stimulette den2x

for denervated muscles

OPERATING INSTRUCTIONS
for the
ELECTROTHERAPY DEVICE

Stimulette den2x

Revision C

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1 GENERAL INFORMATION

1.1 Description of device

The **stimulette den2x** is a compact, high-performance two-channel electrotherapy device **to be used exclusively for denervated muscles**. It features the latest microcontroller technology, a graphic LCD and simple operation by touch sensors.

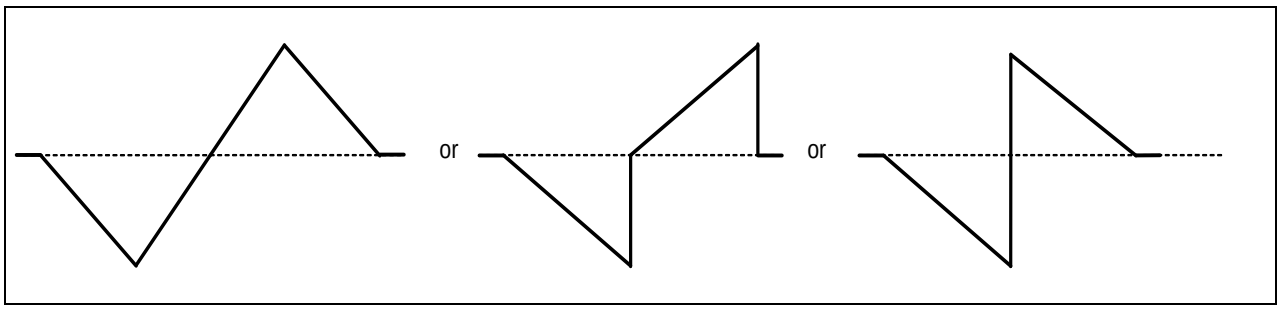
!WARNING!
The current limits (effective value limits) stipulated by the norms are exceeded for reasons of the medical benefit. This stimulator can put out a current of up to **±300mA, without a DC component**. However, the implemented redundant safety system fulfills all other requirements of the medical technology standard.

Up to **12 individual biphasic current waveforms** can be programmed and assigned to function keys. The creation of these current waveforms is, by a user friendly self-explanatory menu design, uncomplicated, and does not require extensive schooling.
Ramp currents and rectangular current waveforms with envelope may be chosen. The frequency or the behavior of the desired current waveform over time is adjusted by various time parameters (rise time, decay time, impulse duration, interpulse interval, etc.).

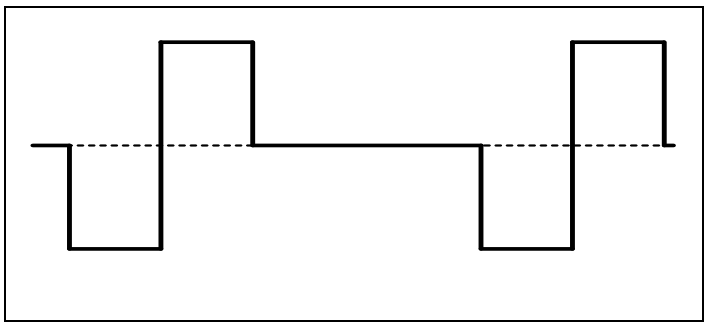
The simple and solid design provides for maximum ease of use.

The following demonstrates available current waveforms.

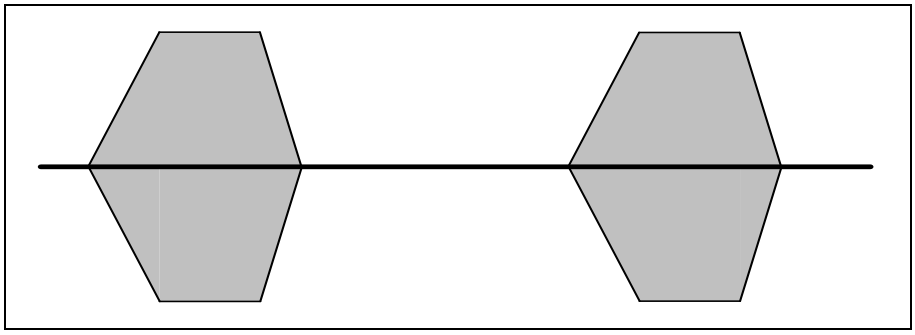
Ramp



Rectangle



Envelope (surge) for both current waveforms



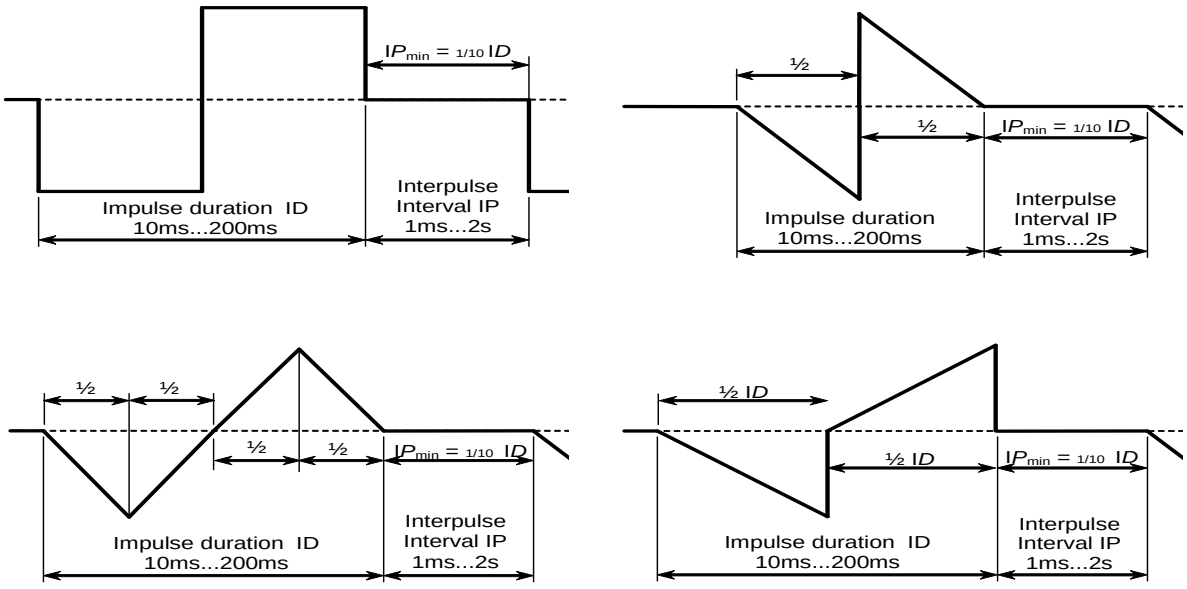
1.2 User programmable current waveforms

The adjustments of the user programmable current waveforms are made after selection of key PS1 through PS12 and subsequent selection of the parameters, see item 3.3.

Impulse duration always consists of a negative impulse followed by a positive impulse. This means the entire duration of the biphasic impulse sequence. Only biphasic current waveforms can be programmed.

The following parameters are programmable:

- Impulse amplitude: max. 300mA
- Impulse waveform: Rectangle/ ramp (3 different waveforms)
- Impulse duration ID: 10msec.....200msec
- Interpulse interval IP: 1msec.....2sec
  IP ≥ 1/10 ID



It is not possible to program an interpulse interval that is shorter than ¼ of the impulse duration (only steps of 5 are possible).

Impulse data:

The following table shows the **limits** of adjustment and the resulting impulse energy of one pos. or neg. single pulse. These maxima occur **with rectangular currents** and are calculated with a 330 Ohm reference resistor. When using ramp currents of the same frequency, less energy is generated.

