User Manual

Combi 400
Duo 400
Pulson 400
Vaco 400

CE 0344

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Abbreviations

General

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
H.A.C.	Hospital Antiseptic Concentrate. See § 9.2.
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

User manual 400-Series

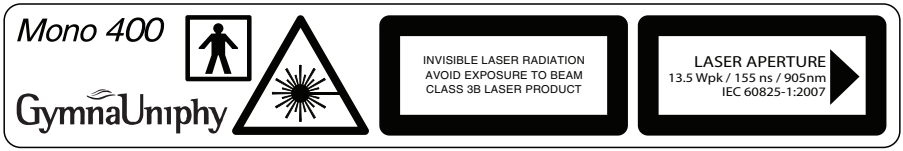
Devices for electrotherapy, ultrasound therapy, combination therapy and laser therapy with integrated GTS functionality GTS.

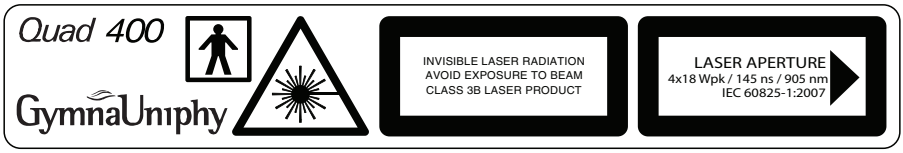
	Electro therapy	Ultrasound therapy	Combination therapy	Laser therapy	Vacuum (optional)
					
Combi 400	x	x	x	x	x
Duo 400	x				x
Pulson 400		x			

Symbols on the equipment and accessories

	Manufacturer
	Date of manufacturing and country of origin (Slovakia)
	CE mark with identification number of the notified body
	Serial number
	Do not dispose of this electrical equipment in domestic waste!
	Caution
	Applied part type BF
	Consult and observe the instructions for use (manual)
	Class II
	Earth
	Laser warning sign
	Points to laser aperture and shows direction of beam
	You must wear protective goggles

Label on laserprobe





Symbols in the manual

	Warning or important information.
	ET symbol: only for devices with electrotherapy applications, Combi400, Duo400.
	US symbol: only for devices with ultrasound applications, Combi400, Pulson400.
	LA symbol: only for devices with laser applications, Combi400.
	Vaco symbol: only for devices that can work with the vacuum unit, Combi400, Duo400
	CO symbol: only for devices with combined ultrasound and electrotherapy applications, Combi400

Contents

1. Safety

1.1 General

1.1.1 Intended use

This 400 series is intended for electrotherapy goals: symptomatic pain relief, muscle stimulation, eliciting cellular effects, and S/D curve diagnostics.

Together with these possibilities the 400 series gives the user a variety of additional therapy forms as ultrasound therapy, combination therapy, laser therapy.

The intended users are physiotherapists; physiotherapist assistants, physiotherapy students, nurses and medical degree doctors who have the "legal" competence in their own country in order to use it.

The intended patients to be treated are:

- All patients suffering from neurological and/or musculoskeletal conditions and skin lesions, on anatomical locations as defined in the indications list.
- All patients with chronic pain of non-recoverable nature.
- All patients with a need for muscle diagnosis and muscle stimulation.

This device has been designed to be used in the framework of professional healthcare activities in environments like sport facilities, hosptals excluding OR and surgeries in residential area.

1.1.2 Principle of Operation

General

The device is a table top, mains powered electrical equipment of protection class II with functional earth. It is MDD risk class IIa and all applied parts are of type BF. It has a plastic enclosure which contains all modules except the detachable component Vaco 400 on which the main unit can be stacked. Use of a 100-240 Vac all range power supply avoids the need for a voltage selector. It supplies all other modules with a well regulated low voltage DC current.

User Interface module

The user interface consists of a 10.4" TFT full color graphic LCD with touch screen on which the various buttons can be found to operate the equipment. There are two rotaries at the bottom of it for direct control of the output currents and/or the ultrasound beam intensity depending on the selected operating mode. It is driven by a microcomputer that runs the proprietary software for the device under an operating system. This software can be updated with a memory stick plugged into the USB connector at the back that contains the

update software. This should only be done when no patient is being treated.

Because of the flexibility of the graphic LCD it is also used for displaying selection lists, explanatory texts, stored programs, patient data like S/D curves and so on. The used language can be chosen by the user as can be many other behavioral properties. When needed for data input a keyboard is displayed, configured for the selected language. See § 4 for all details of the user interface.

The microcomputer translates the settings and commands by the user into messages to the function modules to have them perform the required task with the proper parameters. It receives feedback from the modules about their current status and possible conflicts or errors. Where relevant these are processed for display on the screen. Using function modules with their own microcontrollers is necessary because the operating system of the microcomputer for the user interface is not capable to provide the timing accuracy needed.

Electrotherapy module

Using a microcontroller and two digital to analog converters two currents are generated which are amplified and fed to the patient across an isolation to obtain floating patient currents. For the so called unipolar currents, not crossing the zero level, the floating current is rectified first. Amplitude, polarity, pulse width, pulse repetition frequency and envelope can all be adjusted within the allowed ranges. The currents can operate independently or synchronized to obtain so called vector field currents by interference. Using the generator as current source, Constant Current, has the advantage the impedance in the patient circuit has almost no influence on the magnitude. Using it as imperfect voltage source, Constant Voltage, has the advantage that no current spikes will occur during short interruptions of the patient circuit due to e.g. movement of the ultrasound head during combination therapy. The term constant voltage is a bit misleading though. It will drop when the load impedance lowers and the current rises. The circuit is dimensioned in such a way that the output current in mA is equal to the set value in Volts when the load reaches zero Ω.

For high voltage and micro-current the user has no choice of the source type. As the names of the current types suggest this is always CV and CC respectively.

One terminal of patient circuit A can be routed to the treatment surface of the ultrasound head to act as electrode for combination therapy. This is always the negative pole to prevent metal ions migrating from the treatment surface into the body of the patient. Of course it is always possible to direct a current through a tissue whilst exposing it to ultrasound. This avoids the polarity and contact issues and the limitation of available current modes for combination therapy. An interesting variant is selecting one of the 2-channel interferential current modes on channel A and select ultrasound for channel B. The ultrasound head can then be used to irradiate the tissue area where the two currents interfere.

Ultrasound module

The local microprocessor sets the frequency of an oscillator and the supply voltage of the power stage driven by it. The actual values depend on the required operating parameters and the properties of the connected ultrasound head. These properties are collected from the head actually connected so the heads are exchangeable between units. The resulting RF voltage is fed to the selected head of the possible connected two. A piezo transducer converts the RF voltage into ultrasound waves which are conducted into the patient's tissue by the treatment surface. A sufficient amount of coupling gel between the surface and the skin is needed for good acoustic coupling. When there is no or too poor contact this is detected. The RF voltage is switched to CW modulation with a very low duty cycle ratio until the contact is restored. This is needed to prevent overheating of the surface by the ultrasound power not being absorbed by the tissue. Apart from continuous ultrasound a CW modulation with several duty cycle ratios can also be selected at a fixed frequency of 100 Hz.

Although there can be two ultrasound treatment heads plugged in only one of them can be used at a time. This because there are two sizes available and the user can select the appropriate size without having to unplug the head with the unwanted size and plug the other one in.

Laser module

The microcomputer of the user interface handles the safety lock for activating the laser function. The local microprocessor applies power to the supply and control terminals of the laser connector only when instructed to do so by the user interface software and a laser probe is connected. The only terminal always active is the laser probe identification pin. Otherwise the user interface software would not know whether a laser probe is connected or not and show this on the LCD. Once the probe is switched on the green stand by light turns on which makes the button on the probe active. Pressing it switches the stand by light off and the yellow active light on. This is detected by the microcontroller which starts two seconds later sending trigger pulses with the required repetition frequency to the output circuit in the laser probe. There is a safety guard by blocking the pulses when the button is not pressed. A capacitor is discharged through a/the laser diode(s) emitting an invisible infrared laser beam during the pulse. Afterwards the capacitor is recharged.

The duration of the laser pulse depends on the properties of the laser diode(s), the voltage to which the capacitor is charged and its capacitance. This is factory adjusted so all pulses are always the same and the only variable is the repetition frequency. Because the energy of each pulse is identical the user interface software can calculate the total amount of energy from the chosen frequency and treatment duration.

There are two models of laser treatment heads a.k.a. probes available. See § 7.5

for the specifications. Unlike the ultrasound treatment heads only one of them can be connected at a time.

Next to the connector for the laser is an opening behind which sits a light detector. It can be used to measure energy of the pulse emitted by the laser diode. For the cluster probe one must measure each diode separately and calculate the total after all four values are captured. Because the laser beams are very divergent it is most important to keep the probe perpendicular to the front of the main unit and in the center of the opening.

One can insert a remote interlock between the connector for the laser probe and its plug. It has a fully isolated detection circuit. The end of its cable should be connected to a switch or switches in series on the door(s) of the therapy room. The/each switch must be open when the door is open and closed when the door is closed. When the detection circuit is open the button pressed signal and trigger pulses are blocked and the laser probe is deactivated and the user interface knows the treatment is interrupted. When the detection circuit is closed the signals are passed on and everything functions as normal.

Vaco 400 component

This contains a regulated vacuum system. A water container traps the water droplets sucked in with the air passing through the moisturized sponge pads in the suction cups. The patient current flows through a wire in the hoses between the outlet posts and the cups. The level of the vacuum and, when pulsed vacuum is chosen, the duty-cycle and additional deepness of the vacuum is controlled via the user interface of the main device which also provides the DC supply voltage. When the treatment time has elapsed the vacuum is reduced to the minimum level or completely turned off depending on the system setting. When only one channel is used with vacuum the cups of the other channel must be placed on a flat surface or its outlet posts connected to each other with a hose. Shutter valves are not used as those tend to get clogged by dirt.

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.
- Only treat patients with electrical implants (pacemaker) after obtaining medical advice.
- The 'Directive on Medical Devices' from the European Commission 93/42/EEC, requires medical devices to be safe. Therefore it is recommended to perform each year a technical safety inspection. See § 5.1.2.
- 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 a protective 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 § 7.8 and § 7.9.
- Other accessories can lead to an increased emission or a reduced immunity.

1.2.5 Electro therapy

- Simultaneous connection of a patient to a h.f. surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- 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 week. See § 4.10.5.
- The safety standards for electrical stimulation advise not to exceed the current density of 2.0 mA_{rms}/cm^2. Current densities for any electrodes exceeding 2.0 mA_{rms}/cm^2 may require the special attention of the USER.

- However, with iontophoresis treatments, we advise a maximum current density of 0.25 mA_{rms}/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 § 5.1.1.
- 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.
- Performing underwater ultrasound treatments is not recommended due to a possible danger of reflected ultrasound on the hand of the therapist.

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 specification 880-1080 I LB2 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.
- Regularly 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. After starting a non-laser therapy the laser function will be locked again automatic.

1.3 Contraindications CI

Treatments should not be given to patients with the listed conditions:

1.3.1 Electrotherapy

General

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

Specific absolute

- On demand pacemakers

Specific relative for monophasic pulses

- Skin lesions
- Skin infections
- Thrombosis, thrombophlebitis
- Varices

- Epiphyseal disc (children)
- Bleeding tissue and increased risk to haemorrhage
- Superficially implanted materials
- Heart disease, rhythm disorder
- Epilepsy (avoid neck electrode positions)
- Decreased sensibility (patient not able to give feedback)
- Electrode positions near sinus caroticus
- Menses
- Pregnancy (not in the vicinity of the foetus, avoid trunk electrode positions)

Specific relative for biphasic pulses

- Skin infections
- Thrombosis, thrombophlebitis
- Epiphyseal disc (children)
- Bleeding tissue and increased risk to haemorrhage
- Heart disease, rhythm disorder
- Epilepsy (avoid neck electrode positions)
- Decreased sensibility (patient not able to give feedback)
- Electrode positions near sinus caroticus
- Pregnancy (not in the vicinity of the foetus, avoid trunk electrode positions)

1.3.2 Ultrasound therapy

General

- High fever
- Pacemaker (no US head positions in the vicinity of the pacemaker)
- Severe cardiovascular problems
- Psychological problems
- Cancer with tumor metastasis
- Generalised tuberculosis
- Eyes and testis
- Pregnancy (not in the vicinity of the foetus, avoid trunk US head positions)

Specific relative for continuous ultrasound

- Infections
- Acute inflammations
- Thrombosis, thrombophlebitis
- Varices
- Bleeding tissue and increased risk to haemorrhage
- Epiphyseal disc (children)
- Decreased sensibility
- Metal implants
- Menses
- Cement of endoprosthesis
- Diabetes mellitus

1.3.3 Combination therapy

See Contraindications Electro therapy (§ 1.3.1) and Ultrasound therapy (§ 1.3.2).

1.3.4 Laser therapy

General

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

Specific absolute

- Eyes (looking into the laser beam) and testis
- Thyroid gland (local applications)
- Bleeding tissue and increased risk to haemorrhage
- Hypertrophic scars
- Pregnancy (not in the vicinity of the foetus)
- Photo-allergy

1.3.5 Vacuum therapy 

- All contraindications from electro therapy
- Internal infections
- Hemorrhagic risk in the part of the body where the electrodes are placed

1.3.6 Conformity with directives

The Gymna 400 series complies with the requirements of directive 93/42/EEC on medical devices (MDD), directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2) and directive 2002/96/EC on waste electrical and electronic equipment (WEEE).

The device contains no human or animal tissue, no medicinal substances, no blood or blood products from human or animal origin, no latex, no DHEP, and no radioactive substances. It is not intended to administer or transport body fluids.

1.3.7 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

Procedure

1. Check that the equipment was not damaged during transport.
2. Check that the accessories are intact and complete. See § 7.8.
3. 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.

