

# Operating Instructions

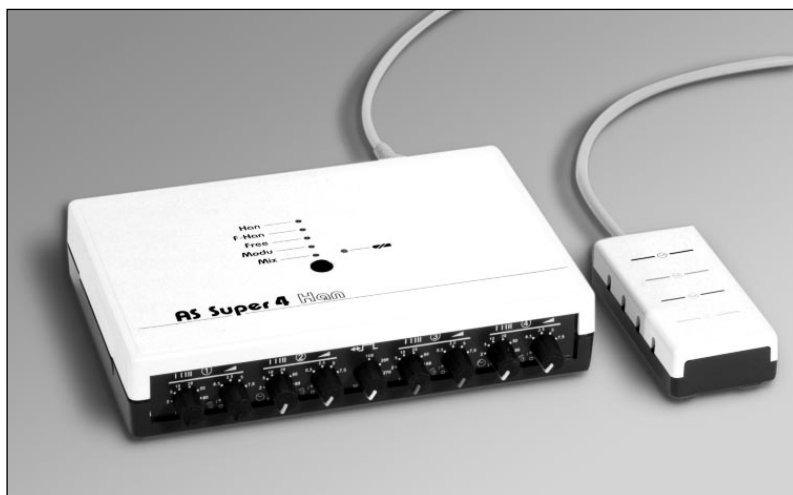
CE 0197

Version 1



## AS Super 4 Han

Electrical Needle Stimulator



REF 209 150

**schwa·medico**

MEDICAL EQUIPMENT & SUPPLIES



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The **AS Super 4 Han** device is a medical product designed for electrical stimulation in acupuncture treatment. Please do not use this device for any other purpose.

The **AS Super 4 Han** is a highly sophisticated device produced under strict quality control. Nevertheless, certain safety measures have to be observed, particularly when the equipment is used on children. When switching the unit off, it is important that the intensity controls for all the individual channels be switched off.

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

#### **To ensure safe use of the device**

- Only use the **AS Super 4 Han** with original accessories.
- Keep the **AS Super 4 Han** away from water or other fluids.
- Do not drop the **AS Super 4 Han**, 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 **AS Super 4 Han** when it is not functioning properly or when it is damaged in any way.
- Store the **AS Super 4 Han** in its original packaging after use to protect it from damage and contamination.
- Take special care when using the equipment on children.

#### **Precautions**

Patients with an implanted electronic device (e. g. pacemaker), pregnant woman and epileptics should not undergo electrotherapy with the **AS Super 4 Han** before consulting a doctor. The **AS Super 4 Han** 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 burning under the electrodes.

Operation near (e. g. 1m 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 cm<sup>2</sup>.

The **AS Super 4 Han** is a high-performance unit, fully capable to meet the requirements of everyday practice. With five operation modes and its four galvanic separate channels the therapist has the

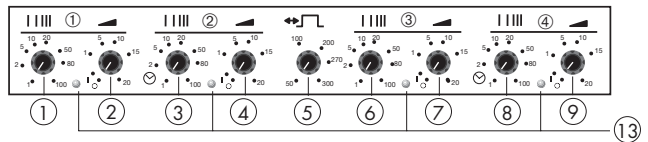
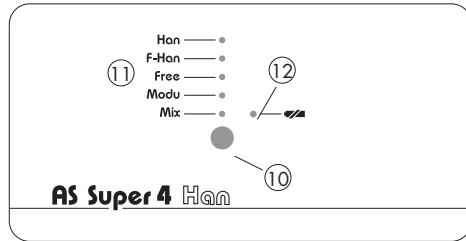
## **Purpose**

## **Important safety instructions**

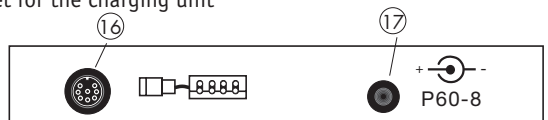
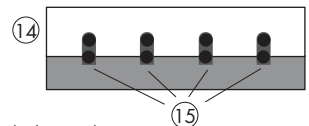
## Description of the device

possibility to stimulate more than eight acupuncture needles simultaneously. The intensity of each channel can be individually and continuously adjusted. Each channel has a constant current characteristic and is equipped with the output short circuit control element (AKS).

An integrated rechargeable battery enables the unit to be operated independent of mains power. Connection to the mains is only required to recharge the battery, using the charging unit supplied.



