User Manual

400 series

gymna®

User Manual 400-Series

Devices for electrotherapy, ultrasound therapy, combination therapy and laser therapy with GTS2

	Electro therapy	Ultrasound therapy	Combination therapy	Laser therapy	Vacuum (optional)
Combi 400	x	x	x	x	x
Duo 400	x				x
Pulson 400		x			

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Symbols on the equipment

Attention, read the manual

Points to laser aperture and shows direction of beam

Manufacturer

Abbreviations

AQ	Accomodation Quotient
CC	Constant Current
CO	Combination therapy
CP	Courte Période
CV	Constant Voltage
DF	Diphasé Fixe
EL	Electrode
EMC	Electromagnetic Compatibility
ESD	Electrostatic Discharge
ET	Electrotherapy
HAC	Hospital Antiseptic Concentrate
LA	Laser therapy
LP	Longue Période
MF	Medium Frequency: with unidirectional and interferential currents Monophasé Fixe: with diadynamic currents
MTP	Myofascial Trigger Point
NMES	Neuro Muscular Electro Stimulation
TENS	Transcutaneous Electrical Nerve Stimulation
US	Ultrasound
VAS	Visual Analogue Scale

Â, Î A circumflex on a symbol indicates a peak value

Symbols in the manual

Warning or important information.

TABLE OF CONTENTS

1 SAFETY

1.1 Purpose

The 400-Series is intended solely for medical applications. A trained professional can use the 400-Series for electro therapy, ultrasound therapy, combination therapy and laser therapy. The device is suited for continuous use.

1.2 Safety instructions

1.2.1 General

- Only qualified people who are trained in the application of the therapies may use the appliance.
- Only a technician authorised by GymnaUniphy N.V. may open the equipment or the accessories.
- Follow the instructions and directions in these user instructions.
- Place the equipment on a horizontal and stable base.
- Keep the ventilation openings at the bottom and rear of the equipment free.
- Do not place any objects on the equipment.
- Do not place the equipment in the sun or above a heat source.
- Do not use the equipment in a damp area.
- Do not let any liquid flow into the equipment.
- Do not disinfect or sterilise the equipment. Clean the equipment with a dry or moistened cloth. *See §5.2.1*.
- The Council directive 93/42/EEC concerning medical devices, requires medical devices to be safe. Therefore it is necessary to perform each year a technical safety inspection. *See §5.1.3*.
- For optimum treatment, a patient investigation must first be performed. On the basis of the findings of the investigation, a treatment plan with objectives will be formulated. Follow the treatment plan during the therapy. This will limit possible risks, related to the treatment, to a minimum.
- Always keep these user instructions with the equipment.

1.2.2 Electrical safety

- Only use the equipment in an area with facilities that meet the applicable legal regulations.
- Connect the equipment to an outlet with an earth terminal. The outlet must meet the locally applicable requirements for medical areas. The device is Class II with a functional earth for EMC purposes

1.2.3 Prevention of explosion

- Do not use the equipment in an area where combustible gases or vapours are present.
- Switch off the equipment when it is not used.

1.2.4 Electro Magnetic Compatibility

- Medical electrical equipment requires special precautions for Electro Magnetic Compatibility (EMC). Follow the instructions for the installation of the equipment. *See §2.*
- Do not use mobile telephones or other radio, shortwave, or microwave equipment in the vicinity of the equipment. This kind of equipment can cause disturbances.
- Only use the accessories that are specified by GymnaUniphy. *See §7*.
  Other accessories can lead to an increased emission or a reduced immunity.

1.2.5 *Electro therapy*

- Do not use the equipment simultaneously with high frequency surgical equipment. This combination can cause burning of the skin under the electrodes.
- Patients with electrical implants (e.g. a pacemaker) may only be treated after obtaining specialist medical opinion.
- Do not use adhesive electrodes with currents that have a galvanic component, such as galvanic, diadynamic, MF rectangular, pulsed rectangular and triangular currents. With these currents, etching of the skin can occur.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Check the electrode cables and the electrodes at least once a month. Check whether the insulation is still intact.
- Check the conductivity of rubber electrodes at least once a a week. *See §4.10.4.*
- The safety standards for electrical stimulation advise not to exceed the current density of 2.0 mA_{rms}/cm^2. However, with iontophoresis treatments, we advise a maximum current density of 0.25 mÂ/cm^2, because of using the MF rectangular current. Exceeding this value can result in skin irritation and burns.
- Always use sterilised gauze with iontophoresis treatments.

1.2.6 *Ultrasound therapy*

- Move the US head evenly over the skin during the treatment. This prevents internal burns.
- The US treatment heads are exchangeable. The device detects the characteristics and supplies the right power at the right frequency.
- Handle the US heads carefully. With rough handling, the characteristics can change. Test the US head if it falls on the ground or knocks against something. See *§5.1.2*.
- Check the US head at least once a month. During the check, look for dents, cracks and other damage that could allow liquids to ingress. Check whether the insulation of the cable is still intact. Check whether all pins are present and straight in the connectors. Replace the US head if the head, the cable or the connector is damaged. See *§5.1*.

1.2.7 Laser therapy

The laser is a class 3B laser product which emits invisible infrared light.

- Make sure the laser warning sign is clearly visible outside the entrance to the therapy room.
- The radiation of a laser probe can cause a physiological effect.
- Use the laser therapy only for therapeutic purposes.
- Use of controls or adjustments or performance of procedures other then those specified in this manual may result in hazardous radiation exposure.
- Start a laser therapy only when all persons in the room wear laser goggles for eye protection. If you do not obey this warning, you can cause blindness. Use goggles with at least the characteristics: I 100 - 1000 L2 and with a clear view of the control, the display and the signal lights. *See §7.5*.
- Do not look into the laser beam during a laser therapy.
- Do not point the laser beam into eyes.
- Do not use the laser near flammable materials or liquids.
- Do not use the equipment if any damage shows.
- Regulary check the output of the laser probe with the test facility. *See §4.10.8*.
- Check the laser probe at least once a month. During the check, look for dents, cracks and other damage. Check whether the insulation of the cable is still intact. Check whether all pins are present and straight in the connectors. Replace the laser probe if the laser, the cable or the connector is damaged. *See §5.1*.
- Place the laser probe in the holder when the laser is not used.
- Lock the laser function when the laser therapy is not used.

1.2.8 Vacuum accessories

- Check the electrode cables and the electrodes at least once a month. Check whether the insulation is still intact. See *§5.1*
- Always use slightly salinated demineralized water to moisturize the vacuum sponges to prevent lime deposits in the watertank, hoses, cups and sponges.
- Use only moisten sponges. Too dry sponges can cause burning of the skin under the electrodes.
- Do not use vacuum electrodes with DC currents. The DC currents cause damage to the vacuum cups by ionization.

1.3 Contraindications

1.3.1 Electro therapy

General

- High fever
- Severe cardiovascular problems
- Psychological problems
- Cancer with tumor metastasis
- Generalised tuberculosis

Specific absolute

- On demand pacemakers

Specific relative for monophasic pulses

- Skin lesions
- Skin infections
- Thrombosis, thrombophlebitis
- Varices
- Increased risk to haemorrhage
- Superficially implanted materials
- Heart disease, rhythm disorder
- Decreased sensibility
- Locat. near sinus caroticus
- Menses
- Pregnancy

Specific for relative biphasic pulses
- Skin infections
- Thrombosis, thrombophlebitis
- Heart disease, rhythm disorder
- Decreased sensibility
- Locat. near sinus caroticus
- Pregnancy

1.3.2 Ultrasound therapy

General
- High fever
- Severe cardiovascular problems
- Psychological problems
- Cancer with tumor metastasis
- Generalised tuberculosis

Specific relative for pulsing ultrasound
- Pacemaker
- Pregnancy

Specific relative for continuous ultrasound
- Infections
- Acute inflammations
- Thrombosis, thrombophlebitis
- Varices
- Increased risk to haemorrhage
- Pacemaker
- Epiphyseal disc (children)
- Decreased sensibility
- Menses
- Cement of endoprosthesis
- Diabetes mellitus

1.3.3 Combination therapy

See contraindications *§1.3.1 Electro therapy, page 13* and *§1.3.2 Ultrasound therapy, page 14*.

1.3.4 Laser therapy

General

- High fever
- Severe cardiovascular problems
- Psychological problems
- Cancer with tumor metastasis
- Generalised tuberculosis

Specific absolute

- Looking into the laser beam
- Thyroid gland (local applications)
- Increased connective tissue production
- Hypertrophic scars
- Pregnancy
- Photo-allergy

1.4 Directives

1.4.1 Medical Devices Directive

The device complies with the essential requirements of the Council directive 93/42/EEC concerning medical devices (MDD) as most recently changed.
The device contains no human or animal tissue, no medical substances, and no blood or blood products from human or animal origin.

1.4.2 Directive on waste electrical and electronic equipment

The device complies with the requirements of directive 2002/96/EC of the European parliament and of the council on waste electrical and electronic equipment (WEEE) as most recently changed.

1.5 Liability

The manufacturer cannot be held liable for injury to the therapist, the patient or third parties, or for damage to or by the equipment used, if for example:

- an incorrect diagnosis is made;
- the equipment or the accessories are used incorrectly;
- the user instructions are wrongly interpreted or ignored;
- the equipment is badly maintained;
- maintenance or repairs are performed by people or organisations that are not authorised to do so by GymnaUniphy.

Neither the manufacturer nor the local GymnaUniphy dealer can be held liable, in any way whatsoever, for the transfer of infections via the vaginal, anal and rectal probes and/or other accessories.

2 INSTALLATION

2.1 Receipt

1. Check whether the equipment has been damaged during transport.
2. Check whether the accessories are intact and complete. *See §7.*
   - Inform your supplier of any damage or defects by no later than within 3 working days after receipt. Report the damage by telephone, fax, e-mail or letter.
   - Do not use the equipment if it is damaged or defective.

2.2 Placing and connection

1. Place the equipment on a horizontal and stable base.
   - Keep the ventilation openings at the bottom and rear of the equipment free.
   - Do not place the equipment in the sun or above a heat source.
   - Do not use the equipment in a wet area.
2. Check whether the mains voltage that is stated on the rear of the equipment corresponds with the voltage of your mains supply. The equipment is suited for a nominal mains voltage from 100 V to 240 VAC / 50-60 Hz.
3. Connect the device to an outlet with an earth terminal.

2.3 Place the Vaco 400 option

The Vaco 400 is designed to be placed underneath a 400-Series device. See *§3.5*.

1. Connect the 5-pin connection cable (4).
2. Connect the 6-pin connection cable (5).

2.4 Use in combination with another device

The Vaco 400 can only be used in combination with:

- The Combi 400
- The Duo 400

2.5 Performing the functional test

1. Switch the equipment on with the switch at the rear of the equipment.
2. When the equipment is switched on, it automatically performs a test.
3. If the display does not light up: *See §6.1.1.*

2.6 Setting language, time and preferences

1. Press ⊘ on the home screen. The System settings menu appears. *See §4.10.1*.
2. Select **Touch panel calibration**.
3. Press **Start** and follow the instructions on the screen.
4. Select **Language** and select the language with which the read-out must work.
5. Select **Date & Time**.
6. Select **Day**.
7. Set the day with ◀ and ▶.
8. Repeat steps 6 and 7 for the Month, Year, Hour, Minutes and Seconds

2.7 Transport and storage

Take account of the following matters if the equipment has to be transported or stored:

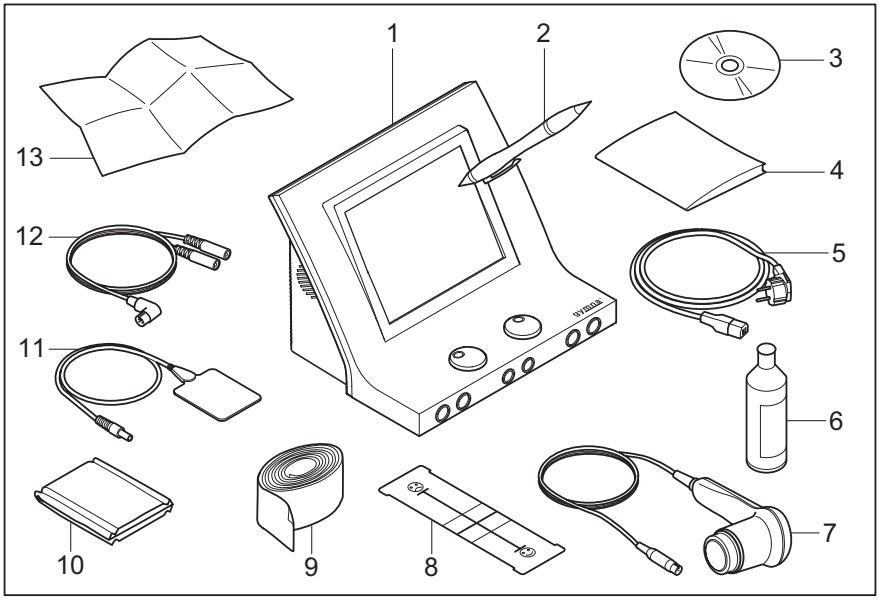
- Transport or store the equipment in the original packaging.
- The maximum period for transport or storage is: 15 weeks.
- Temperature: -20 °C to +60 °C.
- Relative humidity: 10% to 100%.
- Atmospheric pressure: 200 hPa to 1060 hPa.

2.8 Reselling

This medical equipment must be traceable. The equipment, the US head and some other accessories have a unique serial number. Provide the dealer with the name and address of the new owner.

