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The HANDY-CW 100 is a medical product for the stimulation of acupuncture points for diagnosis and therapy by physicians. The laser may only be used by physicians instructed in acupuncture which determine dosing of the laser (selection of therapy time, diagnosis time and laser output) according to their training. For diagnosis and therapy, the laser tip should be placed about 1 to 3 cm above the skin surface.

The IR laser beam works in the upper skin layers, visibly displaying its healing power. That is the reason for its use in ear and body acupuncture, dermatology and in dental medicine where points are relatively close to the skin surface.

**Acupuncture:** Ear and body acupuncture

**Dermatology:** Scars, eczema, acne, herpes labialis and other efflorescences, slow-healing wounds like ulcera cruris

Dental medicine: Aphthas, parodontitis, gingivitis, healing of wounds, diseases of the pulp, pain therapy

The well known contra-indications regarding laser therapy should be observed in any case.

**Relative contra-indications:**

- Children up to 5 years must be treated with reduced output power.
- Pregnancy (uterus as well as hormonally active acupuncture points) as well as lower back and abdomen
- Hormonogenic tissues like thyroid, ovaries and testicles
- Open fontanelles respectively defective calotte as well as epiphyseal region of children
- Malignant growth

**Absolute contra-indications:**

- direct and indirect irradiation of the eyes

**CAUTION! Side-effects:**

**Reddening of the skin and skin burns in the treatment area may occur in case of point-focal irradiation for more than 10 seconds with a distance to the skin of approx. 1 cm.**

The appliance is not approved for use in potentially explosive or damp rooms. Do not store in humid rooms. Only use the laser in inside confined space with an ambient temperature between 10° C and 40° C.

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

- The user has to report the operation of the laser to the respective authorities.
- The laser may only be used by instructed persons ensuring ap-

## Intended use

## Indications

## Contra-Indications

## Instalment instructions

## Important safety instructions

appropriate use of the laser owing to their training or knowledge and experience.

- The user must familiarise himself with the fail-safe mechanisms and normal working conditions of the laser.
- The consulting room has to be marked by a warning sign according to 417-IEC-5152. The respective warning sign will be supplied with the laser.
- Patient and physician and all persons in the range of the laser must wear laser safety glasses.
- The HANDY-CW 100 is secured against unauthorised use with a safety key. After use, the key should be taken out and locked up in a safe place.

### Laser class

The HANDY-CW 100 belongs in laser class 3 B.

**CAUTION! Looking into the laser beam is harmful to the eyes. Safety glasses must be worn. The precautionary measures according to VBG 93 for the application of laser beams must be observed.**

### Explanation of symbols



This product is in accordance with the directive 93/42/EWG for medical products of June 14, 1993.



Read the operating instructions carefully before use!

REF

Symbol for the item and order number. This symbol suffixes the catalogue or order number of the manufacturer.

SN

Serial number symbol. This symbol suffixes the serial number of the manufacturer.



Batch designation symbol. This symbol suffixes the LOT number of the manufacturer.



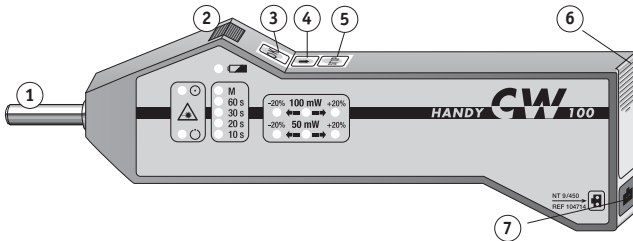
Year of construction symbol. This symbol suffixes the year of construction of the device.

## Technical description

Type of laser	CW-laser diode
Wave length	830 nm
Beam spread	2°
CW output power	100 mW +/- 10 %
Timer settings	10, 20, 30, 60 seconds, M...continuous operation
Power supply	7,2 V = NiCd rechargeable battery
Power consumption	200 mA
Battery	110 mAh
Charging time	5 h
Max. treating time	30 minutes
Laser class	3 B, according to the directive DIN EN 60825-1/07.94
Class	IIa, according to the directive for medical products 93/42/EWG, annex IX

## Technical data

### Description of the Handy Laser



#### 1. Probe tip

The probe tip emits an invisible laser beam. For diagnosis and therapy, the laser tip should be placed about 1 to 3 cm above the skin surface.

