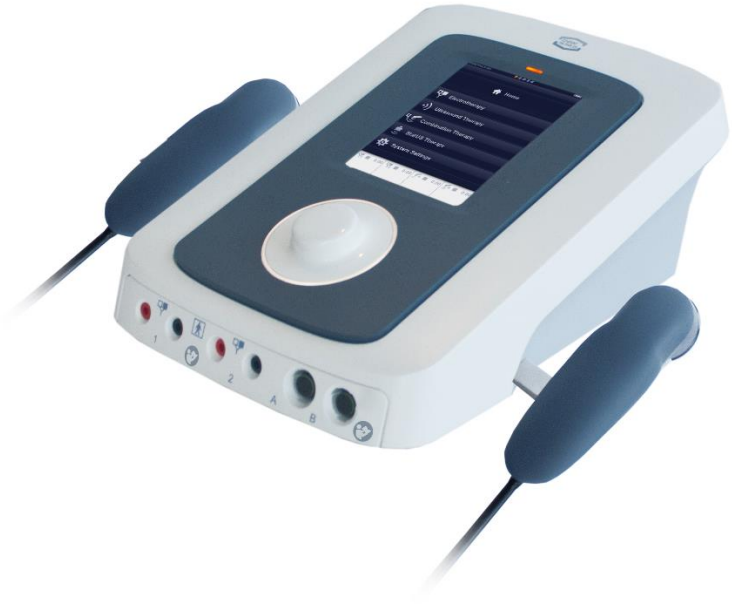
4-SERIES



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CE 0197

Instructions for use

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1 Introduction

Foreword

Welcome to the growing family of new 4-series owners. This product is designed and manufactured by Enraf-Nonius B.V. and is delivered to you with confidence. It was produced using the latest techniques and strict quality control.

This manual has been written for the owners and operators of the 4-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.

Device Description

The 4-series is a family of products for physical therapy. The devices share an identical control panel equipped with a full colour touch panel. The devices are mains powered and can optionally be equipped with a battery for mains independent operation. The family comprises the products described below.

Endomed 482

The Endomed 482 is equipped with two completely identical electrotherapy channels. The electrotherapy channels can be used in combination (linked) or independent. A comprehensive set of current waveforms is available, targeting both pain management and muscle stimulation applications. Protocol driven operation is available, providing both factory or user defined sequences of treatment steps. Protocols can run on linked or independent channels. With independent channels two different protocols can be performed simultaneously.

Sonopuls 490

The Sonopuls 490 is an ultrasound therapy device. The device provides two positions for attachment of an ultrasound applicator. Depending on the device configuration ordered, the Sonopuls 490 comes with an ultrasound head with a large contact area, an ultrasound treatment head with a small contact area or with both applicators. The ultrasound head can operate in continuous or pulsed mode at an ultrasound frequency of 1 MHz or 3 MHz Contact control suspends the application of ultrasonic energy when acoustical contact with the treatment area becomes insufficient. The ultrasound heads are suitable for subaqual treatments.

Sonopuls 492

The Sonopuls 492 is a combination device, combining the functions of the Endomed 482 and the Sonopuls 490 in a single device. With the Sonopuls 492 the simultaneous application of ultrasound and electrotherapy (combination therapy) is also possible. The remaining electrotherapy channel can then be used independently.

StatUS™ Pack 400

For a detailed explanation about the installation and operation of the Sonopuls 490/492 in combination with StatUS Pack 400 (for the application of static ultrasound), please refer to the instructions for use StatUS Pack 400 (art. no. 1629767). This manual (CD-ROM) is located in the packaging of the StatUS Pack 400.

Vacotron 460

Electrotherapy can be applied through standard or vacuum electrodes. With vacuum electrodes, the Vacotron 460 generates the vacuum through which the vacuum electrodes are attached to the patient. The device is placed beneath the Endomed 482 or Sonopuls 492, from which its power is derived and through which it is also operated.

2 Symbols

Symbol used	Description
	Follow the instructions in the Instructions for Use. It is important that you read, understand and observe the precautionary and operating instructions
	General Prohibition Sign. Prohibition is used to mean "You MUST NOT"
	Warning or Caution: Indicates a hazardous situation which, if not avoided, could result in: a. Death or serious injury to the patient (or) b. Minor to moderate injury to the patient (or) c. Damage to the equipment
	General mandatory action sign. Mandatory action is used to mean, "You must…"
	Type B applied part complying with the specified requirements to provide protection against electric shock, particularly regarding allowable patient leakage current and patient auxiliary current.
	Type BF applied part complying with the specified requirements to provide a higher degree of protection against electric shock than that provided by type B applied parts.
	Temperature Range. Indicates acceptable temperature range
	Humidity Limits. Indicates acceptable relative humidity
	Atmospheric Pressure. Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Waste electrical items that can be recycled. Indicates the electrical and electronic components of the device can be recycled and has to be disposed separately.
	Keep the device dry
	Manufacturer name, address and date of manufacture.
	Reference Number or Part Number

SN	Serial Number Indicates the serial number so that a specific medical device can be identified.
CE 0197	CE Mark along with number indicates conformity with European Council of directive concerning Medical Devices and this device is under the direct supervision of the Notified Body.
	Connection electrode cable electrotherapy
	Connections vacuum cables electrotherapy
	Remote control connection
	On/Off push button
	Pulse frequency
	Continuous
	Duty cycle
	Pulse duration
	Ultrasound frequency
~	Alternating current

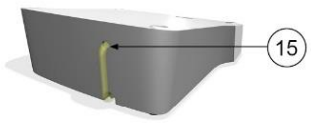
3 Device components

Parts of the device

Parts description

Numbered Part	Description	Purpose
[1]	Power line switch	0 Device disconnected from mains supply 1 Device connected to mains supply
[2]	Connector for mains cable Type number/warning label	Connect supplied mains cable here to power the device. Provides information on the apparatus, such as type and serial number, as well as connection data such as mains voltage and maximum current consumption.
[3]	Remote Control connection	This connection has two functions. 1 Attachment of optional remote-control unit. Used to remotely adjust the output current on the electrotherapy channels or to stop the treatment on all channels. 2 Attachment of a USB-stick. Used for software updates and to backup and restore user data.

Numbered Part	Description	Purpose
		⚠ Do not connect externally powered USB devices or other information technology equipment as this can adversely affect the safety of the patient. ⚠ The supply current of this connection is limited to 100 mA. Do not connect USB mass storage devices such as USB powered hard disks, as this might result in data loss. Only USB-sticks are allowed.
[4]	On/Off push button:	This button is used to turn the device On or Off.
[5]	Power LED indicator:	Green: Device connected to mains supply. When a battery is present, it is charged. Orange: Device operating from battery
[6]	Display with Touch screen technology:	User Interface that allows the operator to control the device and change parameters of treatment protocols.
[7]	Central controller with light ring	Use this controller to scroll through the pages and to adjust the parameters. The light ring is illuminated when the controller is ready to use.
[8]	Connection for Electrode Cable Electrotherapy channel 1	Connection point for the patient cable for Channel 1.
[9]	Connection for Electrode Cable Electrotherapy channel 2	Connection point for the patient cable for Channel 2.
[10]	Multifunctional Connector for accessories Channel A	Connection point to connect accessories such as Ultrasound head or StatUS™ Pack 400 ⚠ 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 Ultrasound Applicators. 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.
[11]	Multifunctional Connector for accessories Channel B	

Numbered Part	Description	Purpose
[12]	Connections Vacuum Cables Electrotherapy channel 1	Connection point for the Vacuum Patient leads for Channel 1.
[13]	Connections Vacuum Cables Electrotherapy channel 2	Connection point for the Vacuum Patient leads for Channel 2.
[14]	Interconnection cable vacuum unit to main unit	Connection cable to connect the Vacuum unit with the main unit.
[15]	Upper hose nipple 	Air inlet for draining the Vacuum Tank. See instructions Vacuum Unit.

⚠

Connections **[8] [9] [12] [13]** are intended for the connection of type BF applied parts complying with the leakage current requirements of IEC 60601-1.

Connections **[10] [11]** are intended for the connection of type B applied parts complying with the leakage current requirements of IEC 60601-1.

4 Package contents

Device

The package contents depend on the device model ordered. The following models are available:

Part Number	Description
1498901	Sonopuls 490 with large ultrasound treatment head
1498902	Sonopuls 490 with small ultrasound treatment head
1498903	Sonopuls 490 with large and small ultrasound treatment head
1498911	Sonopuls 492 with large ultrasound treatment head
1498912	Sonopuls 492 with small ultrasound treatment head
1498913	Sonopuls 492 with large and small ultrasound treatment head
1498920	Endomed 482
1498950	Vacotron 460
1629902	StatUS™ Pack 400

Ultrasound treatment head

The ultrasound models can be supplied with one or two ultrasound treatment heads:

Part Number	Description
1630905	Ultrasound Head Large
1630915	Ultrasound Head Small

Standard accessories for 4-series

Part Number	Description
1498010	Device base (inclination support) (not for Vacotron 460)
3440001	Screwdriver
3444290	Power cord 250V/10A Europe 2.5 meter black
1498756	4-series Information Booklet
1498757	4-series Instructions for Use (CD-ROM)

Standard accessories ultrasound

Part Number	Description
0167154	Information sheet ultrasound gel
0167314	Information sheet Mounting US Head Holder(s)
1498011	Holder for Ultrasound Head 4-series - 1 for each ultrasound treatment head
3442929 (*)	Contact-gel, bottle 250 ml, 1x

(*) = The Sonopuls is delivered with 1 bottle of contact-gel. The article-number 3442929 however represents a box of 12 bottles.

Standard accessories electrotherapy

Part Number	Description
1460266	Moist pads for rubber electrodes 6x8 cm, set of 4 pcs.
3444020	Strap 100x3 cm
3444021	Strap 250x3 cm
2 x 3444129	Rubber electrodes 6x8 cm, 2 mm female, set of 2 pcs.
2 x 3444211	Patient cable 2-core & 2 mm male plugs - black, with coloured clips

Standard accessories vacuum

Part Number	Description
3444505	Sponges Ø 65 mm, set of 4 (for vacuum electrodes Ø 60 mm)
2 x 3444503	Vacuum electrodes Ø 60 mm, set of 2 pcs.
2 x 3444507	Vacuum lead hose red
2 x 3444508	Vacuum lead hose black

Optional accessories

Ultrasound contact-gel

Part Number	Description
3442929	Contact-gel, bottle 250 ml, box of 12
3442930	Contact-gel, bottle 850 ml, box of 12
3442931	Contact-gel, canister of 5 L
3442932	Dispenser-set for 5 L canister

Adhesive electrodes

Part Number	Description
3444222	Adhesive electrodes Ø 2.0 cm, 2 mm female, 10 sheets of 8 (also for EMG)
3444056	EN-Trode Ø 3.2 cm, 2 mm female, 10 sheets of 4
3444135	EN-Trode Ø 5.0 cm, 2 mm female, 10 sheets of 4
3444057	EN-Trode 5x5 cm, 2 mm female, 10 sheets of 4
3444058	EN-Trode 5x9 cm, 2 mm female, 10 sheets of 4

Rubber electrodes

Part Number	Description
3444128	Rubber electrodes 4x6 cm, 2 mm female, set of 2
3444129	Rubber electrodes 6x8 cm, 2 mm female, set of 2
3444130	Rubber electrodes 8x12 cm, 2 mm female, set of 2

Moist pads for rubber electrodes

Part Number	Description
1460273	Moist pads for rubber electrodes 4x6 cm, set of 4
1460266	Moist pads for rubber electrodes 6x8 cm, set of 4
1460275	Moist pads for rubber electrodes 8x12 cm, set of 4

Fixation straps

Part Number	Description
3444020	Strap 100x3 cm
3444021	Strap 250x3 cm
3444022	Strap 100x5 cm
3444023	Strap 250x5 cm

Point electrodes

Part Number	Description
3444180	Point Electrode (pen model), 5 mm Ø, 2 mm female, incl 10 conductive rubber caps

Adapters

Part Number	Description
2523524	Adapter plug, 2 mm female, 4 mm male, red
2523523	Adapter plug, 2 mm female, 4 mm male, black

Patient cable

Part Number	Description
3444211	Patient cable 2-core & 2 mm male plug - black, with colored clips

Remote control

Part Number	Description
1498800	Remote control 4-series

Bag

Part Number	Description
3444675	Carrierbag 4-series

Battery

Part Number	Description
2501016	Battery Pb 12 V, 2 Ah

Vacuum accessories Vacotron 460

Part Number	Description
3444509	Vacuum electrodes Ø 30 mm, set of 2
3444503	Vacuum electrodes Ø 60 mm, set of 2
3444504	Vacuum electrodes Ø 90 mm, set of 2
3444516	Sponges Ø 30 mm, set of 4 (for vacuum electrodes Ø 30 mm)
3444505	Sponges Ø 65 mm, set of 4 (for vacuum electrodes Ø 60 mm)
3444506	Sponges Ø 95 mm, set of 4 (for vacuum electrodes Ø 90 mm)
3444507	Vacuum lead hose, red
3444508	Vacuum lead hose, black

Stacking adapter

Part Number	Description
1498000	Stacking adapter for a combination with Sonopuls 492, StatUS™ Pack 400 and Vacotron 460

Ordering information

For the ordering information of the 4-series, standard accessories and optional accessories we refer to the website www.enraf-nonius.com.