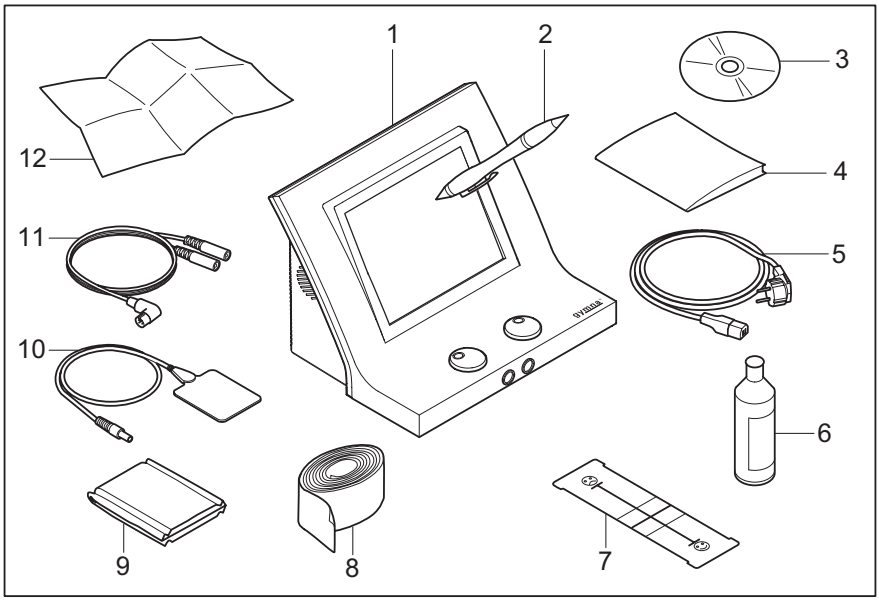
3 DESCRIPTION OF THE EQUIPMENT

3.1 Combi 400 with standard accessories



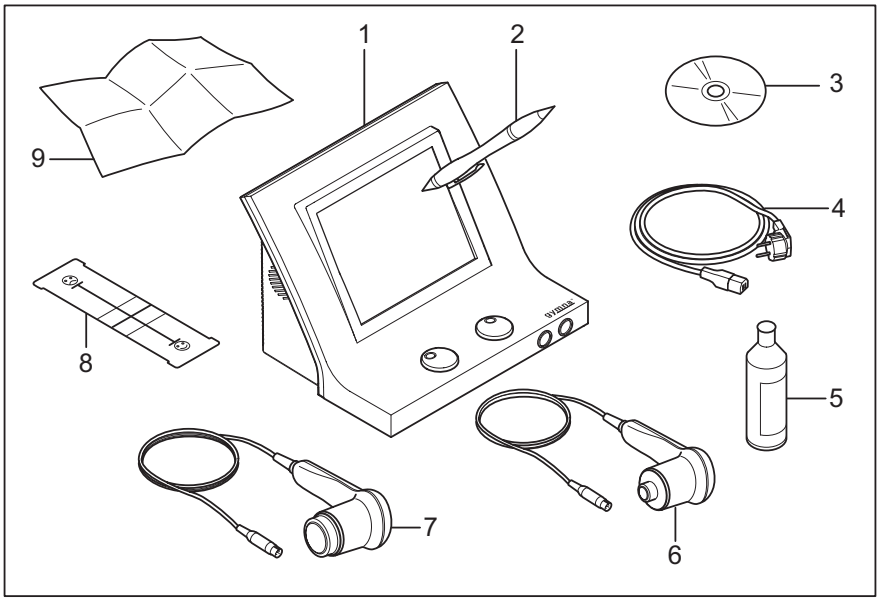
1. Combi 400. *See §3.5.*
2. Touchscreen pen
3. CD-ROM User manual
4. Safety instructions
5. Power cord
6. Contact gel
7. US head large incl. holder
8. VAS score card
9. Elastic fixation straps (4 pieces)
10. EL sponges for rubber electrode (4 pieces)
11. Rubber electrodes (4 pieces)
12. Two-ply electrode cable (2 pieces)
13. Quickstart guide

3.2 Duo 400 with standard accessories



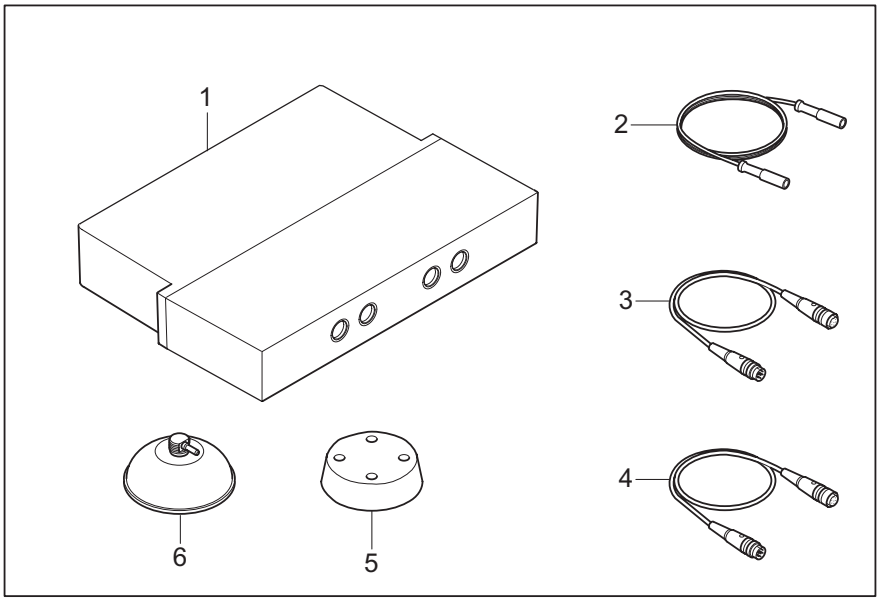
1. Duo 400. *See §3.5.*
2. Touchscreen pen
3. CD-ROM User manual
4. Safety instructions
5. Power cord
6. Contact gel
7. VAS score card
8. Elastic fixation straps (4 pieces)
9. EL sponges for rubber electrode (4 pieces)
10. Rubber electrodes (4 pieces)
11. Two-ply electrode cable (2 pieces)
12. Quickstart guide

3.3 Pulson 400 with standard accessories



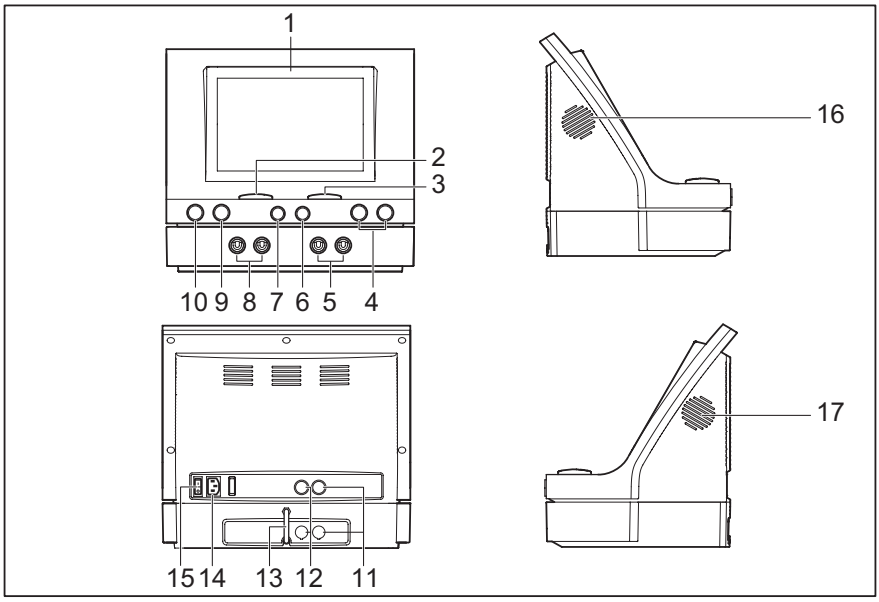
1. Pulson 400. *See §3.5.*
2. Touchscreen pen
3. CD-ROM User manual
4. Power cord
5. Contact gel
6. US head small with holder
7. US head large with holder
8. VAS score card
9. Safety instructions
10. Quickstart guide

3.4 Vaco 400 with standard accessories



1. Vaco 400 vacuum unit
2. Vacuum hose light grey (2 pieces)
3. Vacuum hose dark grey (2 pieces)
4. Connection cable; 1 x 5 pin and 1 x 6 pin
5. Sponge for vacuum electrode (4 pieces)
6. Vacuum electrode (4 pieces)

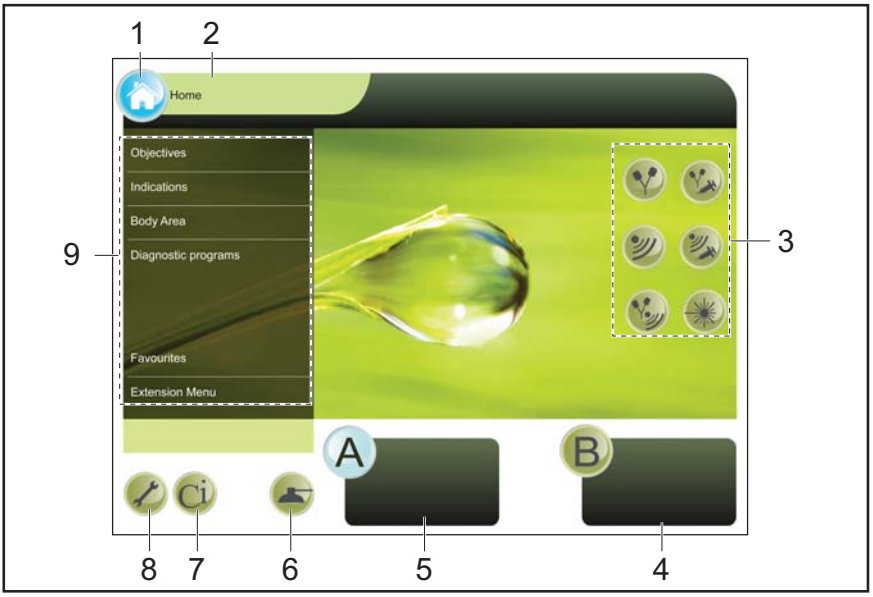
3.5 Components of 400-Series



1. Display. *See §3.6.*
2. Intensity of channel A
3. Intensity of channel B
4. Connectors for US head
5. Vacuum electrode, channel B
6. Connector for electro therapy, channel B
7. Connector for electro therapy, channel A
8. Vacuum electrode, channel A
9. Laser test eye
10. Connector for laser probe
11. Power and communication cable between main unit and Vaco 400 option
12. Electro therapy cable between main unit and Vaco 400 option
13. Water drain hose
14. Connection to mains supply
15. On/off switch
16. Fan
17. Speaker

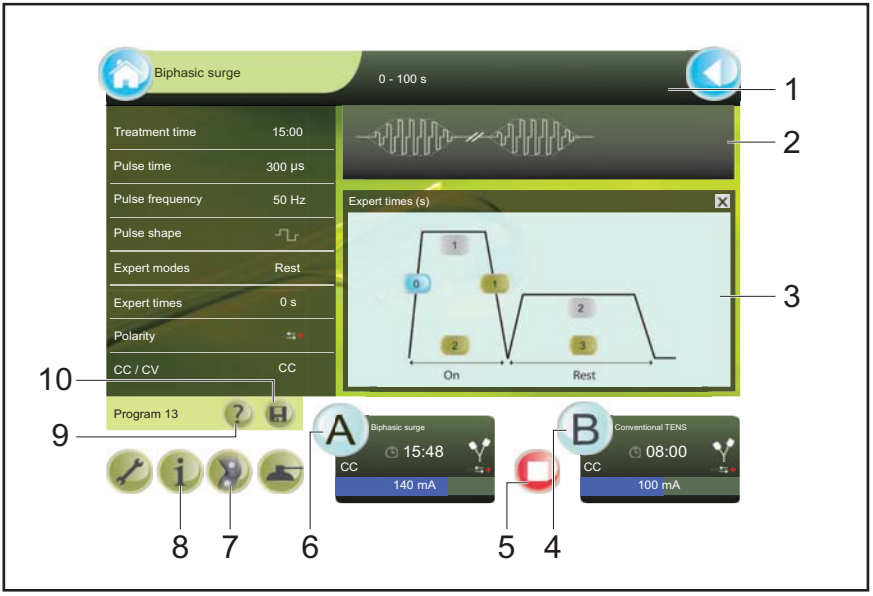
3.6 Display

3.6.1 Home menu



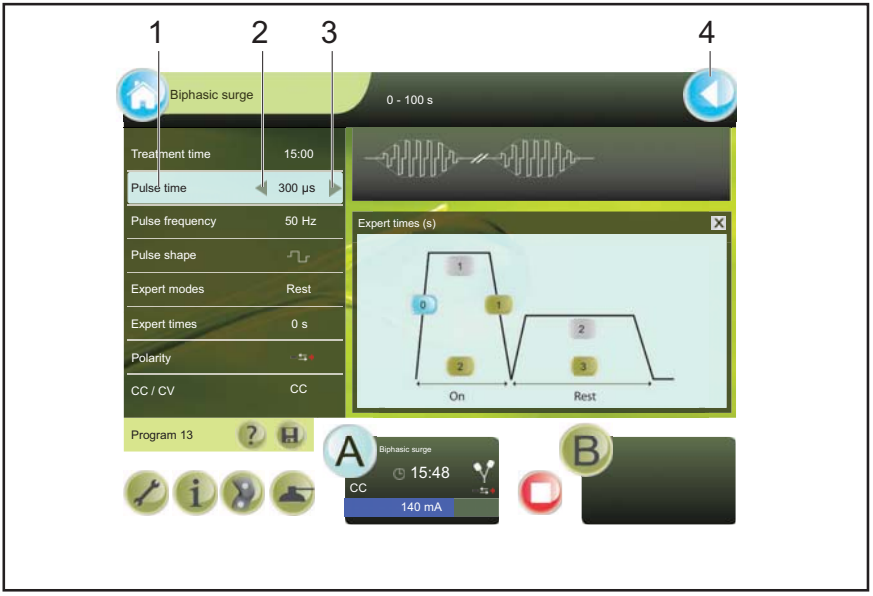
1. Home button
2. Title of the screen
3. Therapy selection
4. Window channel B parameters
5. Window channel A parameters
6. Vacuum settings button
7. Contraindications button
8. System settings button
9. On screen menu. Submenus may appear next to this menu.

3.6.2 *Therapy display*



1. Message ruler
2. Current form
3. Pulse information
4. Channel B button
5. Stop treatment button
6. Channel A button
7. Electrode placement for electro therapy, ultrasound and laser treatment
8. Therapy information button
9. Technical support
10. Save program into memory

3.6.3 Therapy set parameters display



1. Selected parameter
2. Down button
3. Up button
4. Go back button

3.6.4 Touch screen buttons

The touch screen buttons shown depends on the selected display. A button is invisible when the function of the button is not available. The colours of the touch screen buttons are:

Light green — The button is disabled.

