



PierenStim Parese  
DEVICE FOR ELECTROSTIMULATION

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## Purpose of use

The PierenStim Parese serves for the stimulation current therapy of atonic paresis on persons under the instruction of a qualified therapist. Electrical impulses are delivered via the skin (transcutaneous) by means of electrodes. This causes muscle fibre stimulation. The PierenStim Parese transcutaneous muscle stimulator is a sophisticated device which is manufactured under stringent quality control conditions. The following safety precautions have to be observed at all times.

## Using the device safely

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

- » The device is only to be used with original accessories.
- » Keep the PierenStim Parese well away from water or other liquids.
- » Never use the PierenStim Parese if it is damaged or not working properly.
- » The PierenStim Parese should not be operated at the same time as other high frequency devices (for example mobile telephones) owing to the possible interaction of the electro-magnetic fields of such devices with the PierenStim Parese. This can lead to an increased current flow.
- » The simultaneous connection of the patient to a high frequency surgical device can cause burns under the electrodes.
- » A minimum surface area of the electrodes of 2 cm<sup>2</sup> must be observed.
- » Use only the enclosed sponge electrodes and do not exceed the total number of 60 applications.
- » The device must not be used when operating machines or during activities which require increased attention levels. This particularly applies when driving.
- » Do not let the PierenStim Parese fall down or handle improperly or expose to extreme temperatures or high humidity levels (use only at temperatures between 10 °C and 40 °C and a relative humidity level below 90 %).
- » Special care should be observed when using on or in the vicinity of children.

- » Store the device in its original packaging and protect against damage and contamination.

## Contra-Indications

When should the PierenStim Parese not be used or only after consultation with the physician ?

- » Users with metallic or electronic implants, for example heart pacemakers or pumps.
- » Users with cardiac rhythm irregularities.
- » Users during pregnancy.
- » Users susceptible to paralytic fits.
- » Users with skin disorders in the area of electrode application.
- » Users with malignant diseases in the area of application.

## Possible Side-Effects

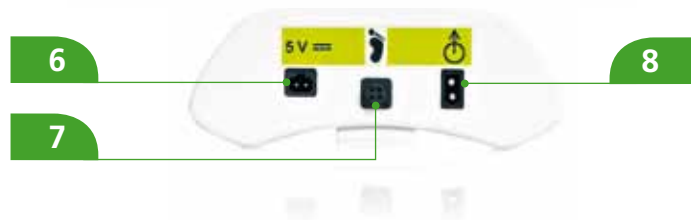
- » Skin reactions: These can be the result of incompatibility with the electrode materials or as a reaction to the electrical impulse. A slight, but not ongoing reddening of the skin in the vicinity of the electrode is normal following a treatment session. Treatment must be discontinued if there is a more long-lasting skin problem such as persistent reddening, blisters, wounds, burning, itching or similar occurrences; In such cases a physician should be consulted.
- » The electrodes may only be attached to undamaged skin.
- » Muscular pain: Muscular strain can occur if the muscle stimulation is too intensive or protracted.

## Description of the device

- 1 Display
- 2 Program key
- 3 Editing key / pause key
- 4 Modification key (+, -)
- 5 ON/OFF key



- 6 Power pack socket
- 7 No function
- 8 Output socket



## Description of the illustrations



Attention: Read accompanying documents, especially user manual!



By labelling with CE certificate, the manufacturer states that the product meets all requirements of the respective EU Directive.

A conformation evaluation process has been successfully completed. The code number of the conformation evaluation process is given in accordance with the CE labelling of the involved notified body.



BF type application part. Protection against electric shock.



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



The serial number of the product follows this symbol.



The year of construction of the product follows this symbol.

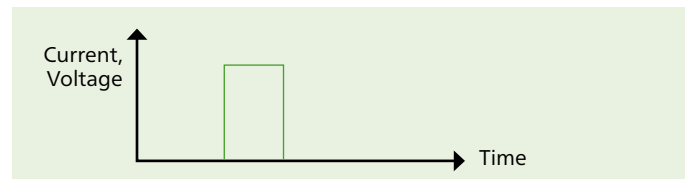


This equipment is marked with the recycling symbol of the EU-Directive 2002/96/EG. It means that at the end of the life of the equipment you must dispose of it separately at an appropriate collection point and not place it in the normal domestic unsorted waste system. This will benefit the environment for all.

