



# INSTRUCTION MANUAL

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MEDIZINTECHNIK GMBH

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# IMPORTANT NOTE

PLEASE MAKE SURE TO READ ALL INFORMATION PROVIDED IN THIS INSTRUCTION MANUAL AND IN THE INSTRUCTION MANUAL OF TIPSTIM® GLOVE BEFORE USING TIPSTIM®.

THIS INSTRUCTION MANUAL IS AN INTEGRAL PART OF THE MEDICAL DEVICE.  
PLEASE BE SURE TO KEEP IT WITH THE MEDICAL DEVICE.

Do not use the **tipstim**® system if you do not fully understand any aspect of operating the system. Please refer to a qualified supplier for assistance.

## **Intended use**




The electrotherapy device **tipstim**® is a class IIa medical device. It is intended for sensitive electrical stimulation of the finger tips and for tone regulation in the treatment of spasticity of the upper extremities.

## **Medical application areas**

**tipstim**® is designed to be used for the treatment of patients suffering from incomplete sensomotoric hemi- or monoparesis (paralysis) after stroke or craniocerebral trauma as well as for the treatment of CRPS (Complex Regional Pain Syndrome Type 1).

# SAFETY INSTRUCTIONS AND WARNINGS

## Explanation of graphic symbols and product marking

-  **DANGER** Indicates a direct hazard carrying a high risk of death or serious injury if not avoided.
-  **WARNING** Indicates a medium risk which could result in death or serious injury if not avoided.
-  **CAUTION** Indicates a possible danger that may result in minor or moderate injury if not avoided.



Consult instruction manual



Manufacturer



Year of production



Application part Type BF



Serial number



Reference number



"ON"/"OFF"



CE-marking and identification number of the notified body involved



Caution – follow the instructions



Protect medical device from moisture



Keep away from sunlight and from heat



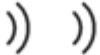
Medical device not to be disposed of with normal/household waste



Not suitable for pacemaker wearers



Prevention of danger/risk



Acoustic signals



Temperature



Humidity



Air pressure

## Precautions



# DANGER



**Possible risk of interference with cardiac pacemakers**

→ **tipstim®** should not be used by patients fitted with a pacemaker  
Exception: explicit permission by a medical specialist.

**Possible risk of danger to patients with cardiac damage**

→ **tipstim®** should not be used by patients with cardiac damage.  
Exception: explicit permission by a medical specialist.

**Danger to children and untrained users**

→ Keep away from Children and untrained users

**Possible risk of damage to implanted medical products**

→ **tipstim®** should not be used by patients with medical implants.  
Exception: explicit permission by a medical specialist.

**Possibility of deviations in the output parameters by unauthorized attempts to repair**

- Do not open the **tipstim®**.  
Do not attempt to repair the device.

**Risk of deviations in the output parameters or electric shock caused by liquid in the device**

- Do not expose the device to high humidity. Do not clean **tipstim®** with water or other liquids. Not to be used outdoors.

**Ignition of highly combustible substances**

- Always keep the device away from highly combustible materials.

**Use by several patients: Health risk by contamination, residue of chemicals and impaired functional performance.**

- Make use of a validated process according to the current legal requirements when reprocessing this device.

**Possible risk to health (heart, head, genitalia, spinal cord, neck) by electrical stimulation**

- Only use the device as per the instructions at all times.

**Incorrect use of tipstim® can lead to possible damage to health**

- Only use the device as per the instructions at all times and always keep this instruction manual with the device.



## **WARNING**

**Risk of burning the skin by high-frequency surgical unit at the electrode contact point**

- **Simultaneous connection** to a surgical device with a high frequency can lead to burning of the skin at the electrode contact points.

**Combustible/explosive substances in the immediate surroundings could be ignited**

- Do not operate the device close to combustible/explosive substances or flames of any type.

**To avoid deviations in the output parameters by environmental conditions**

- Observe the predefined operating and storage conditions at all times.

**Possible risk of infection for patients designated to use sterile products only**

➔ Do not use the device if sterile environmental conditions are required.

**Risk by uncontrolled actions**

➔ Do not use the device with patients suffering from seizure disorders (e.g. epilepsy), increased epileptogenicity or severe cognitive impairments.  
Exception: explicit permission by a medical specialist.

**Risk of electrical shock or injury caused by non-approved accessories**

➔ Please make sure to use approved accessories only.

**Risk of infections**

➔ To avoid risk of infections - accessories/consumables are intended for single-patient use only.

**Risk by improper use**

➔ Only use **tipstim®** with accessories provided and in combination with approved medical devices that are compatible with tipstim®.

**Risk by electrical shock**

➔ Do not connect the device or its components/accessories directly to mains power supply.



**CAUTION**

**Deviations in the output parameters**

➔ Do not operate the device in the vicinity of therapeutic shortwave or microwave devices as this will cause deviations in the output of the device.

**Pain or other health problems during treatment**

➔ Stop using the device immediately, consult a medical specialist and notify the manufacturer without delay.