Green — The button is enabled.

Blue — The button is selected. The home button and the go back button are always blue.

Blinking — Applies to the channel A and B buttons: The parameter information is not visible because of the selected function. Click to return to the parameter information.

Red — The stop treatment button is always red.

3.7 Display symbols

Electro therapy

Ultrasound therapy

Combination therapy

Iontophoresis

Phonophoresis

Laser therapy

A Channel A

B Channel B

Treatment time

3.8 Parameter symbols

3.8.1 Electro therapy

Polarity indication Red +, no vacuum

Polarity indication Red-, no vacuum

Alternating polarity, no vacuum

Polarity indication Red +, with vacuum

Polarity indication Red-, with vacuum

Alternating polarity, with vacuum

Vacuum

Biphasic pulse shape, symmetrical

Biphasic pulse shape, asymmetrical

CC Constant Current

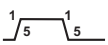
CV Constant Voltage

mÂ mA peak

V̂ Volt peak

Frequency sweep mode

12s/12s

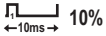


1s/5s -1s/5s

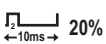
6s/6s

1s/1s

3.8.2 Ultrasound therapy



US duty cycle 10%



US duty cycle 20%

US duty cycle 30%

US duty cycle 40%

US duty cycle 50%

US duty cycle 100%


US head, ERA 4 cm^2


US head, ERA 1 cm^2

$\hat{I}_{set}$ Set US intensity

W/cm² Unit of the set US intensity

P_{pk} Peak US output power

W Unit of the Peak US output power

3.8.3 Laser therapy

P_{av} Set average power


Laser emission detected


Monoprobe

E_{tot} Total administered energy

E_{set} Recommended energy to be administered to the patient


Clusterprobe

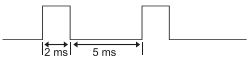
3.9 Current shapes

3.9.1 Unidirectional currents

Iontophoresis direct current


Direct current


Rectangular pulse



2-5 current (UltraReiz)

Triangular pulse

MF constant

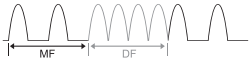
Iontophoresis MF constant

3.9.2 Diadynamic currents

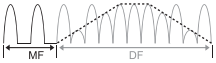
Diadynamic DF

Diadynamic MF

Diadynamic RS



Diadynamic CP



Diadynamic LP

3.9.3 Interferential currents

2-pole MF

Isoplanar vector field surge

Isoplanar vector field

Dipole vector

3.9.4 TENS currents

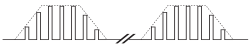
TENS conventional/brief intense

TENS low frequency

TENS burst

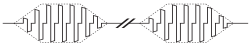
TENS random frequency

3.9.5 NMES currents

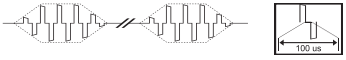


Rectangular surge

Triangular surge



Biphasic surge

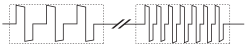


Intra pulse interval surge

2-pole MF surge

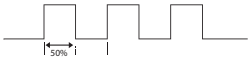
Dipole vector field

Russian stimulation



Han stim

3.9.6 Microcurrents

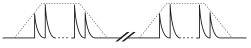


Microcurrent

Microcurrent surge

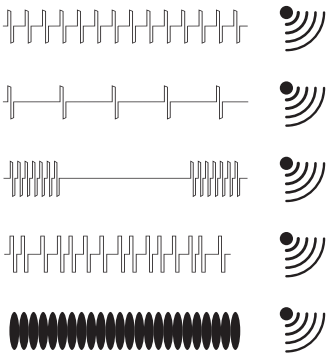
3.9.7 High voltage currrents

High voltage



High voltage surge

3.9.8 *Current shapes combination therapy*



Ultrasound + conventional TENS
Ultrasound + brief/intense TENS

Ultrasound + low frequency TENS

Ultrasound + burst TENS

Ultrasound + random frequency TENS

Ultrasound + 2-pole MF

4 OPERATION

4.1 Therapy selection

You can select a therapy in different ways, via the menu entries or via the direct therapy keys.

- **Objectives**: Select a therapy on the basis of an objective. *See §4.1.2.*
- **Indications**: Select a therapy on the basis of a medical indication. *See §4.1.3.*
- **Body area**: Select a therapy on the basis of a body part. *See §4.1.4.*
- **Diagnostics**: Perform a diagnosis, for example to determine the rheobase and the chronaxie. *See §4.1.5.*
- **Memory**: Select a therapy that you previously saved. *See §4.1.6.*
- **Anatomical library**: Access to the anatomical library information. *See §4.7.*
- **Contra indications**: Press to display an overview with contra indications for the different therapies. *See §4.1.7.*

4.1.1 Therapy selection via therapy keys

Button	Therapy	Button	Therapy
	Electro therapy		Iontophoresis
	Ultrasound therapy		Phonophoresis
	Combination therapy		Laser therapy

4.1.2 Therapy selection via objectives

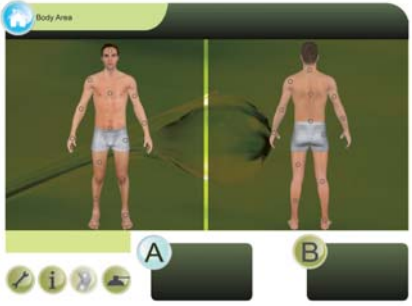
1. Press Objectives in the home menu.
2. Select the objective.
3. Select the therapy method.
4. Follow the on screen options to select the desired treatment.

4.1.3 Therapy selection via indication list

1. Press Indications in the home menu.
2. Select the indication:
   - Use the on screen keyboard to type the first character of a therapy.
   - Use the scrollbar on the right side of the screen.
3. Select the therapy method.
4. Follow the on screen options to select the desired treatment.

4.1.4 Therapy selection via body area

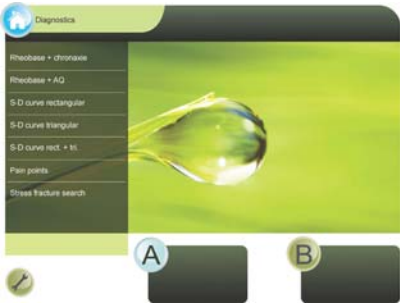
1. Press Body Area in the home menu.
2. Select a blue circle to select the body part to treat.
3. Select the indication.
4. Follow the on screen options to select the desired treatment.



4.1.5 Diagnostic program selection

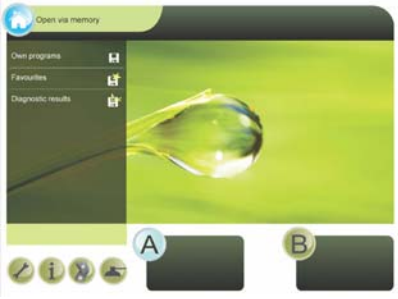
With the diagnostic programs, you can investigate the state of the electrical sensitivity of the neuro-muscular system.

1. Press Diagnostics in the home menu.
2. Select the desired diagnosis. *See §4.8.*



4.1.6 Memory selection

1. Press Memory in the home menu.
2. *See §4.9.* for a description of the memory functions.



4.1.7 Contra indication selection

1. Press Ci in the home menu.
2. Select the therapy for which you want to see the contra indications.

4.2 Performing therapy

4.2.1 Set and start therapy

1. Select the desired menu until the treatment appears.
2. Change the value of the parameter with ◀ and ▶. The setting range of the parameter is shown at the top of the screen. You can change the parameter as long as the parameter is highlighted.
3. Start the therapy: rotate intensity knob A or B to start the treatment and to set the desired intensity. The set intensity is displayed in the screen.

4.2.2 Set channels A and B

The 400-Series has two separated electro therapy channels A and B.

The channels A and B can be used independently. You can treat two different indications simultaneously with two different types of current.

1. Press Ⓑ or Ⓐ to select the other channel.
2. Select the desired treatment for the second channel. *See §4.1.*
3. Set the parameters for the second channel.

Both channels are selected simultaneously and automatically in case of:

- Alternating channels choice with NMES currents (expert mode).
- Combination therapy

Copy channel

On the second channel, you can set the same parameters for electro therapy as for the first set channel.

1. Press ⊘. The System setting menu appears. *See §4.10.*
2. If necessary, change the parameter Copy parameters to ON.
3. Select the desired treatment. *See §4.1.*

Clear channel

1. Make sure that the intensity is set to zero.
2. Press Ⓐ or Ⓑ to select the channel that you want to clear.
3. Press ◀. The channel is cleared.

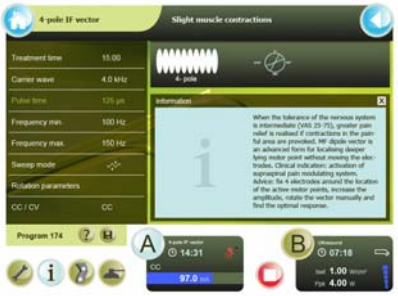
4.2.3 Immediately stop treatment

1. Press ▢. All active treatments are stopped immediately. The parameter settings are retained.
2. Set the intensity of the channel again to continue the treatment.

4.2.4 Therapy and help information

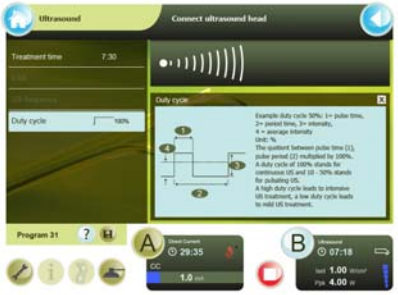
Therapy information

1. Check if the ⓘ button is available. the button is not available for default therapy functions.
2. Press the ⓘ button. The therapy information is displayed.



Help information

1. If not already done, select a treatment. *See §4.2.1.*
2. For parameter information, select a parameter
3. Press the ? button. The help information is displayed.



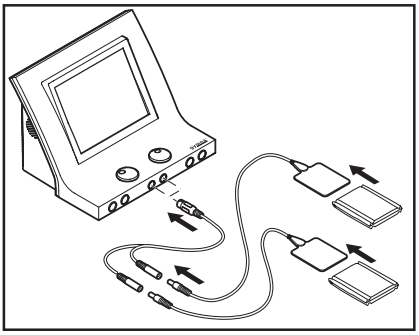
4.3 Electro therapy

4.3.1 Performing electro therapy with electrodes

1. Select the desired electro therapy program.
2. Place the electrodes. With indication list and body area treatments, the electrode placing button becomes available. Press the button to see a photo of the electrode placement.
3. Rotate intensity knob A or B to start the electro therapy and to set the desired intensity. *See §4.2.1.*
4. Check the patient's reaction. Repeat this check regularly during the treatment.
5. The equipment stops the treatment and indicates that the treatment is completed. Remove the electrodes.

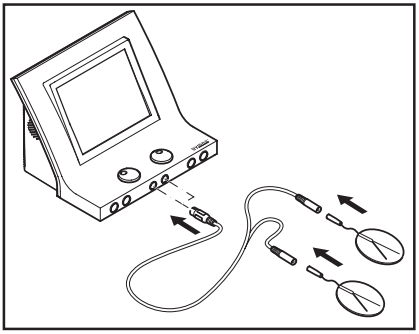
Placing the rubber electrodes

1. Moisten two EL sponges with water.
2. Slide a rubber electrode into each sponge.
3. Place the sponges on the part of the body that must be treated.
4. Fasten the sponges to the part of the body with the elastic fixation straps.
5. Connect the two-ply cable to connector Y$_A$ or Y$_B$ of the 400-Series.



Placing the adhesive electrodes

1. If possible, disinfect the parts of the body where the adhesive electrodes are to be placed.
2. Place the electrodes on the part of the body that must be treated.
3. Connect the connectors of the adhesive electrodes to the red and black connectors of the two-ply electrode cable.
4. Connect the two-ply electrode cable to connector Y$_A$ or Y$_B$ of the 400-Series.

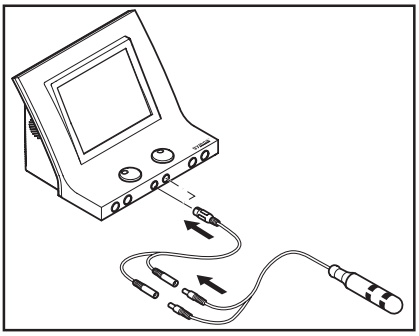


Do not use adhesive electrodes with currents that have a galvanic component, such as galvanic, diadynamic, MF rectangular, pulsed rectangular and triangular currents. These currents can cause skin etching.

4.3.2 *Perform electro therapy with vaginal, anal or rectal stimulation probe*

- Considering the very personal and intimate character of these treatments, a probe may only be used for one patient.
- Never disinfect the probes in an autoclave. The probes can be damaged by the extreme temperature.

1. Clean the probe with a medical tissue, such as Sternosept. Rinse with clear water and dry with a clean towel. Do not immerse the probe.
2. Select the desired electro therapy program.
3. Connect the probe to the 400-Series.



The stimulation probes are not detected by the equipment. Select only alternating currents with a Constant Voltage (CV) setting, such as TENS, NMES, and 2-pole interferential currents. This prevents skin etching and unpleasant stimulations.

4. Place the probe.
5. Rotate intensity knob A or B to start the treatment and to set the desired intensity.
6. Check the patient's reaction. Repeat this check regularly during the treatment.
7. The equipment stops the treatment and indicates that the treatment is completed. Remove the stimulation probe.
8. Clean the stimulation probe. *See §5.2.6.*

4.3.3 *Electro therapy with sequential steps*

A treatment with sequential steps consists of a succession of the same current form, but additional with different parameter settings.

Advantages

- You can distinguish between different phases in a treatment, for example preparation, core effect and cooling.

Set new intensity between sequential steps

The intensity determines the peak value during the treatment. When changing to a following step, the intensity is retained if safety allows. Sometimes, it is necessary to increase the intensity for the following step. If the intensity cannot be maintained for safety reasons, the intensity returns to zero. In this case, the treatment is stopped. You must now set the intensity again.

