

## **Interference Current Stimulation Device**





**User Manual** 

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### Warnings and safety precautions



Warning! Warnings which have to be observed by all means!



### **Caution!**

Observe the instructions for use!



#### Note!

Information that will facilitate your work.

### 1 Introduction

#### **1.1 Intended Use**

The device with interference current named **Stereodynator** is a microprocessor controlled electrical stimulus device for Electro Therapy. The wide range of usage qualifies this medical device for use in physiotherapeutic departments of clinics as well as in modern well-equipped private medical practices.

All accessories of the previous series can also be used with the new generation in the same manner. A suction application aid for vacuum therapy as well as a module for ultrasound therapy with continuous and impulse ultrasound waves are optionally available. The control elements for suction application aid and ultrasound have already been integrated in the software and can be activated by upgrading the device.

A stereodynamic interference current is generated through the superposition of three middle-frequency currents flowing in different directions. The stimulating lower frequencies are generated through interference of two phase shifted circuits in the area of superposition. The additional third circuit generates, as opposed to classical interference methods, on one side a slow change in intensity and on the other side a rhythmic shifting of the interference field. These dynamics of the stimulation location and the intensity decrease the habituation effect and therefore improve the therapeutic effect. The **Stereodynator** uses the three-dimensional interference method. The special characteristics are as follows:

- Local stimulation effect.
- Multi-site stimulation effect.
- Intensity dynamics.
- Dynamic behavior of stimulation site coupled with endogenous/exogenous stimulation shifting.

Programs improve the handling: The **Stereodynator** is equipped with several programs which automatically set the treatment frequency and the treatment time.

The stimulating effect can alternatively be administrated endogenously or exogenously. During endogenous application, the interference is generated through superposition of the electrical circuits in the body. This allows an intense effect. During exogenous application, the interference is created in the medical device. The stimulating effect takes place directly underneath the electrodes on the body surface. In addition to the three-circuit interference current, the **Stereodynator** offers a complete selection of single circuit currents for all known therapeutic procedures.

The **Stereodynator** is particularly suitable for:

- Pain therapy with three-dimensional interference current.
- Muscle toning and muscle detoning.
- Galvanization and iontophoresis.
- Pelvic floor stimulation.
- Treatment of urinary and fecal incontinence.
- Treatment of paralyses with complete or partial muscular degeneration.
- Treatment of atrophies due to inactivity or weakened muscles after longer periods of inactivity.
- Electrical stimulation therapy without electrolytic side effects and only slight muscle fatigue.
- Treatment of pain, muscle spasms, functional diseases of the locomotor system, such as sports injuries, peripheral circulatory disturbances, influencing of the vegetative system with diadynamic currents, ultrastimulation current, microstimulation current, TENS- and TENS Burst currents, high-voltage currents and middle-frequency currents.

In medical diagnosis it is suitable for:

- Qualitative and quantitative determination of faradic excitability.
- Determination of the rheobase, chronaxy and accommodability.
- Recording of stimulus intensity/stimulus time characteristics (I/T curves) with defined, measurable and reproducible rectangular and triangular pulses (exponential current).
- MF test according to Dr. Lange.
- Extensive non-invasive electro-diagnostics of peripheral paralyses.
- Neurodiagnostic examinations with galvano-palpations.

### **2 Operating Concept**

The **Stereodynator** is equipped with a touch screen display, one on/off switch, four connecting plugs for patient cables, two connecting plugs for ultrasound probes and the intensity regulator.

The **Stereodynator** is being operated via the control panel of the large touch screen. The user will obtain explanations regarding the device's operation and functionality of individual elements via a direct help system during operation. Consequently, operation is explained in broad outline only.

### 2.1 Control Panel



#### 2.1.1 Touch screen with direct help system

The touch screen should be operated with marked pressure of the fingertip. Pointed objects are unsuited for operation and can destroy the touch screen.

Every button is clearly labled. Through the optics, the user can differentiate operating buttons from non-operating buttons.

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In the case of doubt the user can obtain further information via the direct help system.

In order to adjust numerical data the arrow keys may either be pressed repeatedly or pressed constantly for automatic increase/decrease of the value.

The scrollbars are used like with a PC: press the scrollbar and then pull into the desired direction.

#### 2.1.2 Frequently used therapies

All frequently used functions are directly accessible on the front screen. To this purpose, the seven most used therapies and the three therapies applied last are listed on the right side. From here, they can directly be selected. An additional symbol indicates whether a certain therapy is being used more often (upwards arrow) and also names the type of therapy (electro therapy, stereo-, combination- or ultrasound therapy).



Figure 2 View of Touch screen display.

During daily operation, the user can thus recall typically used therapies with only one touch. Additional therapies can either be recalled according to a patient's name, i.e. via log book, or after indications or name of therapy.

#### 2.1.3 Direct help menu

The user of the **Stereodynator** is guided on the screen. The direct help menu gives information about the selected buttons.

