

QuickZap[®]

POWER

+ Swiss made



Instruction manual

Fritonex AG

Instruction manual

This instruction manual is considered an integral part of the device. It shall be kept within reach at all times. Exact compliance with these instructions is essential for the correct handling of the device as well as for the safety of patient and user.

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1. Illustration of the device

Handholds with cable to plug connection of the device

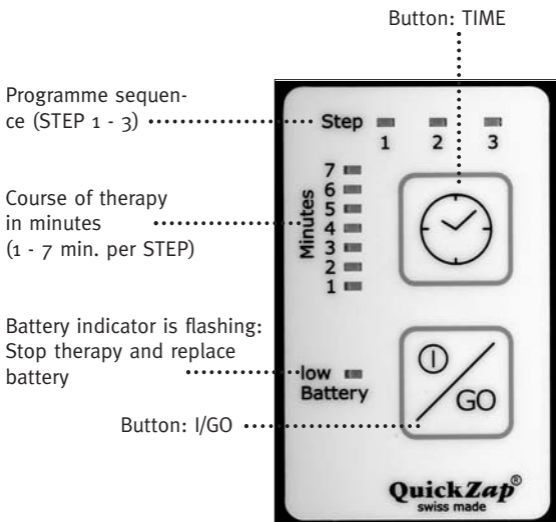
Plug connection for cable to handholds








Gold faces on either side of the device

Battery compartment
One 6LR61 9-volt alkaline battery

2. Control panel with functions



- 1.**  Turning on the device (push button briefly)
- 2.**  Select number of minutes (1 - 7 minutes)
 Anzeige 
- 3.**  Start therapy (push button briefly) (manual STEP selection)
- 4.**  Turning off the device (push button for an extended period of time or device will automatically turn off after 30 seconds)

3. Description of the device

Intended use

The Power QuickZap is intended for the electronic stimulation of nerves. It is used for self-treatment of symptoms and pain.

Its application does not replace treatment or instructions from a doctor, but has a positive influence on symptoms and pain.

Using the device can alleviate pain. Please refer to the instruction manual for detailed information on the «Handling».

Function designation

The transcutaneous electronic nerve stimulation device Power QuickZap is an easy to use, battery-operated electronic device designed to stimulate the nerves.

Corresponding nerve points are stimulated directly with electronic impulses. The device can be operated by persons who do not have formal medical training.

Self-treatment is safe and without side effects. The device is described in the enclosed easy to follow instruction manual to make self-treatment a straightforward process. The handling of the device is intended to suit users with no medical training. Various applications as well as corresponding therapy times are outlined in the instruction manual.

4. Quick start guide

Before using for the first time

Immediately after receipt, the device should be inspected for transport damage and be subject to a function test. In case of transport damage, the shipper shall be notified immediately and a damage report be drawn up to support any claim for damages. In addition to name and address of the recipient, the protocol shall include the date of receipt, type and serial number of the device as well as a description of the damage. The original packaging should be kept during the guarantee period to ensure that the device can be returned in its original packaging if necessary.

Every device is tested by the manufacturer in terms of functionality and safety before being shipped. Please observe the following to ensure that the device continues to operate properly following transport and installation:

The operator should only start using the device after carrying out a function test.

5. Specifications

Display:	Time of therapy in minutes, 7 light-emitting diodes Therapy steps 1 - 3 Exchange light-emitting diode battery
Error messages:	Intermittent tone: handholds or contact areas are not applied properly Continuous tone: handholds have short circuited
Battery:	6LR61 9-volt block battery
Output voltage:	AC, maximum 9-volt pp and minimum 6-volt pp
Duration of treatment:	3 - 21 minutes
Programme sequence:	3 steps
Measurements:	13.5 x 8.3 x 3 cm
Weight:	430 gr including accessories
Application class:	BF
Safety class:	Ila unit
Operation:	10°C - 40°C Humidity 30% - 75% without condensation, air pressure 700 hPa - 1060 hPa

Graphic symbols:



Please refer to instruction manual!



Type BF

6. Handling

1. Turning on the device: push I/GO button briefly.
2. Set appropriate therapy time per step by means of TIME button. Start with one minute per step, i.e. the complete treatment time is 3 minutes. Increase the time with every treatment by 1 minute per step. Complete steps 1 and 2 (see below and beside) once a day.
3. Place device on trigger point.
4. Start treatment by pushing the I/GO button.
5. You will hear a beep signal after completion of every step.
6. The end of the treatment is announced with two beep signals.
7. Turning off the device: push I/GO button for a prolonged period of time or device turns off automatically after 30 seconds.

Error message: Insufficient or no skin contact is indicated with continuous beep signals.