Warning:

Do not use the equipment if it is damaged or defective.

2.2 Placing and connection

Procedure

1. Place the equipment on a horizontal and stable base.

Warning:

- 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 a protective earth terminal.

2.3 Place the Vaco 400 underneath Combi- or Duo 400

The Vaco 400 is designed to be placed underneath a 400-Series device.

See § 3.5.

Procedure

1. Connect the 5-pin connection cable (12)
2. Connect the 6-pin connection cable (11).
3. When used in combination with the Combi400, mount the Ultrasound Head holder underneath the Vaco400, instead of the Combi400.
4. When using the accessory Gymna mobile 400 see § 7.9.5.

2.4 Use in combination with another device

The Vaco400 can only be used in in combination with:

- The Combi400
- The Duo400

2.5 Touchscreen application

The 400 series has a touchscreen. Except for the intensity knobs all settings and treatment possibilities can be selected by touching the applicable option with a fingertip.

Procedure

1. If the touchscreen does not respond correctly, calibrate the touchscreen. See § 4.10.3.

2.6 Performing the functional test

The first time you start the equipment, the set-up wizard automatically opens. See § 4.10.

Procedure

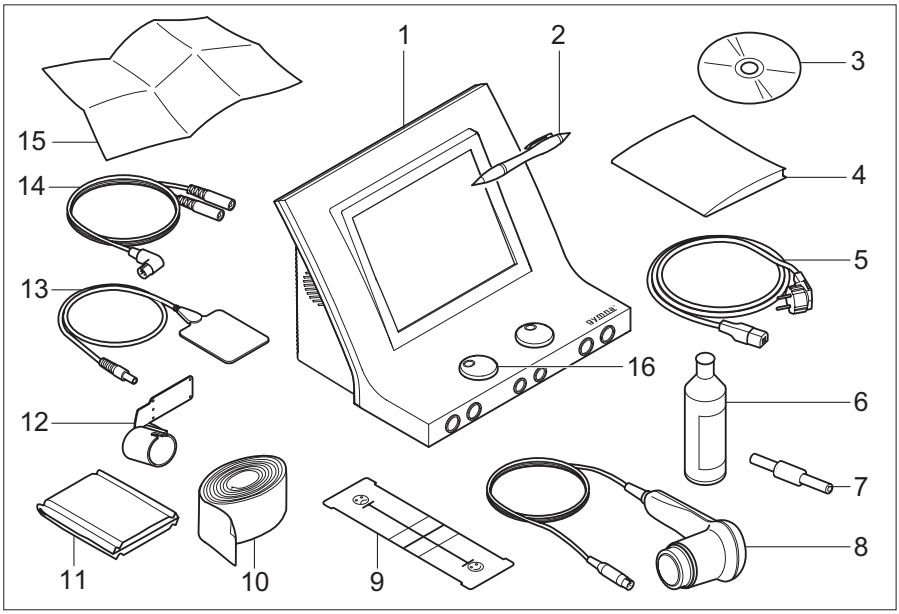
1. Switch the equipment to on with the switch at the rear of the equipment. When the equipment is switched on, it automatically performs a test.
2. If the display does not light up refer to see § 6.1.1.
3. If necessary, change to the desired language. See § 4.10.3.

2.7 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.

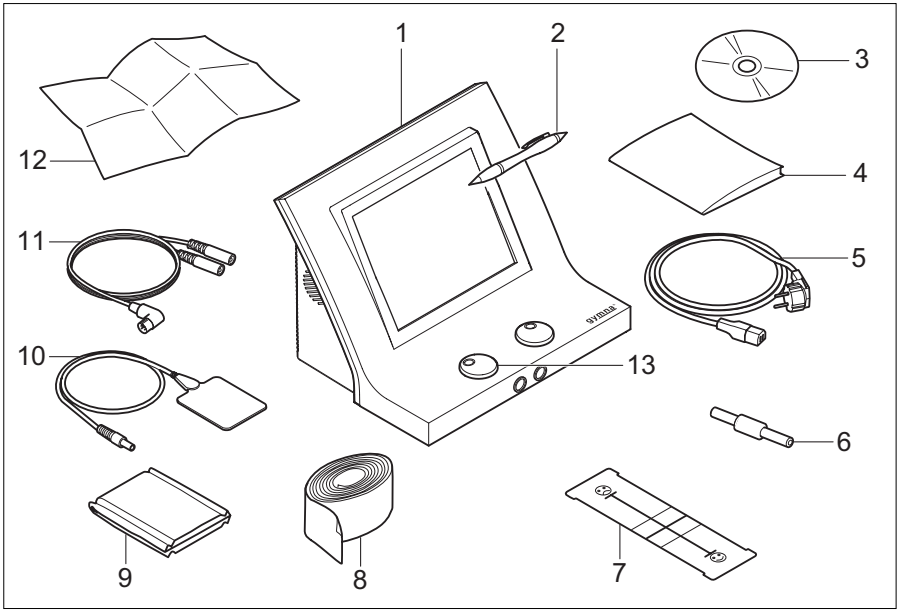
3. Description of the equipment

3.1 Combi 400 with standard accessories



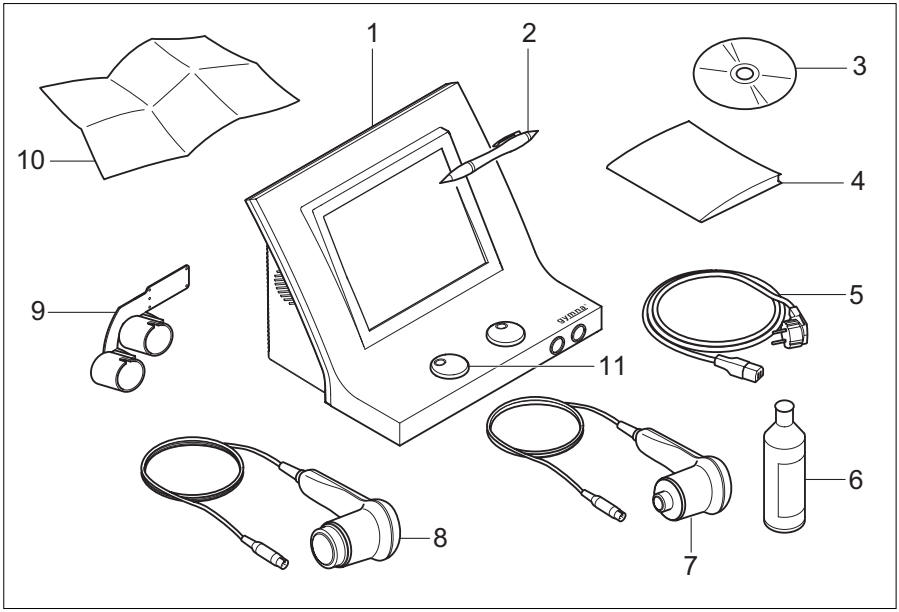
1 Combi 400. See § 3.5.
2 Touchscreen pen
3 CD-ROM User manual
4 Safety instructions
5 Power cord
6 Contact gel
7 Test plug
8 US head large incl. holder
9 VAS score card
10 Elastic fixation straps (4 pieces)
11 EL sponges for rubber electrode (4 pieces)
12 Ultrasound head holder
13 Rubber electrodes (4 pieces)
14 Two-ply electrode cable (2 pieces)
15. Quickstart guide
16 Rotary button silver See § 7.8.1.

3.2 Duo 400 with standard accessories



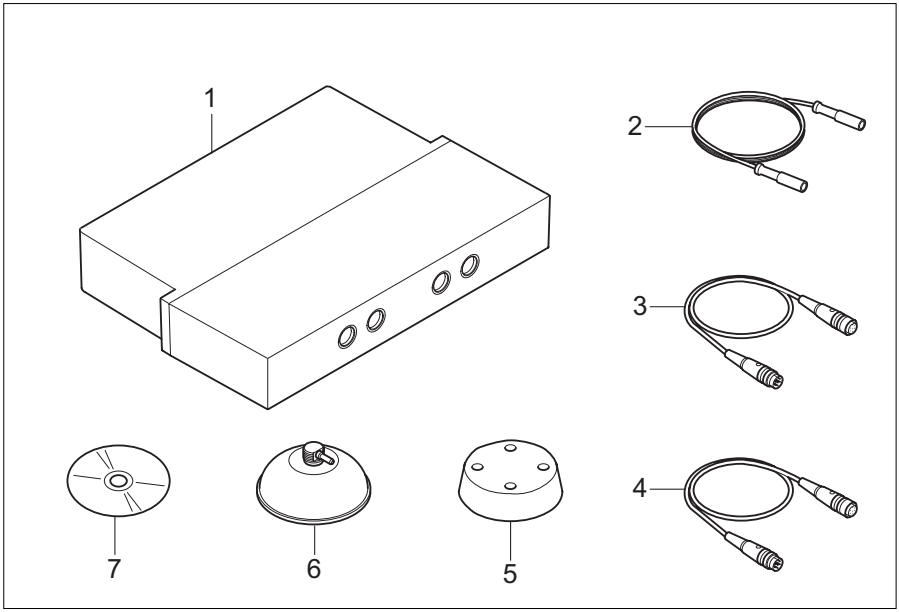
1 Duo 400.
2 Touchscreen pen
3 CD-ROM User manual
4 Safety instructions
5 Power cord
6 Test plug
7 VAS score card
8 Elastic fixation straps (4 pieces)
9 EL sponges for rubber electrode (4pieces)
10 Rubber electrodes (4 pieces)
11 Two-ply electrode cable (2 pieces)
12 Quickstart guide
13 Rotary button silver See § 7.8.1.

3.3 Pulson 400 with standard accessories



1 Pulson 400.
2 Touchscreen pen
3 CD-ROM User manual
4 Safety instructions
5 Power cord
6 Contact gel
7 US head small with holder
8 US head large with holder
9 Double ultrasound head holder
10 Quickstart guide
11 Rotary button silver See § 7.8.1.

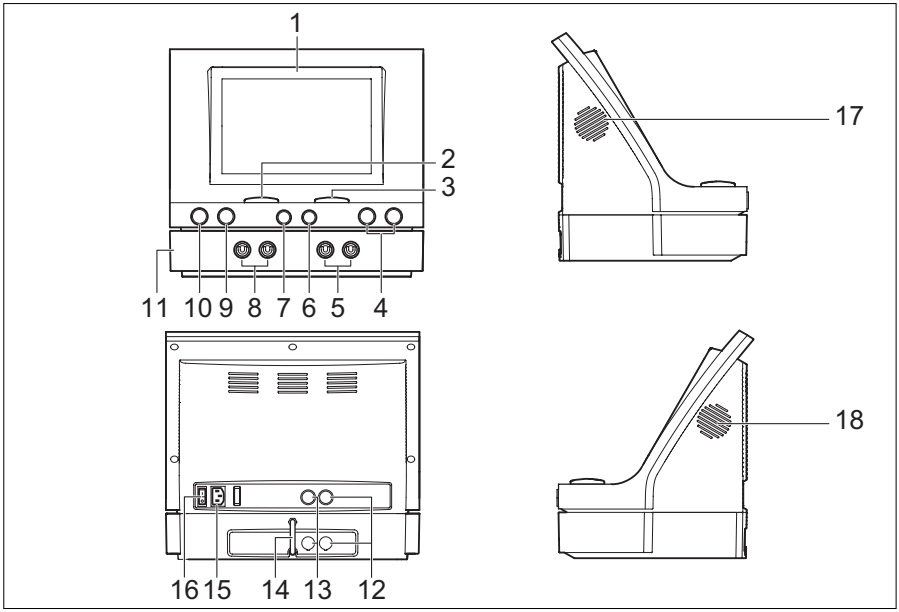
3.4 Vaco 400 with standard accessories



1 Vaco 400
2 Vacuum hose (2 x light grey, 2 x dark grey)
3 Connection cable power and communication (6-pin)
4 Connection cable electro therapy (5-pin)
5 Sponge for vacuum electrode (4 pieces)
6 Vacuum electrode (4 pieces)
7 CD-ROM User manuals

All vacuum settings and adjustments can be performed on the touchscreen of the main device. See § 4.11.

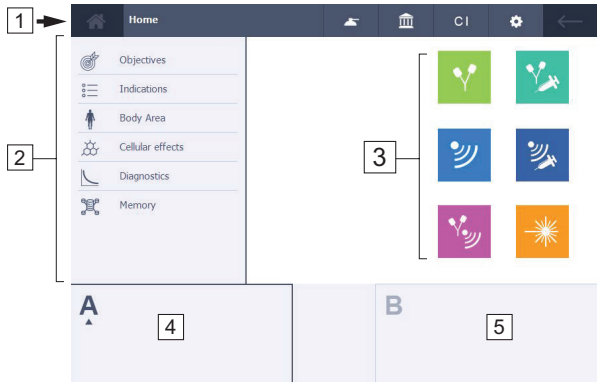
3.5 Components of the 400-Series



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 Vaco 400 unit (optional)
12 Power and communication cable between main unit and Vaco 400 option
13 Electro therapy cable between main unit and Vaco 400 option
14 Water drain hose
15 Connection to mains supply
16 On/off switch
17 Fan
18 Speaker

3.6 Display

3.6.1 Home menu



1 Screen header. See § 3.6.3.

2 Navigation area / onscreen menu entries. Submenus may appear beside this menu.

3 Direct therapy method selection See § 3.6.2.

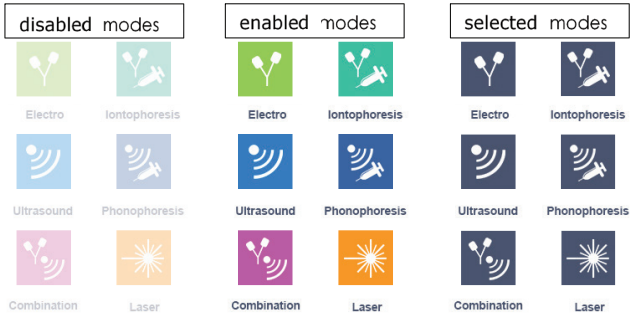
4 Output window channel A: left side (selected channel has a dark border)

5 Output window channel B: right side (the not selected channel is light blue).
The output windows are controls. Tap in the middle of an output window to select that channel.

