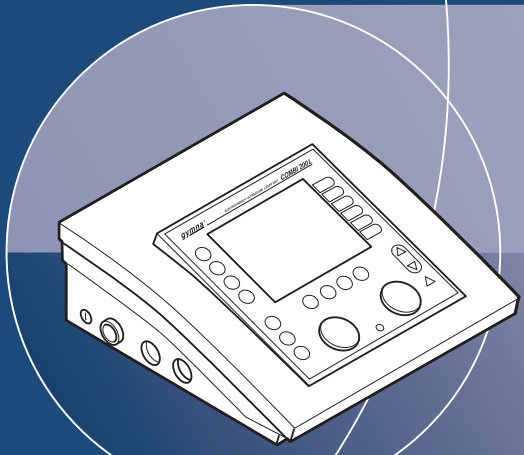
User Manual



COMBI 200L

User Manual Combi 200L

Device for electrotherapy, ultrasound therapy, combination therapy and laser therapy

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Abbreviations

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

Symbols on the equipment


Read the manual


Sensitive to electrostatic discharge


Manufacturer

Symbols on the laser probe


Laser warning sign


Points to laser aperture and shows direction of beam


Type B applied part

Symbols in the manual

Warning or important information.

TABLE OF CONTENTS

1 SAFETY

1.1 Purpose

The Combi 200L is intended solely for medical applications. You can use the Combi 200L for electrotherapy, ultrasound therapy, combination therapy and laser therapy. The device is suited for continuous use.

1.2 Safety instructions

1.2.1 General

- Only qualified people who are trained in the application of the therapies may use the appliance.
- Only a technician authorised by GymnaUniphy N.V. may open the equipment or the accessories.
- Follow the instructions and directions in these user instructions.
- Place the equipment on a horizontal and stable base.
- Keep the ventilation openings at the bottom and rear of the equipment free.
- Do not place any objects on the equipment.
- Do not place the equipment in the sun or above a heat source.
- Do not use the equipment in a damp area.
- Do not let any liquid flow into the equipment.
- Do not disinfect or sterilise the equipment. Clean the equipment with a dry or moistened cloth. *See §5*.
- Only treat patients with electrical implants (pacemaker) after obtaining medical advice.
- The 'Directive on Medical Devices' from the European Commission (93/42/EEG) requires that safe devices are used. It is recommended to perform a yearly technical safety inspection. *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.

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 accompanying accessories that are supplied by GymnaUniphy. *See §7*.
  Other accessories can lead to an increased emission or a reduced immunity.

1.2.5 *Electrotherapy*

- Do not use the equipment simultaneously with high frequency surgical equipment. This combination can cause burning of the skin under the electrodes.
- 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.
- Check the electrode cables and the electrodes at least once a month. Check whether the insulation is still intact. *See §5.1.*
- The safety standards for electrical stimulation advise not to exceed the current density of 2.0 mA_{rms}/cm^2.
  However, with iontophoresis treatments, we advise a maximum current density of 0.25 mÂ/cm^2, because of using the MF rectangular current. Exceeding this value can result in skin irritation and burns.
- Always use sterilised gauze with iontophoresis treatments.

1.2.6 *Ultrasound therapy*

- Move the US head evenly over the skin during the treatment. This prevents internal burns.
- The US treatment heads are exchangeable. The device detects the characteristics and supplies the right power at the right frequency.
- Handle the US heads carefully. With rough handling, the characteristics can change. Test the US head if it falls on the ground or knocks against something. *See §5.1.1.*
- 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.*

1.2.7 Laser therapy

The laser is a class 3b laser product and has an invisible beam.

- Make sure the laser warning sign is clearly visible outside the entrance to the therapy room.
- The radiation of a laser probe can cause a physiological effect.
- Use the laser therapy only for therapeutic purposes.
- Use of controls or adjustments or performance of procedures other then those specified in this manual may result in hazardous radiation exposure.
- Start a laser therapy only when all persons in the room wear laser goggles for eye protection. If you do not obey this warning, you can cause blindness. Use goggles with at least the characteristics: l 100 - 1000 L2 and with a clear view of the control, the display and the signal lights. *See §7.10*.
- Do not look into the laser beam during a laser therapy.
- Do not point the laser beam into eyes.
- Do not use the laser near flammable materials or liquids.
- Do not use the equipment if any damage shows.
- Regulary check the output of the laser probe with the test facility. *See §4.9.8*.
- 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.
- Remove the key of the laser lock when the laser therapy is not used.

1.3 Medical Devices Directive

The device complies with the essential requirements of the Medical Device Directive of the European Committee (93/42/EEC) as most recently changed.

1.4 Liability

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

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

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

2 INSTALLATION

2.1 Receipt

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

2.2 Placing and connection

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

2.3 Performing the functional test

1. Switch the equipment on with the switch at the rear of the equipment.
2. When the equipment is switched on, it automatically performs a test. Check whether the indicator lamps next to Y_A and Y_B light briefly during the test.
3. If the lamps do not light up: *See §6.*

2.4 Setting contrast and selecting language

1. Press ⏎ for 5 seconds. The **System setting** menu appears. *See §4.9.*
2. Press ▢ next to **Contrast**, 1st key from the top.
3. If necessary, change the contrast with △ and ▽.
4. Press ▢ next to **Language**.
5. If necessary, change the language with △ and ▽.
6. Press ⏎ to return to the start menu.

2.5 Transport and storage

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

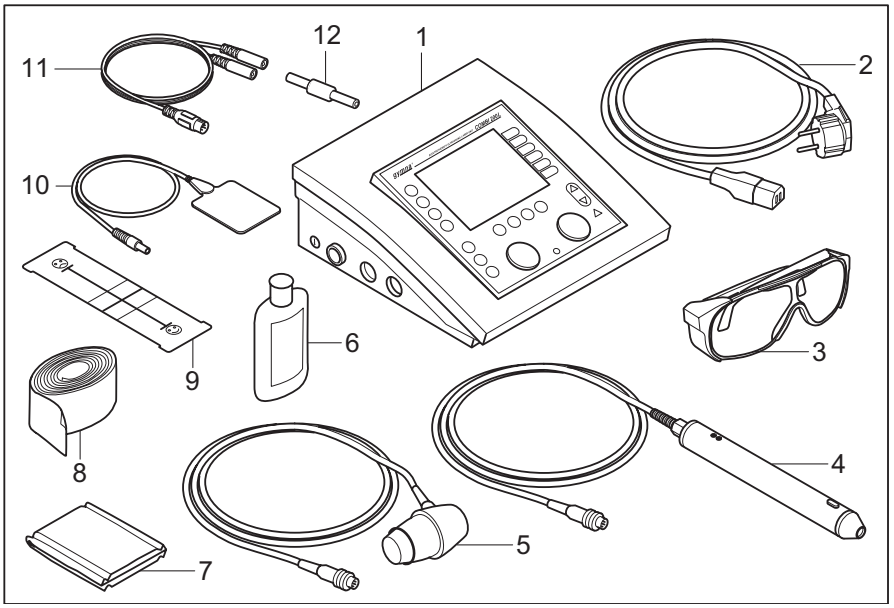
- Transport or store the equipment in the original packaging.
- The maximum period for transport or storage is: 15 weeks.
- Temperature: -20 °C to +60 °C.
- Relative humidity: 10% to 100%.
- Atmospheric pressure: 200 hPa to 1060 hPa.

2.6 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.