#### 2. Safety key

After use, the key should be taken out and locked up in a safe place.

#### 3. OK key

Press the OK key to start the laser or to confirm a selected setting.

#### 4. ➡-key

Select the required setting by pressing the ➡-key.

#### 5. STOP-key

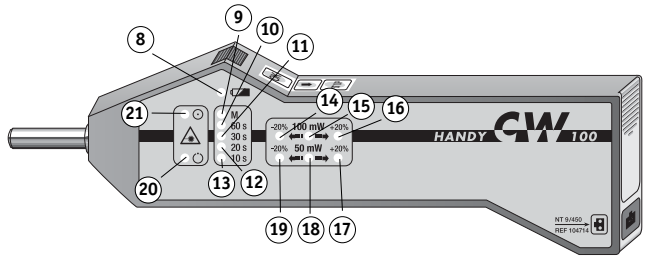
Press the STOP key to return to the basic setting or to stop therapy. By keeping the STOP key pressed (for approx. 2 seconds), the laser is switched off.

## Description of the control display

### 6. Battery compartment

### 7. Socket

The power supply NT9/450 may be connected to this socket.



### 8. Battery LED

If the battery LED illuminates, the battery must be charged respectively changed.

### 9. Timer setting M (manual)

With this setting, therapy time is in continuous operation mode.

### 10. Timer setting 60 s

The laser stops automatically after a therapy time of 60 seconds.

### 11. Timer setting 30 s

The laser stops automatically after a therapy time of 30 seconds.

### 12. Timer setting 20 s

The laser stops automatically after a therapy time of 20 seconds.

### 13. Timer setting 10 s

The laser stops automatically after a therapy time of 10 seconds.

### 14. Laser power 100 mW -20%

The continuously controlled laser output power diverges -20% from the value set.

### 15. Laser power 100 mW

This setting selects the highest output power.

### 16. Laser power 100 mW +20%

The continuously controlled laser output power diverges +20% from the value set.

### 17. Laser power 50 mW +20%

The continuously controlled laser output power diverges +20% from the value set.

**18. Laser power 50 mW**

This setting selects half of the laser output power.

**19. Laser power 50 mW -20%**

The continuously controlled laser output power diverges -20% from the value set.

**20. Laser ready symbol**

The laser ready symbol means: CAUTION: The laser is ready to work. After 2 seconds, the laser will be ready to emit the invisible laser beam by pressing the OK key.

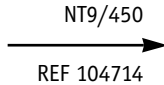
The flashing laser ready symbol means: CAUTION: Dangerous laser radiation is emitted.

**21. Laser warning symbol**

The flashing laser warning symbol means: CAUTION: Dangerous laser radiation is emitted.

A type BF application which assures protection against electric shock according to the requirements for regulation IEC 601-1, especially in respect to the authorised current leakage.

**Socket for the power supply NT9/450**



**The illuminating laser ready symbol means:**

CAUTION: The laser is ready to work. After 2 seconds, the laser will be ready to emit the invisible laser beam by pressing the OK key.

**The flashing laser ready symbol means:**

CAUTION: Dangerous laser radiation is emitted.

**The illuminating laser warning symbol means:**

CAUTION: Dangerous laser radiation is emitted.

When the yellow battery LED illuminates, the battery has to be charged respectively changed.

**Explanation of the special symbols**



## Warning signs

There are the following warning signs on the front of the laser:

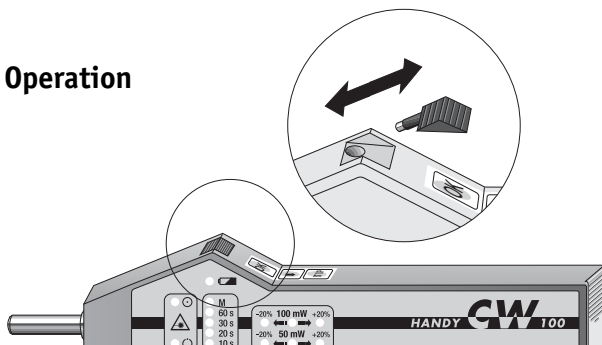


Laser warning sign: left

Invisible laser radiation  
Avoid eye or skin exposure  
Laser Class 3B, according to  
DIN EN 60825-1/07.94

Laser class: right

## Operation



### Starting the laser

- Place the enclosed safety pin in the opening near the OK key.
- All displays will illuminate for approx. 2 seconds (apart from -20% and +20%) and then the basic setting will appear (M flashes).