Setting a treatment with sequential steps

1. Select a sequential program. The Step time and the step parameters are directly related to the momentary selected sequential step number.
2. If desired, readjust the individual step time. Via step parameters you can have a more detailed look (in read-only mode) to the individual current form settings of the selected sequential step.
3. Rotate intensity knob A or B to start the treatment and to set the desired intensity.

Skip step in treatment

1. Press ▢ to temporarily interrupt the treatment.
2. Select Seq. step nr. and select the desired step.
3. Rotate intensity knob A or B to continue the treatment again and to set the desired intensity.

4.3.4 Performing iontophoresis

With iontophoresis, medicines are administered to the body as electrically charged particles (ions) by means of a direct current. To do this, a direct current is used.

1. Apply the medicine on a sterile gauze. *See §8.1.*
2. Place the gauze on the electrode. Make sure that the polarity corresponds with the medicament used.
3. Place the electrodes.
4. Select an Iontophoresis program.
5. **Set the intensity between 0.1 and 0.2 mÂ/cm^2.** The intensity depends on the surface area of the electrodes. With electrodes of 6 x 8 cm (=48 cm^2), the current setting must be between 4.8 and 12 mÂ.

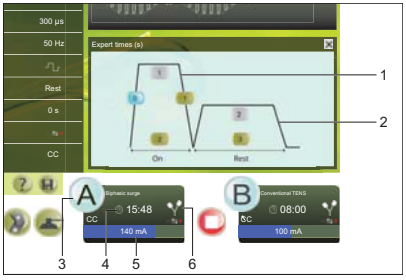
To prevent etching or burns, never exceed 0.2 mÂ/cm^2.

4.3.5 Use of vacuum suction cups

If the vacuum module is available the controls for it appear in the menu. Channel A or B can be selected separately to use normal electrodes or suction cups. Even if only one channel uses suction cups, all four of them must be connected to the vacuum module. The cups have automatic valves shutting them off when they are hanging free. Otherwise the vacuum pump would run continuously and deeper vacuum levels can not be reached. *See §4.11.* for detailed vacuum information.

4.3.6 Read-out values for electro therapy

1. On-time (for NMES currents)
2. Off-time (for NMES currents)
3. Channel select button
4. Remaining treatment time
5. Intensity
6. Polarity

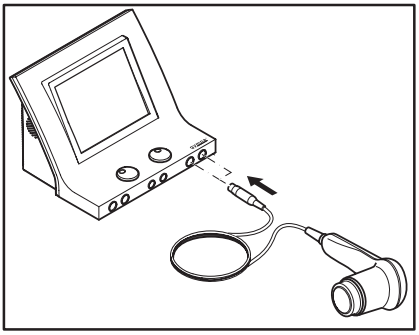


Progress of current

With NMES currents, the progress of the current is graphically displayed. This gives a clear insight into the phase in which the current is at that moment. In this way, you can optimally guide the patient during the execution of the exercise.

4.4 Ultrasound therapy

4.4.1 Performing ultrasound therapy



1. Connect the US head into one of the two connectors of the 400-Series. You can connect two different US heads, but only one US head can be in operation at one time. The device detects which type of US head is connected to the connector.
2. Select the desired ultrasound therapy.
3. Apply contact gel to the skin to be treated and to the US head.
4. Place the head on the skin.
5. Rotate intensity knob A or B to start the ultrasound therapy.
6. Move the US head evenly over the skin during the treatment. This prevents internal burns.
7. Check the patient's reaction and the effect of the treatment. Repeat this check regularly during the treatment.
8. The equipment stops the treatment and indicates that the treatment is completed.

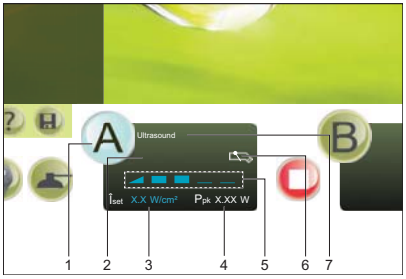
4.4.2 Phonophoresis

Phonophoresis is used to enhance transdermal transport of several drugs, especially anti-inflammatory NSAID and local anestetics.

1. Use the medicines (gel ointment) instead of the US contact gel.
2. Select Objectives or the direct therapy key .
3. If desired, change the default parameters.

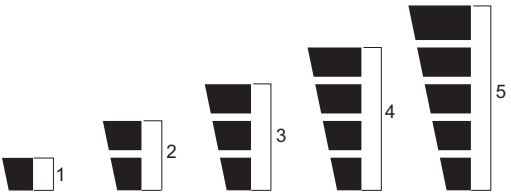
4.4.3 Read-out values for ultrasound therapy

1. Channel select button
2. Remaining treatment time
3. $\hat{I}_{set}$
4. P_{pk}
5. Contact of the US head
6. Type of US head
7. Ultrasound therapy



Contact of the US head

The contact of the US head with the skin:



1 Bad contact, US head switched off (0 W).
2 Bad contact.
3 Sufficient contact.
4 Good contact.
5 Very good contact.

Test the US head if its conduction is bad. *See §5.1.2.*

$\hat{I}_{set}$ (W/cm^2)
The power (W) of the US head per cm^2.

P_{pk} (W)
The peak power of the US head ($\hat{I}_{set}$ * ERA). The peak power delivered therefore depends on the size of the US head and the contact with the skin. This value is 0.0 W if the contact with the skin is bad. In this case, the ultrasound treatment of the equipment is stopped to prevent overheating of the transducer.

4.4.4 Indicator light of the US head

The indicator light of the US head provides the following information.

Blue indication light	**Situation**
Short flash:	The US head is properly connected and selected or the end of treatment is reached.
Continuous:	The US emission is in progress.
Blinking:	Bad contact of the US head with the skin.

4.5 Combination therapy

4.5.1 Performing combination therapy

- With combination therapy, the US head is always the negative pole. The electrode is the positive pole. Notice that the polarity can be flipped in the electro therapy menu.
- With combination therapy, a maximum current density of 2.0 mA_{rms}/cm^2 is advised. Exceeding this current density can result in skin irritation and burns. The intensity depends on the surface area of the US head. For the 4 cm^2 US head, the current setting may be a maximum of 8 mA_{rms}; for the 1 cm^2 US head, a maximum of 2 mA_{rms} applies.

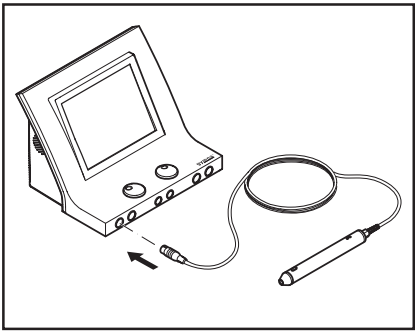
1. Select for combination therapy. Channel A is used for electro therapy and channel B is used for ultrasound therapy.
2. Select the current shape.
3. Connect the two-ply electrode to the electro therapy connector A and connect the US head to a US connector.
4. Apply contact gel to the skin to be treated and to the US head.
5. Place the head on the skin.
6. Rotate intensity knob A to start the electro therapy. Set the desired voltage.
7. Rotate intensity knob B to start the ultrasound therapy
8. Check the contact between the US head and the skin. The following indications can indicate a bad contact:
   - The treatment stops.
   - The peak power of the ultrasound treatment goes to 0.0 Watt.
9. Check the patient's reaction and the effect of the treatment. Repeat this check regularly during the treatment.
10. The equipment stops the treatment and indicates that the treatment is completed.

4.6 Laser therapy

4.6.1 Laser safety

Start a laser therapy only when all persons in the room wear laser goggles for eye protection.

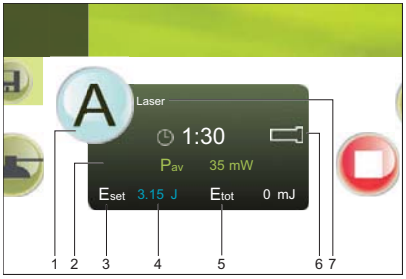
4.6.2 Performing laser therapy



1. Make sure all persons wear laser goggles.
2. Plug the connector of the laser probe into the connector of the 400-Series.
3. Select for laser therapy.
4. Unlock the laser by entering the access code. *See §4.10.2.* for changing the access code.
5. Select the desired laser therapy. The green indicator light on the laser probe lights up. With Indication list treatments or selecting by body area, the placing button becomes available. Press the button to see a photo of the laser probe placement.
6. Hold the laser probe over the location to be treated.
7. Press the black button on the laser probe to start the laser therapy. The yellow indicator light on the laser probe lights up. Hold the button down, releasing it will pause the treatment.
8. Check the patient's reaction and the effect of the treatment. Repeat this check regularly during the treatment.
9. The equipment stops the treatment on reaching the dosis set and indicates that the treatment is completed.

4.6.3 Read-out values

1. Channel select button
2. Laser test symbol; visible if the laser detector detects laser emission.
3. E_{set}
4. Remaining treatment time
5. E_{tot} (during therapy) or E_p (during laser energy measurement)
6. Type of connected laser probe
7. Laser therapy



P_{av} (µW or mW)
The set average power (µW or mW) of the laser probe (E_p * frequency).

E_{tot} (mJ or J)
The total administered energy (mJ or J) of the current treatment (P_{set} * treatment time).

E_{set} (mJ or J)
Recommended energy to be administered to the patient.
.

4.6.4 Testing laser emission

1. Set a laser therapy. *See §4.6.2.*
2. Place the laser probe output perpendicular on the laser test eye.
3. Press and hold the black knob on the laser probe during the laser test. The laser test symbol appears on the read-out screen.
4. The E_{tot} value increases every second with the P_{av} until the The E_{tot} value reaches the E_{set} value.
5. Release the black knob on the laser probe.

You can also test the energy per pulse of the laser probe. *See §4.10.8.*

4.6.5 Indicator lights on the laser probe

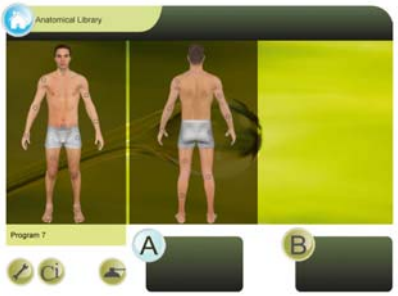
The indicator lights on the laser probe provides the following information.

Indication light	Situation
Continuous green	The laser therapy is selected, but the laser probe has no laser emission.
Continuous yellow	The laser emission is in progress.
Flashing yellow	The 2 s safety delay is activated to avoid laser emission by accident or the laser treatment finished.

4.7 Accessing the anatomical library

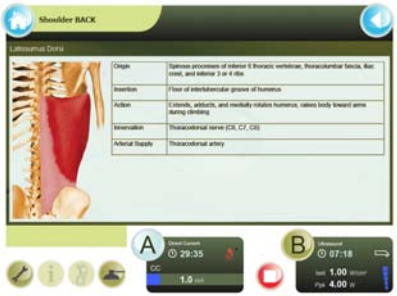
You can access the anatomical library for anatomical information on the musculoskeletal system.

1. Press ⌂.
2. Select Anatomical Library.
3. Select the body part you want to display information of.



4. Select an item from the list.

5. Anatomical information is displayed (two examples are shown).



Information is also available during the therapy. Go to the home menu and select the anatomical library.

4.8 Diagnostics

With the diagnostic programs, you can investigate the state of the electrical sensitivity of the neuro-muscular system:

- Rheobase and chronaxie. *See §4.8.1.*
- Rheobase and AQ. *See §4.8.2.*
- Determine an S-D curve. *See §4.8.3.*
- Pain points. *See §4.8.4.*

4.8.1 Determining rheobase and chronaxie

1. Select Diagnostics.
2. Select Rheobase and chronaxie.
3. Rotate intensity knob A (or knob B) to start the treatment. The set intensity is displayed in the screen.
4. Increase the intensity in steps of 0.1 mÂ, until you observe a minimal muscle twitch.

5. Select **Confirm amplitude**. The measured rheobase (in mÂ) is saved.
6. The equipment now doubles the rheobase (mÂ). The pulse time changes to 0.1 ms. Increase the pulse time by ▶, until you observe a a minimal muscle twitch.
7. Select **Confirm pulse time**. The chronaxie is saved. The result screen appears.

8. If desired, press 💾 to save the data in the memory. *See §4.9.1.*

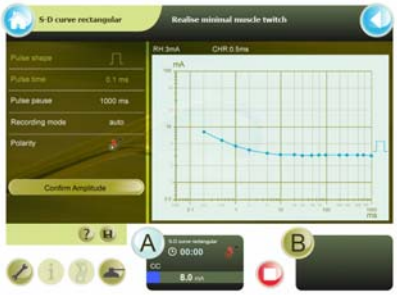
4.8.2 Determining rheobase and Accomodation Quotient (AQ)

1. Select Diagnostics.
2. Select Rheobase and AQ.
3. Determine the rheobase as with rheobase and chronaxie. *See §4.8.1.*
4. Select **Confirm amplitude**. The measured rheobase is saved.
5. The equipment now selects a triangular pulse.
6. Increase the intensity in steps of 0.1 mÂ, until you observe a minimal muscle twitch.
7. Select **Confirm amplitude**. The measured AQ is saved. The result screen appears.
8. If desired, press 💾 to save the data in the memory. *See §4.9.1.*

4.8.3 Determine an S-D curve

1. Select Diagnostics.
2. Select S-D curve rectangular, S-D curve triangular or S-D curve rect. + tri.
3. If desired, change the Recording mode. If Manual is selected for the Recording mode, you can skip or repeat a measurement with ◀ and ▶.
4. Select **Auto mode** or **Manual mode**

Auto mode



1. Rotate intensity knob A to start the treatment.
2. Increase the intensity in steps of 0.1 mÂ, until you observe a tangible or visible contraction
3. Select **Confirm Amplitude**. The measurement result is directly shown on the graph. In auto mode, a new pulse value and shape is selected.
4. Repeat steps 1 to 3 for all measurements.
5. When **END** appears as pulse time, the measurement is completed. The diagnostic result screen appears. If desired, press Ⓗ to save the data in the memory. *See §4.9.1.*

Manual mode

Follow the steps of Auto mode. After each **Confirm Amplitude**, the default pulse shape and pulse time may be changed if desired.
In Manual mode a step may be skipped, redone or steps can be measured in random order. In Auto mode the measurement sequence is fixed.