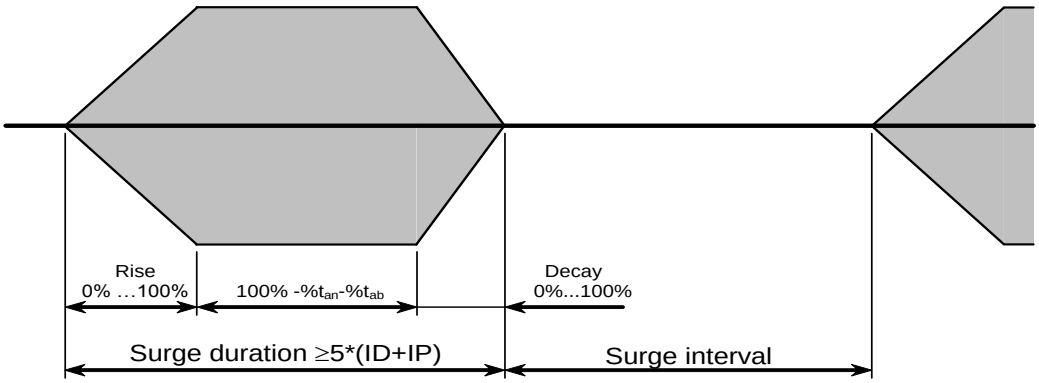
Single impulse duration (pos. or neg. impulse)	Interpulse interval	Frequency	Current intensity	Singel impulse energy (pos. or neg. impulse)
5 msec	10 msec	50 Hz	300 mA	148.5 mJ
100 msec	2000 msec	0.45 Hz	300 mA	2.97 J

Surge:

- Surge duration: 100msec.....11sec
- Rise: 0% ... 100% surge duration
- Decay: 0% ...100% surge duration
  The sum of rise and decay cannot be set to exceed 100%
- Surge interval: 0msec.....11sec

Please note that the range for adjusting the surge parameters is calculated based on the selected impulse duration and interval as follows, and is automatically adjusted:

- Surge duration ≥ 5 x (impulse duration + interpulse interval)
- Surge interval ≥ surge duration

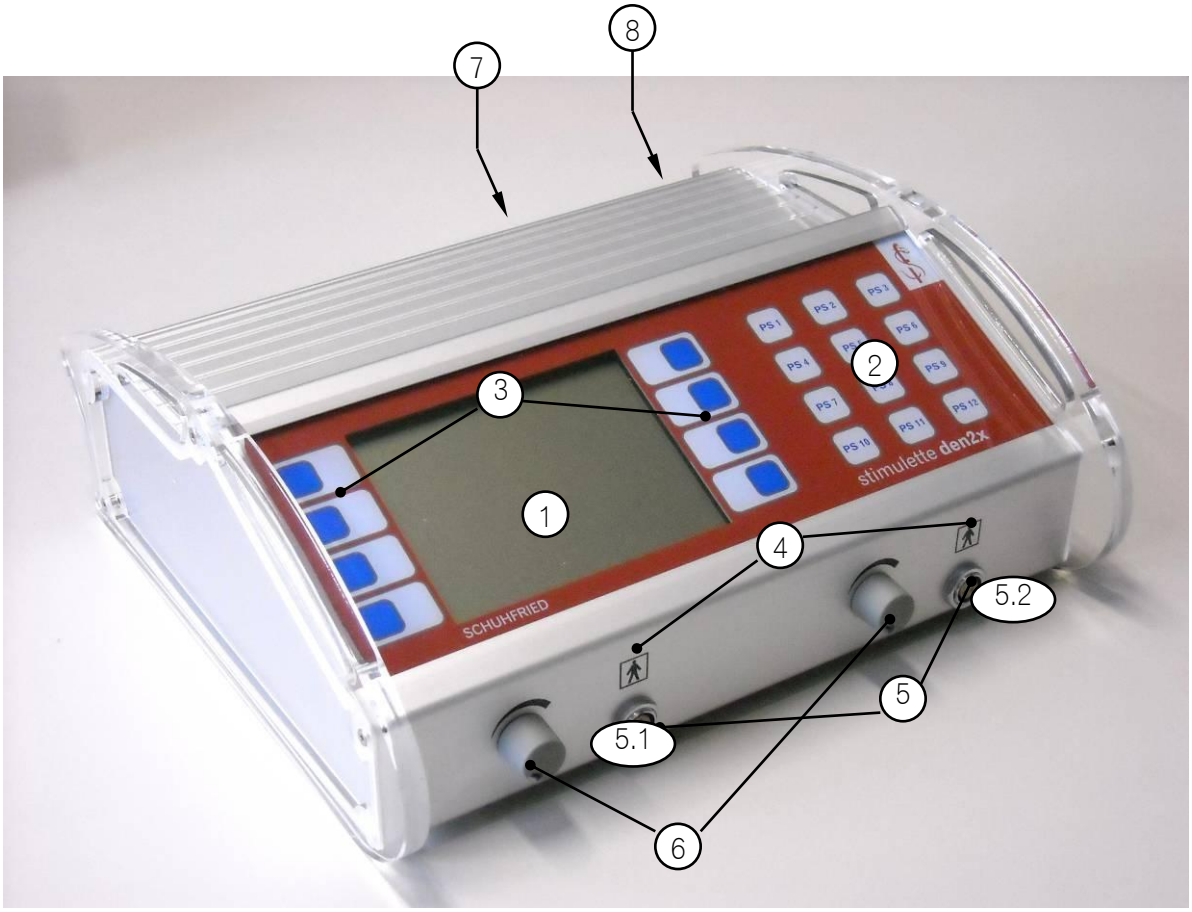


The range of steps for the respective ranges of time periods is defined as follows:

- 10msec .... 200msec→ steps of 5msec
- 200msec ..... 1sec→ steps of 50msec
- 1sec ..... 11sec→ steps of 1sec

1.3 Description of hardware

1.3.1 Picture of device



① Multifunction display
② Current waveform keys
③ Keys for further adjustments
④ Warning “Degree of protection against electric shock BF”
⑤ Patient connector socket
  5.1 Channel 1
  5.2 Channel 2

⑥ Intensity control
⑦ Device identification plate (on back of device)
⑧ Power switch and fuse box (on back of device)

① Multifunction display

The multifunction display (backlit LCD module) allows for good readability from various visual angles and under various light conditions. The multifunction display shows the following information:

- Status signal after switching on
- Error messages
- Selected current waveform
- Impulse sequence
- Current peak value
- Treatment period
- Impulse bar display

② Current waveform keys

The desired programmed current waveform is adjusted with the current waveform keys. The present current waveform is indicated on the display.

③ Keys for further adjustments

With these keys, various selections can be made, depending on the menu item. The respective function is always shown in updated form on the display. If a function is not defined on the display at this point, the respective key is not assigned in this menu item.

④ Warning “Degree of protection against electric shock BF”

This symbol indicates that the device has an isolated (ungrounded) part in its application (patient’s electrical circuit), and is therefore running in the “Body floated – BF” mode.

⑤ Patient connector socket

The patient connector socket serves to connect the patient cables to the device.
The electrode with the red lead is the positive pole, the one with the yellow lead is the negative pole.
After a negative impulse, a positive impulse is emitted immediately.

⑤.1 Channel 1
⑤.2 Channel 2

⑥ Intensity control

The intensity control serves to start and terminate the treatment, as well as to adjust the peak intensity of the therapeutic current.