To open the direct help menu, first touch the "?"-button on the screen and then the button about which you desire information. A new window opens where the information is shown. In order to close this window you need to touch the "X"-button.

Available buttons are indicated in light grey. Unavailable buttons are indicated in dark grey. If you push an unavailable button, information about the use of this button is shown on the screen automatically.



Figure 3: Direct help menu as shown on the display

#### 2.2 Intensity regulator

During therapy the output voltage is set with the **Intensity regulator.** It is furnished in the form of a rotor pulse generator. The current increases by turning clockwise and it is reduced by turning counter-clockwise. The current intensity is shown on the display in mA. In order to reach a certain intensity the user may have to turn the regulator clockwise for more than one rotation if necessary.

### **3** Start of Operation

#### **3.1** Transport and Assembly

The **Stereodynator** is a portable unit. To place the unit, each flat surface is appropriate. Keep a wall distance of at least 20 cm. The device should neither be placed in front of radiators nor should it be covered by pillows or blankets while in operation. The lower side of the unit must be a plane area.

For maximum usability there is a special device cart available (see chapter 11, accessories) which matches in design and function with the new **Stereodynator**. This device cart is perfect for the placement of the unit and various accessories. With the device cart the **Stereodynator** is mobile and always ready for use. For therapy it can easily be moved to the patient.

The **Stereodynator** corresponds to the regulations DIN/VDE 0750, EN 60601. It is a device of protection class I. Within the scope of the Medical Device Directive (MDD) the current stimulation device belongs to class IIa.



### Warning!

The unit is not designed to be operated in places with the inherent risk of explosions. If it is used in dangerous areas of anesthesia departments, the possibility of an explosion cannot be excluded.

If the patient and/or the patient cable is directly exposed to a radiator of a medical device for high frequency heat therapy, damage of the device or danger to the patient cannot be excluded. As a rule, a clearance distance of 3 m is sufficient.

#### 3.2 Connecting and Switch-On

The current stimulation device has been adjusted for the connection to a supply voltage of 100 to 240 V. It is not necessary to switch over the voltage – the device adjusts automatically to the right voltage.

Irrespective of the adjusted supply voltage, the device is appropriate for mains frequencies of 50 to 60 Hz.

Connect the **Stereodynator** with the mains cable to a socket with protective ground. The protective ground must work correct

The device is switched on by the main switch on the back of the device.



### Warning!

It is only allowed to connect USB-Sticks for data backup and update! *Never* connect a PC or another USB-device to this connector!

It is not allowed to use the two holder for Ultrasound probes as carrier handle!



Figure 4: Back and side view of the device

#### 3.2.1 Device Settings

You reach the device settings menu by pressing the button "settings" (see Fig. 2). In the device settings menu all settings can be performed. With the direct help function you are able to retrieve all information corresponding to the special menu item.

### 4 Therapy

The **Stereodynator** guides the user through the application of the therapy. With the direct help menu all buttons and their functions are explained directly on the screen.

On the right side of the screen therapy programs can be selected directly from this list of favourites or with the sub-menues "More Therapies" or "Indications".

First, choose the channel you want to use and then you can select the desired current type with the program lists. The direct help menu will give you information about the following steps of the therapy.



Figure 5: Touchscreen with chosen therapy program (indication)

### 5 Electrodes

Basically all standard electrodes are connectable in electrotherapy. Plate electrodes and rubber electrodes are appropriate for large-area treatments.

The electrode handpiece with fingertip switch and connecting cable is particularly suitable **to make a diagnosis**. With the switch single pulses can be started. With the handpiece also small areas can be treated. Additionally you need an electrode set.

**The therapy** can be executed without any problem with suction electrodes or plate electrodes. For each indication of the chosen therapy program you find a picture on the screen of the **Stereodynator** which shows how to apply the electrodes.

#### **5.1 Electrode Positioning**

**The positioning of the patient** and/or muscle to be treated is very important. The therapy shall always be carried out in a comfortable and relaxed position. The joints shall be placed in an angular position, in a mid-position, from which both the flexor as well as the extensor muscles can be stimulated.

In general the preparation and application of the electrodes is carried out as follows:

- 1. Always put a wet electrode intermediate layer or electrode pocket between the electrode and the skin in order to avoid current sensations on the skin. The layer must always be about 1 cm larger than the electrode itself.
- 2. Put the electrode completely into the electrode pocket, so that the pocket protrudes on the open side with about 1 cm.
- 3. After multiple use the electrode intermediate layer or electrode pocket can slightly shrink. If the distance of about 1 cm is no longer given, the intermediate layer or pocket must be replaced.
- 4. Prior to the initial use, the macroporous intermediate layers and pockets made of viscose sponge must be thoroughly washed out under running water to remove manufacturing residues.
- 5. To moisten the intermediate layer or pocket put them into normal tap water, or better into 1% salt solution. The intermediate layers or pockets should be soaked, then removed and dropped; do *not* wring them out.
- 6. If necessary, flatten deformed electrodes, insert them into the pocket and/or put them on the intermediate layer. Place them on the area to be treated and fit them to the given body surface. Use only thick and well moistened sponges.
- 7. Apply the holding strap in such a manner that the electrode fits perfectly.
- 8. The sponge pockets or intermediate layers have to be cleaned after the expiration of treatment, (*see chapter 7.2.3*).