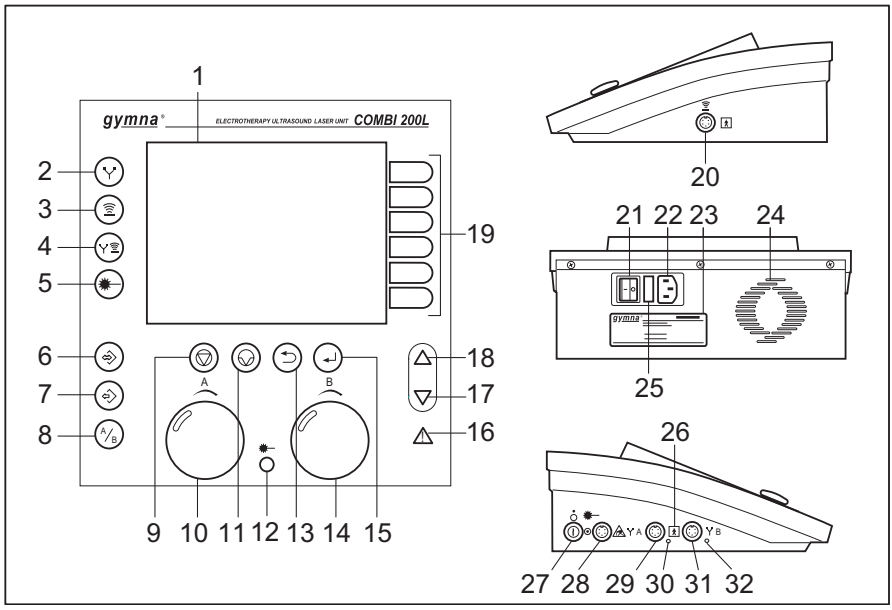
3 DESCRIPTION OF THE EQUIPMENT

3.1 Combi 200L and accessories



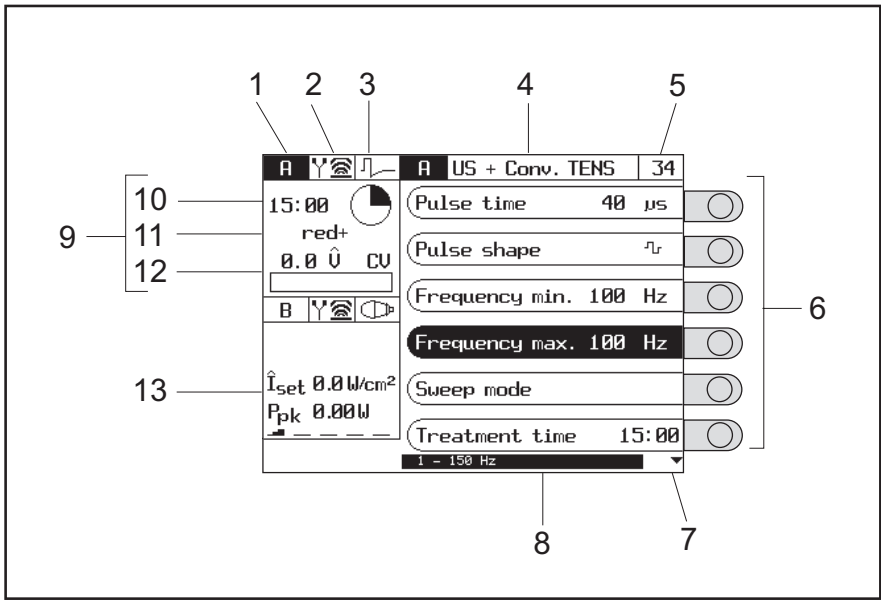
1. Combi 200L. *See §3.2.*
2. Power cord
3. Laser goggles. Optional accessory. *See §7.10.*
4. Laser probe. Optional accessory. *See §7.10.*
5. US head
6. Contact gel
7. EL sponges for rubber electrode (4 pieces)
8. Elastic fixation straps (4 pieces)
9. VAS score card
10. Rubber electrodes (4 pieces)
11. Two-ply electrode cable (2 pieces)
12. Test connector

3.2 Components of Combi 200L



1. Display. *See §3.3.*
2. Electrotherapy
3. Ultrasound therapy
4. Combination therapy
5. Laser therapy
6. Memory
7. Start menu
8. Channel selection: A or B
9. Stop
10. Intensity of channel A
11. Pause
12. Laser test eye
13. Return to previous menu
14. Intensity of channel B
15. Enter
16. Indication: Read manual
17. Down
18. Up
19. Select parameter or menu
20. Connector for US head
21. On/off switch
22. Connection to mains supply
23. Type plate
24. Ventilation opening
25. Fuse holder
26. Indication: Floating patient circuit
27. Laser lock
28. Connector for laser probe
29. Connector for electrotherapy, channel A
30. Indicator lamp for channel A
31. Connector for electrotherapy, channel B
32. Indicator lamp for channel B

3.3 Display



1. Channel
2. Therapy
3. Current shape
4. Title of the screen
5. Program number
6. Parameters with selection knobs
7. Use ▽ to go to the next parameters
8. Explanation or recommendation
9. Screen for channel A (here, electrotherapy). *See §4.3.5.*
10. Remaining treatment time
11. Polarity
12. Set intensity
13. Screen for channel B (here, ultrasound therapy). *See §4.4.2.*

3.4 Display symbols

3.4.1 General

	Electrotherapy	**A**	Channel A
	Ultrasound therapy	**B**	Channel B
	Combination therapy	**A + B**	Channel A and B simultaneously
	Laser therapy		Treatment time
SEQ	Sequential current shapes	 **0:00**	Treatment completed

3.4.2 Current shape groups

	Unidirectional currents		2-pole medium frequency
	Diadynamic		4-pole Interferential
	TENS currents		4-pole interferential with vector
	NMES currents		Diagnostic programs

3.5 Symbols for current shapes in memory menu

	Medium frequency unidirectional current		Burst TENS
	Unidirectional rectangular current		Rectangular surge current
	Unidirectional triangular current		Triangular surge current
	Conventional TENS		Biphasic surge current
	Low frequency TENS		Intrapulse interval surge current
	Random TENS		2-pole medium frequency surge current

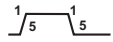
CP	CP (diadynamic)		2-pole medium frequency
DF	DF (diadynamic)		Dipole vector field
LP	LP (diadynamic)		Rheobase and chronaxie
MF	MF (diadynamic)		Rheobase and AQ

3.6 Parameter symbols

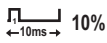
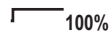
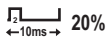
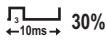
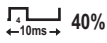
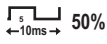
3.6.1 Electrotherapy

Red+ **Red-**	Polarity indication	**CC**	Constant Current
+ ⇆ -	Alternating polarity	**CV**	Constant Voltage
	Biphasic pulse shape, symmetrical	**mÂ**	mA peak
	Biphasic pulse shape, asymmetrical	**V̂**	Volt peak

Sweep mode

	12s/12s		1s/5s -1s/5s
	6s/6s		1s/1s

3.6.2 Ultrasound therapy

	US duty cycle 10%		US duty cycle 100%
	US duty cycle 20%	**$\hat{I}_{set}$**	Set US intensity
	US duty cycle 30%	**P_{pk}**	Peak US output power
	US duty cycle 40%	**W/cm^2**	Unit of the set US intensity
	US duty cycle 50%		

3.6.3 Laser therapy

$\bar{P}_{set}$ Set average power

E_{tot} Total administered energy

E_p Energy per pulse

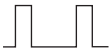
 Wear goggles

 Monoprobe

 Clusterprobe

3.7 Current shapes

3.7.1 Unidirectional currents

 Rectangular pulse current

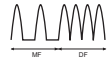
 Triangular pulse current

2-5 current (UltraReiz)

 Medium frequency rectangular current

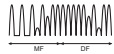
3.7.2 Diadynamic currents

 MF



CP

 DF



LP

3.7.3 Interferential currents

 2-pole medium frequency

 4-pole interferential with rotating vector

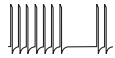
 4-pole Interferential

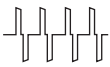
3.7.4 TENS currents

 Conventional TENS, asymmetrical

 Conventional TENS, alternating symmetrical

 Conventional TENS, alternating asymmetrical

 TENS burst

 Conventional TENS, symmetrical

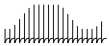
 TENS burst, alternating

3.7.5 NMES currents

Rectangular surge current

Triangular surge current

Medium frequency surge current (2- and 4-pole)



Biphasic surge current

Intrapulse interval surge current

4 OPERATION

4.1 Therapy selection

You can select a therapy in different ways, with the therapy keys or with the parameters in the Start menu:

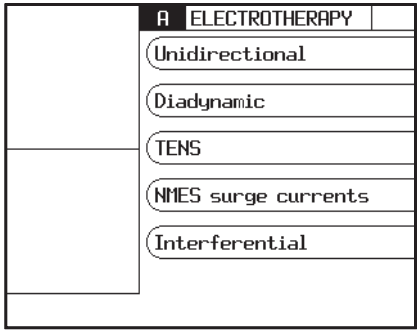
- **Therapy keys**: Quickly select a therapy with therapy keys, , and . *See §4.1.1.*
- **Objectives**: Select a therapy on the basis of an objective. *See §4.1.2.*
- **Indication list**: Select a therapy on the basis of a medical indication. *See §4.1.3.*
- **Program number**: Select a certain program number or a program number that you previously saved. *See §4.1.4.*
- **Diagnostic programs**: Perform a diagnosis, for example to determine the rheobase and the chronaxie. *See §4.1.5.*
- **Contra indications**: Display an overview with contra indications for the different therapies. *See §4.1.6.*

Besides this, you can change the system settings. *See §4.9.*

4.1.1 Therapy keys

Electrotherapy selection

1. Press : Electrotherapy.
2. Select the current shape group with .
3. Select the current shape with .



Ultrasound therapy, direct selection

1. Press : Ultrasound therapy. The Ultrasound screen appears.

Combination therapy, direct selection

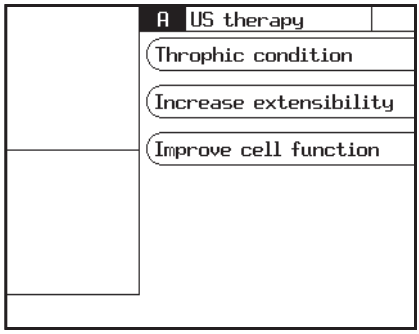
1. Press : Combination therapy.
2. Select the current shape with . *See §4.5.1.*

Laser therapy, direct selection

1. Press : Laser therapy. The Laser therapy screen appears.

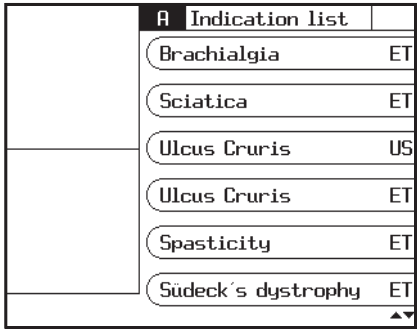
4.1.2 Therapy selection via objectives

1. Press ⏻ to go to the start menu.
2. Select **Objectives**.
3. Select **Electrotherapy**, **Ultrasound therapy** or **Laser therapy**.
4. Select the desired treatment with ◯.



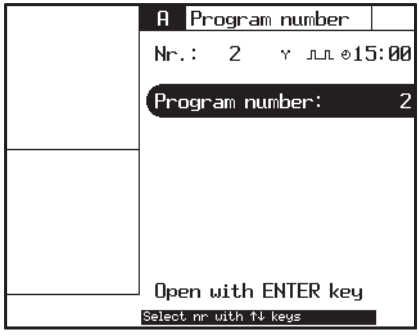
4.1.3 Therapy selection via indication list

1. Press ⏻ to go to the start menu.
2. Select **Indication list**.
3. Go to the following indications with △ or ▽. *See §9.1.4.*
4. Select the desired indication with ◯.
   - ET: Electrotherapy
   - US: Ultrasound therapy
   - LA: Laser therapy
   - CO: Combination therapy



4.1.4 Program number selection

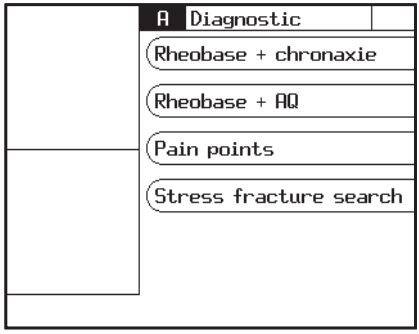
1. Press ⏻ to go to the start menu.
2. Select **Program number**.
3. Select the desired program with △ or ▽. *See §9.1.*
4. Press ↵. *See §4.8.*



4.1.5 Diagnostic program selection

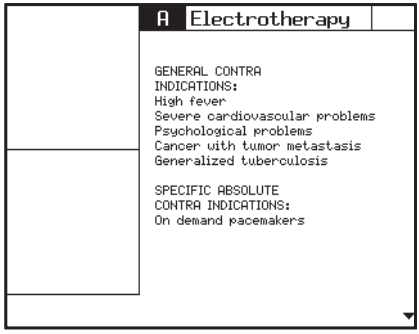
With the diagnostic programs, you can localise and treat pain points, and look for stress fractures, etc.

1. Press ⏎ to go to the start menu.
2. Select Diagnostic programs.
3. Select the desired diagnosis with ◯. *See §4.7.*



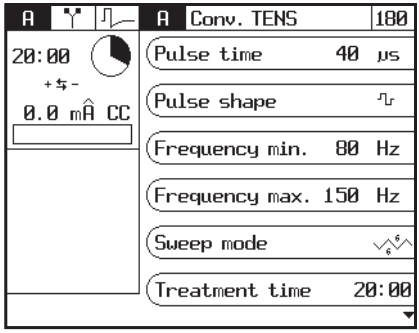
4.1.6 Contra indication selection

1. Press ⏎ to go to the start menu.
2. Select Contra indications.
3. Select the therapy for which you want to see the contra indications.



4.2 Performing therapy

4.2.1 Set and start therapy



1. Press ⏻ to go to the start menu.
2. Select the desired menu with ▭ until the treatment appears.
3. Select the desired parameters with ▭. You can only change the outlined parameters.
4. Set the **Treatment time** as follows: Press once on ▭ to set the minutes, press twice on ▭ to set the seconds.
5. Change the value of the parameter with △ and ▽. The setting range of the parameter is shown at the bottom of the screen. You can change the parameter as long as the parameter has a black background.
6. Start the therapy:
   - Electrotherapy or ultrasound therapy: Rotate intensity knob A or B to start the treatment and to set the desired intensity. The set intensity is displayed in the screen.
   - Laser therapy: *See §4.6.1*.

4.2.2 Set channels A and B

The Combi 200L has two separated electrotherapy channels A and B. The only restriction is that both are in the CC mode or the CV mode.

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

1. Press ⏻ for 5 seconds. The **System setting** menu appears. *See §4.9*.
2. If necessary, change the parameter **Copy parameters** to **OFF**.
3. The selected channel has a black background. If desired, press Ⓐ/Ⓑ to change the first channel.
4. Select a treatment. *See §4.1*.
5. Set the parameters for the first channel. *See §4.2.1*.
6. Press Ⓐ/Ⓑ to select the other channel.
7. Select a treatment for the second channel. *See §4.1*.
8. Set the parameters for the second channel. *See §4.2.1*.

Both channels are selected simultaneously and automatically in case of:

- 4-pole current shapes
- Combination therapy

Copy channel

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

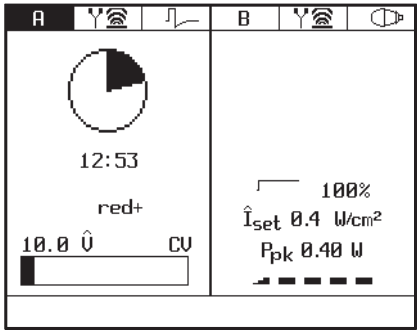
1. Press ⏎ for 5 seconds. The System setting menu appears. *See §4.9.*
2. If necessary, change the parameter Copy parameters to ON.
3. Select a treatment. *See §4.1.*
4. Set the parameters for the first channel. *See §4.2.1.*
5. Press A/B to select the other channel. The treatment including the settings are copied to the other channel.
6. If desired you can change the parameters or the treatment of the selected channel.

Clear channel

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

4.2.3 Opening the intensity screen

1. Set and start the treatment. *See §4.2.1.*
2. Press ↵. The intensity screen appears.
   The left part of the screen shows channel A. The right part of the screen shows channel B.
3. Press ⏎ to return to the setting menu.



4.2.4 Temporary interruption of treatment

1. If the other channel has to pause: Select this channel with A/B.
2. Press ⏯ during the treatment. The treatment time of the selected channel is stopped. Pause appears on the screen. The parameter settings are retained.
3. Press on ⏯ again to restart the treatment. The intensity now increases gradually to the set level and the treatment time continues again.