**Danger of injury by damage to accessories**

➔ Avoid squeezing or pulling the connection cables.  
Damaged parts must not be used.



**Danger of injury by damage to the casing**

- ➔ Avoid damaging the casing. Take care not to drop the device.  
Do not use damaged devices.

**Danger of injury by electrical shock when starting or ending therapy session**

- ➔ Switch on the device only after all accessories have been connected correctly.  
Always completely switch off the device before unconnecting any accessories.

**Danger of injury by electrical shock when changing batteries**

- ➔ Switch off device and remove all accessories before changing batteries.

**Danger of injury by electrical shock**

- ➔ Operate the device only with closed battery compartment.

**Tissue damage around conductive implants**

- ➔ Do not use the device close to conductive implants.

**Damage to surgical wounds, to injured skin and other skin irritations**

- ➔ Do not use the device close to fresh surgical wounds or damaged skin.

**Damage to health in case of infectious diseases and fever**

- ➔ Do not use the device.

**Danger of injury when operating machinery simultaneously**

- ➔ Do not use the device.

**Danger of injury by high electrical currents in case of sensitivity disorders**

- ➔ Talk to your medical specialist about which level of intensity to use.

**Health impairments of stroke patients**

- ➔ Please make sure to use the device 2 weeks after stroke at the earliest.

**Health impairments of patients suffering from polyneuropathy or peripheral nerve lesion in the region of the upper extremities**

- ➔ Do not use the device.

**Impairment of the treatment success due to interaction caused by a simultaneous therapy with anticonvulsants**

- ➔ Device may only be used under medical supervision.

# MODE OF OPERATION AND CONFIGURATION

## Scope of delivery

**tipstim®** is delivered as a set and consists of following components:

- 1 **tipstim®** pulse generator
- 1 pack of mignon batteries (4 pcs.)
- 1 instruction manual
- 1 K4med electrode cable

## Optional components

- 4 NiMH rechargeable batteries 2500 mAh + 1 external charger
- PTA-USB-cable for PC connection and PTA-Software
- Programming instructions for medical experts

## Consumables

You also need **tipstim® glove** to start the therapy and/or possibly skin surface electrodes to treat spasticity.

- **tipstim® glove**
- 4 TENS/EMS electrodes 50x50 mm (optional)

