

6-series

User Manual



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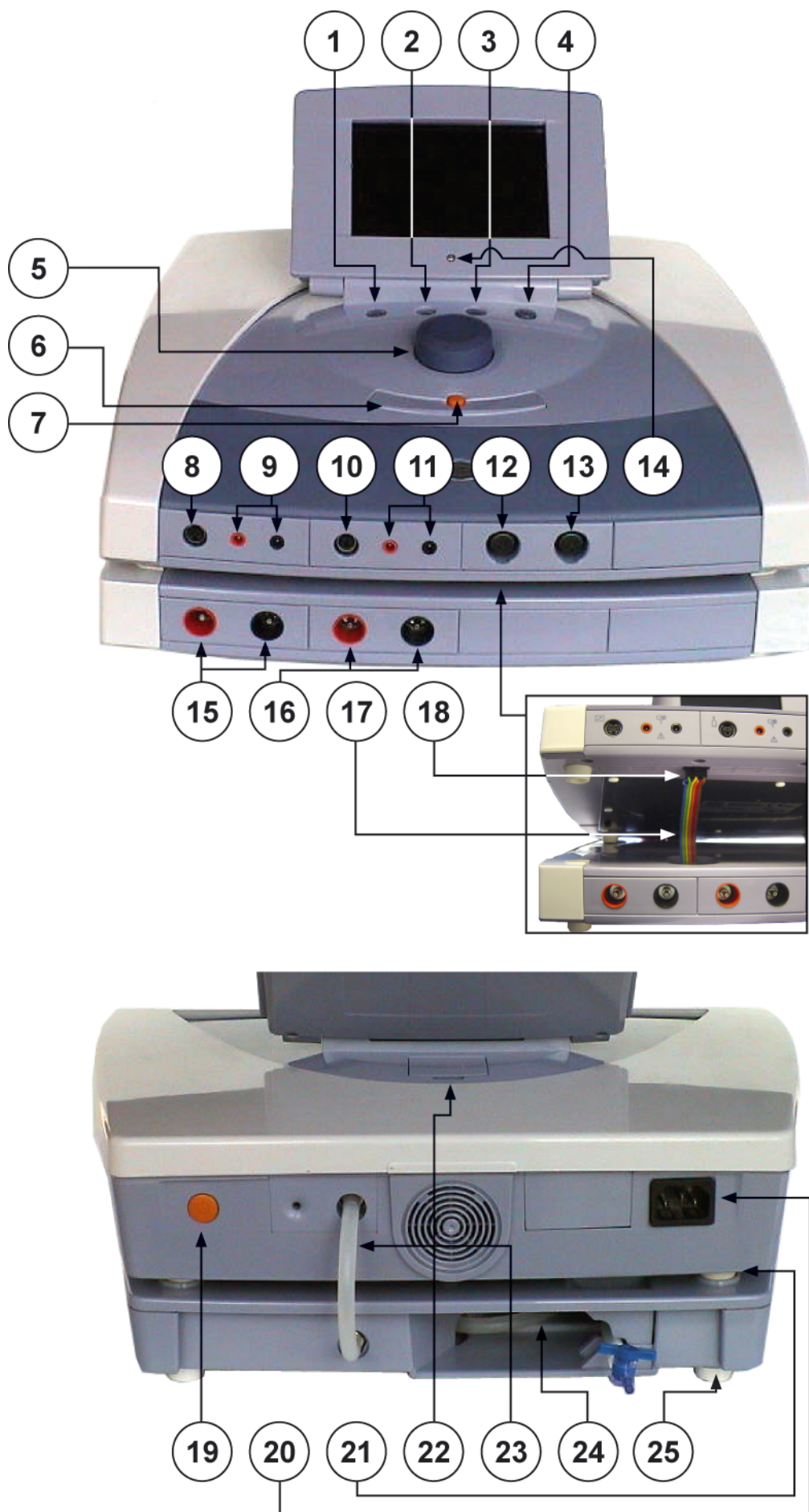


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6-series

User Manual





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1 Product Description

The 6-series is based on a modular system. This means that a number of modules are integrated within a single structure.

The base module consists of a user interface and an Endomed electro therapy module, which has two independent current channels.

The 6-series offers protocol driven operation, providing either factory or user defined sequences of treatment steps. Protocols can run on linked or independent channels.

With independent channels, two different protocols can be run simultaneously. All settings can easily be adjusted via the user interface, which is shown on the graphical colour display.

The therapy modules, - Endomed electro therapy, Sonopuls ultrasound and Vacotron vacuum - are described below.

WARNING (USA only): *The 600-series is a prescription device that should only be used under the supervision or by the order of a physician or other licensed healthcare provider.*

1.1 Endomed electrotherapy module

The 6-series is equipped with two completely identical electrotherapy channels.

A comprehensive set of current waveforms is provided for both pain management and muscle stimulation applications. One electro-module with 2 channel electrotherapy is mounted in the Endomed 682, two electro-modules are mounted in the Endomed 684. In the Endomed 684 it's possible to work completely independent with 2+2 channels electrotherapy or 4 completely independent channels 1, 2, 3 and 4.

1.2 Sonopuls ultrasound module

The ultrasound module has one multi-frequency ultrasound channel. The multi-frequency ultrasound applicators for the 6-series provide both 1 and 3 MHz operation. The applicators can be used with both, large and small treatment surfaces and are suitable for subaquatic treatments. Contact control suspends the application of ultrasonic energy when acoustical contact with the treatment area becomes insufficient.

The user can connect two ultrasound treatment heads. These can be activated from the ultrasound menu.

The simultaneous application of ultrasound and electrotherapy (combination therapy) is also possible. The remaining electrotherapy channel can then be used independently.

1.2.1 StatUS module

StatUS stands for **Stationary Ultra Sound**: the application of ultrasound *without moving the treatment head* (= stationary). In the normal course of events, ultrasound energy is administered by moving ('making circles') the treatment head. This moving of the treatment head (also called the *dynamic or semi-stationary method*) is essential because a few unfavourable phenomena occur both within an ultra-sound bundle as well as in the tissue, which may lead to tissue damage (so-called 'hot spots'). StatUS-therapy, on the other hand, makes use of two special forms of modulation that ensure that the peaks in intensity in the ultra-sound bundle are strongly reduced, diminishing the risk of cavitation and preventing the occurrence of 'hotspots'.

These modulation forms are:

1. Duty Cycle Modulation
2. Amplitude Modulation

1.3 Vacotron vacuum module

The continuous and pulsed vacuum module allows vacuum electrodes to be positioned quickly and easily. Furthermore, it is extremely simple to switch between the treatment with vacuum electrodes and treatment with flexible rubber electrodes. This makes the vacuum module an ideal aid for electrode placement.

Vacuum electrodes make good contact with the skin which means that effective use is made of the whole electrodes area. The massage effect resulting from the pulsed vacuum ensures a good flow of blood through the skin under the electrodes. This reduces the resistance of the skin and increases the effectiveness of the stimulating current.

1.4 EMG module

The EMG module is equipped with 2 EMG channels for surface electrodes, vaginal and anal electrodes. The pressure sensor can be used in combination with vaginal and anal pressure probes.

Several measure methods are applicable via de EMG channels and these channels can be used in combination with the stimulation current wave forms from the electrotherapy module.

Myofeedback (or EMG-Feedback) is a method, whereby the electrical activity of a muscle is registered and passed on as quantitative information (feedback) to:

- the patient (to influence his/her motoric activity)
- the MD/therapist (to determine and evaluation of the movement process of the patient during voluntary movements)

2 Foreword

2.1 This manual

This manual has been written for the owners and operators of the 600-series. It contains general instructions on operation, precautionary practices, maintenance and parts information. In order to maximize the use, efficiency and lifespan of your unit, please read this manual thoroughly and become familiar with the controls as well as the accessories before operating the unit.

Specifications put forth in this manual were in effect at the time of publication. However, owing to Enraf-Nonius BV's policy of continual improvement, changes to these specifications may be made at any time without obligation on the part of Enraf-Nonius BV.

2.2 Product liability

A law on Product Liability has become effective in many countries. This Product Liability law implies, amongst other things, that once a period of 10 years has elapsed after a product has been brought into circulation, the manufacturer can no longer be held responsible for possible shortcomings of the product.

To the maximum extent permitted by applicable law, in no event will Enraf-Nonius or its suppliers or resellers be liable for any indirect, special, incidental or consequential damages arising from the use of or inability to use the product, including, without limitation, damages for loss of goodwill, work and productivity, computer failure or malfunction, or any and all other commercial damages or losses, even if advised of the possibility thereof, and regardless of the legal or equitable theory (contract, tort or otherwise) upon which the claim is based. In any case, Enraf-Nonius's entire liability under any provision of this agreement shall not exceed in the aggregate the sum of the fees paid for this product and fees for support of the product received by Enraf-Nonius under a separate support agreement (if any), with the exception of death or personal injury caused by the negligence of Enraf-Nonius to the extent applicable law prohibits the limitation of damages in such cases.

The opposing party (product's user or its representative) shall disclaim Enraf-Nonius from all claims arising from third parties, whatever nature or whatever relationship to the opposing party.

3 Precautionary Instructions

In this section general Warnings and Precautions are listed, that you should be aware of when using the 6-series. See also chapter 4 for Warnings and Precautions that are application specific.

WARNING:

- Federal law (USA only) restricts this device to sale by, or on the order of, a physician or licensed practitioner. This device should be used only under the continued supervision of a physician or licensed practitioner.
- Make certain that the unit is electrically grounded by connecting only to a grounded electrical service receptacle conforming to the applicable national and local electrical codes.
- Do not operate the unit in an environment of short-wave or micro-wave diathermy use as this can result in burns beneath the electrodes.
- Care must be taken when operating this equipment around other equipment. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with it.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when electrical stimulation is being utilized.
- This equipment is not suitable for use in the presence of flammable anesthetics mixture with air, oxygen, or nitrous oxide.
- This device should be kept out of the reach of children.

CAUTION:

- Read, understand and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any electrical stimulation device. Observe the precautionary and operational decals placed on the unit.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.
- Handle ultrasound applicator with care. Inappropriate handling of the ultrasound applicator may adversely affect its characteristics.
- Inspect ultrasound applicator for cracks which may allow the ingress of conductive fluid before each use.
- Inspect ultrasound applicator cables and associated connectors before each use.
- Do not operate the 600-series when connected to any unit other than Enraf-Nonius BV devices.
- This unit should be operated, transported and stored in temperatures between 10 °C and 40 °C (50 °F and 104 °F), with a Relative Humidity ranging from 10%-90%.
- Do not expose the unit to direct sunlight, heat radiated from a heat radiator, excessive amounts of dust, moisture, vibrations and mechanical shocks.
- In the case of ingress of liquids, unplug the unit from the mains supply and have it checked by an authorized person (see the paragraph on technical maintenance)
- Before administering any treatment to a patient you should become acquainted with the operating procedures for each mode of treatment available, as well as the indications, contraindications, warnings and precautions. Consult other resources for additional information regarding the application of electrotherapy.

4 *Intended Use: electrotherapy*

4.1 Pain Management

Pain Management is the use of electrical stimulation for pain relief.

4.1.1 Indications/Contraindications

Indications:

- Symptomatic relief of chronic, intractable pain. Management of pain associated with post-traumatic or postoperative conditions.

Contraindications:

- This device should not be used for symptomatic pain relief unless etiology is established or unless a pain syndrome has been diagnosed.
- This device should not be used on patients with demand-type cardiac pacemakers.
- This device should not be used over cancerous lesions.
- Electrode placements that apply current to the carotid sinus region (anterior neck) must be avoided.
- Electrode placements that apply current transcerebrally (through the head) must be avoided.
- Electrode placements that apply current transthoracically (the introduction of electrical current into the heart may cause cardiac arrhythmias) must be avoided.

Warnings:

- Benefits of TENS currents have not been established for pain of central origin.
- This device is to be used as a symptomatic treatment for pain and has no curative value. Patients should be cautioned and their activities regulated if pain that would otherwise serve as a protective mechanism is suppressed.
- The long-term effects of chronic electrical stimulation are unknown.
- Safety has not been established for the use of therapeutic electrical stimulation during pregnancy.
- Stimulation should not be applied over swollen, infected, or inflamed areas of skin eruptions e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- See also chapter 3, Precautionary Instructions, for general Warnings and Precautions.

Precautions:

- Isolated cases of skin rash may occur at the site of electrode placement following long-term applications. The irritation may be reduced by use of an alternate conductive medium or an alternative electrode placement.
- Effectiveness of this treatment is dependent upon patient selection.
- See also chapter 3, Precautionary Instructions, for general Warnings and Precautions.

Adverse Effects:

- Skin irritation and burns beneath the electrodes have been reported with the use of therapeutic electrical stimulation.

4.1.2 Current Waveforms

For pain management the 6-series offers the current waveforms described in paragraph 4.3 - 4.3.9.b.

4.2 Muscle Stimulation

Muscle Stimulation is the use of electrical stimulation to treat muscle dysfunction.

4.2.1 Indications/Contraindications and Adverse Effects for Muscle Stimulation

Indications:

- Relaxation of muscle spasms.
- Prevention or retardation of disuse atrophy.
- Increasing local blood circulation.
- Muscle re-education.
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- Maintaining or increasing range of motion.

Contraindications:

- This device should not be used on patients with demand-type cardiac pacemakers.
- This device should not be used over cancerous lesions.
- Electrode placements that apply current to the carotid sinus region (anterior neck) must be avoided.
- Electrode placements that apply current transcranially (through the head) must be avoided.
- Electrode placements that apply current transthoracically (the introduction of electrical current into the heart may cause cardiac arrhythmias) must be avoided.

Warnings:

- The long-term effects of chronic electrical stimulation are unknown.
- Safety has not been established for the use of therapeutic electrical stimulation during pregnancy.
- Stimulation should not be applied over swollen, infected, or inflamed areas of skin eruptions e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- See also chapter 3, Precautionary Instructions, for general Warnings and Precautions.

Precautions:

- Adequate precautions should be taken when treating individuals with suspected or diagnosed heart problems, or epilepsy.
- Caution should be used when there is a tendency to hemorrhage following acute trauma or fracture.
- Caution should be used following recent surgical procedures when muscle contraction may disrupt the healing process.
- Caution should be used over the menstruating uterus.
- Caution should be used over areas of the skin which lack normal sensation.
- Some patients may experience skin irritation or hypersensitivity due to electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternative conductive medium, or alternate electrode placement.
- See also chapter 3, Precautionary Instructions, for general Warnings and Precautions.

Adverse Effects:

- Skin irritation and burns beneath the electrodes have been reported with the use of therapeutic electrical stimulation.

4.2.2 Current Waveforms

For muscle stimulation the 6-series offers the current waveforms described in paragraphs 4.3.3 - 4.3.6. These waveforms are often applied in combination with a surge program, which consists of a sequence of exercise and rest periods. Two options are available here:

- Reciprocal application, where stimulation alternates between agonists and antagonists. This is accomplished through asynchronous stimulation over two current channels with an appropriate delay between the two channels.
- Co-contract application, where two channels operate synchronously to co-contract agonist and antagonist or different sections of a larger muscle group.

See paragraph 11.2.11.a for the available parameters.

4.3 Description: Current Waveforms

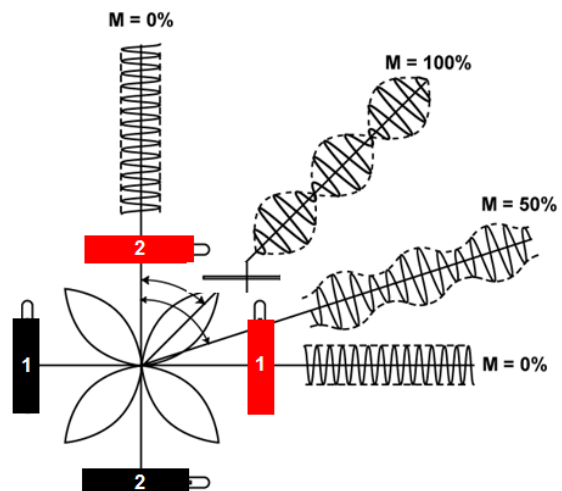
4.3.1 4 Pole Interferential Currents

With the interferential current type a medium frequency carrier frequency is used to pass the low frequency stimulation (beat) frequency through the skin. The relatively low resistance of the skin to the carrier frequency contributes to the patient comfort that is often associated with this current type. Interferential currents are all AC currents without any residual DC components. Several variations of the interferential current type are known, the following of which are available in the 600-series:

4.3.1.a Classical Interferential

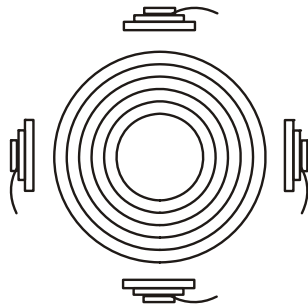
With this therapy method four electrodes are used and two non modulated currents are generated. The frequency of one channel is fixed at the carrier frequency, while the other channel has a variable frequency, based on the Beat frequency and Frequency Modulation settings. Interference occurs where the two currents intersect in the tissue. The modulation depth (which determines the current amplitude of the stimulation) depends on the direction of the currents, and can vary from 0 to 100%. 100% modulation depth only occurs at the diagonals (and hence at the intersection) of the two currents. This is of course a theoretical situation, based on the assumption that the tissue is homogeneous. In reality, the tissue is heterogeneous, so that the current balance between the two channels has to be used to get the 100% modulation depth (Fig. 1). The current balance can also be used to compensate for differences in sensation occurring under the electrode pairs.

Modulation depth is only 100% at the diagonals.



4.3.1.b Isoplanar Vector

The isoplanar vector technique is intended to increase the area where effective stimulation occurs. Amplitude modulation occurs in the equipment and a special phase relation between the two channels ensures a 100% modulation depth between the four electrodes in all positions.

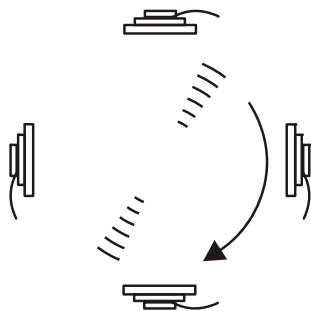


Modulation depth is 100% over the entire treatment area.

The advantage of this method is that the positioning of the four electrodes to effectively treat the affected tissue is less critical. The sensation of the Isoplanar vector mode is soft and equally divided over the treatment area.

4.3.1.c Dipole Vector Manual

With the dipole vector technique the currents from the two electrode pairs are vectorially summed in the tissue. The effect is that stimulation only occurs into the direction of the resulting vector, which can be adjusted over a range of 360°. Amplitude modulation occurs in the equipment and the modulation depth is 100%.



Stimulation with 100% modulation depth only occurs into the direction of the vector.

The advantage of this method is that the direction of the stimulation can be adjusted electronically after positioning the electrodes.

4.3.1.d Dipole Vector Automatic

With the automatic dipole technique the dipole vector described above is rotated at an adjustable speed. If the current amplitude is increased exceeding the motorial threshold, the tissue will contract and relax rhythmically. The automatic dipole vector current is ideally suited for areas where mechanical pressure (massage) is not desirable.

Parameters:

Carrier frequency, expressed in kHz, is the base frequency of the alternating current.

Beat frequency, expressed in Hz, defines the channel frequency difference in classical interferential mode and the rate at which the amplitude is internally modulated in the vector modes.

Frequency Modulation, expressed in Hz, defines a variable frequency range that is summed to the Beat frequency i.e when the Beat frequency is set to 80 Hz and the Frequency modulation is set to 40 Hz, the final frequency will vary from 80 – 120 Hz. Frequency modulation is often used to prevent accommodation to stimulation or to improve patient tolerance.

Modulation Program defines the time and sequence in which the frequency will sweep through the Frequency modulation range. See for the available Modulation programs fig 13.11– 13.11.3.

Balance defines the difference in current amplitude between the two channels. Only available in classical interferential mode.

Vector position adjustment defines the angle of the dipole vector with respect to the position of the electrodes.

Rotation Speed, expressed in s, defines the time elapsed during one revolution of the vector in automatic dipole vector mode.

4.3.2 Biphasic Pulsed Currents (TENS)

4.3.2.a Asymmetrical and Alternating Asymmetrical

The asymmetrical biphasic pulsed current waveform is often used in TENS (Transcutaneous Electrical Nerve Stimulation) applications. This waveform is characterized by variable phase duration and variable pulse frequency. Its typical amplitude, duration, and rate of rise and decay are unequal for each phase with respect to the baseline. The waveform is fully balanced, i.e. the phase charges of each phase are equal. See fig 13.1 for a graphical representation.

A variation to the standard biphasic asymmetrical pulsed current is the alternating one, in which the successive pulse phases alternate with respect to the baseline. See fig 13.1.2 for details. This waveform is also fully balanced.

To prevent accommodation to stimulation or to improve patient tolerance, the pulse frequency can be varied through frequency modulation. Several frequency modulation programs are available. See fig 13.11 – 13.11.3 for details.

Parameters:

Phase Duration, expressed in μs , is the elapsed time from the beginning to the termination of the initial pulse phase. See fig 13.1 for details.

Pulse Frequency, expressed in Hz or pps (pulses per second), defines the repetition rate of the TENS pulses. See fig 13.1 for details.

Frequency Modulation, expressed in Hz, defines a variable frequency range that is summed to the Pulse frequency i.e when the Pulse frequency is set to 80 Hz and the Frequency modulation is set to 40 Hz, the final frequency will vary from 80 – 120 Hz.

Modulation Program, defines the time and sequence in which the frequency will sweep through the Frequency modulation range. See for the available Modulation programs 13.11 – 13.11.3.

4.3.2.b Burst Asymmetrical and Burst Alternating Asymmetrical

The burst biphasic and burst biphasic alternating asymmetrical pulsed currents are variations to their non burst counterparts, in which the continuous train of pulses is interrupted by pulse pauses. See fig 13.1.3 and fig 13.1.4 for details. A burst frequency can be set for treating chronic pains, where the use of continuous stimulation with a low pulse frequency would be too painful. Each burst lasts for 100ms and the burst rate can be adjusted separately. With this milder TENS waveform it is easier to exceed the motorial threshold stimulus.

Parameters:

Phase Duration, expressed in μs , is the elapsed time from the beginning to the termination of the initial pulse phase. See fig 13.1 for details.

Pulse Frequency, expressed in Hz or pps (pulses per second), defines the repetition rate of the TENS pulses. See fig 13.1 for details.

Burst Frequency, expressed in Hz, defines the repetition rate of bursts of pulses. A burst consists of a train of pulses. Each burst lasts for 100ms and the number of pulses in a burst depends on the selected Pulse frequency i.e at a Pulse Frequency of 100Hz, 10 pulses are available in each burst. Burst mode can not be selected when Frequency modulation is active. See fig 13.1.3 for details.

4.3.2.c Symmetrical

TENS current pulses can also be used for muscle stimulation applications. Often the symmetrical biphasic pulsed current waveform is used. See fig 13.1.5 for a graphical representation. The specified phase duration applies to both pulse phases, which doubles the amount of available energy with respect to the asymmetrical pulsed current waveform. This waveform is fully balanced (no residual DC components are present).

Parameters:

Phase Duration, expressed in μs , is the elapsed time from the beginning to the termination of a pulse phase. The phase duration applies to each pulse phase. See fig 13.1.5 for details.

Phase Interval, expressed in μs , is the elapsed time between the positive and the negative pulse phase. See fig 13.1.5 for details.

Pulse Frequency, expressed in Hz or pps (pulses per second), defines the repetition rate of the TENS pulses. See fig 13.1.5 for details.

Frequency Modulation, expressed in Hz, defines a variable frequency range that is summed to the Beat frequency i.e when the Beat frequency is set to 80 Hz and the Frequency modulation is set to 40 Hz, the final frequency will vary from 80 – 120 Hz.

Modulation Program defines the time and sequence in which the frequency will sweep through the Frequency modulation range. See for the available Modulation programs fig 13.11 – 13.11.3.

Surge Program can be used to adjust repeated sequences of contraction and rest periods. See paragraph 11.2.11.a for details.

4.3.2.d Burst Symmetrical

The burst biphasic symmetrical pulsed current is a variation to its non burst counterpart, in which the continuous train of pulses is interrupted by pulse pauses. See fig 13.1.3.6 for details. A burst frequency can be set for treating chronic pains, where the use of continuous stimulation with a low pulse frequency would be too painful. Each burst lasts for 100ms and the burst rate can separately be adjusted. With this milder TENS waveform it is easier to exceed the motorial threshold stimulus.

Parameters:

Phase Duration, expressed in μs , is the elapsed time from the beginning to the termination of the initial pulse phase. See fig 13.1.5 for details.

Phase Interval, expressed in μs , is the elapsed time between the positive and the negative pulse phase. See fig 13.1.5 for details.

Pulse Frequency, expressed in Hz or pps (pulses per second), defines the repetition rate of the TENS pulses. See fig 13.1.5 for details.

Burst Frequency, expressed in Hz, defines the repetition rate of bursts of pulses. A burst consists of a train of pulses. Each burst lasts for 100 ms and the number of pulses in a burst depends on the selected Pulse frequency i.e. at a Pulse Frequency of 100Hz, 10 pulses are available in each burst. Burst mode can not be selected when Frequency modulation is active. See fig 13.1.3 for details.

4.3.3 Premodulated

As with Interferential currents, a medium carrier frequency is used to pass the low frequency stimulation (beat) frequency through the skin. See fig 13.2 for the current waveform. 'Premodulated' implies that amplitude modulation occurs in the equipment, allowing it to be applied with a single electrode pair.

The Premodulated alternating current is often used where the objective is to strengthen the muscle and change the distribution of muscle fibers (twitch speed). The Beat frequency is used to affect the muscle fiber distribution. The optimum carrier frequency for this purpose varies between 2000 – 4000 Hz.

At a low Beat frequency (up to about 20 Hz) the muscle becomes 'red', while at a higher Beat frequency (up to about 150 Hz) the muscle becomes 'white'. This can be used to increase the explosive release of energy in high-jumpers, provided that is supplemented by functional exercises. The most comfortable tetanic contractions are obtained at a Beat frequency between 40 and 80 Hz.

Muscle stimulation is normally applied with a Surge program, allowing the muscles to rest between exercise cycles.

Parameters:

Carrier Frequency, expressed in kHz, is the base frequency of the alternating current.

Beat Frequency, expressed in Hz, defines the rate at which the amplitude is internally modulated.

Frequency Modulation, expressed in Hz, defines a variable frequency range that is summed to the Beat frequency i.e. when the Beat Frequency is set to 80 Hz and the Frequency modulation is set to 40 Hz, the final frequency will vary from 80 – 120 Hz.

Modulation Program defines the time and sequence in which the frequency will sweep through the Frequency modulation range. See for the available Modulation programs fig 13.11 – 13.11.3.

Surge Program can be used to adjust repeated sequences of contraction and rest periods. See paragraph 11.2.11.a6 for details.

4.3.4 Russian Stimulation

This current type is an intermittent alternating current with a carrier frequency around 2500 Hz. See fig 13.3 for the current waveform. Russian Stimulation was first used by Kots, a lecturer in sports medicine at the Moscow State Academy. Kots used it for muscle strengthening in prosthesiology and in the training of Russian cosmonauts. With this technique the electro stimulation is applied both to individual muscles and to groups (either directly or via the nerve). In direct stimulation, a frequency of 2500 Hz was found to produce the greatest contraction, while the optimum frequency in indirect stimulation was 1000 Hz.

A specific feature of this type of muscle stimulation is that the alternating current is interrupted 50 times per second. This results in a pulse train, comparable to the 'burst' in TENS. The total duration of the pulse train is 20ms, giving a phase duration/phase interval ratio of 1:1. Kots uses a Burst frequency of 50 Hz, approximately in the middle of the frequency spectrum used to produce tetanic contraction (40-80 Hz). In addition to the 1:1 ratio, Kots also describes a phase duration/phase interval ratio of 1:5.

The amplitude should be increased until a powerful contraction is produced (from the motor stimulation level up to the limit of tolerance). As with all muscle stimulation applications a Surge program can be used, allowing the muscles to rest between exercise cycles.

Parameters:

Carrier Frequency, expressed in kHz, is the base frequency of the alternating current.

Burst Frequency, expressed in Hz, defines the repetition rate of the bursts.

Burst / Interval Ratio, defines the ratio of the burst length to the interval between the bursts. The sum of the burst and interval duration is the reciprocal of the burst frequency i.e. with a burst frequency set at 50 Hz and a burst / interval ratio of 1:5, the burst duration will be $20 * 1/6 = 3.3\text{ms}$ and the interval duration will be $20 * 5/6 = 16.7\text{ms}$.

Surge Program can be used to adjust repeated sequences of contraction and rest periods. See paragraph 11.2.11.a for details.

4.3.5 Micro Current

Micro Current is a monophasic rectangular waveform with manually selectable or alternating polarity. See fig 13.4 for a graphical representation. Many therapists prefer Micro Current therapy because of the low current amplitudes used. Alternating polarity can be used to average out the DC component, thereby reducing the formation of electrolysis by-products.

Parameters:

Frequency, expressed in Hz, is the number of cycles delivered per second.

Alternation mode defines whether the polarity of the wave is automatically alternating or not.

Alternation Sequence, expressed in s, defines the polarity reversal timing in the alternating mode.

Surge Program can be used to adjust repeated sequences of contraction and rest periods. See paragraph 11.2.11.a for details. Surge programs are only available in the non alternating mode.

4.3.6 High Voltage

This current type has a twin peak monophasic waveform with a fixed duration of 64 μ s between the two voltage peaks. The amplitude is adjusted in volts rather than in mA. The short rise time and short duration of each voltage peak (approximately 7 μ s) is well suited to nerve stimulation and efficient discrimination between sensory, motor and pain responses. The very short pulse duration of high voltage creates a stimulation which is quite comfortable, and one which most patients can tolerate. The very short pulse duration followed by a very long interpulse interval eliminates the formation of any appreciable chemical or thermal effects in the tissue. High voltage is used for stimulating nerves and muscles, causing muscle contractions. Examples for clinical use are to treat acute or chronic pain, edema absorption and ulcer healing. Muscle contraction or motor response of isolated muscle groups, superficial or deep, can be easily and comfortably stimulated. The relative comfort and depth of penetration may be the key for the usefulness of high voltage stimulation in clinical conditions such as tendon transplants, joint mobilization and muscle re-education.

Parameters:

Pulse Frequency, expressed in Hz or pps (pulses per second), defines the repetition rate of the twin pulses. See 13.5 for details.

Frequency Modulation, expressed in %, defines a variable frequency range that is subtracted from the Pulse frequency i.e. when the Pulse frequency is set to 80 Hz and the Frequency modulation is set to 50%, the final frequency will vary from 40 – 80 Hz.

Modulation Program defines the time and sequence in which the frequency will sweep through the Frequency modulation range. See for the available Modulation programs fig 13.11 – 13.11.3.

Alternation Mode defines whether the polarity of the pulses is automatically alternating or not.

Alternation Sequence, expressed in seconds, defines the polarity reversal timing in the alternating mode.

Surge Program can be used to adjust repeated sequences of contraction and rest periods. See paragraph 11.2.11.a for details. Surge programs are only available in the non alternating mode.

4.3.7 Diadynamic Currents

The Diadynamic currents were introduced by Bernard⁽²⁾ and they have won a significant position in the history of European physiotherapy. They are now somewhat unfairly dismissed as outdated when compared with Interferential currents or TENS. Diadynamic currents are mainly used for pain reduction and the improvement of blood circulation.