### Selecting the therapy time

The therapy time M / 60 s / 30 s / 20 s / 10 s can be selected by pressing the  $\leftrightarrow$ -key and confirming with the OK key.

### Selecting laser output

The laser output 100 mW / 50 mW can be selected by pressing the  $\leftrightarrow$ -key and confirming with the OK key.

### Starting therapy

After pressing the OK key, the laser ready symbol appears. After approx. 2 seconds, the laser will be ready to emit the invisible laser beam by pressing the OK-key. As long as the invisible laser radiation is emitted, the laser warning symbol appears, the laser ready symbol flashes and the pilot light illuminates.

### Controlling laser output power

The laser output power is being steadily controlled during therapy. In case the laser output power diverges -20% or +20%, the respective yellow warning lamp illuminates. Switch off the laser and contact schwa-medico.

Therapy ends with the expiration of the selected therapy time. Therapy can also be stopped at any time by pressing the STOP key.

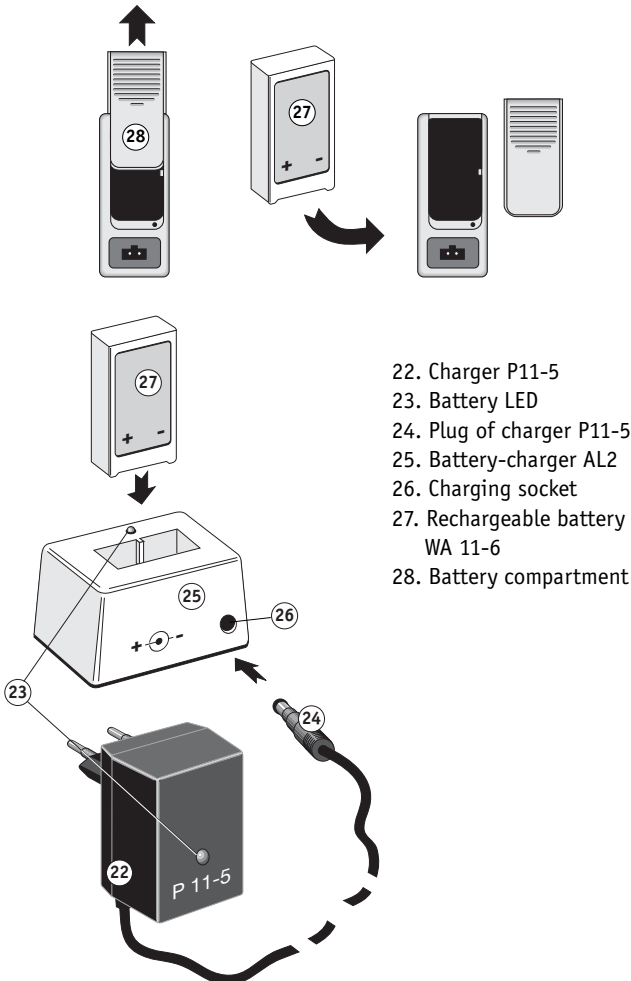
## Stopping therapy

By keeping the STOP key pressed (for approx. 2 seconds) the laser stops. In case no setting is made or the battery LED illuminates, the laser will be stopped automatically after approx. 1 minute.

## Stopping the laser

## Battery care

### Description



If the battery symbol appears in the display, the rechargeable battery WA 11-6 in the HANDY-CW 100 needs to be changed. First, switch off the device, then open the battery compartment and take out the battery. Charging with the charger P11-5 takes approx. 5 hours.