# Technical description

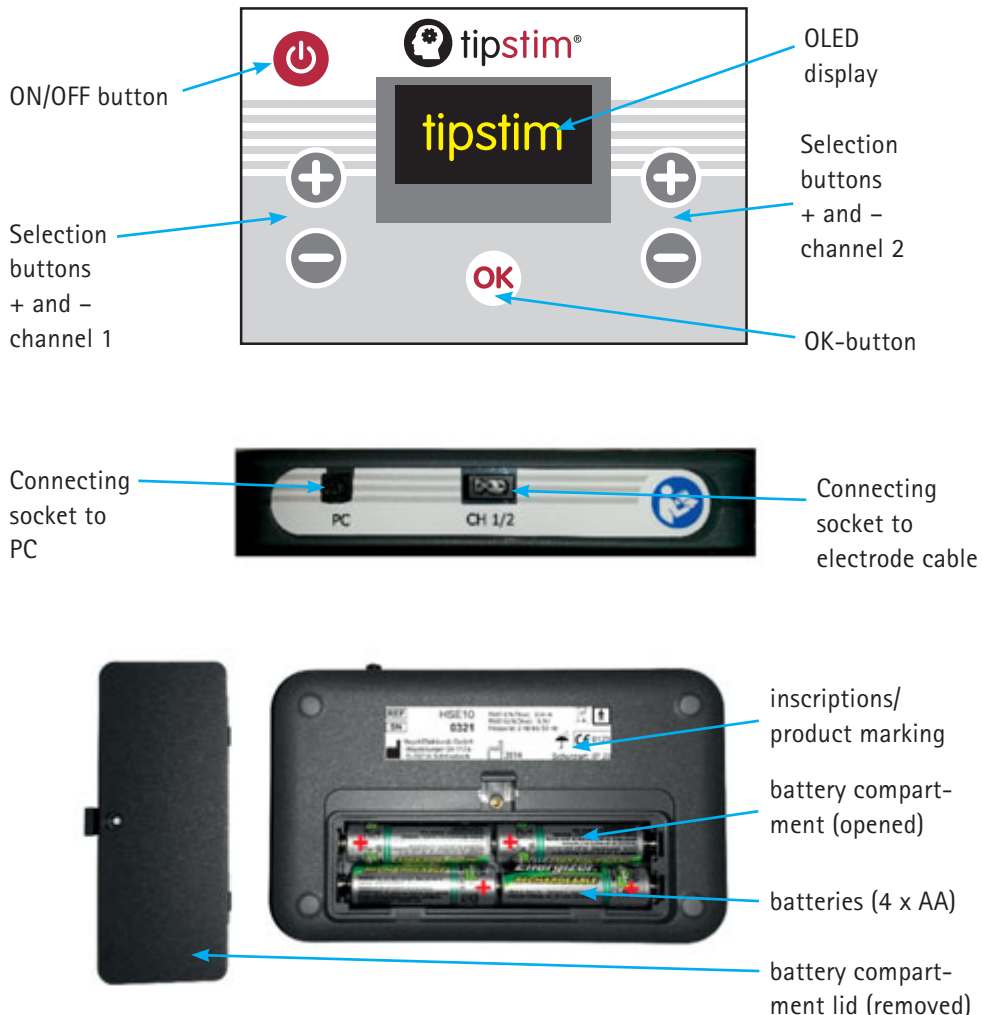
## Construction of therapy device



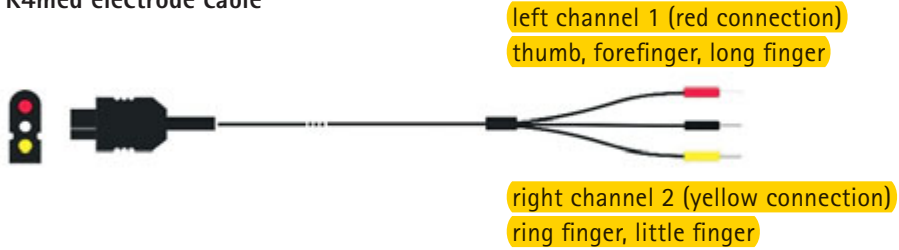
# WARNING

### → Damage to health by infections

Consumables/accessories are for single-patient use only.



## K4med electrode cable

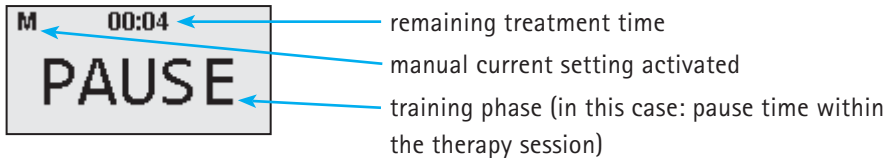
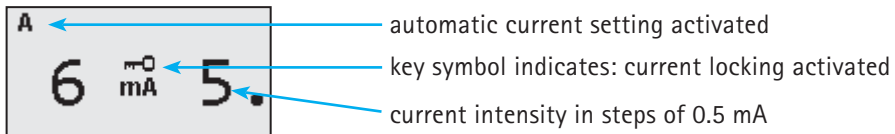


## Overview of signals

### Acoustic signals

- )) one short beep indicates: button pressed
- )) )) two beeps indicate: button locking
- )) )) )) )) )) **repeated signals indicate:**  
**current flow interrupted or substantially decreased**  
(display is blinking; repeated acoustic signal after 30 seconds)

### Optical signals and pictograms



## Environmental conditions during operation

### CAUTION



→ **Danger to the operator/user in case of defect**  
Medical device may only be operated at an ambient temperature between 5°C and 35°C.



→ Medical device to be protected from moisture



→ Medical device to be protected from strong sunlight and strong heat sources



→ Medical device not to be used in dusty environment



→ Medical device only to be operated at a relative humidity of 30-75%



→ Medical device only to be operated at a relative pressure between 700-1060 hPa

## Therapy settings and installation instructions

To carry out tip-stimulation after stroke you need a **tipstim® glove**.

### CAUTION

→ The usability of **tipstim glove®** is limited to 100 applications, 60 minutes each.

By means of an integrated counter **tipstim®** will remind you of changing **tipstim® glove** for a new one after 90 therapy sessions. Display will show following message:

Please change the Glove.  
Only 2 sessions remaining.

Display will show the remaining number of sessions until **tipstim® glove** has to be changed for a new one. Please confirm this message by pressing the "OK"-button.

You should prepare to change **tipstim® glove** for a new one now.

For assistance please contact the manufacturer or your local supplier.

On completion of 100 therapy sessions with a single **tipstim® glove** display will show following message:

**ATTENTION!**  
Please change  
glove!

Please change **tipstim® glove** for a new one immediately.

Please confirm the change of **tipstim® glove** by keeping the selection button "-" of channel 1 pressed (left channel, please refer to "technical description" in the menu) while switching on **tipstim®** by pressing the "ON/OFF"-button. Display will show a code request. **Please enter the 4-digit code that has been delivered along with your new tipstim® glove as follows:** Please use the selection buttons "+" and "-" to enter the first digit. Confirm your entry by pressing the "OK"-button. Now enter the 2nd digit as described above and continue until all 4 digits have been entered. Display will now show following message:

RESET (Y/N)  
CONFIRM WITH  
OK-BUTTON

Please confirm by pressing the "OK"-button. The message will no longer appear and the integrated counter starts at zero again.

## Preparing a therapy session

Please choose a quiet place for the therapy session. You should be sitting comfortably or lying down. Please make sure the device is secured and protected from falling down. When preparing the therapy session the device must be switched off. The first setting of the correct current intensity has to be made by your doctor/medical expert.