1. Frequency knob for channel 1
2. ON/OFF knob and current adjustment for channel 1
3. Frequency knob for channel 2, respectively for the first time in the operation mode **F-Han**
4. ON/OFF knob and current adjustment for channel 2
5. Pulse width knob for all channels
6. Frequency knob for channel 3
7. ON/OFF knob and current adjustment for channel 3
8. Frequency knob for channel 4, respectively for the first time in the operation mode **F-Han**
9. ON/OFF knob and current adjustment for channel 4
10. Operation mode selector
11. Operation mode LED
12. Operation LED
13. Pulse LED
14. Distributing-box
15. Output sockets for the individual channels
16. Socket for distributing-box
17. Socket for the charging unit



Operation mode: **Han-Stimulation** . . . . .

Operation mode: **Free Han-Stimulation** . . . . .

Operation mode: **Free Frequency** . . . . .

Operation mode: **Frequency Modulation** . . . . .

Operation mode: **Mix Mode** . . . . .

Operation LED (the battery has to be charged when the LED illuminates red)

Knop for setting the frequency . . . . .

Knop for setting the pulse width . . . . .

Knop for setting the intensity (here channel 1) . . . . .

Knop for setting the time in operation mode **F-Han**

Socket for distributing – box . . . . .

Socket for charging unit **P60-8** . . . . .

Product name of the charging unit to be applied . . . . .

Conform with directive 93/42/EEC of 14 June 1993 concerning medical devices

Caution: Please read the “operating instructions”! . . . . .

Article n° . . . . .

Serial n° of the device . . . . .

The device has a NiMH rechargeable battery. This battery is reusable. Please observe the regulations for re-use. The manufacturer commits agrees to take back old devices and to dispose of the rechargeable batteries properly.

BF type application part . . . . .

## Explanation of symbols

**F-Han**

**Free**

**Han**

**Modu**

**Mix**



**P 60-8**



**REF**

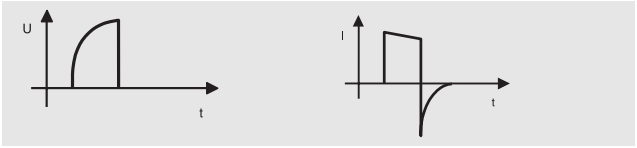
**SN**



## Specifications

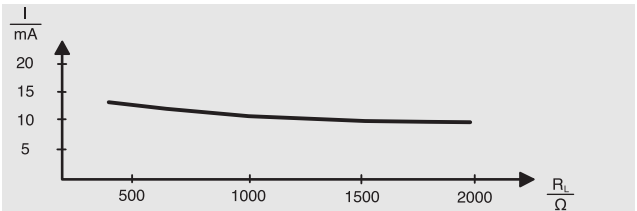
Four-channel electrostimulator with galvanic separate channels, constant current characteristic, integrated rechargeable batteries and output short circuit control element (AKS).

### Pulse forms



with ANSI/AAMI standard load

### Change in output current depending on load



Output current per channel	10 mA max.
Pulse width	50 - 300 $\mu$ s (variable)
Frequencies	1 - 100 Hz
Pulse form	rectangular with AKS
Power supply	9.6 Volt NiMH rechargeable battery
Current consumption	20 mA (min.)
Dimensions	48x205x153 mm
Weight	approx. 750 g

## Starting the device

Before operating the unit, connect the distributing-box to the back of the **AS Super 4 Han**. First connect the cables with the miniature crocodile clips to the acupuncture needles. Next, plug the cables into the distributing-box. Please observe that the cables have the same colour like the output sockets of the distributing-box. After setting up the application as described here, make sure that the intensity of the individual channels is set to zero or that the channels are switched off entirely.

### Note: Acupuncture needles are not supplied with the unit.

After switching on the channel the respective pulse LED flashes dependent on the adjusted frequency. The operation LED lights up green when the rechargeable batteries are loaded. When the LED gives a red light you have to recharge the battery.

## Operation mode selection

After switching on the device the operation mode LED flashes. During this time, the operation mode can be changed.

### Locking the operation mode selection

Operation mode selection is locked when the selector is not used for 10 sec. The operation mode LED stops flashing.

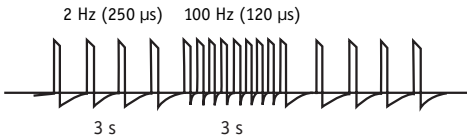
### Unlock the operation mode selection

Operation mode selection is unlocked when the operation mode selector is used for 4 sec. The operation mode LED flashes.

### Use the operation mode selector to adjust the following operation modes:

#### Han – Stimulation

All channels change automatically the frequency as follows: 3 sec 100 Hz – 3 sec 2 Hz. The pulse width changes when the frequency is adjusted.



#### Free Han – Stimulation

Same as the operation mode “Han”, but all above-mentioned parameters can be changed.