⑦ Device identification plate

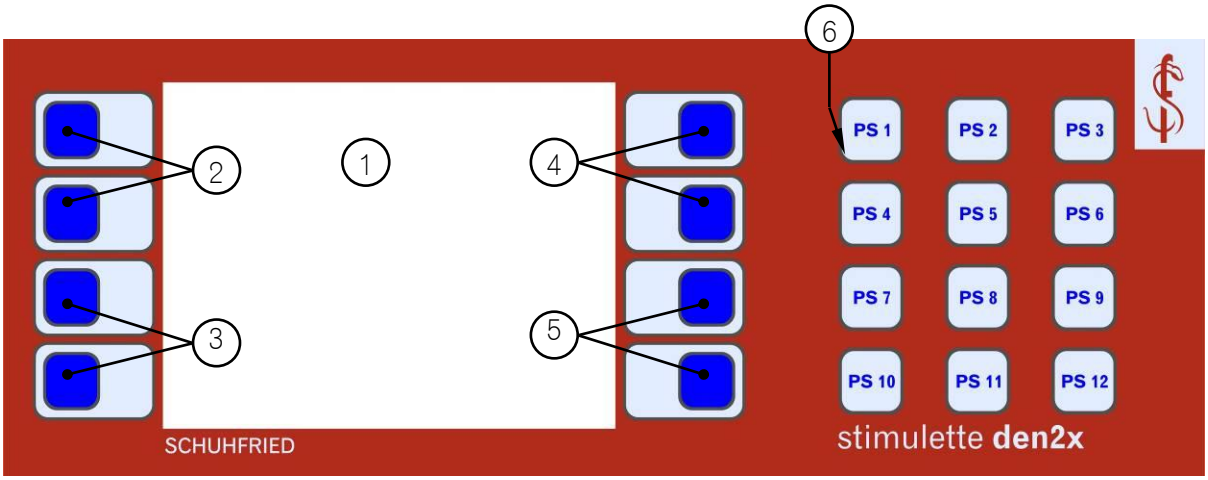
The device identification plate contains device-specific and technical data, as well as, e.g., the warning “see accompanying documents!” This symbol is a reminder that before putting the device into operation, the accompanying documents are to be studied thoroughly.

⑧ Power switch and fuse box

In the “O” position, the power switch separates all poles from the supply voltage. By flicking the switch to position “1”, the device is turned on.
The fuse box with the fuses is located beneath the power switch – for more information, please see item 4.5.

1.3.2 Keyboard

The keyboard is equipped with touch sensors, which allow for operation and execution of the key functions by a light touch. The menu navigation is described in chapter 3.3.



① Multifunction display
②, ③, ④, ⑤ Parameter keys and programming keys
⑥ Current waveform keys

① Multifunction display

See above.

② Treatment duration, impulse waveform and surge selection keys

These keys are for adjusting, e.g., the treatment time in between 1 and 59 minutes – see item 3.3.4, the impulse waveform – see item 3.3.2 or the surge – see item 3.3.3

③ Selection keys for impulse sequence, signal interval and surge interval and password

With these keys, the interpulse interval, surge parameters and the password are adjusted.

④ Selection keys for adjustment of programmed current waveforms, signal duration, surge duration and max. current

This key leads to the set-up of the programmable current waveforms. Further, the keys are assigned to the signal duration, surge duration and the adjustment of the max. current

⑤ Selection keys for continue, special adjustments and finishing

⑥ Current waveform keys

Selection of program memory.

2 START-UP

2.1 Set-up

The device should be set up in a level, dry location. The power cable supplied is plugged into the IEC output on the back, and the electrode cables are plugged into the patient connector sockets in front.

Set-up and operation of the device in wet rooms or rooms at risk of explosion is not permissible.

The electrotherapy device stimulette den2x is delivered to be connected to a line voltage of approximately 110/230V, and a line frequency of 50/60 Hz.

The device is to be connected with the included three prong power cord to a power outlet with protective ground.

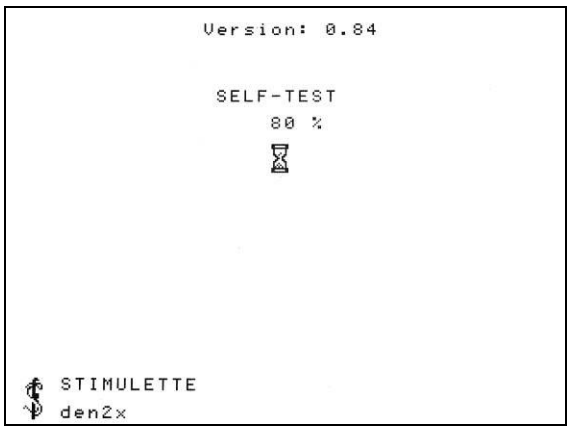
The safety of the device is only warranted with flawless electrical installation, the protective grounding of the device does not work in the absence of a protective ground wire!

3 OPERATION

3.1 Switching on and self-test/ firmware status

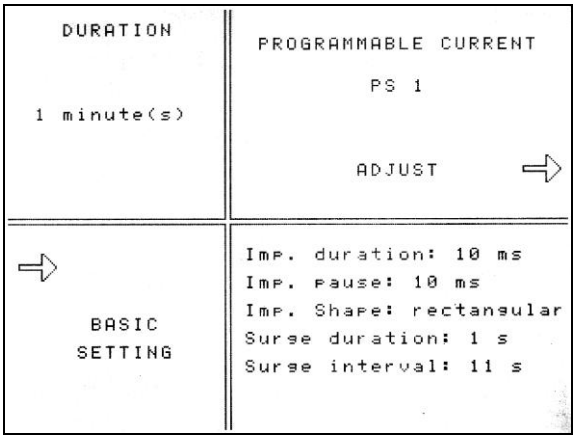
Before switching on, the intensity controls have to be turned off. After switching on the power, there is an acoustic signal, and the display's background illumination lights up.

The device powers up with the following message:



The firmware version is displayed by the numerals after "Version:"

Now, the device tests its functions, and changes into operating mode after successful completion of the self-test:

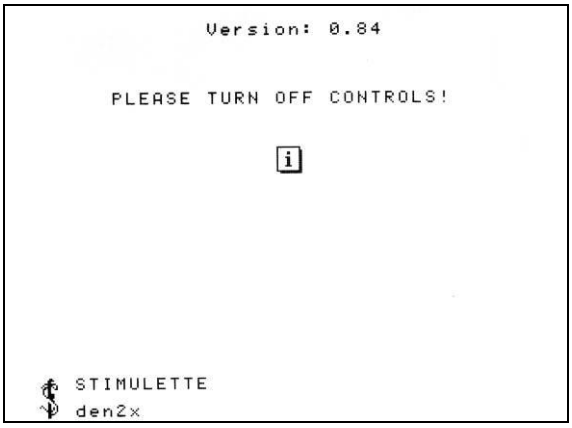


A brief acoustic signal announces that the device is ready for therapy, and the device restores the settings (internally) saved at the time of the last shutdown.

Notes:

a) If the device was switched on with an upregulated intensity control, a safety circuit prevents the start of a treatment. The patient connectors are current free.

An acoustic signal and the following error message are emitted:

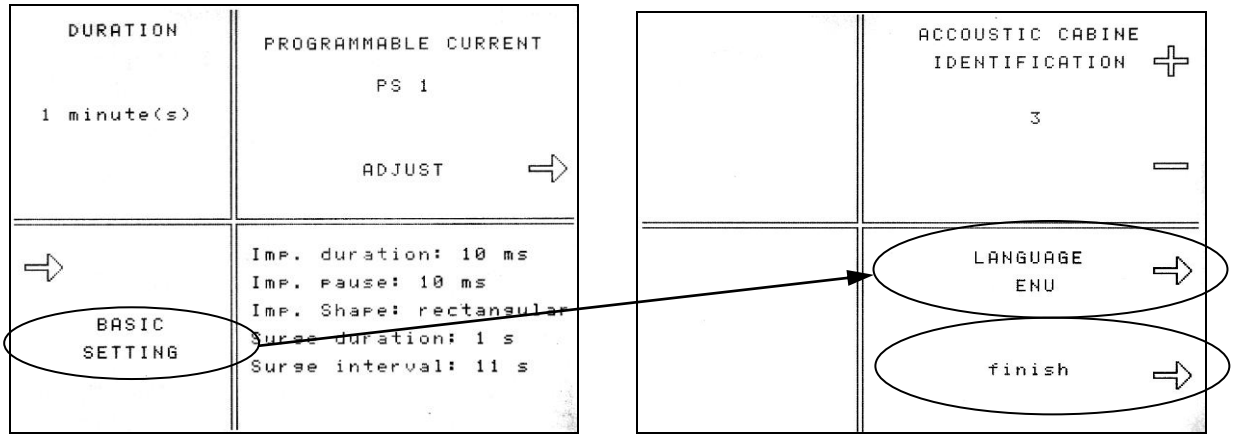


The intensity control has to be turned down until a click is heard (control is turned off). Then the device continues with the self-test.

b) After switching the device off with the power switch, there has to be a wait period of at least ten seconds before switching it on again.