The therapy should not be unpleasant or painful; however, you should feel a clear electrical tingling sensation.

When using **tipstim® glove** please consult the instruction manual of **tipstim® glove**.

### *Further hints*

- Please clean and dry thoroughly the skin area to be treated. In case of using the optionally available self-adhesive surface electrodes the skin area to be treated must be completely depilated.
- Connect the plug of the electrode cable (k4med) to the socket (CH 1/2) of the device.

- Connect the opposite end of the electrode cable (k4med) to **tipstim® glove** – please refer to the separate instruction manual of **tipstim® glove** for further details. If treating spasticity connect it to the optionally available self-adhesive surface electrodes.
- Please use **tipstim® glove** or surface electrodes in accordance with your medical expert's instructions.

## Performing a therapy session

There are 2 ways to perform a therapy session.

- 1: Therapy with **tipstim® glove**.
- 2: Reducing spasticity via optionally available surface electrodes – by means of electrical stimulation of the hand lifter.

If menu heading "AUTOREPEAT" is selected, **tipstim®** will automatically choose the right intensity of stimulation. In order to use this function the device must be started by the prolonged pressing (min. 3 seconds) of the "ON/OFF"-button. Otherwise the therapy session starts with the current setting.

## Current setting

### Program 1: Therapy with tipstim® glove

Switch on the device by pushing the "ON/OFF"-button. You will enter the menu "current setting".

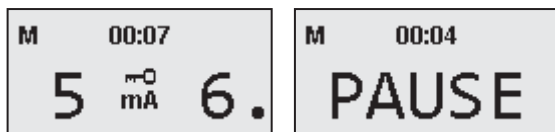
Set the current by pressing the selection buttons "+" and "-" until you feel a clear electrical tingling sensation. A precise determination of the current intensity to be chosen is not possible since every individual has subjectively different perceptions. Moreover, the perception depends on the skin resistance which may vary from day to day with one and the same individual. If you have found a well-perceived current intensity please press the "OK"-button. The current intensity has now been stored for the next therapy session.

By pressing the selection buttons "+" and "-" of channel 1 (left channel) you may choose the intensity for your thumb, forefinger and long finger. By pressing the selection buttons "+" and "-" of channel 2 (right channel) you may choose the intensity for your ring finger and little finger. The intensity chosen is shown in the display.



If no further operation is done for 8 seconds the current intensity setting will be locked. This state is displayed by a small key. From now on it is only possible to reduce the current intensity. To increase the intensity again you first have to push the "-"-button followed by pushing the "+"-button again.

If you have found a well-perceived current intensity please press the "OK"-button. The Program will start now and run automatically. It can be interrupted at any time by pushing the "ON/OFF"-button. Phases "current" and "pause" alternate.



### Program 2: Treatment of spasticity with surface electrodes (optional)

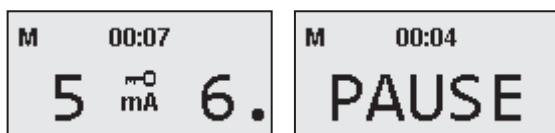
Switch on the device by pushing the "ON/OFF"-button. You will enter the menu "current setting".

By pressing the selection buttons "+" and "-" of channel 1 you can choose the intensity for the left channel. By pressing the selection buttons "+" and "-" of channel 2 you can choose the intensity for the right channel. The intensity chosen is shown in the display.

If no further operation is done for 8 seconds the current intensity setting will be locked. This state is displayed by a small key. From now on it is only possible to reduce the current intensity. To increase the intensity again you first have to push the "-"-button followed by pushing the "+"-button again. The intensity chosen is shown in the display.



Once you have found the suitable current intensity please press the "OK"-button. The Program will start now and run automatically. It can be interrupted anytime by pushing the "ON/OFF"- button. Phases "current" and "pause" alternate.





## Interrupting a therapy session

Therapy can be paused any time by pushing the „OK“-button. Pushing the „OK“-button again will continue the therapy session.

## Finishing a therapy session

Therapy will automatically stop at the end of the timed treatment program. NOTE: therapy can be stopped anytime by pushing the "ON/OFF"-button.

After switching off the device the **tipstim® glove** or optionally available surface electrodes can be removed. Please place all components back in their original packaging.

## Cleansing and disinfection

### Taking care of the self-adhesive surface electrodes (optional extra)

In case the self-adhesive, reusable electrodes no longer stick, moisten the sticky side with some water drops. Before placing the electrodes, wash the skin with soap and water or with an alcohol wipe.

### Cleansing of the device

Light soiling can easily be removed with a dry, non-abrasive cloth. If the device is heavily soiled you may clean it with a damp, non-abrasive cloth using soap or washing lotion. Always dry the device with a soft cloth.



**CAUTION**

### → Danger by device defect

Never clean this medical device under running water.