3.6.2 Direct therapy method selection

Each therapy method key has its own fixed color settings to emphasize the color-based graphical user interface. You can choose between 'full colored' therapy icons or 'line colored' therapy icons to give the graphical user interface a personalized touch. Customizing can be performed via the System settings menu or via the setup wizard. See § 4.10.

Full colored therapy icons

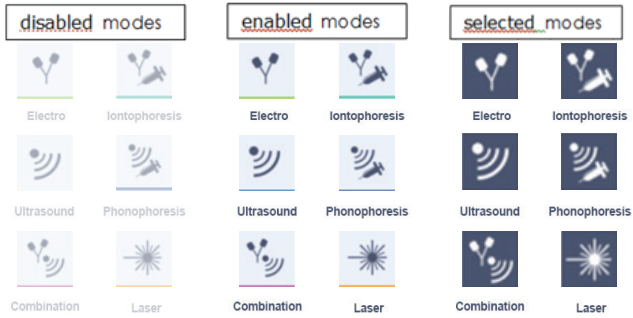


1 Disabled modes. Keys do have a high gradient transparency.

2 Enabled modes

3 Selected modes. Key is colored dark blue.

Line colored therapy icons



1 Disabled modes. Keys do have a high gradient transparency.

2 Enabled modes

3 Selected modes. Key is colored dark blue.

Different conditions of the therapy keys

Enabled modes: This therapy method can be selected.

Disabled modes: Applying this therapy method is currently not possible. Keys do have a high gradient transparency.

Selected modes: You have already selected this therapy method. Key is colored dark blue.

3.6.3 Screen header buttons

1 Home button
2 Screen title (variable content)
3 Vacuum settings button (See § 4.11)
4 Anatomical library button (See § 4.7)
5 Contra Indications button (See § 1.3)
6 System settings button (See § 4.10.2)
7 Go back button

Additional information

1 Home button and Go Back button

	Home button in enabled status		Go Back button in enabled status
	Home button in disables status		Go Back button in disabled status

2. Screen title: the variable text field 'Vacuum settings' functions as the URL shortener.

3. Vacuum button: Only visible when a Vaco device is connected to the main device.

	Enabled
	Selected

4. Anotomical library

	Enabled
	Selected

5. Contraindication

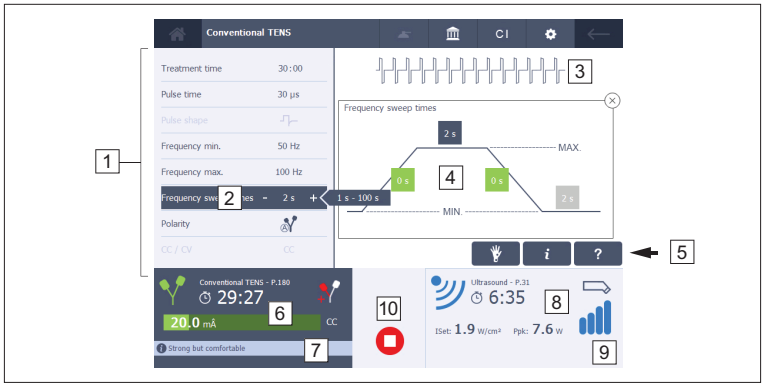
	Enabled
	Selected

6. System settings

	Enabled
	Selected

3.6.4 Therapy parameters display

The screen below has electro therapy on channel A and ultrasound on channel B. Note the screen title of the selected therapy in the screen header. See § 3.6.3.



1 parameter field of chosen therapy

2 selected parameter with up/down button (pop-up for range)

3 current form drawing (or therapy) See § 3.7 and § 3.8.

4 guided drawing to support (re)-adjustments

5 functional keys for applied therapy See § 3.6.5.

6 therapy overview of selected channel A (in the example ET)

7 double message rule for channel A (advice & warning)

8 therapy overview on channel B but not selected (in the example US)

9 double message rule for channel B (advice & warning)

10 Stop button (Red colored key.): only appears when a therapy is operational on a certain channel, except for laser therapy.

3.6.5 Function keys for applied current

	
	
	
	
The blue buttons are in enabled modes.	The inverted buttons are in selected modes.

1. Save treatment protocol into Memory (See § 4.9)
2. Placement pictures for electro, ultrasound, laser (See § 4.2.6)
3. Therapy information button (See § 4.2.6)
4. Technical help (about therapy or selected parameter) (See § 4.2.6)

Attention:

These function keys are invisible when the specific functionality is not valid at that particular moment.

3.6.6 Therapy symbols in the output window.

	Electro therapy
	Ultrasound therapy
	Combination therapy
	Iontophoresis
	Phonophoresis

	Laser therapy
A	Channel A (if still free)
B	Channel B (if still free)
	Treatment time

3.6.7 Parameter symbols

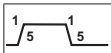
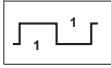
Electro therapy

	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
	Use only red+ polarity in Combination therapy
	Use only red+ polarity of vacuum in Combination therapy

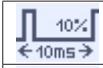
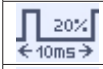
	Biphasic pulse shape, symmetrical
	Biphasic pulse shape, asymmetrical
CC	Constant Current
CV	Constant Voltage
mÂ	mA peak
V̂	Volt peak

Frequency sweep mode

	12s/12s
	6s/6s

	1s/5s - 1s/5s
	1s/1s

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 1 cm^2
	US head, ERA 4 cm^2
$\hat{I}_{set}$	Set US intensity
W/cm^2	Unit of the set US intensity
P_{pk}	Peak US output power
W	Unit of the Peak US output power

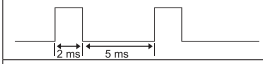
Laser therapy

P_{av}	Set average power
	Laser emission detected
	Monoprobe

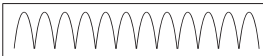
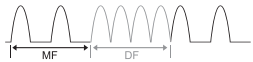
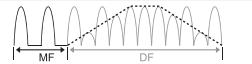
E_{tot}	Total administered energy
E_{set}	Recommended energy to be administered to the patient
	Clusterprobe

3.7 Current shapes

Unidirectional currents

	Iontophoresis direct current
	Direct current
	Rectangular pulse
	2-5 current (UltraReiz)
	Triangular pulse
	MF constant
	Iontophoresis MF constant

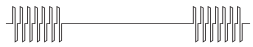
Diadynamic currents

	Diadynamic DF
	Diadynamic MF
	Diadynamic RS
	Diadynamic CP
	Diadynamic LP

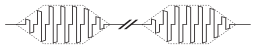
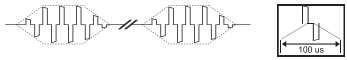
Interferential currents

	2-pole MF
	Isoplanar vector field
	Dipole vector
	Classical interferential

TENS currents

	TENS conventional / high frequency
	TENS low frequency
	TENS burst
	TENS random frequency

NMES currents

	Rectangular surge
	Triangular surge
	Biphasic surge
	Intra pulse interval surge
	2-pole MF surge
	Isoplanar vector field surge
	Russian stimulation
	Han stim (pain relief goal)

Microcurrents

	Microcurrent
	Microcurrent surge
	Microcurrent modulated

High voltage currents

	High Voltage
	High Voltage surge

3.8 Current shapes with combination therapy

Unidirectional currents in combination with ultrasound

	US + Rectangular pulse
	US + 2-5 current (UltraReiz)
	US + Triangular pulse
	US + MF constant

Diadynamic currents in combination with ultrasound

	US + Diadynamic DF
	US + Diadynamic MF
	US + Diadynamic RS
	US + Diadynamic CP
	US + Diadynamic LP

TENS currents in combination with ultrasound

	US + conventional TENS US + high frequency TENS
	US + low frequency TENS
	US + burst TENS
	US + random frequency TENS

Medium frequency currents in combination with ultrasound

	US + 2-pole MF
	US + Russian stimulation

Microcurrent in combination with ultrasound

	US + Microcurrent modulated

High voltage in combination with ultrasound

	US + High voltage

4. Operation

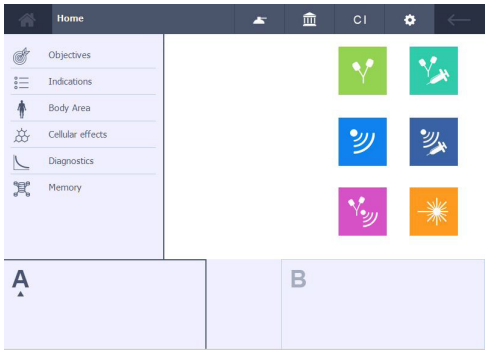
4.1 Therapy selection

You can select a therapy in different ways, via the menu entries or via the direct therapy keys. At the start these selections are automatic performed for the left channel A which is in focus.

The output windows are controls.

Tap in the middle of output window B to select the other channel B.

(the channel that is in focus has an output window with a border or a dark blue background).



- **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 area. See § 4.1.4.
- **Cellular effects**: Access to the pre-programmed list to achieve the therapeutic goal of cellular effects. See § 4.1.5.
- **Diagnostics**:Perform a diagnosis, for example to determine the rheobase and the chronaxie. See § 4.1.6.
- **Memory**:Select a therapy that you previously saved. See § 4.1.7.

4.1.1 Therapy selection via therapy buttons

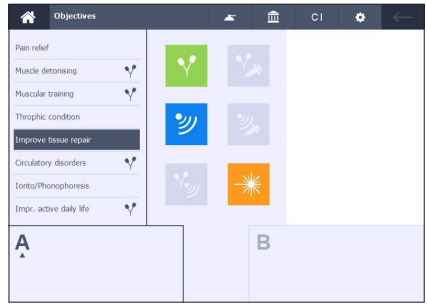
Either it opens a deeper menulist wherein the desired choice can be made, or it immediately opens the pre-programmed therapy settings.

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

4.1.2 Therapy selection via objectives

Procedure

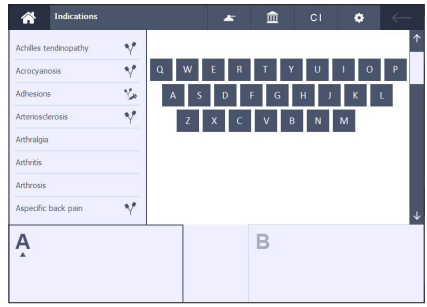
1. Press Objectives in the home menu.
2. Select the objective.
3. Select the therapy method.
4. Follow the on screen options to select the desired treatment.



4.1.3 Therapy selection via indication list

Procedure

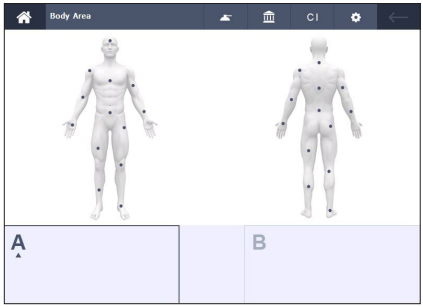
1. Press Indications in the home menu.
2. Select the indication:
   - Use the on screen keyboard to type the first character of a therapy.
   - Use the scrollbar on the right side of the screen.
3. Select the therapy method.
4. Follow the on screen options to select the desired treatment.
5. Placement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



4.1.4 Therapy selection via body area

Procedure

1. Press Body Area in the home menu.
2. Choose the desired location.
3. Select the indication.
4. Follow the on screen options to select the desired treatment.
5. Placement pictures are available.



4.1.5 Cellular effects

Procedure

1. Choose for cellular effects if the patients' pathology is still curable.

Note:

The physical effects of microcurrent are at cell level, producing all kinds of chemical reactions in order to restore the cell's normal function.

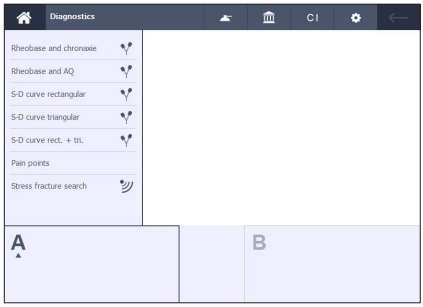
2. The available screen info will guide you to the most optimal protocol.

4.1.6 Diagnostic program selection

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

Procedure

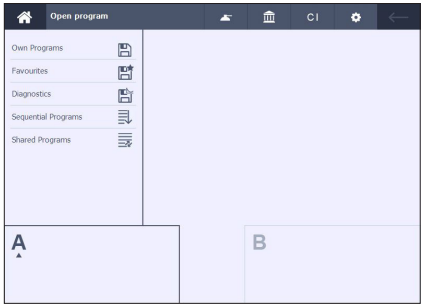
1. Press Diagnostics in the home menu.
2. Select the desired diagnostic. See § 4.8.



4.1.7 *Memory selection*

Procedure

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

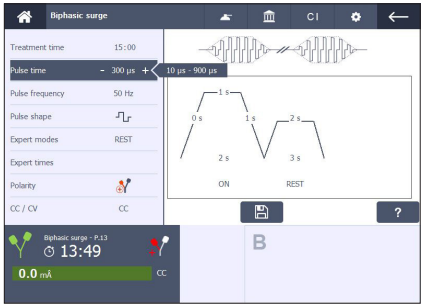


4.2 Performing therapy

4.2.1 *Set a therapy*

Procedure

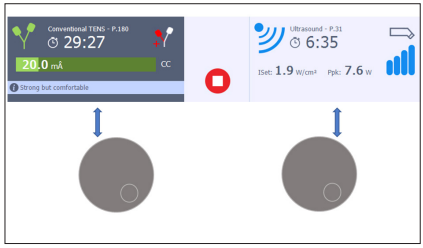
1. Make via the Home button the desired selections until the treatment parameter screen appears.
2. Select a parameter and change the value with - and + button.
3. The parameter range is shown on the right side as long as the selected parameter is highlighted.