4.8.4 Pain points

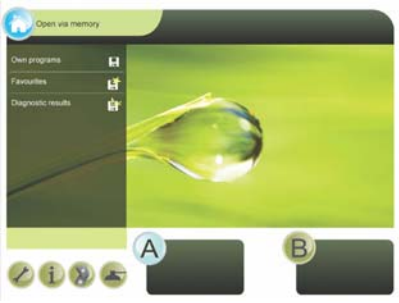
1. Select Diagnostics.
2. Select Pain points.

4.9 Memory

The memory functions are accessible:

- from the Ⓗ button in the diagnostics operation or program to save into memory;
- from Memory function in the Home menu, to retrieve a saved result.

4.9.1 Saving a program or diagnostic result



1. Press (H) from a therapy or diagnostic.
2. From the save program menu:
   - Select (H) to save as own program.
   - Select (H) to save as favourite.
   - Select (H) to save a diagnostic result.
3. The first free program number is selected.
   If desired, use the scroll bar to scroll through the list.

4. Enter the name of the program.
   Use the name or the number of the patient, for example.
5. Select **Apply** to save or **select Cancel** to leave the Memory function without saving.

The programs have a unique number, different programs or diagnostic results can be given the same name. Once stored, it is not possible to assign a program or diagnostic result to another program number.

4.9.2 *Use a saved program*

Select a saved program

1. Access the memory:
   - Select to show the own program list.
   - Select to show the diagnostic result list.
   - Select to show the favourite list again.

2. Select to sort the list in alphabetical order or to sort the list in numeric order.
3. If necessary, use the scroll bar and select the program or diagnostic result.

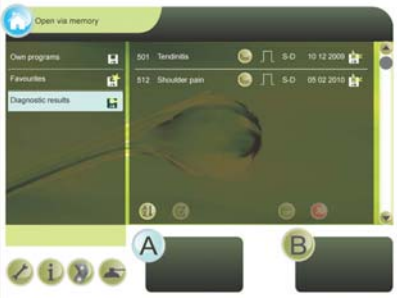
The (Edit), (Open), (Delete) and (Move) buttons are available.

Rename a program or diagnostic

1. Select the program to be renamed.
2. Press . The text *"Program will be saved as:"* and the keyboard screen appears.
3. Enter a new name for this program.
4. Select **Apply** to confirm or **Cancel** to leave the program name unchanged.

Open a program or diagnostic

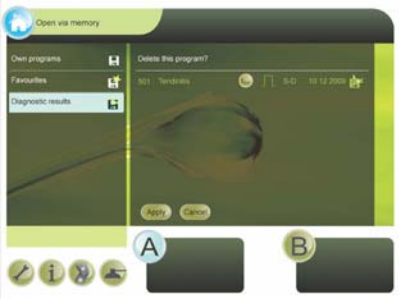
1. Press .
   When the other channel is active, the open button is not available if the program conflicts with the active channel.



When a diagnostic was selected, the diagnostic information appears. Diagnostic information is read-only.
When a program was selected, a therapy program appears. If desired, start the therapy.

Delete a program or diagnostic

1. Press ⊗. The text *"Delete this program?"* appears.
2. Select **Apply** to confirm or **Cancel** to keep the program.



Move a program

1. Press the move key:
   - When the favourite list is selected, press to move a program to the own program list.
   - When the own program list is selected, press to move a program to the favourite list
2. Select **Apply** to confirm or **Cancel** to stop the move action.

4.10 System settings

With the system settings, you can adapt the Standard settings of the equipment. You can not change the system settings during a therapy.

4.10.1 Changing the system settings

1. Press ⊘ for system settings
2. Select the desired system setting.
3. Select a parameter and change the value with ◀ and ▶.

4.10.2 System settings description

Touch panel calibration
Press **Start** and follow the instructions on the screen.

Language
The language selection: select the language with which the read-out must work.

Date & Time
Date and time settings. Select Day, Month, Year, Hour, Minutes, or Seconds and change the value with ◀ and ▶.

Input Panel / Keyboard (QWERTY or AZERTY)
Changes the appearance of the keyboard on displays where a keyboard is shown.

Sound
Change the sound values with ◀ and ▶.

Copy channel parameters (on, off)
Choose that channels A and B are the same (on) or are different (off). *See §4.2.2.*

Synchronise channels (on, off)
Available when Copy channel parameters is ON. Choose that both channels run with one treatment timer (on) or each channel uses its own treatment timer. This option is not allowed for NMES currents and 4-pole current shapes.

System information
System information of the equipment.
Always have this information available when you contact the technical service department.

Error history
The total number of error reports that the equipment has had and details about the last 10 error reports.
Always have this information available when you contact the technical service department.

Start up into
Enter or modify start up information. *See §4.10.3.*

Laser key code
Choose a new Laser key code to access laser functions.

Accessories test
Selects one of the accessory tests:
- Plate electrode test. Tests the condition of the rubber electrodes. *See §4.10.4.*
- ET cable test. Tests the elector therapy cables. *See §4.10.5.*
- Vacuum hose test. Tests the vacuum hoses (if vacuum function is present). *See §4.10.6.*
- Laser energy measurement. Tests the laser probe. *See §4.10.8.*

Working hours accessories (hours, minutes, sec.)
The time that the accessories for elector therapy, ultrasound therapy or laser therapy have been in use. For this, the output of the channel must have been higher than zero. Submenu Reset working hours allows to reset the number of working hours of a plate electrode, an US head or a laser probe to zero.

Stop timer if bad US contact
On: The treatment stops during a bad contact of the US head.

Restore all programs 1-50
The contents of all the program numbers 1 - 50 are restored to the default settings of the manufacturer.

Memory path entry
The choice setting will immediately open the desired sub path.

Erase memory
Via this menu it is possible to delete parts of the memory or the whole memory in one step.

4.10.3 Set text for start up screen

You can set your own text for the start up screen. For example, you can put your name or address information here.

1. Press ⊘.
2. Select Start up info.
3. follow the on screen instructions to enter the desired start up information.
4. Select **Apply** to save the start up information or **Cancel** to leave it unchanged.

4.10.4 Plate electrode test

1. Press ⊘.
2. Select Accessories test.
3. Select Plate electrode test.
4. Connect the electrode cable to channel A with the electrodes.
5. Place the electrodes on each other, without the sponges. Make sure that the electrodes make contact over the whole surface.
6. Set the amplitude to 20 mA with rotary knob A.
7. If the electrodes function correctly, the following message will appear Condition electrodes: OK.
8. Turn the amplitude back to 0 mA.

4.10.5 Cable test

1. Press ⊘.
2. Select Accessories test.
3. Select Cable test.
4. Connect the electrode cable to channel A with the electrodes.
5. Connect the test plug to the connectors of the cable.
6. Set the amplitude to 20 mA with rotary knob A.
7. If the cables function correctly, the following message will appear Condition cable: OK.
8. Turn the amplitude back to 0 mA.

4.10.6 Vacuum hose test

1. Press ⊘.
2. Select Accessories test.
3. Select Suction Cup test.
4. Follow the instructions on the screen.

4.10.7 Suction cup test

1. Press ⊘.
2. Select Accessories test.
3. Select Suction Cup test.
4. Connect two suction cups with the vacuum hoses to channel A of the vacuum module.
5. Switch on the vacuum.
6. Place the cups against each other, with moisturised sponges. Make sure that the sponges make contact over the whole surface.
7. Set the amplitude to 20 mA with rotary knob A
8. If the cups and sponges function correctly, the following message will appear: *Condition cups & sponges: OK*.
9. Turn the amplitude back to 0 mA and switch off the vacuum.
10. If the test fails, try again after moisturizing the electrodes with lightly salinated water.

4.10.8 Laser energy measurement

1. Do the laser energy measurement on a 'cold' (not recently used) laser probe for a reliable test.
2. Make sure all persons wear laser goggles.
3. Plug the connector of the laser probe into the connector ✹← of the 400-Series.
4. Unlock the laser by entering the access code.
5. Press ⊘. The System settings menu appears.
6. Select Accessories test.
7. Select Laser energy measurement.
8. Test the monoprobe or clusterprobe.

Test the monoprobe

1. Place the laser probe output perpendicular on the laser test eye ✹←.
2. Press and hold the black button on the laser probe during the laser test. The laser test symbol ✹← appears on the read-out screen.
3. Move the probe a bit to-and-fro to obtain the maximum value.
4. Release the black button on the laser probe.
5. Make sure the measured E_p value correspond within ±20% with the E_p value of the supplier control report of the laser probe.
6. Press ⊘ to go back to the System settings screen.
7. Lock the laser function.

Test the clusterprobe

1. Place the laser probe output perpendicular over the laser test eye ✹⊣. with the first laser diode.
2. Press and hold the black button on the laser probe during the laser test. The laser test symbol ✹– appears on the read-out screen.
3. Rotate the probe a bit to-and-fro to obtain the maximum value.
4. Release the black button on the laser probe.
5. Repeat the measurement for the other laser diodes.
6. Calculate the sum of the four measured E_p value.
7. Make sure the E_p sum value correspond within ±20% with the total E_p value of the supplier control report of the laser probe.
8. Press ⊘ to go back to the System settings screen.
9. Lock the laser function.

4.11 Vacuum ⏏

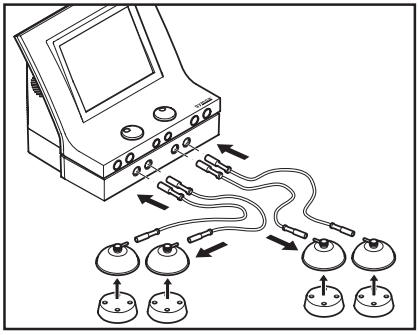
4.11.1 Selection to use normal electrodes or suction cups

1. Press the ⏏ button to access the vacuum parameters.
2. Select Vacuum pump and On to switch the vacuum pump on.
3. Select Vacuum channel A and B to switch one or both vacuum electrode channels On.
4. To use normal electrodes, select one or both Vacuum channel A and B to Off.

4.11.2 Connect and prepare the vacuum electrodes

- Use always demineralized water with vacuum electrodes to avoid lime deposits in the watertank, hoses and sponges.
- Use moist sponges only. Too dry sponges can cause a bad electrical contact and burn the skin.
- Do not use vacuum electrodes with DC current. The DC current causes damage to the vacuum cups by ionization.

1. Connect the vacuum electrodes to the vacuum hoses.



2. Connect the four vacuum hoses. Select two cables with the same hose colour for each channel.
   1 Connect the red connectors from the vacuum hoses to the output connectors with the red dot.
   2 Connect the black connectors from the vacuum hoses to the output connectors with the black dot.
3. Moisten the round sponges.
4. Put the sponges in the vacuum electrodes.

4.11.3 Vacuum parameter settings

Select vacuum level

1. Select an electro therapy
2. Press the button to access the vacuum parameters.
3. Select Working pressure.
4. Use ◀ and ▶ to adjust the vacuum level.

Selecting pulsed vacuum

1. Press the button to access the vacuum parameters.
2. Select Vacuum rhythm.
3. Use ◀ and ▶ to select continuous or one of the pulsating vacuum massage-effect modes.

4.11.4 Vacuum treatment

Start treatment

1. Place the vacuum electrodes on the part of the body that must be treated. The vacuum electrodes stay in place due to underpressure. Too high suction cause patient discomfort, change the working pressure if necessary. *See §4.11.3.*
2. Rotate intensity knob A or B to start the treatment and to set the desired intensity.
3. Check the patient's reaction. Repeat this check regularly during the treatment.

End of treatment

1. The vacuum stops automatically two minutes after the treatment stops. This to prevent injury to the skin of the patient by prolonged exposure to vacuum
2. Remove suction cups with a finger under the rim. Air is let in and the cups can are released. The suction cups release immediately by switching off the vacuum pump.

4.11.5 The water reservoir is full

1. The *"Water reservoir full"* warning appears on the screen. Finish the present treatment. After you turn the vacuum off, you can not restart the vacuum.
2. Empty the water reservoir with the drain hose. The start of a vacuum treatment is possible.

5 INSPECTIONS AND MAINTENANCE

5.1 Inspections

	Component	Check	Frequency
	Electrode cables and electrodes	Damage Insulation intact	At least 1x per month
	Electrode cables, electrodes, suction cups and vacuum hoses	Conductivity *See §4.10.4.* to *§4.10.7.*	At least 1x per week
	Vacuum electrodes	Cleaning. *See §5.2.3.*	After every treatment
	Vacuum sponges	Cleaning. *See §5.2.4.*	After every treatment
	Vacuum hoses and water reservoir	Cleaning. *See §5.1.1.*	Weekly
	US head	Dents, cracks or other damage	At least 1x per month
		Test US head. *See §5.1.2.*	With bad operation or at least 1x per year
	Cable of US head	Damage Pins in connector straight	At least 1x per month
	Laser probe	Dents, cracks or other damage	At least 1x per month
		Test the laser probe. *See §4.6.4.* and *§4.10.8.*	Every day
	Cable of laser probe	Damage Insulation intact Pins in connector straight	At least 1x per month
	Equipment	Technical safety inspection. *See §5.1.3.*	At least 1x per year

5.1.1 Cleaning the vacuum hoses and the water reservoir

1. Empty the water reservoir with the drain hose.
2. Connect the vacuum hoses.
3. Put the ends of the vacuum hoses in a 70% alcohol solution.

4. Select ⏏ from the starting screen and start the vacuum pump.
5. Suck the liquid up until the *"Water reservoir full"* warning appears.
6. Stop the vacuum pump
7. Empty the water reservoir.
8. Repeat steps 3 until 7 with pure water.

5.1.2 US head test

Test the US head if its conduction is bad. This is the case when the indication bar for the P_{pk} value displays one or two blocks:

 or .

1. Select an ultrasound therapy.
2. Place the US head in a bowl with water.
3. Rotate intensity knob A or B to start the treatment.
4. Check in the screen of the channel to see if the P_{pk} value is increasing.
5. Contact your local GymnaUniphy dealer if the indication bar still displays a bad contact.