3.2 Language Preference

In the "*basic settings*" you can change the language.



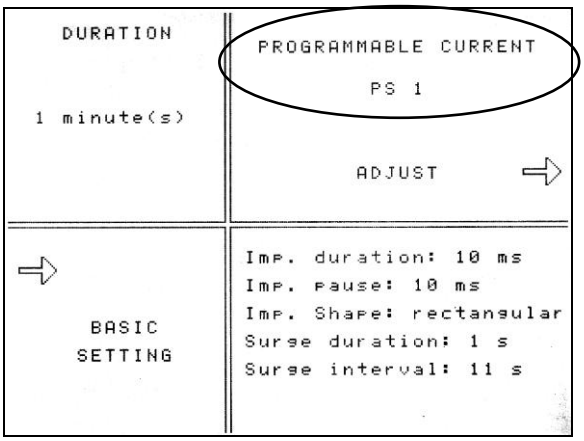
Confirm your changes to the language with „*finish*".

3.3 Adjustment of the user programmable current waveforms

3.3.1 General information

If a key is held, the automated key repetition is activated and remains active until the key is released. If the key does not react anymore after a prolonged period of action, briefly lift the finger from the key and try again after a short break. Keyboard sensitivity is recalibrated at regular intervals. Coming close with the finger is sufficient to activate a key. Touch sensors – mechanical pressure is not necessary.

All adjustments can only be made in the inactive state (intensity control turned off → no treatment). The set values are saved when a treatment begins. Also, these data remain saved when the device is turned off and are automatically restored when the device is turned on again.



The user programmable current waveforms are selected with one of the 12 current waveform keys (see ⑥ in chapter 1.3.2). The presently active current waveform is indicated on the display.

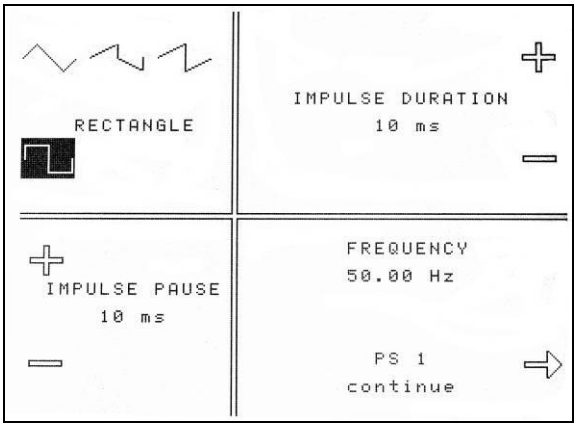
All current waveform parameters are adjusted with the "*ADJUST*" key.

The order described is to be observed.

3.3.2 Impulse waveform – pulse duration – pulse interval

Four impulse waveforms are available.
"RAMP" 1 to 3 and *"RECTANGLE"*

The *"IMPULSE PAUSE"* and the *"IMPULSE DURATION"* can be adjusted with
+ and −.

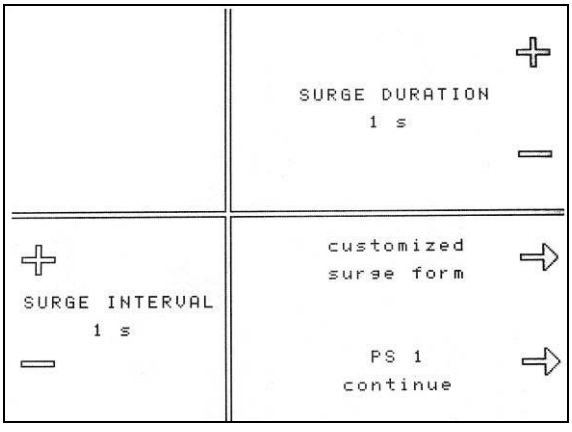


With every change in the impulse parameters, the adjustment of the signal frequency is calculated and displayed.

"CONTINUE" leads to the surge adjustments.

3.3.3 Surge

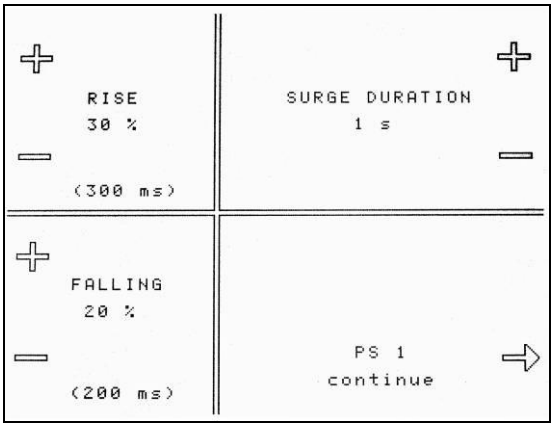
The *"SURGE INTERVAL"* and the *"SURGE DURATION"* can be adjusted with
+ and −.



"CONTINUE" brings you to further adjustments of item 3.3.4 (duration – maximal current value – password – activated current waveforms).

"CUSTOMIZED SURGE FORM" brings you to further adjustments of the surge.

The *"RISE"* and *"DECAY"* of the surge can be adjusted with + and −.
The sum of rise time and decay time cannot exceed the maximum of 100% (e.g. a rise of 100% and a decay of 70% is not possible – however, less than 100% is possible, e.g. a rise of 10% and a decay of 10%)



"CONTINUE" brings you to further adjustments of duration – maximal current value – password – activated current waveforms.

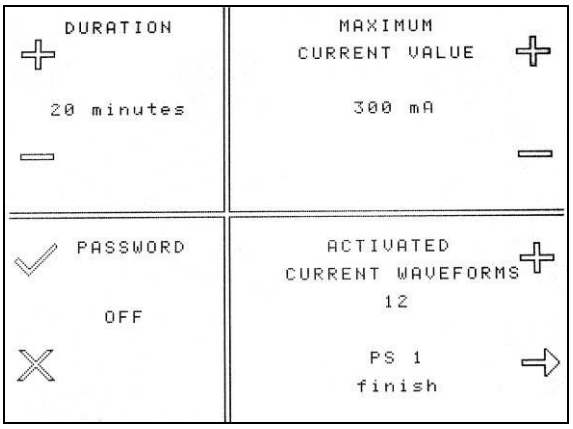
3.3.4 Duration – maximal current value – password – activated current waveforms

The *"DURATION"* of the session and the *"MAXIMAL CURRENT VALUE"* are adjusted with

and .

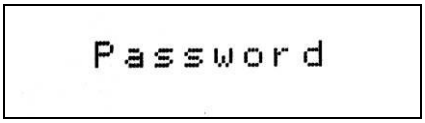
"ACTIVATED CURRENT WAVEFORMS" indicates how many current waveforms you may select from for the patient.

With the key, 1 through 12 can be selected. In the image displayed, the value 2 has been set, meaning that PS1 or PS2 can be selected.



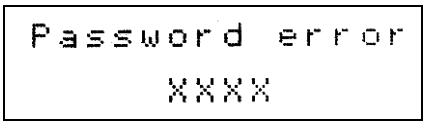
Further, a *"PASSWORD"* may be activated with and deactivated with .

When the password prompt is activated, the current waveforms can only be changed by password.
The following display appears:



You will find the password on the data safety sheet.