#### Note!

The above mentioned applies for the application of suction electrodes accordingly.!



## Warning!

- Do not apply the electrodes on injured skin. Even minor abrasions can cause a burning to the patient. Herewith the intensity of current by the patient can be erroneously judged. If a treatment cannot be avoided, apply zinc ointment to cover.
- It is recommended not to exceed the current density of 2 mA/cm<sup>2</sup> in all electrode surfaces. In case of galvanization the limiting value is 0.2 mA/cm<sup>2</sup> and in case of iontophoresis it is 0.1 mA/cm<sup>2</sup>.
- Do not use disposable (self adhesive) electrodes in case of currents with galvanic portion, there is the danger of acid burns!!

#### 5.1.1 Monophase Electrode Techniques

In case of monophase techniques, direct and indirect stimulation are distinguished. Generally the cathode is used as a stimulating electrode. In case of direct stimulation it is applied on the nervous stimulant point (all muscles react) and in case of indirect stimulation on the muscle stimulant point (only the stimulated muscle reacts). Apply the electrolytically inactive electrode (mostly a large anode) distally.

For differentiated therapeutic treatments and easy electro-diagnostics it is recommended to use the electrode handpiece as an electrolytically active electrode.

#### 5.1.2 Biphase Electrode Techniques

A characteristic of this method is that both (mostly equally large) electrodes are applied on the muscle to be stimulated or on the functionally related muscle group. The cathode is to be placed distally.

#### **5.2 Single-Pole Electrodes**

The use of single-pole electrodes is applicable for all therapy currents. For large-area treatment we recommend the use of plate electrodes, for all other applications the use of self-cut electrodes. The last-mentioned need an electrode connector for current supply. Both electrode types have to be connected to the device with a patient cable.

The electrode size depends on the area that should be passed by the current. Under small electrodes the current flow will be more concentrated and more localized than when applying large electrodes. The application area depends on the clinical picture.



### Warning!

As far as current types are concerned for which there exists the threat of cauterization (currents with galvanic portion), the maximum recommended current density is  $0.5 \text{ mA/cm}^2$  electrode surface. In case of galvanization the limit value is  $0.2 \text{ mA/cm}^2$  and in case of iontophoresis  $0.1 \text{ mA/cm}^2$ .

Electrode	Surface	Max. Current / Galv / Iontophoresis
Conductive rubber electrode	$12 \text{ cm}^2$	24 mA / 2.4 mA / not useful/
3 cm x 4 cm		1.2 mA
Conductive rubber electrode	$48 \text{ cm}^2$	96 mA / 9.6 mA / not useful/
6 cm x 8 cm		4.8 mA
Conductive rubber electrode	$96 \text{ cm}^2$	192 mA / 19.2 mA / 9.6 mA
8 cm x 12 cm		
Plate electrode	$108 \text{ cm}^2$	216 mA / 21.6 mA / 10.8 mA
9 cm x 12 cm		

Table 1: Maximum Current of conductive rubber electrodes and plate electrodes

#### 5.3 Three-pole electrodes

The triple-pole electrodes can be used for stereodynamic interference currents.

The conductive rubber electrodes of the three circuits are placed in two flexible three-pole star electrode sets (I and II) and are attached to a common patient cable. There are three sizes available (small, standard and large). Electrode pockets are necessary for the application and fixing material for the bandage (*see chapter 11 Accessories*).

Each stereodynamic electrode set is placed into a well moistened pocket so that the black conductive rubber electrodes face the humidity carrier.

#### **Electrode position:**

- A) If the electrodes are placed opposite to each other (**transverse current flow, transregional**) the cable connections must point at the opposite direction.
- **B**) If the electrodes are placed on one side (**longitudinal current flow**), their cables must point at the same direction.

Only if these electrode positions are followed, the flow paths of current of the three circuits can transpose and optimal stereodynamic stimulation currents are generated.

In special cases (e.g. depending on the application in the case of shoulder-arm syndrome) it is possible to deviate from this general rule.

You can also use triple-pole suction electrodes if your device is equipped with a suction application aid. This also applies to the application with suction electrodes.



#### **5.4 Suction Electrodes**

Instead of the above-mentioned electrodes, suction electrodes can be used for faster application. Depending on the device configuration, the suction application aid is either optional or standard (part no. 025-0-1000-V or 025-0-1000-UV).



