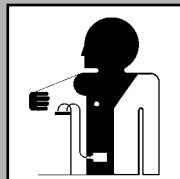


Operating Instructions

CE 0197

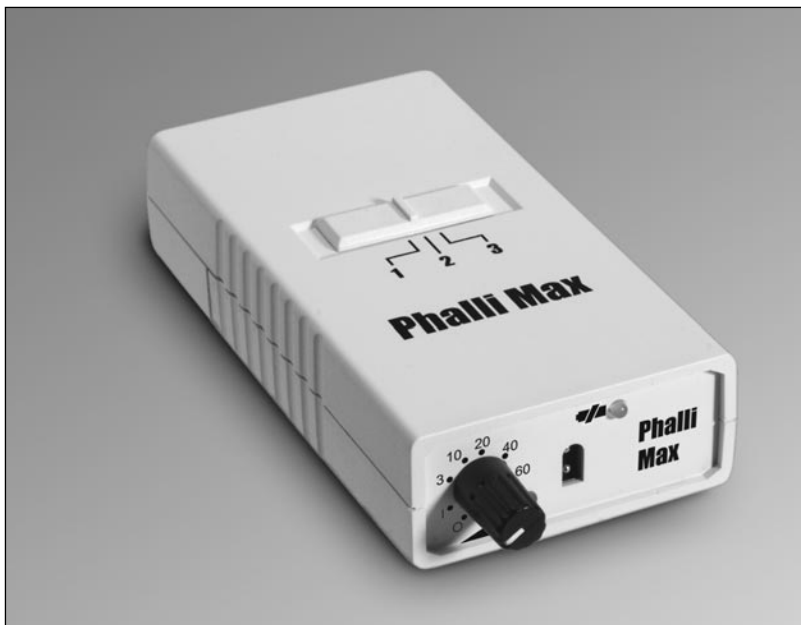
451600-0168

Version 0



Phalli Max

Transcutaneous nerve stimulator



Art. No. 104109

schwa·medico

MEDICAL EQUIPMENT & SUPPLIES



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The Phalli Max device was designed for transcutaneous muscle and nerve electrostimulation. Please do not use this device for any other purpose.

Please read these user instructions carefully before using the device.

To ensure safe use of the device

- Only use the Phalli Max with original accessories.
- Keep the Phalli Max away from water or other fluids.
- Do not drop the Phalli Max, 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 Phalli Max when it is not functioning properly or when it is damaged in any way.
- Store the Phalli Max 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 Phalli Max before consulting a doctor. The Phalli Max may only be connected to one patient at a time.

Warning

Connecting the patient at the same time to a high-frequency surgical unit may cause burns under the electrodes.

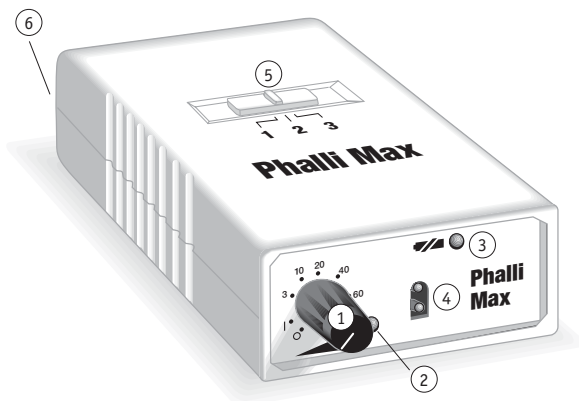
Operation near (e.g. 1 m) from a short-wave or microwave device may cause fluctuations in the baseline values of the electrotherapy device.

The minimum area of the electrodes should not be less than 2 cm².

Purpose

Important safety instructions

Device description



1. ON/OFF switch and intensity regulator
2. Pulse indicator lamp
3. Device-on indicator lamp
4. OUT hub
5. Function selector
6. Battery compartment

Explanation of the symbols



Caution: Please read the user instructions.