When entered wrong, the following appears:

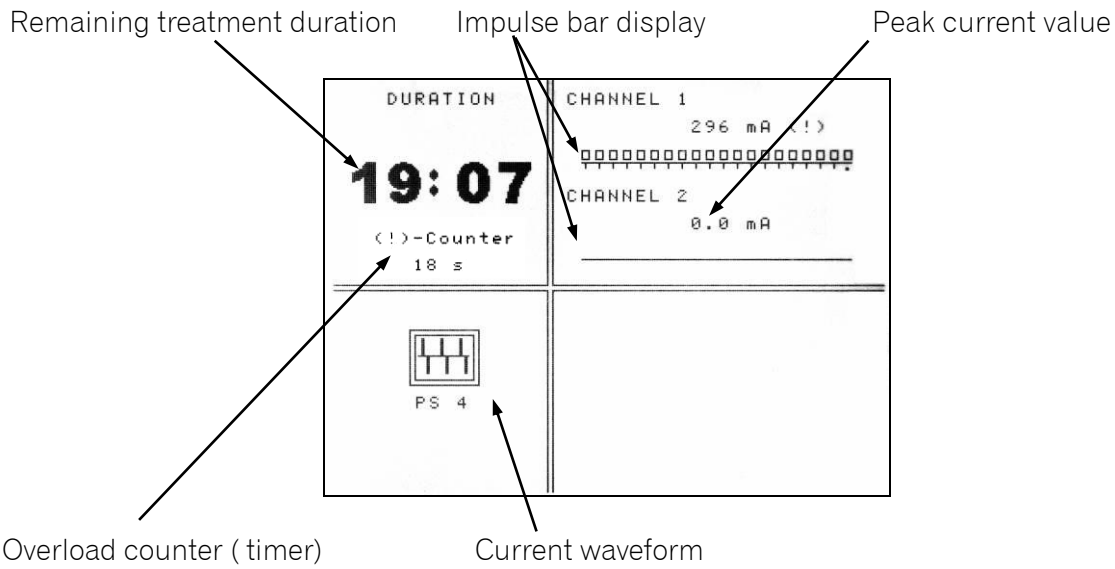


The password may be entered wrong any number of times (no lockout).

"FINISH" saves all settings and returns to the initial display.

3.4 Treatment

After all adjustments have been made and the electrodes have been placed, the treatment is started by slowly upregulating the intensity control.
The display emits the following information:



The impulse bar display shows the presently emitted peak current value of the selected current waveform.

The current display shows the peak value with a resolution of 0.1mA up to 10mA, and above this, with a 1mA resolution. We would like to point out that the display of the peak current value also indicates current flow during an interpulse interval. The impulse bar display reflects the actual state of the current.

As previously described, the bar display shows the current value at the respective moment. This value is to be watched when upregulating the intensity, particularly for those current waveforms with long interpulse intervals. Changes in intensity should only be made during impulse output (patient feedback). In addition, an acoustic warning signal is emitted if the current is increased during the current interval.

If the patient impedance becomes too high (e.g., due to an error in electrode placement), the voltage available to the device is insufficient to provide a sufficiently large current (overload). This status is symbolized by an exclamation mark after the current display. In this case, the status of the electrodes should be checked, and/or the intensity should be decreased until the exclamation mark disappears. Additionally, an overload timer appears. If the overload persists for 20 seconds, the treatment is terminated.
A slight warming of the chassis during operation is, due to the powered parts in the device, completely normal.

3.5 End of treatment

There are two ways to end the treatment:

a) Turning off the intensity control

By slowly turning down the intensity control, the treatment is terminated, and the device reenters its basic state. The treatment period reassumes the value that was entered before the start of treatment, and all the other settings remain saved.

b) End of treatment period

At the end of the treatment period, the device automatically turns off the current and beeps three times. The display shows the following:

In order to return to the basic state, the intensity control has to be turned off. The treatment period reassumes the value that was selected before the start of treatment, and all the other adjustments remain saved.

3.6 Treatment recommendations for attending physicians and therapists

Patients are classified as “Class 0” through “Class 4”, which is easily incorporated in the clinical findings. For “Class 2 and 3”, at least a simple force measuring system is needed (e.g. spring scale).

Table with therapy recommendations: *(based : Table 3 “The Wien home-based FES Training for human complete LMN denervated muscles”):*

Stimulation and trainings parameter				
Trainings phase	Timeline (month)*	Stimualtion parameters	Training parameters	Functional class
1	0-4	120-150 ms ID / 400 ms IP; 4 second SD / 4 second SP	3-4 x 3 minutes with 1-2 minutes pause; 5 days/week	0 or 1
2	2-6	70-100 ms ID / 400 ms IP; 5 seconds SD / 5 seconds SP	4-5 x 3 minutes with 1-2 minutes pause; 5 days/week	1 or 2
3	4-12	35-50 ms ID / 10-15 ms IP 2 second SD / 2 second SP	4-6 x 20-40 rep. 1-2 minutes pause; 5 days/week	3 or 4

ID…impulse duration; IP…impulse pause (interpuls interval); SD…stimulation duration (surge duration); SP…stimulation pause (surge interval)
*Varying with denervation time at the beginning of stimulation
Functional classes:
0=no torque measurable, no contraction/twitch visible;
1=no torque measurable, but contraction/twitches visible;
2=torque measureable between 0,1 and 2,9 Nm;
3=torque measured more than 3,0 Nm, but not able to stand;
4=able to stand in parallel bars/standing frame

4 ADDITIONAL NOTES

4.1 Warnings and symbols

This symbol refers to the accompanying documents. Since the output of the device can deliver high voltages, caution is advised. Conscientious reading of the manual is, therefore, imperative before starting operation.

This symbol marks the device for a degree of protection against electrical shock BF. This means that the device has an isolated (ungrounded) part in its application (patient's electrical circuit).

Symbol of the manufacturing date: The manufacturing date is shown next to this symbol.

Symbol for the serial number: The serial number of the device is shown next to this symbol.

This symbol indicates that the device has to be put in a separate collection of electrical and electronic devices, or is taken back by the manufacturer.

Additional warnings:

Set-up and operation of the device in wet rooms or rooms at risk of explosion is not permissible.
ELECTRICAL MEDICAL DEVICES are subject to special standards regarding electromagnetic compatibility (EMC) and are to be installed and operated in accordance with the EMC guidelines presented in the accompanying documents.
The device must not be used immediately next to or stacked with other devices; should this become necessary after all, the device has to be watched to ensure it is operating as intended.
The device may only be operated by qualified personnel, or by persons who have been trained by qualified personnel.

High frequency surgical devices:

Simultaneous connection of the patient to a high frequency surgical device can lead to burns under the stimulating electrodes.

Shortwave or microwave devices

Operation of a shortwave or microwave device in the immediate vicinity of the stimulator can lead to fluctuations in the output values of the stimulator. We are decreasing the potential of this interference by installation of a high frequency filter in the patient's electrical circuit.

Current intensity:

The den2x exceeds the maximal current values specified by the norm. The stimulation of denervated muscles requires substantially higher current values. For this reason, **amplitudes up to ±300mA** are possible. In order to avoid the **risk of chemical burns** by badly adhering or dried out electrodes, **the safety electrodes with the protection edge are to be used exclusively**.

Effective current densities of up to 2.7 mA/cm² are possible. In general, **the user's heightened attention** is necessary from 2 mA/cm² on.

Maximally possible current densities:

Electrode surface	[cm²]	70	154
Max. current intensity	[mA]	300	300
Max. effective values	[mA]	190	190
Max. effective current density	[mA/cm²]	2.7	1.2
Max. impulse current density	[mA/cm²]	4.29	1.95

IMPORTANT!

When using the smaller 70 mm² electrodes the stimulus current should not exceed 150 mA. Over 150 mA particular care is required because of the greater current density. Danger of burning!

Use absolutely mandates **supervision by a physician**.