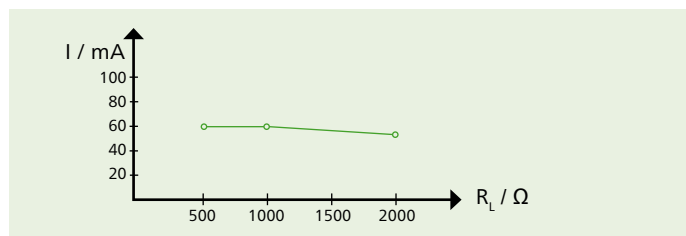
## Technical data

1 channel muscle stimulator with constant current characteristic and 8 integrated programs.

*At load of 1 kΩ real*



*Alteration to the output current  
Dependent on the load resistance*



Output current at a load of 1 k $\Omega$  real

60 mA, stepless regulation

Impulse width

10 ms to 2 sec.

Impulse form

Time shifted direct current impulse alternating polarity  
or monophasic impulse

Current take-up

approx. 60 mA (without load)

Voltage supply

4 x 1.5 V batteries (Alkaline LR6 AA)  
or mains circuit adapter 5 V / 2400 mA

Dimensions

L x B x H 15.0 x 10.0 x 5.5 cm

Weight

approx. 380 g



## Operating the PierenStim Parese

### Switching on the device

The PierenStim Parese is ideally operated using the main circuit adapter (SNT 5-2400). Connect the included adapter SNT 5-2400 to the socket (no. 6) on the PierenStim Parese and the plug on the mains adapter into the mains power socket. If mains power operation is not possible, insert the included batteries into the device (please refer to the section "Replacing The Batteries"). Switch on the PierenStim Parese with the **ON** key. The device starts first with P1, then with the program number which was operational when the device was last switched off.

### Program selection

Press the **P** key to change to the next program. Once the last program (P8) is attained, the device jumps again to program 1 (P1). If the editing function is in use (free parameters settings for user programs U1 to U6), they appear after program 8 (P8).

### Program description

The PierenStim Parese provides 8 integrated programs.

#### Program 1

Rectangular impulse with alternating polarity

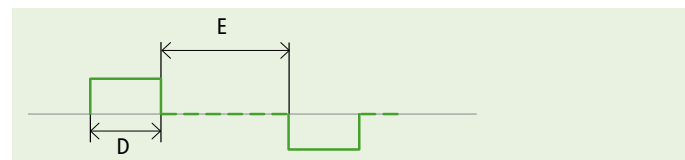
D...Pulse width 50 ms

E...Pause 500 ms ( $E = 10 \times D$ )

Therapy session time 15 min

Usage: Treatment for non-serious paralysis

Alternative: Program 4



### Program 2

Trapezoidal impulse with alternating polarity

D... Pulse width 150 ms

A... Rising ramp ( $A = 1/4 \times D$ )

B... Working time ( $B = 2/4 \times D$ )

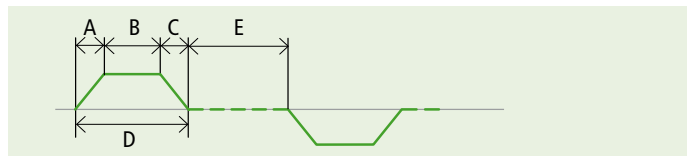
C... Decreasing ramp ( $C = 1/4 \times D$ )

E... Pause 1.5 s ( $E = 10 \times D$ )

Therapy session time 15 min

Usage: Treatment for more serious paralysis

Alternative: Program 5



### Program 3

Triangular impulse with alternating polarity

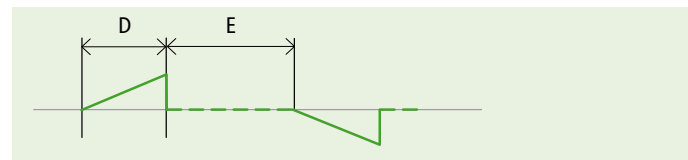
D... Pulse width 300 ms

E... Pause 3.0 s ( $E = 10 \times D$ )