4.2.5 Immediately stop treatment

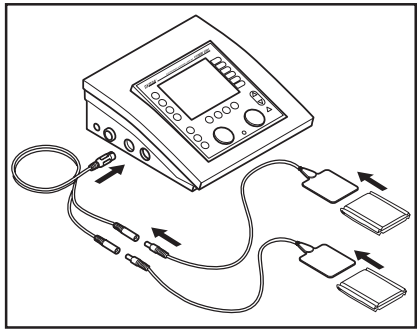
1. Press ⏹. All active treatments are stopped immediately. Stop appears on the screen. The parameter settings are retained.
2. Set the intensity of the channel again to continue the treatment.

4.3 Electrotherapy

4.3.1 Performing electrotherapy with electrodes

1. Select the desired electrotherapy program.
2. Place the electrodes. *See page 30: Placing rubber electrodes* and page *31: Placing the adhesive electrodes*. With some treatments, the Electrode placing parameter refers to the number in the placing diagrams.
3. Rotate intensity knob A or B to start the electrotherapy and to set the desired intensity. See *§4.2.1*.
4. Check the patient's reaction. Repeat this check regularly during the treatment.
5. The equipment stops the treatment and indicates that the treatment is completed. Remove the electrodes.

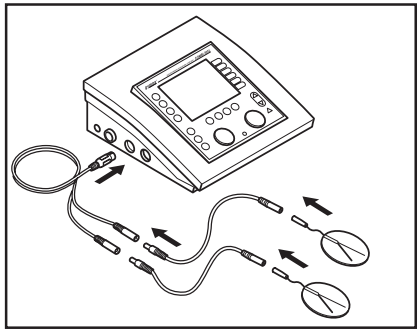
Placing rubber electrodes



1. Moisten two EL sponges. 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 rubber electrode with the red connector to the red connector of the two-ply electrode cable.
6. Connect the rubber electrode with the black connector to the black connector of the two-ply electrode cable.
7. Connect the two-ply cable to connector Y_A or Y_B of the Combi 200L.

Placing the adhesive electrodes

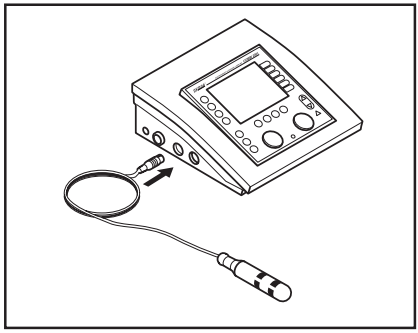
Do not use adhesive electrodes with currents that have a galvanic component, such as galvanic, diadynamic, MF rectangular, pulsed rectangular and triangular currents. These currents can cause skin etching.



1. If possible, disinfect the parts of the body where the adhesive electrodes are to be placed.
2. Place the electrodes on the part of the body that must be treated.
3. Connect the connectors of the adhesive electrodes to the adapter cables.
4. Connect the adapter cables to the two-ply electrode cable.
5. Connect the two-ply electrode cable to connector Y_A or Y_B of the Combi 200L.

4.3.2 Perform electrotherapy with vaginal, anal or rectal stimulation probe

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



1. Clean the probe carefully with soap and water.
2. Select the desired electrotherapy program.

3. Connect the probe to the Combi 200L. The vaginal and anal probes are immediately detected by the equipment. To prevent unpleasant stimulations, you can only set alternating currents with a Constant Voltage (CV) setting, such as TENS, NMES, and 2-pole interferential currents.

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

4. Apply an antiseptic lubricant to the probe.
5. Place the probe.
6. Rotate intensity knob A or B 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 *§5.2.4*.

4.3.3 Electrotherapy with sequential steps

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

Advantages

Electrotherapy with sequential steps has several advantages:

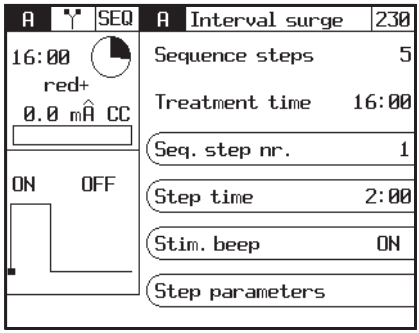
- In one electrotherapy, you can realise several objectives.
- In a treatment with one objective, you can place different accents in the objective.
- You can distinguish between different phases in a treatment, for example preparation, core effect and cooling.

Set new intensity between sequential steps

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

Setting a treatment with sequential steps

1. Select a treatment whereby you can set sequential steps, for example with **Objectives, Electrotherapy, Muscular training, Specific muscle functions, Endurance**.
   You can also select a program directly with the program number.
2. Set the **Step time** and **Stimulation beep** parameters for the different steps.
   Select **Seq. step. nr.** to select a different step.
3. Rotate intensity knob A or B to start the treatment and to set the desired intensity.



Skip step in treatment

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

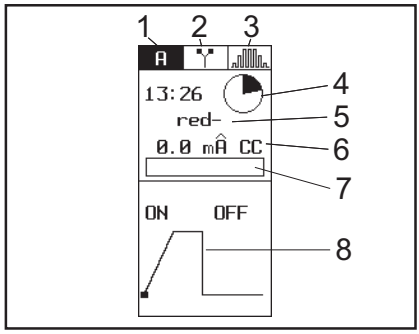
4.3.4 Performing iontophoresis

1. Apply the medicament on a sterile gauze. See *§8.1*. Care must be taken in administering medicaments (allergies, contra indications, ...).
2. Place the gauze on the electrode. Make sure that the polarity corresponds with the medicament used.
3. Place the electrodes. See page *30: Placing rubber electrodes* and page *31: Placing the adhesive electrodes*.
4. Select **Electrotherapy, Unidirectional, Medium freq. constant**.
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.

To prevent etching or burns, never exceed 0.25 mÂ/cm^2.

4.3.5 Read-out values

1. Channel
2. Electrotherapy
3. Current shape
4. Remaining treatment time
5. Polarity
6. Present intensity
7. Graphical representation of intensity
8. Progress of current



Progress of current
With NMES currents and 4-pole current shapes, the progress of the current is graphically displayed. This gives a clear insight into the phase in which the current is at that moment. In this way, you can optimally guide the patient during the execution of the exercise. With the simultaneous application of two NMES currents, the current is only graphically displayed in the intensity screen.
Press ↵ to open the intensity screen.

4.3.6 Parameters

The following parameters are given alphabetically. The setting range or the selection possibilities of the parameters depend on the treatment chosen.

Active rest (s)
The duration of the rest period. During the rest period, a low frequency current is applied to stimulate the recovery process.

Burst (Hz)
The frequency of the biphasic pulses. The burst consists of a series of pulses that is repeated several times per second. Each burst consists of a low frequency current with high internal pulse frequency (70 - 100 Hz) and a long pulse duration (100 - 250 µsec).

Carrier wave (kHz)
The carrier wave frequency, expressed as the number of cycles per second. The frequency of this medium frequency current corresponds with the cycle duration. A high frequency results in a short pulse duration. A carrier wave frequency of 2 kHz is suited for muscle stimulation.

CC / CV
Constant Current (CC) or Constant Voltage (CV).

- When using a dynamic electrode technique, only use alternating 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.
- With a rectal stimulation probe, select only alternating currents with Constant Voltage (CV), such as TENS, NMES, and 2-pole interferential currents. This prevents skin etching and unpleasant stimulations. The rectal stimulation probe is not detected by the equipment.

Characteristics of Constant Current:
- The voltage increases with an increasing load impedance (a worsening contact).
- Within the stated limits, a variation in the load impedance has hardly any effect on the current.
- Without a load, the voltage will go to the maximum level within a short time. After this, an error message will appear on the screen and the current wil be switched off.

Characteristics of Constant Voltage:
- With a decreasing load impedance, the current increases.
- Without a load, the output voltage is equal to the set value.
- With a short circuit, the output current in mA is equal to the set voltage in V.

Electrode placing
Instructions for placing the electrodes. Consult the placement diagrams.

Frequency min./max. (Hz)
The minimum and maximum frequency of the current cycles, expressed as the number of cycles per second. Within the set sweep mode, the frequency changes within these limits. During the treatment, frequency modulation is desired to prevent habituation. It is recommended to select a fairly low minimum frequency for this (< 20%).