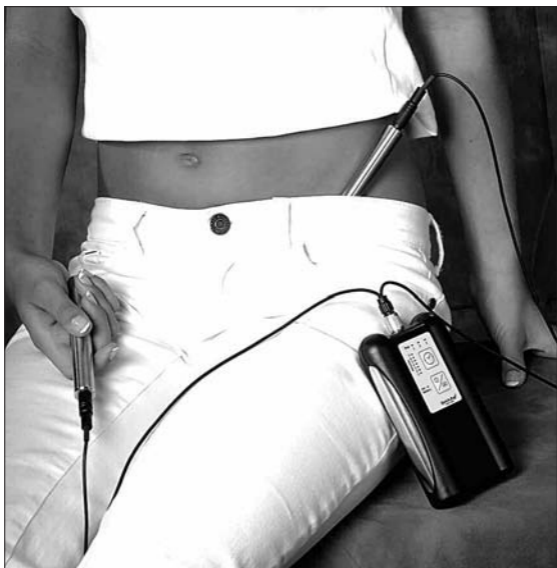
Step 1

Local treatment at trigger point



Step 2

Treatment of abdominal area



Please ensure good body contact. Moisten skin with water if necessary.

Consume large quantities of water before and after the treatment

7. Indications

- Pain relief

8. Contraindications

- Pregnancy: do not use the device
- Patients with a cardiac pacemaker: do not use the

device

- Open wounds: do not use the device
- Fresh scars: do not use the device
- Do not use in combination with other devices

9. Safety tips

- Power QuickZap may only be used for the electronic stimulation of nerves and musculature
- Do not use the device for patients who have been fitted with a cardiac pacemaker
- Simultaneous use with other devices is prohibited
- Power QuickZap may only be operated with a 9-volt battery
- Remove the battery if the device is not being used for a prolonged period of time
- Power QuickZap may only be operated with the accessories included in the range of delivery
- Fritonex AG is only responsible for the reliability and safety of Power QuickZap if:
 - Power QuickZap is operated in accordance with the instruction manual
 - expansions and modifications are carried out only by persons who are authorised by Fritonex AG
- Please recycle the batteries in accordance with national regulations
- Power QuickZap should be disposed of as hazardous waste

10. Care, maintenance and storage

Effective protection of the Power QuickZap from damage includes:

- Appropriate operation and maintenance
- Protection from moisture and dirt
- Wipe electrodes after every use to disinfect them
- Power QuickZap should be stored in a dry place

11. Errors and malfunctions, function test

- Discharge of the battery is displayed on a battery indicator LED
- After being turned on, Power QuickZap automatically runs a battery test
- An acoustic warning signal during therapy indicates that the electrodes have not been properly applied

12. Accessories

- Hand electrodes
- Instruction manual
- 6LR61 9-volt battery
- Portable case for Power QuickZap

13. Guarantee

Device and accessories shall be inspected for transport damage immediately after receipt. Corresponding claims for damages can only be asserted if the vendor or shipper have been notified immediately. A damage report shall be compiled.

- The guarantee for Power QuickZap is two years from the day of delivery.
- The extent of guarantee includes free repair of the device, provided the damage was caused by a material or manufacturing error.
- Additional claims, particularly claims for damages, are excluded.
- The repair may only be carried out by Fritonex AG, one of its agencies or authorised specialist dealers. The guarantee shall become void if improper modifications or repairs are carried out.
- The guarantee period will neither be extended nor renewed because of guarantee work.
- Fritonex AG reserves all rights to this instruction manual, particularly the right of duplication and distribution as well as translation. No part of this instruction manual

may be copied or distributed in any form without prior written consent from Fritonex AG.

- Information contained in this instruction manual may be modified or upgraded by Fritonex AG.

14. Safety inspection

§ 6 of the directive on installing, operating and using active medical products stipulates regular safety inspections to guarantee the safety of the device against age, wear and tear etc.

The operator is responsible for having these safety inspections carried out on the device to the prescribed extent and in due time. Safety inspections may only be carried out by the manufacturer or by explicitly authorised persons.

The following safety inspections are required for Power Quick-Zap:

- Examination of labelling and instruction manual
- Visual inspection of device and accessories for damages
- Function test of all sensors and control lamps on the device

15. CE-Conformity declaration

CE 0197

The company	Fritonex AG Breiten CH-3636 Forst declares that
the medical product	Power QuickZap to which this declaration is referring to, conforms with the general and supplementary requirements regarding the safety and the electro-magnetic tolerability of medical electric apparatus and systems according to the following
standards	EN 60601-1:1990+A1:1993+A2:1995 EN 60601-1-2:2001 This medical product complies with the basic requirements and provisions outlined in
the directive	93/42/EWG

The medical product described was developed, manufactured and tested according to the quality management system

EN ISO 9001:2000 and EN ISO 13485:2003.

Conformity of the quality management system is acknowledged and monitored by the technical inspection agency

TÜV Rheinland Product Safety GmbH.

Responsible for distribution:

Fritonex AG, Breiten, CH-3636 Forst
(Switzerland)



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