### Warning!

- For current types for which there exists the threat of cauterization (currents with galvanic portion), the maximum recommended current density is 0.5 mA/cm<sup>2</sup> electrode surface. In case of galvanization the limit value is 0.2 mA/cm<sup>2</sup>.
- In case of iontophoresis do not use suction electrodes.

Suction electrode	Surface	Max. current value / Galv
Electrode plate, small	$10 \text{ cm}^2$	20 mA / not useful/
(Sponge = $\emptyset$ 36 mm)		2 mA
Electrode plate, standard	21 cm <sup>2</sup>	42 mA / not useful/
$(\text{Sponge} = \emptyset 52 \text{ mm})$		4,2 mA
Electrode plate, large	40 cm <sup>2</sup>	80 mA / 8 mA
(Sponge = $\emptyset$ 72 mm)		

 Table 2: Maximum current of the suction electrodes

#### **5.5 Electrode Handpiece**

The electrode handpiece is made for small, local treatments and simple electrodiagnostics. The electrode handpiece (electrolytically active electrode) is firmly connected to the patient cable. With a second wire the plate electrode is connected (electrolytically inactive electrode). In addition an electrode set is required consisting of metal shaft, electrode pockets and rubber rings.

The following procedure is advisable:

- 1. Connect the electrode handpiece.
- 2. The electrode handpiece will be recognized by the device.

Note!



### 6 Ultrasound Therapy Module

Depending on the device configuration, the ultrasound therapy module is either an optional or a standard device (part no. 025-0-1000-U or 025-0-1000-UV). With the Ultrasound probe either Ultrasound therapies as also combination therapies with Ultrasound and current can be done.



#### Note!

- The ultrasound frequency can be changed to 1 or 3 MHz.
- The frequency for pulsed mode is 100 Hz.
- The selectable parameters are continuous or pulsed mode 1:1, 1:2, 1:5, 1:10 or 1:20.
- The coupling status of the probe is shown by an LED on the probe housing and also as a graphic illustration on the display. The LED will be off in case of insufficient coupling. The LED will be on in case of good contact.
- As a standard setting the ultrasound power is shown in W/cm<sup>2</sup> on the display.



### Warning!

- Do not forget the contact gel!
- The ultrasouns probe is to be treated with care. External influences such as a mechanical shock or impact can alter the characteristics of the ultrasound probe. We recommend to carry out a visual examination at least once a year to check for fissures that would allow liquids to soak in, as well as to make sure that the cables and connectors are flawless.

	Power for				
	$5 \text{ cm}^2 \text{ u}$	ltrasound probe	$2.5 \text{ cm}^2$ ultrasound probe		
1 MHz	<b>0.5</b> to 15 W	<b>0.1</b> to 3 W/cm <sup>2</sup>	<b>0.1</b> to 7.5 W	<b>0.1</b> to 3 W/cm <sup>2</sup>	
3 MHz	<b>0.1</b> to 7.5 W	<b>0.1</b> to 1.5 W/cm <sup>2</sup>	<b>0.1</b> to 2.5 W	<b>0.1</b> to 1.5 W/cm <sup>2</sup>	

Table 3: Setting options of the ultrasound power, increments are shown in bold.



### Note!

Unless the ultrasound probe is coupled to the patient, no therapy time will pass. When the probe is coupled again, the therapy time will resume. Hence, the ultrasound probe can be removed during the treatment.

!!

### Note!

The Ultrasound probe can be exchanged. After switching on the unit or respectively after plugging the Ultrasound probe each probe will be calibrated individually.

### 7 Maintenance

Functionality, reliability and safety characteristics of the **Stereodynator** are guaranteed only upon handling the device in accordance with the operating instructions. Safety control, maintenance work, repair work and modifications must only be carried out by the manufacturer or by service agents authorized by him. In case of a failure, parts which influence the safety of the device must only be replaced by original spare parts of the manufacturer. The electric installation must correspond to the requirements in accordance with VDE/IEC. **The device does not contain any parts which need maintenance work done by the user.** 

#### 7.1 Safety Controls

The device is subject to the provisions of the Medical Device Directive. The safety controls have to be carried out on the basis of this directive. Thereby, the operator regulation has to be observed in particular.

Irrespective of the legal rules or beyond the scope of the Medical Device Directive, it is recommended to have the device checked by the manufacturer or by a service agency authorized by him at 12- months intervals.

The check shall consist of at least the following criteria:

- Electrical safety check in accordance with the test plan of the manufacturer.
- Check of the device in respect of external integrity.
- Check of all display and operating elements in respect of damages.
- Check of all inscriptions in respect of legibility.

#### 7.2 Cleaning, Disinfection and Care

#### 7.2.1 Cleaning of the Device

For cleaning and disinfection of the current stimulation device and its accessories (except electrode fleece, electrode pockets or felts, (*see chapter 7.2.3*) there should not be used any agents containing higher portions of phenol derivatives, alcohol, compounds of chlorine or peracetic acid. It is recommended to use disinfectants on aldehyde basis. Never use an abrasive. Fingerprints on the touchscreen should be cleaned with a dry cloth or some isopropanol.