Bernard uses the term 'Diadynamic Current' to refer to a monophasic (MF – Monophasé Fixe) or double-phase (DF – Diphasé Fixe) rectified alternating current. The frequency was directly derived from the mains supply, resulting in sinusoidal pulses with a duration of 10ms. This phase time of 10ms will mainly depolarize thick fibers. Stimulation of thin fibers can only be obtained at higher current amplitudes.

2 Bernard, Pierre D.
La thérapie diadynamique,
Paris, Editions 'Physio', 1962.

CAUTION:

- Diadynamic currents are monophasic currents that produce electrolysis by-products. These by-products can result in burns beneath the electrodes. Always use properly moistened sponge / electrode combinations to absorb these by-products during treatment. See paragraph 10.1.5 for details.

The following variations are available:

4.3.7.a MF (Monophasé Fixe)

Is a single phase rectified sinusoidal current with a frequency of 50 Hz. See fig 12.6.1 for details. MF is a vibrating waveform that easily induces contractions.

4.3.7.b DF (Diphassé Fixe)

Is a dual phase rectified sinusoidal current with a frequency of 100 Hz. See fig 13.6.2 for details. DF is usually experienced as a slight vibration. It is a pleasant waveform that is often used as an introduction to CP or LP.

4.3.7.c LP (Longues Périodes)

Is a slow alternation between six seconds of MF current and a six-second DF current. In the DF phase the intervals between the MF pulses are filled with additional pulses with gradually increasing and decreasing amplitude. See fig 13.6.3 for details. LP is smoother than CP.

4.3.7.d CP (Courtes Périodes)

Is a rapid alternation between one second of MF current and one second of DF current. See fig 13.6.4 for details. CP has a strong resorbing effect.

4.3.7.e CPid

Is identical to CP, except that the current amplitude during the MF phase is 12.5% lower than during the DF phase. See fig 13.6.5 for details. Normally a lower frequency is experienced to be more aggressive than a higher frequency. CPid prevents this difference in sensation.

Parameters:

Surge Program can be used to adjust repeated sequences of contraction and rest periods. See paragraph 11.2.11.a for details. Surge programs are only available with MF and DF.

4.3.8 IG Pulsed Currents

IG currents are triangular pulsed currents. Monophasic and biphasic versions are available. The monophasic IG30 current consists of a single pulse with a rising slope of 30ms followed by falling slope of 10ms. See fig 12.7 for details. The biphasic version (fig 13.7.2.1) has two such phases with opposite polarity. The other types refer to fixed pulses of 300 + 100µs with envelopes of 50ms for the IG50 current, 100ms for the IG100 current and 150ms for the IG150 current. See fig 13.7.3 thru 13.7.8 for details. The IG currents can be used with pain management and blood circulation applications.

CAUTION:

- The monophasic IG currents are, as their name implies, monophasic currents that produce electrolysis by-products. These by-products can result in burns beneath the electrodes. Always use properly moistened sponge / electrode combinations to absorb these by-products during treatment. See paragraph 10.1.5 for details.

4.3.9 Galvanic Current

4.3.9.a Direct Galvanic Current

Galvanic current works when combined with the correct ionized/electrically charged solutions, (i.e. they are ions carrying either a positive or negative electrical charge, or will ionize with electricity).

This makes it possible to influence the skin's ability to absorb serums into the intracellular spaces in the dermis. The absorption process is called iontophoresis because the electrical currents literally carry ions into the tissues between the cells (see fig 12.10.1 for details).

CAUTION:

- The Direct Galvanic Current is a monophasic current that produces electrolysis by-products. These by-products can result in burns beneath the electrodes. Always use properly moistened sponge / electrode combinations to absorb these by-products during treatment. See paragraph 10.1.5 for details.

4.3.9.b MF Interrupted Galvanic Current

The medium frequency interrupted galvanic current is a monophasic rectangular waveform with a pulse frequency of 8000 Hz and a duty cycle of 90%. See fig 13.10.2 for details. As opposed to direct galvanic current, the pulsed waveform provides increased patient comfort.

CAUTION:

- The MF interrupted galvanic current is a monophasic current that produces electrolysis by-products. These by-products can result in burns beneath the electrodes. Always use properly moistened sponge / electrode combinations to absorb these by-products during treatment. See paragraph 10.1.5 for details.

4.3.10 Faradic Rectangular or Triangular pulsed current

Faradic currents are often used for muscle stimulation applications that are based on prior diagnostics. See fig 12.8.1 and 12.8.2 for the current waveforms. The diagnostic objective is to obtain information on the sensitivity of the neuromuscular apparatus to electrical stimulation. This gives an indication of the degree of denervation of the muscle tissue. With this technique the relationship between the current amplitude and phase duration of a rectangular and triangular pulse is plotted in a strength/duration curve. The strength/duration curve is recorded by observing the current amplitude required at various phase duration values (ranging from 0.01 to 1000ms) that produce a just perceptible (i.e. just visible or palpable) contraction of a muscle or muscle group. The values observed can be plotted on graph paper with a logarithmic scale. In the case of reduced or absent sensitivity to electrical stimulation, the strength/duration curve gives an indication of the current waveform, phase duration and current amplitude of the electrical stimulus to be used in any therapy that may be applied.

CAUTION:

- Faradic currents are monophasic currents that produce electrolysis by-products. These by-products can result in burns beneath the electrodes. Always use properly moistened sponge / electrode combinations to absorb these by-products during treatment. See paragraph 10.1.5 for details.

Parameters:

Phase Duration, expressed in ms or s, is the elapsed time from the beginning to the termination of the pulse phase. See fig 12.8.1 and 12.8.2 for details.

Phase Interval, expressed in ms or s, is the elapsed time between succeeding pulse phases. See fig 12.8.1 and 12.8.2 for details.

Surge Program can be used to adjust repeated sequences of contraction and rest periods. See paragraph 10.2.9 for details.

4.3.11 Träbert, 2 – 5 Current

The 2-5 or 'Ultra-Reiz' current was introduced by Träbert.¹ It is often used to treat headaches and neck pain. The 2-5 current is a faradic rectangular pulsed current with a phase duration of 2ms and a phase interval of 5ms. These settings are the default settings for the faradic rectangular current waveform and result in a pulse frequency of approximately 143 Hz. Träbert offered no explanation for the choice of these parameters. Nevertheless, many workers have adopted the therapy and it is still applied with success. A remarkable effect is the freedom from pain which can appear from just the first treatment and which can last for several hours. See fig 12.9 for a graphical representation.

1 Träbert, H.
Ultra-Reizstrom, ein neues therapeutisches Phänomen,
Elektromedizin 2, 1957 (7).

CAUTION:

- Faradic currents are monophasic currents that produce electrolysis by-products. These by-products can result in burns beneath the electrodes. Always use properly moistened sponge / electrode combinations to absorb these by-products during treatment. See paragraph 10.1.5 for details.

Parameters:

Phase Duration, expressed in ms or s, is the elapsed time from the beginning to the termination of the pulse phase. The default setting is 2ms. See fig 12.9 for details.

Phase Interval, expressed in ms or s, is the elapsed time between succeeding pulse phases. The default setting is 5ms. See fig 12.9 for details.

4.4 The Strength-Duration Curve (SD Curve)

To achieve a better understanding of the excitability of nerves and muscles, we must consider the strength (amplitude) and duration (ON time) of the applied current, since a relation exists between the strength and the duration necessary to elicit a threshold response from nerve and muscle. By varying the strength and duration of the electrical stimulus, it is possible to plot a curve called the strength-duration (SD) curve that gives a graphic illustration of the excitability of nerve and muscle. The strength-duration curves for nerve muscle are very characteristic and are readily reproducible.

Although the shape of the SD curve is similar for both nerve and muscle, the position of the curve on the graph will vary according to the innervation status of the muscle (innervated, partially denervated, or completely denervated).

Two important numerical values that can be determined from the SD curve are the rheobase and the Chronaxie.

The rheobase (threshold) is the minimal strength of an electrical stimulus of infinite duration that is capable of exciting a tissue (nerve or muscle).

Chronaxie is the duration of an electrical stimulus of twice the rheobase value that will cause a minimal response (ie, muscle twitch).

The Chronaxie of an intact nerve (healthy, innervated muscle) is much lower (approximately 0.03 ms) than that of a denervated muscle (approximately 10 ms). These values illustrate the fact that healthy, innervated muscle is much more excitable than is unhealthy, denervated muscle. Therefore, healthy, innervated muscle will respond best to a stimulus of sufficient amplitude and of short duration, whereas an impulse of long duration and of greater amplitude is required to effectively stimulate denervated muscle. Therefore, the SD curve illustrates the relationship between the time (duration) that an electrical stimulus required to produce a threshold response (muscle twitch)

5 *Intended Use Ultrasound therapy and StatUS*

5.1 **Ultrasound**

Ultrasound is a mechanical energy consisting of high-frequency vibrations applied by means of an ultrasound applicator. These vibrations pass through the tissue of the body and are gradually absorbed and transformed into heat. The resulting temperature increase triggers biological changes to occur in the tissue for the relief of pain, relaxation of muscle spasms and reduction of joint contractures.

5.1.1 **Indications/Contraindications and Adverse Effects for Ultrasound**

Indications:

- Ultrasound is indicated for conditions that benefit from the application of deep heat: relief of pain, muscle spasms and joint contractures. The objective of therapeutic ultrasound in the treatment of selected medical conditions associated with the chronic and sub chronic conditions of bursitis/capsulitis, epicondylitis, ligament sprains, tendinitis, scar tissue healing and muscle strain is to reduce pain.

Contraindications:

- The established contraindications to heat therapy itself.
- In an area of the body where a malignancy is known to be present.
- Over or near bone growth centers until bone growth is complete.
- Over the thoracic area if the patient is using a cardiac pacemaker.
- Over a healing fracture.
- Over ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result.
- In the presence of metal implants of any type.
- Patients with sensory loss on the area to be treated.
- The gonads or to the developing fetus.
- The heart.
- The brains.
- The testicles.
- The eyes.
- Facial sinus as this exposes the eyes to the same hazards.
- Ultrasound should not be used on unconscious patients.

Precautions and Warnings:

- Precaution should be taken when using therapeutic ultrasound on patients with hemorrhagic diatheses.
- Ultrasound treatment presents a potential safety hazard in patients whose pain response has been decreased because of disease, previous surgery, ionizing radiation therapy, chemotherapy, or general or regional anesthesia. It may cause burns. Do not use on insensitive areas or in the presence of poor circulation.
- Large thermal doses may result in regions of thermal aseptic necrosis which may not be apparent on inspection of the skin.
- See also chapter 3, Precautionary Instructions, for general Warnings and Precautions.

Relevant Hazards:

- Use of ultrasound in treating areas above the shoulders may pose relevant hazards. While it is recognized that certain specific conditions involving the eyes can and have been treated by specialists qualified by training, knowledge and experience to administer such treatments, such application carries with it recognized hazards of applying heat to the eyes.
- Treatment of the facial sinus exposes the eyes to the same hazards.
- Treatment of the thyroid, as well as lymph nodes in the neck, may expose the patient to as yet undetermined effects inasmuch as the safety of such treatments has not yet been established.

Potential Adverse Effects:

- Cataracts.
- Male sterility.
- Enhanced drug activity.
- Thermal stress.

5.1.2 Parameters

Ultrasound Frequency, expressed in MHz, is the frequency of the ultrasound waves. The ultrasound frequency determines the penetration depth, which has the largest value at 1 MHz. The ultrasound frequency can be set at 1 MHz or 3 MHz.

Duty Cycle, expressed in %, defines the ratio of the pulse duration to the pulse repetition time. Ultrasound can be applied in pulsed or in continuous mode. When the Duty Cycle is set to 100%, the apparatus operates in continuous mode.

Effective Radiation Area (ERA) expressed in cm^2 , defines the cross-sectional area of the ultrasound beam (See technical specifications for details). The Effective Radiation Area is fixed and defined by the size of the ultrasound applicator.

Ultrasound Power is the ultrasound output expressed in W. The ultrasound output display can be toggled between W and W/cm^2 . In pulsed mode the power during the pulse is displayed. The time averaged power can be obtained by multiplying this value with the Duty Cycle.

Ultrasound Amplitude, expressed in W/cm^2 , is the quotient of Ultrasound Power and Effective Radiation Area. The ultrasound output display can be toggled between W and W/cm^2 . In pulsed mode the Amplitude during the pulse is displayed. The time-averaged Amplitude can be obtained by multiplying this value with the Duty Cycle.

5.2 Combination Therapy

Combination therapy is the combined application of ultrasound and electrical stimulation. With combination therapy the metal surface of the ultrasound applicator becomes the negative electrical stimulation electrode, while the lead wire with the red connector remains the positive electrical stimulation electrode. Combination therapy is available with all current waveforms, but limited to channel 2.

Combination therapy is typically used for the reduction of muscle spasm.

The combined Contraindications and Adverse Effects of paragraph 4 and 5 apply.

5.3 StatUS Therapy

StatUS stands for **Stationary Ultra Sound**: the application of ultrasound *without moving the treatment head* (= stationary). In the normal course of events, ultrasound energy is administered by moving ('making circles') the treatment head. This moving of the treatment head (also called the *dynamic or semi-stationary method*) is essential because a few unfavourable phenomena occur both within an ultra-sound bundle as well as in the tissue, which may lead to tissue damage (so-called 'hot spots'). StatUS-therapy, on the other hand, makes use of two special forms of modulation that ensure that the peaks in intensity in the ultra-sound bundle are strongly reduced, diminishing the risk of cavitation and preventing the occurrence of 'hotspots'.

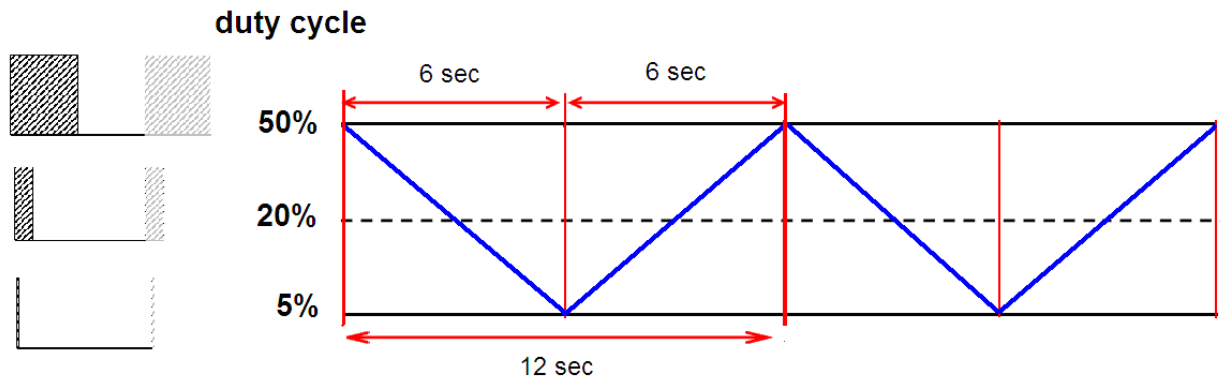
These modulation forms are:

1. Duty Cycle Modulation
2. Amplitude Modulation

Duty Cycle Modulation

Duty cycle can be described as the proportion between the duration of the pulse and the duration of the interval. The duty cycle is expressed in a percentage (%). The device is working in a continuous modus when the duty cycle is 100%.

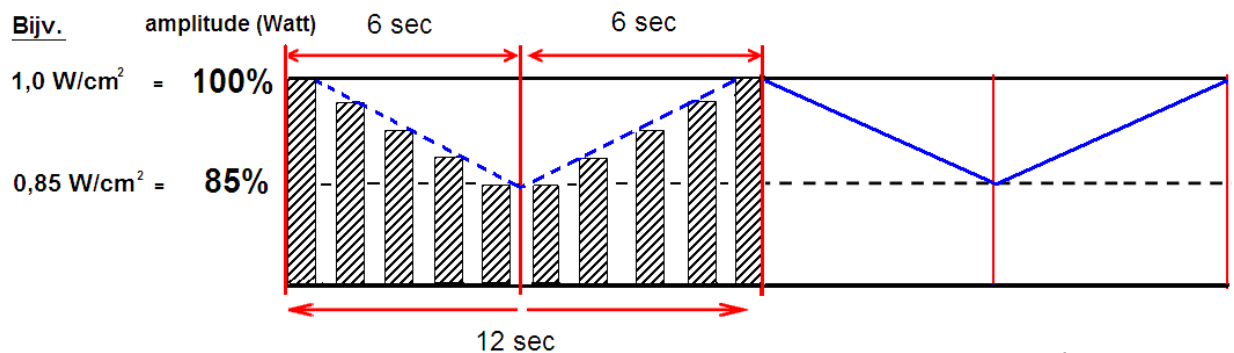
Duty cycle *modulation* implies that the duty cycle fluctuates automatically in a flowing pattern. The modulation is characterised by a fixed duration of a total of 12 seconds, during which time the (pre) set duty cycle goes to 5% and back again. So, if the duty cycle is set at 50%, then it will gradually drop to 5% in 6 seconds and then increase again from 5% to 50% in 6 seconds as well. And so the modulation actually ensures that the pulse duration is automatically reduced or increased.



Duty Cycle Modulation with text 'example of the modulation when Duty Cycle is set at 50%'

Amplitude Modulation

Amplitude Modulation involves varying the ultra-sound intensity. This form of modulation is also characterised by a rhythmic period of 12 seconds. The intensity (W/cm^2) is set at 100%. The intensity will gradually drop from 100% to 85% in the first 6 seconds, after which it will increase back up to 100% in the next 6 seconds.



Amplitude Modulation with text 'example of the modulation when intensity is set at 1.0 W/cm²'

Both forms of modulation can be switched on and off independent of one another. This (de) activation is achieved by selecting the desired function on the parameter display (see page). The standard (factory) setting for both modulation forms is 'modulation on'.

When both modulations are activated, they run synchronous (in phase) and they start 'from high to low'. The difference between the minimum and the maximum level of the effective output is the greatest in this way.

⚠ CAUTION:

StatUS-therapy, on the other hand, makes use of two special forms of modulation that ensure that the peaks in intensity in the ultra-sound bundle are strongly reduced, diminishing the risk of cavitation and preventing the occurrence of 'hotspots'.

6 *Intended use Vacuum*

The continuous and pulsed vacuum module allows vacuum electrodes to be positioned quickly and easily. Furthermore, it is extremely simple to switch between treatment with vacuum electrodes and treatment with flexible rubber electrodes. This makes the vacuum module an ideal aid for electrode placement.

Vacuum electrodes make good contact with the skin, which means that effective use is made of the whole electrodes area. The massage effect resulting from the pulsed vacuum ensures a good blood through the skin under the electrodes. This reduces the resistance of the skin and increases the effectiveness of the stimulation current.

7 *Intended use Myofeedback*

Myofeedback is a form of feedback, in which the patient receives electronically recorded information about his own physiological processes. The electromyographic recording used in the diagnostics and treatment of the moving mechanism is an indispensable supplement to the study of movement. When we place electrodes on the skin to obtain information from an EMG signal about the underlying musculature, we must be acquainted with the development of the EMG signal and the construction and function of the motor mechanism. Thus, properties and mutations in the musculature, the joints system, the sensory and the neural system can be found in the motor system and also in the EMG recording.

Surface EMG provides us with detailed information about the organ-specific properties of a muscle, such as:

- the activation of the muscle;
- the muscle's capacity for relaxation;
- coordination between muscles;
- the tiredness of a muscle;
- the capacity of a muscle to lengthen.

This makes Myofeedback especially suitable as a measuring instrument for charting our locomotive operations (Figure 1).

7.1 Parameters

Sensitivity, allows changing the sensitivity from the measurement range. For surface EMG the read-out is in μV and the pressure read-out is in hPa.

Shift, this parameter makes it possible to zoom-in on a specific area in the graphic to have a better feedback for the patient.

Threshold can be used as target function in feedback therapy. In combination with electro stimulation the threshold triggers the start, or end of the stimulation.

Graph, here you can select the graphical feedback on the screen. There are 2 feedback possibilities, by bar or curve. The colours are not changeable.

Sound, is the acoustic feedback during the treatment. Several settings are possible.

Record, this parameter need to be use as start en registration of the treatment.

Analyze, at the end of the treatment time or after the use of the Stop you can analyze the whole session. Select the icon ◀▶ in the analysis menu to move the cursor in the curve. The value from that position will be displayed on the screen. To zoom-in on that area you can use the loop icon.

Report, here you can find the result of the last session in figures.

Cycles, here you can set the repetitions of the training. This parameter is only applicable in Myofeedback mode; Excerice/ Rest and Template and the Myofeedback + Stimulation mode.

Template, select here the curve type. There are six different training curves available .

7.2 Indications/Contraindications and Adverse Effects for Myofeedback

Indications

- Loss of coordination (voluntary muscles)
- Craniomandibular dysfunction
- Tension headache / Migraine
- Stress-related disorders
- Low-Back Pain
- Respiratory diseases
- Orthopedic, post-traumatic and post-surgical disorders
- Peripheral nerve lesions
- Mimic (Facial) Rehabilitation
- Pelvic Floor Reeducation (Incontinence)

Contraindications

Because Myofeedback therapy does not “do” anything to the body, few contraindications exist. Myofeedback therapy is not recommended for persons with severe psychosis, depression, or obsessional neurosis, nor for debilitated patients or those with psychopathic personalities. However, because resulting functional improvements can require strenuous physical effort, individuals interested in Myofeedback may need to be aerobically fit.

Precautions and Warnings:

Myofeedback is dangerous for diabetics and others with endocrine disorders, as it can change the need for insulin and other medications. Please check with the doctor to see whether this is an appropriate treatment for you.

8 Package Contents

6-series unit range:

1600905	Endomed 682
1600915	Endomed 682V
1600925	Endomed 684
1600935	Endomed 684V
1600945	Sonopuls 692
1600955	Sonopuls 692V
1600948	Sonopuls 692 S
1600957	Sonopuls 692V S
1600961	Sonopuls 690 S
1600965	Myomed 632
1600966	Myomed 632 X
1600968	Myomed 632 UX
1600967	Myomed 632 U
1600970	Myomed 632V
1600971	Myomed 632V X
1600972	Myomed 632V U
1600973	Myomed 632V UX

8.1 Standard Accessories electrotherapy 682 – 692 - 632

3444208	Electrode cable 2mm black
3444209	Electrode cable 2mm purple
3444129	Flexible rubber electrode 6 x 8 cm, 2 sets of 2 pc
1460266	Sponges 6 x 8 cm, 1 set of 4 pc
3444020	Fixation strap 100 x 3 cm, 1 pc
3444021	Fixation strap 250 x 3 cm, 1 pc
1600751	User manual 600-series
3444290	Power cord

8.2 Standard Accessories electrotherapy 684

3444208	Electrode cable 2mm black
3444209	Electrode cable 2mm purple
3444210	Electrode cable 2mm grey
3444216	Electrode cable 2mm light grey
3444129	Flexible rubber electrode 6 x 8 cm, 4 sets of 2 pc
1460266	Sponges 6 x 8 cm, 2 sets of 4 pc
3444020	Fixation strap 100 x 3 cm, 2 pc
3444021	Fixation strap 250 x 3 cm, 2 pc
1600751	User manual 600-series
3444290	Power cord

8.3 Standard Accessories ultrasound 690 - 692

1601901	Ultrasound applicator, 1-3 MHz, ERA 5 cm ²
	Ultrasound gel, bottle of 250 ml
1600810	Ultrasound treatment head holder
xxxxxxx	Ultrasound Contact-gel, 1 bottle

8.4 Standard Accessories Vacuum 682V – 692V – 632V

3444507	Electrode cable red, 2 pc
3444508	Electrode cable black, 2 pc

- 3444078 Dummy
- 3444503 Vacuum electrode Ø 60mm, 2 set of 2 pc.
- 3444505 Sponges Ø 65 mm, set of 4 pc.

8.5 Standard Accessories Vacuum 684V

- 3444507 Electrode cable red, 4 pc
- 3444508 Electrode cable black, 4 pc
- 3444078 Dummy
- 3444503 Vacuum electrode Ø 60mm, 4 set of 2 pc.
- 3444505 Sponges Ø 55 mm, 2 sets of 4 pc.

8.6 Standard Accessories StatUS

- 1601921 Ultrasound treatment head 5 cm² , 1 & 3 MHz StatUS
- xxxxxx x Gelpad for StatUS set of 6 pc
- 3442942 Fixation ring for gelpad StatUS, 3 pc

8.7 Standard Accessories EMG 632

- xxxxxxx Set Adhesive Electrodes for stimulation & EMG, 0,1pc
- 3444673 EMG cable 6-serie, 2pc
- 3444674 EMG reference cable 6-serie, 1pc

8.8 Optional Accessories

- 1601911 Ultrasound applicator, 1-3 MHz, ERA 0.8 cm²
- 1600811 Ultrasound treatment head holder for 2 heads
- 3444128 Flexible rubber electrode 4 x 6 cm, set 2 pc
- 3444130 Flexible rubber electrode 8 x 12 cm, set 2 pc
- 1460273 Sponges, 4 x 6 cm, set 4 pc
- 1460275 Sponges, 8 x 12 cm, set 4 pc
- 3444056 Self adhesive electrodes, size 32mm Ø, 1 pack = 10 sheets of 4 pc
- 3444135 Self adhesive electrodes, size 50mm Ø, 1 pack = 10 sheets of 4 pc
- 3444143 Self adhesive electrodes, size 70mm Ø, 1 pack = 10 sheets of 4 pc
- 3444057 Self adhesive electrodes, size 50x50mm, 1 pack = 10 sheets of 4 pc
- 3444058 Self adhesive electrodes, size 50x90mm, 1 pack = 10 sheets of 4 pc
- 3444146 Self adhesive electrodes with double lead, size 50x100mm, 1 pack = 10 sheets of 2
- 1497801 Remote control 2 channels
- 3442940 Gelpad StatUS™ 8 x 6 pcs
- 3442941 Gelpad StatUS™ 40 x 6 pcs
- 3444118 Vaginal EMG probe
- 3444117 Anal EMG probe
- 3444042 Vaginal pressure probe
- 3444048 Connection hose with air-inlet for vaginal probe 3444042
- 3444043 Anal pressure probe
- 3444045 Connection hose for pressure probe 3444043
- 3444044 Connecting hose for vaginal pressure sensor 3444042
- 3442929 Contact-gel, bottle 250 ml, box of 12
- 1600820 EN-Point
- 3444222 Pregelled disposable electrodes for EMG and stim.
- 3444302 Pregelled disposable electrodes, 25 pcs
- 3444380 Silicon electrode 5x5 cm TENS
- 3444505 Sponges Ø 95 mm, set of 4 (for vacuum electrodes Ø 90 mm)
- 3444503 Vacuum electrodes Ø 90 mm, set of 2x2
- 3444667 Snap-connector, 2 mm female, 3 pcs
- 1600830 Myocombox



9 Installation

9.1 Units without a Vacotron module

- Remove the 6-series unit and any additional items ordered from the carton and inspect for damage that may have occurred during shipment.
- Place the unit on a desk or EN-Car. Ensure that there is sufficient air flow below the unit (do not place the unit on a table-cover).
- If necessary, adjust the adjustable foot [21], so that the unit does not wobble.

9.2 Units with a Vacotron module

- Remove the 6-series unit and any additional items ordered from the carton and inspect for damage that may have occurred during shipment.
- Place the vacuum unit on a desk or EN-Car.
- If necessary adjust the vacuum unit's adjustable foot [25], so that the vacuum unit does not wobble.
- Place the main unit on top of the vacuum unit.
- If necessary adjust the main unit's adjustable foot [21], so that the main unit does not wobble.
- Push the vacuum hose [23] over the hose nipples on both units.
- Carefully lift the main unit at the front and insert flat cable [17] into connector [18].

9.3 Connection to mains supply

- Insert the mains cable into socket [20] and connect it to a wall socket. Status indicator LED [14] indicates that the unit is connected to the mains supply.

CAUTION:

- Do not place the unit in a location where the power cord could be tripped over or pulled out during treatment.
- Do not attempt to use the unit if it is not properly grounded. Make certain that the unit is electrically grounded by connecting it only to a grounded electrical service receptacle conforming to the applicable national and local electrical codes regarding medical environments.
- The unit will initialize. This may take a while. During initialization LED [14] blinks yellow.
- At the end of the initialization the unit enters standby mode. LED [14] is now continuously yellow.
- Start the unit by pushing the standby button [19] ¹.
- The unit starts by executing the self test, during which LED [14] blinks green.
- At the end of the self test the unit enters the Home menu and is ready for use. LED [14] is now continuously green.
- When you have finished treatments push the standby button [19] ¹ again to leave the unit in standby mode.

¹ When you push the standby button for more than two seconds, the unit will completely reinitialize and enter standby mode.

10 Application Notes

10.1 Electrotherapy

⚠ CAUTION:

- Connection of accessories other than the ones specified by the manufacturer can adversely affect the safety of the patient and correct functioning of the equipment, and is therefore not permitted.
- To prevent infection, electrodes and sponge pads should not be used on broken skin.

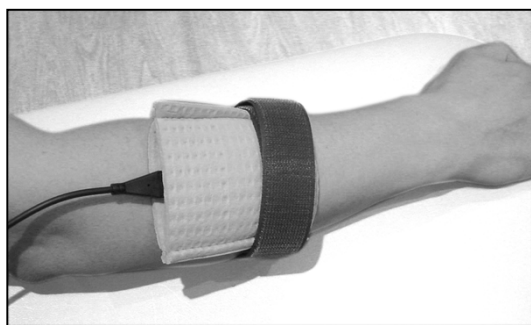
10.1.1 Before treatment

- Check the patient for contraindications and warnings as described in paragraph 4
- Test the heat sensibility of the treatment area.
- Rinse the treatment area. Shaving hairy skin is recommended.

10.1.2 Flexible rubber electrodes

We recommend using the flexible rubber electrodes in combination with the supplied sponge pads. When properly moistened, the sponge pads ensure low impedance between the skin and the stimulator during treatment and they are easily cleaned afterwards. Follow the guidelines below when using these electrodes.

- Prior to initial use thoroughly rinse the sponge pads in warm tap water to remove the impregnating agent.
- Before application saturate the sponge pads with tap water. In areas with soft tap water use a saline solution instead. This will improve electrical conduction.
- The supplied sponge pads have three layers. With AC currents, apply one sponge layer between the skin and the electrode for minimum resistance.
- With DC currents, apply two sponge layers between the skin and the electrode. Two layers provide more absorbing capacity for electrolysis by-products.
- Fix the electrode/sponge pad assembly to the patient using the supplied fixation straps. Depending on the electrode size, use two or three wraps to maximize the contact surface. See the illustrations below.



Wrong application of fixation straps, resulting in poor electrical conductivity.



Correct application of fixation straps, resulting in good electrical conductivity.

- Use the stimulator in the Constant Current (CC) mode. This will maintain the set current amplitude, even when the impedance of the sponge pads increases during treatment caused by water evaporation.
- Keep the sponge pads well moistened during treatment, especially with DC currents. If the current display starts blinking, it is an indication of poor electrical contact.
- After use clean the sponge pads as described in the User Maintenance instructions.

CAUTION: Do not use electrodes on open wounds



10.1.3 Vacuum electrodes

There is a choice of large and small electrodes. The areas of the electrodes correspond to those of the 4 x 6cm and 6 x 8cm flexible rubber electrodes. The vacuum electrodes are sufficiently flexible to ensure optimum contact with the skin, but rigid enough to prevent any changes in the contour of the part being treated, allowing full advantage to be taken of the massage effect of the pulsed vacuum.