4.2.2 *Start a therapy*

Procedure

1. There is a ONE to ONE relationship between the intensity rotary knobs and the output windows.
2. Rotate the corresponding intensity knob to start the treatment and to set the desired intensity.
3. The set intensity is displayed in the corresponding output window.



Note:

With Laser therapy the desired E_{set} is adjusted See § 4.6.2.

4.2.3 All therapy possibilities

1. The table shows an overview of all possible therapy methods on the 2 independent channels.
2. It shows separate, simultaneous or combined therapy method possibilities.
3. This table is meant for the Combi 400 being the most extensive and complete device.
4. Table is also valid for Duo 400 & Pulson 400 but of course limited!

Channel A (left side)	Channel B (right side)
ET	-
-	ET
ET (2-pole)	ET (2-pole)
ET	US
ET	LA
US	-
US	ET
US	LA
-	US
LA	-
-	LA
LA	ET
LA	US
CO (ET part)	CO (US part)

Both channels are automatically selected in case of:

- Synchronic electrotherapy channels
- Alternating - and synchronic channels choice with NMES currents (expert mode)
- Combination therapy

4.2.4 Set electrotherapy on both channels A & B

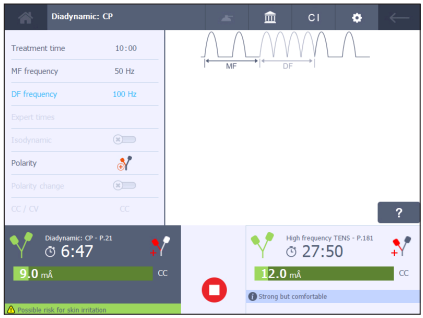
The 400-Series has two separated electro therapy channels A and B.

The channels A and B can be used independently.

You can treat two different pathologies simultaneously with two different currentform types.

Procedure

1. Select either channel A or B and make the desired choices until you reach the parameter screen.
2. Select the other channel.
3. Select the desired treatment for this other channel. See § 4.1.
4. All treatment parameters for both channels can be set totally independent.



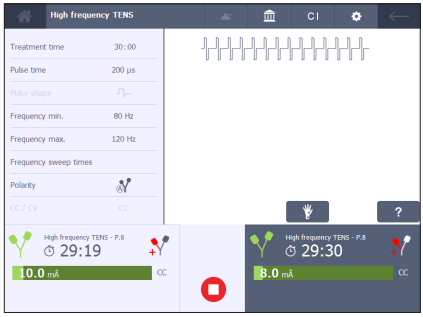
5. Rotate the corresponding intensity knob to start the treatment and to set the desired intensity. Perform this for both channels.
6. Both treatments will run independent from each other with their own treatment timer.

Copy channel parameter

The goal is to use the same parameter settings on both electro therapy channels.

Procedure

1. Verify that the 'Copy channel' parameter is in On-mode in the System settings menu. See § 4.10.2.
2. Select the desired electrotherapy protocol on one channel.
3. If necessary make desired parameter changes.
4. Select the other channel.
5. Automatic the same treatment program is now copied on this other channel.



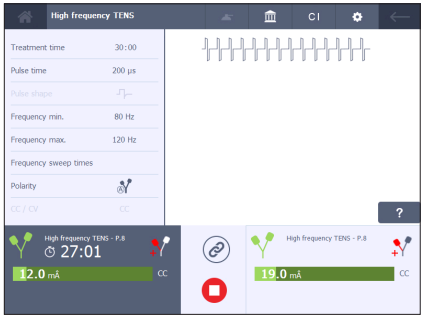
6. If necessary parameters can still be changed channel-independently.
7. Rotate the corresponding intensity knob to start the treatment and to set the desired intensity. Perform this for both channels.
8. Both treatments will run independent from each other with their own separate treatment timer.

Let copy channels run synchronized

The goal is to use the same parameter settings on both electro therapy channels and let them run synchronized with one common treatment timer.

Procedure

1. Verify that both the parameters 'Copy channel' and 'Synchronic channels' are in On-mode in the System settings menu. See § 4.10.2.
2. Perform the same actions as explained in above 'Copy channel parameter'.



3. In the output control window will appear an extra 'synchronic channels button' in the enabled mode .
   Both treatments will still run independent from each other with their own separate treatment timer.
4. When the synchronized button is selected both electro channels run synchronized with one common treatment timer .

What is the benefit of synchronic electro channels?

Imagine this treatment is performed simultaneously on a left and right shoulder. This synchronic channels behavior avoids an annoying unbalance at the treatment end, because both separate intensities will fade out to zero at exactly the same moment due to one common treatment timer. Resulting in optimal patient comfort!

Attention:

- This synchronic channels button is NOT valid for NMES current form types.
- Specific for 1 channel NMES currents the expert modes parameter offers 2 choices. Either Synchronic channels or Alternating channels. With these 2 choices becomes the therapy a 2 channel electrotherapy.

4.2.5 Immediately stop treatment

Procedure

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.

Attention:

There is no stop button for laser therapy. Just release the push button on the laser probe.

4.2.6 Guided therapy information

Note:

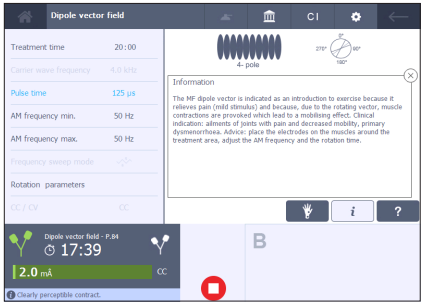
The anatomical library is also part of the Guided therapy. For more details refer to § 4.7.

Therapy information

The *i* button is available for Indications, Objectives, Iontophoresis and Body area protocols.

Procedure

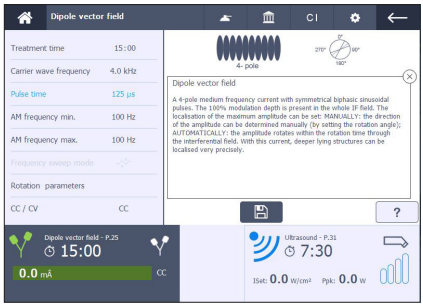
1. Press the *i* button.
   The therapy information is displayed.



Help information

Procedure

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.



Note:

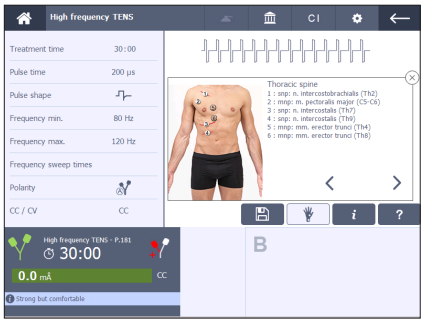
By default, the help information for the selected therapy method or the current form is displayed if no parameter is selected.

Placement pictures

With the Indication list and Body area treatments, becomes the placement pictures button available.

Procedure

1 Press the button to see a photo of the accessories placement. Often an extended list of anatomical locations is offered.

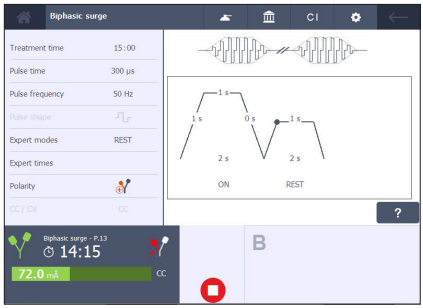


Progress of current form

With NMES currents, the progress of the current is graphically displayed for the selected channel.

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.



4.2.7 Output window content for electro and ultrasound

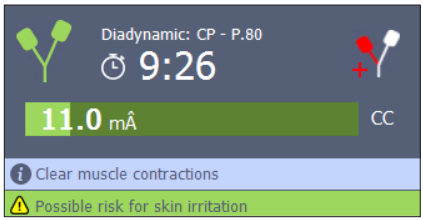
The color-based output window content summarizes the already selected therapy method. The therapist keeps the overview even when the screen content in the navigation area is focused on the other channel.

Visualization of the fixed therapy color settings recurs in:

- therapy method icon
- intensity bar (with electro)
- contact detection (with ultrasound)
- advice / warning message rule

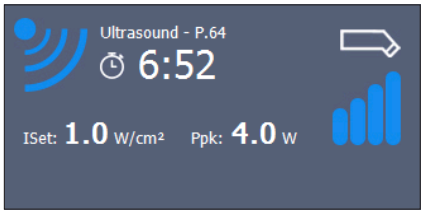
Selected output window has darker blue background.

Read out values for electrotherapy



1. Colored electrotherapy symbol (replaces A or B).
2. Current form name
3. Program number P.xxxx
4. Remaining treatment time
5. Applied polarity
6. Applied with vacuum (optional)
7. Set Intensity (graphical bar)
8. CC or CV modes
9. Advice message rule
10. Warning message rule

Read out values for ultrasound



1. Colored ultrasound symbol (replaces A or B).
2. Ultrasound
3. Program number P.xxxx
4. Remaining treatment time
5. Applied US-head size
6. Set intensity (I_{set}) in W/cm²
7. Peak Power (P_{pk}) in W
8. Contact detection bargraph
9. Advice message rule (empty in example)
10. Warning message rule (empty in example)

Flashing of the colored therapy symbol

Applies to character A or B or to the colored therapy symbol in the channel output window. It indicates the info displayed in the on screen navigation area is not related to the channel output window. For example a selection on the System settings button when already a treatment protocol is selected results in the flashing behavior. Just push the flashing symbol to return to the previous screen.

4.2.8 Clear the output window of a channel.

Procedure

1. Select the channel that you want to clear.
2. Make sure the intensity is set to zero for that particular channel.
3. Select Goback to go to the previous menu list.
4. Or, select Home.

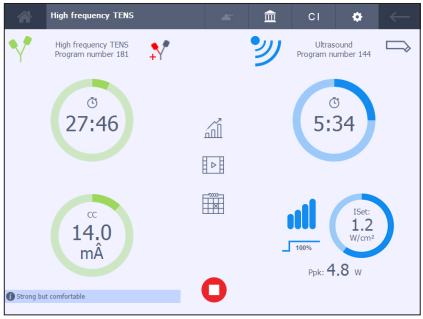
4.2.9 Open the enlarged application screen

The enlarged color based application screen summarizes the already selected therapy method at a single glance. The therapist keeps the overview (even from a distance) while it can contribute to get the patient more restful.

Visualization of the fixed therapy color settings recurs in this screen.

Procedure

1. Select a therapy on a channel untill the output window is filled.
2. Click once on the focussed output window (dark blue) to open the enlarged application screen.



This example shows a simultaneous application of electrotherapy and ultrasound.

Click once in the enlarged application screen to leave this screen.

4.3 Electro therapy

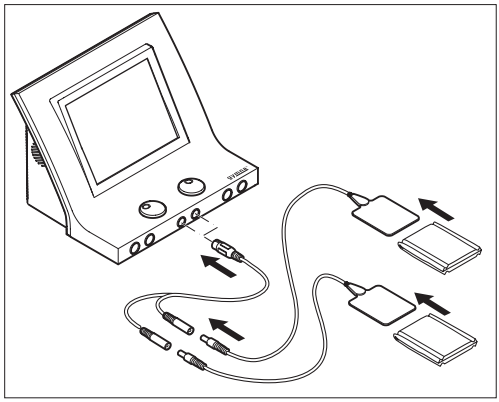
4.3.1 Performing electro therapy with electrodes

Procedure

1. Select the desired electro therapy program.
2. Place the electrodes. If necessary make use of the guided therapy information. See § 4.2.6.
3. Rotate the corresponding intensity knob to start the electro therapy and to set the desired intensity.
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.
6. Remove the electrodes.

Placing the rubber electrodes

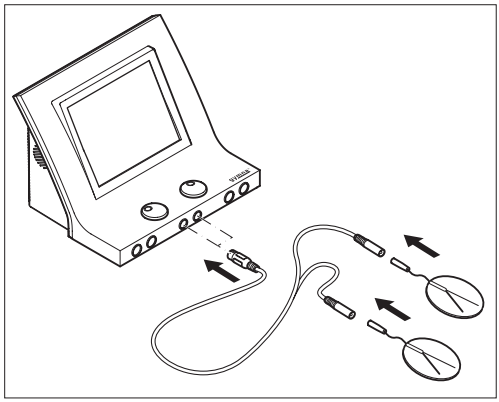
Procedure



1. Moisten two EL sponges thoroughly with water. In case of poor conduction,use water with a saline solution to improve the conductivity of the EL sponges.
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 both rubber electrodes and to connector Y A or Y B of the 400-Series.

Placing the adhesive electrodes

Procedure



1. If possible, disinfect and, if necessary shave 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 cable to connector Y A or Y B of the 400-Series.

Attention:

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 and burns under the electrode area.

Attention:

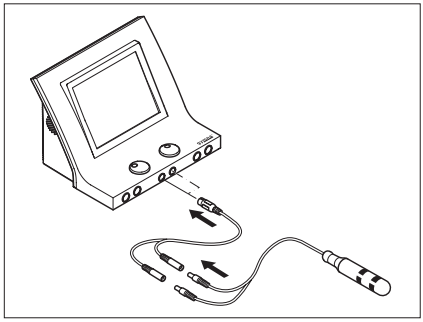
When using a dynamic electrode technique, only use currents with Constant Voltage (CV). This prevents unpleasant stimulations for the patient when the contact is temporarily interrupted during the placement, movement and removal of the electrode.