The device is not suited for heat sterilization or for sterilization with gases.



### Warning!

# Prior to cleaning or disinfection unplug the mains plug out of the socket!

The current stimulation device is suited for wiping disinfection. Make sure that no liquids soak the device. Under no circumstances the plug or socket must get wet. Do not sprinkle the device for cleaning or disinfection.

#### 7.2.2 Cleaning of the Electrodes

You can clean the electrodes after a treatment by using some warm water. Dry the electrodes with a cleaning tissue or let them air-dry.



#### Note!

The conductivity of the electrodes is optimized by the use of a certain amount of graphite. Consequently, when using and cleaning the electrodes, black colour may come off.

#### 7.2.3 Cleaning of the Electrode Sponges and Electrode Pockets

- 1. Put the material into neutral soap-suds and rub it slightly. If necessary, disinfect with disinfectant solution, but do *not* put it into it.
- 2. Leave the parts in the neutral soap-suds or tap water over night.
- 3. Take them out and wash them several times thoroughly under cold or warm running water.
- 4. Let them drain but do *not* wring them out.

### 8 Warnings and Safety Precautions



### Warning!

- For patients with implanted electronic device electrical stimulation treatment is to be carried out only after having checked any risks.
- Jewellery and eyeglasses have to be taken off during the treatment.
- Turn off cellular phones and radiophones or place them in a distance of 3 m from the device.
- Cardiac pacemakers are extremely vulnerable. Here the therapy should only be carried out under continuous pulse and ECG control.
- If the patient and/or the patient cable is in the direct range of a high-frequency, short-wave or micro-wave therapeutic device, a damage to the device or an injury to the patient cannot be excluded. Please keep a clearance distance of 3 m.
- A simultaneous connection of the patient to a high-frequency surgery device can lead to burns under the electrical stimulus electrodes.
- It is recommended not to exceed the current density of 2 mA/cm<sup>2</sup> on all electrode surfaces.
- For current types with the threat of cauterization (all currents with galvanic portion), the maximum recommended current density is  $0.5 \text{ mA/cm}^2$  electrode surface. For galvanization the limit value is  $0.2 \text{ mA/cm}^2$  and for iontophoresis  $0.1 \text{ mA/cm}^2$ .
- Do not use disposable (self adhesive) electrodes with currents with galvanic portion since there is the threat of cauterization!!
- The unit is not designed to be operated in places with the inherent risk of explosions. If it is used in dangerous areas of anesthesia departments, the possibility of an explosion cannot be excluded.
- In case of short circuit the lithium battery, the battery can explode. Only service staff should change the battery.
- In case of any visible failure contact gbo Medizintechnik AG or one of the service agencies authorized by gbo Medizintechnik AG immediately.

#### 8.1 Contraindications for use of ultrasound

An exact diagnosis must be made before the therapy is started. The diagnosis determines the specific treatment with ultrasound.

Regardless of the low dosage and the relatively wide field of application, distinct contraindications have become evident. The "harmfulness" frequently discussed in the literature is of secondary importance, because no organic damage can be caused with the stated low dose, provided that the static exposure to ultrasound is avoided.



### Warning!

#### Ultrasound is contraindicated in case of:

- Changes to the skin, particularly with infectious diseases and birthmarks
- Tumorous diseases of all stages
- Feverish conditions
- Poor general condition and general atrophy
- Active tuberculosis, regardless of stage and localization
- Acute inflammations
- Stomach ulcers
- Following recent Thoriam-X treatment, X-ray depth treatment
- Diabetes mellitus
- Pregnancy
- Vascular diseases of the extremities (thrombophlebitis, thrombosis, varicosis)
- Disorders of coagulation of blood
- Acute joint rheumatism.



### Warning!

In addition to this group of diseases one should aim to exclude certain organs from a direct treatment. **Do not expose the following organs to direct treatment:** 

- Eyes, brain and spinal marrow
- Laminectomy-related spinal incisions
- Anaesthetised areas
- Heart and lungs
- No exposure to heart segments with functional heart complaints.
- No exposure to the epiphysis zones of children.

### Note!

• This list is not exhaustive. In individual cases the attending doctor should decide on contraindications and criterias for the treatment.

• In case of all visible failures contact gbo Medizintechnik AG or one of the service agencies authorized by gbo Medizintechnik AG immediately.