Keep the sponge pads well moistened during treatment.

After use clean the sponge pads as described in the User Maintenance instructions.

10.1.4 Self-adhesive electrodes

Self-adhesive electrodes have higher series impedance than flexible rubber electrodes. This can cause the stimulator to terminate treatment at higher current amplitudes. When this occurs it is recommended to continue the treatment with flexible rubber electrodes, combined with properly moistened sponge pads.

Self-adhesive electrodes are not recommended for use with currents that contain a DC component.

CAUTION: Do not use electrodes on open wounds.

10.1.5 Electrolytic effects

Electrolysis occurs under the electrodes when current types with a DC component are applied. Because the greatest concentration of electrolytic by-products caused by ion migration occur under the electrodes, we recommend the use of the supplied sponges to keep the effects to a minimum. Make sure that the sponges are kept well moistened and place the thick side of the sponge between the flexible rubber electrodes and the patient.

10.1.6 Current density

In the particular standard for Electrical Nerve and Muscle Stimulators, IEC 60601-2-10, it is recommended not to exceed a current density of 2 mA r.m.s. / cm², otherwise skin irritations or burns can occur. For current types that contain a DC component we recommend not to exceed a current density of 0.2 mA / cm².

To find the maximum recommended current amplitude in mA for the Interferential, Premodulated and Russian Stimulation current waveforms, multiply the electrode surface in cm² by two. For all other current waveforms the stimulator output current can never exceed 50 mA r.m.s. This implies that with an electrode surface of 25 cm² the current density can never exceed 2 mA r.m.s. / cm². As a rule of thumb for smaller electrodes, such as the 3.2mm self adhesives, the maximum current setting available on the stimulator for a given current waveform should proportionally be reduced.

For a precise calculation of the r.m.s. value of a pulsed current waveform the following formula can be used:

$$I_{RMS} = I_{peak} \sqrt{(\text{Phase duration } [\mu\text{s}] * \text{pulse frequency } [\text{Hz}] * 10^6)}$$

For symmetrical TENS currents, the Phase duration should be multiplied by 2. The value of the peak current I_{peak} can be taken from the current display.

Electrodes should be placed with care, ensuring good electrical contact over the entire electrode surface.

10.1.7 Connection and disconnection reactions

Constant Current (CC) output characteristics may cause unpleasant connection and disconnection reactions if the electrodes are not securely placed or lose contact with the skin. Make sure the current amplitude is set to 0 mA when you apply or remove the electrodes. Use the Constant Voltage (CV) output mode with dynamic electrode applications.

10.2 Ultrasound

10.2.1 Contact Control

The ultrasound applicator has a contact control function that suspends treatment when the acoustical contact with the body drops below a certain level (see paragraph 14.1). The indicator light on the applicator is turned on to signal this situation, the ultrasound Amplitude display will start blinking and the treatment timer will stop counting down. During this situation the applicator emits a small amount of energy to sense restoration of acoustical contact. You may experience this when the applicator only partially contacts the body. When contact restoration is sensed the treatment is resumed at the set Amplitude.

The contact control function does not work at Amplitudes below 0.2 W/cm².

10.2.2 The contact medium

To ensure efficient transfer of energy, a contact medium is required between the ultrasound applicator and the body. Air causes virtually total reflection of the ultrasound energy. The best medium for the transfer of ultrasound energy is a gel.

- The gel should be applied to the part of the body to be treated and then spread out with the ultrasound applicator.
- Never apply the gel to the ultrasound applicator. The applicator will register this as acoustical contact and may emit ultrasound energy, which could damage the applicator.

If the body surface is very irregular, making it difficult to obtain good contact between the ultrasound applicator and the body, or if direct contact must be avoided (e.g. due to pain), the affected area may be treated under water (subaquatic method). The water should be degassed (by previous boiling) in order to prevent air bubbles arising on the ultrasound applicator and the body.

10.2.3 Before treatment

- Check the patient for contraindications. See section 5.1.1 for details.
- Test the warmth sensibility of the treatment area.
- To optimize ultrasound transmission, clean the skin of the treatment area with soap or a 70% alcohol solution.
- Strong hair growth has to be shaved.

10.2.4 During treatment

- The ultrasound applicator has to be moved constantly, also with the semi-static method. During treatment the displayed ultrasound Amplitude can vary around the set value, caused by fluctuations in acoustical coupling.
- Ask the patient regularly for his/her findings. If necessary the treatment will have to be adapted. The Amplitude can be reduced or the continuous mode can be changed to pulsed mode or vice versa.

- When there are signs that the ultrasound transmission is bad, add more contact gel or spread it with the applicator.

CAUTION:

- The ultrasound applicator is a precision instrument. Great care has been taken during the development and in production to obtain the best possible beam characteristics. Rough treatment (jarring or dropping) can adversely affect these characteristics, and must therefore be avoided.

10.2.5 After treatment

- Clean the skin of the patient and the ultrasound applicator with a towel or tissue. Clean the applicator with a 70% alcohol solution.
- Check for the effects that can be expected (for example pain, circulation and mobility).
- Ask the patient to inform the therapist of any reactions.

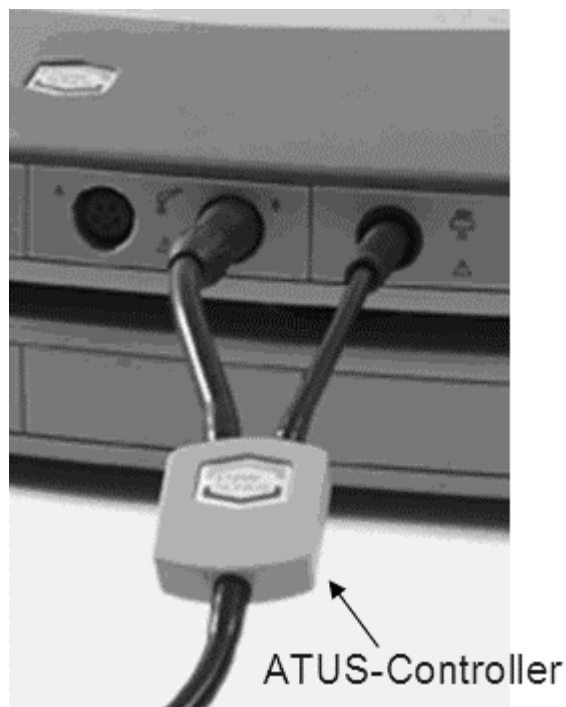
10.3 StatUS

10.3.1 Connecting the StatUS-applicator

Make sure that the logo of the ATUS-controller is pointing upward.

Plug in the left plug of the ATUS-controller in connection B of the UG-module [1].

Connect the right plug to the StatUS-module [2].



A special gel cushion (gel pad) is placed on the head for a proper transfer of the ultra-sound energy. Do not use regular (fluid) Sonogel, as it is sucked into the vacuum pump. The gel pad is held in position using a fixation. The vacuum pressure ensures that the head can be placed on the body quickly and easily and that the head remains in contact with the body surface.

10.3.2 Applying the fixation

Press the fixation included across the treatment head (see photograph hereunder)
Make sure that the ridge on the inner side of the fixation [A] falls in the groove of the treatment head [B]



10.3.3 Applying the gel pad (gel cushion)

Place a gel pad in the ring (see photograph...). The StatUS-applicator is now ready for use.
The gel pads are intended for once-only use. Instructions are supplied with the gel pads. Read these carefully.



You are also referred to chapter 10.3 for instructions on operating the device.

Warning: only use the original Enraf-Nonius gelpads! Do not use liquid gel as this will be sucked into the vacuum tubes and pump, causing malfunction!
Any warranty claim will be rejected if liquid gel residue is found in any of these components.

Warning: since the StatUS-applicator transfers ultrasound energy into the tissue at a most efficient and effective way, we advise you to use lower intensity settings than the usual intensity settings for 'traditional' (semi-stationary or dynamic) ultrasound.

10.4 EMG

10.4.1 Connections

E1 : EMG channel 1
REF : Reference cable
E2 : EMG channel 2
P : Pressure channel



Headphone connector, (backside of the unit) for the raw EMG signal

The connection with the MyoComBox is wireless via Bluetooth. This is only possible if the X module is integrated.



CAUTION

- Connection of accessories other than the ones specified by the manufacturer can adversely affect the safety of the patient and correct functioning of the equipment, and is therefore not permitted.

11 Operating Instructions

11.1 Operator Controls

(See jacket flap)

[1] Standby button

With this push button the 6-series is switched between On and Standby. Pushing this button for more than two seconds will reset the device.

[2] Connector for mains cable

To disconnect the device from the power line, unplug the power cord.

Type number/warning sticker

Provides information on the apparatus, such as type and serial number, as well as connection data such as mains voltage and maximum current consumption.

[1] Selection button for:

Electrotherapy channel 1

Push the button to view or adjust all parameters of electrotherapy channel 1.

[2] Selection button for:

Electrotherapy channel 2.

Push the button to view or adjust all parameters of electrotherapy channel 2.

[3] Selection button for:

Ultrasound channel

Push the button to view or adjust all parameters of the ultrasound channel.

[4] Selection button for:

Optional module.

[5] Central controller

Use this controller to select menu items and to adjust all parameters including current amplitude and ultrasound intensity.

[6] Confirmation button for:

Confirmation of all settings and selections.

[7] Assist button for:

Secondary functions, such as Stop, Home, Pause, Continue and Protocol Information. The Assist button also provides access to the Vacotron module, when one is installed.

[8] Connection for Remote Control of Electrotherapy channels

[9] Connection Electrode Cable Electrotherapy channel 1

[10] Connection for additional accessories

[11] Connection Electrode Cable Electrotherapy channel 2

[12] Connection Ultrasound applicator A

[13] Connection Ultrasound applicator B

⚠ CAUTION:

- Connection of accessories other than the ones specified by the manufacturer can adversely affect the safety of the patient and correct functioning of the equipment, and is therefore not permitted. For combined applications only use Enraf-Nonius type BF equipment. The very low leakage current of this type of equipment ensures absolute safe therapy.
- The ultrasound applicator is a precision instrument. Great care has been taken during the development and in production to obtain the best possible beam characteristics. Rough treatment (jarring or dropping) can adversely affect these characteristics, and must therefore be avoided.
- Connection of accessories other than the ones specified by the manufacturer can adversely affect the safety of the patient and correct functioning of the equipment, and is therefore not permitted.
- The selection for activating the output is in the ultrasound menu

[14] Status LED

This lamp can indicate one of the following device states:

- Off Not connected to power line
- Yellow blinking Initializing
- Yellow continuous Standby
- Green blinking Performing self test
- Green continuous Ready for use

[15] Connections Vacuum Cables Electrotherapy channel 1

[16] Connections Vacuum Cables Electrotherapy channel 2

[17] Interconnection cable vacuum unit to main unit

[18] Electrotherapy output to vacuum unit

[21] Adjustable foot main unit

[22] Secure Digital memory card slot

[23] Vacuum hose between vacuum unit and main unit

[24] Water separation reservoir emptying hose

[25] Adjustable foot vacuum unit

11.2 Basic Operation

11.2.1 Turn on the apparatus

- Start the unit by pushing the standby button [19].
- The unit starts by executing the self test, during which LED [14] blinks green.
- At the end of the self test the unit enters the Home menu and is ready for use. LED [14] is now continuously green.

11.2.2 Navigation and display organization

The display is organized as a spreadsheet of four sheets, one for each channel. The channels refer to the application modules accessible at the front of the unit. A sheet can be selected with the channel selection button [1, 2, 3, 4] and shows the parameters belonging to that channel. Each sheet has a tab, in which the output amplitude of that channel is displayed, as well as other important information, such as the remaining treatment time. The tab information is continuously visible.

Each sheet contains a list of therapy parameters. A parameter can be selected with the central controller [5] and opened by pressing the confirmation button [6]. When opened, a pop-up window appears, in which the parameter can be changed, using the central controller [5]. Pressing the confirmation button [6] again takes you back to the parameter list. To adjust the output amplitude, first press the channel selection button [1, 2, 3, 4] and then adjust the amplitude with central controller [5]. Pressing the confirmation button [6] takes you back to the parameter list.

For some applications, such as interferential therapy and combination therapy, two adjacent channels can be linked. Linked channels are indicated by a combined tab. The tab halves show the output amplitude of each channel, while the parameters on the remainder of the sheet apply to both channels.

When you turn on the unit, you will first enter the Home menu. In the Home menu none of the channels are selected. The Home menu provides a structured access to all therapies available within the unit, with appropriate parameter defaults. Just select a menu item using the central controller [5] and press the confirmation button to navigate to the next screen. You can navigate back to the previous screen by directing the cursor to the back arrow at the top of the screen and pressing the confirmation button [6]. Anywhere in the navigation, you can jump back to the Home menu, by pressing the Assist button [7] and selecting the Home entry in the pop-up list that appears.

11.2.3 Home menu

The Home menu gives access to all functions of the unit. Select the desired function or therapy with the central controller [5] and enter the next menu by pushing the confirmation button [6].



11.2.4 Therapy Wizard

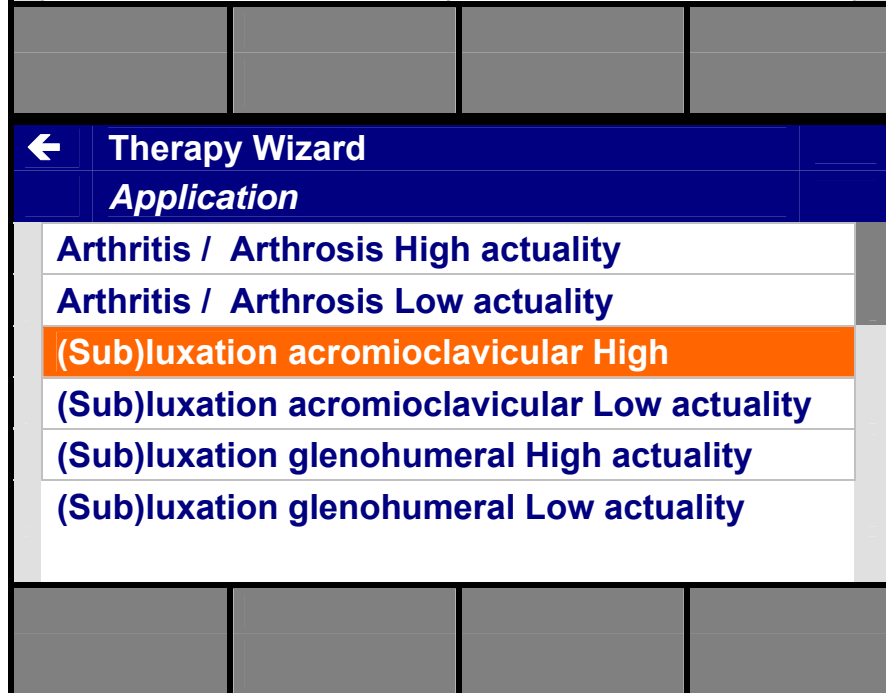
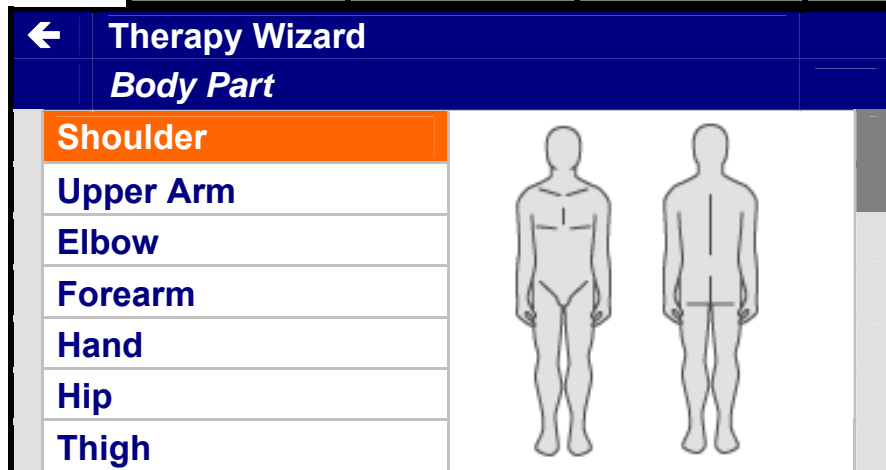
The Therapy Wizard guides you through a wide range of treatment suggestions. You select either Body Part or Application. Under the personal protocols you can retrieve your personal stored protocols.

- Select the desired choice with the central controller [5] and enter it with the confirmation button [6]

- Select the treatment area with the central controller [5] and enter with the confirmation button [6]
- To return to the home menu, push the assist button [7] and select Home menu.

- Select the treatment with the central controller [5] and enter with the confirmation button [6]

- Select the current channels in the "Channel Selection"
- 1+2 channels are linked
- 1 independent channel
- 2 independent channel



The display is showing the select protocol and pre-programmed parameter setting.

Use the Assist button [7] for:

- Therapy information
- Electrode placement by picture
- Storing
- Pause

It's always possible to change parameter setting.

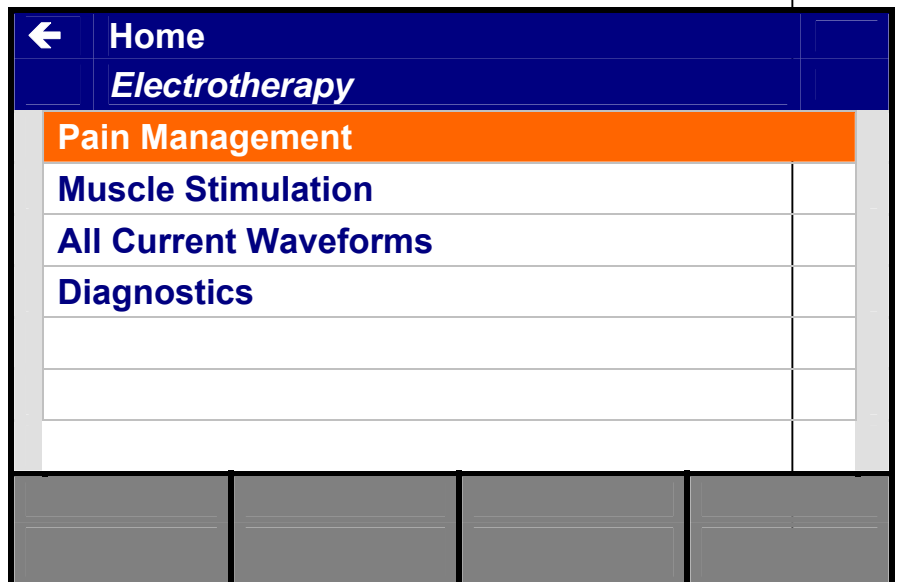
← Pain Management 1+2	
<i>(Sub)luxation acromioclavicular High</i>	
Premodulated	
Treatment Time	20:00
Carrier Frequency	6.0 kHz
Beat Frequency	100 Hz
Frequency Modulation	0 Hz
Modulation Program	1/1 s
Surge Program	
▶ 19:50	
15.0 mA	14.3 mA

11.2.5 Electrotherapy

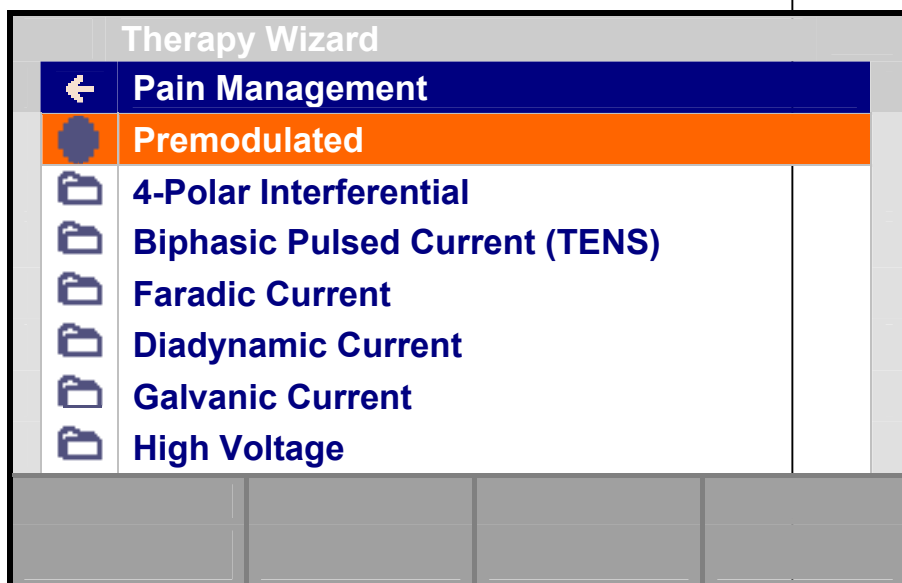
- Select electrotherapy with the central controller [5] in the main menu.
- Enter the selection by pushing the confirmation button.
- For easy and simple access to Current Waveforms we divided them in different groups.
 - Pain management here you can find all Current Waveforms for pain management
 - Muscle stimulation here you can find all Current Waveforms for muscle stimulation
 - Quick access to all Current Waveforms
 - Diagnostics here you enter the diagnostic part to generate S/D curves
- Select the desired choice with the central controller [5] and enter with the confirmation button [6]

Sonopuls 692	
Home	
Therapy Wizard	
Electrotherapy	
Ultrasound Therapy	
Combination Therapy	
System Settings	

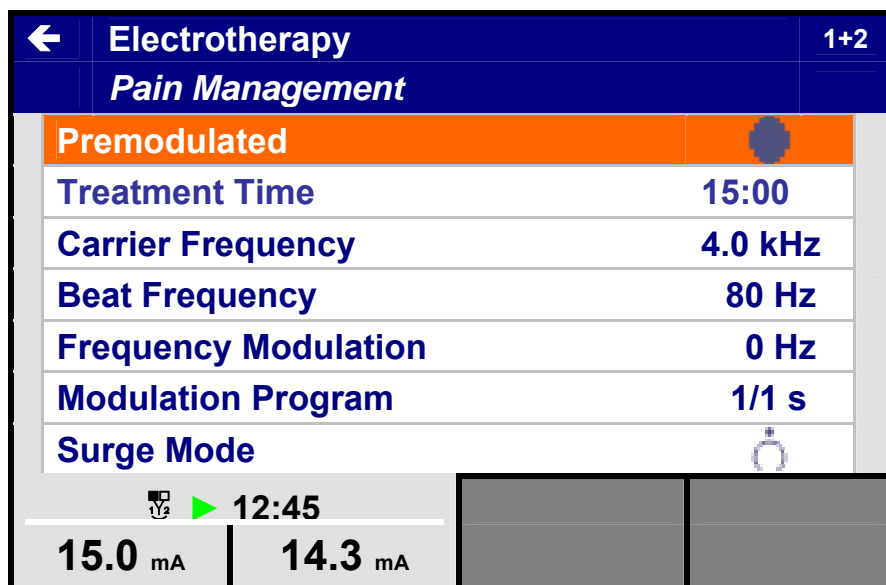
- Select the desired application with the controller [5] and enter with the confirmation button [6]



- Select the desired current with the central controller [5] and enter with the confirmation button

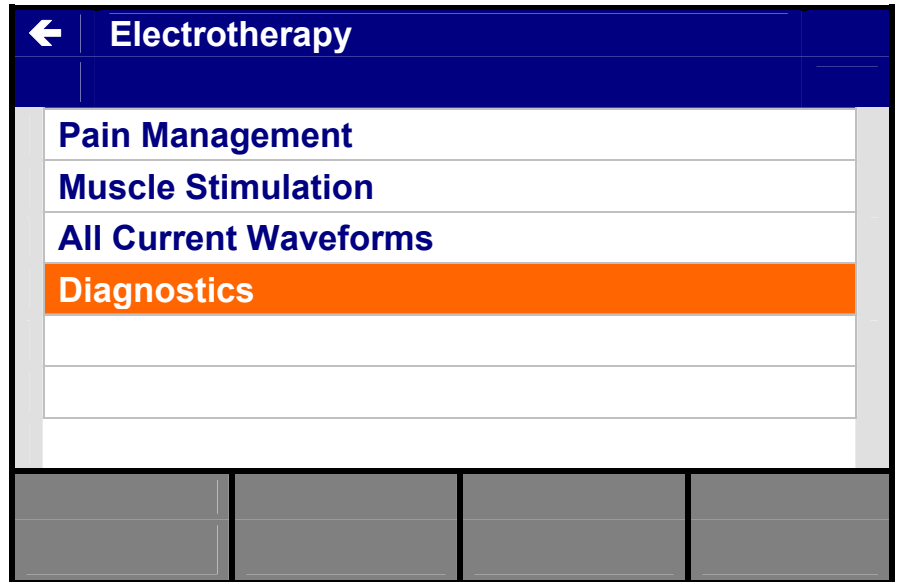


- Changing parameters
- Select the parameter with the central controller [5] and enter with the confirmation button [6]
- The range of the parameter is shown in the pop-up screen.
- Push the confirmation button [6] to return
- Select other parameter or start the therapy with the intensity

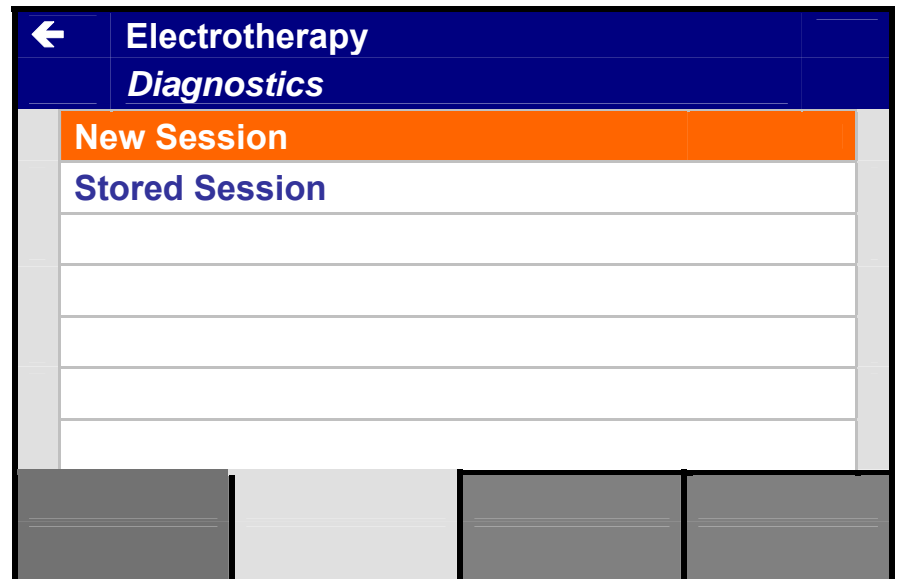


11.2.5.a Diagnostics

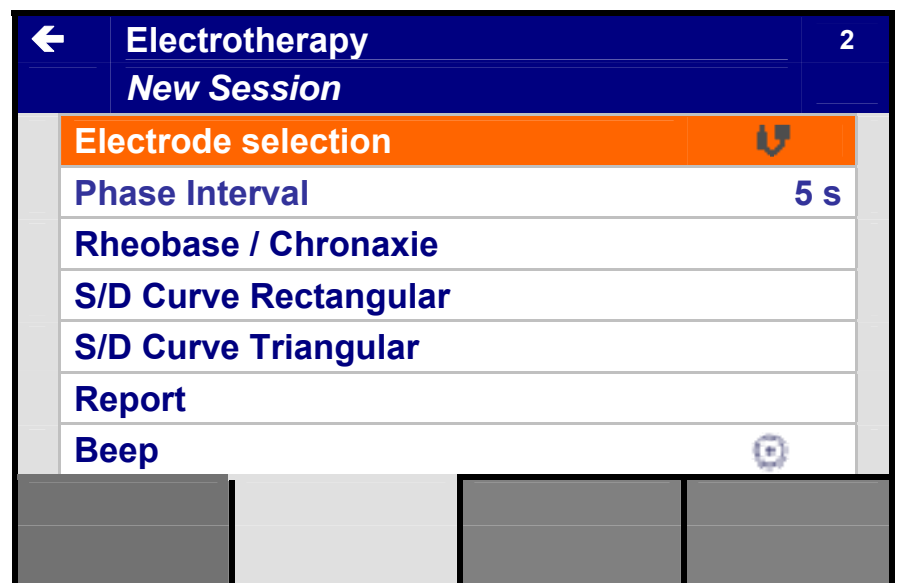
- Select Diagnostics application with the controller [5] and enter with the confirmation button [6]
- Select new session
- Select channel 1 or 2. Channel 2 offers additional to channel one the use of a Search Probe.
- Connect the special probe on connector [10]



- Select New Session



- Select channel 2
- Select Search Probe with the central controller [5] and enter with the confirmation button [6] Select On or Off.
- Read the information on in the pop-up screen concerning the return electrode. (use the negative electrode as return electrode)



11.2.5.a.1 Rheobase/ Chronaxie

- Select Rheobase / Chronaxie with the central controller [5] and enter with the confirmation button [6]

Electrotherapy 2

Diagnostics

Electrode selection

Phase Interval 5 s

Rheobase / Chronaxie

S/D Curve Rectangular

S/D Curve Triangular

Report

Beep

mA

- Start with the Rheobase. The phase duration is fixed on 500ms.
- To start push the confirmation button [6] you activate the intensity setting. Use the central controller [5] to adjust the intensity.
- Confirm the value by pushing the confirmation button [6]
- Repeat by pushing the confirmation button [6] again.

Diagnostics 2

Rheobase / Chronaxie

80 mA

10

1

0.1 1 10 100 1000 ms

Rheobase

500 ms

Chronaxie

5.0 mA

- Select Chronaxie with the central controller [5] and confirm with the confirmation button [6]
- The retrieved intensity in the Rheobase will be doubled automatic.
- Adjust the Phase duration with the central controller [5] until the muscle contract.