5 Installation

Inspection

⚠ In case of damage from transport is noticed, contact your local distributor.
DO NOT USE the device!

Immediately upon unpacking the device, perform the following steps:

- Verify the delivery documents to make sure that the delivery is complete.
- Verify that the packaging contains all the items listed in the standard accessories list.
- Check the external components and accessories for possible damage due to transport.

System without a Vacotron

- Remove the 4-series device and any additional items ordered from the carton and inspect for damage that may have occurred during shipment.
- Place the device on a desk or EN-Car. Ensure that there is sufficient air flow below the device (do not place the device on a table-cover).
- If required, place the unit on the supplied inclination foot to improve display legibility.

System with a Vacotron

- Remove the vacuum 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. Ensure that there is sufficient air flow below the device (do not place the device on a table-cover).
- Remove the 4-series device and any additional items ordered from the carton and inspect for damage that may have occurred during shipment.
- Place the main device on top of the vacuum unit.
- Carefully lift the main device at the front and insert flat cable [17] into connector [18].

Connection to mains supply

⚠ Use of any other cable other than the supplied cable is strictly PROHIBITED as it affects patient safety and the proper function of the device.

⚠ Do not place the device in a location where the power cord could be tripped over or pulled out during treatment!

⚠ Do not attempt to use the device if it is not properly grounded. Make certain that the device is electrically grounded by connecting it only to a grounded electrical service receptacle conformable with the applicable national and local electrical codes regarding medical environments!

⚠ To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protected earth.

- Insert the mains cable into socket [1] and connect it to a wall socket.
- Set power line switch [1] to On (1)
- Power LED indicator [5] is lit green indicating that the device is connected to the mains supply.
- Turn on the device with push button [4]
- The device will initialize and perform a self-test. This may take a while.
- At the end of the self-test the device enters the Home menu and is ready for use.

Placing the optional battery

⚠ Do not interchange the black and red wires as this will damage your device!

⚠ The battery contains material that is noxious to the environment. Observe the local regulations when disposing of the battery!

⚠ Due to the high current demand of ultrasound applications, we recommend to explicitly use batteries supplied by Enraf-Nonius B.V. (part number 2501016).

- Remove the mains cable from the power line connector [1].
- Place the 4-series device upside down and on a soft surface.
- Remove the two screws from the battery cover using the supplied screwdriver.
- Slide and lift the battery cover.
- Align the battery on the bottom of the main unit with the polarity of battery terminals in the correct position. The polarity is marked at the bottom of the battery compartment.
- Locate the black wire and attach it to the – terminal of the battery.
- Locate the red wire and attach it to the + terminal of the battery.
- Slide the battery upside down into the battery compartment taking care that the wires do not get jammed.
- Place and slide the battery cover back into position.
- Secure the battery cover with the two screws using the supplied screwdriver.
- Place the device back on its feet.
- Reconnect the mains cable to the power line connector [1].

Operation from battery

- Leave power line switch [1] in the Off position (0) and turn on the device on using push button [4].
- Power LED indicator is lit orange, indicating that the device is operating from the battery.
- The charge status of the battery is indicated in the right hand top corner of the display.
- When you have finished the treatments, turn off the device using push button [4].

With the power line switch [1] to On (1), the battery is automatically charged, independent of the state of the on/off push button [4]. We recommend to use the apparatus from the powerline whenever possible. This will increase the service life of the battery.

Disconnection of mains supply

Systems without a battery

- When you have finished treatment, turn the device off by setting the power line switch [1] to Off (0). The device is now disconnected from the mains supply.

Systems with a battery

- Turn off the device with push button [4].
- Power indicator LED [5] is still lit green, indicating that the device is still connected to the mains supply and that the battery is being charged.
- Set power line switch [1] Off (0) to stop charging and to disconnect the unit from the mains supply.

6 Intended use and intended user

Electrotherapy

Electrotherapy is intended to be used for pain relief, and to treat muscle dysfunction.

Ultrasound therapy

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.

Combination therapy

Combination therapy is the combined application of ultrasound and electrical stimulation. With combination therapy the metal surface of the ultrasound treatment head 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.

Intended user

The 4-series device is intended to be used, and shall only be used, by or under the supervision of professional users in the field of physical therapy and rehabilitation, who understand the benefits and limitations of electrotherapy and ultrasound therapy.

7 Indications

The 4-series can be used for the below mentioned symptoms or medical conditions.

Electrotherapy

Pain Management

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

Muscle Stimulation

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Muscle re-education
- Maintaining or increasing range of motion

Ultrasound therapy

- 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.

Combination therapy

- Reduction of muscle spasm

8 Contraindications

The 4-series **MUST NOT** be used for the below mentioned symptoms or medical conditions.

Electrotherapy

All

- Pregnancy (do not apply anywhere over abdomen/pelvic region). Safety has not been established for the use of therapeutic electrical stimulation during pregnancy.

Pain management

- 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 trans cerebrally (through the head) must be avoided.
- Electrode placements that apply current trans thoracically (the introduction of electrical current into the heart may cause cardiac arrhythmias) must be avoided.

Muscle stimulation

- 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 sinus carotid region (anterior neck) must be avoided.
- Electrode placements that apply current trans cerebrally (through the head) must be avoided.
- Electrode placements that apply current trans thoracically (the introduction of electrical current into the heart may cause cardiac arrhythmias) must be avoided.

Ultrasound therapy

- 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 foetus
- The heart
- The brains
- The testicles
- The eyes
- Ultrasound should not be used on unconscious patients

*= Does not apply to LIPUS (Low Intensity Pulsed Ultrasound)

Combination therapy

The combined Contra-indications of ultrasound therapy and electrotherapy apply.

Precautions and warnings

Ultrasound therapy

- Precaution should be taken when using therapeutic ultrasound on patients with hemorrhagic diathesis.
- Ultrasound treatment presents a potential safety hazard in patients whose pain response has been decreased because of disease, previous surgery, ionizing radiation therapy, chemotherapy, general or regional anaesthesia. It could cause burns. Do not use on insensitive areas or in the presence of poor circulation.
- Large thermal doses could result in regions of thermal aseptic necrosis which could not be apparent on inspection of the skin.
- Always ensure proper hygiene (see chapter 14 for cleaning).
- Only apply the applicator on intact skin. When treating damaged skin (for example ulcers), only place the applicator on the edges of the wound, never on the wound itself.
- Dual Channel Ultrasound is intended for a single patient only.
- See also chapter 9 if the user manual, Precautionary Instructions, for general Warnings and Precautions.

Combination therapy

- Combination therapy is only allowed with a single ultrasound head connected.

Relevant hazards

Ultrasound therapy

- 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 thyroid, as well as lymph nodes in the neck, may expose the patient to as yet undetermined effects, in as much as the safety of such treatments has not yet been established.

Side effects

Electrotherapy

Common side effects reported during or after treatment are generally mild in nature. They may include but are not limited to:

- skin damage or irritation, for instance
    - local erythema
    - skin redness
    - tenderness/soreness
    - topical allergic reactions to the electrode gel
- worsening in condition such as
    - deterioration of symptoms
    - increase of pain
- systemic symptoms, such as
    - lightheadedness, dizziness nausea, vomiting,
    - headache, migraine, or neurological effects.
    - general malaise

Adverse events that are seldom seen are

- Burns
- Discomfort caused by electrotherapy treatment
- Etching beneath the electrodes

Ultrasound therapy

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

Combination Therapy

The combined adverse effects of ultrasound therapy and electro therapy apply.

9 Precautionary instructions

Warning!

If the use of this device may have caused or contributed to an undesirable event such as death or serious injury to the user, the manufacturer AND the competent authority of the Member State MUST be notified immediately!

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.

Keep yourself informed of the contra-indications.

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.

This device should be kept out of the reach of children.

This equipment is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide.

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

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.

It is recommended that the 4-series should not be used after extreme temperature fluctuations.

The device should not be used when any sort of mechanical damage is noticed.

Do not operate the unit in an environment of short-wave or micro-wave diathermy.

Caution!

Always determine the dosage based on the patient's perception of heat. Any sensation greater than mild warmth could cause a burn.

Do not operate the 4-series when connected to any unit other than Enraf-Nonius B.V. devices.

Do not use this device in so called "Wet Rooms" (hydrotherapy rooms).

This unit should be operated in temperatures between 10 °C and 40 °C (50 °F and 104 °F), with a Relative Humidity ranging from 10 - 90 % (non-condensing).

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.

Handle ultrasound treatment head with care. Inappropriate handling of the ultrasound treatment head may adversely affect its characteristics.

Inspect ultrasound treatment head for cracks and other mechanical defects which may allow the ingress of conductive fluid before each use.

10 General instructions

Ultrasound therapy

⚠ During treatment, the patient may not feel unpleasant sensations amounting to pain. A mild sensation of excitation is permissible.

⚠ If, as result of treatment, headache, vertigo, fatigue and/or other (autonomic nervous) reactions develop, subsequent treatment should be given at a lower intensity.

⚠ With continuous and pulsed ultrasound at high intensity a sensation of heat may be felt. Only a mild sensation of warmth is acceptable.

Before treatment

Please make sure you have read and understood the content of this manual before you start treatment.
Check the patient for any possible contra-indications.
Test the thermal sensitivity of the treatment area.
The skin of the area in question is cleaned (removal of grease) with soap or 70 % alcohol to permit optimal transmission of the ultrasound.

Starting treatment

Position the treatment head (do not forget to apply gel on the patient).
When adequate contact is made, the timer will start.
When the contact between the treatment head and the patient is not adequate, LED ring (contact control indicator) in the treatment head will turn on.

During treatment

The treatment head is kept in slow continuous motion, also for the semi-static method.
During treatment, the displayed ultrasound amplitude can vary around the set value, caused by fluctuations in acoustical coupling. The patient is regularly asked to report any sensations felt. If necessary, the treatment is modified;
The intensity can be reduced or a switch is made from continuous to pulsed ultrasound.
If there are indications of poor transfer of the ultrasound energy the contact medium can be reviewed if necessary, add more contact gel or spread it with the ultrasound treatment head.

Important!

In order to ensure efficient transfer of energy, a contact medium is required between the treatment head and the body. Air reflects virtually all of the ultrasound energy. The best medium for the transfer of ultrasound energy is a gel.

- For preference, use Enraf-Nonius Contact-Gel®, as this allows the excellent characteristics of the treatment heads to be used to their full advantage.
- The gel should be applied to the part of the body to be treated and then spread out with the treatment head.

Ending treatment

Treatment can be stopped by taking off the treatment head from the patient and setting the timer to zero. Treatment stops automatically when the treatment time has elapsed.

After treatment

The patient's skin and the ultrasound treatment head are cleaned with a towel or tissue.
The ultrasound treatment head must be cleaned as described in chapter 14.
The expected effects are checked (e.g. pain, circulation, and mobility).
The patient is asked to comment subsequently on any reactions that may occur.

Electrotherapy

⚠ During treatment, the patient may not feel unpleasant sensations amounting to pain. A mild sensation of excitation is permissible.

⚠ If, as result of treatment, headache, vertigo, fatigue and/or other (autonomic nervous) reactions develop, subsequent treatment should be given at a lower intensity.

Before treatment

Please make sure you have read and understood the content of this manual before you start treatment.
Check the patient for any possible contra-indications.
The skin of the area in question is cleaned (removal of grease) with soap or 70 % alcohol. Shaving hairy skin is recommended.
Test the sensitivity of the treatment area.
Position the electrodes and/or sponges (do not forget to moisten).

During treatment

Intensity is set at the desired level.
The patient is regularly asked to report any sensations felt. If necessary, the treatment is modified.

Ending treatment

Treatment can be stopped by pressing the stop icon on the touchscreen or setting the timer to zero.
Treatment stops automatically when the treatment time has elapsed.

After treatment

Remove the electrodes and/or sponges.
Clean the patient's skin with a towel or tissue.
The expected effects are checked (e.g. pain, circulation, and mobility).
The patient is asked to comment subsequently on any reactions that may occur.

11 Operation

Set up

Turn on the apparatus

Switch the unit ON via the push button [4].
The unit starts by executing the self-test.
At the end of the self-test a beep sound can be heard and the unit enters the Home menu and is ready for use.

Display screen

The display is organized as a spreadsheet of 4 sheets, one for each channel. The channels refer to the patient connector groups accessible at the front of the unit. A sheet can be selected by touching its tab. The tab shows important information, such as the output amplitude and the remaining treatment time. This information is continuously visible, also when the sheet is not selected.