5.1.3 Technical safety inspection

The 'Directive on Medical Devices' from the European Commission (93/42/EEG) requires that safe devices are used. It is recommended to perform a yearly technical safety inspection. If the legislation in your country or your insurer prescribes a shorter period, you must adhere to this shorter period.

- Only a technician authorised by GymnaUniphy N.V. may open the equipment or the accessories.
- The inspection may only be performed by a suitably qualified person. In some countries this means that the person must be accredited.

Inspection points

The technical safety inspection contains the following tests:

1. Test 1: General: Visual inspection and check on the operating functions
2. Test 2: Electro therapy
3. Test 3: Ultrasound therapy
4. Test 4: Laser therapy
5. Test 5: Electrical safety inspection: measurement of the earth leakage current and patient leakage current according to DIN/VDE 0751-1 ed. 2.0.

Inspection result

1. A registration must be maintained of the technical safety inspections. Use the inspection report in the appendix for this purpose. *See §8.5.*.
2. Copy this appendix.
3. Complete the copied appendix.
4. Keep the inspection reports for at least 10 years.

The inspection is successful if all inspection items are passed.
Repair all faults on the equipment before the equipment is put back into operation.
By comparing the registered measurement values with previous measurements, a possible slowly-deteriorating deviation can be ascertained.

5.2 Maintenance

Component	Check	Frequency
Main unit	Cleaning. *See §5.2.1.*	As required
Electrodes (Rubber, metal and suction cups)	Cleaning. *See §5.2.3.*	After every treatment
Sponges and sponge bags	Cleaning. *See §5.2.4.*	After every treatment
Fixating bandages	Cleaning. *See §5.2.5.*	If necessary
Vaginal, anal and rectal stimulation probe	Cleaning and disinfecting. *See §5.2.6.*	After each use
US head	Cleaning. *See §5.2.7.*	After each use
Laser probe	Cleaning. *See §5.2.8.*	After each use

Accessories that come in contact with the body of the patient must be washed with pure water after the disinfection to prevent allergic reactions.

5.2.1 Cleaning the 400-Series main unit

Do not disinfect or sterilize the main unit

1. Remove dust with a dry cloth.
2. If necessary, remove dirt with a damp cloth.

5.2.2 Cleaning the touch screen

Use of incorrect cleaners can result in optical impairment of touch panel and/or damage to functionality.

- Cleaner must be neither acid nor alkali (neutral pH)
- Do not use abrasive cleaners
- Do not use organic chemicals such as: paint thinner, acetone, toluene, xylene, propyl or isopropyl alcohol, or kerosene.

Use a microfiber cloth for the touch screen. The cloth may be used dry or lightly dampened with a cleaner:

- Use a commercially available touch screen cleaner.
- Do not apply the cleaner to the touch screen, apply to the cloth.
- Dampen the cloth, do not wet.

1. If a cleaner is used, lightly dampen the microfiber cloth with a cleaner.
2. Wipe the surface gently with the microfiber cloth.

5.2.3 Cleaning the rubber, metal and suction cup electrodes

1. Clean the electrodes in a non-aggressive soap solution or in a 70% alcohol solution.
2. Rinse the electrodes thoroughly with water.
3. Dry the electrodes.

5.2.4 Cleaning the sponges and sponge bags

1. Rinse the sponges thoroughly with water or clean them with a 70% alcohol solution.
2. Rinse the sponges thoroughly with slightly salinated demineralized water.
3. Let the sponges dry if not put to use immediately after cleaning.

5.2.5 Cleaning the fixation bandages

1. Clean the fixation bandages in a 70% alcohol solution or another disinfectant.
2. Rinse the fixation bandages in water.
3. Let the fixation straps dry.

5.2.6 Cleaning and disinfecting vaginal, anal and rectal stimulation probes

- Considering the very personal and intimate character of these treatments, a probe may only be used for one patient.
- Never disinfect the probes in an autoclave. The probes can be damaged by the extreme temperature.

Immediately after every treatment
1. Clean the probe carefully with soap and water.
2. Place the probe in an HAC solution of 1% or in a 70% alcohol solution for at least 30 minutes.
3. Dry the probe with a clean towel.
4. Store the probe in a plastic bag that is provided with the name of the patient.

Before reusing the probe:
1. Clean the probe carefully with soap and water.
2. Apply an antiseptic lubricant to the probe. *See §4.3.2.*

5.2.7 Cleaning the US head

1. Clean the US head with a lightly moistened soft cloth.
2. Disinfect the treatment surface with a cotton bud that is soaked in a 10% HAC solution.
3. Rinse the US head thoroughly with clean water.

5.2.8 Cleaning the laser probe

- The laser probe is not waterproof.
- Do not scratch the aperture pane.

1. Clean the laser probe with a lightly moistened soft cloth.
2. Disinfect the treatment surface with a cotton bud that is soaked in a 10% HAC solution.

6 MALFUNCTIONS, SERVICE AND GUARANTEE

6.1 Malfunctions

Component	Problem	Solution
400-Series	Equipment cannot be switched on	*See §6.1.1.*
	Equipment does not react to commands or a fault report appears	*See §6.1.2.*
	Foreign language on the screen	Change the language. *See §4.10.1.*
Vacuum electrodes	Contamination by ionization	See *§6.1.3*
EL sponges or vacuum sponges	Furring	Replace the sponges
	Bad conduction	Replace the sponges

6.1.1 Equipment cannot be switched on

1. Check if the mains voltage has failed.
2. Check if the main switch is switched on (“I”).
3. Check if the power cord is in order. If necessary, replace the power cord.
4. Contact your dealer if the equipment still cannot be switched on.

6.1.2 Equipment does not react to commands or an error message appears

The safety system of the equipment has ascertained a fault. You cannot continue to work. An instruction usually appears on the screen.

1. Disconnect the connection to the patient.
2. Switch the main switch off (“O”).
3. Wait 5 seconds and switch the main switch on again (“I”).
4. Contact your dealer if the equipment still does not react to commands.

6.1.3 Remove the contamination from the vacuum electrodes

1. Clean the vacuum electrodes. See *§5.2.3*.
2. Use steel wool or sandpaper for metal with fine grains (‘P 400’ or higher) to remove the contamination.
3. Replace the vacuum electrodes if the contamination is still present.

6.2 Service

- Only a technician authorised by GymnaUniphy N.V. may open the equipment or the accessories to perform repairs. The equipment does not contain any components that may be replaced by the user.
- If possible, open the screen with the system settings before you contact the technical service department. *See §4.10.*

Service and guarantee are provided by your local GymnaUniphy dealer. The conditions of delivery of your local GymnaUniphy dealer apply. If you have qualified technical personnel that are authorised by GymnaUniphy to perform repairs, your dealer can provide diagrams, spare parts lists, calibration instructions, spare parts and other information on request, for a fee.

6.3 Guarantee

GymnaUniphy and the local GymnaUniphy dealer declares itself to be solely responsible for the correct operation when:

- all repairs, modifications, extensions or adjustments are performed by authorised people;
- the electrical installation of the relevant area meets the applicable legal regulations;
- the equipment is only used by suitably qualified people, according to these user instructions;
- the equipment is used for the purpose for which it is designed;
- maintenance of the device is regularly performed in the way prescribed. *See §5.2.*
- the technical life time of the equipment and the accessories is not exceeded;
- the legal regulations with regard to the use of the equipment have been observed.

The guarantee period for the equipment is 2 (two) years, beginning on the date of purchase. The date on the purchase invoice acts as proof. This guarantee covers all material and production faults. Consumables, such as sponges, adhesive electrodes and rubber electrodes, do not fall under this guarantee period.

This guarantee does not apply to the repair of defects that are caused:

- by incorrect use of the equipment,
- by an incorrect interpretation or not accurately following these user instructions,
- by carelessness or misuse,
- as a consequence of maintenance or repairs performed by people or organisations that are not authorised to do so by the manufacturer.

6.4 Technical life time

The expected life time of the equipment is 10 years, calculated from the date of manufacture. See the type plate for this information.
In so far as possible, GymnaUniphy will supply service, spare parts and accessories for a period of 10 years from the date of manufacture.

7 TECHNICAL INFORMATION

7.1 General

Dimensions 400-Series (w x h x d)	360 x 285 x 260 mm
Weight 400-Series	5 kg
Weight including accessories	6 kg
Mains voltage	100 - 240 VAC, 50-60 Hz
Maximum power, in operation	85 VA
Safety class	Class II with functional earth (earthed socket required)

7.2 Electro therapy

7.2.1 General

Insulation classification	Type BF (floating patient circuit)
Treatment time	0 - 60 min.
Current limitation	The smallest value: - 150% of the set value, or: - 110% of the maximum for the selected current shape
Accuracy	Set current value mÂ at 500 Ω - typically ± 10%
CC/CV mode	For all current shapes, with the exception of medium frequency rectangular current
Polarity	Red-, red + and alternating polarity, if applicable

7.2.2 Current shapes

Unidirectional currents

- **Direct current**
- **Rectangular pulse**
- **2 - 5 current (Ultra Reiz)**
- **Triangular pulse**
- **Medium frequency constant**
- **Iontophoresis - Medium frequency constant**
- **Iontophoresis - Direct current**

Pulse time	0,1 ms - 6 s
Pulse pause	1 ms - 6 s
Intensity of CC	0 - 80 mÂ at 300 to 1000 Ω
Intensity of CV	0 - 80 V_{peak}

Diadynamic currents

- **MF, DF, CP, LP**

Intensity of CC	0 - 80 mÂ at 300 to 1000 Ω
Intensity of CV	0 - 80 V_{peak}
ISO	on / off

TENS currents

- **Conventional TENS**
- **Low frequency TENS**
- **Brief intense TENS**

Pulse time	10 - 900 µs
Pulse shape	symmetrical, asymmetrical
Frequency min.	1 - 500 Hz
Frequency max.	1 - 500 Hz
Intensity of CC	0 -120 mÂ at 300 to 1000 Ω
Intensity of CV	0 -120 V_{peak}

- **Random frequency**

See TENS specification, with the exception of:

Pulse frequency	1 - 5000 Hz, with automatic random frequency variation of +/-35% maximum

- **Burst**

See TENS specification, with the exception of:

Pulse frequency	20 - 500 Hz
Burst frequency	1 - 10 Hz

NMES currents

- **Monophasic rectangular surge**
- **Monophasic triangular surge**

Pulse time	0,1 - 5 ms
Pulse frequency	1 - 150 Hz
Intensity of CC	0 - 80 mÂ at 300 to 1000 Ω
Intensity of CV	0 - 80 V_{peak}

- **Biphasic surge**
- **Intrapulse interval surge (with a constant interval between positive and negative pulse of 100 µs)**

Pulse time	10 - 900 µs
Pulse frequency	1 - 500 Hz
Intensity of CC	0 - 120 mÂ at 300 to 1000 Ω
Intensity of CV	0 - 120 V_{peak}

- **Russian stimulation**

Intensity of CC	0 - 100 mÂ at 300 to 1000 Ω
Intensity of CV	0 - 100 V_{peak}
Burst frequency	20 - 100 Hz

- **2-pole medium frequency surge**
- **Isoplanar vector field surge**

Intensity of CC	0 - 100 mÂ at 300 to 1000 Ω
Intensity of CV	0 - 100 V_{peak}
Carrier wave frequency	2 - 10 kHz
AM frequency	1 - 200 Hz

- **Expert parameters**

Serial duration (ON)	1 - 100 s
Serial pause (OFF)	0 - 100 s

Interferential currents

- **2-pole medium frequency**
- **Isoplanar vector field**

Intensity of CC	0 - 100 mÂ at 300 to 1000 Ω
Intensity of CV	0 - 100 V_{peak}
Carrier wave frequency	2 - 10 kHz
AM frequency min.	0 - 200 Hz
AM frequency max.	0 - 400 Hz
Frequency sweep mode	0/1/0, 1/5/1, 6/0/6, 12/0/12

- **Dipole vector field**

See 2-pole medium frequency and isoplanar vector field

Rotation mode	0 - 20 s
Rotation angle	0 - 355°
Segment angle	0 - ±30°
Segment time	0 - 10 s

Microcurrents

- **Microcurrent continuous**
- **Microcurrent surge**

Intensity of CC	0,1 µA - 1 mA at 300 to 1000 Ω

High voltage currents

- **High voltage continuous**
- **High voltage surge**

Intensity of CV	0 - 500 V_{peak}

7.3 Vacuum option

Volume water reservoir	± 180 ml
Working pressure continuous vacuum	38 - 320 hPa
Working pressure pulsation vacuum	46 - 480 hPa
Massage effect (increase of vacuum during the pulse relative to the set base level)	0: 1,00 x (continuous) 1: 1,20 x 2: 1,35 x 3: 1,50 x
Vacuum rhythm	1,5/1,5 - 1,5/3,0 - 1,5/4,5 s (on/off time)

7.4 Ultrasound therapy

7.4.1 General

Insulation classification	Type BF
Peak power	0 - 2 W/cm^2, duty cycle = 100% 0 - 3 W/cm^2, duty cycle < 100%
Accuracy of intensity	± 10% of maximum at set values above 10% of this maximum
Treatment time	0 - 30 min.
Deviation of time clock	< 0,5%
Modulation frequency	100 Hz
Modulation type	CW (rectangular on/off)
Repetition period of pulses	10 ms

7.4.2 Modulation and pulse duration

Modulation duty cycle	**100**	**50**	**40**	**30**	**20**	**10**	**%**
Pulse time	∞	5	4	3	2	1	ms
Ratio of p_{tm} - p	1	2	2,50	3,33	5	10	

7.4.3 US heads

US head, model US404			
Acoustic operating frequency	**1,0**	**3,2**	**MHz**
Output power	8,0	8,4	W
Effective intensity of output voltage	2,0	2,0	W/cm^2
Effective Radiating Area (ERA)	4,0	4,2	cm^2
Beam Non-uniform Ratio (BNR)	4,5	7,0	
Maximum intensity of beam	9,0	14,0	W/cm^2
Beam type	Convergent	Collimated	

US head, model US401			
Acoustic operating frequency	**1,0**	**3,2**	**MHz**
Output power	2,6	2,2	W
Effective intensity of output voltage	2,0	2,0	W/cm^2
Effective Radiating Area (ERA)	1,3	1,1	cm^2
Beam Non-uniform Ratio (BNR)	6,8	1,1	
Maximum intensity of beam	13,6	6,2	W/cm^2
Beam type	Divergent	Collimated	

7.5 Laser therapy

7.5.1 General

Insulation classification	Type B
Laser classification	Class 3B

7.5.2 Monoprobe: Mono400

Number of laser diodes	1
Nominal ocular hazard distance	214 mm
Wave length	905 nm
Energy per pulse	2,35 µJ
Pulse peak power	13,5 W
Maximum average power	70,5 mW
Pulse frequency	2 - 30000 Hz
Pulse width at 50% of the peak power	155 ns
Beam surface at laser aperture	12,9 mm^2
Beam divergence	Dual mode 10° and 45°

7.5.3 Clusterprobe: model Quad400

Number of laser diodes	4
Nominal ocular hazard distance	95 mm
Wave length	904 nm
Total energy per pulse	10,8 µJ
Pulse peak power	4 x 18 W
Maximum average power	54 mW
Pulse frequency	2 - 5000 Hz
Pulse width at 50% of the peak power	145 ns
Beam surface at laser aperture	4 x 5,3 mm^2
Composite beam divergence	21°

7.6 Environmental conditions

Temperature	+10 °C to +40 °C
Relative humidity	30% to 75%
Atmospheric pressure	700 hPa to 1060 hPa

7.7 Transport and storage

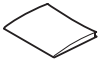
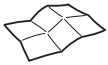
Transport weight	6 kg
Storage temperature	-20 °C to +60 °C
Relative humidity	10% to 100%, including condensation
Atmospheric pressure	200 hPa to 1060 hPa
Transport classification	Single piece, by post

The transport and storage specifications apply to equipment in the original packaging.