Diagnostics 2

Rheobase / Chronaxie

80 mA

10

1

0.1 1 10 100 1000 ms

Rheobase

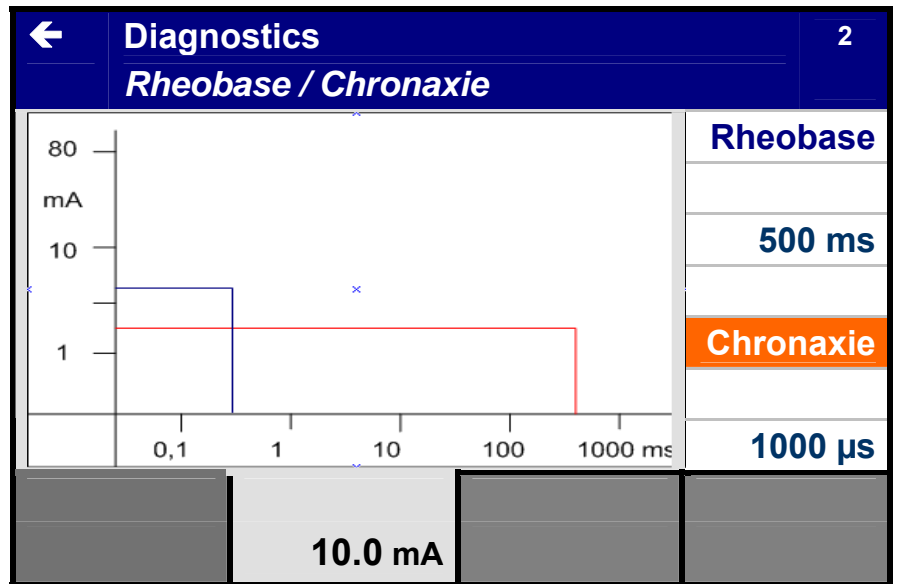
500 ms

Chronaxie

1000 μs

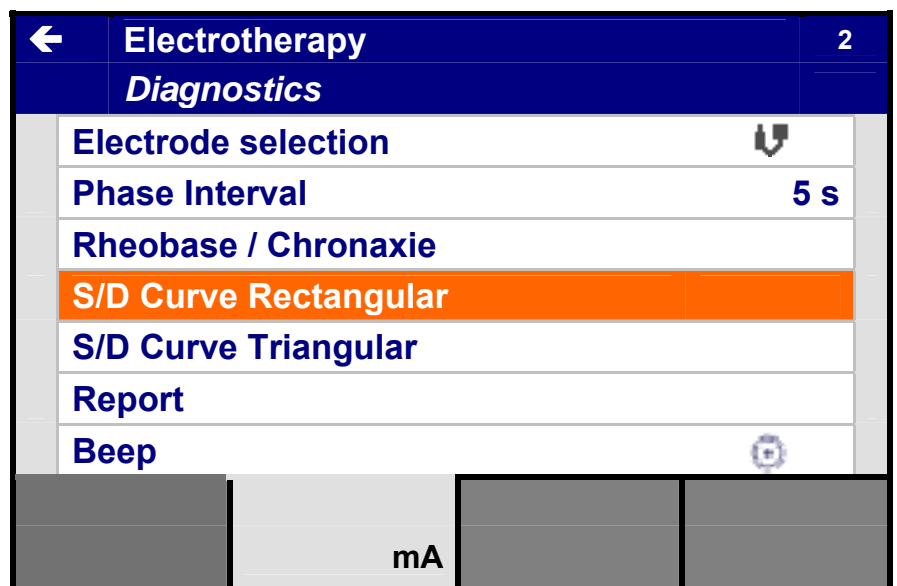
10.0 mA

- Push the confirmation button [6] to accept and to see the complete curve
- Return to the previous menu via the central controller [5]
- Select Report to see the results by figures.

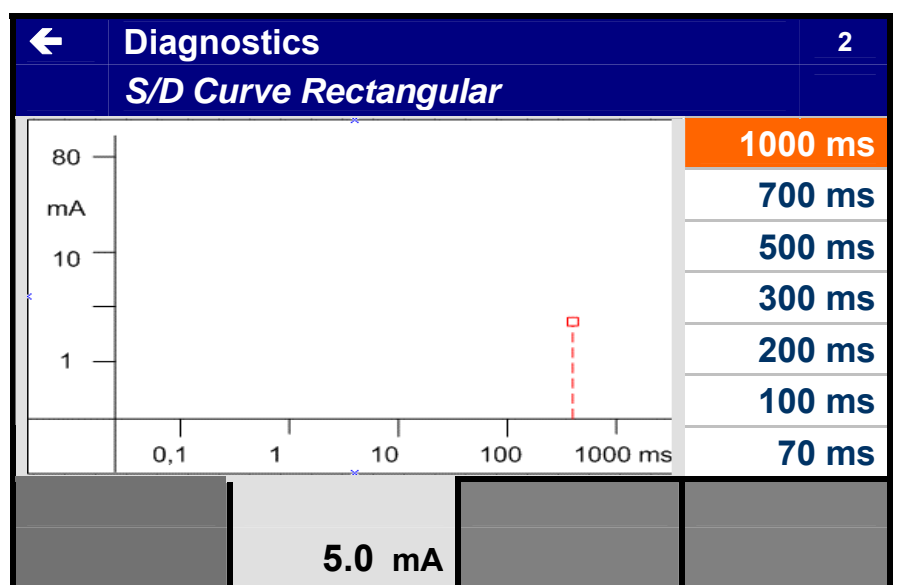


11.2.5.a.2 S/D Curve

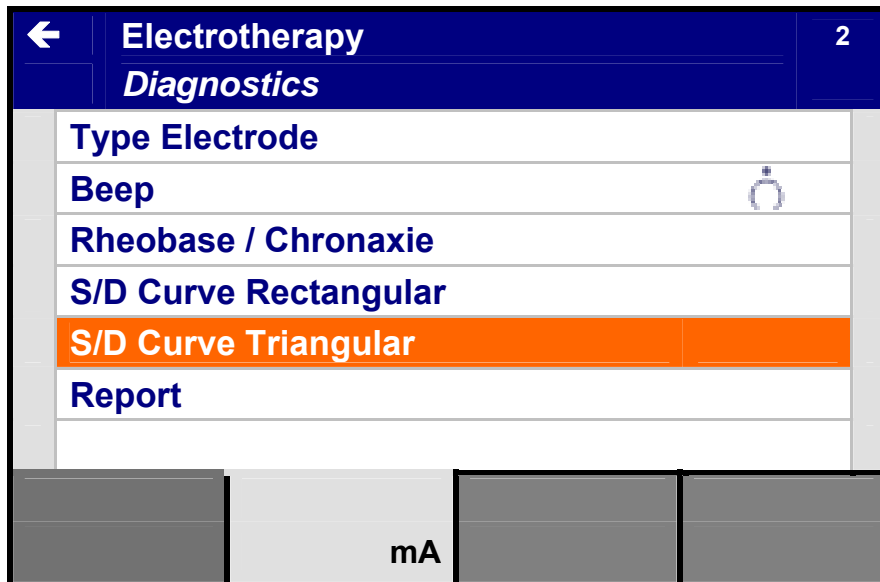
- Select S/D Curve Rectangular with the central controller [5] and enter with the confirmation button [6]



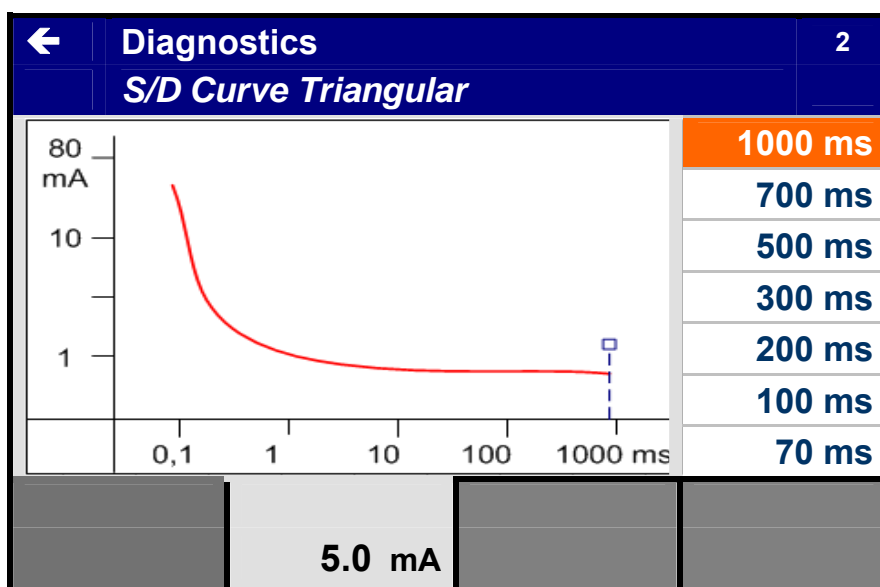
- Select the phase duration with the central controller [5], you can start on highest (1000 ms) or lowest value (50 μs)
- Push the confirmation button [6] you activate the intensity setting.
- Use the central controller [5] to adjust the intensity.
- Every push on the special probe or every beep will generate one pulse.
- Confirm the value by pushing the confirmation button [6]
- Select the second the next phase duration with the central controller in the list. To receive a correct calculation you need to select minimum 10 different phase durations, always include 500 ms.
- Select “←” (left corner) to return to the previous menu.



- Select S/D Curve Triangular with the central controller [5] and enter with the confirmation button [6]



- Select the phase duration with the central controller [5], you can start on highest (1000 ms) or lowest value (100 μ s)
- Push the confirmation button [6] you activate the intensity setting.
- Use the central controller [5] to adjust the intensity.
- Every push on the special probe or every beep will generate one pulse.
- Confirm the value by pushing the confirmation button [6]
- Select the second the next phase duration with the central controller in the list. To receive a correct calculation you need to select minimum 10 different phase durations, always include 500 ms.
- Select "←" (left corner) to return to the previous menu.



- Select report
- You can store the results by pushing the assist button [7]
- Select store
- Push the confirmation button [6].
- The results will be stored under:
 - Diagnostics
 - Stored sessions

← Diagnostics		2
Report		
Rheobase	1.6 mA	
Chronaxie	10 ms	
Effective Phase Duration	1000 ms	
Accommodation Threshold	4.2 mA	
Accommodation Quotient	2.6	
Optimal Phase Duration	30.0 ms	
Amplitude	2.8 mA	
[Buttons]		

11.2.6 Ultrasound therapy

- Using the central controller [5], select Ultrasound in the Home menu.
- Enter the selection with the confirmation button [6].

Sonopuls 692	
Home	
Therapy Wizard	
Electrotherapy	
Ultrasound Therapy	
Combination Therapy	
System Settings	
[Buttons]	

- Select personal protocols or manual settings with the central controller [5] and enter with the confirmation button [6].
- Under personal protocols we offer you a range of treatment suggestions.
- Under manual settings you can adjust all parameters.

← Ultrasound Therapy	
Manual Settings	
Personal Protocols	
[Buttons]	
A ■ 0:00	
0.00 W/cm ²	

- Changing parameters
- Select the parameter with the central controller [5] and enter with the confirmation button [6]
- Adjust the setting in the pop-up screen
- The range of the parameter is showing in the pop-up screen.
- Push the confirmation button [6] to return
- Select other parameter or start the therapy with the intensity

← Ultrasound		3
Treatment Time	06:00 min	
Applicator	A	
Ultrasound Frequency	1 MHz	
Duty Cycle	100 %	
Pulse Frequency	100 Hz	
Units	W/cm ²	
		A 06:00 1.50 W/cm ²

11.2.7 Combination therapy

- Using the central controller [5], select Combination in the main menu.
- Enter the selection with the confirmation button [6].

Sonopuls 692	
Home	
Therapy Wizard	
Electrotherapy	
Ultrasound Therapy	
Combination Therapy	
System Settings	

- Select personal protocols or manual settings with the central controller [5] and enter with the confirmation button [6].
- Under personal protocols you can retrieve your stored protocols.
- Under manual settings you can adjust all parameters..

← Combination Therapy		
Manual Settings		
Personal Protocols		
		A ■ 0:00 0.00 W/cm ²

- Using the central controller [5], select a parameter.
- Enter the selection with the confirmation button [6]
- Adjust the parameter in the pop-up with the central controller [5]
- The range of the parameter is shown in the pop-up screen.
- Push the confirmation button to return.

← Combination Therapy		2
Premodulated		
Treatment Time	7:00	
Carrier Frequency	4.0 kHz	
Beat Frequency	80 Hz	
Frequency Modulation	0 Hz	
Modulation Program	1/1 s	
Output Mode	CV	
<div style="text-align: center;"> 07:00 A 0.0 mA 1.50 W/cm² </div>		

11.2.8 StatUS Therapy

- Using the central controller [5], select StatUS Therapy in the main menu.
- Enter the selection with the confirmation button [6].

Sonopuls 692 S	
Home	
Therapy Wizard	
Electrotherapy	
Ultrasound Therapy	
Combination Therapy	
StatUS Therapy	
System Settings	
<div style="text-align: right;"> A ■ 0:00 0.00 W/cm² 0 </div>	

- Select personal protocols or manual settings with the central controller [5] and enter with the confirmation button [6].
- Under personal protocols you can retrieve your stored protocols.
- Under manual settings you can adjust all parameters..

← StatUS Therapy	
Manual Settings	
Personal Protocols	
<div style="text-align: right;"> A ■ 0:00 0.00 W/cm² 0 </div>	

- Push the selection button [4] and adjust the pressure with the central controller [5]

StatUS		3+4
Treatment Time	0:00	
Ultrasound Applicator	B	
Ultrasound Frequency	1 MHz	
Duty Cycle	20 %	
Duty Cycle Modulation		
Amplitude Modulation		
Pulse Frequency	100 Hz	
		B ■ 7:00
		0.00 W/cm ² 45

- Using the central controller [5], select a parameter.
- Enter the selection with the confirmation button [6]
- Adjust the parameter in the pop-up with the central controller [5]
- The range of the parameter is shown in the pop-up screen.
- Push the confirmation button to return.
- Push the selection button [3] to adjust the intensity from the ultrasound

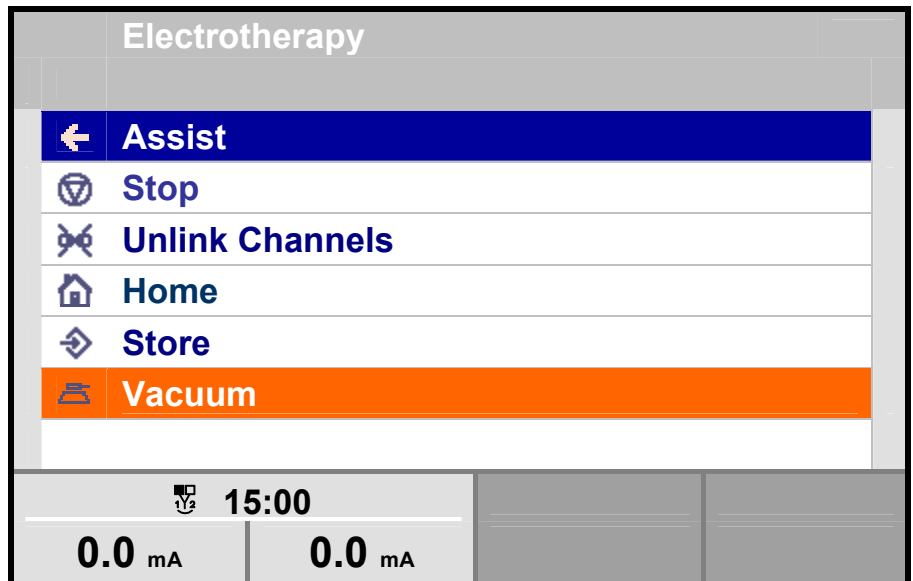
StatUS		3+4
Treatment Time	7:00	
Ultrasound Applicator	B	
Ultrasound Frequency	1 MHz	
Duty Cycle	20 %	
Duty Cycle Modulation		
Amplitude Modulation		
Pulse Frequency	100 Hz	
		B ■ 7:00
		0.00 W/cm ² 45

Warning: only use the original Enraf-Nonius gelpads! Do not use liquid gel as this will be sucked into the vacuum tubes and pump, causing malfunction!
Any warranty claim will be rejected if liquid gel residue is found in any of these components.

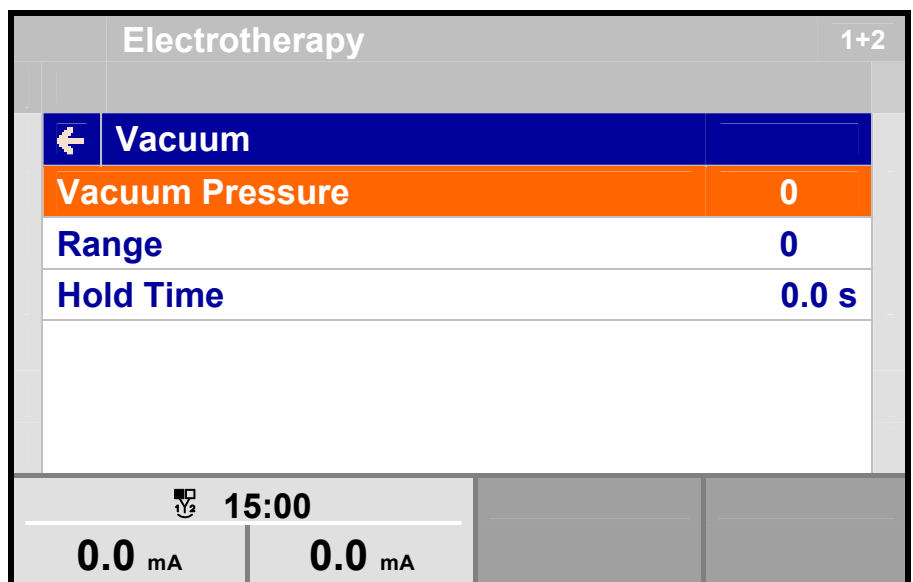
Warning: since the StatUS-applicator transfers ultrasound energy into the tissue at a most efficient and effective way, we advise you to use lower intensity settings than the usual intensity settings for 'traditional' (semi-stationary or dynamic) ultrasound.

11.2.9 Vacuum adjustment via Assist button

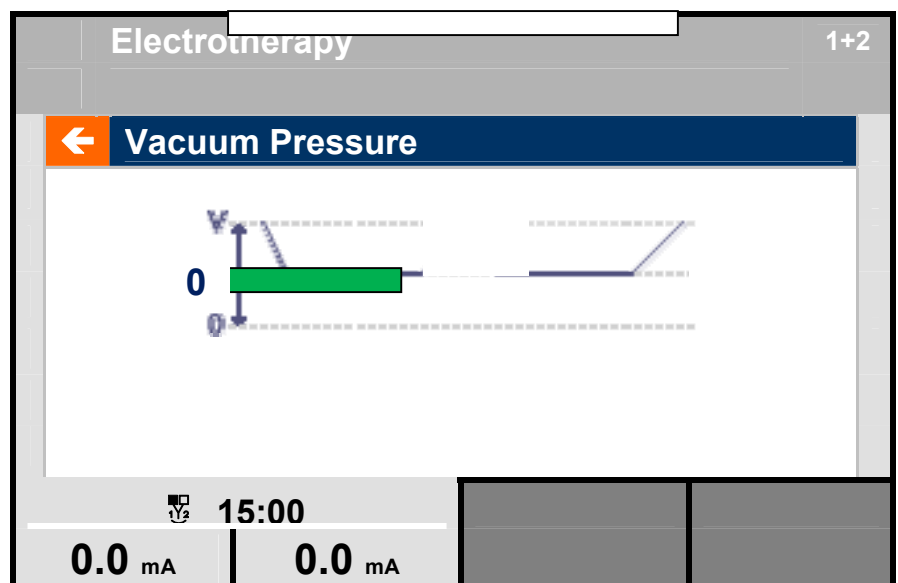
- Push the Assist button [7]
- Select in the pop-up with the central controller [5] Vacuum
- Push the confirmation button to return.



- Select in the pop-up with the central controller [5] Vacuum pressure



- To start the vacuum unit, adjust the pressure with the central controller [5]
- Push the confirmation button to return

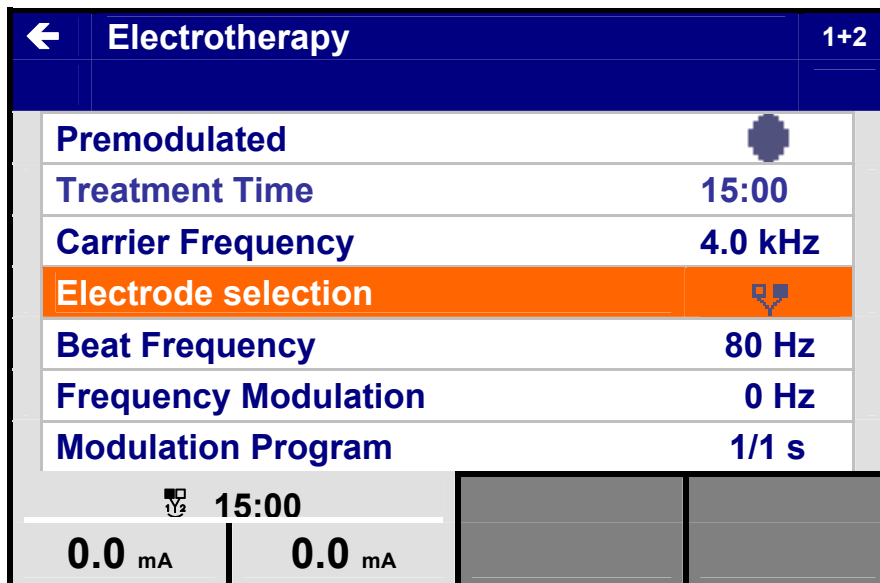


11.2.9.a Vacuum pulsed mode

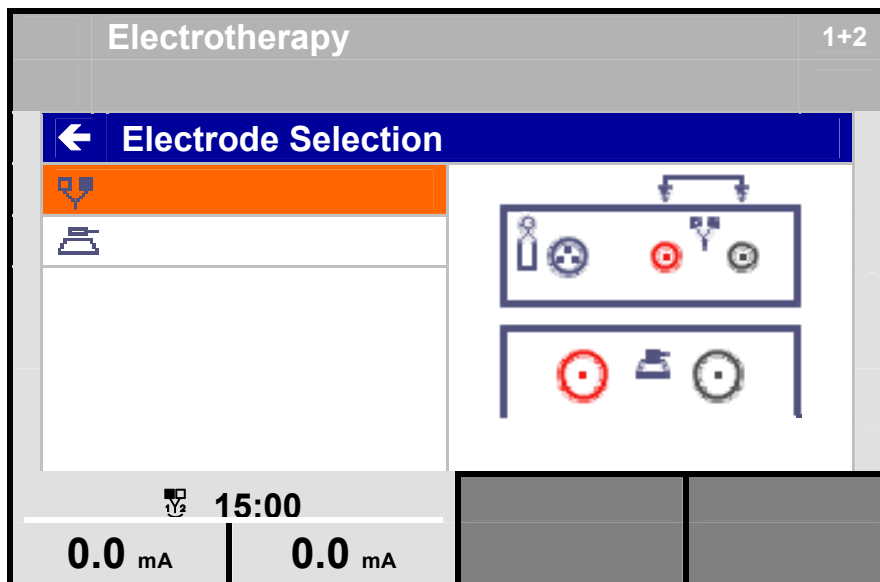
The underlining reason for vacuum pulsation is creating a massage effect during a treatment session. This is achieved by rhythmically varying the amount of suction under the electrode cups. To allow pulsation the range must be set between 10-30%. Ideally the setting should be between 50-70%. The minimum vacuum setting that allows pulsation is 15. If during treatment the vacuum setting is reduced below 15 then the pulsation range will also automatically be reduced to insure that the amount of suction does not drop below the minimum needed for preventing the cup to fall off. The pressure under the cup will rhythmically pulse between the vacuum setting and the selected range. The rhythm cycle can be adjusted with the parameter "Hold time" and can be adjusted from 0 to 2.5 seconds in steps of 0.5 seconds. The hold time setting is applied when the lower vacuum limit is reached. (Please see par.12.13)

11.2.9.b Vacuum electrode selection

- Using the central controller [5], select electrode selection.
- Enter the selection with the confirmation button [6]



- Select in the pop-up with the central controller [5] electrodes or Vacuum cups.
- Push the confirmation button to return.



11.2.9.c Default Setting Vacuum Module

Frequent users of vacuum therapy can change the default setting for this module. Go to the System Setting to change the default settings for the default vacuum Pressure and the electrode selection.

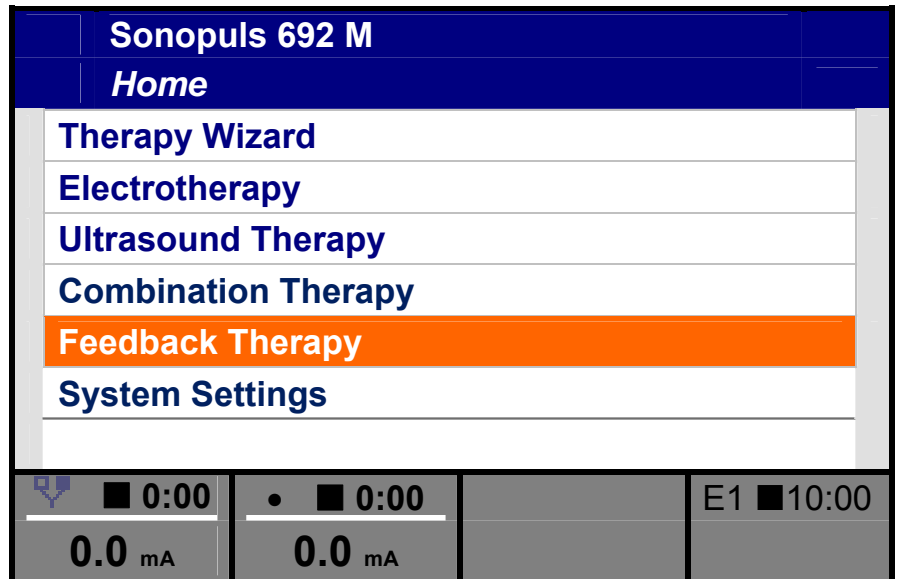
To activate the new default settings switch the unit on/off with the reset button.

11.2.10 Feedback Therapy

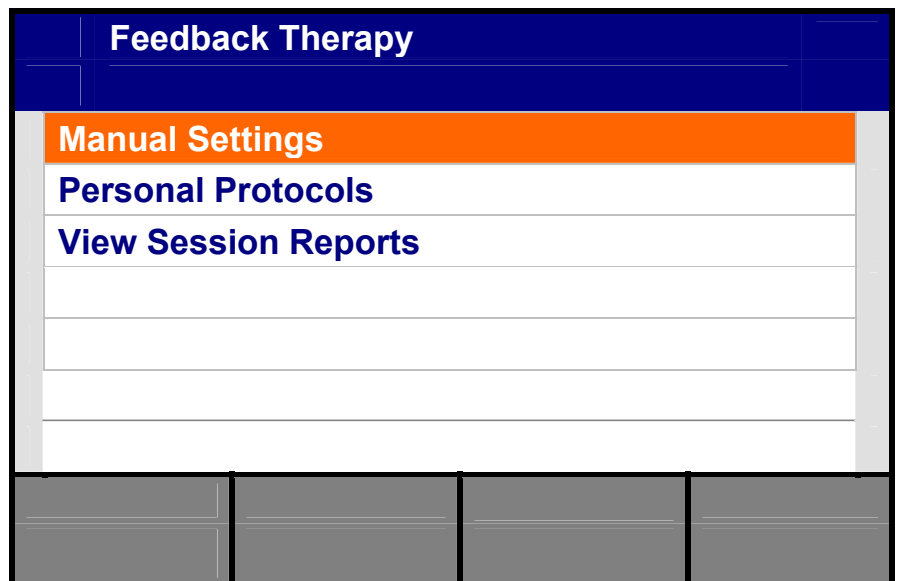
1. Place the reference electrode on the skin and connect it with the unit.
2. Place the EMG electrodes on the skin and connect these with the unit.

CAUTION

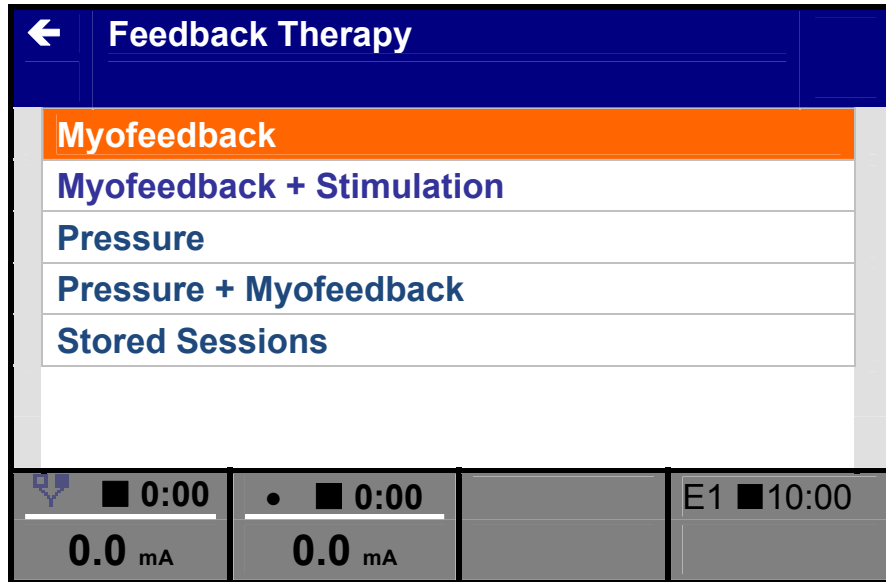
- Connection of accessories other than the ones specified by the manufacturer can adversely affect the safety of the patient and correct functioning of the equipment, and is therefore not permitted.
- Using the central controller [5], select Feedback Therapy in the main menu.
- Enter the selection with the confirmation button [6].



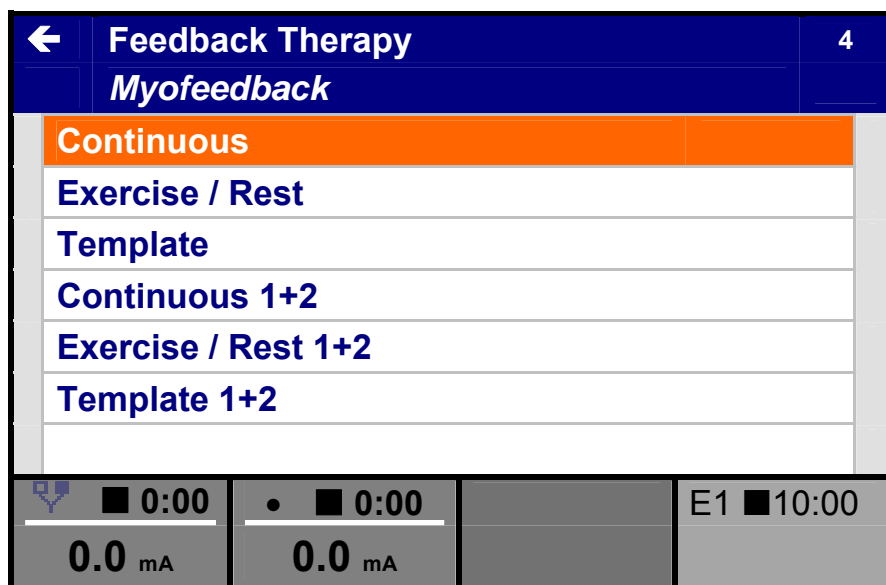
Select manual settings using the central regulator [5] and press the confirmation key [6].



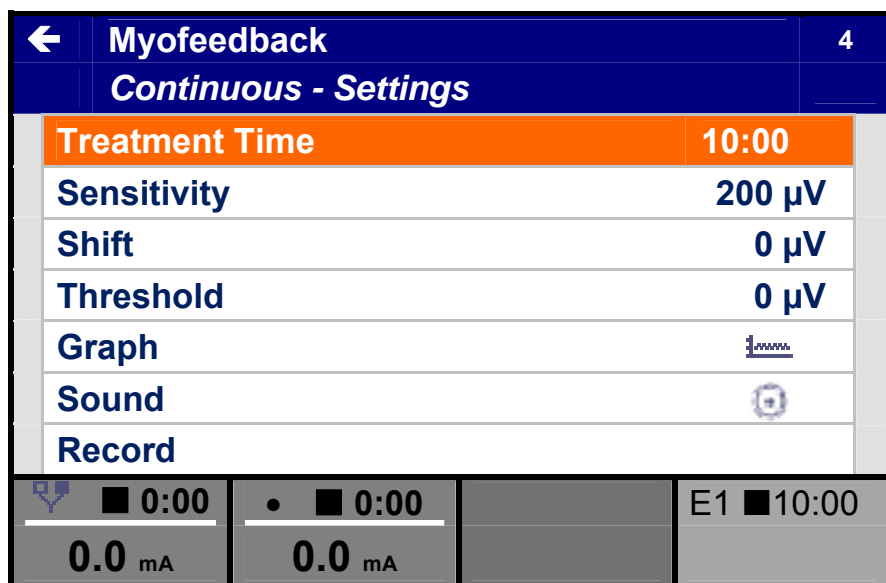
- Select Myofeedback with the central controller [5] and enter with the confirmation button [6].