[A] Device name.
[B] Navigation level. Shows where you reside in the navigation.
[C] Battery indicator (only visible when operating from the battery).
[D] Navigation bar. Provides screen dependent buttons for several functions. See paragraph *Navigation Bar* for details.
[E] Screen header. Shows the name of the screen, such as Manual Operation or the name of the selected Clinical Protocol.
[F] Parameters are indicated with icons. When a parameter is selected, its name appears here.
[G] Screen body. Shows the parameters of a selected channel or, when no channels are selected, the menu buttons.
[H] Channel tab. Used to select a channel and to display and adjust the output amplitude of that channel. See paragraph *Channel tab information* for details.

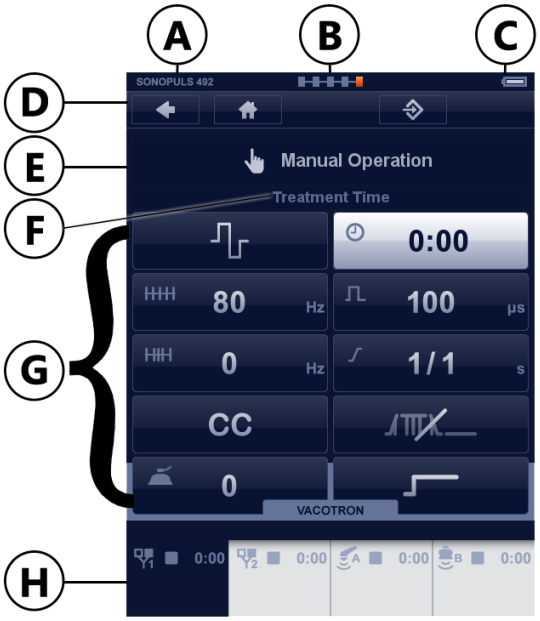


FIGURE 1

A selected sheet gives an overview of the parameters belonging to that channel. A parameter can be selected by touching it, which causes its colour to be changed into white and the light ring around the central controller [7] to be illuminated. The parameter can now be adjusted with the central controller [7]. The parameter can be closed by touching it again or by touching another parameter.
To adjust the output amplitude of a channel, touch the tab of the selected channel again. Its colour will change into orange. The output amplitude can now be adjusted with the central controller [7].
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 by touching the button to

navigate to the next screen. You can navigate back to the previous screen by touching the back arrow at the top of the screen. Anywhere in the navigation, you can jump back to the Home menu, by touching the home button.

Navigation bar

The following buttons can appear in the navigation bar [D].

Button	Meaning
	Back, return to previous screen.
	Home, return to Home screen.
	*Page number / number of pages* in multi-page menu screens or *treatment step number / number of treatment steps* in sequential protocols.
	System Settings.
	Store therapy settings or a programmed sequential protocol in a favorite.
	Delete favorite.
	Pause treatment. The output current decreases to 0 and the treatment timer suspends counting down.
	Start/Continue treatment. The output current increases to the previous value and the treatment timer resumes counting down.
	Accept the selected option.
	Stops treatment on all channels simultaneously.

Channel tab information

Channel Tab Illustration			[I] [J] [K] [L] [M]
[I]	Output Indicator		Standard electrodes
			Vacuum electrodes
			Ultrasound treatment head A
			Ultrasound treatment head B
			Combination Therapy
[J]	Channel Status		Channel stopped
			Channel paused
			Channel running
[K]	Remaining treatment time. When a sequential protocol has been loaded, the value indicates the total remaining treatment time of the sequential protocol.		

[L]	Output value
[M]	Unit of Output value: µA, mA, V, W, W/cm^2

Adjusting current amplitude
To adjust the output current, touch the tab of the selected channel. Its colour will change to orange, after which the current amplitude can be set with the central controller [7].
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 *Classical interferential* 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, touch the Start/Continue button in the navigation bar.

CC/CV mode
Depending on the selected current waveform, the electrotherapy channels can be used in the Constant Current (CC) or Constant Voltage (CV) 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.

Current polarity
When DC currents are used, the red connection is the positive connection and the black one the negative connection.
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.

Surge programs
Surge programs allow you to program sequential increases and decreases in current amplitude. See Figure 30 for details. Surge programs should not be confused with protocols:
- A single treatment step of a protocol could contain a surge program.

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. In this case, a delay time can be set between the start of the surge on channel 1 and channel 2.
A treatment with a Surge Program is started by first finding the desired current amplitude. During this time, the system pauses. When the current amplitude has been established, the treatment can be started by touching the Start/Continue button in the navigation bar.

Parameters:
See Figure 30 for details.

Ramp up time, expressed in seconds, defines the time in a surge program during which the current is increased from 0 to the adjusted level. See Figure 30 for details. The Ramp up time can be adjusted in increments of 0.1 second.

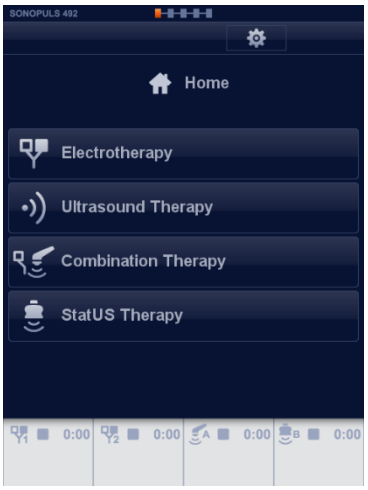
Hold time, expressed in seconds, defines the time in a surge program during which the current is kept at the adjusted level. See Figure 30 for details. The hold time can be adjusted in increments of 1 second.
Ramp down time, expressed in seconds, defines the time in a surge program during which the current is decreased from the adjusted level to 0. See Figure 30 for details. The ramp down time can be adjusted in increments of 0.1 second.
Interval time, expressed in s, defines the time in a surge program during which the current is kept at 0. See Figure 30 for details. The interval time can be adjusted in increments of 1 second.
Delay time, expressed in seconds, defines the time delay between the start of the surge program on channel 1 and channel 2. See Figure 30 for details. The delay time can be adjusted in increments of 0.1 second.
Beep, if enabled, generates a short beep at the start of each surge.

Navigation

Electrotherapy

Home

The Home menu gives access to all functions of the unit. Select the desired function or therapy by touching the button.
The next screen appears.

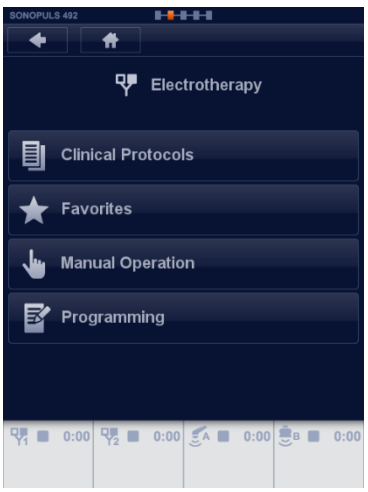


Electrotherapy “Clinical Protocols”

The electrotherapy menu gives access to functions

- Clinical Protocols
- Favorites
- Manual Operation
- Programming

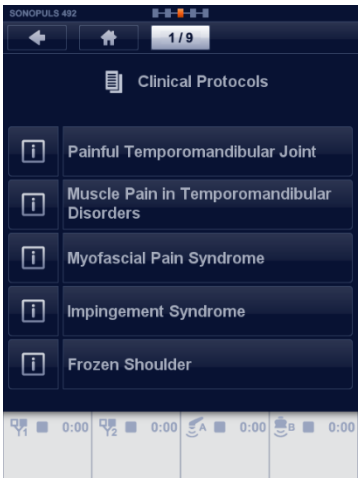
Select Clinical Protocols by touching the button.
The next screen appears.



Use the central controller to scroll through the list and select the clinical protocol by touching the button.

The channel selection screen appears.

For therapy information touch the info button on the left side of the protocol and the therapy info will appear.

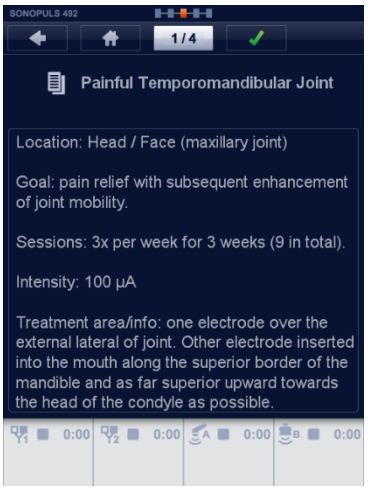


Therapy information

Use the central controller to scroll through the pages, in most cases the first page is text followed by one or more illustrations.

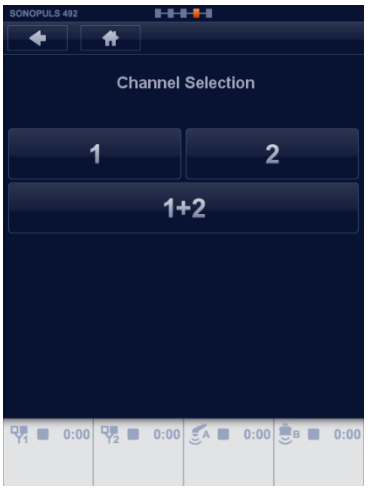
Touch the accept button ✓ in the navigation bar.

The channel selection screen appears.



Channel Selection

Here you can select the channels for electrotherapy.
When channel 1 is selected, channel 2 is still available for another therapy.
When Channel 1+2 is selected both channels have the same parameters. Only the intensity can be set differently.



Parameter screen (therapy screen)

In this screen, the user can adjust the intensity or change the parameter by touching the button and changing the value with the central controller.

If there is a vacuum unit available the user can set the vacuum settings direct from the menu.

Intensity setting

To set the intensity, touch sheet 1 (Channel 1).
Read-out change to orange colour and adjust with the central controller.

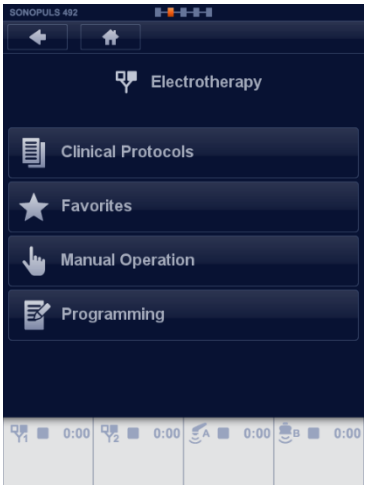
Timer starts count-down.

Electrotherapy "Manual Operation"

The electrotherapy menu gives access to functions

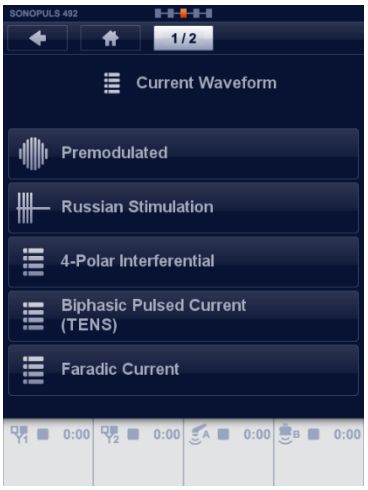
- Clinical Protocols
- Favorites
- Manual Operation
- Programming

Select Manual Operation by touching the button.
The next screen appears.



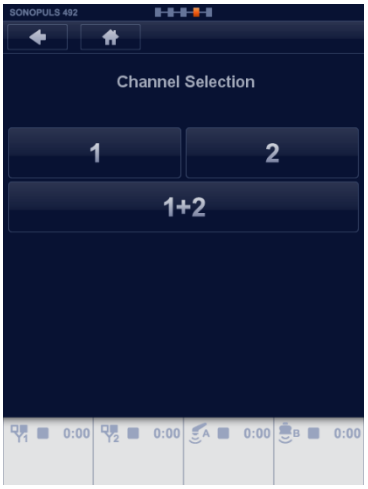
Select from the list a current waveform
Scroll to the next page with the central controller [7] or select the current waveform by touching the button.

Note: some of these selections are groups and in the next screen another list appears from which the current waveform can be selected.



Channel Selection

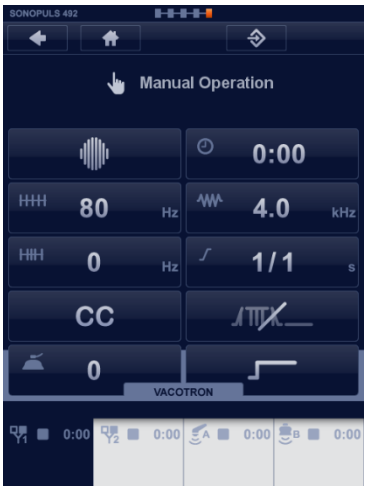
Here you can select the channels for electrotherapy.
When channel 1 is selected, channel 2 is still available for another therapy.
When Channel 1+2 is selected both channels have the same parameters. Only the intensity can be set differently.



Parameter screen

Adjust the parameters by touching the button and change the value with the central controller [7].