Isodynamic (on, off)
LP and CP use two phases: MF and DF. The MF phase is more intense than the DF phase. If the patient is very sensitive, this difference in perception can be adjusted with this parameter.
On: Reduce the amplitude of the MF phase by 12.5%.

Off time (off) (s)
The interval between two series of current pulses.

On2 amplitude
The amplitude of the pulses during the On2 period. This amplitude can be set as a percentage of the set amplitude during the On period.

On2 frequency
The frequency of the pulses during the On2 time.

On time (on) (s)
The time that the series of current pulses is switched on.

Polarity
The polarity of the current pulse.

Polarity change (on, off)
Switch polarity between red+ and red- during the treatment.

Pulse pause (ms or s)
The duration between the current pulses.

Pulse shape
The shape of the electrical pulse. See *§3.6.1*.

Pulse time (µs, ms or s)
The duration of the current pulse.

Rest amplitude (%)
The amplitude of the pulses that is maintained during the active rest period. The active rest period stimulates recovery, which is otherwise realised by the "*Off* time". The amplitude during the active rest period is set as a percentage of the amplitude during the "*On* time".

Rest frequency (Hz)
The frequency that is maintained during the active rest period of the NMES current.

Rotation angle (0 - 355°)
The actual angle between the line with the maximum amplitude and the line between the electrodes of channel B. If Manual is selected for Rotation mode, you can let this angle rotate step by step. This makes it possible to localise deeper treatment points.

Rotation mode (manual, auto)
The maximum amplitude is present at one line in the rotation field (with 100% modulation depth).

- Auto: The line with maximum amplitude and 100% modulation depth automatically rotates 360° through the interference field during the set rotation time.
- Manual: Position this line manually in the interference field. You do not need to move the electrodes for this.

Rotation time (0 - 20 s)
The time in which the line with maximum amplitude and 100% modulation depth rotates 360° through the interference field. Use a short rotation time (3 - 5 s) to prevent habituation. Use a long rotation time (10-15 s) to localise deeper treatment points.

Segment angle (0, 15, 30°)
With the segment angle, a certain segment can be stimulated. The segment angle can be set when the Rotation angle is set to Manual.

Segment time (s)
The time in which the rotation angle changes within the set segment angle.

Seq. step nr. (1 - 5)
The number of the sequential step that is activated. See *§4.3.3*.

Seq. steps
The maximum number of sequential steps. See *§4.3.3*.

Step time (mm:ss)
The time in which the selected sequential step number is performed.

Stimulation beep (on, off)
Switch stimulation beep on or off.

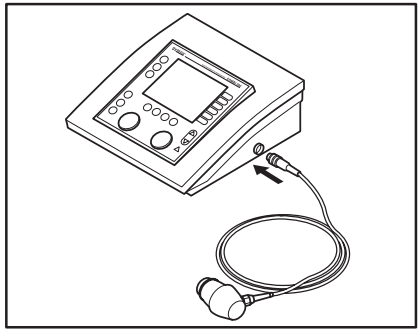
Sweep mode
This parameter is only available if Frequency min deviates from Frequency max. The frequency cycle consists of four steps with fixed set values: increase, hold, decrease and hold. During the treatment, frequency modulation is desired to prevent habituation.

Treatment time (mm:ss)
The duration of the treatment.

4.4 Ultrasound therapy

4.4.1 Performing ultrasound therapy

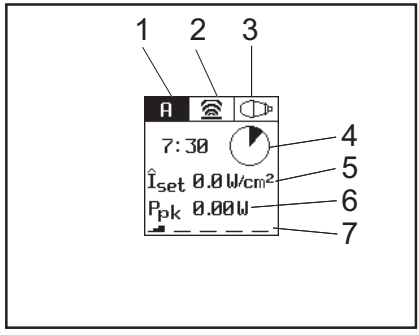
Move the US head evenly over the skin during the treatment. This prevents internal burns.



1. Plug the connector of the US head into the connector of the Combi 200L.
2. Select the desired ultrasound therapy. With some treatments, the parameter Head placement refers to the number in the placing diagrams.
3. Apply contact gel to the skin to be treated and to the US head.
4. Place the head on the skin.
5. Rotate intensity knob A or B to start the ultrasound therapy.
6. Move the US head evenly over the skin during the treatment. This prevents internal burns.
7. Check the patient's reaction and the effect of the treatment. Repeat this check regularly during the treatment.
8. The equipment stops the treatment and indicates that the treatment is completed.

4.4.2 Read-out values

1. Channel
2. Ultrasound therapy
3. Type of US head
4. Remaining treatment time
5. Îset
6. Ppk
7. Contact of the US head



Contact of the US head
The contact of the US head with the skin:
- : Bad contact, US head switched off (0 W).
- : Bad contact.
- : Sufficient contact.
- : Good contact.
- : Very good contact

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

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

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

4.4.3 Parameters

Treatment time (mm:ss)
The duration of the treatment.

Duty cycle (10, 20, 30, 40, 50%, continuous)
Ratio of the pulse duration to the period duration.
- Continuous: Continuous ultrasound (100%).
- 10, 20, 30, 40, 50%: Pulsating ultrasound.

Select a high duty cycle for an intensive treatment. Select a low duty cycle for a mild treatment.

ERA (cm^2)
The effective radiating area expressed in cm^2 of the treatment head connected. This area equals the cross-sectional area of the beam at the treatment surface. The ERA depends on the frequency. This parameter remains empty if no US head is connected.

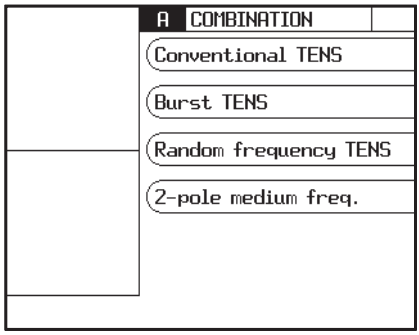
Head placement
Instructions for placing the US head. Consult the placement diagrams.

US frequency (MHz)
The frequency of the US head. The absorption at a US frequency of 3 MHz is three times higher and the penetration depth is three times less than at a US frequency of 1 MHz. Use 3 MHz for superficial tissue and 1 MHz for deeper tissue.

4.5 Combination therapy

4.5.1 Performing combination therapy

- With combination therapy, the US head is always the negative pole. The electrode is the positive pole.
- 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 US204 (9 cm^2), the current setting may be a maximum of 18 mA_{rms}; for US201 (3 cm^2), a maximum of 6 mA_{rms}.

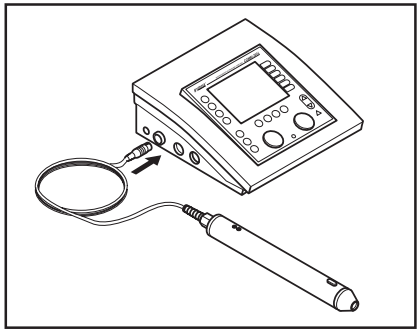


1. Press : Combination therapy.
2. Select the current shape.
3. Place the electrode. Make sure that the electrode is connected to the red connector A of the Combi 200L. See page *30: Placing rubber electrodes* and page *31: Placing the adhesive electrodes*.
4. Apply contact gel to the skin to be treated and to the US head.
5. Place the head on the skin.
6. Rotate intensity knob A to start the electrotherapy. Set the desired voltage.
7. Rotate intensity knob B to start the ultrasound therapy
8. Check the contact between the US head and the skin. The following indications can indicate a bad contact:
   - The treatment stops.
   - The peak power of the ultrasound treatment goes to 0.0 Watt.
9. Check the patient's reaction and the effect of the treatment. Repeat this check regularly during the treatment.
10. The equipment stops the treatment and indicates that the treatment is completed.

4.6 Laser therapy

4.6.1 Performing laser therapy

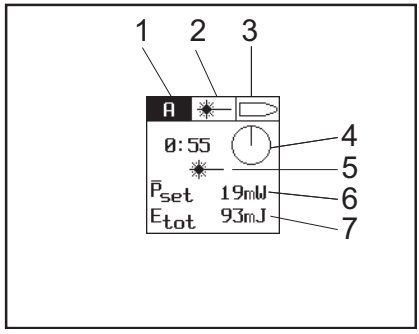
Start a laser therapy only when all persons in the room wear laser goggles for eye protection.