- Select Continuous with the central controller [5] and enter with the confirmation button [6]



- Using the central controller [5], to select a parameter, select by pushing the confirmation button [6].
- Change the value with the central controller
- Go to Record to start treatment and registration

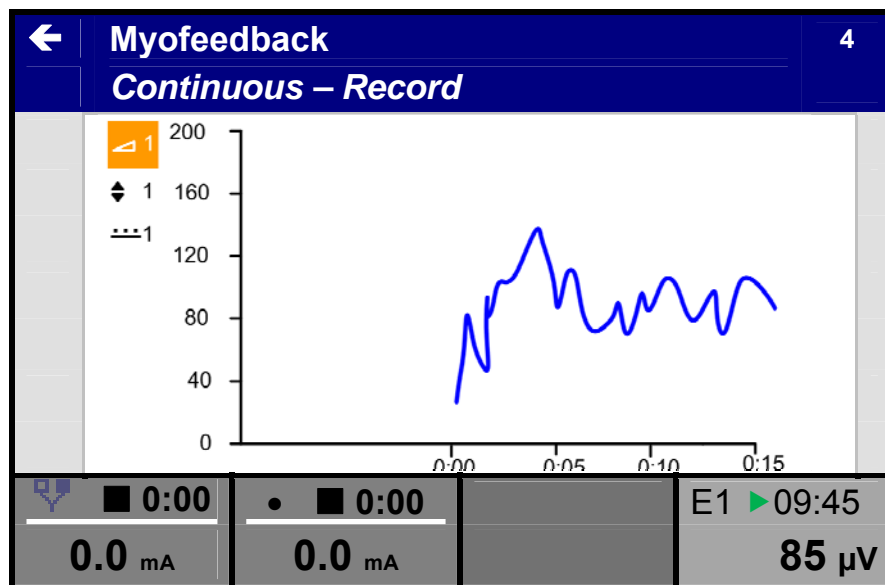


- Treatment and registration runs

Note!

Following parameters are adjustable during the treatment:

- Sensitivity
- Shift
- Threshold
- Stop the training via the assist button or wait until the training is finished.
- Go one step back and select analyze or report.
- Store these data via the assist button on a USB stick. This only possible in combination with the MyoComBox



- The final result screen depends on the selected exercises parameters
- The parameters included can be stored on the internal memory on the unit.
- Graph and figures can only be exported to an USB stick via the Myocombox.

Myofeedback	
Continuous - Report	
Mininum	304 µV
Maximum	355 µV
Average	319 µV
Total recording time	0:25
15:00	15:00
0.0 mA	0.0 mA

11.2.10.a Connecting to the MyoComBox

A device with a feedback therapy module has some special settings.

In order to be able to work with the MyoComBox the device has to be connected to the MyoComBox by means of the “System Settings.”

1. Turn on the MyoComBox (make sure that the Bluetooth antenna is in one of the USB connections of the MyoComBox).
2. Go to the “System Settings” via the Home menu. Select the MyoComBox and then select “Search.” The device will show the serial numbers of the available MyoComBox(es) in a list. Connect the device to the MyoComBox of your choice by selecting the serial number from the list. Check that the serial number corresponds to the number on the left in the LCD screen of the MyoComBox.
3. Set the time and date of the MyoComBox.
4. Designate a system name if desired. This name will be displayed in the selected MyoComBox.

In addition to these settings there is also the option of setting a notch filter. The notch filter removes artifacts from the EMG signal that are the result of the power supply frequency. Set the

notch filter to 60 Hz if the power supply frequency is 60 Hz. The default is 50 Hz (this is the power supply frequency in most countries). It is also possible to completely turn off this filter, but we do not recommend this.

11.2.10.b Exporting Reports and Measuring Data

Prepare your USB memory stick for use on your computer. Create the files in which you wish to save the export. We recommend that you name the folder the same name as the name of the patient.




Insert your USB memory stick into the MyoComBox.

Once the measurement has been completed the data can be exported from the MyoComBox to the USB memory stick. To do this go to the analysis screen, press on the orange “Assist” key and select “Save.” Then select the file from which you want to write the data to the USB memory stick.

When you then insert this USB memory stick into your computer you can open the data files. You can import them as a .txt file (text file with tab-separated data) or create a report from the data with the aid of the MyoComBox Data Viewer by Enraf-Nonius (article number 1600840). It is easy to make a standard report with this program; in addition, up to five measuring sessions can be compared. The program can be downloaded from www.enraf-nonius.com.

11.2.10.c Sensitivity setting

- Using the central controller [5], to select Sensitivity and push the confirmation button [6].

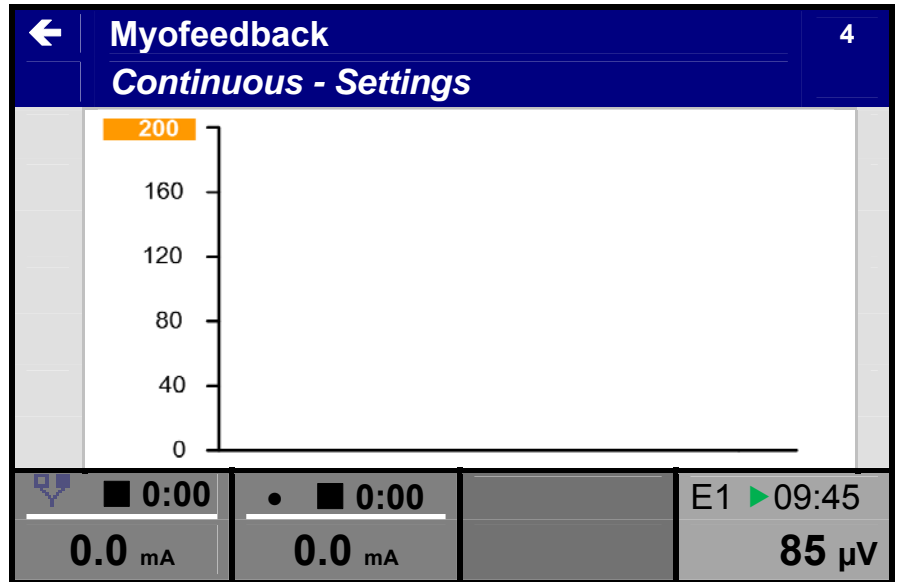
← Myofeedback		4
Continuous - Settings		
Treatment Time	10:00	
Sensitivity	200 μV	
Shift	0 μ V	
Threshold	0 μ V	
Graph		
Sound		
Record		
 0:00	 0:00	E1 10:00
0.0 mA	0.0 mA	

- Change the value with the central controller [5] and push the confirmation button [6] to return

Note!

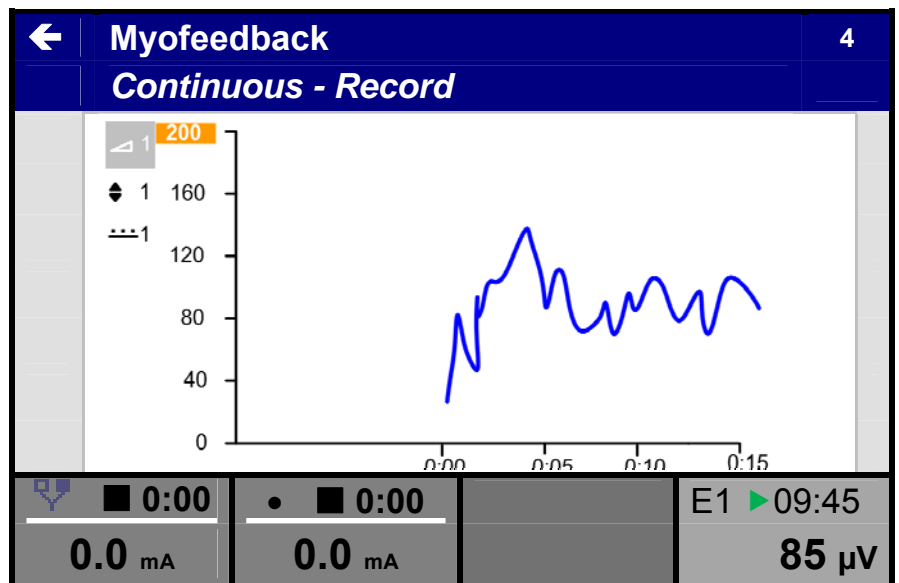
During this setting the measurement is active without any registration

Sensitivity can also be change during the treatment



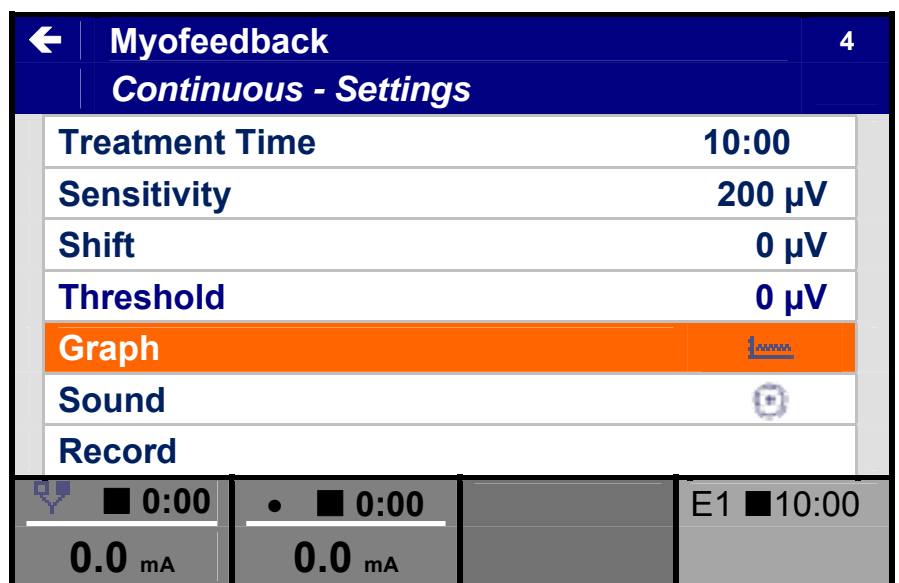
Sensitivity setting during treatment.

- Push the confirmation button [6] and change the value with the central controller [5] and push the confirmation button [6] again to return



11.2.10.d Threshold Setting

- Using the central controller [5], to select Threshold and push the confirmation button [6].

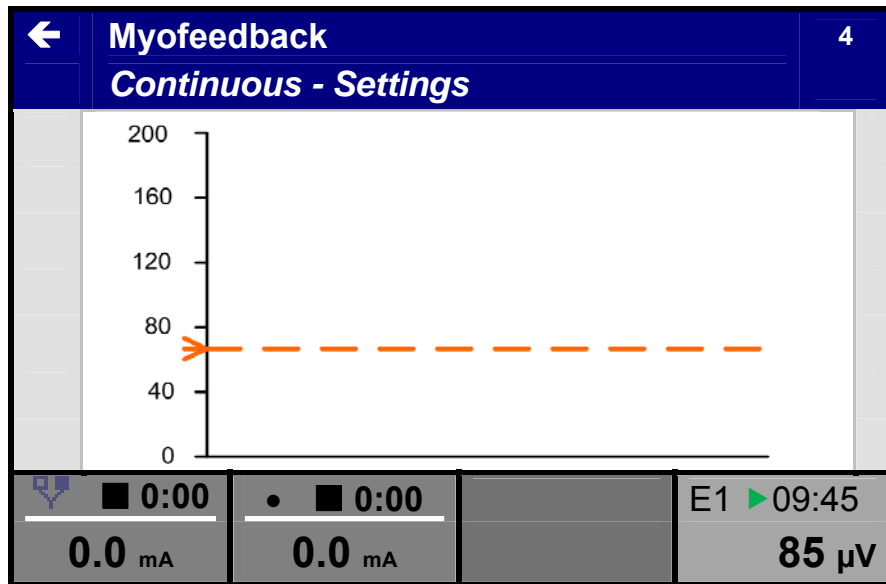


- Change the value with the central controller [5] the line will move during the setting.
- Push the confirmation button [6] to return

Note!

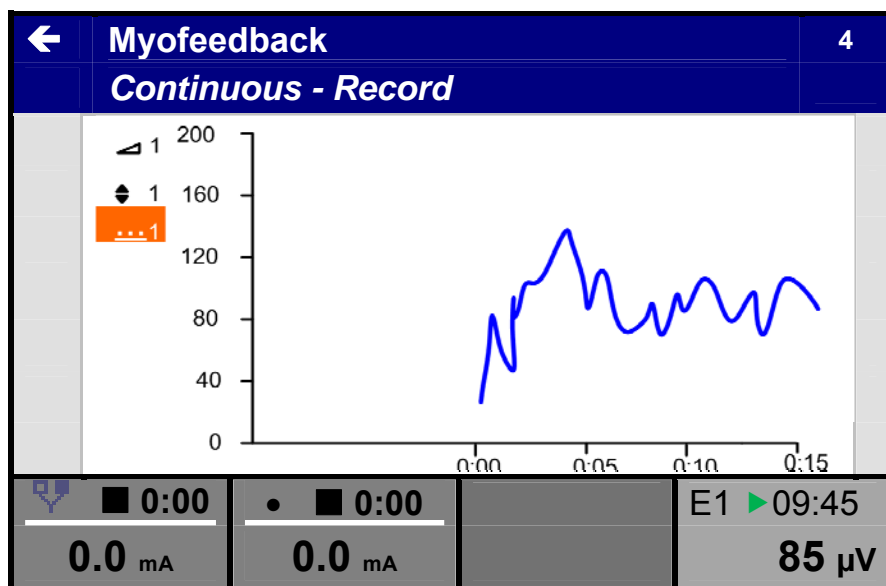
During this setting the measurement is active without any registration

Sensitivity can also be change during the treatment

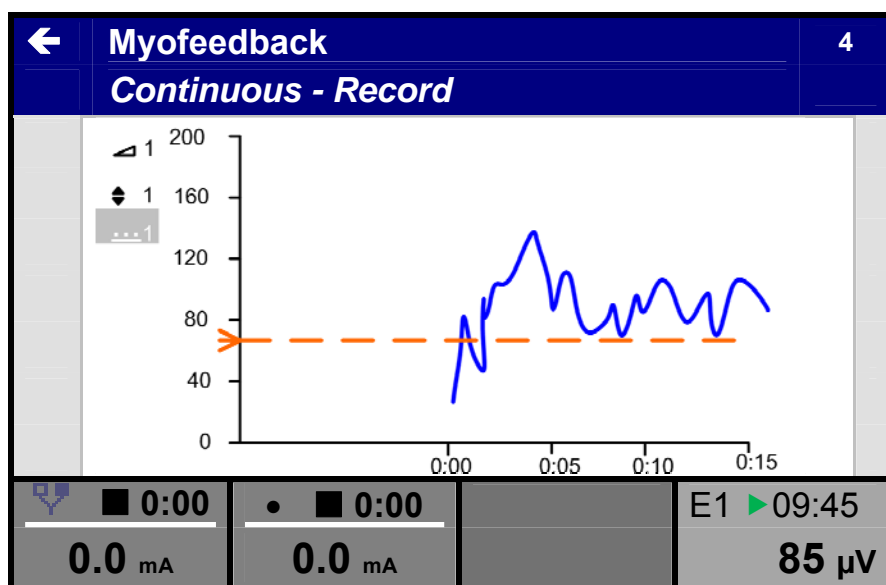


Threshold setting during treatment

- Select the Threshold icon with the central controller [5]

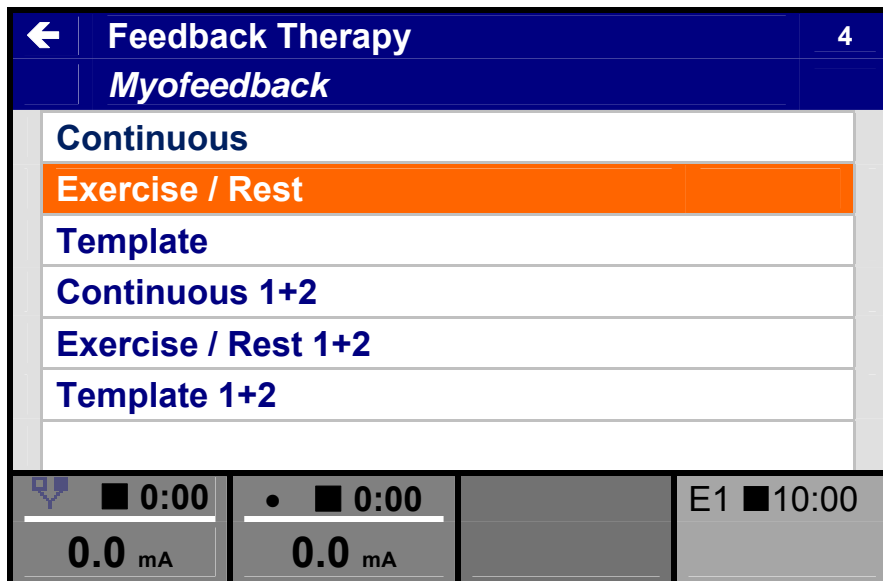


- Push the confirmation button [6] and change the value with the central controller [5] and push the confirmation button [6] again to return



11.2.10.e Exercise / Rest

- Select Exercise / Rest with the central controller [5] and enter with the confirmation button [6]

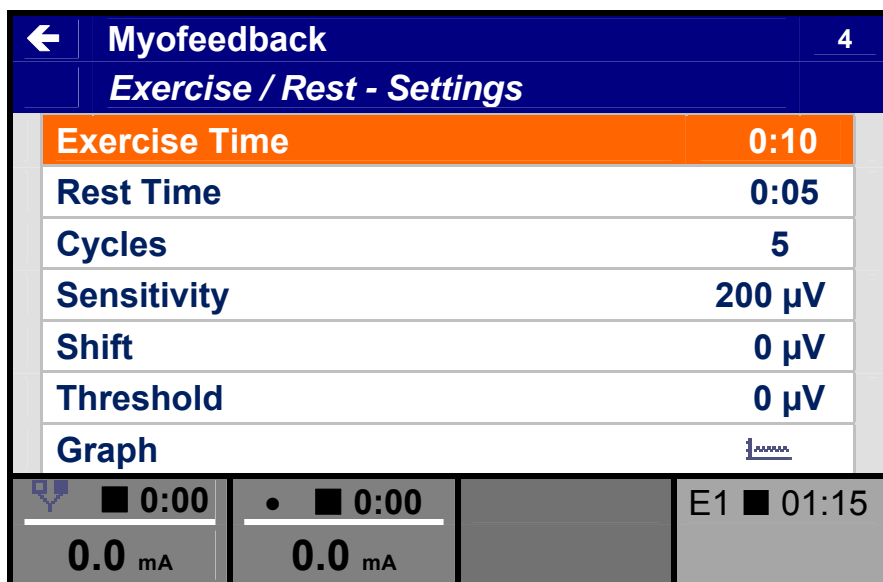


- Using the central controller [5], to select Threshold and push the confirmation button [6].

Adjust:

- Exercise Time in sec
- Rest Time in sec
- Cycles (amount of repetitions)
- Sensitivity

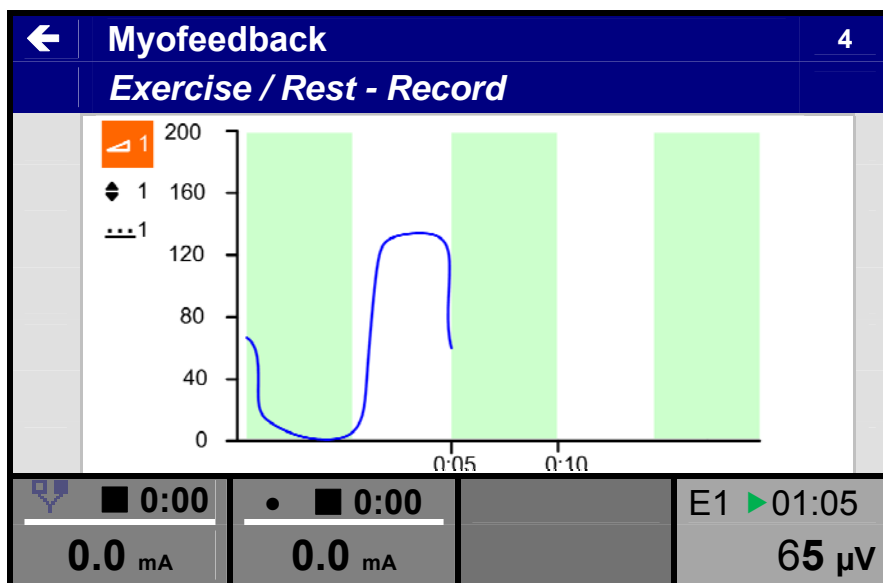
Go to record to start the treatment



White area is the Exercise time
Green area is the Rest time

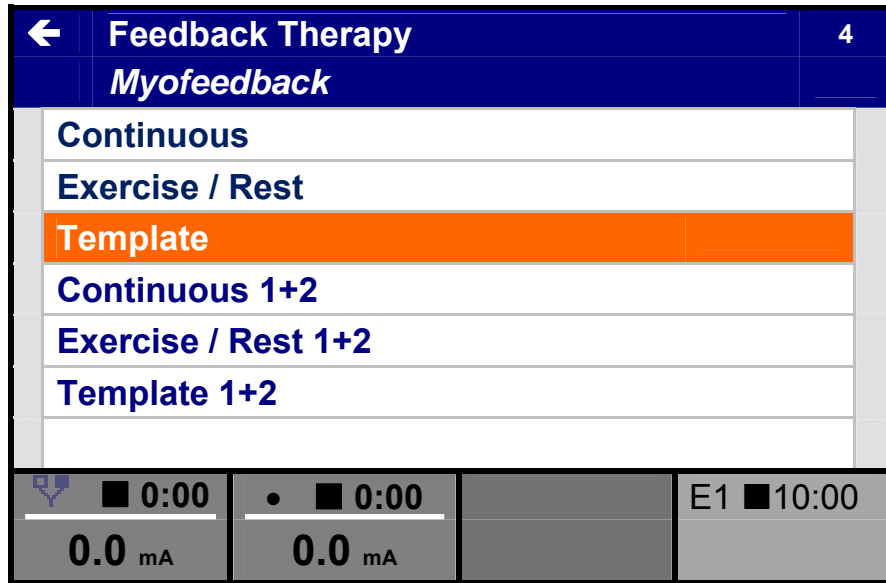
Note!

- Stop the treatment via the assist button
- Use the pause under the assist button to interrupt the treatment. Use the same button to start again.



11.2.10.f Template

- Select Template with the central controller [5] and enter with the confirmation button [6]

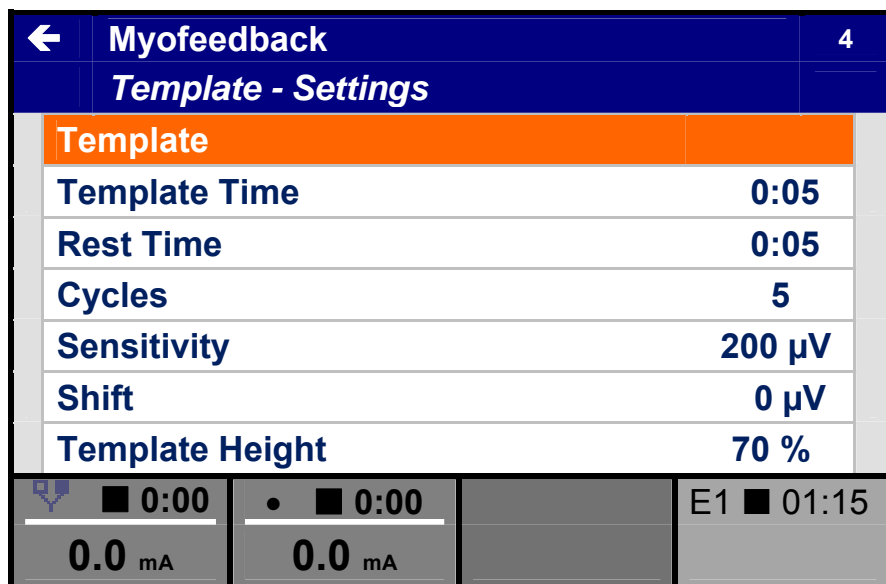


- Using the central controller [5], to select Threshold and push the confirmation button [6].

Adjust:

- Template
- Template Time in sec
- Rest Time in sec
- Cycles (amount of repetitions)
- Sensitivity
- Template Height (feedback on screen)

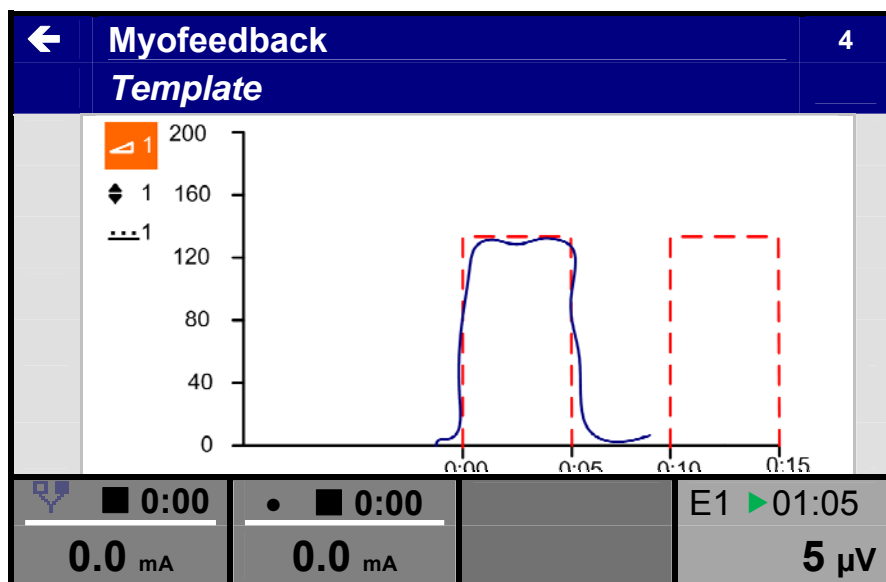
Go to record to start the treatment.



The template form is displayed in orange as the guide line for the patient to follow.

Note!

- Stop the treatment via the assist button
- Use the pause under the assist button to interrupt the treatment. Use the same button to start again.



11.2.10.g Shift

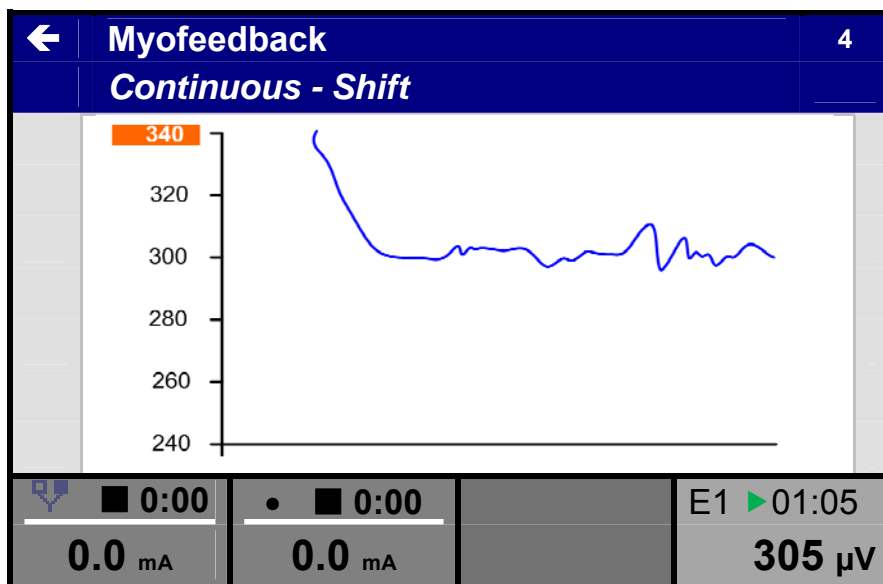
Shift is a special tool only available in the Myomed 6- series. The function of this parameter is to zoom-in on a specific area in the graphic to have a better feedback for the patient. This is useful for patient with muscle Hypertonia.

The adjustment is as follow:

- Define the ideal bandwidth in the sensitivity setting screen.
- Set the sensitivity back to the ideal bandwidth, the signal will disappear in the graphic. Go back to the setting menu and select Shift.
- Scroll with the shift until the signal is back on the screen. The sensitivity range is much lower and only for a limited range.

Note!

- The shift range is linked to the Sensitivity setting.



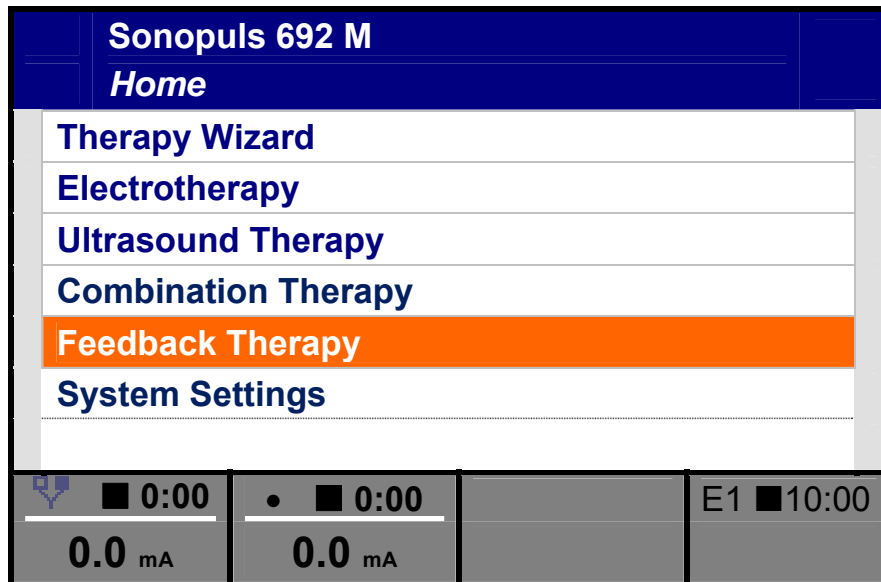
11.2.10.h Myofeedback + Stimulation

1. Place the reference electrode on the skin and connect it with the unit.
2. Place the EMG electrodes on the skin and connect these with the unit.

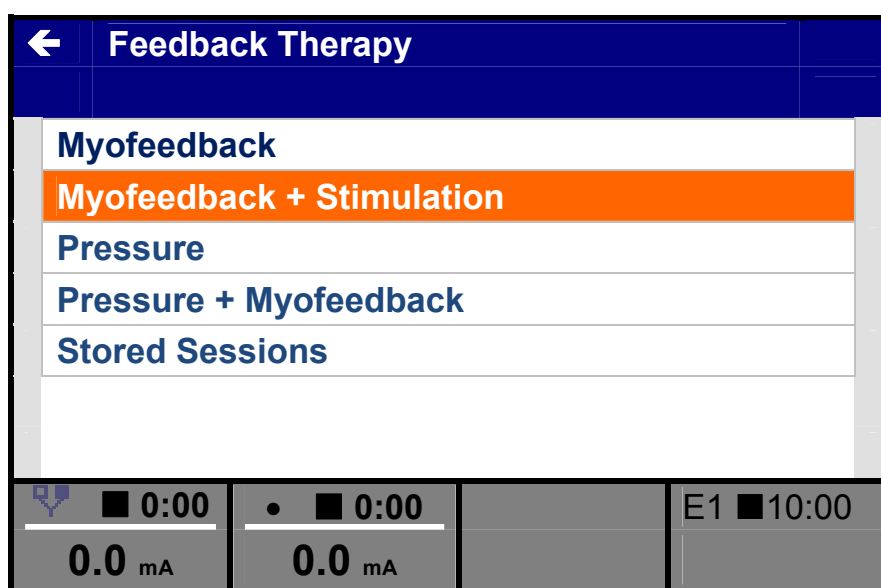
CAUTION

- Connection of accessories other than the ones specified by the manufacturer can adversely affect the safety of the patient and correct functioning of the equipment, and is therefore not permitted.