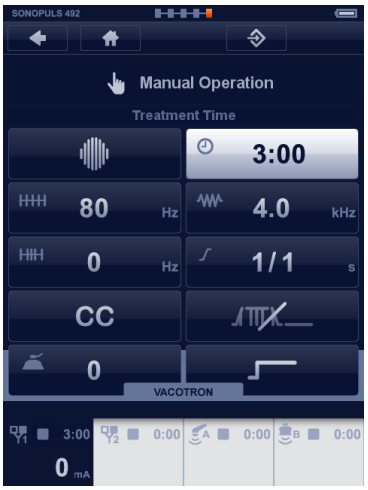
Note: some parameters are grouped and in the next screen the settings can be changed the same way as above.



Treatment time adjustment

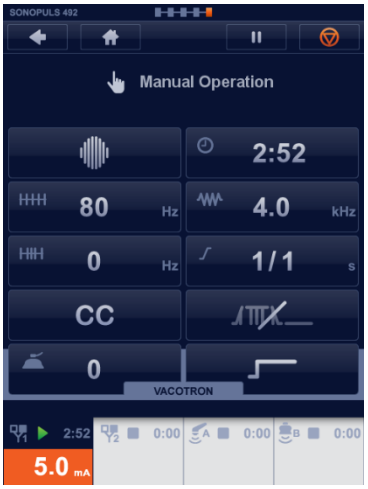
Touch the timer button, the colour changes into white and adjust the treatment time with the central controller [7].

Repeat this for all other parameters.



Start the therapy by adjusting the intensity with the central controller [7].

- To pause the treatment, touch the pause button in the navigation bar.
- To continue the treatment, touch the run button in the navigation bar.
- To Stop the treatment, touch the STOP button in the navigation bar.

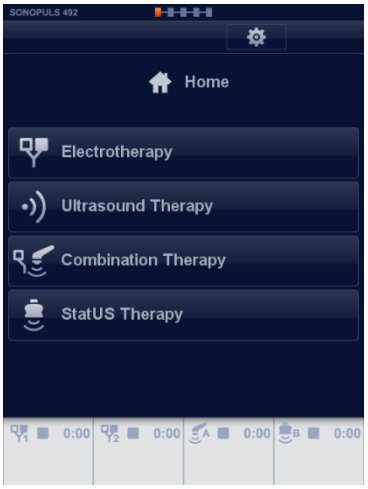


Ultrasound Therapy

The Home menu gives access to all functions of the unit.

Select in the Home menu ultrasound therapy by touching the button “Ultrasound Therapy”.

The next screen appears.

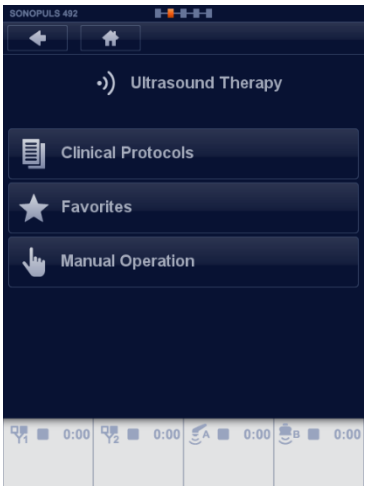


Ultrasound Therapy “Clinical Protocols”

The Ultrasound Therapy menu gives access to functions

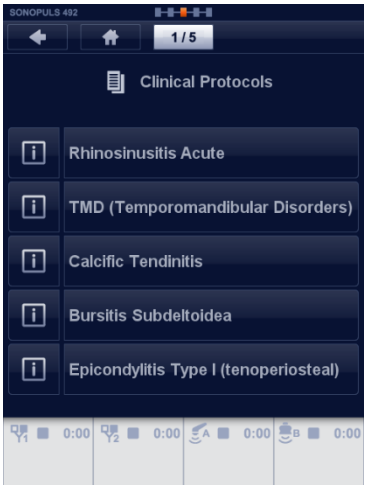
- Clinical Protocols
- Favorites
- Manual Operation

Select Clinical Protocols by touching the button.
The next screen appears.



Use the central controller to scroll through the list and select the clinical protocol by touching the button.

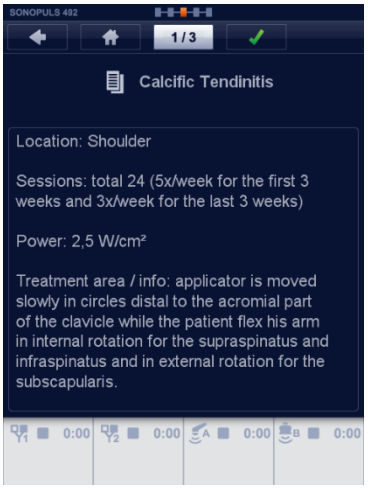
For therapy information touch the info button left of the protocol and the therapy info will appear.



Therapy information

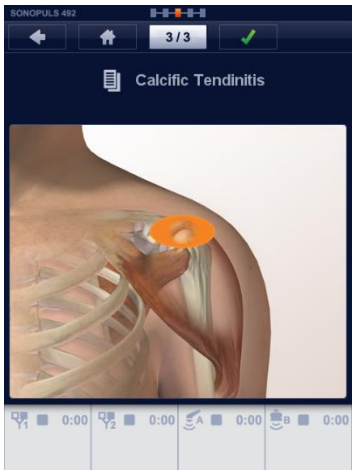
Use the central controller [7] to scroll through the pages, in most cases the first page is text followed by one or more illustrations.
Touch the accept button ✓ in the navigation bar.

The parameter screen appears.



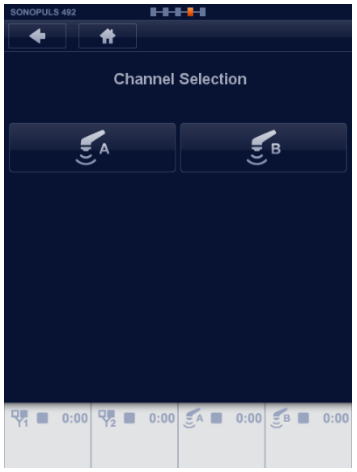
Touch the accept button ✓ in the navigation bar.

The parameter screen appears.



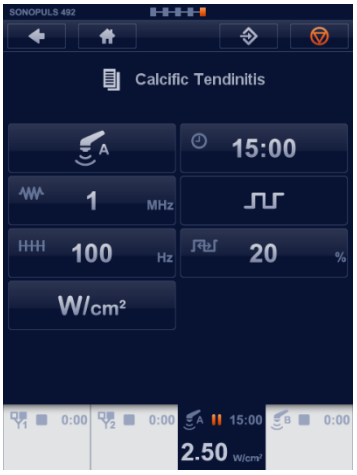
Channel Selection

Here you can select the channels for Ultrasound.
When channel A is selected, channel B is still available for another therapy. (Functionality may be limited if the dual channel mode is not activated.)



The count-down starts when there is sufficient contact between the applicator and the treatment surface.
Parameters can always be changed, before or during the treatment.

Note: the light ring on the ultrasound treatment head will turn off when sufficient contact is established.

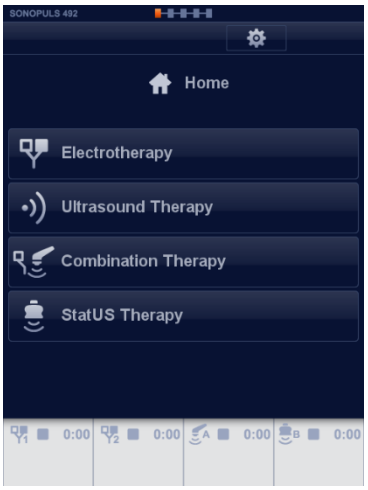


Combination Therapy

This therapy combines ultrasound and electrotherapy.

The Home menu gives access to all functions of the unit. Select in the Home menu combination therapy by touching the button “Combination Therapy”.

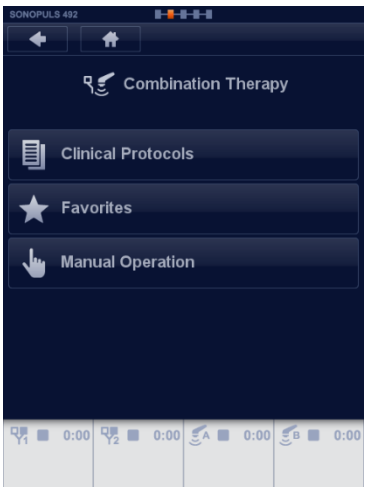
The next screen appears.



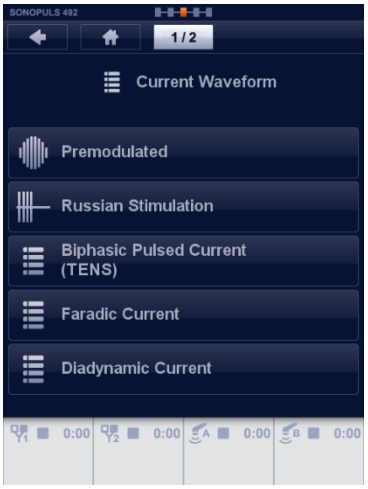
The Combination menu gives access to functions

- Clinical Protocols
- Favorites
- Manual Operation

Select Manual Operation by touching the button.
The next screen appears.

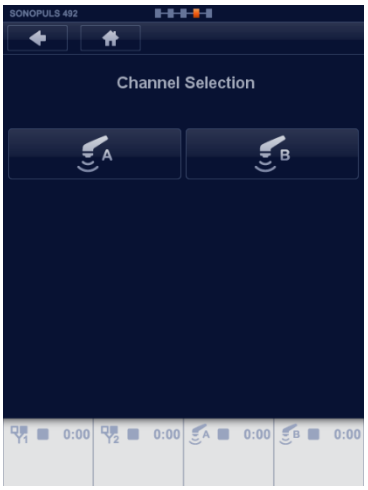


Select in this menu the current waveform by touching the button.

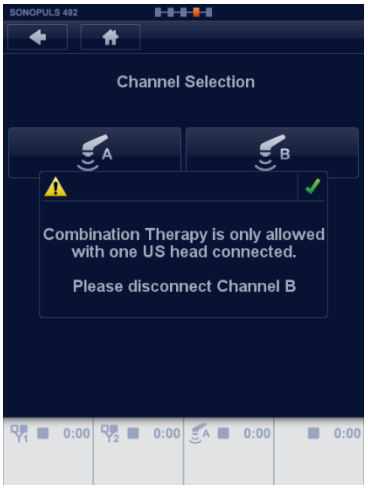


Channel Selection

Here you can select the channels for Ultrasound.

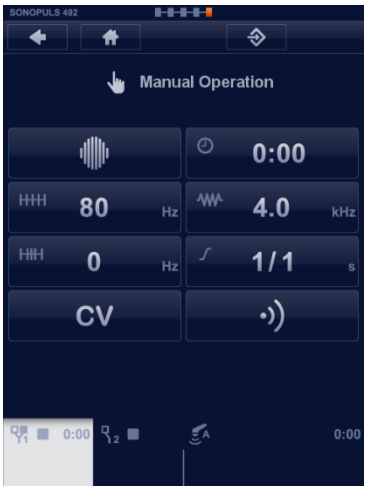


Note: A notification may appear if there are more than 1 Ultrasound treatment head connected. Follow the instructions of the notification.

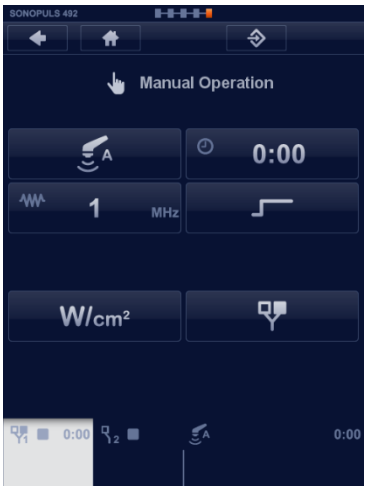


Adjust the current parameters and treatment time

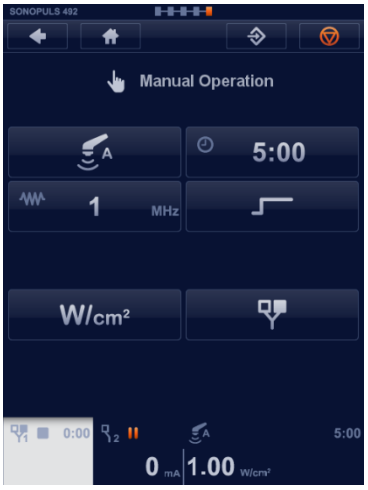
- Touch the parameter button and adjust with the central controller [7].



- Select the ultrasound button to adjust the ultrasound parameters.
- Touch the electrotherapy button to return to the previous electrotherapy screen.