7.8 Standard accessories

Article numbers can change in the course of time. Check the article numbers in the most recent catalogue or ask your dealer.
The drawings are merely indicative, no rights can be derived from them.

7.8.1 General

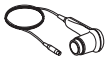
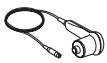
	Quantity	Description	Art. no.
	1	Power cord[1]	100.689
	1	VAS score card	115.684
	1	Touch screen pen Gymna	316.151
	1	Safety instructions	115.684
	1	Quick start manual Gymna 400	340.494
	1	CD-ROM User manual Gymna 400-Series multi language	311.872

1 This power cord has a CEE 7/7 type plug. For countries with other outlets, a different power cord with the appropriate plug is supplied.

7.8.2 Standard accessories electro therapy

	Quantity	Description	Art. no.
	2	Electrode cable double core mini	340.406
	2	Rubber electrode 6 x 8 cm, 2 mm (per 2 pces)	340.468
	1	Chamex bag - 6 x 8 cm (per 4 pces)	100.658
	4	Elastic fixing straps - 5 x 60 cm	108.935

7.8.3 Standard accessories ultrasound therapy

	Quantity	Description	Art. no.
	1	US head, 1/3 MHz - ERA 4 cm^2 incl. holder	340.204
	1	Contact gel, 500 ml	114.827
	1	US head, multi-frequency,1/3 MHz - ERA 1 cm^2, incl. holder[1]	340.201

1 Standard for Pulson 400, optional for Combi 400.

7.8.4 Standard accessories vacuum

	Quantity	Description	Art. no.
	1	Connection cable: ET device - Power and communication	318.167
	1	Connection cable: ET device - Electro therapy	318.164
	1	Vacuum hose dark grey (per 2 pces: black/red connector)	102.801
	1	Vacuum hose light grey (per 2 pces: black/red connector)	102.800
	1	Vacuum electrode - 60 mm (per 4 pces)	114.668
	1	Sponge for vacuum electrode - 60 mm (per 4 pces)	114.689

7.9 Optional accessories

Article numbers can change in the course of time. Check the article numbers in the most recent catalogue or ask your dealer.
The drawings are merely indicative, no rights can be derived from them.

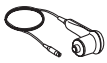
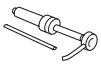
7.9.1 Optional accessories electro therapy

	Quantity	Description	Art. no.
	1	Vaginal stimulation probe Novatys	329.978
	1	Vaginal stimulation probe V2B	330.594
	1	Vaginal stimulation probe Optima 3	330.572
	1	Vaginal stimulation probe Perisize 4+	330.583
	1	Rectal stimulation probe	112.166
	1	Anal stimulation probe Analia	329.989
		Anal stimulation probe Analys+	330.561
	1	Adapter cable 2 mm female to 4 mm male	340.429
	4	Elastic fixing strap - 5 x 30 cm	108.934
	4	Elastic fixing strap - 5 x 120 cm	108.936
	2	Rubber electrode 4 x 6 cm, 2 mm	340.446

	Quantity	Description	Art. no.
	2	Rubber electrode 8 x 12 cm, 2 mm	340.481
	4	Chamex bag for electrode 4 x 6 cm	100.657
	4	Chamex bag for electrode 8 x 12 cm	100.659
	4	Adhesive electrode, 2,5 x 5 cm	326.810
	4	Adhesive electrode, 5 x 5 cm	326.821
	4	Adhesive electrode, 5 x 10 cm	326.832
	4	Adhesive electrode round, 3 cm diameter	326.799
	1	Pin electrode 15 mm diameter with grip and sponge	114.142
	10	EL sponges for pin electrode	109.944

Advice: Replace the electrode material at least every 6 months.

7.9.2 Optional accessories ultrasound therapy

	Quantity	Description	Art. no.
	1	US head, multi-frequency,1/3 MHz - ERA 1 cm^2, incl. holder[1]	323.595
	1	Contact gel, can 5 l	100.019
	1	Pump for can, 5 l	100.020

1 Standard for Pulson 400, optional for Combi 400.

7.9.3 Optional accessories laser therapy

	Quantity	Description	Art. no.
	1	Mono400, monoprobe, incl. holder	340.252
	1	Quad400, clusterprobe, incl. holder	340.263
	1	Laser goggles I 800-1000 L2	111.890
	1	Remote interlock for laser	116.227

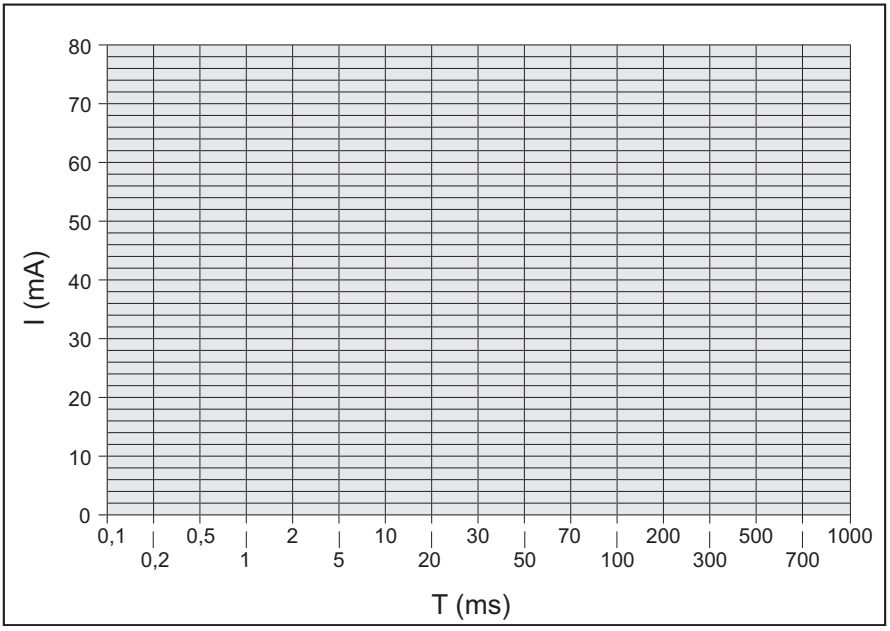
8 APPENDICES

8.1 Agents for iontophoresis

Agent	Property	Application and form
Calcium (+)	Analgeticum and sedative	Application: post-traumatic pain, distorsion, algodistrophic syndromes and neuralgia. Form: 2% calcium chloride solution.
Magnesium (+)	Analgeticum and fibrolyticum	Applications as with calcium. 10% magnesium chloride solution.
Iodine (-)	Sclerolyticum	Application: stubborn scars, cutaneous adherences, sickness of Dupuytren, stiffness of joints and adhesive capsulitis. Form: 1-2% potassium iodine solution
Salicylate (-)	Anti-inflammation agent	Application: periphlebitis, osteoarthritis, ab-articular rheumatism, articulary stiffness and adhesive capsulitis. Form: 2% sodium salicylate solution.
Procaine and lidocaine (+)	Anti-inflammation agent	Application: production of local anaesthesia, in the neuralgia of the trigeminal nerve, e.g. with acute inflammation. Form: 2% solution.
Histamine (+)	Revulsive and vasodilator	Application: degenerative and articulary rheumatic pains, such as cramp. **Maximum duration of iontophoresis: 3 min.** Longer treatment causes allergic reactions and cephalgia. Form: 0,02% bicarbonate solution.
Coltramyl (+)	Myorelaxant	Application: contractures. Form: solutions up to 0,04%. 2 ml coltramyl (4mg/ampoule), to be dissolved in 8 ml distilled water.
Indocid (-)	A.I.N.S.	Application: inflammatory illnesses. Form: 1% solution. 50 mg freeze-dried powder, to be dissolved in 5 ml distilled water.
Voltaren (-)	A.I.N.S.	Application: inflammatory illnesses. Form: 0,75% solution. 3 ml (75 mg/ampoule), to be dissolved in 7 ml distilled water.
Acetic acid	A.I.N.S.	Application: To dissolve deposition layers caused by ossifying myositis and periarticular ossification. Form: 2% water solution.

8.2 Diagnostic S-D curve

Physiotherapist:	Date of investigation:
Name of patient:	Date of birth: M/F
Anamnesis:	
Evaluation (neuro-muscular):	Accommodation Quotient:
Rheobase: mA	Chronaxie: ms
Conclusion:	
Treatment:	



8.3 Electrode, US head and laser probe placements

Select the therapy via indication list to get information about the placement. *See §4.3.1*.

8.3.1 Electro therapy

Select the electrode placement button to show the optimal location for the placement of the electrodes.

The description next to the illustration gives information to the precise anatomic location. The description of the location is often explained with the abbreviations:

pnp	peripheral nerve point	snp	skin nerve point
mnp	motor nerve point	mtp	myofascial trigger point
n	nerve	nn	nervi
m	muscle	mm	musculi
r	ramus	rr	rami

8.3.2 Iontophoresis

Press the electrode placement button to show the iontophoresis treatment method on screen.

8.3.3 Ultrasound therapy

Select the electrode placement button to show the optimal location for the placement of the US head.

8.3.4 Combination Therapy

The electrode placement button for combination therapy shows the US head placement. The electrode is not shown in the illustration. Place the electrode near to the US head.

8.3.5 Laser therapy

Select the electrode placement button to show the optimal location for the placement of the laser probe.

8.4 EMC directive

Use only cables, electrodes and US heads that are specified in this manual. See *§7*. The use of other accessories can have a negative effect on the electromagnetic compatibility of the equipment.
If you use the 400-Series in the vicinity of other equipment, you must check that the 400-Series is functioning normally.
The following paragraphs contain information about the EMC properties of the equipment. Because this information is intended for technicians, the information is given in English.

8.4.1 Guidance and declarations

Guidance and manufacturer's declaration - electromagnetic emissions		
The 400-Series devices are intended for use in the electromagnetic environment specified below. The customer or the user of a 400-Series device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The 400-Series devices use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class B	The 400-series devices are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-3	Class B	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The 400-Series devices are intended for use in the electromagnetic environment specified below. The customer or the user of a 400-Series device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact / ± 8 kV air No loss of performance	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV power / ± 1 kV I/O No loss of performance	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV diff. / ± 2 kV comm. No loss of performance	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity			
The 400-Series devices are intended for use in the electromagnetic environment specified below. The customer or the user of a 400-Series device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	U_T - 100% (0,5 period) No loss of performance U_T - 60% (5 periods) No loss of performance U_T - 30% (25 periods) No loss of performance U_T - 100% (5 seconds) Device resets to a safe state. (60601-1 § 49.2)	Mains power quality should be that of a typical commercial or hospital environment. If the user of a 400-Series device requires continued operation during power mains interruptions, it is recommended that the 400-Series device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration - electromagnetic immunity			
The 400-Series devices are intended for use in the electromagnetic environment specified below. The customer or the user of a 400-Series device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of a 400-Series device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 V_{rms} AM 1 kHz 80% 150 kHz to 80 MHz	10 V.....0,15-80 Mhz 51 V.....6,78 Mhz 54 V.....13,56 Mhz 50 V.....27,12 Mhz 45 V.....40,68 Mhz	$d = 0{,}35\sqrt{P}$ $d = 0{,}07\sqrt{P}$ $d = 0{,}06\sqrt{P}$ $d = 0{,}07\sqrt{P}$ $d = 0{,}08\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m AM 1 kHz 80% 80 MHz to 2,5 GHz	10 V/m..0,08-1,0 Ghz 26 V/m....1,4-2,0 Ghz 30 V/m...433,92 Mhz 30 V/m.....915 Mhz	$d = 0{,}35\sqrt{P}$ 80 MHz to 800 MHz $d = 0{,}70\sqrt{P}$ 800 MHz to 2,5 GHz $d = 0{,}12\sqrt{P}$ $d = 0{,}23\sqrt{P}$
Radiated RF ENV 50204	3 V/m CW 200 Hz d.c. 50% 895 MHz to 905 MHz	30 V/m.895-905 Mhz	$d = 0{,}23\sqrt{P}$
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and manufacturer's declaration - electromagnetic immunity			
The 400-Series devices are intended for use in the electromagnetic environment specified below. The customer or the user of a 400-Series device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey can be considered. If the measured field strength in the location in which a 400-series device is used exceeds the applicable RF compliance level above, the 400-series devices should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 400-series device. b. Over the frequency range 150 kHz to 80 MHz, field strengths must be less than 10 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the 400-series device			
The 400-Series device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of a 400-Series device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 400-Series devices as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 0,35\sqrt{P}$	80 MHz to 800 MHz $d = 0,35\sqrt{P}$	800 MHz to 2,5 GHz $d = 0,70\sqrt{P}$
0,01	0,04	0,04	0,07
0,1	0,11	0,11	0,22
1	0,35	0,35	0,70
10	1,11	1,11	2,21
100	3,50	3,50	7,00
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

8.5 Technical safety inspection

400-Series with serial number ..... is / is not[1] in good working order		
	Inspection performed by:	Owner:
Location:	Name:	Name:
Date:	Initials:	Initials:

1 Cross out what does not apply.

If a specific test does not apply to this equipment, place a mark in the NA (not applicable) column.