- Using the central controller [5], select Feedback Therapy in the main menu.
- Enter the selection with the confirmation button [6].

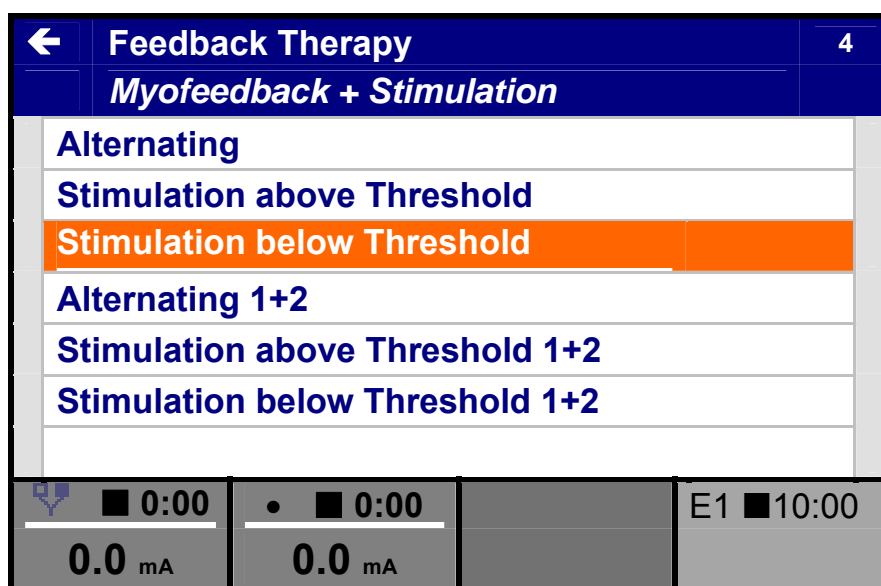


- Select Myofeedback +stimulation with the central controller [5] and enter with the confirmation button [6].



11.2.10.i Alternating

- Select Alternating with the central controller [5] and enter with the confirmation button [6]



- Select a current wave form with the central controller [5] and enter with the confirmation button [6]

The screenshot shows a menu titled 'Feedback Therapy' with a sub-menu 'Myofeedback + Stimulation'. The 'Premodulated' option is selected and highlighted in orange. Other options include Russian Stimulation, Biphasic Pulsed Current (TENS), Faradic Current, Diadynamic Current, and High Voltage. At the bottom, there are three control panels: the first shows '0.0 mA' under 'E1', the second shows '0.0 mA' with a pulse icon, and the third shows a timer at '10:00'.

- Using the central controller [5], to select a parameter and push the confirmation button [6].

Adjust:

- Rest Time in sec
- Exercise Time
- Stimulation Time
- Cycles (amount of repetitions)
- Sensitivity
- All stimulation parameters.

The screenshot shows the 'Myofeedback + Stimulation' menu with the sub-menu 'Alternating - Settings'. Parameters are listed in a table:

Rest Time	0:05
Exercise Time	0:05
Stimulation Time	0:05
Cycles	5
Sensitivity	200 μ V
Shift	0 μ V
Threshold	0 μ V

At the bottom, there are three control panels: the first shows 'E1' with a pulse icon, the second shows '0.0 mA' with a pulse icon, and the third shows a timer at '01:15'.

Note!

Previous to the start via record we advise to adjust the stimulation level first.

Push the button [1] to activate the stimulation setting for channel 1 and adjust with the central controller [5].

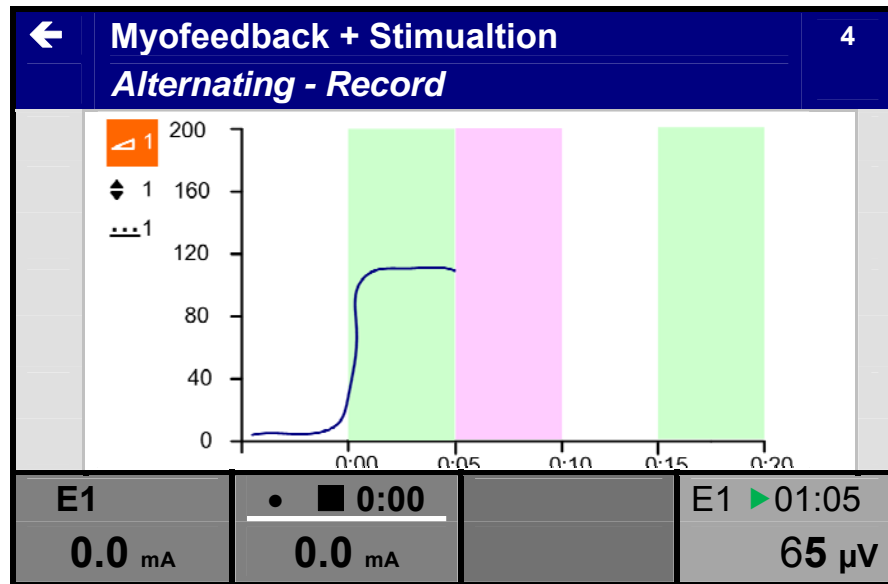
The current indications for the EMG channels will be displayed as usual in current channel 1 and 2. The electrode indication will change to E1 for channel 1 and E2 for channel 2

Go to record to start the treatment.

White area is the Exercise time
 Green area is the Rest time
 Orange is the stimulation time; in that field is during the stimulation time no extra feedback, only the colour background

Note!

- Stop the treatment via the assist button
- Use the pause under the assist button to interrupt the treatment. Use the same button to start again.



11.2.10.j Stimulation above Threshold

In this mode the stimulation will be activated automatically when the contraction is above the threshold during the exercise time. The stimulation time will be followed by a rest time.

- Select Stimulation above Threshold with the central controller [5] and enter with the confirmation button [6]

The screenshot shows a software interface titled "Feedback Therapy" with a sub-header "Myofeedback + Stimulation". The main display is a menu with the following options: "Alternating", "Stimulation above Threshold" (highlighted in orange), "Stimulation below Threshold", "Alternating 1+2", "Stimulation above Threshold 1+2", and "Stimulation below Threshold 1+2". Below the menu, there are four control panels: "E1" with "0.0 mA", a central panel with a play/pause icon and "0:00", another "E1" with "0.0 mA", and a final panel with a play icon, "10:00", and "E1".

- Select a current wave form with the central controller [5] and enter with the confirmation button [6]

Feedback Therapy 4

Stimulation above Threshold

	Premodulated
	Russian Stimulation
	Biphasic Pulsed Current (TENS)
	Faradic Current
	Diadynamic Current
	High Voltage

E1 0.0 mA | 0.0 mA | 0:00 | E1 10:00

- Using the central controller [5], to select a parameter and push the confirmation button [6].

Adjust:

- Rest Time in sec
- Exercise Time
- Stimulation Time
- Cycles (amount of repetitions)
- Sensitivity
- Threshold
- All stimulation parameters.

Myofeedback + Stimulation 4

Stimulation above Threshold – Settings

Rest Time	0:05
Exercise Time	0:05
Stimulation Time	0:05
Cycles	5
Sensitivity	200 µV
Shift	0 µV
Threshold	80 µV

E1 0.0 mA | 0.0 mA | 0:00 | E1 01:15

Note!

Previous to the start via record we advise to adjust the stimulation level first.

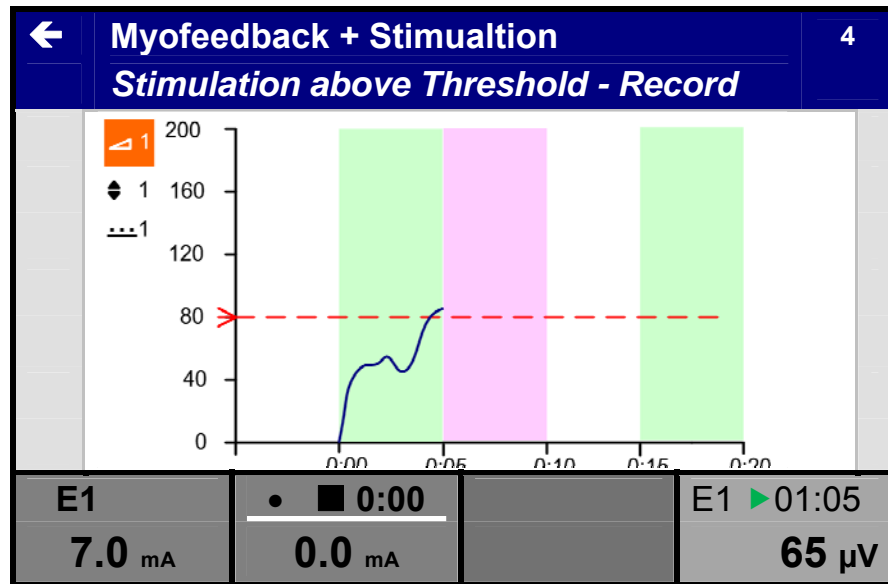
Push the button [xx] to activate the stimulation setting for channel 1 and adjust with the central controller [5]

Go to record to start the treatment.

White area is the Exercise time
 Green area is the Rest time
 Pink is the stimulation time, in that field is during the stimulation time no extra feedback, only the pink background

Note!

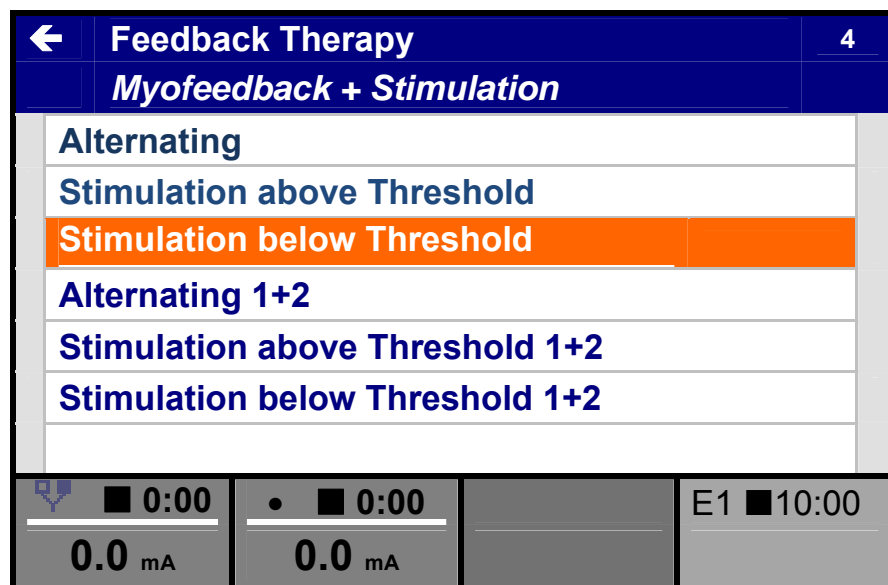
- Stop the treatment via the assist button
- Use the pause under the assist button to interrupt the treatment. Use the same button to start again.



11.2.10.k Stimulation below Threshold

In this mode the stimulation will be activated automatically when the contraction is below the threshold during the exercise time. The stimulation session will always be followed by a rest time.

- Select Stimulation below Threshold with the central controller [5] and enter with the confirmation button [6]



- Select a current wave form with the central controller [5] and enter with the confirmation button [6]

Feedback Therapy 4

Stimulation below Threshold

	Premodulated
	Russian Stimulation
	Biphasic Pulsed Current (TENS)
	Faradic Current
	Diadynamic Current
	High Voltage

0:00 0.0 mA 0:00 0.0 mA E1 10:00

- Using the central controller [5], to select a parameter and push the confirmation button [6].

Adjust:

- Rest Time in sec
- Exercise Time
- Stimulation Time
- Cycles (amount of repetitions)
- Sensitivity
- Threshold
- All stimulation parameters.

Myofeedback + Stimulation 4

Stimulation below Threshold – Settings

Rest Time	0:05
Exercise Time	0:05
Stimulation Time	0:05
Cycles	5
Sensitivity	200 µV
Shift	0 µV
Threshold	80 µV

0:00 0.0 mA 0:00 0.0 mA E1 01:15

Note!

Previous to the start via record we advise to adjust the stimulation level first.

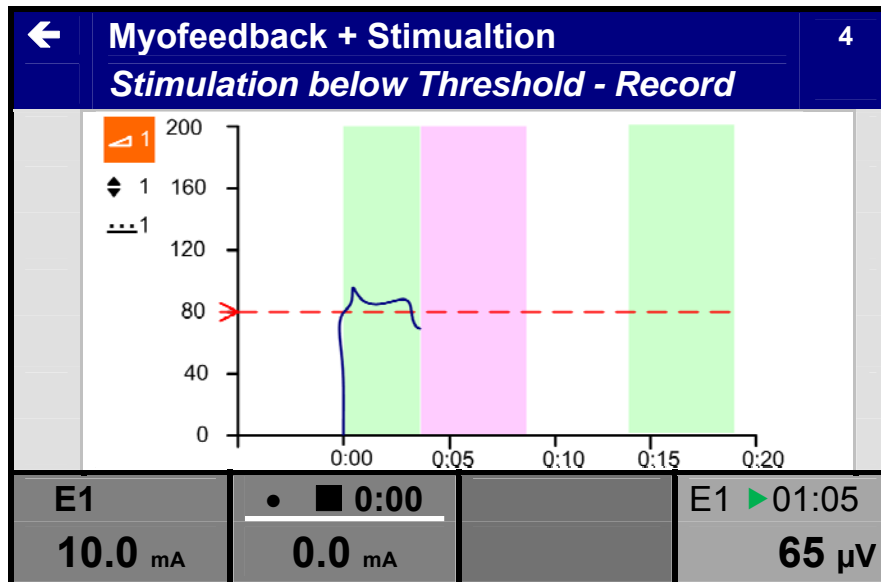
Push the button [xx] to activate the stimulation setting for channel 1 and adjust with the central controller [5]

Go to record to start the treatment.

White area is the Exercise time
 Green area is the Rest time
 Orange is the stimulation time, in that field is during the stimulation time no extra feedback, only the pink background

Note!

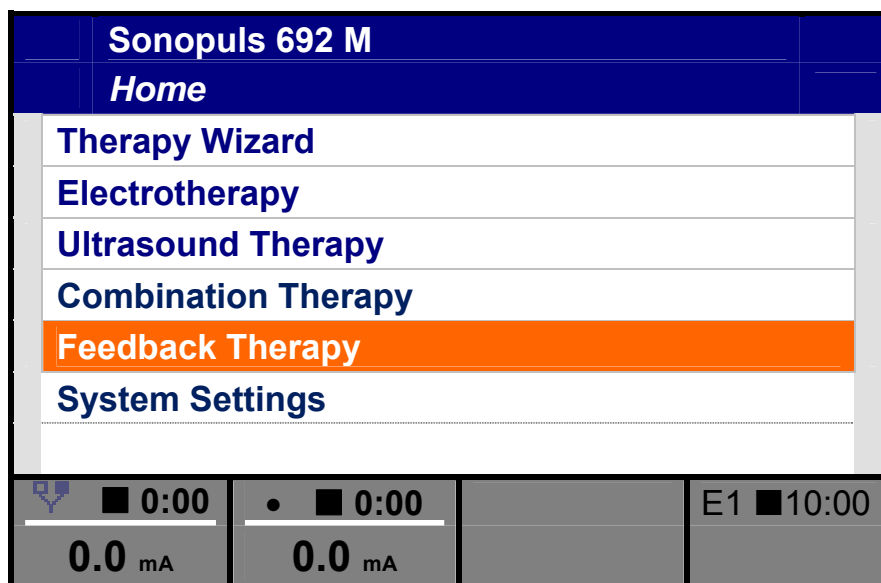
- Stop the treatment via the assist button
- Use the pause under the assist button to interrupt the treatment. Use the same button to start again.



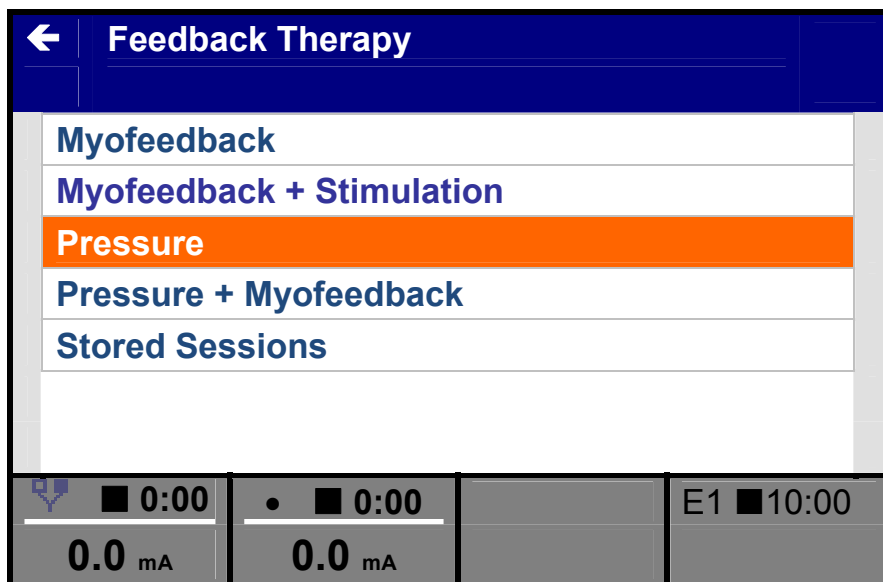
11.2.10. IPressure

⚠ CAUTION

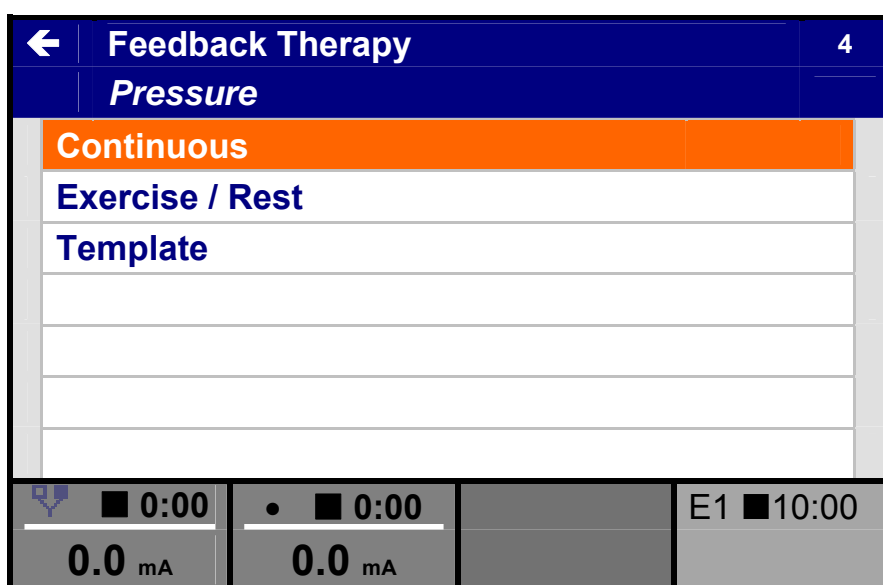
- Connection of accessories other than the ones specified by the manufacturer can adversely affect the safety of the patient and correct functioning of the equipment, and is therefore not permitted.
- Using the central controller [5], select Feedback Therapy in the main menu.
- Enter the selection with the confirmation button [6].



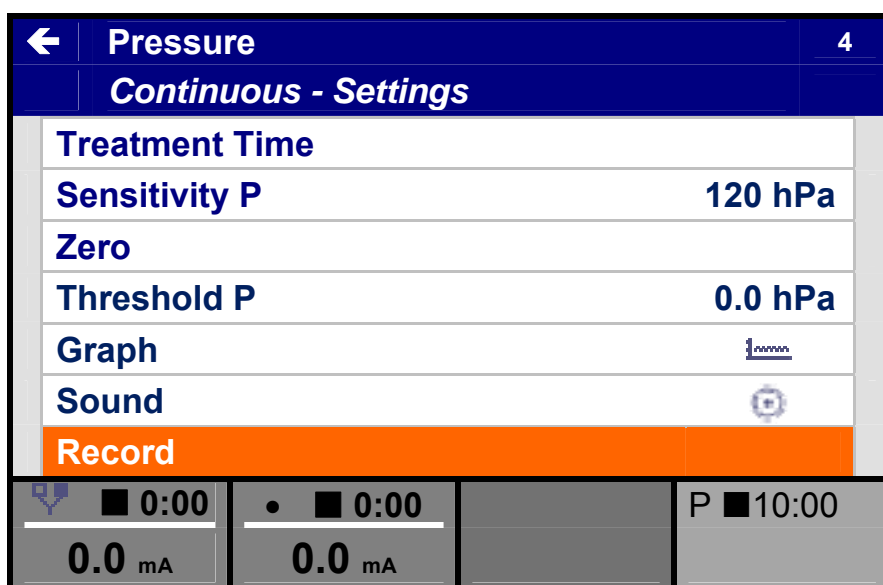
- Select Pressure with the central controller [5] and enter with the confirmation button [6].



- Select Continuous with the central controller [5] and enter with the confirmation button [6].



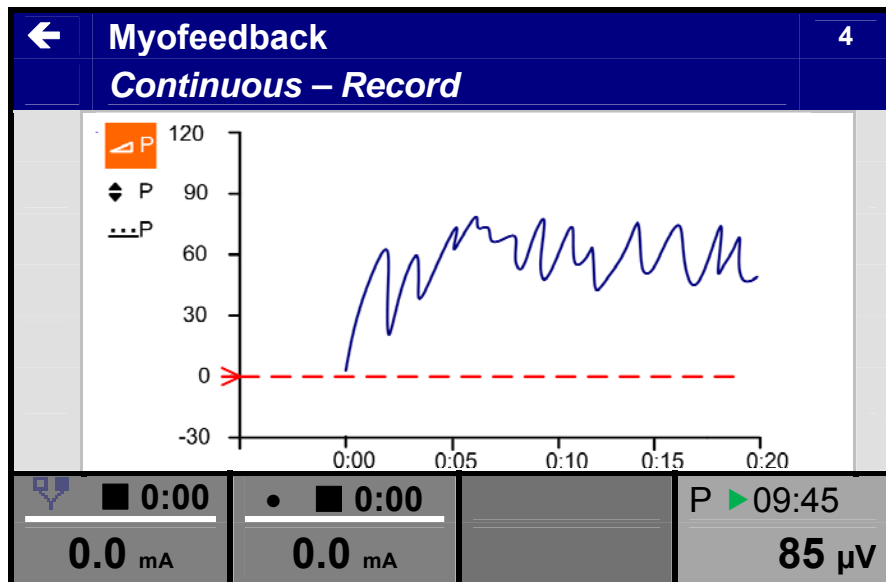
- Using the central controller [5], to select a parameter, select by pushing the confirmation button [6].
- Change the value with the central controller
- If the setoff value is too high or not wanted, use the Zero setting to reset the value to zero. Push the confirmation button to reset!
- Go to Record to start treatment and registration



- Treatment and registration runs

Note!
Following parameters are adjustable during the treatment:

- Sensitivity P
- Shift P
- Threshold P



11.2.10.m EMG feedback with 2 channels

The adjustment for two channels is the same as the adjustment for one channel. The feedback is always for both channels as bar, curve ore combined curve visual in the display.

The real-time value will be showing in de display (in the right tab) as follow:

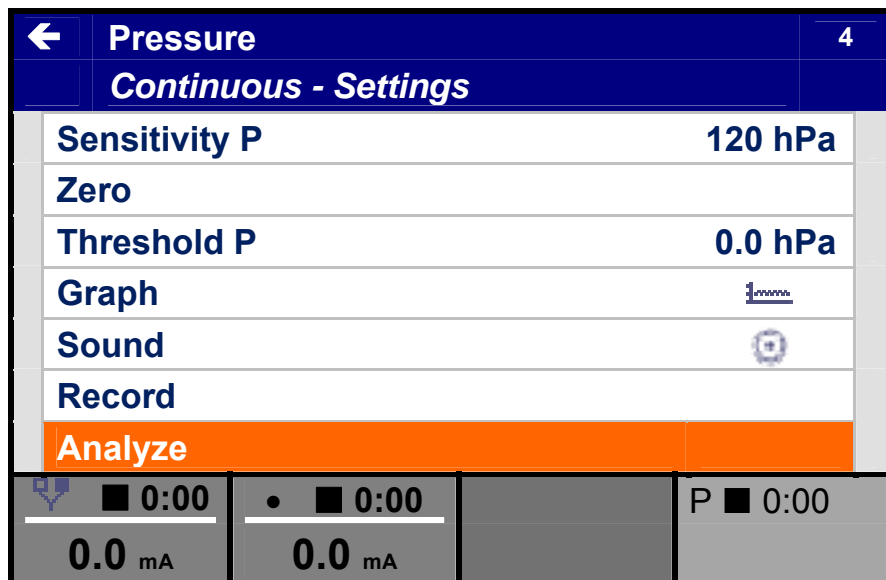
- E1 is for channel 1
- E2 is for channel 2

To change the read-out value in the display between EMG channel 1 and 2:

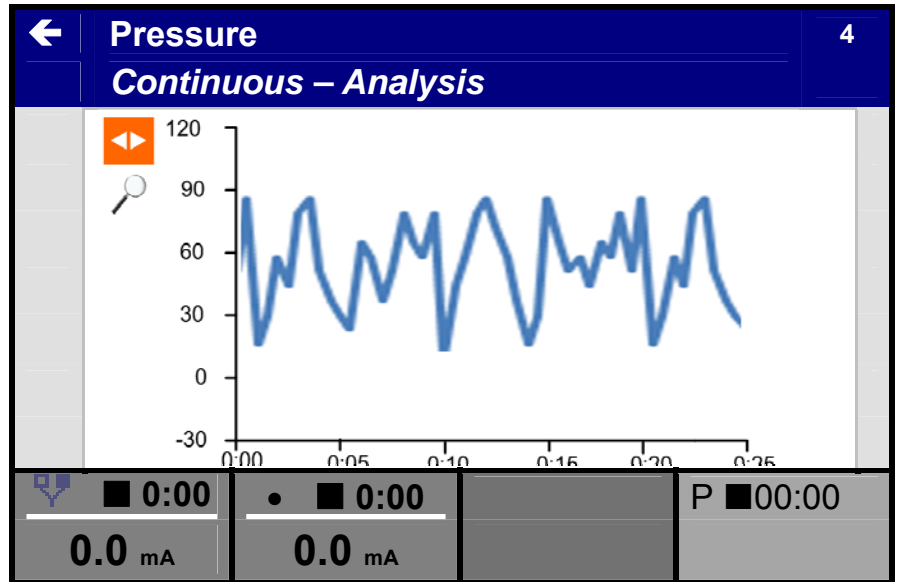
- Push the button [4] and change the read-out with the central controller [5] between E1 and E2.

11.2.10.n Analyze

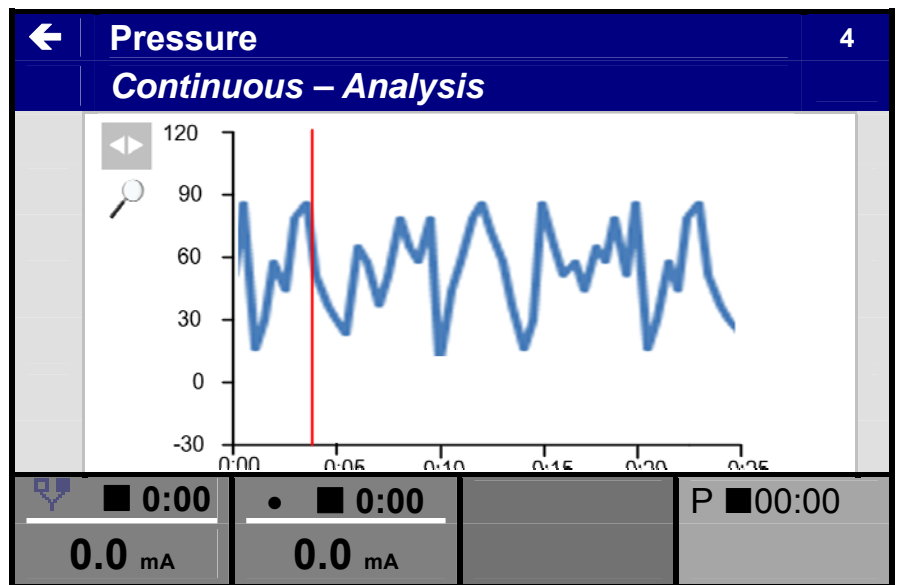
At the end of the treatment go to Analyze with the central controller [5] and push the confirmation button [6]



Select the cursor ◀▶ and push the confirmation button [6].

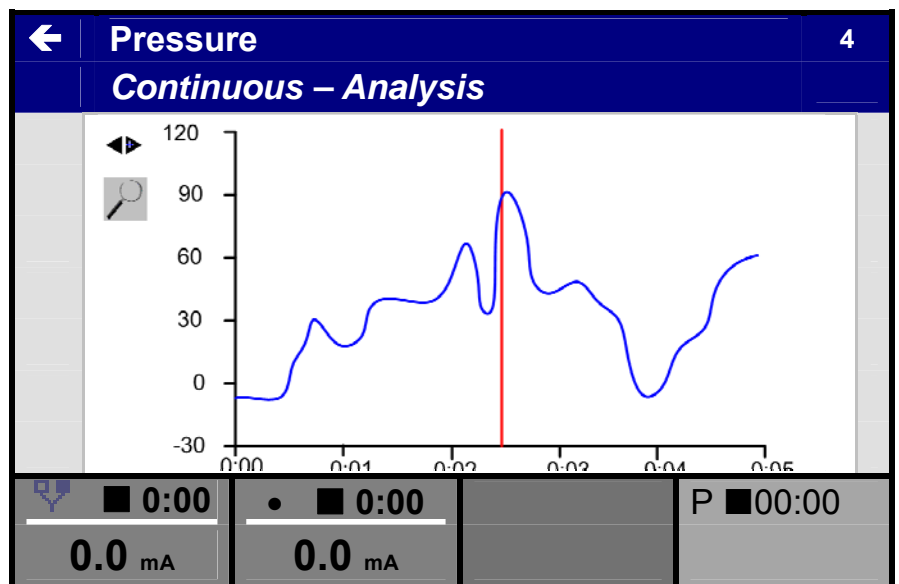


Move the cursor line with the central controller [5] and accept with the confirmation button [6].



Select the loupe with the central controller [6] and push the confirmation button [6].

Change the timeline with the central controller to zoom in on the area.



Go back to the previous screen to select report.

11.2.10.o Report

Go to report with the central controller [5] and push the confirmation button [6]

← Pressure		4
<i>Continuous - R</i>		
Zero		
Threshold P	0.0 hPa	
Graph		
Sound		
Record		
Analyze		
Report		
0:00	0:00	P 0:00
0.0 mA	0.0 mA	

The displayed results are from the complete session.