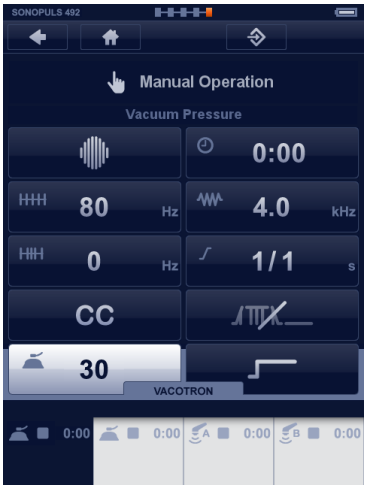
- Touch the ultrasound read-out and adjust the intensity with the central controller [7].
- Touch the current read-out channel 2 to adjust the current intensity. (Electrode and treatment head need to be in contact with the patient when in CC mode.)



Vacuum

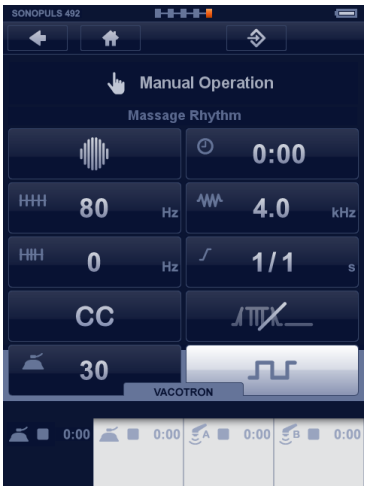
If a unit is equipped with a Vacotron it's possible to select either rubber electrodes or vacuum cups.

- Touch the – button and adjust the pressure using the central controller [7]. The vacuum cups are automatically selected when the pump starts to run.



Continuous – Pulsed mode

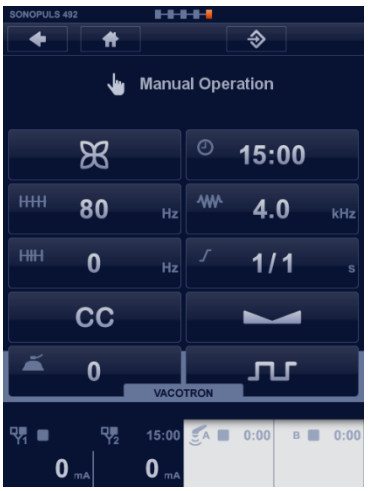
- Touch the – button and select the desired massage rhythm using the central controller [7]. You can choose between Continuous, Pulsed mode 1 s and Pulsed mode 2 s.



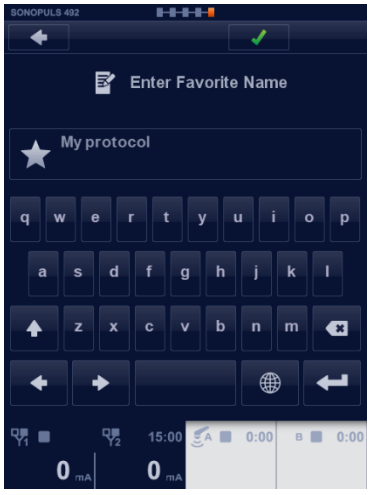
Storing Favorites

When a treatment screen is completely set as required, its settings can be stored in a Favorite for later use:

- As long as the treatment has not been started, a Store button is available on the navigation bar. To store your settings, touch the Store button in the Navigation bar.



- Enter the name of your Favorite using the keyboard.
- Touch ✓ to store your Favorite under the name just entered.



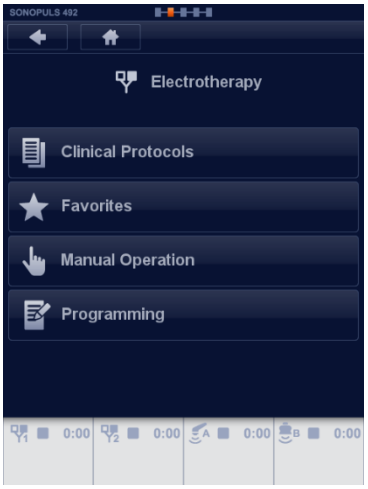
Note:

- Once saved, Favorites can be retrieved from the Electrotherapy, Ultrasound Therapy, and Combination Therapy menus.
- 4-polar treatments are automatically saved and loaded as a dual channel treatment.
- Vacuum settings are not saved.
- Stored Favorites can be sorted alphabetically (via the System Settings menu).

Programming a Sequential Protocol

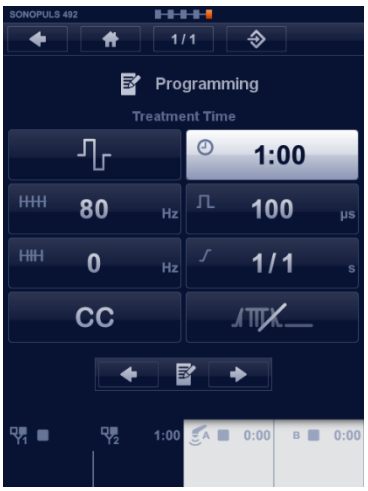
A sequential protocol consists of a series of treatment steps that are executed in a sequence until the end of the protocol is reached.

- Select Programming in the electrotherapy menu.



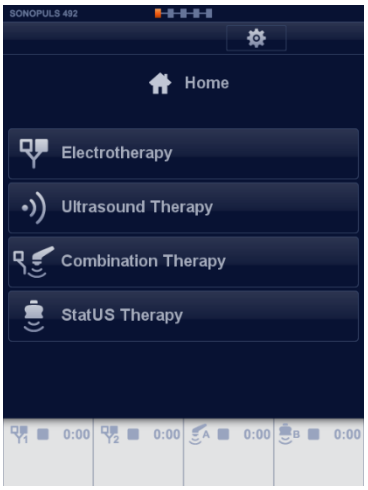
- When a treatment screen is completely set as required, touch the "next" button to add a next step.
- Continue with the remaining treatment steps until you have reached the end of your protocol.
- Touch the Store button in the navigation bar.
- Enter the name of your sequential protocol as described in paragraph *Storing Favorites*.

Sequential protocols are stored under the Favorite menu.

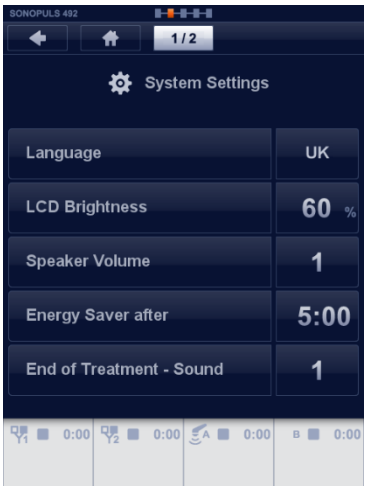


System Settings

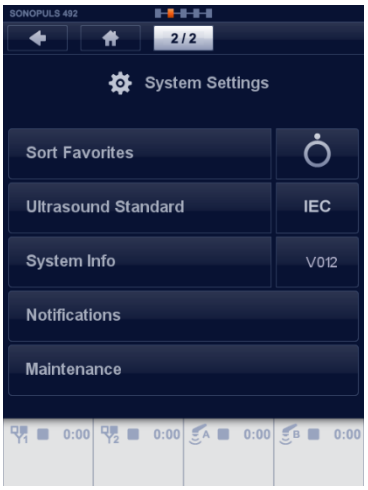
The Home menu gives access to all functions of the unit. Select in the Home Menu System Settings by touching the button "System Settings" in the navigation bar.



In this screen, you can personalize the unit. Several settings can be changed or adjusted. Touch the Back arrow in the navigation bar to return to the Home menu.



- Language, touch the language button and select the desired language using the central controller [7]. Touch the language button again or touch another button to confirm.
- LCD Brightness, here you can change the intensity of the backlight of the screen.
- Speaker volume can be adjusted in 5 levels.
- Energy Saver after, allows the user to select the duration until energy saving activities are enabled.
- End of Treatment – Sound, allows the user to select 5 different type of EOT sound each with 4 additional signal beeps.



- Sort Favorites, when enabled will automatically sort the Favorites alphabetically.
- Ultrasound Standard, determines the ERA calculation model (USA or IEC).
- System Info, the current installed system version
- Notifications, sub-menu where various notifications can be changed.
- Maintenance, sub-menu where maintenance routines can be accessed.

Shut down the device

Turn off the device as described in “Disconnection of mains supply”.

12 Application information

Before starting the treatment please make sure:

- You have read and understood the content of this manual.
- You strictly follow the WARNINGS and CAUTIONS mentioned under precautionary instructions.
- Check the patient for any possible contra-indications.

- 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.

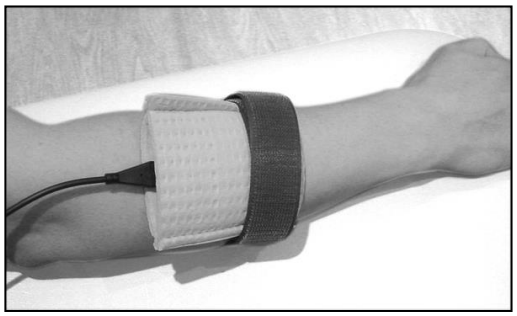
Electrotherapy

- Do not use electrodes on open wounds.

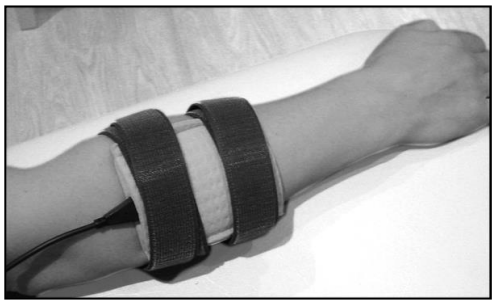
Flexible rubber electrodes

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. Preferred is to use a saline solution instead because of the improved 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 (close to dripping when lightly squeezed) during treatment, especially with DC currents. Remoisten when treatment exceeds 10 minutes. If the current display starts blinking, it is an indication of poor electrical contact.
- After use clean the sponge pads as described under “cleaning and disinfection”.

Vacuum electrodes
There is a choice of large and small electrodes. The areas of the electrodes correspond to those of the 4 x 6 cm and 6 x 8 cm 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 (close to dripping when lightly squeezed) during treatment. Remoisten when treatment exceeds 10 minutes. After use clean the sponge pads as described under *Cleaning and Disinfection*.

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.

Ultrasound therapy

Contact control
The ultrasound head has a contact control function that suspends treatment when the acoustical contact with the body drops below a certain level. The indicator light on the ultrasound head is turned on to signal this situation, the ultrasound channel status icon changes to pause and the treatment is resumed at the set Amplitude.
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 ultrasound head only partially contacts the body. When contact restoration is sensed the treatment is resumed at the set Amplitude.
Note: The contact control function does not work at Amplitudes below 0.2 W/cm^2.

The contact medium
⚠ Never apply the gel directly 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 (subaqual method). The water should be degassed (by previous boiling) in order to prevent air bubbles arising on the ultrasound applicator and the body.

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.

Vacuum

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

- See paragraph *Vacuum electrodes* for the application of the vacuum electrodes.
- When you use only one vacuum channel, close the other channel with one of the vacuum cables not in use.

Electrolytic effects

Electrolysis occurs under the electrodes when current types with a DC component are applied. Because the largest 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 electrode and the patient.

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. / cm^2, otherwise skin irritations or etching can occur. For current types that contain a DC component we recommend not to exceed a current density of 0.2 mA / cm^2.

To find the maximum recommended current amplitude in mA for the Interferential, Premodulated and Russian Stimulation current waveforms, multiply the electrode surface in cm^2 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 cm^2 the current density can never exceed 2 mA r.m.s. / cm^2. 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:

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

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.

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.

13 Description – Current waveforms and Ultrasound parameters

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, of which the following are available in the 4-series:

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 obtain the 100% modulation depth (fig 2). The current balance can also be used to compensate for differences in sensation occurring under the electrodes.

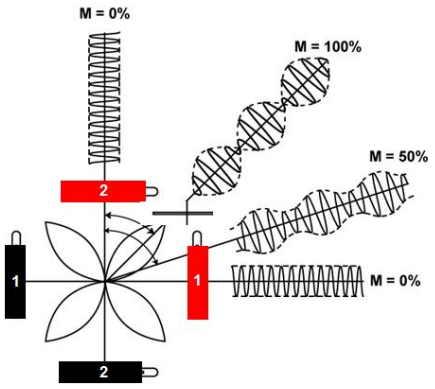


FIGURE 2
Modulation depth is only 100% at the diagonals.

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.

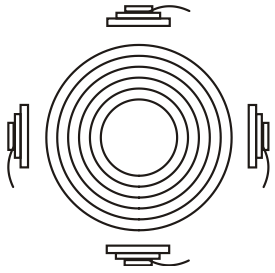


FIGURE 3
Modulation depth is 100% over the entire treatment area.

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.

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 360º. Amplitude modulation occurs in the equipment and the modulation depth is 100%.