1. Make sure all persons wear laser goggles.
2. Plug the connector of the laser probe into the connector ✹— of the Combi 200L.
3. Put the laser lock in the ON position (horizontal).
4. Select the desired laser therapy. The green indicator light on the laser probe lights up. With selection via **Indications**, the **Probe placement** parameter refers to the number in the laser placing diagrams.
5. Place the laser probe on the skin.
6. Press the black knob on the laser probe to start the laser therapy. The yellow indicator light on the laser probe lights up. Hold the knob to keep the laser probe active during the treatement.
7. Check the patient's reaction and the effect of the treatment. Repeat this check regularly during the treatment.
8. The equipment stops the treatment and indicates that the treatment is completed.
9. Release the black knob on the laser probe.
10. Put the laser lock in the OFF position (vertical).

4.6.2 Read-out values

1. Channel
2. Laser therapy
3. Type of connected laser probe
4. Remaining treatment time
5. Laser test symbol
6. $\overline{P}_{set}$
7. E_{tot} (during therapy) or E_p (during laser energy measurement)



E_p (µJ)
The energy per pulse (µJ).

$\overline{P}_{set}$ (µW or mW)
The set average power (µW or mW) of the laser probe (E_p * frequency).

E_{tot} (mJ or J)
The total administered energy (mJ or J) of the current treatment ($\overline{P}_{set}$ * treatment time).

4.6.3 Parameters

Probetype
The type of laser probe: mono or cluster.

Frequency (Hz or kHz)
The frequency of the laser probe.

Repeat mode (on, off)
Off: The E_{tot} value is reset to zero after the treatment time ends.
On: The E_{tot} value is kept after the treatment time ends. The E_{tot} value is the sum of the total administered energy from the performed treatments.

Treatment time (mm:ss)
The duration of the treatment.

Probe placement
Instructions for placing the laser probe. Consult the laser placing diagrams.

4.6.4 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.

4.6.5 Testing laser emission

1. Set a laser therapy. See *§4.6.1*.
2. Place the laser probe output perpendicular on the laser test eye ✹⊣.
3. Press and hold the black knob on the laser probe during the laser test. The laser test symbol ✹— appears on the read-out screen.
4. Make sure the E_{tot} value increases every second by the $\overline{P}_{set}$ value.
5. Release the black knob on the laser probe.
6. Press ⏻ to go back to the start menu.
7. Put the laser lock in the OFF position (vertical).

You can also test the energy per pulse of the laser probe. See *§4.9.8*.

4.7 Diagnostic programs

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

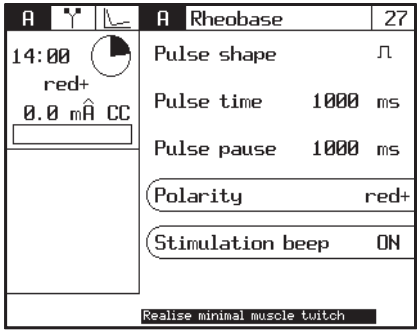
- Rheobase and chronaxie. See *§4.7.1*.
- Rheobase and AQ. See *§4.7.2*.
- Manually determine an I/T curve. See *§4.7.3*.

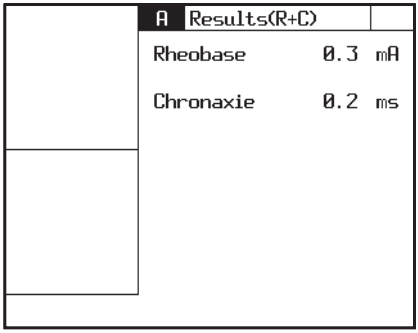
Besides this, there are diagnostic programs for localisation:

- Pain points. See *§4.7.4*.
- Stress fracture search.

4.7.1 Determining rheobase and chronaxie

1. Press ⏻ to go to the start menu.
2. Select **Diagnostic programs**.
3. Select **Rheobase and chronaxie**.
4. If desired, change the **Polarity** and **Stimulation beep** settings.
5. Rotate intensity knob A to start the treatment. The set intensity is displayed in the screen.
6. Increase the intensity in steps of 0.1 mÂ, until you observe a tangible or visible contraction.
7. Press ↵. The measured rheobase (in mÂ) is saved.
8. The equipment now doubles the rheobase (mÂ). The pulse duration changes to 0.1 ms. Increase the pulse duration by △, until you observe a tangible or visible contraction.
9. Press ↵. The chronaxie (in ms) is saved. The results screen appears.
10. If desired, press ⏻ to save the data in the memory. See *§4.8.1*.





4.7.2 Determining Rheobase and Accomodation Quotient (AQ)

1. Press ⏻ to go to the start menu.
2. Select Diagnostic programs.
3. Select Rheobase and AQ.
4. Determine the rheobase as with Rheobase and chronaxie. See *§4.7.1*.
5. Press ↵. The measured rheobase is saved.
6. The equipment now selects a triangular pulse. Increase the intensity in steps of 0.1 mÂ, until you observe a tangible or visible contraction.
7. Press ↵. The measured AQ is saved. The results screen appears.
8. If desired, press ⏻ to save the data in the memory. See *§4.8.1*.

4.7.3 I/T-curve

1. Select Electrotherapy, Unidirectional, triangular pulse.
2. Place the electrodes. Place the anode (+) on the spinal column (cervical for the upper limbs, dorsal for the rump or lumbal for the lower limbs). Place the cathode (-) on the motor point of the muscle to be investigated.
3. Set the pulse duration to 1000 ms.
4. Increase the pulse duration until you observe a tangible or visible contraction. Note this value in the graph. See *§8.2*.
5. Repeat steps 3 and 4 for the pulse durations 700 ms, 500 ms, 300 ms, 200 ms, 100 ms, 70 ms, 50 ms, 20 ms, 10 ms, 5 ms, 2 ms, 1 ms, 500 µs, 200 µs, 100 µs.

4.7.4 Pain points

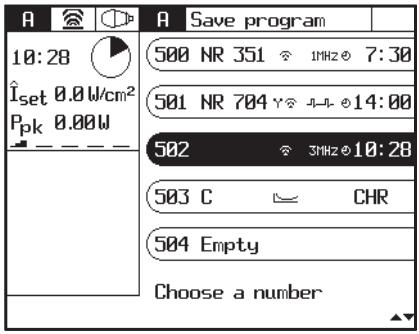
1. Press ⏻ to go to the start menu.
2. Select Diagnostic programs.
3. Select Pain points.
4. Select the diagnostic program for pain points.

4.8 Programs

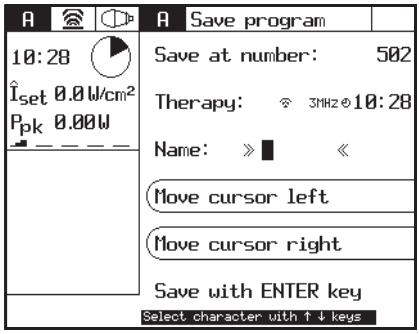
You can save 20 of your own programs for later use: programs 500 up to and including 519. You can modify these programs for much-used or specific current shapes for a certain patient.

4.8.1 Saving a program

1. Select a therapy. See *§4.1*.
2. Change the settings for the patient. See *§4.2*.
3. Press ⏎.
4. Select **Save**.
5. Select a free program number with ◯.
   If desired, go to the following programs with △ or ▽.



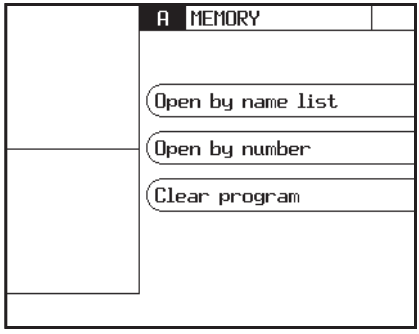
6. Enter the name of the program. Use the name or the number of the patient, for example.
   - Select a character with △ and ▽.
   - Select **Cursor to left/right** to move the cursor.
7. Press ↵ to save the program.