To transfer these parameters you need to have the X module and the MyoComBox

← Pressure		4
<i>Continuous - Report</i>		
Minimum	0.0 hPa	
Maximum	122.6 hPa	
Average		
Total execution time	0:30 s	
0:00	0:00	P 0:00
0.0 mA	0.0 mA	

11.2.11 System Settings

- Using the central controller [5], select System Settings in the Home Menu
- Enter the selection with the confirmation button [6].

Sonopuls 692	
Home	
Therapy Wizard	
Electrotherapy	
Ultrasound Therapy	
Combination Therapy	
System Settings	

- Select the desired setting with the central controller [5].
- Enter the selection with the confirmation button [6].
- Adjust the setting in the pop-up screen with the central controller [5].
- The range of the parameter is shown in the pop-up screen.
- Push the confirmation button [6] again to return.
- Return to the Home menu.

← System Settings	
Language	English
LCD brightness	100
Speaker Volume	88
Default Settings	
Ultrasound Standard	USA
System Info	V019
Service	

11.2.11.a Change Language

- Go to System Settings in the Home menu
- Push the confirmation button [6] and select Language with the central controller [5].
- Push the confirmation button [6] and select the desired Language in the list with the central controller [5]. Confirm the new language by pushing the confirmation button [6]
- The unit will reboot automatically

11.2.11.b Backup -and restore personal data

- Go to System Settings in the Home menu
- Push the confirmation button [6] and select Service with the central controller [5].
- Insert a SD card in the card sleeve [2]
- Select Backup personal data with the central controller [5] to store the personal protocols on the SD card or select restore personal protocols to restore the personal protocols from the SD Card in the unit memory.

11.2.12 Special parameter settings

11.2.12.a Surge programs

Surge programs allow you to program sequential increases and decreases in current amplitude. See fig 13.12 for details. Surge programs should not be confused with protocols:

- A single treatment step of a protocol could contain a surge program.

The surge program options that are available depend on whether the 600-series is operating with independent or linked channels.

With independent channel operation the surge programs run independently over both channels. They can independently be enabled and their parameters can individually be set. When the current channels are linked, the surge programs are also linked, which implies that their parameters have identical values. The following options are available in this case:

- Synchronous
- Asynchronous
- Alternating

In the Synchronous mode the surge pattern runs synchronously on both channels.

In the Asynchronous mode a delay time can be set between the start of the surge program on channel 1 and channel 2.

In the Alternating mode the stimulation period (ramp-up + hold + ramp-down) on one channel coincides with the rest period on the other channel.

To start the program push the Assist button and deactivate the pause symbol by selecting Continue with the central controller and the confirmation this with confirmation button [6].

Parameters:

Ramp-up time, expressed in s, defines the time in a surge program during which the current is increased from 0 to the adjusted level. See fig 13.122 for details. The ramp-up time can be adjusted in increments of 0.1s.

Hold time, expressed in s, defines the time in a surge program during which the current is kept at the adjusted level. See fig 13.122 for details. The hold time can be adjusted in increments of 1s.

Ramp-down time, expressed in s, defines the time in a surge program during which the current is decreased from the adjusted level to 0. See fig 13.122 for details. The ramp down time can be adjusted in increments of 0.1s.

Interval time, expressed in s, defines the time in a surge program during which the current is kept at 0. See fig 13.122 for details. The interval time can be adjusted in increments of 1s.

Delay time, expressed in s, defines the time delay between the start of the surge program on channel 1 and channel 2. See fig 13.122 for details. The delay time can be adjusted in increments of 0.1 s.

11.2.12.b Current amplitude

The current amplitude is adjusted using the central controller [5].

Select the channel by pushing knobs [1] or [2].

The current amplitude can only be adjusted when the clock has been set.

With 4 polar interferential current waveforms the current amplitude operates on both channels simultaneously. In this case a balance facility is available for the classical interferential current waveform (see paragraph 4.3 for details).

The unity of the displayed current amplitude depends on the previously selected current waveform and can be expressed in **mA**, **µA** or **V**.

A treatment is started by adjusting the current amplitude, unless a surge program has been selected. To start a surge program, push the Assist button and deactivate the pause symbol with the central controller and the confirmation button [6].

11.2.12.c CC/CV mode

Depending on the selected current waveform, the electrotherapy channels can be used in the Constant Current or Constant Voltage mode. It is advised to use the CV mode with dynamic electrode applications. In CV mode the output current depends on the electrical contact with the patient and can therefore vary. You can change the CC/CV setting in the parameter menu.

11.2.12.d Current polarity

When DC currents are used, the red terminal is the **positive** terminal and the black one the **negative** terminal.

Manually changing the polarity during a treatment will result in a current decaying to 0, followed by a current with the opposite polarity, rising to a value equal to 80% of the previous value.

11.2.13 Ultrasound power/Amplitude

The ultrasound Amplitude is adjusted with the central controller [5]. Push the channel button [3] and adjust the Amplitude with the central controller.

- The ultrasound Amplitude can only be adjusted when the clock has been set.

The ultrasound Amplitude can be displayed in W or $\frac{W}{cm^2}$. You can change this setting in the ultrasound parameter menu.

During treatment the displayed ultrasound Amplitude can vary around the set value, caused by fluctuations in acoustical coupling. A blinking display indicates insufficient acoustical coupling.

11.3 Memory functions

The 600-series is equipped with a memory to store protocols. Push the Assist button [7] and select store in the pop-up with the central controller [5]. Follow the instruction on the screen.

11.3.1 Protocols via Therapy Wizard

The 600-series provides a number of pre-programmed protocols available via Body Part or Application. These protocols only serve as a guide and you should use your own expertise in applying them.

A protocol consists of one or more treatment steps that are sequentially executed. Each treatment step has its own current waveform, parameter settings and treatment time.

Electrotherapy protocols can constitute either single or dual channel applications. Prior to loading a single channel protocol, the target channel must first be specified. When a single channel protocol is executed, a completely different single channel protocol can be executed at the other channel. It is also possible to link the current channels, which causes the protocol to be executed on both channels. Dual channel protocols can only be loaded when the current channels are linked.

11.3.1.a Loading a protocol

- In the Home menu, select Therapy Wizard with the central controller [5] and enter by pushing the confirmation button [6]
- Select a protocol via Body Part, Applications or by a protocol number.
- Select a target channel in the Channel Selection menu. Select 1+2 if you want to link the channels, causing the protocol to be run on both channels.

- The display shows the first treatment step of the selected protocol. The total treatment time of the protocol is displayed in the channel tab.
- Optionally push the assist button [7] for information about the protocol, electrode placement and other information.
- Start the treatment by adjusting the current amplitude with controller [5]
- Push assist button [7] and deactivate pause to start the therapy in case a surge program was selected.

When a protocol is executed, the display shows the remaining treatment time of the running treatment step, while the total treatment time of the protocol is displayed in the channel tab. When the selected protocol consists of only one treatment step, both times displayed are identical. Each treatment step is terminated with a short beep. When the end of the protocol has been reached, a standard “end-of-treatment” beep is given.

11.3.1.b Storing a protocol

Prior to the execution of a modified protocol, it can be saved for later use under Personal protocols.

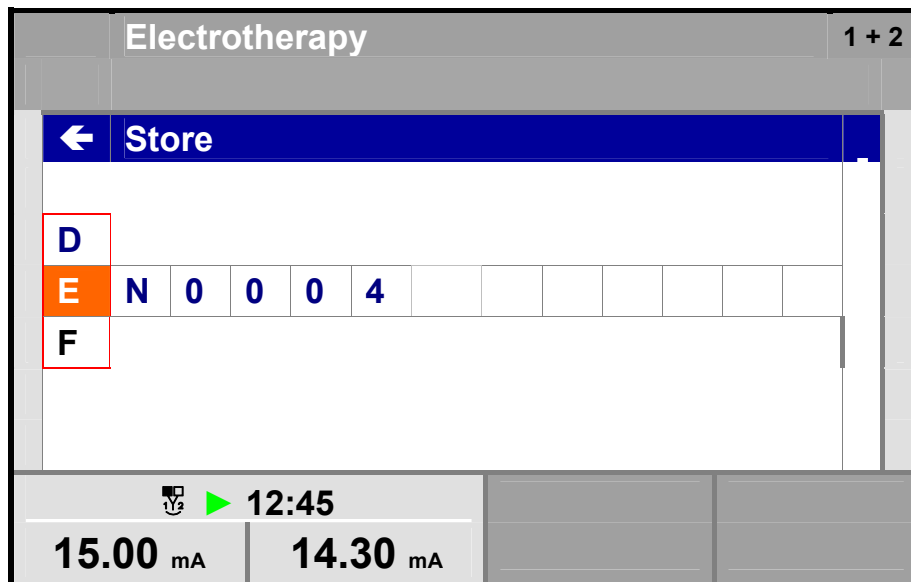
- Push assist button [7] and select store with the central controller [5]
- Follow the instructions on the screen.



- The setting will be stored under Personal setting by number
- Push the confirmation button [6] to accept
- To change the name, select ◀▶ with the central controller [5]



- Remove the cursor with the central controller [5] to the desired position
- Push the confirmation button [6] to modify the first character
- Note: Store the settings before starting the treatment.



12.1 User Maintenance

12.1.1 Cleaning of apparatus

To clean the unit, turn it off and unplug the power supply. Clean the unit with a damp cloth. Do not use abrasive cleaners. A small amount of mild household detergent may be used, if needed.

12.1.2 Cleaning display panel

The display panel contains an anti-reflective coating, which needs special care when cleaned. Use a soft and dry cotton cloth or micro fiber tissue to clean the panel. To remove fingerprints or grease, use a non-abrasive glass cleaning agent. Apply a small amount of the cleaning agent to a soft cotton cloth and then carefully clean the panel.

CAUTION:

- Do not spray the cleaning agent directly on the glass panel.
- Do not use cleaning agents that contain strong alkalis, lye, acid, detergents with fluoride or detergents with ammonia.
- Avoid touching the glass panel with your bare fingers.

12.1.3 Electrodes and accessories

Between patient uses, the rubber electrodes should be cleaned with lukewarm water. To disinfect the electrodes or to remove stubborn stains of dirt, use a 70% alcohol solution. The alcohol solution can cause the black color to be stained, but this does not affect the operation of the electrodes.

Between patient uses, the sponge pads should be washed in warm water, using a household cleaner. After washing they must be rinsed with clear water, thoroughly drained and then dried. Damaged sponge pads should be replaced.

12.1.4 Patient cable

Clean the patient cable with a damp cloth. Use lukewarm water and a non-abrasive household cleaner. Do not use an alcohol solution. Check the cable regularly for damages and/or bad electrical contact. We advise, keeping a spare patient cable in stock.

12.1.5 Ultrasound applicator

To prevent corrosion, clean and dry the contact surface immediately after use. Make sure that no ultrasound gel remains on the applicator. We further recommend cleaning the applicator and cable daily, using lukewarm water. The applicator can be disinfected using a cloth moistened with a 70% alcohol solution. Check the applicator and cable regularly for damage.

12.1.6 Cleaning of the StatUS Applicator (Stationary Ultrasound Head)

General

The treatment head and the cable must be regularly checked for damage such as hairline tears which would allow fluid to penetrate.

Ultrasound Head Surface

Clean the contact surface of the stationary ultrasound head after each use.

The treatment heads may be disinfected with a moist cloth dipped in 70% alcohol solution.

Cable/Rubber Cup

We recommend cleaning the cable and the rubber cup daily with a moist cloth. Use lukewarm water and a little household cleanser if necessary (no abrasives or no alcohol solutions).

Note!

- Do not rinse the head under running water!
- Never immerse the head in water or other (cleaning) liquids!
- For proper cleaning of the head's contact surface, the rubber cuff may be folded back on one movement (see Figure A).

If necessary, you can push up the head a bit from beneath (see Figure B).

ATTENTION: Never fold the entire cuff ! (See Figure C.)

Note:

In order to guarantee good transmission of the ultrasound energy, you must use original Enraf-Nonius gelpads.

Do not use regular (liquid) sonogel because this will be sucked up into the vacuum pump! Warranty claims in which the remnants of regular ultrasound gel are found in the pump, hoses or connections will be rejected by Enraf-Nonius.

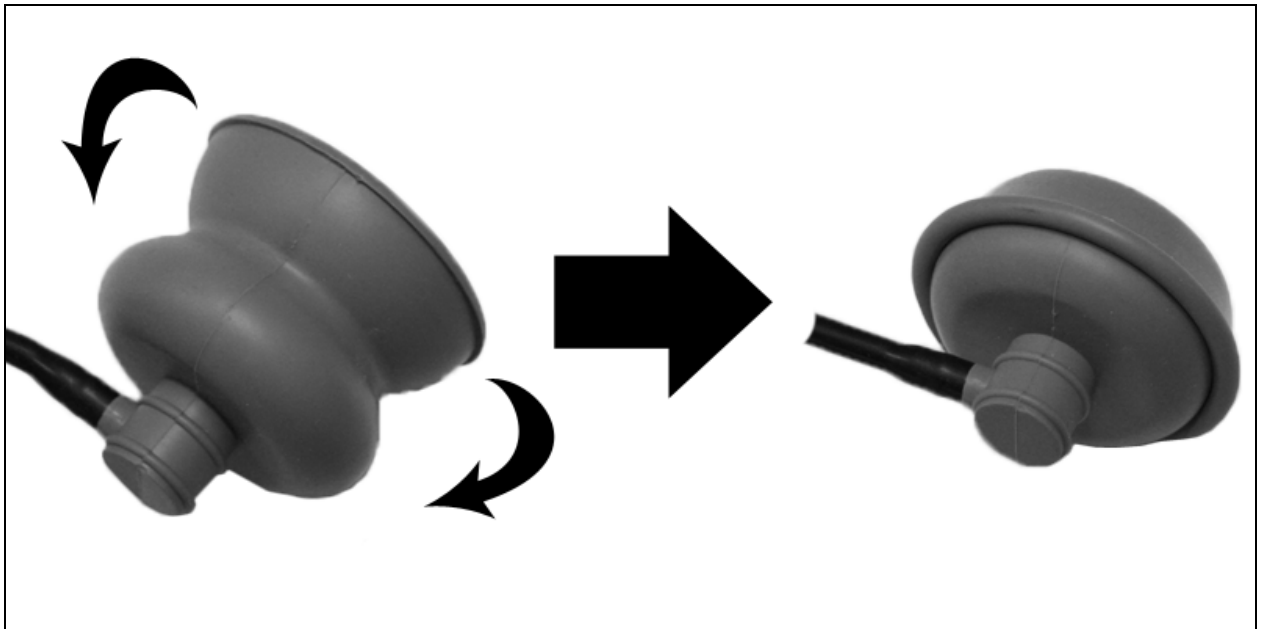


Figure A

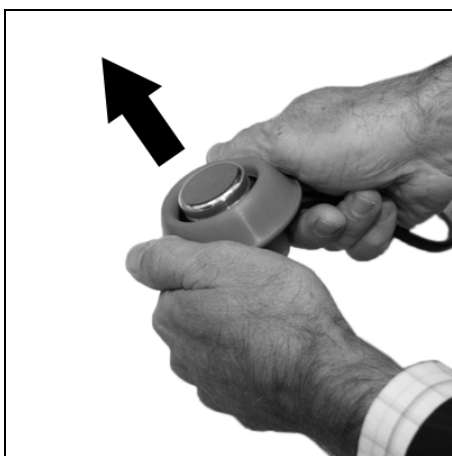


Figure B



Figure C

12.1.7 Water reservoir of vacuum unit

Treatment unit

First switch off the unit and disconnect the mains. Remove the connection cable of the electrotherapy unit. The unit can be cleaned with a damp cloth. Use lukewarm water and, if required, a liquid household detergent. Do not use abrasive cleaners.

Electrodes and sponges

The vacuum electrodes and sponges should be cleaned with lukewarm water. In the case of persistent dirt, and for disinfection, a 70% alcohol solution may be used.

Sponges should be replaced regularly. It is recommended to keep sponges and a spare electrode in stock.

Calcium scale can be deposited on the metal surfaces of the electrodes. This has an insulating effect. In order to maintain optimum conductivity, these surfaces should be regularly cleaned and polished.

Electrode cables

Check the cables regularly for damage and/or poor contacts. It is recommended to keep a spare electrode cable in stock.

Water reservoir

If the water reservoir is full a pop-up screen will appear. The unit should then be switched off and the water reservoir should be emptied by removing the hose [23] outside the unit, opening the valve and letting the liquid run out. After this the valve should be closed and stored back into the unit. The unit can be turned on again.

Cleaning the water reservoir and hoses

Before you run the cleaning procedure, the peripheral ends of the vacuum tubes should be placed in a cup with cleaning liquid (see below) so the Vacotron can be cleaned internally with this liquid. After this turn the vacuum pump on to full power until the reservoir is full with cleaning liquid. If the reservoir is full, empty it as described above.

The following registered products may be used for disinfecting the water reservoir:

BAKTOLAN to 5%, CHINOSOL to 1%, CHLORAMIN solution, ELMOCID Gamma to 2%
MEFAROL to 1%, MERCKOJOD to 1%, MERFEN, PERHYDROL, PERODIN, SAGROTAN to 2%, ZEPHIROL to 5%.

12.2 Troubleshooting

12.2.1 Error code

When the apparatus is turned on, it will first execute a self test. When an error is detected, both during the self test and during normal operation, a pop-up screen will appear on the display. When the error is displayed, all outputs will be disabled. When this situation occurs, remove all cables and switch the apparatus off and on again. When the error re-appears, stop using the device and contact your supplier.

12.2.2 Insufficient or no output current

Insufficient or no output current is usually preceded by a blinking current display or pop-up screen with warning messages

- Poor electrical contact or broken patient cable.
- Insufficiently moistened sponges. If necessary, use a saline solution to improve the electrical conductivity of the water.
- Too high current amplitude with self adhesive electrodes. Try to continue the treatment with flexible rubber electrodes.

If the problem occurs in CC mode, the current amplitude will ramp down to 0 and will have to be readjusted when the problem has been removed.

If none of the above scenarios appear to be the problem, stop using the device and contact your supplier.

12.3 Technical Maintenance

On request a service manual can be made available containing: spare part list, descriptions, calibration instructions and other information which will assist the user's appropriately qualified technical personnel to repair those parts of the equipment which are designated by the manufacturer as repairable.

CAUTION:

- Electrical safety of the device relies on a proper earthed electrical connection via the power cord. It is therefore necessary to have this connection checked annually.
- To ensure continued compliance with the 21 CFR 1050.10 standard, this unit should be adjusted and safety tested once each year. Procedures laid down in the service manual should be followed. This may be carried out by your supplier, or by another agency, authorized by the manufacturer. It is also recommended that a service history record is maintained. In some countries this is even obligatory.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

WARNING:

- This unit operates with high voltages. No attempt should be made to disassemble the unit. Maintenance and repair should be carried out by authorized personnel only. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.

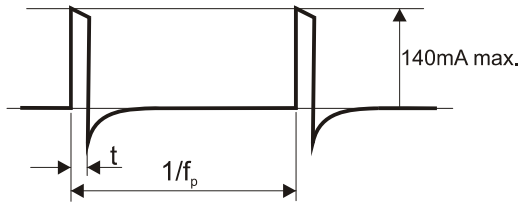
12.4 End of life

The 6-series contains materials that can be recycled and/or are noxious to the environment. Specialized companies can disassemble the unit and sort out these materials. When you dispose of the unit, find out about local regulations concerning waste management.

13 Illustrations

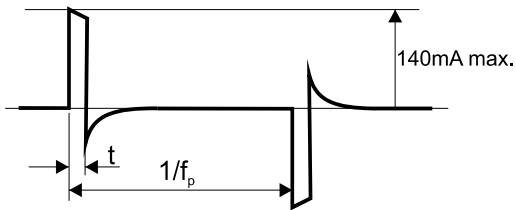
13.1 Biphasic Pulsed Current TENS

13.1.1 Asymmetrical



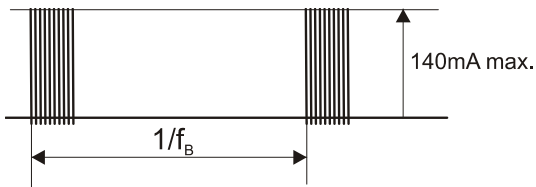
- t Phase duration
- f_p Pulse frequency

13.1.2 Asymmetrical Alternating



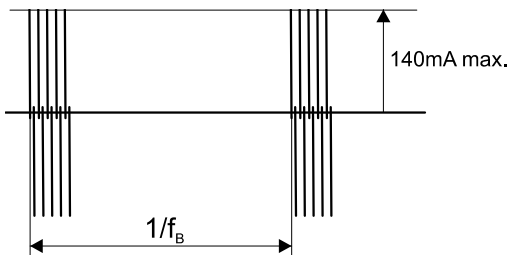
- t Phase duration
- f_p Pulse frequency

13.1.3 Burst Asymmetrical



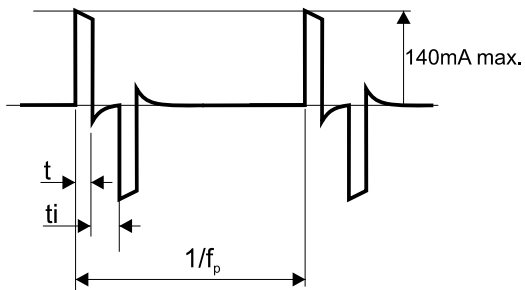
- f_B Burst frequency

13.1.4 Burst Asymmetrical Alternating



- f_B Burst frequency

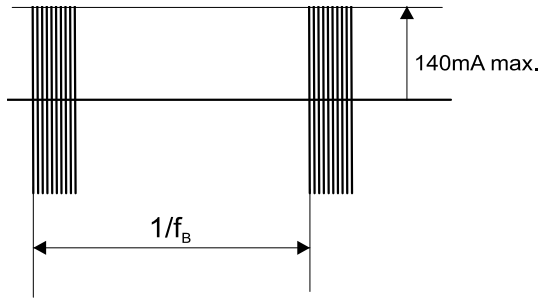
13.1.5 Symmetrical



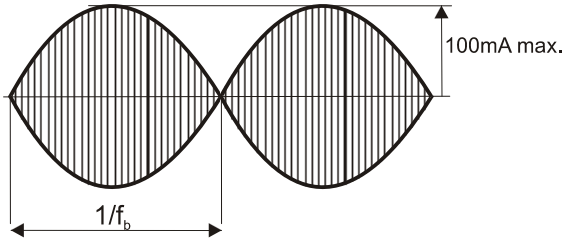
- t Phase duration
- t_i Phase interval
- f_p Pulse frequency

13.1.6 Burst Symmetrical

- f_B Burst frequency

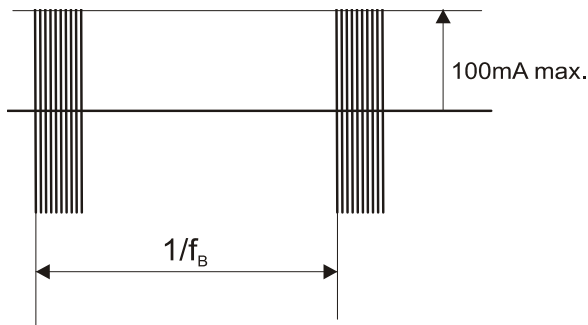


13.2 Premodulated / Isoplanar vector / Dipole vector



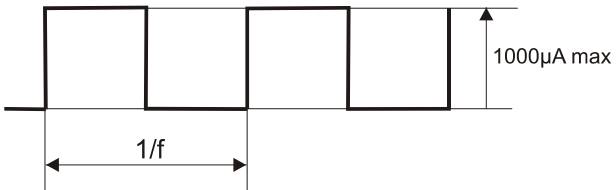
f_c Carrier frequency
 f_b Beat frequency

13.3 Russian Stimulation



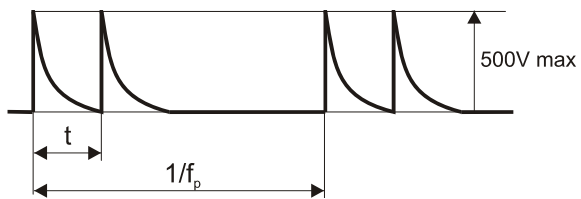
f_c Carrier frequency
 f_B Burst frequency

13.4 Micro Current



f Frequency

13.5 High Voltage



t Peak interval - 64 μ s fixed
 f_p Pulse frequency

13.6 Diadynamic Current

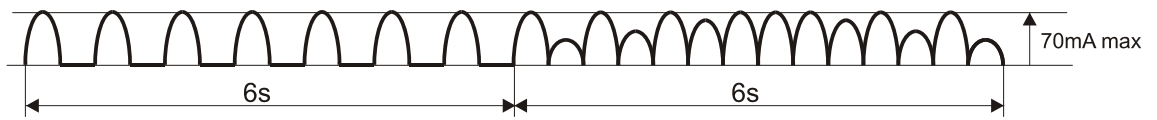
13.6.1 MF



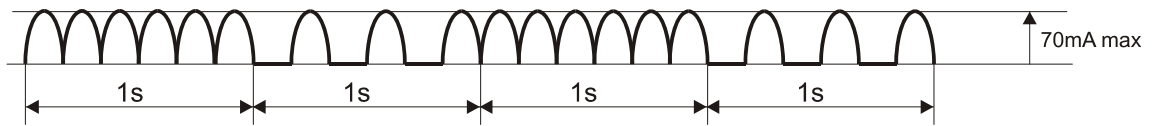
13.6.2 DF



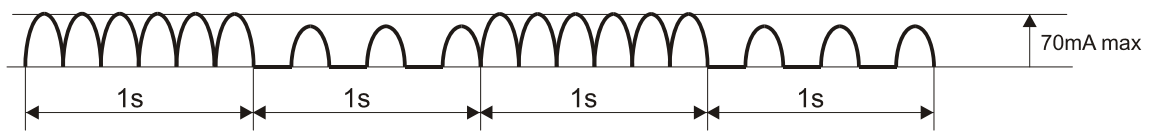
13.6.3 LP



13.6.4 CP

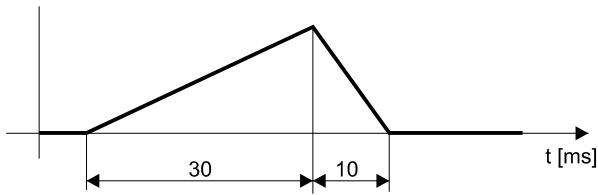


13.6.5 CPid

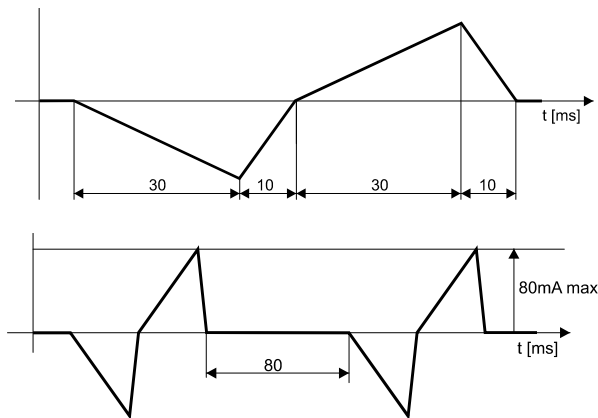


13.7 IG Pulsed Currents

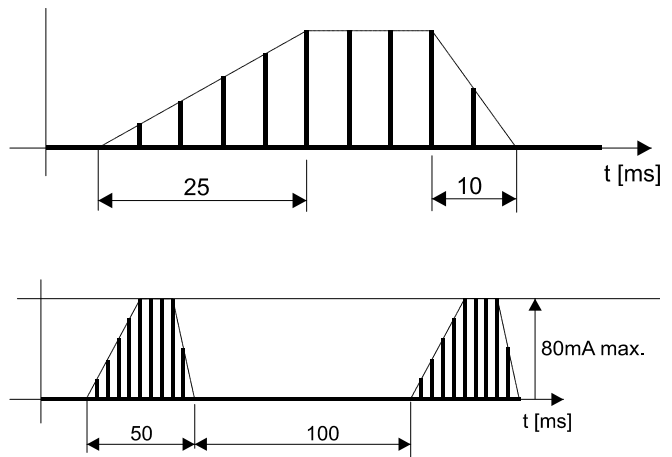
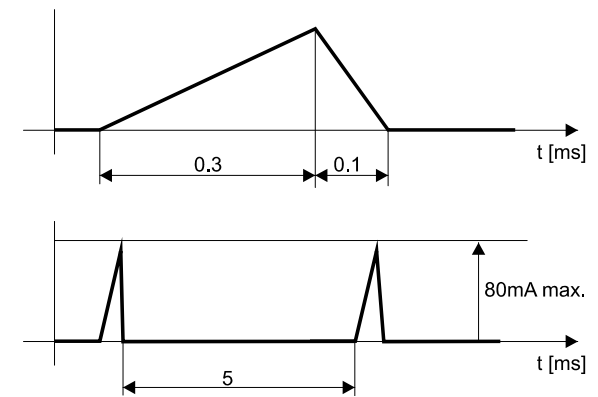
13.7.1 IG30 Monophasic



13.7.2 IG30 Biphasic

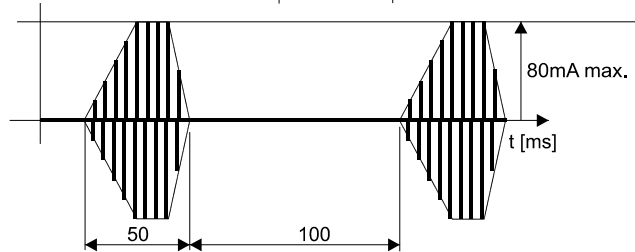
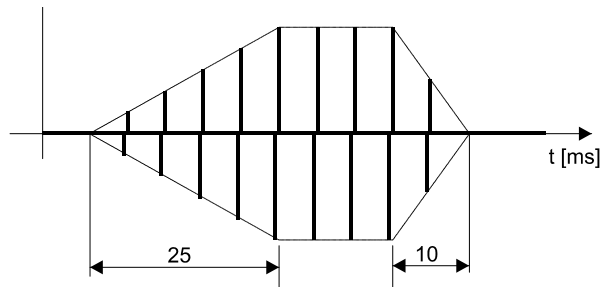
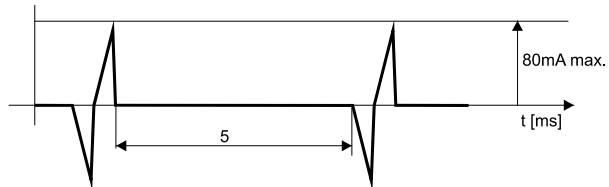
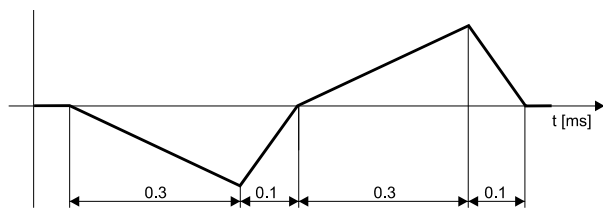