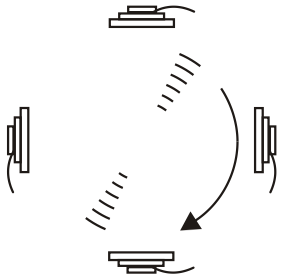


FIGURE 4
Stimulation with 100% modulation depth only occurs into the direction of the vector.

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

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 (figure 26-28).
- **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 seconds, defines the time elapsed during one revolution of the vector in automatic dipole vector mode.

Biphasic pulsed currents (TENS)

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 figure 6 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 (figure 7). 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 (figure 26-28).

Parameters:

- **Phase duration**, expressed in microseconds (µs), is the elapsed time from the beginning to the end of the initial pulse phase.
- **Pulse frequency**, expressed in Hz or pps (pulses per second), defines the repetition rate of the TENS pulses.
- **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.

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. 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 last 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 microseconds (µs), is the elapsed time from the beginning to the end of the initial pulse phase.
- **Pulse Frequency**, expressed in Hz or pps (pulses per second), defines the repetition rate of the TENS pulses.
- **Burst Frequency**, expressed in Hz, defines the repetition rate of bursts of pulses. A burst consists of a train of pulses. Each burst last 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.

Symmetrical

TENS current pulses can also be used for muscle stimulation applications. Often the symmetrical biphasic pulsed current waveform is used. 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 microseconds (µs), is the elapsed time from the beginning to the end of a pulse phase. The phase duration applies to each pulse phase.
- **Pulse Frequency**, expressed in Hz or pps (pulses per second), defines the repetition rate of the TENS pulses.
- **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.

- **Surge Program** can be used to adjust repeated sequences of contraction and rest periods.

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 Figure 12 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 last 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 microseconds (µs), is the elapsed time from the beginning to the end of the initial pulse phase.
- **Pulse Frequency**, expressed in Hz or pps (pulses per second), defines the repetition rate of the TENS pulses.
- **Burst Frequency**, expressed in Hz, defines the repetition rate of bursts of pulses. A burst consists of a train of pulses. Each burst last 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.

Premodulated

As with Interferential currents, a medium carrier frequency is used to pass the low frequency stimulation (beat) frequency through the skin. '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.
- **Surge Program** can be used to adjust repeated sequences of contraction and rest periods.

Russian stimulation

This current type is an intermittent alternating current with a carrier frequency around 2500 Hz. See Figure 6 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 largest 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 20 ms, 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 kHz, is the base frequency of the alternating current.
- **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 ms and the interval duration will be 20 * 5/6 = 16.7 ms.
- **Surge Program** can be used to adjust repeated sequences of contraction and rest periods.

Micro current

Micro Current is a monophasic rectangular waveform with manually selectable or alternating polarity. 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 per second.
- **Alternation mode** defines whether the polarity of the wave is automatically alternating or not.
- **Alternation Period**, 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. Surge programs are only available in the non-alternating mode.

High voltage

This current type has a twin peak monophasic waveform with a fixed duration of 64 µs 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 µs) 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.

- **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 40 – 80 Hz.
- **Modulation Program** defines the time and sequence in which the frequency will sweep through the Frequency modulation range.
- **Alternation Mode** defines whether the polarity of the pulses is automatically alternating or not.
- **Alternation Period**, expressed in seconds, defines the polarity reversal time in the alternating mode.
- **Surge Program** can be used to adjust repeated sequences of contraction and rest periods. Surge programs are only available in the non-alternating mode.

Diadynamic currents

⚠ Diadynamic currents are monophasic currents that produce electrolysis by-products. These by-products can result in etching beneath the electrodes. Always use properly moistened sponge / electrode combinations to absorb these by-products during treatment.

The Diadynamic currents were introduced by Bernard (*) and have won a significant position in the history of European physiotherapy. Diadynamic currents are mainly used for pain reduction and the improvement of blood circulation.
Bernard uses the term 'Diadynamic Current' to refer to a monophase (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.

(*) Bernard, Pierre D. La thérapie diadynamique, Paris, Editions 'Physio', 1962.

The following variations are available:

MF (Monophasé Fixe)
MF is a single phase rectified sinusoidal current with a frequency of 50 Hz. MF is a vibrating waveform that easily induces contractions.

DF (Diphasé Fixe)
DF is a dual phase rectified sinusoidal current with a frequency of 100 Hz. DF is usually experienced as a slight vibration. It is a pleasant waveform that is often used as an introduction to CP or LP.

LP (Longues Périodes)
LP 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. LP is smoother than CP.

CP (Courtes Périodes)
CP is a rapid alternation between one second of MF current and one second of DF current. CP has a strong resorbing effect.

CPid
CPid is identical to CP, except that the current amplitude during the MF phase is 12.5% lower than during the DF phase. 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. Surge programs are only available with MF and DF.

Galvanic current

Continuous galvanic current

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

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.

Interrupted galvanic current

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

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

Faradic current

Faradic rectangular or triangular pulsed current

⚠ Faradic currents are monophasic currents that produce electrolysis by-products. These by-products can result in etching beneath the electrodes. Always use properly moistened sponge / electrode combinations to absorb these by-products during treatment.

Faradic currents are often used for muscle stimulation applications that are based on prior diagnostics. 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 1000 milliseconds) 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.

Parameters:

- **Phase Duration**, expressed in milliseconds or seconds, is the elapsed time from the beginning to the end of the pulse phase.
- **Pulse Frequency**, expressed in Hz or pps (pulses per second), defines the repetition rate of the current pulses.
- **Surge Program** can be used to adjust repeated sequences of contraction and rest periods.

Träbert, 2 – 5 Current

⚠ Faradic currents are monophasic currents that produce electrolysis by-products. These by-products can result in etching beneath the electrodes. Always use properly moistened sponge / electrode combinations to absorb these by-products during treatment.

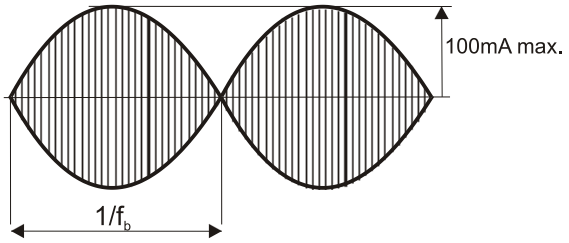
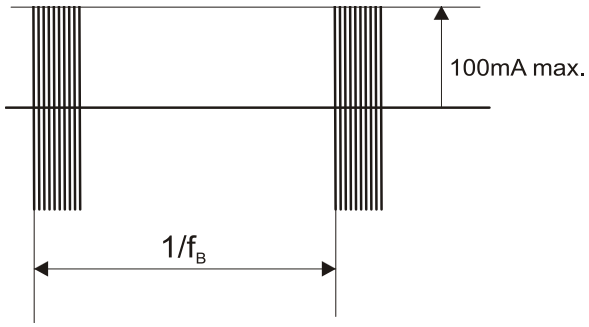
The 2-5 or 'Ultra-Reiz' current was introduced by Träbert (*). It is often used to treat headaches and neck pain. The 2-5 current is a faradic rectangular pulsed current with a phase duration of 2 milliseconds and a phase interval of 5 milliseconds. These settings are the default settings for the faradic 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 specialists have adopted the therapy and it is still applied with success.

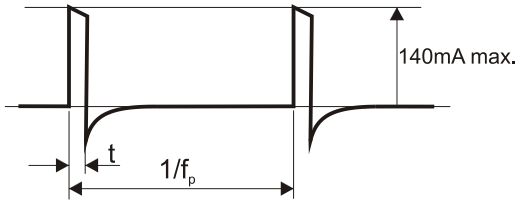
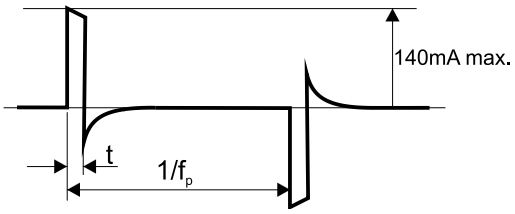
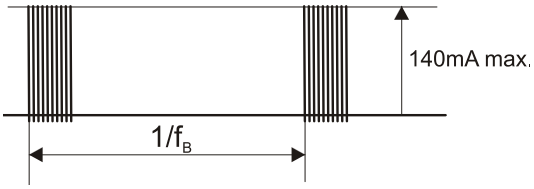
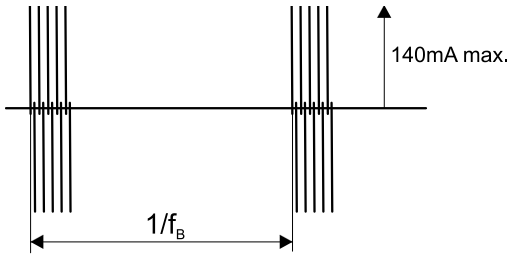
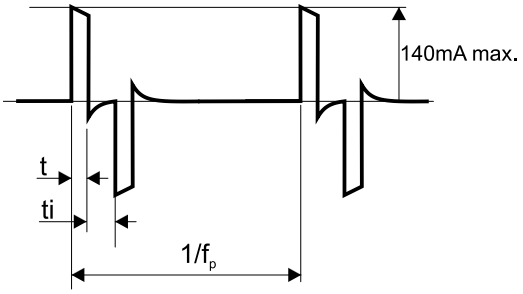
(*) Träbert, H. Ultra-Reizstrom, ein neues therapeutisches Phänomen, Elektromedizin 2, 1957 (7).

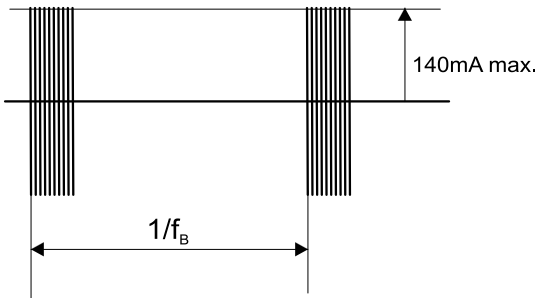
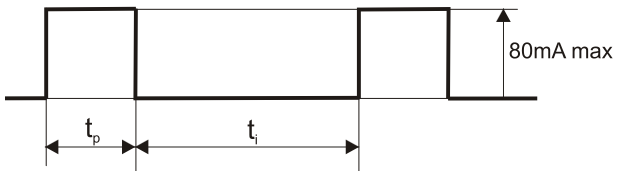
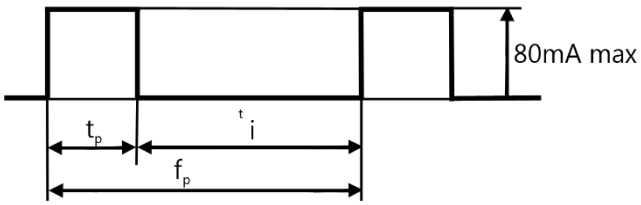
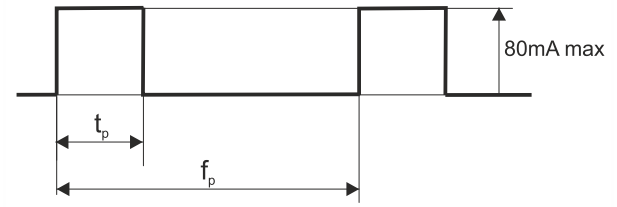
Parameters:

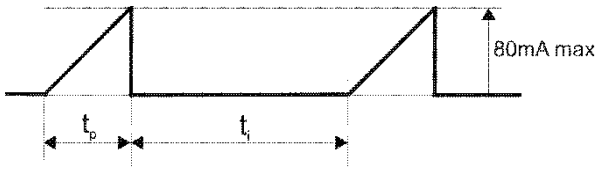
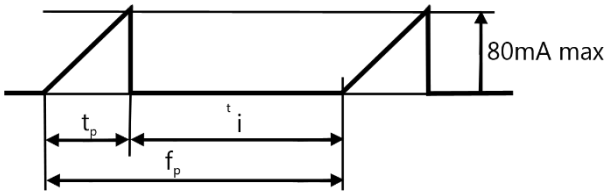
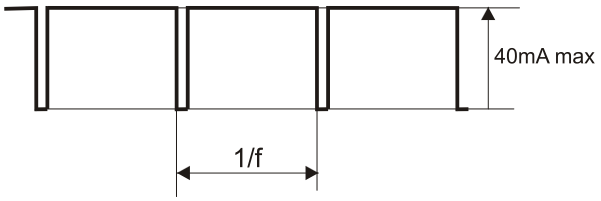
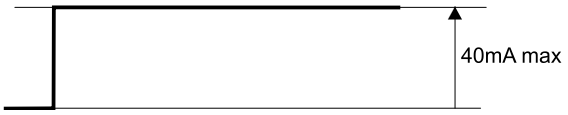
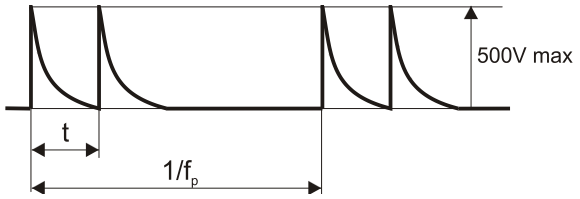
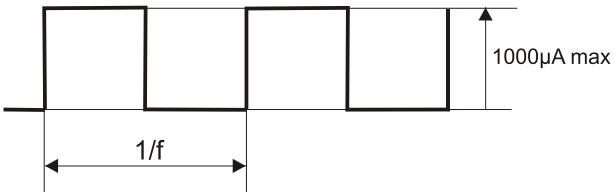
- **Phase Duration,** expressed in milliseconds or seconds, is the elapsed time from the beginning to the end of the pulse phase. The default setting is 2 milliseconds.
- **Phase Interval,** expressed in milliseconds or seconds, is the elapsed time between successive pulse phases. The default setting is 5 milliseconds.