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### **10 Technical Data**

Mains voltage and frequency:	100 – 240 V, 50-60 Hz				
Power consumption*:	max. 200VA				
Mains fuse :	T 5A L 230V				
Output current:	max. 125 mA <sub>neak</sub>				
Output voltage:	max. 200 V				
MDD device class:	IIa				
Protection against ingress of:	I acc. to IEC 601 / V	DE 0750			
Protection class:	BF acc. to IEC 601				
Protection degree:	IP X0				
Dimensions*:	max. 35 cm x 29 cm x	x 35 cm (W x H x D)			
Weight*:	max. 13 kg without a	ccessories			
Color:	Aluminium nature an	odized and grey RAL 7016			
Display:	15" TFT LCD Touch	screen			
Battery:	CR 2032				
environmental conditions:	operation of the	temperature range +10 °C +40 °C			
	device:	relative humidity of air 30 75 %			
	transport and	temperature range +5 °C +50 °C			
	storage:	relative humidity of air $< 90$ %, non condensing			
Current types:	See chapter 10.1	· · · · · · · · · · · · · · · · · · ·			
	Carrier Frequency	2kHz – 10kHz Sinus wave			
	Low frequency	0.1Hz – 200Hz			
	Accuracy	± 10%			
Therap.ultrasound module:	Continuous and pulse mode 1:5, 1:10, 1:20				
Ultrasound frequency:	1/3 MHz				
Ultrasound power:	max. 3 W per 1 $cm^2 r$	adiating surface at 1 MHz			
	max. 1.5 W per 1 $\text{cm}^2$ radiating surface at 3 MHz				
Ultrasound probe:	e: $2.5 \text{ cm}^2 \text{ and } 5 \text{ cm}^2 \text{ radiating surface}$				
	Accuracy $\pm 10\%$				
Suction application					
Suction:	At least 180 mbar in maximum position				
Suction massage frequency:	cv: 0 - 30 pulses per minute				

\*) dependent on the device type and/or whether the device is equipped with therapeutic ultrasound modules and suction application modules.

By request of technical personnel gbo Medizintechnik can offer spare part lists and circuit diagrams.

gbo Medizintechnik AG reserves the right to modify design and specifications without prior notice.

#### **10.1 Current types**

The **Stereodynator** offers a large variety of current types for therapy. For details see the direct help menu on the display of the device. The following current types are available as therapeutic programs with the **Stereodynator**:

Current	Graphics	Pulse duration	Pause duration	D.C. portio	Frequen cy	Max. output	Max. output
		T in ms	R in ms	n in %	in Hz	Voltage Vpeak	current mApeak
Diadynamic currents							
CP (Courtes périodes)				47.25	50 / 100	200	80
CP-id (MF-part lowered)				45	50 / 100	200	80
DF (Diphasé fixe)				63	100	200	80
LP (Longues périodes)				46	50/100	200	80
MF (Monophasé fixe)				31.5	50	200	80
MM (Monophasé modulé)				20	100	200	80
RS (Rhythme syncope)				15.25	50	200	80
Pulsed							
Galvanic current	1 1 1 1 1 1 1 1 1 1 1 1 1 1			100	0	70	70'
High voltage		0.02 - 0.06	5 ms – 1 s	0	1 – 200	200	80
Impulse galvanization IG 30	↓ 30 ms 50 ms 30 ms	30.0	50.0	18	12.5	200	80
Impulse galvanization IG 50	50 ms 70 ms 50 ms	50.0	70.0	0.3	8.3	200	80
Frequency modulation FM / 7 – 14 Hz		1	70.9 – 142.4	0.4	7 - 14	200	80
Micro current biphasic		2,5 - 166	2,5 - 166	0	3 – 200	200	80

### Stereodynator

Current	Graphics	Pulse duration T in ms	Pause duration R in ms	D.C. portio n in %	Frequen cy in Hz	Max. output Voltage Vpeak	Max. output current mApeak
Mikro current monophasic		2,5 - 166	2,5 - 166	50	3 – 200	200	80
Faradic current	1 ms 19 ms 1 ms	1.0	19.0	2.6	50	200	80
Ultrastimulation current		2	5	28.6	143	200	80
TENS biphasic	÷.	0.02 – 0.2	5 - 1000	0	1 - 200	200	80
TENS monophasic		0.02 – 0.2	5 - 1000	max 3.8	1 - 200	200	80
TENS Burst biphasic		0.02 - 0.2	5 - 1000	0	1 - 200	200	80
TENS Burst monophasic		0.02 - 0.2	5 - 1000	max 3.8	1 - 200	200	80
Middle frequency current 8 kHz Russian Stimulation (Kots)	1 1 2.5 bit:	1 - 1000	1 - 1000	0	0.5 - 200	200	80
Gym Current	↓ 200 400 200 ms ms ms t		1 - 10	0	0 - 200	200	80
MF sinus modulated				0	0.1 – 200	200	80
Interference							
Interference				0	0.1 – 200	200	80
Dipol Vector				0	0.1 – 200	200	80
Isoplanar Vector				0	0.1 - 200	200	80
Stereodynamic Interference currents							
Stereodyn. Interference				0	0.1 – 200	200	80