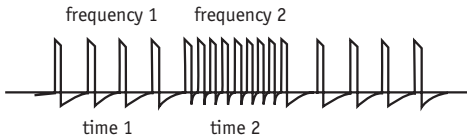
Frequency knob 1 - 1st frequency (1-100 Hz)

Frequency knob 2 - 1st time (1-100 s)

Frequency knob 3 - 2nd frequency (1-100 Hz)

Frequency knob 4 - 2nd time (1-100 s)

The pulse width changes when the frequency is adjusted.

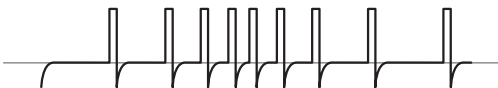


#### Free Frequency

Use the frequency knob to adjust the frequency of the individual channel in the frequency. The pulse width changes when the frequency is adjusted.

#### Frequency Modulation

Frequency modulation of all channels. Frequency is adjusted from 1 Hz to 100 Hz and back to 1 Hz within 10 s.



#### Mix Mode

Channels 1 and 2 have a free frequency and channels 3 and 4 have a Han-Stimulation. The pulse width changes when the frequency is adjusted.

Han

F-Han

Free

Modu

Mix

### **Setting the intensity**

When switching on and rotating the intensity knobs clockwise, the intensity will increase. Slowly increase individually the intensity of the selected channels until the required level is reached and the patient can feel the current. The intensity should be adjusted to a level where the patient ensure an appropriate sensation of current. As a rule, the patient will feel the stimulation mainly at the cathode (blue cable). After a few minutes of stimulation, the feeling will decrease and can be restored by increasing the intensity. During the first few treatment sessions, a certain amount of care should be exercised when increasing the intensity as there is a risk of over-stimulation.

### **Setting the frequency**

In this operation mode the frequency can be adjusted. The respective knobs are used to adjust the corresponding frequency dependent on the indication.

### **Setting the pulse width**

Depending upon the indication, the appropriate pulse width can be adjusted with knob 5.

### **Stopping stimulation**

Stimulation will be stoped by switching off the respective channels.

#### **Attention!**

To switch off the device, all four channels has to be switched off.

### **AKS (output short circuit control element)**

Owing to AKS, long term treatment without the risk of skin burning becomes possible. After each pulse the electrodes are short circuited.

### **Charging the battery**

You can only recharge the batteries by using the charging unit P60-8 supplied. The adapter should first be plugged into the mains socket and the plug into the corresponding socket at the back of the **AS Super 4 Han** (yellow LED on mains adapter lights up). The yellow LED will be extinguished when the battery is fully charged. When disconnecting, first take off the plug from the back of the **AS Super 4 Han** before disconnecting the mains adapter unit from the wall socket.

#### **Technical data of the charging unit**

Using the mains adapter unit P 60-8, the batteries will be charged in approx. 5 hours.

Technical specification and data of the mains adapter unit **P60-8**:

Input : 230 volts  $\sim$  / 50Hz / 35mA / 5W

Output : 12,6V / 140 mA

Temperature range : 0° C to + 40° C

Short circuiting the charge socket on the equipment is strictly forbidden - fire risk!

### **Warning!**

Only use the charging unit **P60-8** indoors and protect from humidity.

The mains adapter **P60-8** may only be used to charge the **AS Super 4 Han**.

Do not short-circuit the Charging unit.

**Do not charge non-rechargeable batteries with this charging unit.**

The manufacturer is only responsible for the safety and performance of the **AS Super 4 Han** device when readjustments, alterations and repairs are carried out by authorised individuals and when the **AS Super 4 Han** 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 by the manufacturer.

We give a guarantee of 1 year from the date of purchase on the **AS Super 4 Han** device. This guarantee does not cover cables and needles.

No special cleaning or care agents are required for the **AS Super 4 Han**. Clean the **AS Super 4 Han** with a soft, dust-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 **AS Super 4 Han** device is classified as a Class IIa medical device.

**Readjustments, alterations and repairs**

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

**Warranty**

**Cleaning and care of the device**

**Classification**

## Technical checks

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

### These include:

1. Checking to see whether the operating 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 kΩ real (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.

## Combination

The **AS Super 4 Han** may be used together with all accessories mentioned in the chapters „Scope of supply“ and „Accessories“.

## Electrical needle stimulation in acupuncture practice

In acupuncture therapy, the acupuncture needles, once set, are often stimulated individually. Stimulation can, following Chinese practice, be effected mechanically, for example by raising, lowering, or rotating the needles - both clockwise and anti-clockwise - or, by a modern variation, namely electrically.