BF type application part



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

Specifications

Single-channel electrotherapy device with constant current characteristics and output short-circuiting switch

Output current with 1k Ω loading	70 mA, infinitely variable
Pulse shape	positive rectangular pulse with negative portion
Current consumption	approx. 12 mA (without load)
Current supply	9V compound battery
Dimensions	2.5 cm x 6 cm x 12 cm
Weight	approx. 200 g

Function type	P1	P2	P3
Frequency	30 Hz	10 Hz	55 Hz
Pulse width	90 μ s	150 μ s	250 μ s
Ramp	1s	1s	1s
Work	3s	2s	5s
Break	6s	4s	10s

Connect the battery before starting the device (please refer to section entitled “Changing the battery”). Then connect the electrodes to the device and position the electrodes.

To do this, connect the electrodes to the separate connections of the cables and then insert the cables with the double plug into the OUT hub (4).

Then use the intensity regulator (1) to switch on the device. After switching on the device, the device-on indicator lamp (3) lights up green. If the device-on indicator lamp (3) lights up red, the battery must be changed (please refer to the section entitled “Changing the battery”).

The function selector (5) is used to set the desired function type.

Turning the intensity regulator (1) in a clockwise direction increases the intensity. The device goes into the preliminary mode. In this mode, the desired intensity may be set without disturbing intensity modulation during the programmes. The pulse indicator lamp (2) starts to flash in relation to the frequency of the set programme. If the pulse indicator lamp (2) is not adjusted for 5 sec, the device starts with the set programme.

The Phalli Max device constantly monitors the settings and the electrode connections. If an operating error is detected, the pulse indicator lamp and the device-on indicator lamp flash alternately.

The following applies to all operating errors:
They may be corrected by turning down the intensity regulator.

The following operating errors are recognised by Phalli Max:

1. Increasing the intensity regulator too rapidly. The pulse indicator lamp and the device-on indicator lamp flash alternately at a fixed, low frequency. The pulse indicator lamp flashes at short intervals and the device-on indicator lamp at long intervals. The intensity is kept at the last correct value.

Correcting the error: Turn down the intensity regulator until the pulse indicator lamp resumes its normal function.

Starting the device

Setting the function type

Setting the intensity

Operating errors

2. Inserting a battery when the device is switched onIf a battery is inserted when the device is switched on (intensity regulator at a value greater than 0), an operating error is displayed as outlined in Point 1. However, no pulses are generated.

Correcting the error: Turn down the intensity regulator until the pulse indicator lamp goes out (do not switch off).

3. Electrode recognitionIf an electrode detaches itself during operation, pulse generation is switched off and an error is displayed. The pulse indicator lamp and the device-on indicator lamp flash alternately very rapidly.

Correcting the error: Check the electrodes and the cable. Then turn down the intensity regulator until the pulse indicator lamp goes out (do not switch off).

Changing the battery

SWITCH OFF THE DEVICE WHEN CHANGING THE BATTERY!!

If the device-on indicator lamp (3) is red, the battery must be changed. To do this, open the battery compartment on the underside of the device by pushing out the lid and remove the battery with the help of the band.

Check polarity when connecting the new battery. A protective circuit prevents the device from being destroyed if the battery is connected incorrectly.

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

Please dispose empty 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 Phalli Max device when readjustments, alterations and repairs are carried out by authorised individuals and when the Phalli Max is used in accordance with the user instructions.

Guarantee

We give a guarantee of 1 year from the date of purchase on the Phalli Max device. This guarantee does not cover cables and electrodes.

No special cleaning or care agents are required for the Phalli Max. Clean the Phalli Max 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.

In accordance with the Law on Medical Devices, the Phalli Max device is classified as being a Class IIa medical device.

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

These include:

1. Checking to see whether the user 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 Ω (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.

Phalli Max	1	item	Item No. 104 109
Type 5 cable	1	item	Item No. 106 711
50x50 self-adhesive electrodes	4	items	Item No. 283 400
15x75 self-adhesive electrodes	12	items	Item No. 281 001
Battery	1	item	Item No. 601 000
Packaging.	1	item	Item No. 105 510

Cleaning and care of the device

Classification

Technical checks

Contents of delivery



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