# MAINTENANCE, STORAGE, TRANSPORT

If you lose this instruction manual please contact the manufacturer or your local dealer for a new one. For any doubts or questions please contact your local dealer, the manufacturer or your treating physician/medical expert.

## Change of batteries

**Operation time of fresh batteries is approx. 10 hours.** If the batteries run out of power a warning sound beeps for one second and the device automatically switches off.

**tipstim®** is supplied with 4 x 1.5 V AA batteries.

To change the batteries

- 1) Open the battery compartment at the rear of the device.
- 2) Remove the empty batteries. Make sure to place the batteries in the correct position with proper polarity!
- 3) Close the battery compartment.



You may also use rechargeable batteries. These can be charged with an external charger. To replace rechargeable batteries please follow the instructions above.

To check the state of charge of the (rechargeable) batteries: Switch off the device. Press the "+"-button of the right channel and keep it pressed. Now press the "ON/OFF"-button once (while keeping the "+"-button pressed). The level of charge will be displayed in the display. A full scale means that the (rechargeable) batteries are fully charged.

## Safety checks

The **tipstim®** device has been manufactured in accordance with the Medical Devices Act and accordingly does not require any safety checks. For details of the applicable standard in your country please contact the local distributor or the manufacturer of this medical device.

## Debugging and repair by untrained users

Untrained users must not attempt to repair or disassemble the device or its components/ accessories. Untrained users may carry out following tests:

error	cause	solution
No current noticeable	The electrode cable is not connected correctly to the socket at the head end of the device	Check the seating of the plug at the device's socket
Current cannot be set or display is blinking (repeated acoustical signal)	Insufficient skin contact	Replace <b>tipstim® glove</b> by a new one. Replace surface electrodes
	Accessories are damaged	Replace accessories
	Current intensity settings locked	Unlocking by pressing "-"-button
Device cannot be switched on	(Rechargeable) batteries are completely discharged	Replace batteries
Device switches off immediately after it has been switched on	(Rechargeable) batteries are completely discharged	Replace batteries
Reduced operating time after recharge of batteries	Rechargeable batteries are worn out (more than 500 charging cycles)	Replace rechargeable batteries

## Debugging and repair by authorized and qualified personnel

Authorized personnel are allowed to carry out repairs of the device and its components/ accessories according to legal and technical standards. All persons wishing to be authorized must to participate in a training course run by the manufacturer. The training course is fee-paying.

## Storage and transport



### CAUTION



- **Danger to user due to defective or improper use of device**  
→ Medical device may only be operated at an ambient temperature between 5°C and 35°C



- Medical device to be protected from moisture



- Medical device to be protected from strong sunlight and strong heat sources

- Medical device not to be used in dusty environment



- Medical device only to be operated at a relative humidity of 30-75%



- Medical device only to be operated at a relative pressure between 700-1060 hPa

# ENVIRONMENTAL PROTECTION AND DISPOSAL

## Pulse generator **tipstim**<sup>®</sup> and K4med electrode cable

This medical device is in conformity with the requirements of guideline 2011/65/EU of the European Parliament and Council (dated June, 8, 2011 and amendments) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

**tipstim**<sup>®</sup> consists of many valuable raw materials. Please dispose of the device following strict European and national regulations on safe disposal of goods under Green Laws.

Do not disassemble the device under any circumstances.

**tipstim**<sup>®</sup> is not to be disposed of with normal/household waste. Only dispose using a reputable recycling company or return the device to the supplier.

With proper operation and care, **tipstim**<sup>®</sup> has a life cycle of 10 years and K4med electrode cable of 3 years. This shall not preclude that, within these periods, repairs may be required.

## **tipstim**<sup>®</sup> glove

Please observe the notes given in the instruction manual of **tipstim**<sup>®</sup> glove.

## Batteries and accumulators

Please dispose of batteries according to your local or national legal provisions (within the EU: guideline 2006/66/EG (dated September 6, 2006) of the European Parliament and Council).

# TECHNICAL INFORMATION

## Display

The OLED display has a resolution of 128 x 64 pixels. The display has a very high contrast, a fast response time and low energy consumption.

OLED displays are subject to a natural aging process due to technical reasons. The manufacturer of the **tipstim**<sup>®</sup> medical device is not responsible for any failure of the OLED display.

## Connections

Three-pole socket at the head of the device allows connection of the electrode cable to the device.

Four-pole socket for connecting the device to a PC via a USB connecting cable (tested with 5000V / optically decoupled).