Current	Graphics	Pulse duration T in ms	Pause duration R in ms	D.C. portio n in %	Frequen cy in Hz	Max. output Voltage Vpeak	Max. output current mApeak
3 Channel currents							
Gym Burning Mode					0.1 – 200	200	80
Gym Current			1 - 10		0.1 - 200	200	80
Diagnoses							
Monophasic (T/R) single pulse mode		0.2 - 2000				200	80
Biphasic (T/R) single pulse mode		0.2 - 2000				200	80
I/T-Curve		0.2 - 1000				200	80
Rheobase/ Chronaxe		0.2 - 1000				200	40/80
MF-Test acc. to Dr. Lange	1 300 ms					200	80

Impedance: 50 – 5000 Hz Carrier frequency: 2 – 10 kHz sinusoidal

### 11 Accessories

For the **Stereodynator** we offer a large variety of accessories.

specification	part number
Standard accessory kit for Stereodynator®	45-38-260EH719
Electrode set, 10 pockets, 2 rubber straps small, 2 rubber straps	
large, 4 fixing buttons	
Therapy set 2 for Stereodynator <sup>®</sup>	45-39-169EH725
Patient cable, 2 rubber electrodes,	
2 elastic straps with velcro fastener, 10 sponge pockets	
Suction electrode set single pole standard for Stereodynator <sup>®</sup>	45-38-500EH722
diameter 50 mm	
STEREO-suction electrode set 3 circuits for Stereodynator <sup>®</sup>	45-38-856EH722
STEREO-suction electrode I, STEREO-suction electrode II,	
paper sheets (100 pcs)	

For detailed information see the enclosed brochure "Stereodynator and accessories". This brochure is also available as a pdf-file by download on our website <u>www.gbo-med.de</u>.

The following versions of the **Stereodynator** are available:

specification	part number
Stereodynator <sup>®</sup>	025-0-1000
Stereodynator <sup>®</sup>	025-0-1000-U
incl. ultrasonic therapy module,	
incl. 1 ultrasonic transducer 5 cm <sup>2</sup> , incl. 1 contact gel, 250 ml	
Stereodynator <sup>®</sup> incl. suction application aid	025-0-1000-V
Stereodynator <sup>®</sup>	025-0-1000-UV
incl. ultrasonic therapy module,	
incl. 1 ultrasonic transducer 5 cm <sup>2</sup> , incl. 1 contact gel, 250 ml	
and incl. suction application aid	
Device cart for <b>Stereodynator</b> <sup>®</sup>	026-0-1000



Figure 7:

**Stereodynator** with accessories and device cart

### 12 Troubleshouting

Each problem that occurs during operation of the unit will be shown in a message window on top of the display and also signalized by an acoustic tone. Most of the problems can be solved by the instructions displayed.

In general:

- 1. The malfunction is shown on the display.
- 2. An acoustic signal is heard.
- 3. Follow the instructions on the display.

Suggestions:

- Turn off and turn on the unit.
- A full selftest of all device functions is performed and the unit is reinitialized. If the unit does not come up to normal state, please call your local service.

#### **12.1 Further errors**

symptom	cause and action
Device cannot be switched on, no display shown.	Please check the main plugs and sockets. If necessary; contact your service agents or the manufacturer.
No acoustic signal is heard. (End of therapy)	Please check the settings of the acoustic tones in the menu. The volume must be greater than 0.

Please contact your service agent or the manufacturer if the problems cannot be solved by the measures mentioned above.

Please note that the unit must be placed on a plane horizontal surface. The device should neither be placed in front of radiators nor should it be covered with pillows or blankets while in operation. Do not cover the ventilation slots on the bottom of the unit either.

### 13 Appendix

#### **Comments According to the Medical Device Directive**

The Stereodynator is a mains operated current stimulation device of protection class I.

The device is in accordance with the EC Medical Device Directive (93/42/EEC) and therefore carries the CE-sign with the number of the "notified body for medical devices". The respective graphical symbol is placed on the type plate.

According to the Medical Device Directive, Stereodynator is a device of class IIa.

The manufacturer is only responsible for the security, operational reliability and functionality of the device if:

- the device is used in accordance with the user manual;
- the electrical installation of the location where the device will be used corresponds to the respective current requirements of electrical safety;
- the device is not used in hazardous environments and humid locations;
- the mountings, add ons, internal adjustments, modifications or repairs are realized only by personnel authorized by the manufacturer;
- the operator regulation of this EC-directive is observed within the scope of the Medical Device Directive.

You may obtain technical support by the manufacturer or the dealers or service authorized by the manufacturer. The manufacturer projects a product life of 10 years.

**Stereodynator** is an electronic device. Disposal has to be done according to regulations for electronic devices. Consumables have to be disposed as residual waste.

On request, the manufacturer will provide you with further technical descriptions for all serviceable parts of the device, such as circuit diagrams, spare part lists and adjustment instructions as far as these are of use for the qualified technical staff of the user.