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

Attention:

- 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.

Procedure



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.
4. Apply an antiseptic lubricant to the probe.
5. Place the probe.
6. Rotate the intensity knob to start the treatment and to set the desired intensity.
7. Check the patient's reaction. Repeat this check regularly during the treatment.
8. The equipment stops the treatment and indicates that the treatment is completed.
   Remove the stimulation probe.
9. Clean the stimulation probe. See § 5.2.7.

Attention:

These stimulation probes and the pen electrode 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. When using the rectal probe or the pen electrode, you must additionally purchase the optional cable part number: 340.428
See § 7.9.1.

4.3.3 Electro therapy with sequential steps

A treatment with sequential steps consists of a succession of multiple current forms with different parameter settings. You can select pre-programmed sequential protocols by the Objectives path or use your own created sequential protocols. See § 4.9.4.

Advantages:

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

Set new intensity between sequential steps

All sequential programs define what the initial intensity must be when switching to the next step. This is done to guarantee patient safety. The intensity is retained if safety allows (= I auto). 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 (= I manual). In this case, the treatment is stopped. You must now set the intensity again.

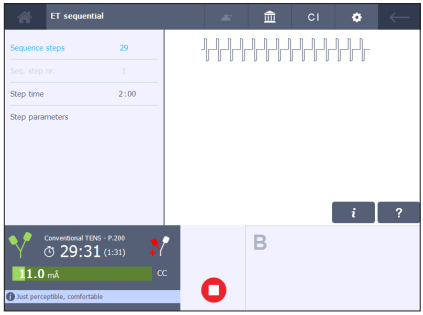
Warning:

With own created sequential protocols the intensity will always decrease to zero at every sequential transition because patient safety cannot be guaranteed.

Setting a treatment with sequential steps

Procedure

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 readonly mode) to the individual current form settings of the selected sequential step.



3. Rotate the intensity knob to start the treatment and to set the desired intensity.

Skip step in treatment

Procedure

1. Press to temporarily interrupt the treatment.
2. Select Seq. step nr. and select the desired step.
3. Rotate the intensity knob to start the treatment 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. The output window of iontophoresis is similar to electrotherapy. Only the fixed therapy method color and symbol varies.

Procedure

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 medicine used.
3. Place the electrodes.
4. Select an Iontophoresis program.
5. Set the intensity between 0.1 and 0.25 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.

Warning:

To prevent etching or burns, never exceed 0.2 mÂ/cm² with IO-Direct and 0.25 mÂ /cm² for IO-MF constant.
Care must be taken in administering medicine (allergies, contra indications,...)

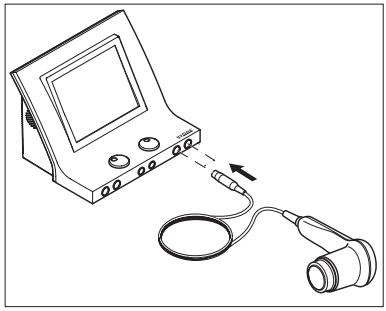
4.4 Ultrasound therapy

4.4.1 Performing ultrasound therapy

Warning:

Move the US head evenly over the skin during the treatment. This prevents internal burns.

Procedure



1. Select the desired ultrasound therapy.
2. Connect the US head to 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 any one time. The device detects which type of US head is connected to the connector. Set the parameter ERA to 1 or 4 cm² to select the corresponding US head if two heads are connected. The blue indication led on the selected US head flashes.
3. Apply contact gel to the skin to be treated and to the US head.
4. Place the head on the skin.
5. Rotate the intensity knob to start the ultrasound therapy.
6. Check the patient's reaction and the effect of the treatment. Repeat this check regularly during the treatment.
7. 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.

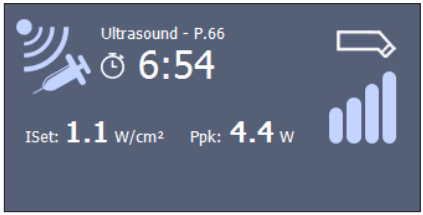
Procedure

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

4.4.3 *Output window content for Phonophoresis & ultrasound therapy*

Notes:

- For the readout values of the ultrasound see § 4.2.7.
- The output window of Phonophoresis is similar to the Ultrasound. Only the fixed therapy method color and symbol varies.



$\hat{I}_{set}$ (W/cm²) The power (W) of the US head per cm².

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 is stopped to prevent overheating of the transducer.

Contact detection of the US head

The bargraph represents the contact detection level of the US head with the skin.

	No bars filled	no contact
	bars partially filled	sufficient to very good contact
	bars completely filled	

Test the US head if its conduction is bad. See § 5.1.1.

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

Warning:

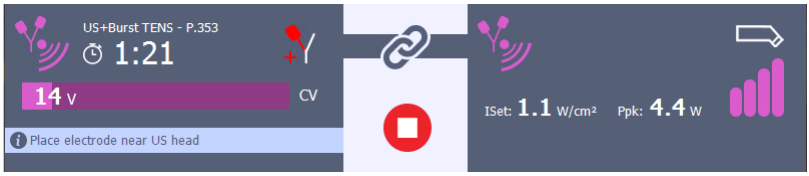
- With combination therapy, the US head is always the negative pole. The electrode is the positive pole.
- With combination therapy, a maximum current density of 2.0 mA_{rms}/cm^2 is advised. Exceeding this current density can result in skin irritation and burns. The intensity depends on the surface 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.

Procedure

1. Select for combination therapy.
2. Select the current shape. The left channel is used for electro therapy and the right channel is used for ultrasound therapy.
3. Connect the two-ply electrode cable to the electro therapy connector A and connect the US head to a US connector.
4. Place the electrode which is connected to the red plug on the patient, while keeping the black plug of the cable free.
5. Apply contact gel to the skin to be treated and to the US head.
6. Place the head on the skin.
7. Rotate the intensity knob to start the electro therapy. Set the desired voltage.
8. Rotate the intensity knob to start the ultrasound therapy.
9. 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.
10. Check the patient's reaction and the effect of the treatment. Repeat this check regularly during the treatment.
11. The equipment stops the treatment and indicates that the treatment is completed.

4.5.2 *Read-out values for Combination therapy*

Electro part Ultrasound part



1.	Colored combination symbol (replaces A or B).	Colored combination symbol (replaces A or B).
2.	US + Current form name	
3.	Program number P.xxxx	
4.	Remaining treatment time	Applied US-head size
5.	Applied polarity (red +)	Set Intensity (I_{set}) in W/cm^2
6.	Applied with vacuum (optional)	Peak power (P_{pk}) in W
7.	Set voltage (graphical bar)	Contact detection bargraph
8.	CV modes (fixed)	-
9.	Advice message rule	Advice message rule
10.	Warning message rule	Warning message rule

4.6 Laser therapy

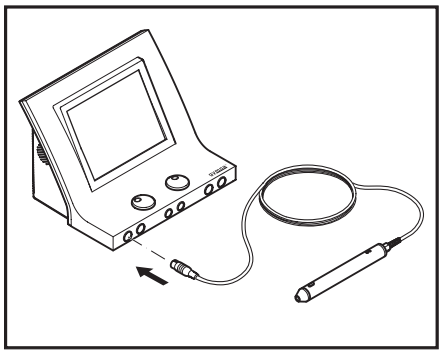
4.6.1 Laser safety

Attention:

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

4.6.2 Performing laser therapy

Procedure



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 § 4.10.3 for changing the access code.
5. Select the desired laser therapy. The corresponding intensity knob can be used to readjust the E_{set} value. 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.
10. Release the black button on the laser probe.

4.6.3 Read-out values for laser therapy

1. Colored laser symbol (replaces A or B).
2. Laser therapy
3. Program number P.xxxx
4. Remaining treatment time
5. Applied laser probe
6. Test laser emission **T**
7. Set energy E_{set} (mJ or J)
8. Total energy (E_{tot}) in mJ or J
9. Average Power (P_{av}) in mW
10. Advice message rule
11. Warning message rule

P_{av} (µW or mW)	The set average power of the laser probe (Ep pulse energy x frequency)
E_{tot} (mJ or J)	The total administered energy of the current treatment (P_{av} x treatment time).
E_{set} (mJ or J)	Recommended energy to be administered to the patient.

4.6.4 Testing laser emission

Procedure

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 **T** appears in the output window behind the probe symbol.
4. The E_{tot} value increases every second with the P_{av} until 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.

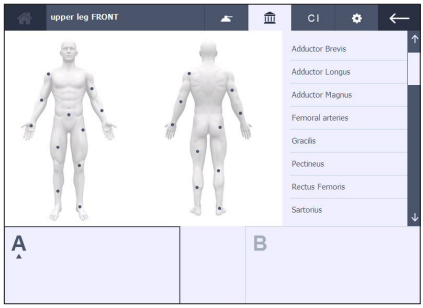
Indication light	Situation
Continuous green:	The laser therapy is selected, but the laser probe has no laser emission.
Continuous yellow:	The laser emission is in progress.
Flashing yellow:	The 2 s safety delay is activated to avoid laser emission by accident or the laser treatment finished.

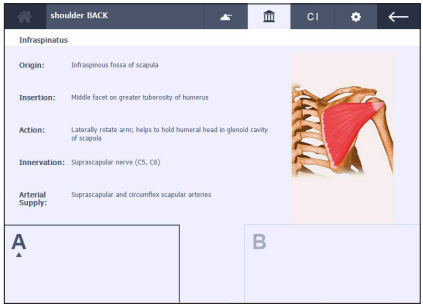
4.7 Anatomical library

You can access the anatomical library for anatomical information on the musculoskeletal system. This is even possible during the treatment therapy and therefore the most convenient way to inform your patient about the injury.

Procedure

1. Select Anatomical Library  .
2. Select the body part you want to display information of and an item from the list.
3. Anatomical information is displayed.





4.8 Diagnostics

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

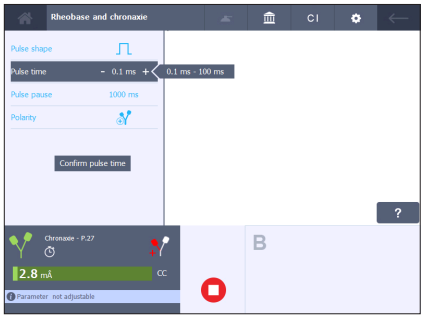
- Rheobase and chronaxie. See § 4.8.1.
- Rheobase and AQ. See § 4.8.2.
- Determine an S-D curve. See § 4.8.3.

Besides this, there are programs for localization:

- Pain points.
- Stress fracture search

4.8.1 Determining rheobase and chronaxie

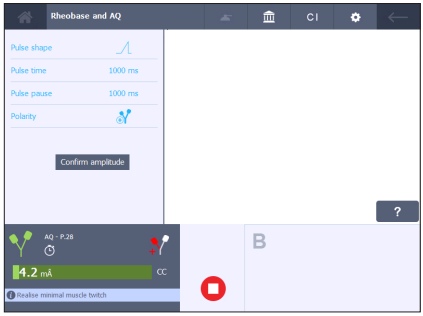
Procedure



1. Select Diagnostics.
2. Select Rheobase and chronaxie.
3. Rotate intensity knob 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 until you observe 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)

Procedure



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

Procedure

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 by changing the pulse time.
4. Select Auto mode or Manual mode.

   Auto mode:

5. Rotate intensity knob to start the treatment.
6. Increase the intensity in steps of 0.1 mÂ, until you observe a tangible or visible contraction
7. Select Confirm Amplitude. The measurement result is directly shown on the graph. In auto mode, a new pulse value and shape is selected.
8. Repeat steps 5 to 7 for all measurements.
9. 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:

10. 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, while in Auto mode the measurement sequence is fixed.

4.9 Memory

There are two different paths to access the memory functionality.

1. Save program:
   Starting from the save program button  either in a therapy parameter screen with zero intensity or after a diagnostic result screen is reached.
   The save program choices are:

as own program		
as favourites		
as diagnostic result		only meant to save results
as sequential program		
as shared program		
change default program		

   All saved programs will have an unique program number.

   There are 500 free locations to save own programs and favourites and 200 free locations for diagnostic results.

   There are 100 free locations to create your own sequential treatment protocols.

   There are 50 free locations to create your shared programs list.

   The philosophy of shared programs is that the same specific programs list can be copied on multiple devices. For this the shared program list needs to be downloaded on USB and allows an upload via the same USB on other devices. See § 4.10.9 for the correct procedure.

2. Open program:

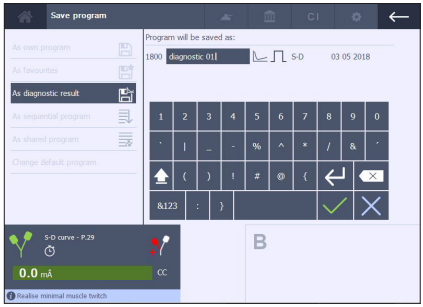
   Select the Memory item in the Home screen to retrieve and open an already saved program or diagnostic result. The open program choices are:

   - own programs
   - favourites
   - diagnostics
   - sequential programs
   - shared programs

4.9.1 Saving a program or diagnostic result

Procedure

1. Press  from a therapy parameter screen or diagnostic result.
2. Choose the desired sub-choice to save.
3. The first free program number is selected.
   If desired, use the scroll bar to scroll through the list and choose another free number.
4. Select  to save or  to leave the Memory function without saving.



4.9.2 Overwrite a saved program

Procedure

1. When you select an already filled program number, you will be requested to confirm that overwrite activity before continuing.

Attention:

This overwrite activity is NOT possible with sequential treatment protocols.

4.9.3 Default therapy programs and specific modification possibilities

With default programs is meant: all programs which can be called up with the direct therapy keys at the right side in the Home screen.

Change default program

Goal is to change and save a default program.