## Mode of operation

### ■ Electrical stimulation

### Setting options for timer

■ Current time: 1...255s

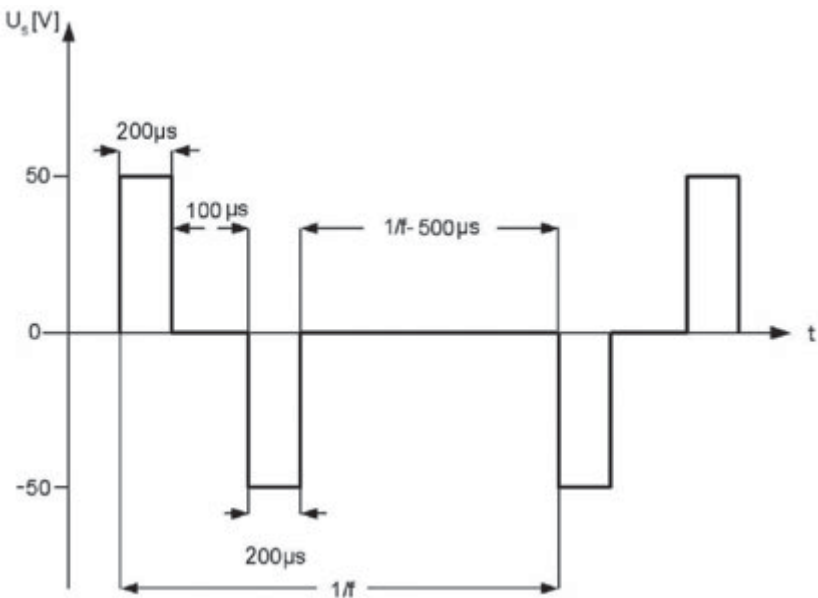
■ Pause time: 1...255s

■ Treatment time: 5...60min and continuous operation

# Output

Kind of current	biphasic
Max. current	50 mA at 500 Ohms at 27Hz
Effect. current	5.0 mA at 1000 Ohms
Pulse width	200 $\mu$ s
Frequency	adjustable: 2 Hz to 50 Hz
Max. Amplitude on 500 Ohms	$\pm 25$ V
Max. amplitude on open output	$\pm 180$ V
Max. energy of a single pulse on a load impedance of 500 Ohms	2.5 mJ at 2 Hz and 500 $\mu$ s pulse width

## Pulse pattern



## Factory settings

	Program 1	Program 2
Stimulation time [s]	2	225
Rise time [s]	0,3	none
Pause time [s]	5	10
Treatment time [min]	60	15

## Power supply

Either

4 x AA-size Mignon batteries R6

or

4 x NiMH rechargeable batteries (mignon cells 2500 mAh, 1, 2 V) plus an extra charger (230V, 50Hz)

## Safety functions

- Avoids an unintended increase in current intensity outside the stimulation phase
- A gentle (reduction in) swelling of the current pulse
- **Electrode alarm function (automatic limitation and adjustment of current in case skin contact of electrodes is too small)**
- Increase of current intensity not possible without previous reduction of intensity (intensity locking after 8 seconds without operation)
- Protection class II; IP 20



## Manufacturer's declaration concerning EMC

Cable length of K4med electrode cable

	cable length	length measured
K4med electrode cable	1, 5 m	1, 5 m

Use of longer cables may lead to increased emission of electromagnetic radiation or to decreased immunity. This device may only be operated with original accessories provided by the manufacturer.

### Manufacturer's declaration – Electromagnetic emissions

(TAB. 201 acc. to DIN EN 60601-1-2)

**tipstim®** is suitable for use in below-mentioned electromagnetic environment. **tipstim®**-user should ensure that the device is being used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidelines
HF- emissions as per CISPR11	group 1	<b>tipstim®</b> uses HF-Energy only for its internal function. For this reason its external HF emission is very low and it is very unlikely that it will interfere with other electronic devices nearby.
HF-emissions as per CISPR11	class B	<b>tipstim®</b> is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Emission of harmonic oscillations acc. to IEC 61 000-3-2	not applicable	
Voltage fluctuations/flicker emissions acc. to IEC 61 000-3-3	not applicable	

### Manufacturer's declaration – Electromagnetic immunity

(TAB. 202 acc. to DIN EN 60601-1-2)


**tipstim®** is suitable for use in below-mentioned electromagnetic environment. **tipstim®**-user should ensure that the device is being used in such an environment.

Immunity tests	testing levels required by IEC 60601	Compliance level	Electromagnetic environment-guidelines
Discharging of static energy acc. to IEC 61 000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Earth floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Magnetic field at a power frequency (50/60 Hz) acc. to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields should be at levels characteristic for a typical location in a typical commercial or hospital environment.

### Manufacturer's declaration – Electromagnetic immunity

(TAB. 204 acc. to DIN EN 60601-1-2)

**tipstim®** is suitable for use in below-mentioned electromagnetic environment. **tipstim®**-user should ensure that the device is being used in such an environment.