Illustrations current waveforms

Premodulated / isoplanar vector / dipole vector  	**FIGURE 5** f_c Carrier frequency f_b Beat frequency
Russian stimulation  	**FIGURE 6** f_c Carrier frequency f_B Burst frequency

Biphasic pulsed current TENS	
Asymmetrical  	**FIGURE 7** t Phase duration f_p Pulse frequency
Asymmetrical alternating  	**FIGURE 8** t Phase duration f_p Pulse frequency
Burst asymmetrical  	**FIGURE 9** f_B Burst frequency
Burst asymmetrical alternating  	**FIGURE 10** f_B Burst frequency
Symmetrical  	**FIGURE 11** t Phase duration t_i Phase interval f_p Pulse frequency

Burst symmetrical  	**FIGURE 12** f_B Burst frequency
Faradic Current	
Träbert, 2 – 5 current  	**FIGURE 13** t_p Phase duration: 2 ms t_i Phase interval: 5 ms
Rectangular pulsed current (ms)  	**FIGURE 14** t_p Phase duration t_i Phase interval
Rectangular pulsed current (Hz)  	**FIGURE 15** t_p Phase duration f_p Pulse frequency

Triangular pulsed current (ms) 	**FIGURE 16** t_p Phase duration t_i Phase interval
Triangular pulsed current (Hz) 	**FIGURE 17** t_p Phase duration f_p Pulse frequency
Galvanic current	
Galvanic interrupted 	**FIGURE 18** f Carrier frequency - 8 kHz fixed Duty cycle - 90 % fixed
Galvanic continuous 	**FIGURE 19**
High voltage 	**FIGURE 20** t Peak interval - 64 µs fixed f_p Pulse frequency
Micro current 	**FIGURE 21** f Frequency

Diadynamic current

MF

FIGURE 22

DF

FIGURE 23

LP

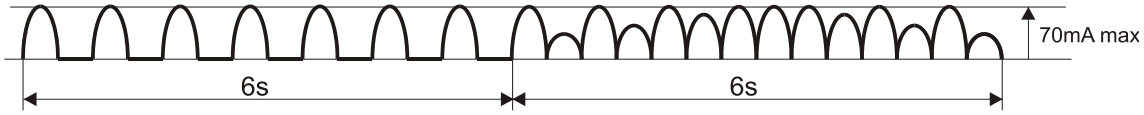


FIGURE 24

CP

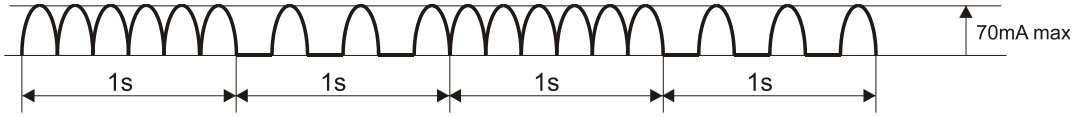


FIGURE 25

CPid

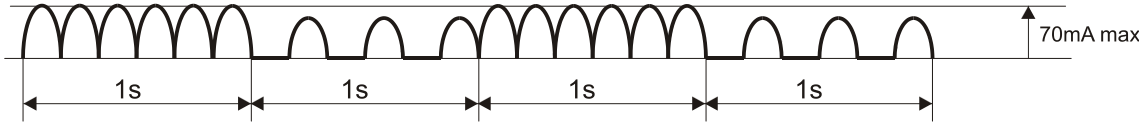


FIGURE 26

Modulation program

Modulation program 1/1

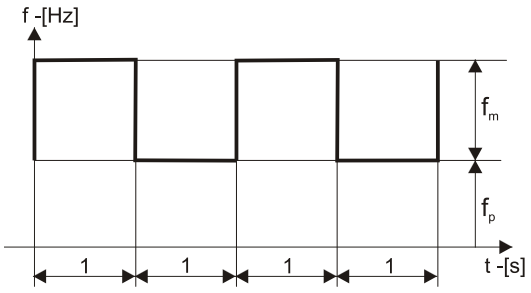


FIGURE 27

f_p Pulse frequency

f_m Frequency modulation

Modulation program 6/6 or 12/12

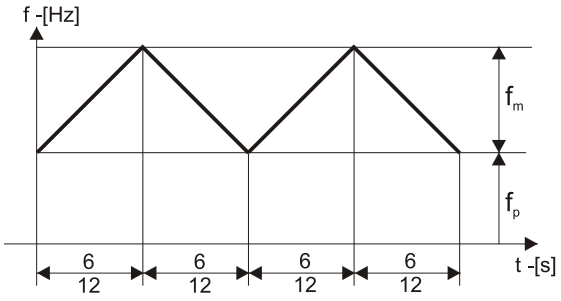


FIGURE 28

6:6 or 12:12

f_p Pulse frequency

f_m Frequency modulation

Modulation program 1/30

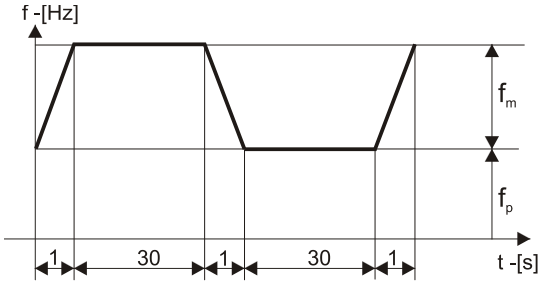


FIGURE 29

1:30

f_p Pulse frequency

f_m Frequency modulation

Surge program

Surge program parameters

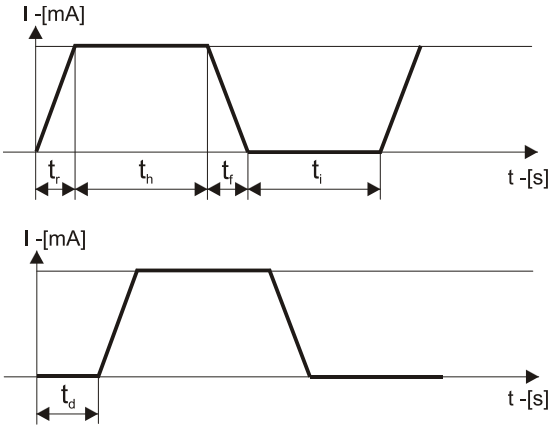


FIGURE 30

t_r Ramp up time

t_h Hold time

t_f Ramp down time

t_i Interval time

t_d Delay time

Current waveforms – Pain management

For pain management, the following current waveforms are recommended.

- 4-Polar Interferential Currents
- Biphasic Pulsed Currents (TENS)
- Premodulated
- Micro Current
- High Voltage
- Diadynamic Currents
- Galvanic Current
- Träbert, 2 – 5 Current

Current waveforms – Muscle stimulation

For muscle stimulation, the following current waveforms are recommended.

- Biphasic Pulsed Currents (TENS)
  - Asymmetrical and Alternating asymmetrical
  - Symmetrical
- Premodulated
- Russian Stimulation
- High Voltage
- Faradic Current
  - Faradic Rectangular or Triangular pulsed current

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.

Current waveforms – Combination therapy

Combination therapy is available with all current waveforms, but limited to channel 2.

Stimulator output parameters

Electrotherapy general

Channels	: 2
Output characteristics	: Constant Current (CC) or Constant Voltage (CV), except for High Voltage (CV) and Microcurrent (CC).
Current amplitude range	: Depending on current waveform
Current amplitude resolution	: 0.2 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, in steps of 1s
Hold time	: 0 – 60 s, in steps of 1 second
Ramp down time	: 0 – 9 s, in steps of 1s
Interval time	: 0 – 120 s, in steps of 1 second
Delay time	: 0.1 – 80 s, below 10s 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

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

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

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°)

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
Surge Program	: Yes
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
Surge Program	: Yes
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 – 400 µs in steps of 5 µs
Pulse Frequency	: 1 – 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 – 140 mA

Burst Symmetrical

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

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
Burst Frequency	: 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 cannot 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 cannot 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 s
Ramp up, ramp down	: 0.5 seconds
Amplitude	: 0 – 500 Volt in steps of 1 Volt

Micro Current

Frequency	: 0 – 1000 Hz
Polarity	: Positive or Negative
Surge Program	: Yes
Amplitude	: 10 µA – 1 mA in steps of 10 µA

Micro Current Alternating

Frequency	: 0 – 1000 Hz, 0 – 100 Hz in steps of 0.1 Hz, 10 – 100 Hz in steps of 1 Hz, 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 up, ramp down	: 0 seconds
Amplitude	: 10 µA – 1 mA in steps of 10 µA

Diadynamic current

Settings	: MF, DF, CP, LP and 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 (ms)

Phase Duration	: 0.02 – 1000 ms
Phase Interval	: 5 – 50 ms in steps of 5 ms, 50 – 100 in steps of 10 ms, 100 – 1000 ms in steps of 100 ms, 1 – 5 seconds in steps of 1 second
Surge Program	: Yes
Polarity	: Positive or Negative
Amplitude	: 0 – 80 mA

Faradic Triangular Pulsed Current (ms)

Phase Duration	: 0.1 – 1000 ms
Phase Interval	: 5 – 50 ms in steps of 5 ms, 50 – 100 in steps of 10 ms, 100 – 1000 ms in steps of 100 ms, 1 – 5 seconds in steps of 1 second
Surge program	: Yes
Polarity	: Positive or Negative
Amplitude	: 0 – 80 mA

Faradic Rectangular Pulsed Current (Hz)

Phase Duration	: 0.02 – 1000 ms
Pulse Frequency	: 0.2 – 1 Hz in steps of 0.1 Hz, 1 – 200 in steps of 1 Hz
Surge Program	: Yes
Polarity	: Positive or Negative
Amplitude	: 0 – 80 mA

Faradic Triangular Pulsed Current (Hz)

Phase Duration	: 0.1 – 1000 ms
Pulse Frequency	: 0.2 – 1 Hz in steps of 0.1 Hz, 1 – 200 in steps of 1 Hz
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

Ultrasound 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.

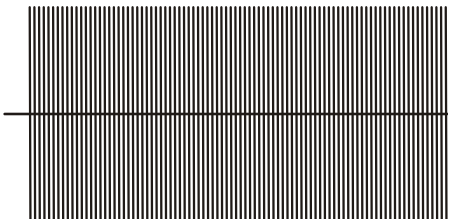
Duty Cycle, expressed in %, defines the ratio of the pulse duration to the pulse repetition time. Ultrasound can be applied in pulsed or in continuous mode. When the Duty Cycle is set to 100%, the apparatus operates in continuous mode.

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.

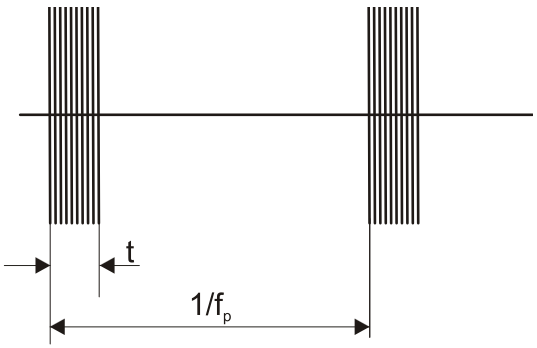
Ultrasound Power is the ultrasound output expressed in W. The ultrasound output display can be toggled between W and W/cm^2. In pulsed mode the power during the pulse is displayed. The time averaged power can be obtained by multiplying this value with the Duty Cycle.

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 by the Duty Cycle.