4.8.2 Selecting a saved program

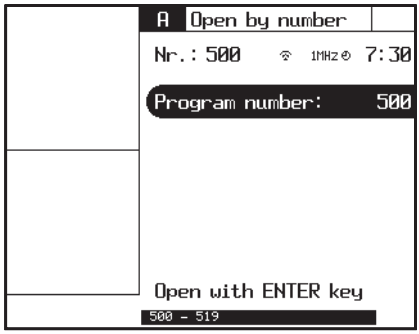
Selecting a program by the name list

1. Press ⏎.
2. Select **Open by name list**.
3. Go to the desired program with △ or ▽.
4. Select this program with ◯.



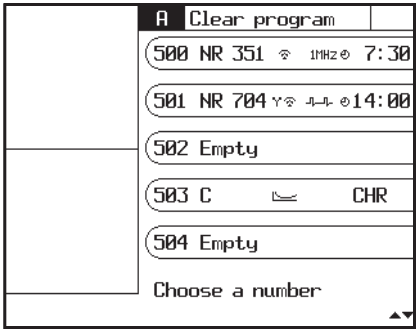
Selecting a program by the number

1. Press ⏎.
2. Select **Open by number**.
3. Select the desired program with △ or ▽.
4. Press ↵.



4.8.3 Clear a program

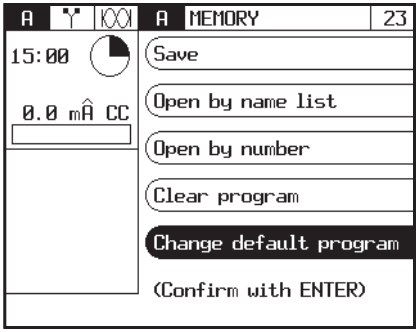
1. Press ⏎.
2. Select **Clear program**.
3. Select the program that must be deleted with ▭.
   If desired, go to the following programs with △ or ▽.
4. Press ↵ to clear the program.



4.8.4 Editing a standard program

Standard programs have a program number that is lower than 50. You can only edit standard programs with the therapy keys.

1. Select a program with the therapy keys Ⓨ, ⓦ, ⓢ or ✺.
2. Press ⏎.
3. Select **Change default program**.
4. Press ↵ to edit the standardprogram.



You can also save an edited standard program under a free program number. See *§4.8.1*.

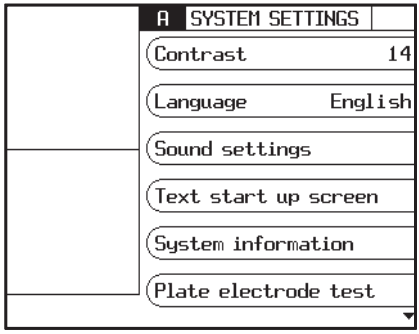
You can reset the standard settings of the standard programs with **Reset Menu**. See *§4.9.2*.

4.9 System settings

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

4.9.1 Changing the system settings

1. Press ⏲ for 5 seconds. The screen appears with the system settings.
2. Change the desired system setting.



4.9.2 Parameters

Contrast (1 - 20)
The contrast of the display.

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

Sound settings
Sound settings. See *§4.9.3*.

Text start up screen
The text that appears in the top of the start up screen, after the equipment is switched on. See *§4.9.5*.

Copy parameters (on, off)
Choose channel A and B the same or different is set by the copy parameter. See *§4.2.2*.

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

Plate electrode test
Test the condition of the rubber electrodes. See *§4.9.6*.

Cable test
Test the cables. See *§4.9.6*.

Laser energy measurement
Test the laser probe. See *§4.9.8*.

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.

Counter working hours (hours, minutes, sec.)
The time that the accessories for electrotherapy or ultrasound therapy have been in use. For this, the output of the channel must have been higher than zero.

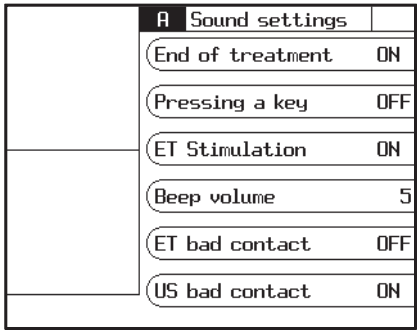
Reset menu
- Reset working hours: Set the number of working hours of a plate electrode or an US head to zero.
- Reset programs 1-50: This restores the standard settings of the standard programs. See *§4.8.4*.
- Erase total memory: Restores the standard settings of the standard programs and of the edited programs.

Press ◯ again to confirm.

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

4.9.3 Setting the sound

1. Press ⏎ for 5 seconds.
2. Select Sound settings,
3. Change the desired sound setting.



4.9.4 Parameters sound settings

End of treatment
On: A sound signal will be heard at the end of the treatment.

Pressing a key
On: A sound signal will be heard every time a key is pressed.

ET stimulation
On: A sound signal will be heard at each pulse of the electrotherapy.

Beep volume (min.1, standard 5, max.10)
The volume of the sound signals.

ET bad contact
On: A sound signal will be heard if the electrode does not make good contact with the skin.

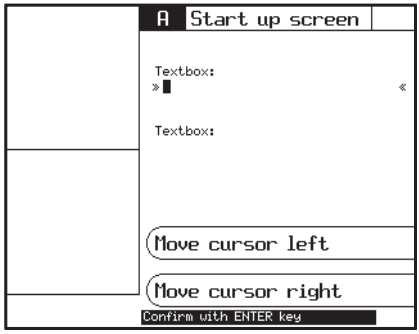
US bad contact
On: A sound signal will be heard if the US head does not make good contact with the skin.

Laser output
On: A sound signal will be heard at each pulse of the laser therapy.

4.9.5 Set text for start up screen

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

1. Press ⮌ for 5 seconds, select Text start up screen.
2. Enter the name for the start up screen.
   - Select a character with △ and ▽.
   - Select Cursor to left/right to move the cursor.
3. Press ↵ to confirm the name.



4.9.6 Cable test

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

4.9.7 Rubber electrodes test

1. Remove the test plug and connect the electrodes to the electrode cable.
2. Place the electrodes on each other, without the sponges. Make sure that the electrodes make contact over the whole surface.
3. Set the amplitude to 20 mA with rotary knob A.
4. If the electrodes function correctly, the following message will appear Condition of electrodes: OK.
5. Turn the amplitude back to 0 mA.

4.9.8 Laser energy measurement

1. Do the laser energy measurement on a 'cold' (not recently used) laser probe for a reliable test.
2. Make sure all persons wear laser goggles.
3. Plug the connector of the laser probe into the connector ✸— of the Combi 200L.
4. Put the laser lock in the ON position (horizontal).
5. Press ⟲ for 5 seconds. The System settings screen appears.
6. Select Laser energy measurem..
7. Test the monoprobe or clusterprobe.

Test the monoprobe

1. Place the laser probe output perpendicular on the laser test eye ✸—T.
2. Press and hold the black knob on the laser probe during the laser test. The laser test symbol ✸— appears on the read-out screen.
3. Move the probe a bit to-and-fro to obtain the maximum value.
4. Release the black knob on the laser probe.
5. Make sure the measured E_p value correspond within ±20% with the E_p value of the supplier control report of the laser probe.
6. Press ⟲ to go back to the System settings screen.
7. Put the laser lock in the OFF position (vertical).

Test the clusterprobe

1. Place the laser probe output perpendicular over the laser test eye ✹⊣T. Place the laser probe against the intensity knob A and B to position the laser diode over the laser test eye.
2. Press and hold the black knob on the laser probe during the laser test. The laser test symbol ✹— appears on the read-out screen.
3. Rotate the probe a bit to-and-fro to obtain the maximum value.
4. Release the black knob on the laser probe.
5. Repeat the measurement for the other laser diodes.
6. Calculate the sum of the four measured E_p value.
7. Make sure the E_p sum value correspond within ±20% with the total E_p value of the supplier control report of the laser probe.
8. Press ⮌ to go back to the **System settings** screen.
9. Put the laser lock in the OFF position (vertical).