#### Comments on electromagnetic compatibility (EMC)

Medical, electrical devices are subject to special precautions concerning the EMC. They must be installed and operated according to the EMC-advice given in the accompanying documents. In particular medical, electrical devices may be influenced by portable and mobile RF-communication devices.

The manufacturer guarantees the conformity of the unit with the EMC-requirements only when using accessories which are listed in the EC declaration of conformity. The usage of other accessories may cause an increased emission of electromagnetic disturbances or may lead to a reduced electromagnetic immunity.

The unit must not be arranged physically close to other devices or stacked with them. If such an order is necessary nevertheless, the unit must be observed in order to check it for the intentional operation.

You find more EMC-comments in the chapter "Warnings and Safety Precautions" of this manual as well as in the Technical Information on the next two pages.

#### In accordance with the EMC-regulations for medical products we are obliged by law to provide the following information.

#### Guidance and manufacturer's declaration — electromagnetic emissions

The equipment is intended for the use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure the compliance with this stipulation

or the equipment should ensure the compliance with this supration				
Emissions test	Compliance	Electromagnetic environment – guidance		
RF emissions,	Group 1	The equipment uses RF energy only for its internal function. Therefore,		
CISPR 11		its RF emissions are very low and are not likely to cause any interference		
		in nearby electronic equipment.		
RF emissions,	Class B	The equipment is suitable for use in all establishments, including		
CISPR 11		domestic establishments and those directly connected to the public low-		
Harmonic emissions,	Class A	voltage power supply network that supplies buildings used for domestic		
IEC 61000-3-2 (*)		purposes.		
Voltage fluctuation/flicker	complies			
emissions, IEC 61000-3-3 (*)	-			
(*) Note: For devices with a power consumption between 75 W and 1000 W only.				

#### Guidance and manufacturer's declaration — electromagnetic immunity

of the acuinment should and	ure the compliance with the	is stipulation	ented below. The customer of the use
Immunity test	IEC 60601- test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD), IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact       ±8 kV air	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst, IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	$\pm 1 \text{ kV}$ for input/output lines	±1 kV for input/output lines	
Surge, IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital
	±2 kV common mode	±2 kV common mode	environment.
Voltage dips, short interruptions and voltage variations on power supply input lines,	<5% U <sub>\u03c0</sub> for ½ cycle (>95% dip)	<5% U <sub>\tau</sub> for <sup>1</sup> / <sub>2</sub> cycle (>95% dip)	Mains power quality should be that of a typical commercial or hospital environment.
IEC 01000-4-11	$\begin{array}{l} 40\% \ U_{\tau} \\ for 5 \ cycles \\ 60\% \ dip) \end{array}$	40% U <sub>τ</sub> for 5 cycles 60% dip)	If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an
	$\begin{array}{l} 70\% \ U_{\tau} \\ for \ 25 \ cycles \\ 30\% \ dip) \end{array}$	$\begin{array}{l} 70\% \ U_{\tau} \\ for \ 25 \ cycles \\ 30\% \ dip) \end{array}$	uninterruptible power supply or a battery.
	$<95\% U_{\tau}$ for 5 s (>5% dip)	<95% U <sub>\tau</sub> for 5 s (>5% dip)	
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should b at levels characteristic of a typical location in a typical commercial or hospital environment.

#### Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for the use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure the compliance with this stipulation.

Immunity test	IEC 60601- test level	Compliance level	Electromagnetic environment –
			guidance
			Portable and mobile RF communications
			equipment should be used no closer to any
			part of the equipment, including cables, than
			the recommended separation distance
			calculated from the equation applicable to the
			frequency of the transmitter.
			Recommended separation distance:
Conducted RF,	3 V <sub>rms</sub>	3 V <sub>eff</sub>	d=1.2√P
IEC 61000-4-6	150 kHz to 80 MHz		
Radiated RF,	3 V/m	3V/m	$d=1.2\sqrt{P}$
IEC 61000-4-3	80 MHz to 2.5 GHz		for 80 MHz to 800 MHz
			d=2.3√P
			for 800 MHz to 2.5 GHz
			Where P is the maximum output power rating
			of the transmitter in watts according to the
			transmitter manufacturer and d is the
			recommended separation distance in meters
			(m).
			Interference may occur in the vicinity of
			equipment marked with the following
			symbol:
			(())

# Recommended separation distances to portable and mobile RF communication equipment

The equipment is intended to be operated in an electromagnetic environment where radiated RF interference is controlled. The user can help to avoid interferences by meeting the minimum separation distances between portable and mobile RF communication equipment (transmitters) according to the maximum output power of the communication equipment.

Rated power of the	Separation distance according to the tranmission frequency (m)			
transmitter (W)	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
	d=1.2√P	d=1.2√P	d=2.3√P	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

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