Continuous ultrasound



Pulsed ultrasound



Explanation of symbols:

	f	Ultrasonic radiation with an acoustic working frequency of 1 or 3 MHz
	f_p	Pulse repetition rate
	dc	Duty cycle
	t	Pulse duration

Ultrasound parameters:

f	Acoustic working frequency: 1MHz or 3MHz
f_p	Pulse repetition rate: 16, 48 and 100 Hz
dc	Duty cycle: 5 – 80 %
t	Pulse duration: 0.5 – 8 ms, set by duty cycle
RTPA	20 – 1.25

Amplitude modulation	Duty cycle	Pulse duration	RTPA	Amplitude modulation	Duty cycle	Pulse duration	RTPA
16Hz	5%	3.1ms	20	48Hz	50%	10.4ms	2
16Hz	10%	6.3ms	10	48Hz	80%	16.7ms	1.25
16Hz	20%	12.5ms	5	48Hz	100%*	20.8ms	1
16Hz	33%	20.6ms	3	100Hz	5%	0.5ms	20
16Hz	50%	31.3ms	2	100Hz	10%	1ms	10
16Hz	80%	50ms	1.25	100Hz	20%	2ms	5
16Hz	100%*	62.5ms	1	100Hz	33%	3.3ms	3.33
48Hz	5%	1ms	20	100Hz	50%	5ms	2
48Hz	10%	2.1ms	10	100Hz	80%	8ms	1.25
48Hz	20%	4.2ms	5	100Hz	100%*	10ms	1
48Hz	33%	6.9ms	3.33				

* = continuous mode

Generator

Peak output Amplitude:

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

Peak output power for 5 cm^2 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 cm^2 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 : 16, 48 and 100 Hz ± 1 %
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 ± 5 % (set by duty cycle)

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

Ref Label		5 cm^2 Applicator	0.8 cm^2 Applicator
FREQ	Ultrasound frequency 1 MHz: 3 MHz:	 0.98 MHz ± 5 % 3.1 MHz ± 5 %	 0.98 MHz ± 5 % 3.1 MHz ± 5 %
ERA_{IEC} ERA_{USA}	ERA (Effective Radiation Area) IEC 60601-2-5 21 CFR 1050.10	 3.2 cm^2 ± 20% 5 cm^2 ± 20%	 0.6 cm^2 ± 20% 0.8 cm^2 ± 20%
TYPE	Beam type 1 MHz: 3 MHz:	 Collimating Collimating	 Collimating Diverging
BNR	BNR (Beam Non-Uniformity Ratio)	6:1 maximum	6:1 maximum
	Side radiation	10 mW/cm^2 maximum	10 mW/cm^2 maximum

Description of ultrasound area

The spatial distribution of the radiated field is a collimated beam (diverging for the 0.8 cm^2 applicator at 3 MHz) of ultrasound energy, with a decreasing Amplitude at increasing distance from the applicator surface. This field distribution applies to 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 can be set under *System Settings* and depends on the ultrasound standard used:

- International: IEC 60601-2-5
- 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 Maintenance and troubleshooting

Cleaning and disinfection

- Before performing any user maintenance, switch off the device and disconnect the plug from the mains supply.
- 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.
- Use no liquid detergents, these can damage the device.
- Do not allow any liquids to penetrate the device or its accessories while cleaning and disinfecting!
- Dry all sockets and connectors that have become wet before any further use!
- Check the applicator and cable regularly for damage.

Device	To clean the unit, turn it off and unplug the power supply. Clean the unit with a damp cloth. Do not use abrasive cleaners.
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.
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.
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 colour to be stained, but this does not affect the operation of the electrodes. Between patient uses, the sponge pads should be washed in running tap water, thoroughly drained, and then dried. Damaged sponge pads should be replaced.
Patient cable	Clean the patient cable with a damp cloth. 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.
Vacuum 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.
Vacuum cables	Clean the vacuum cable with a damp cloth. Do not use an alcohol solution. Check the cable regularly for damages and/or bad electrical contact. We advise, keeping a spare vacuum cable in stock.

Cleaning the water reservoir and hoses

- Detach the vacuum cups from the vacuum cables.
- Place a container filled with a cleaning liquid (*) below the system.
- Place the peripheral ends of the cables in the container.
- Go to System Settings and select Tank Cleaning.
- The water reservoir will be filled with the cleaning liquid until the water reservoir is full.
- Empty the water reservoir as described below (*water reservoir full*).

(*) 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%.

Troubleshooting

⚠ When the device 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.

Errors and warnings indicate an internal problem with the device that must be tested by a field service technician certified by Enraf-Nonius B.V. before any further operation or use of the system. Use of a device that indicates an error or warning may pose a risk of injury to the patient, user, or extensive internal damage to the system. In case of display failure or other obvious defects, unplug the device immediately and notify a certified service technician.

Patient circuit interrupted

There is insufficient or no output current available at the outputs. Possible causes:

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

Battery low

The battery is insufficiently charged to complete the treatment at the currently set therapy levels. Reduce the therapy levels or connect the apparatus to the mains supply.

Water reservoir full

The water separation tank of the Vacotron is full. Continue the treatment with the standard electrodes or empty the tank as follows:

- Set power line switch [1] Off (0).
- Detach the hose from the upper hose nipple [15] and empty the reservoir.
- Reattach the hose to the hose nipple.
- Set power line switch [1] On (1).

Vacuum leak
There probably is a leak in the vacuum system. This error is usually preceded by a continuously running pump trying to reach the set vacuum. To protect the system, the pump is automatically stopped after a certain amount of time. Inspect the vacuum cables and electrodes, set the vacuum back to zero and try again. If the failure persists, stop using the device and contact your supplier.

Ultrasound applicator error
The ultrasound applicator has reported an error. Disconnect the device, wait some time and reconnect it. If the error persists, stop using the device and contact your supplier.

Insufficient DC supply
This problem can sometimes occur with the small ultrasound applicator when operating from the battery. If possible, continue the treatment with reduced therapy levels or connect the apparatus to the mains supply.

Device needs to cool down before you can proceed
The temperature of the device is too high to start treatment. Remove the device from any potential heat sources (such as direct sunlight) and let the device cool down. Restart the device to continue.

Possible risk of skin irritation
This notification is shown when operating a waveform that contains a DC component. Operator should proceed with caution.

The intensity you have set is above the recommended maximum
When increasing the dosage of a StatUS device above the recommended maximum of 1.5W/cm^2 this notification is shown. Operator should proceed with caution.

StatUS applicator error
The StatUS applicator has reported an error. Disconnect the device, wait some time and reconnect it. If the error persists, stop using the device and contact your supplier.

The modulation is OFF. Higher risk of cavitation and/or hotspots
This notification is shown when operating a StatUS with modulations turned off. Turning off the modulation increases the risk of cavitation and / or hotspots. Operator should proceed with caution.

Battery empty. Use power cord
The battery has been completely drained and operation of the device is disabled. Please connect the power cord and charge the battery. Restart the device when connected to mains power to continue operation.

Combination Therapy is only allowed with one US head connected
The notification will be shown when there is more than 1 ultrasound head connected to the device. Combination therapy is only allowed with a single ultrasound head connected. Disconnect the inactive ultrasound head to continue.

Combination therapy is not allowed with StatUS
The notification will be shown when there is a StatUS applicator connected to the device. Combination therapy is not allowed with a StatUS applicator connected. Disconnect the StatUS applicator to continue.

Intended use of dual channel ultrasound therapy is for one patient only
This notification is shown when activating the Dual Channel functionality of the device. The purpose is to remind the operator that the intended us of Dual Channel Ultrasound is for a single patient only.

Favorite is in use on a channel. Please restart the device and try again
This notification is shown when trying to delete a favorite that is currently loaded on one of the channels. Restart the device to clear the loaded favorite or load a different waveform on the blocking channel.

Permitted channels are in use, to free up channel stop active treatment
This notification is shown when trying to use a therapy when all the available channels are already in use. Stop the active treatment by pressing the STOP icon or set the Timer to 0:00 on the blocking channel.

Connected applicator(s) incompatible with chosen therapy. Please connect compatible applicator
This notification is shown when trying to use a therapy when an incompatible applicator is connected. Please disconnect and connect a suitable connector and try again.

Firmware update are not allowed when running on battery. Please connect to mains power
This notification is shown when trying to use upgrade the Firmware of the device while operating on battery power. Firmware upgrades are only allowed when operating on mains power.

Maintenance

Optimize contact control ultrasound applicator
When you experience difficulties with the contact control function of the ultrasound applicator you can try to resolve the problem as follows:

- Ensure that the surface of the ultrasound applicator is clean and dry.
- Place the ultrasound treatment head in the holder.
- Go to System Settings -> Maintenance and select Optimize Applicator A or B.
- Touch the OK-button when the operation is complete.

Back-up and restore favorites
When you have programmed and stored several Favorites, you might want to make a back-up on an external storage device. To store your favorites, proceed as follows:

- Attach a USB-stick to the remote-control connection [3]. Read and obey the warnings and cautions.
- Go to Systems Settings -> Maintenance and select Back-up Favorites.
- If an error occurs during the back-up operation, i.e. USB-stick full, this will be displayed in a pop-up message.
- Touch the OK-button when the operation is complete.
- Detach the USB-stick

To restore your favorites

- Attach the USB-stick containing your Favorites to the remote-control connection [3]. Read and obey the warnings and cautions.
- Go to Systems Settings -> Maintenance and select Restore Favorites.
- If an error occurs during the restore operation, i.e. no favorites found, this will be displayed in a pop-up message.
- Touch the OK-button when the operation is complete.
- Detach the USB-stick

Technical maintenance

⚠ Electrical safety of the device relies on a properly 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.

⚠ 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.

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 qualified technical personnel to repair those parts of the equipment which are designated by the manufacturer as repairable.

All other technical maintenance is restricted to authorized Enraf-Nonius maintenance personnel. Authorized service personnel can make use of 1498770 Service manual 4-series.

Firmware update

If your system requires a Firmware Update, contact your supplier to obtain a USB-stick containing the latest firmware version. Your current firmware version can be viewed under System Settings. To update your firmware, proceed as follows:

- Attach the USB-stick containing the firmware to the remote-control connection [3]. Read and obey the warnings and cautions.
- Go to Systems Settings -> Maintenance and select Update Firmware.
- If an error occurs during the update operation, i.e. no firmware found, this will be displayed in a pop-up message.
- Touch the OK-button when the operation is complete.
- Detach the USB-stick

Expected service lifetime

This device will remain suitable for its intended use as long as it is subjected to yearly maintenance by a qualified service engineer as described in the service manual.
The service engineer will decide whether the device is suitable for use according to the specifications.

End of life

Your 4-series contains materials which can be recycled and/or are noxious for the environment.

Please ensure that you are well informed of the local rules and regulations regarding the removal of equipment and accessories.

15 Specifications

Technical data

Mains voltage:	100 - 240 Volt
Frequency:	50/60 Hz
Max. power input:	100 VA
Patient leakage current:	typically, 1 µA
idem single fault condition:	typically, 2 µA
IP classification	Device: IPX0 Ultrasound head: IPX7
Mode of operation	Continuous operation

Main Unit

Dimensions stand alone	24 x 32 x 12 cm (w x d x h)
Dimensions on inclination foot	24 x 30.5 x 18.2 cm (w x d x h)
Dimensions on Vacotron	24 x 30.5 x 21.6 cm (w x d x h)
Weight	2 kg
Weight including optional battery	3 kg

Vacotron

Dimensions	24 x 28.6 x 9.3 cm (w x d x h)
Weight	2 kg
Vacuum	continuous and pulsed, 0 – 800 mbar, continuously adjustable
Pulsed Vacuum	pulse : pause = 0.5 : 0.5 seconds, 1 : 1 second

Technical modifications reserved

Safety and performance standards

Medical device classification	IIa This equipment complies with all requirements of the Medical Device Directive (93/42/EEC).
Safety class according to IEC 60601-1	I
Applied parts	 Type B applied part (ultrasound applicator)
	 Type BF applied part (electrodes)

Environmental conditions

Environmental conditions for transport and storage

Environmental temperature:	–20° to +70° C
Relative humidity:	10 to 90% (non-condensing)
Atmospheric pressure:	500 to 1060 hPa

Environmental conditions normal use

Environmental temperature:	10° to 40° C
Relative humidity:	10 to 90 % (non-condensing)
Atmospheric pressure:	800 to 1060 hPa

EMC details

⚠ Medical electrical devices such as the 4-series are subject to special precautions with regard to electromagnetic compatibility (EMC) and must be installed and commissioned in accordance with the EMC advice given in the instructions for use.

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the 4-series, including cables specified by the manufacturer. Otherwise degradation of the performance of this equipment could result.

⚠ The 4-series should only be operated with the original power cable specified in the list of contents delivered. Operating the device with any other power cable can lead to increased emissions or reduced interference immunity of the device.

⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The 4-series are classified as a Group 1, Class B devices according to CISPR 11.

The 4-series devices meet the immunity levels for home healthcare environment and professional healthcare facility environment.

The 4-series devices have been tested according to the EN 60601-1-2:2015 standard by an accredited lab and found to be compliant for each emissions and immunity standard or test.

16 Contact

For assistance, please visit our website http://www.enraf-nonius.com

The latest version (in electronic or printed format) of this Instructions for Use can be obtained free of charge from our website www.enraf-nonius.com or by contacting distributor or by calling the telephone number: +31-(0)10-2030600.

The Instructions for Use will be sent (free of charge) to you within 7 (seven) calendar days.

17 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 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.

Enraf-Nonius B.V.
Vareseweg 127 | 3047 AT | Rotterdam | The Netherlands
Tel: +31 (0)10-20 30 600 | info@enraf-nonius.nl

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www.enraf-nonius.com