Image: Protection electrodes – safety electrodes

Use of electrodes

WARNING! Only the **original safety electrodes** may be used.

The electrode gel has to be applied evenly to the safety electrodes. Watch for uniform pressure when positioning the electrodes!

We recommend to change the electrodes every 3 months. After the treatment, the electrode gel should be rinsed off under running water.

Unpleasant sensations or pain and risk of chemical burn

WARNING! The current flowing between the electrodes and the skin of the patient generates an electrolytic effect. The risk of a chemical burn results.

As a precaution, it is mandatory to make sure that the safety electrodes are evenly filled with electrode gel.

If an electrode is used for too long or cleaned with too much intensity, then **the electrode resistance deteriorates** , which may lead to spots of increased current density. These “hot spots” lead to **severe chemical burns**.

Size and placement of electrodes

It is advisable to moisten the skin before fastening the electrodes. As a protection against chemical burns, all electrodes have to be filled with electrode gel. For all treatments possible with this device, the safety electrodes specified in item 4.8 with the surfaces of 70 and 154 cm^2 are to be used. These are fastened with Velcro® tape. Here, it has to be made sure that the tapes do not obstruct the blood and lymph circulation.

Metal implants:

Patients with metal implants within the range of the electrodes must not undergo therapy with stimulation current. In case of implants, the physician needs to be consulted.

Implanted electrical devices (cardiac pacemaker):

Patients with a cardiac pacemaker or similar implanted devices must not undergo stimulation current treatment unless a specialist has been consulted and has approved this matter.

Electrodes and their placement

The electrodes have to be attached to the skin of the patient in a slip-proof manner and with their entire surface. The rubber electrodes have to be immaculate and of low internal resistance. All electrodes used have to fulfill the biocompatibility criteria pursuant to ISO 10993.

Electrode placement in the vicinity of the chest can increase the risk of ventricular fibrillation and should, therefore, not be done. Stimulation across the chest as, e.g., by

placing the electrodes on the left and right hand, must absolutely be avoided. Also avoid touching the large surface electrodes with your hands.
Make sure that the electrodes are in immaculate mechanical condition. Damage to the red insulating layer may lead to passing current through the chest when touched during treatment.

Adhesive electrodes

Adhesive electrodes are prohibited due to the risk of chemical burns.

Vaginal or anal electrodes

The use of vaginal or anal electrodes is prohibited because the current intensities are too high.

The device may only be opened by authorized personnel!

Pull the plug before opening the device!

The device is not meant for operation in areas at risk of explosion!

An application at the chest, as well as at the hands, is life-threatening and therefore prohibited!

At distances of less than one meter to the device, operation of high frequency (HF) senders (e.g., cell phone) should be abstained from!

Use of accessories, converters or cables other than the ones supplied by the manufacturer of the device can lead to increased emission of electromagnetic radiation and to a reduction of the device's immunity to interference.

Patients with an implanted electronic device, or with a metal implant, may only be treated if the approval of a physician has been obtained.

4.2 Safety precautions

Safeguards against faulty cables and too high an electrode resistance:

If a fault occurs in the patient connector cable, the device turns off and reports an "ELECTRODE FAULT" (see item 4.4). Likewise, the device turns off in case of increased electrode resistance. Increased electrode resistance develops when electrodes are used too many times. With cleaning, the conductive particles wash out of the electrode and cause a deterioration of the conductivity and an increase in resistance, respectively. Also, if the electrode slides during treatment or if the electrode gel leaks out, the resistance of the application increases and the device switches off.

Safeguards against operator errors:

a) If the power was switched off at the end of treatment without turning down the intensity control, no current is flowing after turning the device back on. The patient is thus protected from the surprise of abruptly too high a current intensity. Current to the patient only flows after turning the control down to zero and subsequently turning the intensity up again.

b) In order to avoid operator errors, it is not possible to change the current waveform, the impulse sequence or the treatment period once the intensity is upregulated.

c) The current for the treatment has to be increased slowly to warrant a treatment free of pain. As nothing is felt during the current intervals (long intervals can be set), the intensity should only be increased in the current phases that can actively be felt. If the intensity was further increased during the current interval, this leads to an abruptly increased stimulation during the next current pulse, which may be painful. For assistance, an acoustic warning signal is emitted if the current intensity is increased during the current interval. If this signal sounds, adjustment should be stopped until current flows again. Current flow is indicated by bars in the display.

Overload display:

Incorrectly attached electrodes can lead to an abnormal increase in patient impedance. This leads to an overload in the final stage and therefore, to a change in the signal waveform. In order to warrant proper treatment and to avoid skin damage by too high a current density, the device detects an overload and reports it on the display with an exclamation mark after the current display. At the same time, an overload timer is started. Unless the current overload is downregulated within 20 seconds, the device interrupts the treatment and reports an "ELECTRODE FAULT(2)". The timer is reset if the overload lapses temporarily. This way, early termination due to movement artifacts of the electrode during strong muscle twitching is avoided.

Overload is verified by measuring the current to the patient. Therefore, overload is not detected in the signal intervals (despite the current intensity displayed, the current to the patient is zero). For this reason, the overload warning is delayed.

Automated safety checks:

After switching on and in the treatment interval (every 30 min.), the most important components of the device are checked by self-test. At this moment, a session must not and cannot be started. The device continuously self-tests during treatment as well. Should an internal fault occur, the connection between the device and the patient is immediately severed, and the respective error is reported on the display. If a serious error occurs three times, the device is locked and has to be sent in for repair.

4.3 Guidelines and manufacturer's declaration EMC

4.3.1 Electromagnetic emission

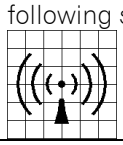
The stimulette den2x is meant to be operated in an environment as described below. The client or the operator of the stimulette den2x should ensure that it is operated in such an environment.

Interference emission measurements	Compliance	Electromagnetic environment - guidelines
HF emissions of interference voltage after DIN EN 55011	Group 2 Class B	The stimulette den2x is intended for use in all institutions including residential areas and others that are directly connected to a public power service that also supplies buildings that are used for residential purposes.
HF emissions of field strength/ radio interference field intensity after DIN EN 55011	Group 1 Class B	
Emissions of harmonic current after DIN EN 61000-3-2	Class A	
Emissions of voltage fluctuations/ flicker after DIN EN 61000-3-3	Compliant	

4.3.2 Electromagnetic immunity to interference

The stimulette den2x is meant to be operated in an environment as described below. The client or the operator of the stimulette den2x should ensure that it is operated in such an environment.

Immunity to interference test	IEC 60601 standard	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) after DIN EN 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	No compliance	Floors should be made of wood or cement, or be covered with ceramic tile. If the floor is covered by synthetic material, the relative humidity has to be at least 30%.
Electrical fast transient/ burst immunity after DIN EN 61000-4-4	± 2kV for power main, input and output connections	± 2kV for power main, input and output connections	The quality of the supply voltage should be rated as for a typical business or hospital environment.
Surges after DIN EN 61000-4-5	± 1 kV L_x – N ± 2 kV L_x – PE, N – PE	± 1 kV L_x – N ± 2 kV L_x – PE, N – PE	
Voltage drops, sh0rt-term interruptions, and fluctuations in the supply voltage after DIN EN 61000-4-11	0 % U_T (100 % drop in U_T) for ½ period 40 % U_T (60 % drop in U_T) for 5 periods 70 % U_T (30 % drop in U_T) for 25 periods 0 % U_T (100 % drop in U_T) for 250 periods	0 % U_T (100 % drop in U_T) for ½ period 40 % U_T (60 % drop in U_T) for 5 periods 70 % U_T (30 % drop in U_T) for 25 periods 0 % U_T (100 % drop in U_T) for 250 periods	The quality of the supply voltage should be rated as for a typical business or hospital environment. If the operator of the stimulette den2x requires continued function also during interruptions of power service, it is recommended to supply the stimulette den2x by an interruption-proof power supply or by battery.
Magnetic field at the supply frequency of 50 Hz/60 Hz after DIN EN 61000-4-8	3 A/m	3 A/m	Magnetic fields at the supply frequency should correspond to the typical ratings found in business and hospital environments.
Note: U_T is the alternating supply voltage before application of the standards.			