You can edit the parameter settings of a default therapy program and store the modified program with its new personalized settings while keeping the fixed program number.

Shared programs

Goal is to create the shared programs list.

You can only use the default therapy programs or edit the parameter settings of a default program to store in the shared programs list.

Sequential programs (not for Pulson)

Goal is to create own sequential treatment protocols.

You can only use the default electro therapy programs or edit the parameter settings of a default electrotherapy program to create own sequential treatment protocols.

4.9.4 Create sequential electrotherapy protocols

The sequential path functions totally independent from all other memory menu items.

The menu item “sequential program” is only selectable if the currentform is a default electro therapy program.

There can be created 100 sequential programs consisting of maximum 5 different sequential steps per individual program.

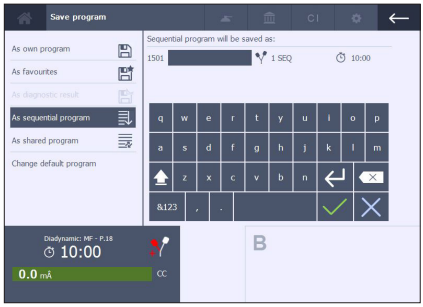
The set intensity automatically fades out to zero at every sequential transition for patient safety reasons. (=I manual)

The user needs to readjust the desired intensity at the start of every new sequential step.

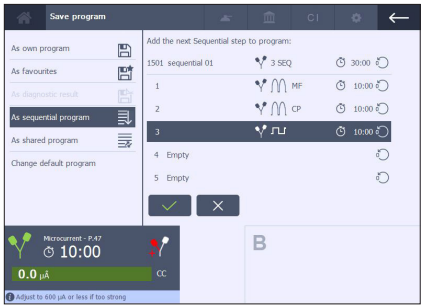
This allows creating sequential steps, having their own specific therapeutic goal within the treatment. (for example: warming up, activation, cooling down,…)

Procedure

1. At the start automatic the 1st free sequential program number is selected and contains already the 1st free sequential program step (= 1 SEQ). From here it is still possible to put this 1st sequential step behind another program number. The sequential program name becomes filled-in while saving the 1st sequential step.



2. Select an already existing sequential program number to add a new sequential step.
   There appears a sequential overview screen. The new sequential step is automatic positioned along the 1st free step.



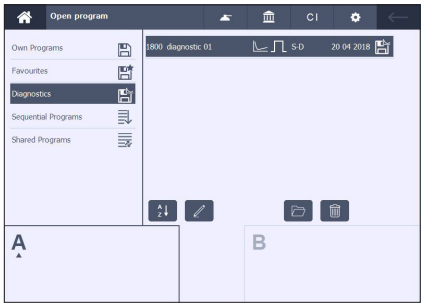
3. It is not possible:
   a) to choose for another free sequential step
   b) to overwrite a filled sequential step
   c) to move a filled sequential step
   d) to delete a filled sequential step
   e) to open a sequential program which contains already 5 sequences. (= 5 SEQ) A guided message will appear to inform you.

4.9.5 Open a saved program

Start from Memory in the Home screen.

Procedure

1. From here you get access to open:
   a) Own programs
   b) Favourites
   c) Diagnostics
   d) Sequential programs
   e) Shared programs
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

Procedure

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

Open a program or diagnostic

Procedure

1. Select the program you want to open.
2. Press  . When the other channel is active, the open button is not available if the program conflicts with the active channel.
3. When a diagnostic was selected, the diagnostic information appears.
4. When a program was selected, a therapy program appears. If desired, start the therapy.

Delete a program or diagnostic

Procedure

1. Select the program you want to delete.
2. Press  . The text "Delete this program?" appears.
3. Select  to confirm or  to keep the program.

Move a program

Procedure

1. Select the program you want to move.
2. Press the move key  :
   a) When the favourites list is selected, it moves the program to the own program list.
   b) When the own program list is selected, it moves the program to the favourites list.
3. Select  to confirm or  to stop the move action.

4.10 Customized settings versus System settings

Beside the language choice you have the possibility to customize the device settings to a much more personal touch, instead of using the default factory System settings.

The setup wizard allows you to customize. See § 4.10.1

The table below shows that there is a huge overlap between both main topics.

Setting	**customize via Setup wizard**	**modifiable in System settings**
Touch panel calibration	-	x
Language	x	x
Date & time	x	x
Keyboard {design}	x	x
Sound	x	x
Copy channel	x	x
Synchronic channels	x	x
System information	-	x
Error History	-	x
Start up info	x	x
Therapy icons {design}	x	x
Vacuum screen {design}	x	x
Laser key code	x	x
Accessories test	-	x
Stop timer if bad US contact	x	x
Restore all default programs	-	x
Memory path entry	x	x
Erase memory	-	x
Customization wizard	-	x
Shared programs {load}	-	x

4.10.1 Customized settings

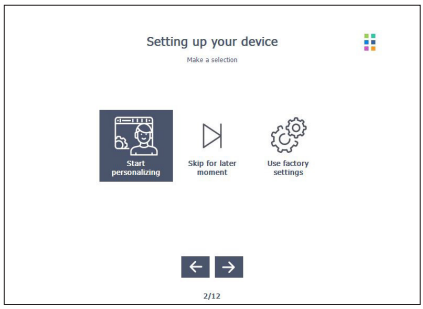
A 'setup wizard' starts up automatic at the 1st power on of your device.

The setup wizard guides you throughout the device settings and allows you to give your gymna 400 series device the desired personalized touch.

Just follow the instructions on the screen and make the desired choices.

Procedure

1. You are free to make use of the setup wizard, skip the wizard temporary, or agree to make use of the default factory System settings.
2. It is still possible to run the setup wizard on a later moment via the System settings menu.



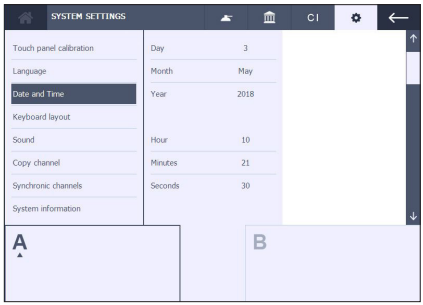
4.10.2 System settings

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

Procedure

1 Press ⚙ in the screen header to open the system settings menu.

2. Select the desired system setting and perform changes.



4.10.3 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.

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

Sound: Change the sound desired values settings.

Copy channel parameters (on, off): Choose that channels A and B are the same (on) or are different (off). See § 4.2.4.

Synchronic 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 valid for NMES currents and 4- pole current shapes. See § 4.2.4.

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 info: Enter or modify start up information. See § 4.10.4.

Therapy icons: Via this way you can choose the desired design representation of the therapy icons with or without the therapy name. See § 3.6.2.

Vacuum screen: Via this way you can choose the desired design representation of the vacuum parameter screen. Either a traditional parameter design or a dashboard design. See § 4.11.

Laser key code: Choose a new Laser key code to access laser functions. The factory value of the Key code = 1234.

Accessories test: Selects one of the accessory tests:

- Plate electrode test. Tests the condition of the rubber electrodes. See § 4.10.5.
- ET cable test. Tests the electro therapy cables. See § 4.10.6.
- Vacuum hose test. Tests the vacuum hoses (if vacuum function is present). See § 4.10.7.
- Laser energy measurement. Tests the laser probe. See § 4.10.8.

Stop timer if bad US contact (on, off): On: The treatment stops during a bad contact of the US head.

Restore all default programs: The contents of all modified default programs 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.

Customization wizard: Via this way it it is possible to run again the setup wizard from the beginning to give your device a much more personal touch. See § 4.10.1.

Shared program (load): The philosophy of shared programs is that the same specific programs list can be spread out over multiple devices. See § 4.10.9 for the correct execute instructions of the upload & download on USB.

4.10.4 Set text for start up screen

You can set your own text for the start up screen. For example, a welcome to the practice or your expertise in the top rules. And some more practise based info in the lower rules.

Procedure

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

4.10.5 Plate electrode test

Procedure

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: OK.
8. Turn the amplitude back to 0 mA.

4.10.6 Cable test

Procedure

1. Press  .
2. Select Accessories test.
3. Select Cable test.
4. Connect the electrode cable to channel A without the electrodes.
5. Connect the short test cable 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: OK.
8. Turn the amplitude back to 0 mA.

4.10.7 Vacuum tube test

Procedure

1. Press  .
2. Select Accessories test.
3. Select vacuum tube test.
4. Follow the instructions on the screen.

Attention:

The test doesn't discover a possible leakage malfunction of the tube.

4.10.8 Laser energy measurement

Procedure

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. Press  . The System settings menu appears.
5. Select Accessories test.
6. Select Laser energy measurement.
7. Test the monoprobe or clusterprobe.

Test the monoprobe

Procedure

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.
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 Ep value correspond within ±20% with the Ep value indicated on the supplier control report of the laserprobe.

Test the clusterprobe

Procedure

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.
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 Ep values.
7. Make sure the Ep sum value correspond within ±20% with the total Ep value indicated on the supplier control report of the laserprobe.

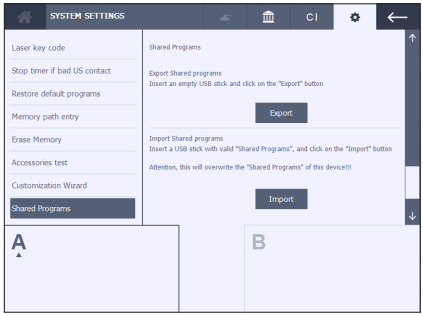
4.10.9 Shared programs up load & down load

Is meant to spread out a specific part of saved programs over multiple devices. This path supports that shared programs can be downloaded on USB (Export) and uploaded on another 400 series device (Import).

Procedure

1 Choose the goal you want to perform.

2. Follow the on screen instructions.



Attention:

If certain functionality is NOT present in the device, then of course those specific treatment protocols are NOT uploaded.

For example NO ultrasound protocols can end up in a Duo 400.

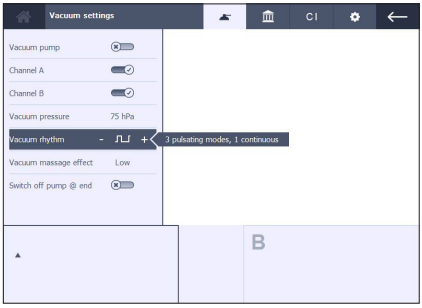
4.11 Vacuum

The application of vacuum must be seen as a benefit to perform electrotherapy treatments or combination therapy treatments to a patient. The use of vacuum cups results in more patient comfort compared to the use of fixation straps.

The screenheader shows the vacuum button when the vacuum module is available. The vacuum unit is powered by the 400 series main device. (See § 2.3) The vacuum parameter settings are reachable on the touchscreen of the main device. A selection on this vacuum button opens the vacuum parameter settings screen.

The design of the vacuum parameter screen can be customized. Via the System settings menu you can choose between traditional parameters or a dashboard design. (See § 4.10) Both designs offer the same vacuum parameter settings.

1. Traditional parameter design
2. Dashboard design (See example § 4.11.3



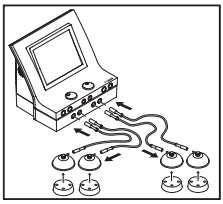
4.11.1 Connect and prepare the vacuum electrodes

Caution:

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

Procedure

1. Connect the vacuum electrodes to the vacuum hoses.



2. Connect the four vacuum hoses.
   Select two cables with the same hose color for each channel.
   a) Connect the red connectors from the vacuum hoses to the right output connectors of each channel .
   b) Connect the black connectors from the vacuum hoses to the left output connectors of each channel.

3. Moisten the round sponges.
4. Put the sponges in the vacuum electrodes.

4.11.2 Selection to use normal electrodes or suction cups

Procedure

1. Press the button in the screen header to access the vacuum parameters.
2. Select Vacuum channel A and B to switch one or both vacuum electrode channels On .
3. Select Vacuum pump and switch the vacuum pump On .
4. The output window of the electrotherapy treatment shows extra a vacuum cup symbol when vacuum is applied for that channel.
5. To use normal electrodes, select one or both Vacuum channel A and B to Off .
6. Switching the vacuum pump to Off does NOT change the parameter setting of both vacuum channels A & B. But the electrotherapy is than automatic applied via the normal ET patient cables.

Caution:

- It is advised to keep all four hoses and vacuum electrode cups 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 cannot be reached when vacuum is applied for one channel while the other vacuum circuit is still open.

4.11.3 Vacuum parameter settings

Working pressure

Procedure

1. Select an electro therapy.
2. Press the button to access the vacuum parameters.
3. Switch on the desired vacuum channel(s) and the vacuum pump.
4. Select Working pressure.
5. Use - and + button to adjust the vacuum level.
6. In the dashboard design is the working pressure (value in hPa) shown in a circle. Select the desired range & fine tune with - and + button.

Vacuum rhythm & massage effect

Procedure

1. Press the button to access the vacuum parameters.
2. Select Vacuum rhythm, either continuous or one of the pulsating vacuum rhythms.
3. In pulsating vacuum it is possible to choose for a massage effect to increase the therapy comfort during the treatment.
4. In the dashboard design are both parameters shown in half circles. Make your choice by a direct selection on an icon.

4.11.4 Vacuum treatment

Start treatment

Procedure

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 can cause patient discomfort . For this change the working pressure or make use of pulsed vacuum rhythm in combination with massage effect. See § 4.11.3.
2. Rotate intensity knob to start the treatment and to set the desired intensity.

3. Check the patient's reaction. Repeat this check regularly during the treatment.

Switch the vacuum pump off at treatment end

Attention:

For some countries it is regulatory obliged that the vacuum pump switches off automatic at the treatment end.