13.7.3 IG50 Monophasic



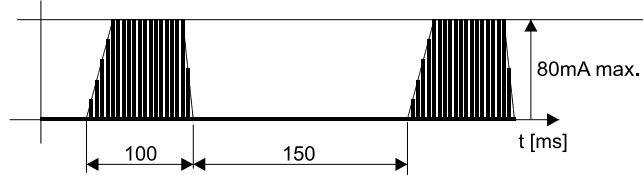
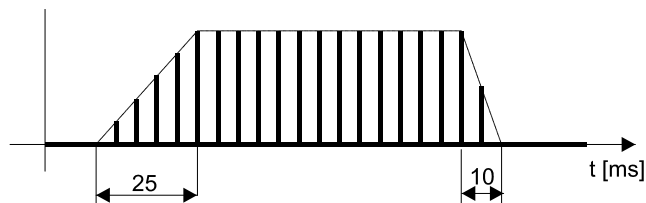
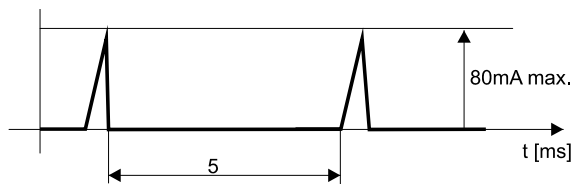
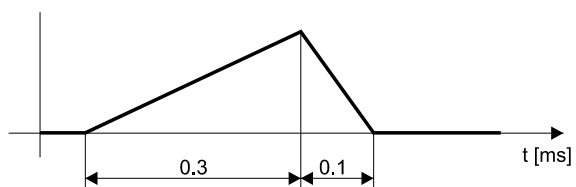
Envelope

13.7.4 IG50 Biphasic



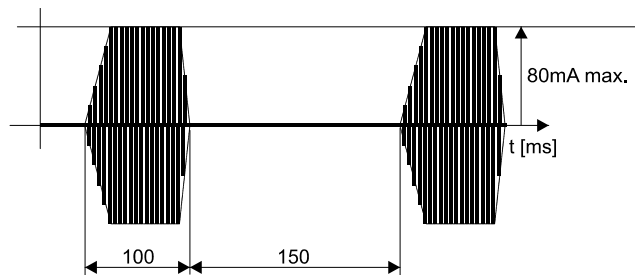
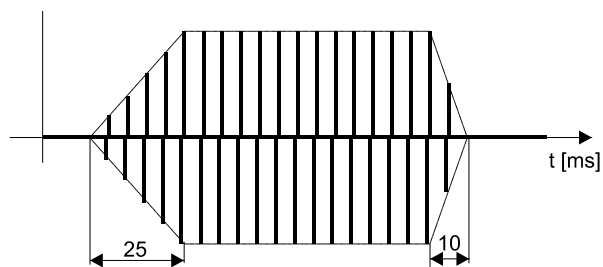
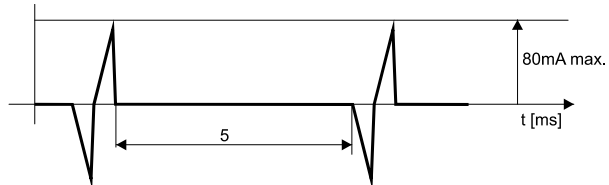
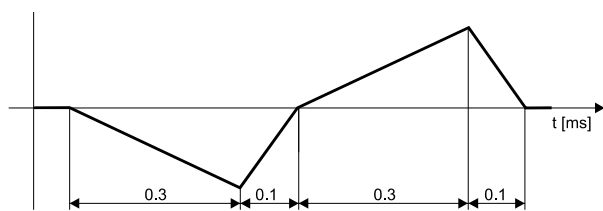
Envelope

13.7.5 IG100 Monophasic



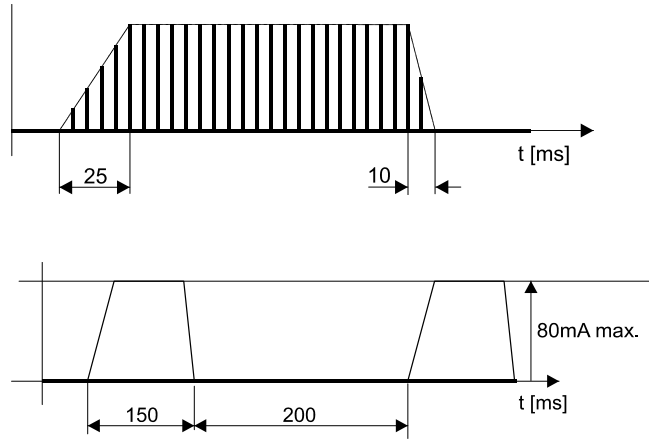
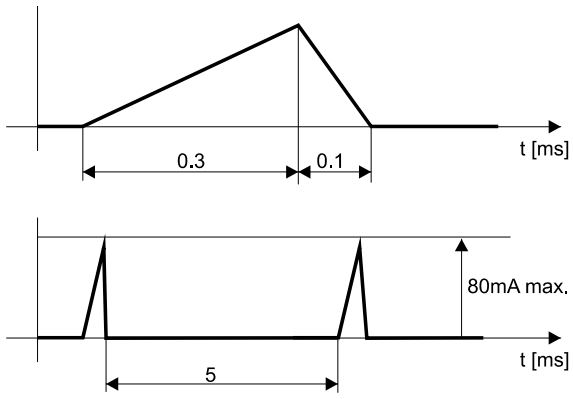
Envelope

13.7.6 IG100 Biphasic



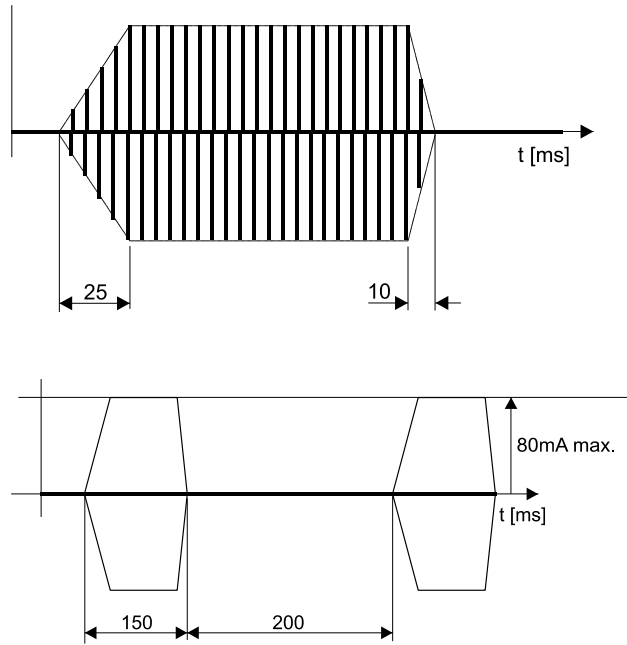
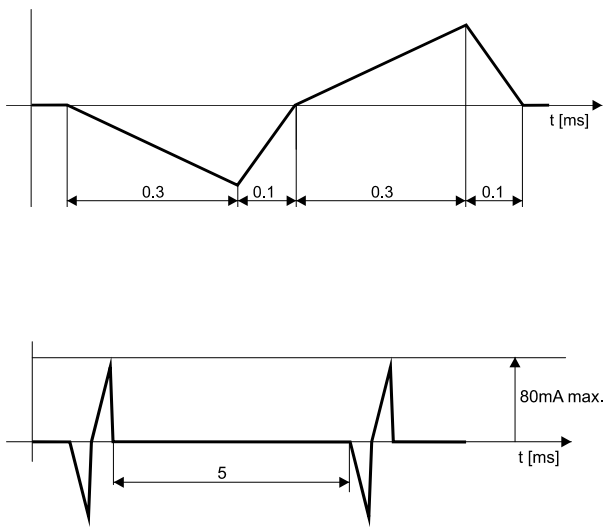
Envelope

13.7.7 IG150 Monophasic



Envelope

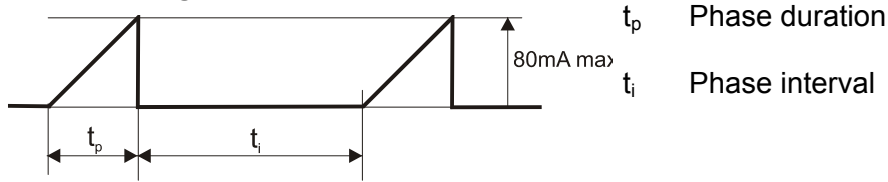
13.7.8 IG150 Biphasic



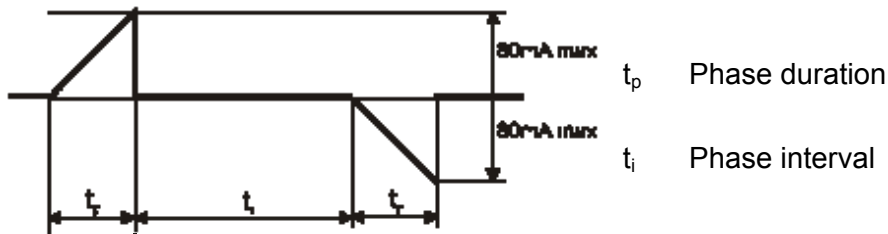
Envelope

13.8 Faradic Pulsed Current

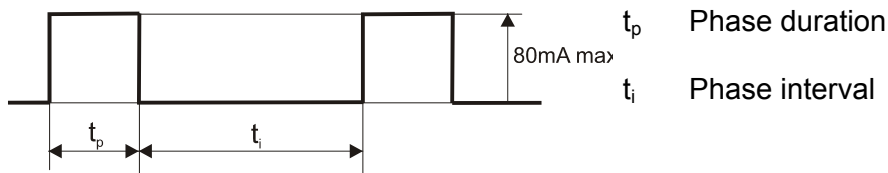
13.8.1 Triangular Pulsed Current



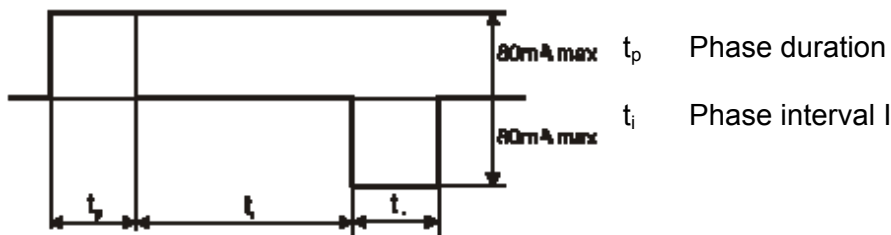
13.8.2 Triangular alternating current



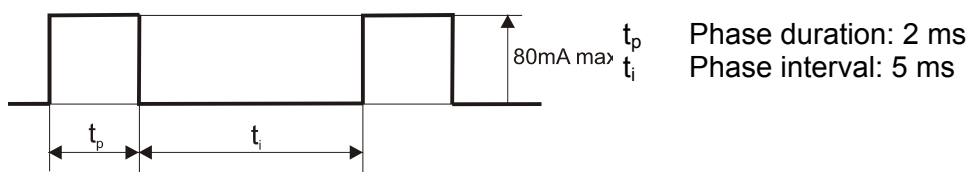
13.8.3 Rectangular Pulsed current



13.8.4 Rectangular alternating current

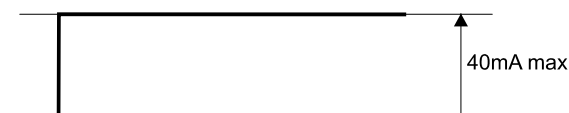


13.9 Träbert, 2 – 5 Current



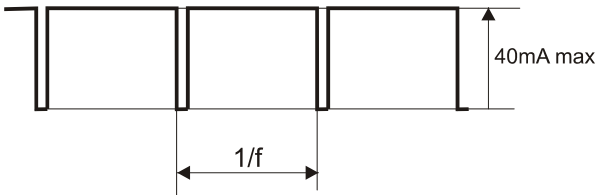
13.10 Galvanic Current

13.10.1 Direct Current



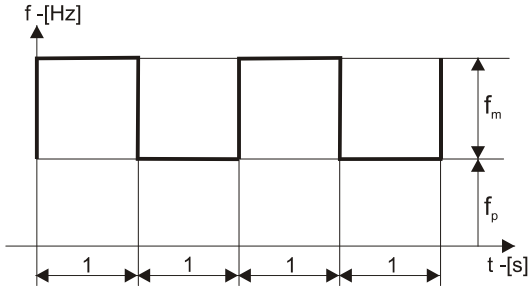
13.10.2 MF (medium frequency) Interrupted Current

f Carrier frequency - 8 kHz fixed
 Duty cycle - 90 % fixed



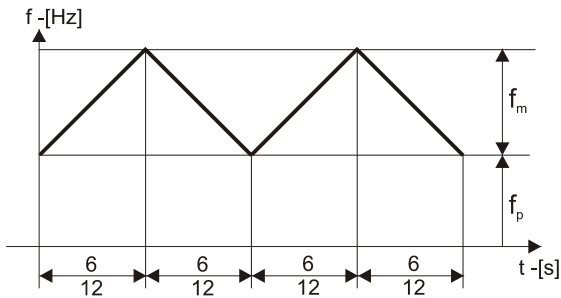
13.11 Modulation program

13.11.1 Modulation program 1/1



- f_p Pulse frequency
- f_m Frequency modulation

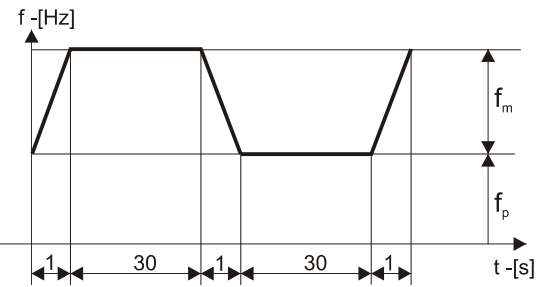
13.11.2 Modulation program 6/6 or 12/12



6 : 6 or 12 : 12

- f_p Pulse frequency
- f_m Frequency modulation

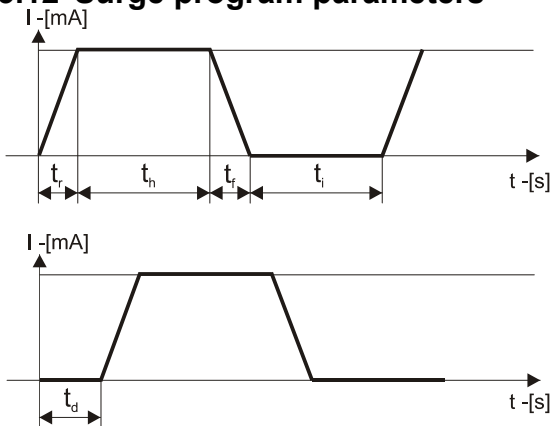
13.11.3 Modulation program 1/30



1 : 30

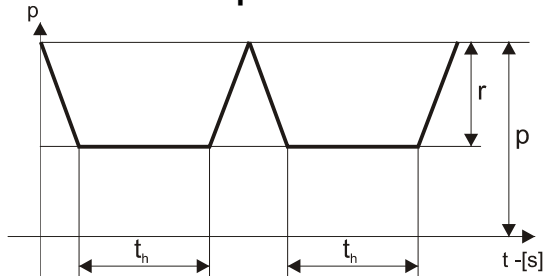
- f_p Pulse frequency
- f_m Frequency modulation

13.12 Surge program parameters



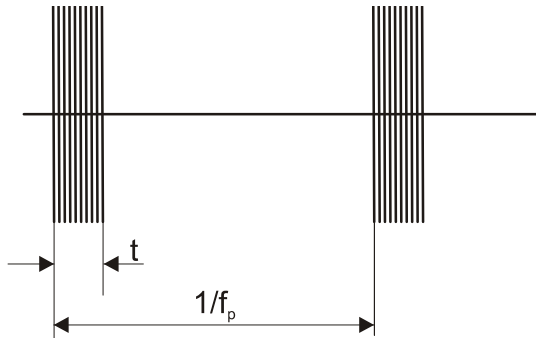
- t_r Ramp up time
- t_h Hold time
- t_f Ramp down time
- t_i Interval time
- t_d Delay time

13.13 Vacuum pulsed mode



p Vacuum pressure
 r Range
 t_h Hold time

13.14 Ultrasound



Ultrasound parameters:
 f_p Pulse frequency, 100 Hz fixed
 t Pulse duration, set by duty cycle
 5 – 80 % and 100 % (100% is continuous wave)
 t 0.5 – 8 ms
 RTPA 20 – 1.25

14 Specifications

14.1 Ultrasound parameters

See fig 13.14 for details.

Generator

Peak output Amplitude:

Duty cycle 5 – 50 % : 0 – 3 W/cm²
 Duty cycle 80 % : 0 – 2.5 W/cm²
 Duty cycle 100 % : 0 – 2 W/cm² (continuous wave)

Peak output power for 5 cm² applicator:

Duty cycle 5 – 50 % : 0 – 15 W
 Duty cycle 80 % : 0 – 12 W
 Duty cycle 100 % : 0 – 10 W (continuous wave)

Peak output power for 0.8 cm² applicator:

Duty cycle 5 – 50 % : 0 – 2.4 W
 Duty cycle 80 % : 0 – 2 W
 Duty cycle 100 % : 0 – 1.6 W (continuous wave)

Output meter uncertainty : ± 20 % for any output above 10 % of maximum

Pulse frequency : 100 Hz ± 1 % fixed
 Duty cycle : 5 – 80 % and 100 % (100 % is continuous wave)
 Pulse duration : 0.5 – 8 ms ± 10 % (set by duty cycle)
 Temporal Peak to Average Ratio (RTPA): 20 – 1.25 ± 10 % (set by duty cycle)

Treatment timer : 0 - 30 min ± 0.1 min, linked to contact control
 Contact control level : 65%

5 cm² Applicator

Ultrasound frequency:
 1 MHz : 0.98 MHz ± 2 %
 3 MHz : 3.1 MHz ± 2 %

ERA (Effective Radiation Area):
IEC 60601-2-5: 2000 : to be determined
21 CFR 1050.10 : to be determined

Beam type:
1 MHz : Collimating
3 MHz : Collimating
BNR (Beam Non-uniformity Ratio) : 6:1 maximum
Side radiation : 10 mW/cm² maximum

0.8 cm² Applicator

Ultrasound frequency:
1 MHz : 0.98 MHz ± 2 %
3 MHz : 3.1 MHz ± 2 %

ERA (Effective Radiation Area):
IEC 60601-2-5: 2000 : to be determined
21 CFR 1050.10 : to be determined

Beam type:
1 MHz : Collimating
3 MHz : Diverging
BNR (Beam Non-uniformity Ratio) : 6:1 maximum
Side radiation : 10 mW/cm² maximum

Description of ultrasound field

The spatial distribution of the radiated field is a collimated beam (diverging for the 0.8 cm² applicator at 3 MHz) of ultrasound energy, with a decreasing Amplitude at increasing distance from the applicator surface. This field distribution applies for the radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 30 °C and with line voltage variations in the range of ± 10% of the rated value. The ultrasonic beam is characterized by the Effective Radiation Area (ERA) and the Beam Non-uniformity Ratio (BNR).

The Effective Radiation Area is the cross-sectional area of the ultrasound beam. Its value depends on the ultrasound standard used: - International: IEC 60601-2-5: 2000
- USA: 21 CFR 1050.10

The Beam Non-uniformity Ratio is the ratio of the maximum ultrasound Amplitude to the average ultrasound Amplitude, measured at the Effective Radiation Area. A low BNR value is indicative for the absence of high and potentially dangerous energy concentrations.

14.2 Stimulator output parameters

Electrotherapy general

Channels : 2
Output characteristics : Constant Current (CC) or Constant Voltage (CV)
Current amplitude range : Depending on current waveform
Current amplitude resolution : 0.1 mA
Treatment timer : 0 - 60 minutes
Polarity reversion direct currents : manual

The maximum current amplitude within the specification is achieved up to a load of 500 Ω (CC).

Surge program

With some current waveforms a surge program is available.

The parameters and their range are as follows:

Ramp-up time : 0 - 9 s, below 1s in steps of 0.1s, otherwise in steps of 1s
Hold time : 0 - 60 s, in steps of 1 second
Ramp-down time : 0 - 9 s, below 1s in steps of 0.1s, otherwise in steps of 1s
Interval time : 0 - 120 s, in steps of 1 second
Delay time : 0.1 - 80 s, below 1s in steps of 0.1s, otherwise in steps of 1s

Interferential, 4 polar

Carrier Frequency : 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10 kHz
 Beat Frequency (AMF) : 0 – 200 Hz in steps of 1 Hz
 Frequency Modulation (spectrum) : 0 - 180 Hz in steps of 1 Hz
 Modulation program : 1/1, 6/6, 12/12, 1/30/1/30 s
 Amplitude : 0 - 100 mA
 Current mode : CC

Isoplanar vector

Carrier Frequency : 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10 kHz
 Beat Frequency (AMF) : 0 – 200 Hz in steps of 1 Hz
 Frequency Modulation (spectrum) : 0 – 180 Hz in steps of 1 Hz
 Modulation program : 1/1, 6/6, 12/12, 1/30/1/30 s
 Amplitude : 0 - 100 mA
 Current mode : CC

Dipole Vector Automatic

Carrier Frequency : 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10 kHz
 Beat Frequency (AMF) : 0 – 200 Hz in steps of 1 Hz
 Amplitude : 0 - 100 mA
 Rotation time : 1 - 10 s in steps of 1 s
 Current mode : CC

Dipole Vector Manual

Carrier Frequency : 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10 kHz
 Beat Frequency (AMF) : 0 – 200 Hz in steps of 1 Hz
 Frequency Modulation (spectrum) : 0 – 180 Hz in steps of 1 Hz
 Modulation Program : 1/1, 6/6, 12/12, 1/30/1/30 s
 Amplitude : 0 - 100 mA
 Resolution vector : 2.25° per step (160 steps over 360°)
 Current mode : CC

Asymmetrical

Phase Duration : 10 - 400 µs in steps of 5 µs
 Pulse Frequency : 1 - 200 Hz, in steps of 1 Hz
 Frequency Modulation : 0 – 180 Hz, in steps of 1 Hz
 Modulation Program : 1/1, 6/6, 12/12, 1/30/1/30 s
 Amplitude : 0 - 140 mA.

Asymmetrical Alternating

Phase Duration : 10 - 400 µs in steps of 5 µs
 Pulse Frequency : 1 - 200 Hz, in steps of 1 Hz
 Frequency Modulation : 0 – 180 Hz, in steps of 1 Hz
 Modulation Program : 1/1, 6/6, 12/12, 1/30/1/30 s
 Amplitude : 0 - 140 mA.

Burst Asymmetrical

Phase Duration : 10 - 400 µs in steps of 5 µs
 Pulse Frequency : 1 - 200 Hz, in steps of 1 Hz
 Burst Frequency : 1 – 9 Hz, in steps of 1 Hz
 Amplitude : 0 - 140 mA.

Burst Asymmetrical Alternating

Phase Duration : 10 - 400 µs in steps of 5 µs
 Pulse Frequency : 1 - 200 Hz, in steps of 1 Hz
 Burst Frequency : 1 – 9 Hz, in steps of 1 Hz
 Amplitude : 0 - 140 mA.

Symmetrical

Phase Duration : 10 - 1000 μ s in steps of 5 μ s
Pulse Frequency : 1 - 200 Hz, in steps of 1 Hz
Phase Interval : 0 – 255 μ s, in steps of 5 μ s
Frequency Modulation (spectrum): 0 - 180 Hz in steps of 1 Hz
Modulation Program : 1/1, 6/6, 12/12, 1/30/1/30 s
Amplitude : 0 - 140 mA.

Burst Symmetrical

Phase Duration : 10 - 1000 μ s in steps of 5 μ s
Pulse Frequency : 1 - 200 Hz, in steps of 1 Hz
Phase Interval : 0 – 255 μ s, in steps of 5 μ s
Burst Frequency : 1 – 9 Hz, in steps of 1 Hz
Amplitude : 0 - 140 mA.

Premodulated

Carrier Frequency : 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10 kHz
Beat Frequency : 0 - 200 Hz in steps of 1 Hz
Frequency Modulation (spectrum) : 0 - 180 Hz in steps of 1 Hz
Modulation program : 1/1, 6/6, 12/12, 1/30/1/30 s
Surge Program : Yes
Amplitude : 0 - 100 mA

Russian Stimulation

Carrier Frequency : 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10 kHz
 Burstfrequency : 0 - 100 Hz in steps of 1 Hz
 Burst / Pause : 1:1, 1:2, 1:3, 1:4, 1:5
 Surge Program : Yes
 Amplitude : 0 - 100 mA

High Voltage (Twin Pulse)

Frequency : 1- 200 Hz in steps of 1 Hz
 Frequency Modulation (spectrum): 0 – 180 Hz in steps of 1 Hz, sum of Pulse frequency and Frequency Modulation can not exceed 200 Hz
 Modulation Program : 1/1, 6/6, 12/12, 1/30/1/30 s
 Surge Program : Yes
 Polarity : Positive or Negative
 Amplitude : 0 – 500 Volt in steps of 1V

High Voltage Alternating (Twin Pulse)

Frequency : 1 – 200 Hz in steps of 1 Hz
 Frequency Modulation (spectrum) : 0 – 180 Hz in steps of 1 Hz, sum of Pulse frequency and Frequency Modulation can not exceed 200 Hz
 Modulation program : 1/1, 6/6, 12/12, 1/30/1/30 s
 Alternating Period : 10 -100 seconds in steps of 10
 Ramp-in, ramp out : 0,5 seconds
 Amplitude : 0 – 500 Volt in steps 1 Volt

Micro Current

Frequency : 0 – 1000 Hz, 0 – 10 Hz in steps of 0,1 Hz, 10 -100 Hz in steps of 1Hz., 100 – 1000 Hz in steps of 10 Hz
 Polarity : Positive or Negative
 Amplitude : 10 µA - 1 mA

Micro Current Alternating

Frequency : 0 – 1000 Hz, 0 – 10 Hz in steps of 0, 1 Hz, 10 -100 Hz in steps of 1Hz., 100 – 1000 Hz in steps of 10 Hz
 Alternating Period : 0,2 – 20 seconds, 0,2 – 1 s in steps of 0,1s., 1 – 20 s in steps of 1 s.
 Ramp-in, ramp out : 0 seconds
 Amplitude : 10 µA - 1 mA,

Diadynamic current

Settings : MF, DF, CP, LP en CPid
 Surge Program : on MF and DF
 Polarity : Positive or Negative
 Amplitude : 0 - 70 mA

MF interrupted galvanic current

Frequency : 8000 Hz
 Duty cycle : 95%
 Polarity : Positive or Negative
 Amplitude : 0 - 40 mA

Direct Galvanic current

Polarity : Positive or Negative
 Amplitude : 0 – 40 mA



Faradic Rectangular Pulsed Current

Phase Duration : 0.02 – 1000 ms
Phase Interval : 5 – 15000 ms
Surge Program : Yes
Polarity : Positive or Negative
Amplitude : 0 - 80 mA

Faradic Triangular Pulsed Current

Phase duration : 0.1 – 1000 ms
Phase interval : 5 – 15000 ms
Surge program : Yes
Polarity : Positive or Negative
Amplitude : 0 - 80 mA

Träbert 2-5 (Rectangular pulsed current)

Phase duration : 2 ms
Interval : 5 ms
Polarity : Positive or Negative
Amplitude : 0 - 80 mA

IG Currents (Impulse Galvanisation) Monophasic

Waveform : IG30, IG50, IG100, IG150
Polarity : Positive or Negative
Amplitude : 0 – 80 mA

IG Currents (Impulse Galvanisation) Biphasic

Waveform : IG30, IG50, IG100, IG150
Amplitude : 0 – 80 mA

14.3 Vacuum unit (Vacotron)

Vacuum pressure : 10- 90 (0 – 600 mbar), continuously adjustable
Pulsed vacuum via vacuum range: adjustable from 10 – 80%
Hold time : 0 – 2,5 seconds in steps of 0,5 second

14.4 EMG

E.M.G. Channels : 2
Sensitivity : 0,5 μ V – 10.000 μ V
Raw EMG signal : 1.500 Hz
Sample frequency : 160 Hz
Bandwidth : 5 – 1.500 Hz
Filtering : digital

Pressure : 1 channel via internal sensor
Range : 0 – 360 hPa

14.5 Safety and Performance standards

IEC 60601-1 : General requirements for the safety of electrical medical systems, including Annex 1, national differences for Australia, Canada and the United States.



Safety class according to IEC 60601-1: class I type BF

IEC 60601-2-5 : Particular requirements for the safety of ultrasonic therapy equipment.

IEC 60601-2-10 : Particular requirements for the safety of nerve and muscle stimulators.

IEC 60601-2-40 : Particular requirements for the safety of electromyographs and evoked response equipment.



: This equipment complies with all requirements of the Medical Device Directive (93/42/EEC).

Medical device classification

: IIa

21 CFR 1050.10

: This equipment complies with all requirements of 21 CFR 1050.10, Performance Standard for Ultrasonic Therapy devices.

21 CFR 898


: This equipment complies with all requirements of 21 CFR 898, Performance Standard for electrode lead wires and patient leads.

14.6 EMC details

Guidance and manufacturer's declaration – electromagnetic immunity			
The 6-series is intended for use in the electromagnetic environment specified below. The customer or the user of the 6-series should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be 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 ± 1 kV for input/output Lines	± 1 kV for power supply lines not applicable	Mains power quality should be that of a typical computer room.
Surge IEC 61000-4-5	± 1 kV line(s)to line(s) ± 2 kV line(s)to earth	± 1 kV line(s)to line(s) ± 2 kV line(s)to earth	Mains power quality should be that of a typical computer room.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 %dip in U_T) for 0,5 cycle 40 % U_T (60 %dip in U_T) for 5 cycles 70 % U_T (30 %dip in U_T) for 25 cycles <5 % U_T (>95 %dip in U_T) for 5 sec	< 5% U_T for 0,5 cycle < 5% U_T for 1 cycle 70% U_T for 25 cycles < 5% U_T For 5 sec.	Mains power quality should be that of a typical computer room. If the user of the 600-series requires continued operation during power mains interruptions, it is recommended that the 600-series be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A / m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical computer room.
NOTE U_T is the a.c.mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity	
The 6-series is intended for use in the electromagnetic environment specified below. The	

customer or the user of the 6-series should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
 <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/ m 80 MHz to 2,5 GHz</p>	<p>3 V</p> <p>3 V/ m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the 6-series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = [3,5/3]\sqrt{P}$</p> <p>$d = [3,5/3]\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = [7/3]\sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol:</p>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
 NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

A Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 6-series is used exceeds the applicable RF compliance level above, the 6-series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the 6-series.

B Over the frequency range 15 kHz to 8 MHz, field strengths should be less than 3 V / m.

Recommended separation distances between portable and mobile RF communications equipment and the 6-series

The 600-series is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 6-series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 6-series as recommended below, according to the maximum output power of the communications equipment.



Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = [3,5/V_1]\sqrt{P}$	80 MHz to 800 MHz $d = [3,5/E_1]\sqrt{P}$	800 MHz to 2,5 GHz $d = [7/E_1]\sqrt{P}$
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 transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

14.7 Technical Data

Mains voltage : 100 – 240 V ± 10%

Mains frequency : 50 / 60 Hz

Main unit:

Dimensions : 39 x 37 x 12 cm (w x d x h)

Weight : 4,75 Kg

Vacotron reservoir :

Dimensions : 39 x 37 x 6 cm (w x d x h)

Weight : 1,5 Kg

Environmental conditions for transport and storage:

Temperature : -10° to +50° C

Relative humidity : 10 to 100 % (contained in original packaging)

Atmospheric pressure : 500 to 1060 hPa

Environmental conditions for normal use:

Temperature : 10° to 40° C

Relative humidity : 10 to 90 % non condensing

Atmospheric pressure : 500 to 1060 hPa

Technical modifications reserved