Immunity tests	testing levels required by IEC 60601	Compliance level	Electromagnetic environment-guidelines
Conducted HF-disturbances acc. to IEC 61000-4-6	3 Veff 150 KHz – 80 MHz	$V_1 = 10 \text{ Vemk @ } 150 \text{ KHz} - 80 \text{ MHz}$	<p>Portable and mobile communication devices should not be used in closer proximity of the <b>tipstim®</b> unit or its cables than the recommended safety distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended safety distance</p> $d = \{3, 5/V_1\} \sqrt{P}$ $d = \{3, 5/E_1\} \sqrt{P} \text{ for } 80\text{MHz to } 800 \text{ MHz}$ $d = \{7/E_1\} \sqrt{P} \text{ for } 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>whereby p is the nominal power output of the transmitters in Watts (W) as per the information given by the manufacturer of the transmitter and d is the recommended separation distance in meters (m).</p> <p>The field strength of stationary transmitters should be lower than the compliance level<sup>b</sup> for all frequencies on the basis of an on-the-spot check<sup>a</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated HF-disturbances acc. to IEC 61000-4-3	3 V/m 80 MHz – 2,5 GHz	$E_1 = 10 \text{ V/m @ } 80 \text{ MHz bis } 2,5 \text{ GHz}$	

Note 1: At 80 MHz and 800 MHz the higher frequency range applies.

Note 2: These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strength of stationary transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM- and FM- radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters an electromagnetic site survey should be considered. If the measured field strength in the location in which **tipstim®** is used, exceeds the applicable, before-mentioned compliance level, **tipstim®** should be monitored to verify normal operation. If abnormal performance is observed additional measures may be necessary such as re-orienting or relocating **tipstim®**.

b) For the frequency range of 150 kHz to 80 MHz field strength should be lower than 10 V/m.

**Recommended safety distances between portable and mobile HF telecommunication devices and tipstim®**

**(TAB. 206 acc. to DIN EN 60601-1-2)**

tipstim® is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. tipstim® user can help avoid electromagnetic interference by maintaining the minimum safety distance between portable and mobile HF telecommunication devices and tipstim® depending on the rated output of the transmitter as given below.

Maximum output power of the transmitter	Safety distance depending on transmission frequency in m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
W	$d = [3,5/\sqrt{V_1}] \sqrt{P}$	$d = [3,5/E_1] \sqrt{P}$	$d = [7/E_1] \sqrt{P}$
0,01	0,12	0,04	0,08
0,1	0,35	0,11	0,22
1	1,11	0,35	0,75
10	3,51	1,11	2,22
100	11,90	12,00	22,00

For transmitters whose nominal power output is not covered by a.m. table, the safety distance  $d$  can be calculated in meters (m) using the formula given in the respective column whereby  $P$  is the nominal power output of the transmitter in Watts (W) as per the information given by the manufacturer of the transmitter.

Note 1: At 80 MHz and 800 MHz the higher frequency range applies.

Note 2: These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

# WARRANTY

The legal warranty applies for **tipstim®** and for all components manufactured by Haynl-Elektronik GmbH.

The warranty claim is not applicable for defects, failures or damages which derive from non-compliance with this the instruction of use as stated in this manual and/or non-compliance with the medical expert's instructions. The warranty does not apply in the event of accidents, misuse, and interventions and changes performed by non-authorized personnel.

Should you experience any problem with the medical device or its components please refer to the manufacturer or your local dealer.

Your local dealer:



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# EXTENDED INFORMATIONS FOR MEDICAL EXPERTS

**tipstim®** is equipped with numerous functions allowing for optimizing individual therapy. The key element of these functions is the main menu.

Therapy is initialized as follows:

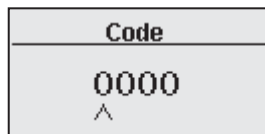
Switch on the device by pressing the "ON/OFF"-button.

After 1-2 seconds the tipstim® logo will appear on the screen.

Immediately press the "OK"-button and keep it pressed.

As soon as the menu heading "code" appears on the screen release the "OK"-button.

- Enter the access code via the selection buttons "+" and "-". The correct entry has to be confirmed by pressing the "OK"- button. The access code is available from your local dealer.



- If the entry was incorrect switch off the device and start again.

The menu is divided into the following 3 main areas:

1. Settings
2. Extras
3. Statistics



**All entries are made via the selection buttons. "+" and "-". If you keep the selection buttons pressed, the selected parameter will automatically be increased or reduced. The correct entry has to be confirmed by pressing the "OK"-button.**

# Settings

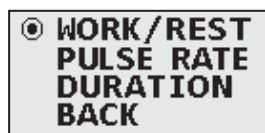
Here you can set all parameters which are relevant for the therapy.

It is possible to configure 2 programs. Program no. 1 is preconfigured for the therapy in combination with **tipstim® glove** while program no. 2 is preconfigured for the treatment of spasticity.

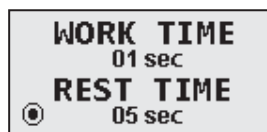
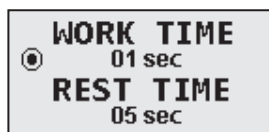
To change parameters of program no. 1: Choose menu heading "PROGRAM 1" and confirm your selection by pressing the "OK"-button.



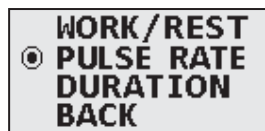
Choose menu heading "WORK/REST" and confirm your selection by pressing the "OK"-button.