Procedure

1. Make your desired choice with the parameter Switch off pump @ end.
2. If yes  than the vacuum pump immediately stops running at a normal treatment end, if allowed by the vacuum condition on the other channel. **Attention**:the parameter vacuum pump is automatic switched to the Off-status to keep the behaviour consistent.
3. If no the vacuum pump keeps running at the treatment end. The vacuum working pressure reduces to 50 hPa automatically 5 minutes after the treatment stops. This to prevent injury to the skin of the patient by prolonged exposure to vacuum.
4. Remove suction cups with a finger under the rim. Air is let in and the cups are released. The suction cups release immediately by switching off the vacuum pump.

4.11.5 The water reservoir is full

Procedure

1. This condition is visualized by the vacuum button  in the screenheader and 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 at the backside of the Vaco device. The start of a vacuum treatment is again 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, and vacuum hoses	Conductivity. See § 4.10.5 to § 4.10.7	At least 1x per week
	Vacuum electrodes	Cleaning. See § 5.2.4.	After every treatment
	Electrode sponges and Vacuum sponges	Cleaning. See § 5.2.5.	After every treatment
	Vacuum hoses and water reservoir	Cleaning. See § 5.2.10.	Weekly
	US head	Dents, cracks or other damage	At least 1x per month
		Test US head. See § 5.1.1.	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 § 5.1.2.	At least 1x per year

5.1.1 Test the correct behavior of the US head(s)

Procedure

1. Select an ultrasound therapy and connect a US head to the device.
2. Keep the head dry (hold it in the air) and increase the intensity to 1.0 W/cm^2. Verify on the screen that:
   a) The P_{pk} value stays 0.00 W.
   b) The contact control bargraph shows bad contact  .
   c) The led on the US head is blinking.
3. Put the head in a large cup of water while the intensity is kept to 1.0 W/cm^2. Verify on the screen that:
   a) The P_{pk} value increases to a value equal to I_{set} x ERA.
   b) The contact control bargraph shows good contact  .
   c) The led on the US head is on.
4. Contact your local Gymnauniphy dealer if a different behavior is observed.

5.1.2 Technical safety inspection

The 'Directive on Medical Devices' from the European Commission (93/ 42/EEG) requires devices to be safe. 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.

Note:

- 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 IEC 62353.

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 § 5.2.1and § 5.2.2	As required
Electrodes (Rubber, metal and suction cups)	Cleaning. See § 5.2.3 and § 5.2.4	After every treatment
Sponges and sponge bags	Cleaning. See § 5.2.5.	After every treatment
Fixating bandages	Cleaning. See § 5.2.6.	If necessary
Vaginal, anal and rectal stimulation probe	Cleaning and disinfecting. See § 5.2.7.	After each use
US head	Cleaning. See § 5.2.8.	After each use
Laser probe	Cleaning. See § 5.2.9.	After each use

Caution:

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 and the vacuum unit

Caution:

Do not sterilize the unit(s).

Procedure

1. Remove dust with a dry cloth.
2. If necessary, remove stains or dirt with a damp cloth.
3. If required, clean the device with a non agressive soap solution, or a non alcoholic disinfection solution or any other agent suitable for surface disinfection that does not harm the material (cover, case, knobs are from lacquered ABS). In case of doubt, please consult an accepted list of disinfectants (e.g. the VAH list of desinfectants).

Caution:

Do not use chloride based agents as these may affect the plastic parts of the device.

5.2.2 Cleaning the touch screen

Caution:

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.

Procedure

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 electrodes

Procedure

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 vacuum electrodes

Procedure

1. Clean the vacuum electrodes (metal electrodes with rubber suction cups) in a nonaggressive soap solution or in a 70% alcohol solution.
2. Rinse the vacuum electrodes thoroughly with water.
3. If present, remove calcium deposits.
4. Turn the cups inside out.
5. Check for dirt and calcium deposits. Remove it if present.
6. Dry the vacuum electrodes.

5.2.5 Cleaning the EL sponges and vacuum unit sponges

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 to improve the conductivity of the sponges..
3. Let the sponges dry if not put to use immediately after cleaning.

5.2.6 Cleaning the fixation bandages

Procedure

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.

5.2.7 Cleaning and disinfecting vaginal, anal and rectal stimulation probes

Caution:

- 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

Procedure

1. Clean the probe carefully with soap and water.
2. Place the probe in an H.A.C. solution of 1% or in a 70% alcohol solution for at least 30 minutes.

Caution:

- Read the instruction leaflet in the packaging of the H.A.C..
- Make sure that the probe connector does not get into the H.A.C. solution.

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

Procedure

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

5.2.8 Cleaning the US head

Procedure

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% H.A.C. solution.
3. Rinse the US head thoroughly with clean water.

5.2.9 Cleaning the laser probe

Caution:

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

Procedure

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% H.A.C. solution.

5.2.10 Cleaning the vacuum hoses and the water reservoir

Procedure

1. Empty the water reservoir with the drain hose.
2. Prepare a container with 180 ml of a 70% alcohol solution.
3. Connect the 4 vacuum hoses without cups.
4. Put the ends of the vacuum hoses in this 70% alcohol solution.
5. Select an electrotherapy program and push  to switch the vacuum pump and both vacuum channels on.
6. Suck the liquid up until the "Water reservoir full" warning appears in the output window.
7. Stop the vacuum pump.
8. Empty the water reservoir.
9. Repeat steps 2 until 8 with pure water.

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 and § 4.10.2
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

Procedure

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.

Procedure

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

Procedure

1. Clean the vacuum electrodes. See § 5.2.4.
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

Caution:

- 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 § 4.10.2.

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 patient cables, sponges, adhesive electrodes, rubber electrodes and vacuum cups, 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

As far as possible GymnaUniphy will supply service, spare parts and accessories for a period of 10 years from the date of manufacture. See the type plate for this information.

7. Technical data

7.1 General

Dimensions 400-Series (w x d x h)	360 x 285 x 260 mm
Dimensions Vaco400 (w x d x h)	360 x 285 x 70 mm
Weight 400-Series	5,15 kg
Weight 400-Series, including accessories	7,85 kg
Weight Vaco400, including accessories	3,00 kg
Mains voltage	100 - 240 VAC, 50-60 Hz
Maximum power, in operation	100 W
Safety class	The device is designed in compliance with EN 60601-1:1990 + A1:1993 + A2:1995 / IEC 60601-1:1988 + A1:1991 + A2:1995. This edition of the standard classifies devices with double or reinforced insulation of the mains part and without protective earth as Class II. A Class II electrical protected device can have a functional earth terminal. This is the earth pin of the mains entry socket, marked by symbol "⏚" to distinguish it from a protective earth terminal. Connecting this pin to the protected earth terminal of the mains outlet or another grounded terminal is needed to achieve the required EMC performance.

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%
Polarity	Red-, Red+ and alternating polarity, if applicable

7.2.2 Current shapes

Unidirectional currents

- Direct current
- Iontophoresis - Direct current

Intensity of CC	0 - 80 mÂ at 300 to 1000 Ω

- Rectangular pulse
- 2 - 5 current (Ultra Reiz)
- Triangular pulse

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 Vpeak

- Iontophoresis - MF constant
- MF constant

Intensity of CC	0 - 80 mÂ at 300 to 1000 Ω
Pulse frequency	10 kHz
Duty cycle	80%

Diadynamic currents

- MF, RS, DF, CP, LP

Intensity of CC	0 - 80 mÂ at 300 to 1000 Ω
Intensity of CV	0 - 80 Vpeak
Isodynamic (CP, LP)	on / off
Expert parameters	
MF time	1 - 100 s
DF time	1 - 100 s
ISO	on/off

TENS currents

- Conventional TENS
- Low frequency TENS
- High frequency TENS

Pulse time	10 - 900 µs
Pulse shape	symmetrical asymmetrical
Frequency min. (base)	1 - 500 Hz
Frequency max. (top)	1 - 500 Hz
Freq. increase time	0 - 100 s
Freq. hold time	0 - 100 s
Freq. decrease time	0 - 100 s
Intensity of CC	0 -120 mÂ at 300 to 1000 Ω
Intensity of CV	0 - 120 V_{peak}

- Random frequency TENS

See TENS specification, with the exception of:
Pulse frequency 1 - 500 Hz, with automatic random frequency variation of -35% of adjusted Pulse frequency.

- 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 Vpeak

- Russian stimulation

Intensity of CC	0 - 100 mÂ at 300 to 1000 Ω
Intensity of CV	0 - 100 Vpeak
Burst frequency	1 - 100 Hz
Carrier wave frequency	2 - 10 kHz

- 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 Vpeak
Carrier wave frequency	2 - 10 kHz
AM frequency	1 - 200 Hz

Expert parameters for NMES currents:

On time (ON)	1 - 100 s
Off time (OFF)	0 - 100 s
Rest time	0 - 100 s
Surge time	0 - 100 s
Shrink time	0 - 100 s
Special modes	OFF. REST. ON2. Frequency variation. Manual stimulation
Alternating channels	ON/OFF / Synchronic (not for Isoplanar vector field surge current)
On2 amplitude	1 - 100%
Rest amplitude	1 - 100%

Interferential currents

- 2-pole medium frequency
- Isoplanar vector field
- Classical Interferential

Intensity of CC	0 - 100 mÂ at 300 to 1000 Ω
Intensity of CV	0 - 100 Vpeak
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 AUTO:

Rotation time	0 - 20 s

Rotation mode MANUAL:

Rotation angle	0 - 350°
Segment angle	0 - 45°
Segment time	0 - 10 s

Microcurrents

- Microcurrent continuous
- Microcurrent surge
- Microcurrent modulated

Intensity of CC	0.1 µA - 1 mA at 300 to 1000 Ω
Frequency min & max	0.1 Hz- 200 Hz
Pulse time min & max	1.0 ms - 1.0 s
Pulse frequency	0,1 Hz - 1 kHz

High voltage currents

- High voltage continuous

Frequency min.	1 - 200 Hz
Frequency max.	1 - 200 Hz
Intensity	0 - 500 V

- High voltage surge

Pulse frequency	1 - 200 Hz
Expert times	0 - 100 s
Intensity	0 - 500 V
Diagnostic programmes:	Rheobase and Chronaxie. Rheobase and AQ. S-D curve rectangular. SD curve triangular. S-D curve rect. + tri.
Intensity of CC	0 - 80 mÂ with 300 to 1000 Ω. with Rheobase max. 40 mÂ
Variable parameter for determination Chronaxie: Pulse time	0.1 - 100 ms
Variable parameter for determination S-D curves: Pulse time 17 fixed steps between	0,05 - 1000 ms
Recording mode	auto / manual

ATTENTION:

- Specific for Combination therapy; the combined therapy of electrotherapy and ultrasound.
- For Combination therapy programs are both the parameter values of the selected currentform valid as well as the parameters of ultrasound therapy.

7.3 Vacuum option

Volume water reservoir	± 180 ml
Working pressure continuous vacuum	50 - 320 hPa
Working pressure pulsation vacuum	50 - 480 hPa
Massage effect (increase of vacuum during the pulse relative to 90% of 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	± 20% of the set values, above 10% of the maximum value
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	2.5	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	3.1	
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 BF
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	2.39 µJ
Peak performance	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 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	905 nm
Energy per pulse	10.1 µJ
Peak performance	4 x 18 W
Maximum average power	50.5 mW
Pulse frequency	2 - 5000 Hz
Pulse width at 50% of the peak power	145 ns
Beam surface at laser aperture	4 x 5 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 400-Series	8.4 kg
Transport weight Vaco400	4.1 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

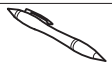
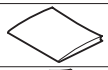
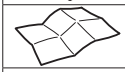
The transport and storage specifications apply to equipment in the original packaging.

7.8 Standard accessories

Article numbers can change in the course of time. Check the article numbers in the most recent datasheet or ask your dealer.

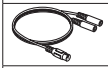
The drawings are merely indicative, no rights can be derived from them.

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	340.505
	1	Safety instructions	323.011
	1	Quick start manual Gymna 400	362.505
	1	CD-ROM User manual Gymna 400-Series multi language	362.516
	2	Rotary button silver[2]	319 025

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 available as an option.
2 Rotary buttons can be exchanged.
Tip to remove:
Use a flat ruler to lift the mounted button carefully. Place the other button gently on the rotary shaft. Finally check if it rotates easily and without resistance.

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
	1	Test plug F/F, 2 mm	330.803

7.8.3 Standard accessories ultrasound therapy

	Quantity	Description	Art. no.
	1	US head, 1/3 MHz - ERA 4 cm^2 incl. holder	360.114
	1	Contact gel, 500 ml	341.088
	1	US head, 1/3 MHz - ERA 1 cm^2, incl. holder[3]	360.111

[3] 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)	340.615
	1	Vacuum hose light grey (per 2 pces: black/red connector)	340.604
	2	Vacuum electrode - 60 mm (per 2 pces)	340.626
	1	Sponge for vacuum electrode - 60 mm (per 4 pces)	340.648

7.9 Optional accessories

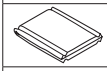
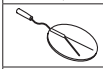
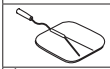
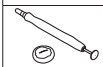
Article numbers can change in the course of time. Check the article numbers in the most recent datasheet or ask your dealer.

The drawings are merely indicative, no rights can be derived from them.

Some of the accessories mentioned above may not have been licensed in accordance with Canadian law or are not admitted to the market of your country for other reasons, hence they are not available in your country.

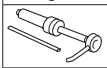
7.9.1 Optional accessories electro therapy

	Quantity	Description	Art. no.
	1	Vaginal stimulation probe Novatys	329.978
	1	Vaginal stimulation probe V2B+	330.594
	1	Vaginal stimulation probe Optima3	330.572
	1	Vaginal stimulation probe Perisize 4+	330.583
	1	Rectal stimulation probe	112.166
	1	Anal stimulation probe Analia	329.989
	1	Anal stimulation probe Analys+	330.561

	Quantity	Description	Art. no.
	1	Adapter cable 2 mm female to 4 mm male (to connect pen electrode or rectal electrode)	340.428
	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
	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, 1/3 MHz - ERA 1 cm^2, incl. holder[3]	360.111
	1	Contact gel, can 5 l	341.099
	1	Pump for can, 5 l	341.121

[3] Standard for Pulson 400, optional for Combi 400.