Immunity to interference tests	IEC 60601 standard	Compliance level	Electromagnetic environment - guidelines
			Portable and mobile radio devices are not to be used at any distance to the stimulette den2x less than the recommended protection distance, which is calculated by the equation appropriate for the radio frequency. Recommended protection distance:
Wireline HF interferences after DIN EN 61000-4-6	3 V_{eff} 150 kHz up to 80 MHz	3 → $V1$ in V	$d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$
Radiated HF interferences after DIN EN 61000-4-3	10 V/m 26 MHz up to 1 GHz	10 → $E1$ in V/m	$d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$ for 80 MHz up to 800 MHz
			$d = \left(\frac{7}{E1}\right) * \sqrt{P}$ for 800 MHz up to 2.5 GHz
			with P as the maximum rated power of the sender in Watt (W), as per the specifications of the sender's manufacturer, and d as the recommended protection distance in meters (m). The field intensity of stationary radio transmitters should, according to an examination on site[a], be less than the level of compliance[b] at all frequencies. Interference is possible in the vicinity of devices with the following symbol: 

Note 1	For 80 MHz and 800 MHz, the higher frequency range applies.
Note 2	These guidelines may not be applicable in all cases. The propagation of electromagnetic forces is influenced by absorption and reflection by buildings, objects and humans.

a) The field intensity of stationary senders, as, e.g. base stations of wireless phones and mobile rural broadcast services, amateur stations, AM and FM radio and TV senders cannot be predicted in theory with any degree of accuracy. In order to determine the electromagnetic field resulting from a stationary HF emitter, examining the site is recommended. If the field intensity determined at the location of the stimulette den2x exceeds the above level of compliance, then the stimulette den2x has to be watched to ensure its normal operation at each place of operation. If unusual power signals are observed, it may be necessary to take additional steps, as, e.g. a different alignment, or a different location of the stimulette den2x.

b) Across the range of frequencies from 150 kHz to 80MHz, the field intensity should be less than [V1] V/m.

4.3.3 Recommended protection distances

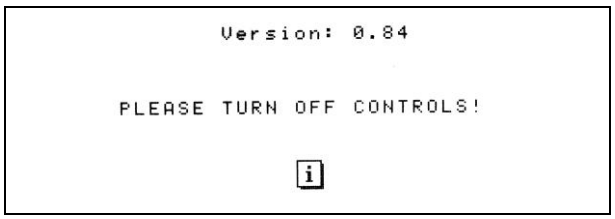
The stimulette den2x is meant to be operated in an electromagnetic environment in which HF interferences are under control. The client or the operator of the stimulette den2x can help with avoiding electromagnetic interferences by complying with the minimum distances indicated below between portable and mobile HF telecommunication devices (senders) and the stimulette den2x - which depends on the output power of the communication device.

Recommended protection distances between portable and mobile HF telecommunication devices and the stimulette den2x			
Power rating of the sender W	Protection distance as a function of the sender frequency m		
	150 kHz up to 80 MHz $d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$	80 MHz up to 800 MHz $d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$	800 MHz up to 2.5 GHz $d = \left(\frac{7}{E1}\right) * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For senders the maximal power rating of which is not indicated in the table above, the distance can be determined by using the equation in the respective column, where P is the maximal power rating of the sender in Watt (W), according to the specifications of the sender's manufacturer.			
Note 1	For 80 MHz and 800 MHz, the higher frequency range applies.		
Note 2	These guidelines may not be applicable in all cases. The propagation of electromagnetic forces is influenced by absorption and reflection by buildings, objects and humans.		

4.4 Error messages

I-POT error:

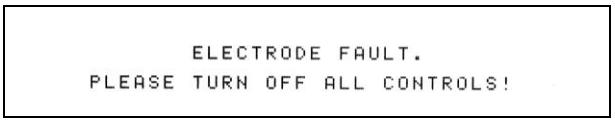
If the device is switched on with an upregulated intensity control, the device reports the following error:



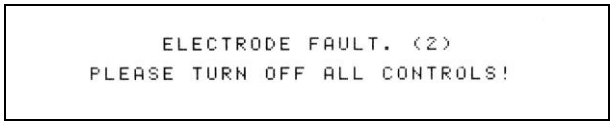
In order to eliminate the error, the intensity control has to be turned off.

Electrode fault:

If there is a fault in the electrode cable, or the electrodes are not correctly connected to the patient or too worn out, turning up the intensity results in the following error message:



or



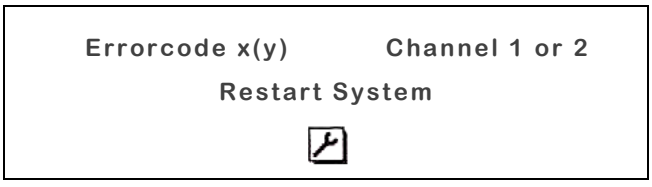
In order to eliminate the error, the intensity control has to be turned off.

After correcting the cause of the error, treatment can be continued by turning up the intensity control. **If electrode faults occur frequently, the safety electrodes are to be replaced.**

Internal fault:

If there is an internal fault during self-test or during treatment, the following error message is displayed:

Error during self-test or during treatment:



In the display above, “x(y)” indicates the respective number of the error. The channel number indicates which one of the two channels is affected by the error.

In any case, technical service has to be informed if there is an internal fault.

4.5 Service

Maintenance:

Maintenance, repair and alterations have to be performed in accordance with the Medizinproduktegesetz (act on medical devices).

The manufacturer notes that alterations of the device and service by unauthorized companies voids the warranty.

For cleaning of the device, the power must be unplugged. The stimulette den2x device is not particularly sensitive to cleaning agents. We recommend alcohol-free disinfectants commonly used in the hospital.

Faulty components have to be replaced with original parts.

Should one of the mains fuses fail, it can be replaced by the operator. The rating and the trigger characteristics have to be the same as the original values (see item 4.12). The internal fuses may only be changed by authorized personnel.

Authorized companies and persons will be supplied with circuit diagrams, lists of replacement parts and descriptions if requested.

Electrode maintenance:

After use, the rubber electrodes are rinsed with luke-warm water without scrubbing (loss of graphite means increased resistance). After this, these are put down for drying or patted dry with cloth or a paper towel.

It is recommended to assign the electrodes to one patient and to use these only for one patient. After being cleaned several times, the electrode is worn out and, therefore, needs to be disposed of.

Only original safety electrodes may be used.

We recommend to only use bipolar patient cables. The use of multipolar cables is within the responsibility of the treating physician.

Maintenance of the electrode pockets (sponge cloth)

The electrode pockets are rinsed in warm water after each use as well. Once a week, these should be cleaned with some laundry detergent at 60° C in the washing machine.

Maintenance of the bandages and the fixing belts

The bandages or fixing belts should also be rinsed or washed at least once a week and should be changed on a regular basis.

Electrode cables

Electrode cables should never be bent or stretched and should be coiled up not too tightly after use, and not over sharp edges, respectively.
Regular controls for damage to the insulation of the cables. If this is the case, replace the cables with new ones.

Electrode clamps

The clamps should be cleaned on a regular basis as dirty electrode clamps dramatically increase transition resistance. This reduces the effectiveness of the therapy (very weak muscle contraction).

In case of strong, intractable contamination (dark coating by residual gel etc.) on the metal parts of the electrode clamps, remove with steel wool or something similar.

4.6 Problems and proposed solutions

Redness:

An even redness of the skin under the electrodes is normal (increased circulation) and disappers again after a few hours.

If an uneven redness appears (e.g. spotty), its further course has to be closely monitored. If the skin alterations persist, the attending physician should be contacted.