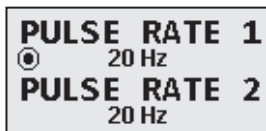
For each program "WORK TIME" and "REST TIME" can be adjusted. By pressing the selection buttons "+" and "-" you may change "WORK TIME" and "REST TIME" in seconds (sec). Confirm your selection by pressing the "OK"-button.



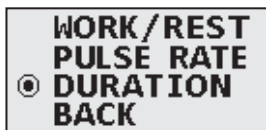
Choose menu heading "PULSE RATE" and confirm your selection by pressing the "OK"- button.



By pressing the selection buttons "+" and "-" you may change the pulse rate for channel 1 ("PULSE RATE 1") and/or channel 2 ("PULSE RATE 2") in Hertz (Hz). Confirm your selection by pressing the "OK"-button.



Choose menu heading "DURATION" to change the treatment time of one therapy session.



By pressing the selection buttons "+" and "-" you can change the duration of the therapy session ("DURATION") in minutes (min). Confirm your selection by pressing the "OK"-button.



If you want to change the parameters for program 2, choose menu heading "PROGRAM 2" and proceed as described above for program 1.

In the heading "SETTINGS" add-on options are available: An auto repeat heading ("AUTOREPEAT") to fix the current output for immediate therapy session, a heading to activate the limitation of the general maximum current output ("LIMIT on/off") and a heading to predefine the maximum current output ("LIMIT DEF.").

Choose menu heading "SETTINGS" and confirm your selection by pressing the "OK"-button.



Choose menu heading "ADVANCED" and confirm your selection by pressing the "OK"-button.



Choose menu heading "AUTOREPEAT" and confirm your selection by pressing the "OK"-button.



By pressing the selection buttons "+" and "-" you can activate ("ON") or disable ("OFF") the "AUTOREPEAT"-function. Confirm your selection by pressing the "OK"-button.

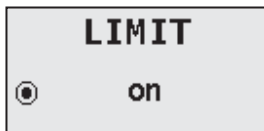


After activating the "AUTOREPEAT"-function the current intensity can be determined once at the beginning of the therapy session. The current intensity selected in the first session after activating "AUTOREPEAT" is retained for the following therapy sessions. Thereafter, when switching on the device, you have to keep the "ON/OFF"-button pressed for at least 3 seconds to activate the preset value. Otherwise the current intensity has to be regulated manually.

Choose menu heading "LIMIT on/off" and confirm your selection by pressing the "OK"-button.



By pressing the selection buttons "+" and "-" you can activate ("ON") or disable ("OFF") the "LIMIT on/off"-function. Confirm your selection by pressing the "OK"-button.





When selecting "ON" the current output of the device is limited.

You may now determine the maximum value for the current intensity. Choose menu heading "LIMIT DEF." and confirm your selection by pressing the "OK"-button



By pressing the selection buttons "+" and "-" you may change the maximum current output ("LIMIT DEF.") in milliampere (mA). Confirm your selection by pressing the "OK"-button (Factory default settings: 15 mA).



## Extras

In the menu heading "EXTRAS" you can adjust the contrast ("CONTRAST") of the OLED-display and you can switch the acoustic signals ("SOUND") on or off.

Choose menu heading "EXTRAS" and confirm your selection by pressing the "OK"-button.



Choose menu heading "CONTRAST" and confirm your selection by pressing the "OK"-button.



By pressing the selection buttons "+" and "-" you may change "CONTRAST". Confirm your selection by pressing the "OK"-button.



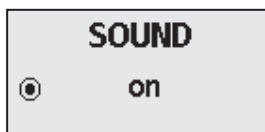
The contrast of the display is preset to 0%. This value is optimal for the OLED-display. This setting should not be changed unless absolutely necessary. Higher contrast settings may lead to premature ageing or a complete loss of the OLED-display.

The menu heading "SOUND" serves to switch the acoustic signals on or off.

Choose menu heading "SOUND" and confirm your selection by pressing the "OK"-button.



By pressing the selection buttons "+" and "-" you may activate ("ON") or disable ("OFF") the acoustic signals ("SOUND"). Confirm your selection by pressing the "OK"-button.



## Statistics

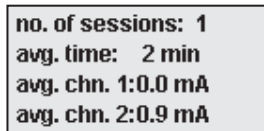
The menu heading "STATISTICS" serves to check all statistical parameters of the training sessions.

Choose menu heading "STATISTICS" and confirm your selection by pressing the "OK"-button.



Statistics displays the following information:

- Total no. of therapy sessions ("no. of sessions:")
- Average treatment time ("avg. time:") in minutes (min)
- Average current intensity channel 1 ("avg. chn.1:") in miliamperes (mA)
- Average current intensity channel 2 ("avg. chn.2:") in milliampères (mA)



Statistical values can be reset via the optionally available PTA-software or via a RESET-function. Please contact the manufacturer or your local dealer for further information.



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