7.9.3 Optional accessories laser therapy

	Quantity	Description	Art. no.
	1	Mono400, monoprobe, incl. holder	360.101
	1	Quad400, clusterprobe, incl. holder	360.104
	1	Laser goggles	339.592
	1	Remote interlock for laser	340.417

7.9.4 Optional accessories vacuum therapy

	Quantity	Description	Art. no.
	2	Vacuum electode - 90mm	340.637
	4	Sponge for vacuum electrode - 90mm	114.687

7.9.5 Optional mobile 400

	Quantity	Description	Art. no.
	1	Gymna Mobile 400	360.808
	1	Vaco Extension Cable Set Mobile 400	360.819
	1	Vaco cups holder on Mobile 400	360.830

8. Appendices

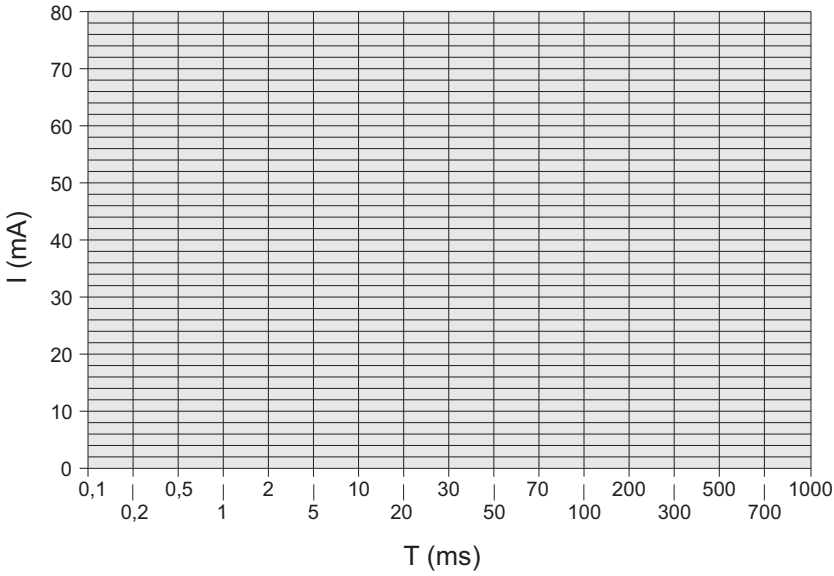
8.1 Agents for iontophoresis

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. Form: 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, abarticular 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 (-)	AINS	Application: inflammatory illnesses. Form: 1% solution. 50 mg freeze-dried powder, to be dissolved in 5 ml distilled water.

Agent	Property	Application and form
Voltaren (-)	AINS	Application: inflammatory illnesses. Form: 0,75% solution. 3 ml (75 mg/ ampoule), to be dissolved in 7 ml distilled water.
Acetic acid	AINS	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 or Body Area to get information about the placement.

8.3.1 Electro therapy

Select the 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

Other information in the illustrations: The electrodes shown on the rear of the body are transparent. The type of electrodes to use is not advised. The size of the shown electrodes is an indication for the advised size. The letters A and B recommend the channel to be used. The symbols + and - recommends the polarity.

8.3.2 Iontophoresis

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

8.3.3 Ultrasound therapy

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

8.3.4 Combination Therapy

The 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 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 § 7.8 & § 7.9.

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.

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	Floor 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.
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% UT (>95% dip in UT) 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 UT - 100% (5 seconds) Device resets to a safe state. (60601-1 see § 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	$d = 0,35\sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m AM 1 kHz 80% 80 kHz to 2,5 GHz	10 V/ m.0.08-1.0 GHz 40 V/m..380-470 MHz 30 V/m....2.3-2.6 GHz	$d = 0,35\sqrt{p}$ ... 80 MHz to 800 MHz $d = 0,70\sqrt{p}$ ... 800 MHz to 2,5 GHz $d = 0,09\sqrt{p}$ $d = 0,23\sqrt{p}$
Radiated RF ENV50204	3 V/m CW 200 Hz d.c. 50% 895 MHz to 905 MHz	40 V/m...895-905 MHz	$d = 0,18\sqrt{p}$
			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[4] in good working order		
	Inspection performed by:	**Owner:**
Location:	Name:	Name:
Date:	Initials:	Initials:
[4] 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, Unidirectional currents, MF constant.	☐	☐
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 "Poor connection to patient" is given if the load is disconnected.	☐	☐
7.	Select channel B, Unidirectional current, MF constant.	☐	☐
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 "Poor connection to 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, Interferential current, 2-pole MF, CV.	☐	☐
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.	Select channel B, Interferential current, 2-pole MF, CV.	☐	☐
17.	At maximum intensity, the output voltage corresponds within 10% with the values on the display.	☐	☐
18.	The output signals correspond with Figure 2 and Figure 3.	☐	☐
19.	Select on channel A Microcurrent Continuous.	☐	☐
20.	At maximum intensity, the output current corresponds within 10% with the value on the display.	☐	☐
21.	The output signals correspond with Figure 4.	☐	☐
22.	Select on channel B Microcurrent Continuous.	☐	☐
23.	At maximum intensity, the output current corresponds within 10% with the value on the display.	☐	☐
24.	The output signals correspond with Figure 4.	☐	☐

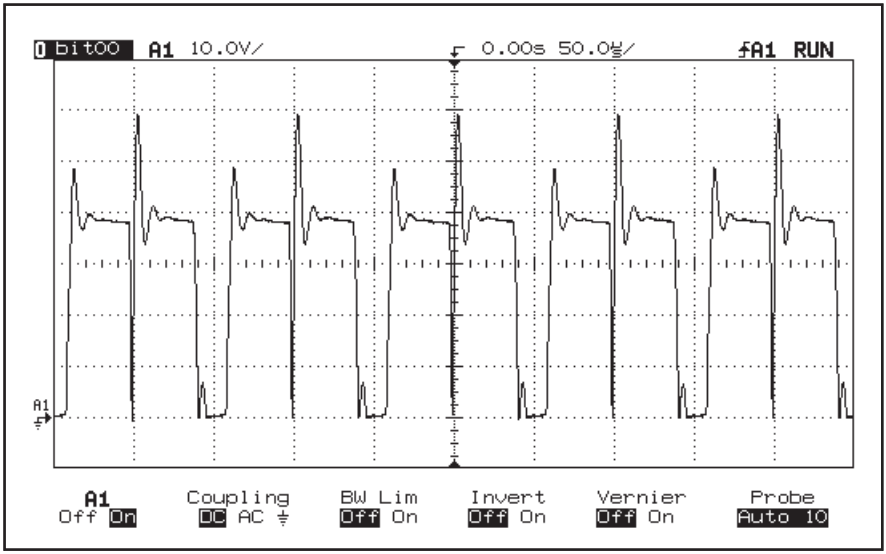


Figure 1.

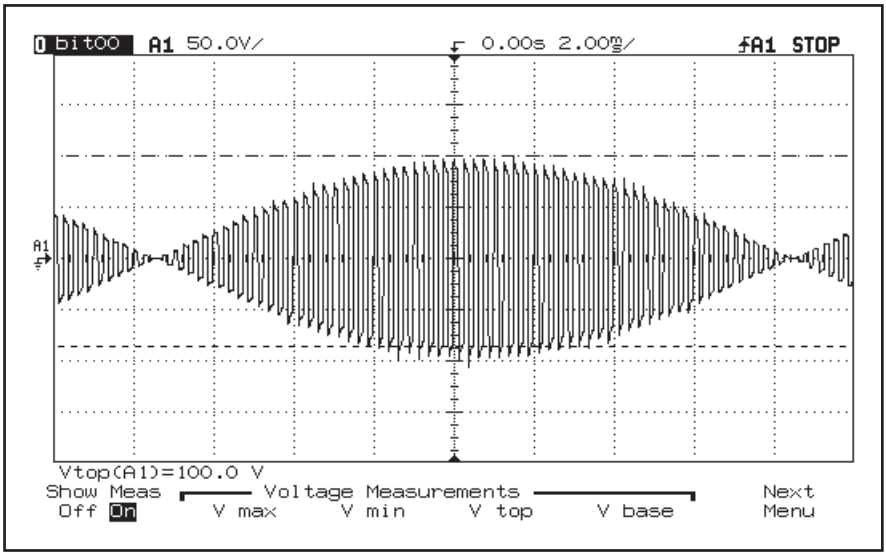


Figure 2.

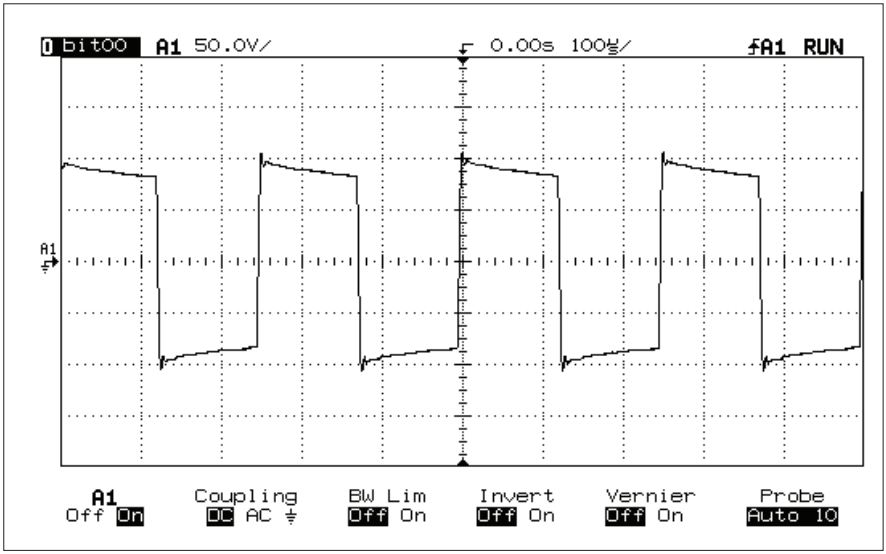


Figure 3.

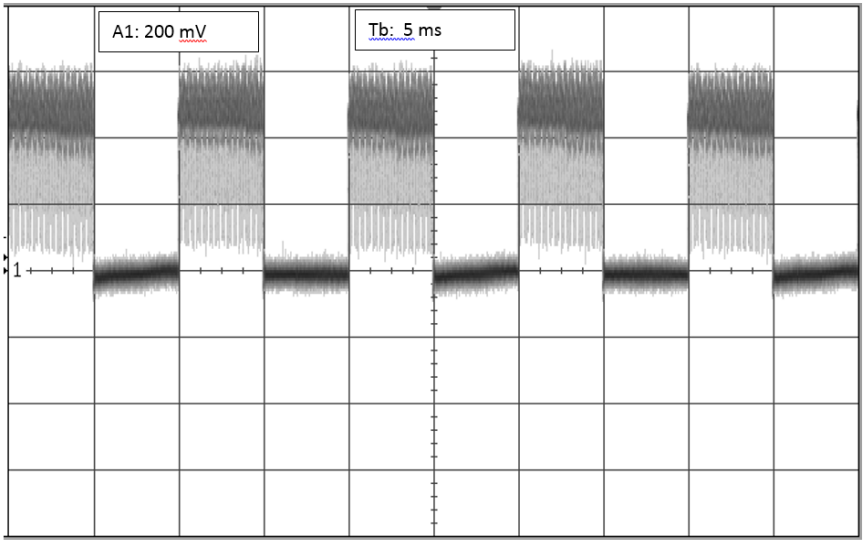


Figure 4.

8.5.3 Test 3: Ultrasound

		Yes	No	NA
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

Warning:

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: 880 - 930 nm.
- The capability to measure: 200 ns pulses of 30 Wpk.
- 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.		
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 Ep value with the laser radiation measurement device. The measured Ep value is .....µJ.		
6.	The measured Ep value corresponds within ±20% with the Ep value of the test protocol of the laser probe.	☐	☐

Test B: The clusterprobe

		Yes	No
1.	Connect the clusterprobe to the 400-Series.	☐	☐
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 Ep values with the laser radiation measurement device. The measured Ep value from laser diode 1 is .....µJ. The measured Ep value from laser diode 2 is .....µJ. The measured Ep value from laser diode 3 is .....µJ. The measured Ep value from laser diode 4 is .....µJ. Stop the laser therapy. The sum of the four measured Ep value is .....µJ.	☐	☐
6.	The sum of the measured Ep values corresponds within ±20% with the total Ep value of the test protocol of the laser probe.	☐	☐

Test C: Calibration of the laser test eye

		Yes	No
1.	Connect the calibrated monoprobe to the 400-Series.		
2.	Select: System settings, Accessories test and Laser energy measurement.		
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 Ep value is .....µJ. Stop the laser energy measurement.		
4.	The measured Ep value corresponds within ±5% with the Ep 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 (IEC 62353)

		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:

_____

_____

_____

_____

8.5.6 Record of used measuring tools

Measurement	Equipment name	SN or identification	Calibration due date
Safety test			
Electrotherapy			
Ultrasound power			
Laser power			

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 (msec)	Delay in action potential of rectangular pulse: triangular pulse	Accomodation Quotient (AQ)
500	1:1.5 to 1:3	1.5 - 4
1000	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.

H.A.C.: Hospital Antiseptic Concentrate. An antiseptic with Chlorhexidine and Cetrimide as active ingredients. This medicine is registered in the Member States of the EEA under the following name: Hibicet Hc

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
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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