Therapy session time 15 min

Usage: Treatment for severe paralysis

Alternative: Program 6



### Program 4

Rectangular impulse with alternating polarity

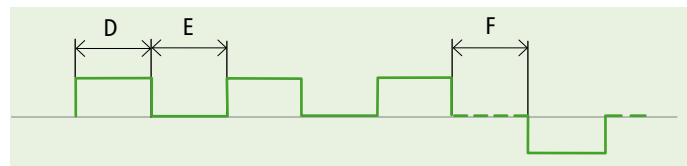
D... Pulse width 50 ms

E... Pause 500 ms ( $E = 10 \times D$ )

F... Impulse group pause 1.5 s ( $F = 3 \times E$ )

Therapy session time 15 min

Usage: Treatment for slight paralysis, alternative to P1



### Program 5

Trapezoidal impulse group with alternating polarity

D... Pulse width 150 ms

A... Rising ramp ( $A = 1/4 \times D$ )

B...Working time ( $B = 2/4 \times D$ )

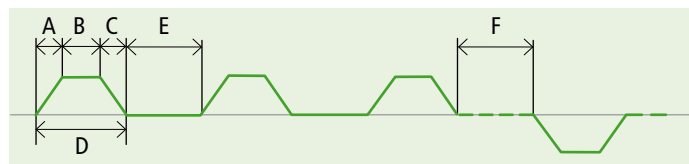
C...Decreasing ramp ( $C = 1/4 \times D$ )

E...Pause 1.5 s ( $E = 10 \times D$ )

F... Impulse group pause 4.5 s ( $F = 3 \times E$ )

Therapy session time 15 min

Usage: Treatment for more serious paralysis, alternative to P2



### Program 6

Triangular impulse group with alternating polarity

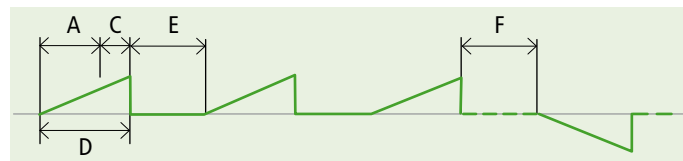
D...Pulse width 300 ms

E...Pause 3.0 s ( $E = 10 \times D$ )

F... Impulse group pause 9.0 s ( $F = 3 \times E$ )

Therapy session time 15 min

Usage: Treatment for severe paralysis, alternative to P3



### Program 7

Diagnosis program (I/t curve: intensity/duration curve) with rectangular impulse of positive polarity

Sequence	Pulse width [ms]	Pause [ms]
1	1000	1000
2	500	1000
3	300	1000
4	200	1000
5	100	1000
6	50	1000
7	30	1000
8	10	1000

### Program 8

Diagnosis program (I/t curve: intensity/duration curve) with triangular impulse of positive polarity

The value (pulse width and pause) for the 8 sequences are identical to the values from program 7.


Please refer to the relevant specialist literature for the generation and evaluation of the I/t curve.

The accompanying I/t curve forms can be used for the documentation of the ascertained measurement values. Because pulse widths of less than 10 ms cannot be measured with the PierenStim Parese, there is here a modified I/t curve which does not necessarily correspond with parameters ascertained on large scale devices.





### Electrode placement

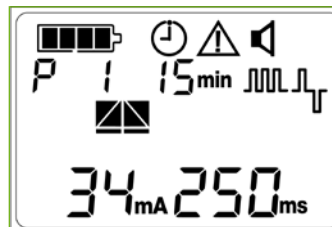
Moisten the sponge electrodes with water. Place the electrodes on the required body locations with the belt strap. Connect the device and the electrodes with the electrode cable.

### Starting the stimulation

The stimulation can now be started with the left-hand  key. The device now changes to the therapy mode.