Burns:

Due to the missing sensitivity in the legs, incorrect electrode application may lead to high local current densities and cause skin burns.

Spotty burns receive dry treatment. In order to permit further stimulation, the affected spot is insulated during each current treatment with zinc paste and small silicone-rubber platelets.
Stimulation without insulation may only take place after complete healing (after approximately 2 – 4 weeks).

Larger burns have to be treated by a physician. In this case, the stimulation has to be deferred.

With increasing duration of the stimulation (2 - 3 months), the skin adapts to the electrostimulation and, as a rule, the risk of burns markedly decreases. After approximately 4 – 5 months, such burns only occur as a result of incorrect handling of the stimulation electrodes.

Weak muscle contraction:

When the muscle is too tired or overused, the strength of muscle contractions may decrease. The reason for this may be too many repetitions or too high a number in the series, too much additional weight, too short an interval between series or too intensive a training program for the week.

An unfavorable posture during stimulation may be the reason for weak contraction of the stimulated muscles.
In all of these cases, the attending physician must be contacted, who adapts the stimulation training.

If diseases occur that considerably impair the general well-being (e.g., the common cold), electrostimulation should be deferred and the attending physician should be contacted.

No or irregular muscle contraction with full stimulation:

If electrodes or electrode pockets make contact with each other, a short may occur. Therefore, before beginning stimulation, attention must be paid to correctly position the electrodes or the electrode pockets.
Too high a transition resistance may be another cause for weak muscle contraction. This may be due to contamination of the electrode clamps (electrode abrasion and gel residues), but also to contamination of the sponge cloth by dander, oil and the microbial flora of the skin, as well as wear of the electrode pockets.

The transition resistance may also be increased by insufficiently moist electrode pockets or by using too little electrode gel.
Using a creme containing fat before electrostimulation also increases skin resistance.

These problems can be avoided if the following is observed:

The clamps should be checked on a regular basis and should be cleaned with steel wool or something similar if needed.

Contamination of the sponge cloth can be avoided by rinsing after stimulation and regular washing in the washing machine. Further, the electrode pockets should be replaced at regular intervals. The electrode pockets must be sufficiently moistened (dripping wet); when using gel electrodes, sufficient gel must be applied.

Before training, the skin over the muscles to be stimulated should be cleaned and degreased.

Current sensation in the abdominal or pelvic area:

If a current sensation occurs in the abdominal or pelvic area during stimulation, a “crossed” connection of the electrode cables to the stimulator has happened.
Therefore, the correct assignment of the cables to the stimulation channels should be checked before beginning stimulation.

Device does not work:

Should the device not work properly for a reason that is not obvious to the user (all of the above potential causes for errors excluded), then technical support must be contacted.

4.7 Overview problems and proposed solutions

PROBLEM	POSSIBLE CAUSES		SOLUTION
Burns	Incorrect electrode placement	Electrode plate touches the skin	Fully insert the electrode plates into the electrode pockets
		Electrode pockets insufficiently moist	Sufficiently moisten electrode pockets (dripping wet)
		Not enough electrode gel	Apply sufficient electrode gel
		Application pressure inhomogen0us (spotty, raised electrodes, electrodes bent in the electrode pockets, irregular bandaging)	Use even pressure for applying the entire electrode
			Checking the electrodes in the electrode pockets
		Metal filaments in the fixing bandages	Use bandages without metal filaments
		For larger burns, monitoring by the attending physician	
	Electrode pockets too thin and worn		Regular replacement of the electrode pockets

No or weak or irregular muscle contraction with full stimulation:	Muscles too tired or	Series interval too short	Consultation with the attending physician
	Overuse	Too many series	
		Too many repetitions	
		Weekly training program too intense	
		Additional training weights too heavy	
	Unfavorable posture during stimulation		Consultation with the attending physician
	Diseases (influenza, other infections)		Defer electrostimulation, contact the attending physician
	Electrode pockets touch each other	Danger of short	Check electrode positioning before start of the stimulation program
	Electrode clamp strongly contaminated	Resistance too high	Check clamps regularly; if needed, clean with steel wool or similar
	Electrode pockets strongly contaminated		Rinse pockets after stimulation, wash once a week
	Electrode pockets are worn		Regular replacement of the electrode pockets

	Electrode pockets insufficiently moist		Use electrode pockets nearly dripping wet
	Not enough electrode gel		Apply sufficient electrode gel
	Rubber electrodes worn		Replace electrodes with new ones
	Too much fat-containing skin creme before therapy	Resistance too high	Place electrodes on cleaned, degreased skin
Current sensation in the abdominal or pelvic area:	Error when clamping the electrodes	Incorrect, “crossed” assignment of the stimulation channels	Check assignment of the cables to the stimulation channels
Device interrupts the treatment with electrode fault or electrode fault (2)	Incorrect electrode placement	Bad electrodes - transition resistance too high	Use new electrodes
		Electrodes not placed flat or too dry	Place electrodes again
		Electrode movements too large with large currents, due to muscle twitching	Attach electrodes more securely
Device does not work:	Technical problem within the device		Consultation with technical support personnel

4.8 Accessories

Only the following, manufacturer approved accessories may be used:

a) Standard accessories:

- Patient cable (bipolar, shielded, with safety connectors)
- Plate electrodes made of rubber with safety edge (sizes 70 and 154)

Size 70 cm² (50 x 140 mm)

Size 154 cm² (110 x 140 mm)

- Sponge pads (sizes 70 and 154)
- Rubber bands
- Electrode gel

4.9 Disclaimer

The manufacturer or distributor only considers himself responsible for the effects on safety, reliability and performance of the device if

- Mounting, additions, new adjustments, alterations or repairs were performed by authorized persons,
- The electric installation of the respective room complies with the IEC requirements or the ÖVE-EN 7 and the ÖNORM/ÖVE E8007,
- Original accessories or accessories approved by the manufacturer are used,
- The device is used in accordance with the operating instructions and
- The operation of the stimulator complies with the regulations of the Medizinproduktegesetz (act on medical devices) and the regulations of the Krankenanstaltengesetz (hospital organization act).

The manufacturer or the distributor takes devices and accessories back for disposal.

4.10 Inspection of the device

According to section 87 of the MPG (Medizinproduktegesetz; act on medical devices), the device is to be inspected at regular intervals, and once a year according to ÖNORM/ÖVE EN62353 (routine testing and testing after repair of medical electrical devices).

Before transfer of loan units to the borrower, the loaning institution minimally has to perform the following tests:

- Complete operating instructions are present
- Device identification plate is present and legible
- Power cable does not have breaks, the insulation is undamaged
- All operating controls are undamaged and in working condition
- Control and display lights are working
- Fuses accessible from the exterior are to be checked for required ratings
- Brief test run, checking of “overload” (with a load of 500Ω) and “electrode fault” (by disconnecting the load)
- Inspection of chassis for visible mechanical damage
- Checking accessories for completeness and proper working condition

4.11 Certificates

See enclosed copies of certificates.

4.12 Technical data

- Supply voltage ..... ~110/230V, ±10% / 60/50Hz
- Input power 160VA
- Mains fuses ..... glass fuse Ø5 x 20mm - 2x T 3,15A L, 250V
- Max. output current intensity (peak value):
  Current waveforms pS01 through pS12 (see item 1.2) ..... up to 300mA
- Patient resistance ..... maximally 330Ω
- Regulated constant current output:
  "Full scale" accuracy of the current measurement ..... better than ±10%
- Permissible environmental conditions:
  Storage and transport temperature ..... -20°C up to +60°C
  Operating temperature ..... +10°C up to +35°C
  Relative humidity ..... 70%, not condensating
- Dimensions (W x H x D) ..... 330 x 123 x 300mm
- Weight 4kg

Protection class I

Degree of protection against electric shock BF

CE 0408

4.13 References

In order to facilitate operation of the device, the following literature is available:

Literature with regard to FES

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