8.5.1 Test 1: General

		Yes	No	NA
1.	The results of earlier safety inspections are available.	☐	☐	☐
2.	The logbook is present.	☐	☐	☐
3.	The type plate and the supplier's label are legible.	☐	☐	☐
4.	The housing, adjusting knobs, keys and display are undamaged.	☐	☐	☐
5.	The power connection and power cord are undamaged.	☐	☐	☐
6.	The output connectors are undamaged.	☐	☐	☐
7.	The electrode connectors and cables are undamaged.	☐	☐	☐
8.	The cables and connectors of the US head(s) are undamaged.	☐	☐	☐
9.	The US head(s) do not display any cracks or other damage that can endanger the insulation.	☐	☐	☐
10.	The automatic self-test at switch-on does not give an error message.	☐	☐	☐
11.	The display does not show any defective points or lines.	☐	☐	☐

8.5.2 Test 2: Electro therapy

		Yes	No
1.	Connect loads of 500 Ω to both normal electrode pairs. Connect an oscilloscope to these pairs (black to ground).		
2.	Select channel A, program 138: galvanic, CC.		
3.	At maximum intensity, the output currents corresponds within 10% with the values on the display.	☐	☐
4.	The output signals correspond with figure 1.	☐	☐
5.	The polarity changes to negative if RED(-) is selected.	☐	☐
6.	The warning "Bad contact with the patient" is given if the load is disconnected.	☐	☐
7.	Select channel B, program 4: MF constant. Select CC.		
8.	At maximum intensity, the output currents correspond within 10% with the values on the display.	☐	☐
9.	The output signals correspond with Figure 1.	☐	☐
10.	The polarity changes to negative if RED(-) is selected.	☐	☐
11.	The warning "Insufficient contact with the patient" is given if the load is disconnected.	☐	☐
12.	Remove the load, so that the unloaded output voltage can be measured.		
13.	Select channel A, program 24: diadynamic, CC.		
14.	At maximum intensity, the output voltage corresponds within 10% with the values on the display.	☐	☐
15.	The output waveform corresponds with Figure 2 and Figure 3.	☐	☐
16.	The polarity changes to negative if RED(-) is selected.	☐	☐
17.	The warning "Insufficient contact with the patient" is given if the load is disconnected.	☐	☐
18.	Select channel B, program 24: diadynamic, CC.	☐	☐
19.	At maximum intensity, the output voltage corresponds within 10% with the values on the display.	☐	☐
20.	The output signals correspond with Figure 2 and Figure 3.	☐	☐

	Yes	No
21. The polarity changes to negative if RED(-) is selected.	☐	☐
22. The warning "Insufficient contact with the patient" is given if the load is disconnected.	☐	☐

Figure 1

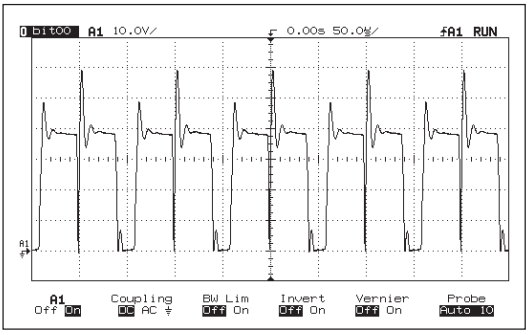


Figure 2

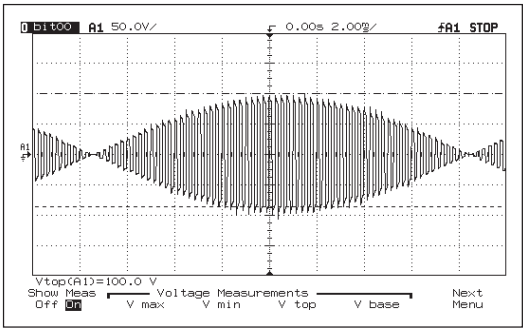
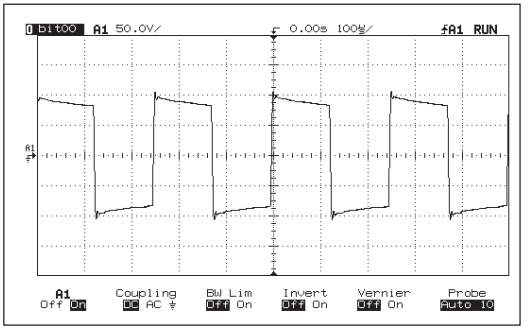


Figure 3



8.5.3 Test 3: Ultrasound

		Yes	No
1.	Connect the treatment head and place it in an ultrasound measurement device. Select an ultrasound therapy.		
2.	Select 1 MHz, continuous (duty cycle 100%), 2 W/cm^2 The measured value is within ±20% of the P_{pk} value in the channel window.	☐	☐
3.	Select 1 MHz, duty cycle 50%, 3 W/cm^2 The measured value is within ±20% of half the P_{pk} value in the channel window.	☐	☐
4.	Select 3 MHz, continuous (duty cycle 100%), 2 W/cm^2 The measured value is within ±20% of the P_{pk} value in the channel window.	☐	☐
5.	Select 3 MHz, duty cycle 50%, 3 W/cm^2 The measured value is ±20% of half the P_{pk} value in the channel window.	☐	☐
6.	Select 3 MHz, duty cycle 50%, 0.5 W/cm^2 With a dry treatment surface, the P_{pk} value becomes 0.	☐	☐
7.	Select 1 MHz, duty cycle 50%, 0.5 W/cm^2 With a dry treatment surface, the P_{pk} value becomes 0.	☐	☐

The maximum power transfer takes place at the operating frequencies. If the equipment does not function at the correct frequency, this results in a too low output power. It is therefore not necessary to check the operating frequencies.

8.5.4 Test 4: Laser therapy

Start a laser therapy only when all persons in the room wear laser goggles for eye protection.

Use for test A and B a laser radiation measurement device with the following specifications:

- The resolution of the measured energy per pulse value is: ≤ 0,1 µJ.
- The wavelength range is: 900 - 910 nm.
- The capability to measure: 200 ns pulses of 30 W_{pk}.
- Capable of capturing a divergent beam with a diameter: ≥ 10 mm.
- Tolerance: ≤ 10%.

	Test A: The monoprobe	Yes	No
1.	Connect the monoprobe to the 400-Series. *See §4.6.2.*		
2.	Select a laser therapy. The green indicator light lights up.	☐	☐

	Test A: The monoprobe	**Yes**	**No**
3.	Press the black knob on the laser probe. The yellow indicator light lights up and the green indicator light goes out.	☐	☐
4.	Release the black knob. The green indicator light lights up and the yellow indicator light goes out.	☐	☐
5.	Start the laser therapy to measure the E_p value with the laser radiation measurement device. The measured E_p value is .....µJ.		
6.	The measured E_p value corresponds within ±20% with the E_p value of the test protocol of the laser probe.	☐	☐

	Test B: The clusterprobe	**Yes**	**No**
1.	Connect the clusterprobe to the 400-Series. *See §4.6.2.*		
2.	Select a laser therapy. The green indicator light lights up.	☐	☐
3.	Press the black knob on the laser probe. The yellow indicator light lights up and the green indicator light goes out.	☐	☐
4.	Release the black knob. The green indicator light lights up and the yellow indicator light goes out.	☐	☐
5.	Start the laser therapy to measure the E_p values with the laser radiation measurement device. The measured E_p value from laser diode 1 is .....µJ. The measured E_p value from laser diode 2 is .....µJ. The measured E_p value from laser diode 3 is .....µJ. The measured E_p value from laser diode 4 is .....µJ. Stop the laser therapy. The sum of the four measured E_p value is .....µJ.		
6.	The sum of the measured E_p values corresponds within ±20% with the total E_p value of the test protocol of the laser probe.	☐	☐

	Test C: Calibration of the laser test eye	**Yes**	**No**
1.	Connect a calibrated monoprobe to the 400-Series. *See §4.6.2.*		
2.	Select: System settings, Accessories test and Laser energy measurement. *See §4.10.8.*		

Test C: Calibration of the laser test eye	Yes	No
3. Place the laser probe output perpendicular on the laser test eye ✹⊣. Start the laser energy measurement. Move the probe a bit to-and-fro to obtain the maximum value. The measured E_p value is .....µJ. Stop the laser energy measurement.		
4. The measured E_p value corresponds within ±5% with the E_p value of the calibrated laser probe.	☐	☐
5. If not, contact the service department of your local dealer.		

8.5.5 Test 5: Electrical safety test (VDE 0751-01)

	Yes	No
1. The resistance of the safety earth is less than 0.2 Ω	☐	☐
2. The housing leakage current is less than 1000 µA	☐	☐
3. The patient leakage current is less than 5000 µA	☐	☐

Notes:

8.6 Disposal

Take account of the following environmental aspects when disposing of the equipment and the accessories:

- The basic device, the cables and the electrodes fall under small chemical waste (electrical and electronic equipment waste). These components contain lead, tin, copper, iron, various other metals and various plastics, etc. Dispose according to national regulations.
- Sponges, sponge bags and gels contain only organic material and do not require any special processing.
- Packaging materials and manuals can be recycled. Deliver them to the appropriate collection points or include them with the normal household waste. This depends on the local organisation of the waste processing.

Notify your dealer about the disposal.

9 REFERENCE

9.1 Literature

A literature list can be sent on request. Please contact GymnaUniphy.

9.2 Terminology

absolute muscle power: The maximum total tension that a muscle can produce.

accomodation: The ability of the nerve tissue to protect itself against stimulations that slowly increase in strength.

Pulse time	Delay in action potential of rectangular pulse: triangular pulse	Accomodation Quotient (AQ)
500 ms	1:1.5 to 1:3	1,5 - 4
1000 ms	1:2 to 1:6	2 - 6

active trigger point: A point that, with stimulation (pressure, stretch or electrical pulse), besides the local pain also generates a projected pain in the area that the patient is complaining about.

antalgic: The pain is reducing.

atrophy: Deterioration in the nourishment state of organs. As a result, the organs become smaller or shrink.

chronaxie: The time threshold that is required for a muscle contraction or a sensory impression, after the occurrence of the necessary minimum required stimulation.

denervation: Switching-off or weakening of the innervation (paralysis).

durability: Being able to frequently repeat a muscle contraction.

epithelisation: Recovery of the epithelium over the bottom of the wound. A unidirectional current can stimulate the epithelisation. Epithelisation can also be activated by an external electrical stimulation.

explosive muscle power: The highest tension that a muscle can produce in the shortest possible time.

HAC®: Hospital Antiseptic Concentrate (0,5% chlorhexidine, 0,5% cetrimide).

hyperalgesia: An increased sensitiveness for pain. Apply a modified dosage in the case of acute hyperalgesia.

injury current: A small unidirectional current between the epidermis and the corium, which occurs after a wound. This current activates the recovery process. With a slow recovery process, an external unidirectional current can be applied to realise the same effect.

innervation: The effect of the nerves on the working of the muscles or glands.

iontophoresis: The flow of ions through a tissue by means of a galvanic current.

isometric contraction: A muscle contraction whereby the length of the muscle remains constant. The external resistance of the muscle must be at least as large as the power that is generated by the contraction. Under isometric circumstances, especially the tension in the muscle increases and muscle cramp is avoided.

loadability: The (maximum) load that can be carried.

loss of muscle tone: The state of tension of muscles reduces.

Myofascial Trigger Point (MTP): A trigger point that is located in the myofascial tissue. The MTP is located in a hard cord of a muscle. The MTPs can be localised with Pain points in the Diagnostics.

Neuro Muscular Electro Stimulation (NMES): Contraction of an innervated muscle or muscle group by means of low or medium frequency electrostimulation. The purpose of NMES is to improve or maintain the movement.

pain threshold: The lowest level of stimulation that causes pain.

pain tolerance threshold: The level of stimulation that can just be tolerated by the patient. The pain tolerance threshold is past the pain threshold.

re-innervation: The restoration of the innervation.

responsiveness: The degree to which a tissue or organ reacts to a stimulation. With a high responsiveness, a mild treatment is desired. With a low responsiveness, a more intensive treatment can be desired. Make a good estimate of the responsiveness to determine the correct dosage.

rheobase: The minimum galvanic current strength required with the stimulation of the nerve to cause a muscle contraction.

sclerolysis: The solution of a hardening of the tissue. The tissue can be chemically and electrically softened with a cathode in combination with chlorine or iodine.

skin etching: Electro-chemical reactions that can be threatening for tissues and organs, especially for the skin. With correct application, a desired effect occurs, for example improvement of the circulation. Skin etching occurs with current shapes that have a direct current component.

slow twitch muscle fibre: Muscle fibres with a low contraction speed. The fibres are fairly thin, produce a small amount of power and have a low fatigue level. See also type I muscle tissue.

tetanic contraction: A persistent muscle contraction, on the basis of several contraction waves that are simultaneously in a muscle. You can cause tetanic contractions with an NMES surge current.

tone: The tension state of tissues.

trophic: The state of nourishment.

type I muscle tissue: Muscle tissue with a low contraction speed.

type II muscle tissue: Muscle tissue with a high contraction speed. Set the parameters as follows for stimulation with NMES:

NMES parameter	**type I**	**type II**
Pulse time	Long	Short
Pulse frequency	Low	High
Pulse amplitude	-	High

NMES parameter	type I	type II
Series duration and series pause	Short	Long
Treatment time	Long	-

VAS score: Score on the Visual Analogue Scale (VAS). Tool for evaluating a clinical complaint from the patient. This usually concerns the degree to which pain is felt. With a high VAS score, a mild treatment is usually adequate. With a lower VAS score, a more intensive treatment is desired.

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