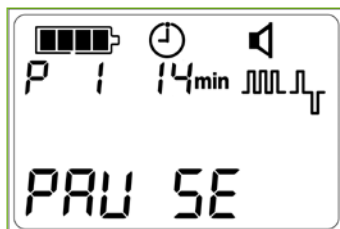
### Setting the intensity

The left-hand  and  keys are used to adjust the intensity to a specific value. As soon as muscular tension occurs then the intensity is adequate. The current level is shown in the lower left-hand display. This level can be varied in the range between 0 and 60 mA in steps of 1 mA. If the  and  keys remain permanently depressed, the intensity is automatically adjusted upwards or downwards. In the interests of safety the automatic intensity adjustment is interrupted every 10 mA.



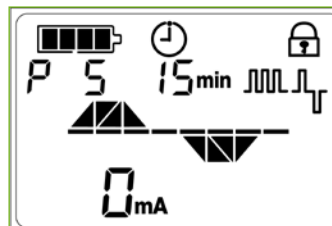
### Stimulation pause

The stimulation can be put on hold at any time with the **E** key. The text "Pause" appears in the display. If the pause key is again depressed the last set intensity starts again.















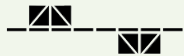

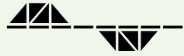

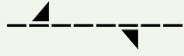








### Program locking

Simultaneously press the left-hand **-** key and the **P** key to lock the keypad. A lock is displayed in the upper right-hand corner of the display. Now, no other program can be selected via the **P** key. It is no longer possible to start the device in the editing mode or to check the therapy session time memory.



The purpose of this lock is to prevent the unintentional alteration to the selected settings for the therapy session. Please use the same key combination to disable the lock.




### Symbols in the display

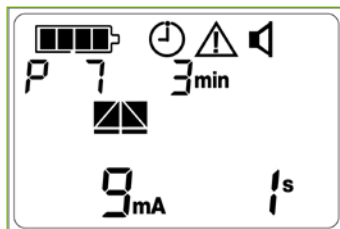
	Selected standard program		Battery charge level empty
	Selected user program		Warning stimulation is active
	Therapy session timer is active		Signal transmitter active, each impulse accompanied by an acoustic signal
	Therapy session timer is not active		Pulse width (P1-P6)
	Positive and negative impulses (P1-P6)		Set intensity
	Impulse group from 3 impulses of the same polarity (P4-P6)		Positive triangular impulse (P3, P6, P8)
	Impulse form trapezoidal positive and negative (P2, P5)		Negative triangular impulse (P3, P6)
	Impulse form trapezoidal positive and negative (P2, P5)		Positive trapezoidal impulse (P2, P5)
	Impulse form triangular positive and negative (P3, P6)		Negative trapezoidal impulse (P2, P5)
	Impulse form positive rectangular (P7)		Positive rectangular impulse (P1, P4, P7)
	Impulse form positive triangular (P8)		Negative rectangular impulse (P1, P4)
	Battery charge level full		Pause between impulses (P1-P8)
			Long pause between impulse groups (P4-P6)




### The Diagnosis programs P7 and P8

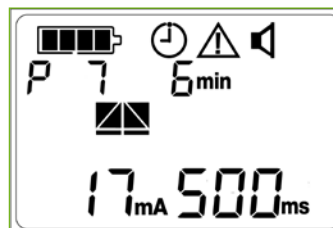
Programs P7 and P8 are provided for the setting of an Intensity/Duration curve also known as I/t curve (I = Intensity and t = Duration/Pulse width).

The values are ascertained as follows:

- » Attach the electrode to the patient.
- » Connect the device and electrode with the electrode cable.
- » Switch on the stimulator with the  key.
- » Select program 7 or 8 with the  key.
- » The stimulation starts with the pulse width of 1000 ms. The active pulse width in milliseconds (ms) is always shown in the lower right-hand corner of the display. Slowly increase the intensity with the left-hand  key until an active muscle movement is perceived. Enter the ascertained value for the current (I: intensity) and the actual pulse width (t: duration) in an I/t diagram (please refer to the enclosed forms).



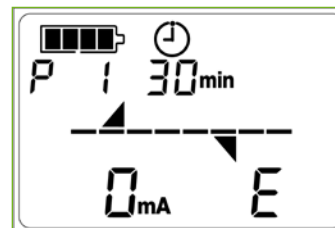
- » Change to the next pulse width with the right-hand  key (4). The intensity is reset to zero. The previous pulse width can also be re-selected with the left-hand  key.
- » The intensity can again be slowly increased with the left-hand  key (4) until an active muscle movement is perceptible. Enter the ascertained value for the current (I: intensity) and pulse width (t: duration) in an I/t diagram.



