 90 %) after every use.

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Art. No. 107090	Size Rubber electrode, round 20 mm Ø	Quantity 2
107060	Rubber electrode, round 25 mm Ø	2
107075	Rubber electrode, 40 x 28 mm	2
107035	Rubber electrode, 56 x 28 mm	2
107020	Rubber electrode, 75 x 30 mm	2
107055	Rubber electrode, 90 x 35 mm	2
107011	Rubber electrode, 38 x 45 mm	2
107010	Rubber electrode, 48 x 48 mm	2
107050	Rubber electrode, 70 x 65 mm	2



Self-adhering electrodes

Technical Data

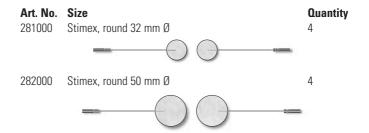
Compound:	conductive and bonding material
Durability:	80-150 treatments
Colour:	grey
Manufacturer:	Pierenkemper GmbH, Germany

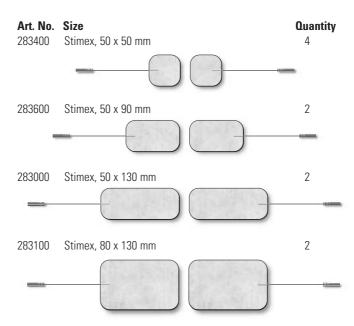
Application

Place self-adhering electrodes directly on appropriate skin treatment area, no special preparation of electrode is necessary. See "Electrode maintenance" below to insure electrode's effectiveness. Do not apply to broken skin!

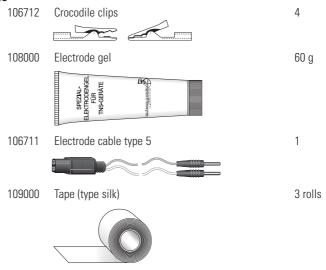
Electrode maintenance

For hygienically 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 electrode's adhesive surface and air dry a couple of spronds before placing on treatment area.





Accessories



Electrode position

Electrodes position programmes pain therapy P2-P4-P5-P6-P7-P8-P10

P2 Lumbago (channel 1 and position Para vertebrae and the lumbar side, channel 2 direct of the ischiadicus nerve)

P4 Chronic pain burst endorphin release

P5 Gate control (channel 1 at 100 Hz) + endorphin release (channel 2 at 2 Hz)

P6 Gonarthrosis-Cxarthrosis

P7 Epicondylitis

P8 Algodystrophie

P10 Gate control classic





Deltoideus





Shoulder



Trapezoid



Knee



Electrode placement for dynamic stimulation for pain therapy and relaxation Electrode placement for relaxation P1, P3, P9 and P20

How the electrodes should be positioned for the programmes

P1 Lumbago

P3 Cervical brachial nevralgia

P9 Massage pain

P20 Muscle relaxation

Latissimus



Trapezoid



Quadriceps



Para vertebea



Leg flexor



Calf



Electrode placement for muscle stimulation and re-education programmes P11-P16

How the electrodes should be positioned for the programmes re-education

P11 Treatment of contractures

P12 Atrophy upper extremities

P13 Atrophy lower extremities

P14 Muscle training upper extremities

P15 Muscle training lower extremities

P16 Dynamic venous reflux





Triceps



Hand exstensor



Back



Biceps



Quadriceps



Leg flexor (hamstrings)



Foot flexor



m. Tibialis



Calf (Gastrochnemius)



schwa-medico Operating Instruction - EMP 2 PRO

Informations:

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