**CAUTION! First, plug the charger into the power outlet and then connect it to the battery-charger AL 2. Put the battery into the battery-charger AL 2 (the green lamp on the charger illuminates). Charging is completed when the green lamp goes off respectively flashes.**

#### Technical data of the charger P11-5 :

**CAUTION! Never use the charger P11-5 outdoors, only use in inside confined space. Keep away from liquids and high humidity. The charger P11-5 may only be used to charge the HANDY-CW 100 (Item No. 205236). Do not shorten the charging unit.**

#### Technical Data:

Input: 230 V ~ / 50 Hz / 17 mA / 1,7 W

Output: 7,25 V / 30 mA

Type: FW 1199

Charging time: 5 h

Ambient temperature: 0°C to +40°C

**To ensure a long working life of the rechargeable batteries they should only be charged when the battery symbol appears in the display. Charging the batteries before the symbol illuminates decreases their working life. Never shorten the contacts on the rechargeable batteries - severe burning may occur.**

#### Explanation of the special symbols



Ni-Cd



Cd

The manufacturer agrees to take back rechargeable batteries to dispose of them properly.

Only dispose of batteries at appropriate collecting points.

The HANDY-CW 100 may be operated with an external power supply NT9/450 (Item No. 104714). The plug of the power supply has to be connected to the respective socket on the laser. When operating with the external power supply, the rechargeable battery in the laser does not have to be removed.

## **General**

During the warranty period of one year from the date of purchase, all repairs which may become necessary and are not due to incorrect use of the appliance will be carried out free of charge by the manufacturer.

The laser tip can be cleaned with 80% alcohol. The rest of the laser and all accessories can be cleaned with a moist, dust-free cloth.

The manufacturer will accept responsibility for the safety and performance of the appliance provided that resetting, modifications and repairs are carried out by him or by authorised persons, and that the device is used in accordance with the operating 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.

The HANDY-CW 100 should undergo a technical safety check every 12 months.

## **Operation with power supply**

## **Warranty**

## **Cleaning and disinfecting**

## **Resetting, modifications and repairs**

## **Circuit diagrams, spare parts list and setting instructions**

## **Maintenance**

## **Laser safety glasses / Laser safety glasses for patients**

### **Laser safety glasses PSB2 for patients**

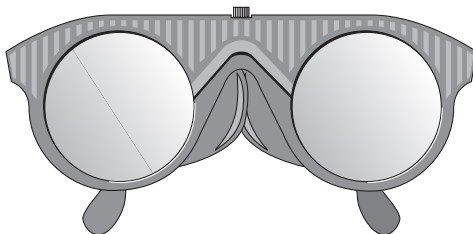
Laser safety glasses for the therapist to be worn during application of the Handy CW 100 must meet the following requirements:

- They have to be suitable for continuous wave laser D
- They have to be suitable for a wave length of 830 nm
- They have to have safety level L5

The laser safety glasses PSB2 are for patient use only and exclusively approved for the laser HANDY-CW 100 (Item No. 205236).

### **The following laser safety glasses are acceptable for the HANDY-CW 100:**

Laser safety glasses with the identification D830 L5 according to DIN EN 207 may be used.



Laser safety glasses PSB2 for patients (Item No. 206 909)

## **Disposal**

The manufacturer agrees to take back old HANDY-CW 100 and to dispose of them properly.

## **Accessories**

All accessories and devices stated in the delivery scope and the following accessories may be used in combination with the HANDY-CW 100:

### **Power supply NT9/450      Item No. 104717**

The laser may only be applied with accessories, wearing parts and single-use articles mentioned in the operating instructions.

- |                                     |                      |
|-------------------------------------|----------------------|
| 1. Charger P 11-5                   | Item No. 206920      |
| 2. Battery-charger AL 2             | Item No. 206930      |
| 3. 2 x rechargeable battery WA 11-6 | Item No. 206940      |
| 4. Transport case                   | Item No. 450980-0034 |
| 5. Laser warning sign               | Item No. 451400-0004 |
| 6. Operating instructions           | Item No. 451600-0103 |

Pierenkemper GmbH, Hörnsheimer Eck 19, D-35578 Wetzlar

## Scope of supply

## Producer





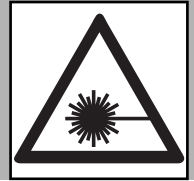


schwa-medico  
Medizinische Apparate  
Vertriebsgesellschaft mbH  
Export Department  
Gehrnsstraße 4  
D-35630 Ehringshausen  
Tel. + 49 6443 8333-717  
Fax + 49 6443 8333-766  
E-Mail [friedrich@schwa-medico.de](mailto:friedrich@schwa-medico.de)  
[www.schwa-medico.com](http://www.schwa-medico.com)

# Operating Instructions

CE 0197

V01



## Handy CW 100

Infrared laser