- » The value of the I/t curve ends at a pulse width of 10 ms or at the pulse width at which no muscle movement is detectable. In total, 8 different pulse widths are available.

### Switching off the device

Press the **⏻** key to switch off the device. If the battery level has fallen below a critical value or outside the stimulation no button has been depressed for a period of two minutes, the device switches off automatically. An acoustic signal is then transmitted.



### Program editing

The parameters for programs 1-6 can be changed. Use the editing mode for this purpose. The new User Programs are named U1 to U6.

Select the program to be changed with the **P** key. Then press the **E** key to start changing the parameters. Press the **P** key at any time to interrupt the editing procedure. No program is then changed.

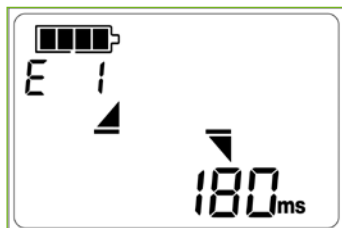
### Starting the editing mode

Press the **E** key and the **⏻** key simultaneously to enter the editing mode. This is only possible if the device is not locked (refer to chapter "program locking"). The active editing function is shown on the down, right corner of the display with an E symbol.

### Editing the impulse width

The first parameter to be edited is the pulse width. Choose a value between 10 ms and 2 s. Change the pulse width in steps of 100 ms with the left-hand **+** and **-** keys. Change the pulse width in steps of 10 ms with the right-hand **+** and **-** keys.

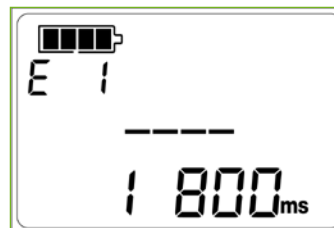




Press the **E** key to save the pulse width and to jump to the next parameter. Press the **P** key to interrupt the editing mode.

### Editing the impulse pause

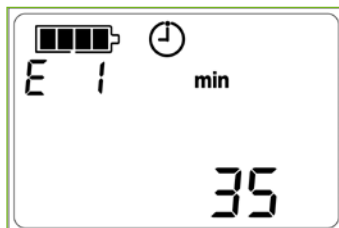
The second parameter to be edited is the pause time. It is automatically set at ten times of the pulse width. Choose a value between 100 ms and 20 ms. Change the pause time in steps of 1 s with the left-hand **+** and **-** keys. Change the pause time in steps of 100 ms with the right-hand **+** and **-** keys.



Press the **E** key to save the pause time and to jump to the next parameter. Press the **P** key to interrupt the editing mode.

### Editing the therapy session time

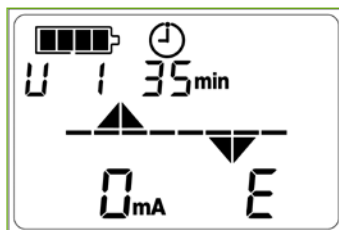
The last parameter to be edited is therapy session time. Choose a value between 1 min and 99 min. It can also be set OFF. The device is not turning OFF at any time. Change the therapy duration time with any **+** and **-** keys.



Press the **P** key to interrupt the editing mode.

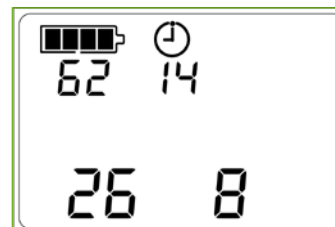
Press the **E** key to save the edited program and return to the therapy mode.

The number of the user program corresponds with the number of the program with which the editing procedure was started. If a user program is re-edited, the old settings are overwritten.