Electrical acupuncture is usually applied to the body but can also be carried out as ear acupuncture. The indications for electro-acupuncture are the same as for conventional acupuncture. The individual points of stimulation are the same. This also applies to the objective of the stimulation, namely sedation or toning.

### Contra-indications

In addition to the contra-indications for conventional acupuncture, the following are also to be considered:

- severe cardiac rhythm impairment
- pregnancy, particularly 1st to 3rd month (with the exception of analgesia during delivery)
- epilepsy (risk of inducing fit)

### Side effects

In addition to the side effects associated with conventional acupuncture, the following should be observed when using the **AS Super 4 Han**.

- over-stimulation: excessive stimulation can result in increasing pain
- skin irritation: in all probability skin irritation will be avoided, even during extended courses of treatment, by using the AKS (short-circuiting output) facility, with which the **AS Super 4 Han** is equipped. This ensures complete discharge of the tissue following each current pulse thereby preventing electrolytic processes which can lead to skin damage.

## 1. Toning

Literature references recommend lower frequencies for toning, namely between 2 and 10 Hz. The effect of the cathode (blue cable) tends to be toning. Pulse width and intensity must be matched to the sensitivity of the particular area of the body to which the needles are applied. As a rule, a pulse width of 200  $\mu$ s will be suitable - less in facial areas. The intensity can be increased until muscle contractions can be felt and observed. These intensify the effect of the acupuncture by depositing endogenous opioids and neurotransmitters.

## 2. Sedation

For sedation, higher frequencies are recommended, namely between 60 and 100 Hz. Pulse width and intensity must be adjusted so that the stimulation is not unpleasant but nevertheless clearly felt. Here, a pulse width of 200  $\mu$ s and less will suffice. The effect of the anode (red cable) tends to be sedative.

### Polarity

Experience in electro-stimulation anaesthesia has shown that, when crossing the centre line of the body, the anode should be applied to the patient's dominant side (the right for right-handed patients) and the cathode to the non-dominant side.

## 3. Stimulation duration

The duration of a session follows the recommendation of conventional acupuncture, lasting 20 - 30 minutes. Longer treatment is also possible due to the AKS facility.

## 4. Point selection

### a) Restricted and excluded points

The Bahui point (governing vessel 20) and the Neiguan point (pericardium 6) as well as points near the carotid sinus (e.g. Di 18) should not be stimulated, as this could lead to cardio-vascular complications. On the other hand, the restricted points, for example those near the eye, are more responsive to electrical than they are to mechanical stimulation, as the position of the needles is not altered.

### **b) Recommended points**

A combination of local and distant points is of advantage. Stimulation of local points, i.e. points in the segment region and "Ashi" points (locus dolendi points) are recommended particularly for analgesia. Combined stimulation with the distant points such as Di 4, Di 11, Lu 7, Ma 36, Bl 40, Gbl 34, MP 6, is ideal. The **AS Super 4 Han** enables the frequency of channels 1 + 2 and 3 + 4 to be adjusted separate from each other. This enables analgesic treatment with high frequency (i.e. sedative) stimulation in the local points zone and low frequency (i.e. toning) stimulation in the distant points zone to be carried out simultaneously.

Simultaneous stimulation of the toning and sedative points on one meridian should be avoided.

The Yin-Yang allocation should be observed, particularly in the distant points area. It is recommended that the anode be used for the Yin points and the cathode for the Yang points.

### **5. Stimulation repetition**

Sedative stimulation can be repeated as frequently as on a daily basis. For chronic conditions, a course of treatment extending over a longer period, but with greater intervals, is indicated; repetition of treatment 1 - 2 times weekly will normally suffice.

1	<b>AS Super 4 Han</b>	Item No. 209 150
1	<b>AS Super 4 Han</b> distributor-box	Item No. 209 151
1	Charging unit P 60-8	Item No. 104 704
1	Cable type 10 (b/w)	Item No. 106 715
1	Cable type 10 (grey)	Item No. 106 716
1	Cable type 10 (red)	Item No. 106 717
1	Cable type 10 (yellow)	Item No. 106 718

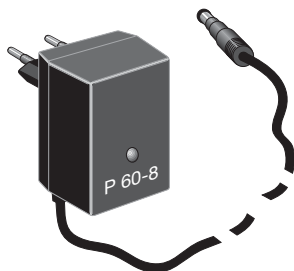
## Scope of supply

Art. No.	Size	Quantity
106 715	cable type 10 (b/w)	1 pc.
106 716	cable type 10 (grey)	1 pc.
106 717	cable type 10 (red)	1 pc.
106 718	cable type 10 (yellow)	1 pc.



## Accessories

104 703	charging unit P60-8	1 pc.
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