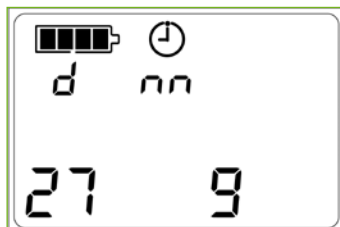
### Therapy session time memory management and time setting

The PierenStim Parese contains a real time clock. In addition there is information saved on up to 99 therapy sessions which have been carried out. Up to 3 therapy sessions can be saved each day. The therapy session time must be of at least one minute duration in order to be saved. Simultaneously press the left-hand **-** key and the **E** key to enter the memory mode. Up left in the display is the number of the saved therapy sessions (62). Up, in the middle, appears the actual time of the internal clock (14: 2 PM). The day and the month are displayed on the lower line (26, 8: 26th of August).



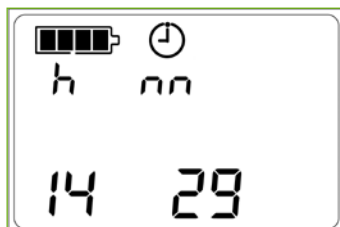
### Setting the day and the month

Press the **E** key to change the day and month. Press the left-hand **+** and **-** key to change the day. Press the right-hand **+** and **-** key to change the month. Press the **E** key to save the changes and jump to the setting of the time.



### Setting the hour and the minutes

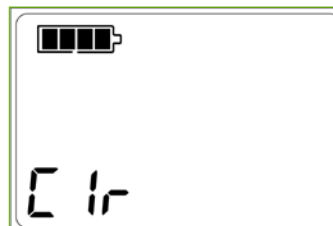
Press the left-hand **+** and **-** key to change the hours. Press the right-hand **+** and **-** key to change the minutes.



Press the **E** key to save the changes. If the device contains no saved therapy session information you will return directly to the program selection mode.

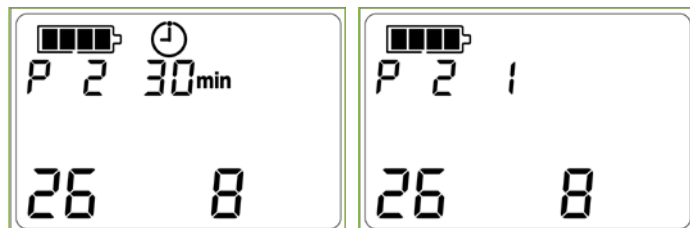
### Deleting the therapy session time memory

If information regarding therapy sessions has been saved, the information text "Clr" is displayed down in the display. If you press the **E** key all therapy session information will be deleted. Should the therapy session information not be deleted then press the **P** key. In both cases you now return to the program selection mode.



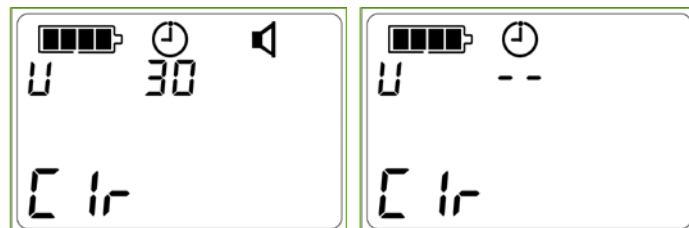
### Reading the therapy session time memory

In the overview menu press the **P** key to read information on the individually saved therapy sessions. The program number and the actual therapy session time are displayed in the upper line. The day and the month of the therapy session appear in the lower line. You can scroll between the different therapy sessions by pressing the **+** and **-** keys. Please note that a maximum of three therapy sessions can be saved in any one day. Press the **P** key to return to the program selection mode.



### Deleting basic settings and user programs

Switch off the device. Simultaneously press the P key and the left-hand **-** key and turn the device on with the **ON** key. The menu for changing the basic settings will be opened.



### Deleting user programs

As long as the device contains user programs, the display will show a U and a Clr. Press the left-hand **-** key to delete the user program. The deletion procedure will be confirmed with an acoustic signal and the text deleted.

### Switching the signal transmitter ON and OFF

If you are irritated by the acoustic warning signal at every impulse during the stimulation, this function can be de-activated. If the loudspeaker symbol is displayed this means that the signal transmitter is active. To de-activate the acoustic signal press the **E** key. The loudspeaker symbol will disappear. To re-activate the signal transmitter, press the **E** key again.

### Switching the therapy session timer ON and OFF

Normally, each therapy session is automatically terminated by the device once the therapy session time has elapsed. If the therapy session timer is active, a 30 is displayed beneath the timer symbol. This function can be switched off by pressing the right-hand **-** key. Instead of the 30, two slashes are displayed. The timer function can be switched on again by pressing the right-hand **-** key again.

### Operations with the mains circuit adapter

The PierenStim Parese can be operated with the mains circuit adapter SNT 5-2400 as follows:

- » Take account of the operating instructions of the mains adapter.
- » Plug the mains adapter into the mains socket.
- » Plug the end of the cable into socket no. 6.
- » Further information can be found in chapter „Switching On The Device“ of the operating instructions.

### Replacing the batteries

The battery level is shown during operations by the battery symbol. If the voltage falls below a critical value, the PierenStim Parese switches off automatically or can no longer be switched on. It is then necessary to insert new batteries in the device (4 x 1.5 V alkaline batteries, for example Type LR6 AA).

- » Switch off the device.
  - » Open the battery compartment cover.
  - » Remove the empty batteries from the compartment.
  - » Insert 4 new batteries into the battery compartment.
- Take care to observe the polarities.

» Close the battery compartment with the cover.

If the device is not to be used for longer periods, please remove the batteries. Used batteries must be disposed of in accordance with local regulations.

## Classification according to MPG

The PierenStim Parese has been classified as Class IIa in accordance with Appendix IX of the EC Guideline 93/42/EEC for medical devices.

## Technical controls

With commercial use in Germany, a technical control on the PierenStim Parese must be carried out every 24 months.

The technical control comprises:

1. Checking the accompanying paperwork and the presence of the operating instruction manual.
2. Checking the equipment for completeness.
3. Sight check

» for mechanical damage.

» for any damage to all cables and plug connections.

### 4. Functional safety

» Checking the output signals at a load resistance of 1 k $\Omega$  (current and voltage).

» Checking the frequency.

» Checking the impulse width.

These technical controls are only to be carried out by suitably qualified technicians.

## New settings, modifications and repairs

The manufacturer of the PierenStim Parese regards himself as responsible for the safety and performance only as long as new settings, modifications and repairs are carried out by persons authorised by him and providing the PierenStim Parese is operated in accordance with the instructions in the operating manual.

## Circuit diagrams, spare parts listings and setting instructions

If requested, we are pleased to provide the user's suitably qualified technicians with circuit diagrams, spare parts listings and setting instructions.

## Warranty

Legal right of warranty is applied according to German Civil Code.

## Guarantee

The manufacturer issues a guarantee of 12 months from the date of purchase.

The guarantee does not apply in the following cases:

- » damage due to improper handling
- » defects the customer is aware of on the date of purchase

- » damage caused by the customer
- » for wearing parts and consumable supplies like, for instance, battery, cables and electrodes.

## Care and cleaning

### *PierenStim Parese*

No special care or cleaning agents are necessary for the PierenStim Parese. The PierenStim Parese and the cable should be cleaned with a soft, fluff-free cloth. Care should be taken that no moisture gets into the interior of the device. If, nevertheless, moisture has penetrated, the device must be subjected to a technical control before any re-use.

### *Sponge electrodes*

These electrodes have been designed for multi-use. Used under normal conditions, the electrodes can be used for up to 60 applications.

The rubber electrodes are enclosed in an adequately moistened spongy pouch and during treatment it must

be ensured that a sufficient moisture level is continuously maintained.

After each and every treatment session it is necessary to remove the rubber electrodes from their pouch and to rinse in clear water and then to allow to dry out.

If the electrodes are stored in a moist condition there will occur stains (mildew) on the electrodes and as such they may no longer be used.

### Delivery content

Article	Quantity	REF
PierenStim Parese device	1 piece	462117
Cable type 5.16	1 piece	106352
1.5 V Alkaline batteries (LR6 AA)	4 pieces	450780-0001
Sponge electrodes 50 x 70 mm	2 pieces	462042
Belt strap	2 pieces	462120
Mains circuit adapter SNT 5-2400	1 piece	462054
Case	1 piece	- / -
Operating instructions	1 piece	451600-0324
Form for the I/t curve	1 piece	451720-0013