5 INSPECTIONS AND MAINTENANCE

5.1 Inspections

Component	Check	Frequency
Electrode cables and electrodes	Damage Insulation intact	At least 1x per month
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 *§4.6.5.* and *§4.9.8.*	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 US head test

Test the US head if its conduction is bad. This is the case when the indication bar for the Ppk value displays ▂ — — — — or ▂ ▄ — — — .

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

5.1.2 Technical safety inspection

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

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

Inspection points

The technical safety inspection contains the following tests:

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

Inspection result

1. A registration must be maintained of the technical safety inspections. Use the inspection report in the appendix for this purpose. See *§8.4*.
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
Rubber electrodes	Cleaning. See *§5.2.1*.	After every treatment
EL sponges	Cleaning. See *§5.2.2*.	After every treatment
Fixation bandages	Cleaning. See *§5.2.3*.	If necessary
Vaginal, anal and rectal stimulation probe	Cleaning and disinfecting. See *§5.2.4*.	After each use
US head	Cleaning. See *§5.2.5*.	After each use
Laser probe	Cleaning. See *§5.2.6*.	After each use

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

5.2.1 Cleaning the electrodes

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

5.2.2 Cleaning the EL sponges

1. Clean the EL sponges with a 70% alcohol solution.
2. Rinse the EL sponges thoroughly with water.

Or:

1. Soak the EL sponges with water.
2. Put the EL sponges into boiling water for one minute.
3. Soak the EL sponges with a saline solution to improve their conductivity.

5.2.3 Cleaning the fixation bandages

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

5.2.4 Cleaning and disinfecting vaginal, anal and rectal stimulation probes

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

Immediately after every treatment

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

- Read the instruction leaflet in the packaging of the HAC.
- Make sure that the probe connector does not get into the HAC 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:

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

5.2.5 Cleaning the US head

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

5.2.6 Cleaning the laser probe

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

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

6 MALFUNCTIONS, SERVICE AND GUARANTEE

6.1 Malfunctions

Component	Problem	Solution
Combi 200L	Equipment cannot be switched on	See *§6.1.1*.
	Equipment does not react to commands or a fault report appears	See *§6.1.3*.
	Foreign language on the screen	Change the language. See *§4.9.2*.
EL sponges	Furring	Replace the sponges
	Bad conduction	Replace the sponges

6.1.1 Equipment cannot be switched on

1. Check if the mains voltage has failed.
2. Check if the main switch is switched on ("I").
3. Check if the power cord and the fuses are in order. If necessary, replace the fuse. See *§6.1.2*.
4. Contact your dealer if the equipment still cannot be switched on.

6.1.2 Replacing a fuse

1. Switch the main switch off ("O").
2. Unplug the power cord from the equipment.
3. Pull the fuse holder carefully out of the equipment. If necessary, use a screwdriver.
4. Replace the fuse. If necessary, order new fuses from your dealer.
5. Install the fuse holder and plug in the power cord.
6. Switch the main switch on again ("I").

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

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

1. Disconnect the connection to the patient.
2. Switch the main switch off ("O").
3. Wait 5 seconds and switch the main switch on again ("I").
4. Contact your dealer if the error message reappears.

6.2 Service

- Only a technician authorised by GymnaUniphy N.V. may open the equipment or the accessories to perform repairs. The equipment does not contain any components that may be replaced by the user.
- If possible, open the screen with the system settings before you contact the technical service department. See *§4.9*.

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.*;
- the technical life time of the equipment and the accessories is not exceeded;
- the legal regulations with regard to the use of the equipment have been observed.

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

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

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

6.4 Technical life time

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

7 TECHNICAL INFORMATION

7.1 General

Dimensions Combi 200L (w x h x d)	266 x 275 x 100 mm
Weight Combi 200L	3,650 kg
Weight including accessories	4,6 kg
Mains voltage	100 - 240 VAC, 50-60 Hz
Maximum power, in operation	85 VA
Safety class	Class I (earthed socket required)
Insulation	Type BF (floating patient circuit)
Fuses	2 x T2AL250V

7.2 Electrotherapy

7.2.1 General

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

7.2.2 Current shapes

Medium frequency rectangular current

Intensity	0 - 80 mÂ with 300 to 1000 Ω

Rectangular pulsed current, Triangular pulsed current, 2-5 Current (Ultra Reiz)

Pulse time	0,1 ms - 6 s
Pulse pause	1 ms - 6 s
Intensity of CC	0 - 80 mÂ with 300 to 1000 Ω
Intensity of CV	0 - 80 V_{pk} with I < 80 mA

MF, DF, CP, LP

Intensity of CC	0 - 80 mÂ with 300 to 1000 Ω
Intensity of CV	0 - 80 V_{pk} with I < 80 mA
ISO	on / off

Conventional TENS, Low frequency TENS

Pulse time	10 - 650 µs
Pulse shape	symmetrical, asymmetrical
Frequency min.	1 - 150 Hz
Frequency max.	1 - 150 Hz
Intensity of CC	0 -120 mÂ with 300 to 1000 Ω
Intensity of CV	0 -120 V_{pk} with I < 120 mA

Random frequency TENS

See TENS currents, with the exception of:

Pulse frequency	1 - 150 Hz, with automatic stochastic frequency variation of +/-35% maximum

Burst TENS

See TENS currents, with the exception of:

Pulse frequency	20 - 150 Hz
Burst frequency	1 -10 Hz

Rectangular surge current, Triangular surge current

Pulse time	0,1 - 5 ms
Pulse frequency	1 - 150 Hz
Intensity of CC	0 - 80 mÂ with 300 to 1000 Ω
Intensity of CV	0 - 80 V_{pk} with I < 80 mA

Biphasic surge current, Biphasic surge intrapulse interval

(with a fixed interval between positive and negative pulses of 100 µs)

Pulse time	10 - 650 µs
Pulse frequency	1 - 150 Hz
Pulse shape	symmetrical, asymmetrical (only for Biphasic surge current)
Intensity of CC	0 - 120 mÂ with 300 to 1000 Ω
Intensity of CV	0 - 120 V_{pk} with I < 120 mA

2-pole medium frequency surge current, 4-pole interferential surge current

Carrier wave frequency	2 - 10 kHz
AM frequency	1 - 200 Hz
Intensity of CC	0 - 100 mÂ with 300 to 1000 Ω
Intensity of CV	0 - 100 V_{pk} with I < 100 mA

Expert parameters for NMES currents

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

2-pole medium frequency current, 4-pole interferential current

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

4-pole interferential with rotating vector

See 2- en 4-pole interferential	
Rotation time	0 - 20 s
Rotation angle	0 - 355°
Segment angle	0 - ±30°
Segment time	0 - 10 s

7.3 Ultrasound therapy

7.3.1 General

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

7.3.2 Modulation and pulse duration

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

7.3.3 US heads

US head, model 204			
Acoustic operating frequency	**1,1**	**3,2**	**MHz**
Output power	8,1	9,5	W
Effective intensity of output voltage	2,0	2,0	W/cm^2
Effective Radiating Area (ERA)	4,1	4,7	cm^2
Beam Non-uniform Ratio (BNR)	4,5	5,8	
Maximum intensity of beam	9,0	11,7	W/cm^2
Beam type	Collimating	Collimating	

US head, model 201			
Acoustic operating frequency	**1,1**	**3,2**	**MHz**
Output power	3,8	2,8	W
Effective intensity of output voltage	2,0	2,0	W/cm^2
Effective Radiating Area (ERA)	1,9	1,4	cm^2
Beam Non-uniform Ratio (BNR)	5,2	3,3	
Maximum intensity of beam	10,5	6,6	W/cm^2
Beam type	Collimating	Collimating	

7.4 Laser therapy

7.4.1 General

Safety class 3B laser product

7.4.2 Monoprobe: mono 200

Number of laser diodes	1
Nominal ocular hazard distance	214 mm
Wave length	905 nm
Energy per pulse	2,35 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	12,9 mm^2
Beam divergence	Dual mode 10° and 45°

7.4.3 Clusterprobe: quad 200

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

7.5 Environmental conditions

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

7.6 Transport and storage

Transport weight	5,5 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.

7.7 Standard accessories

	Quantity	Description	Art. no.
	2	Two-conductor electrode cable	108.725
	2	Rubber electrode no. 2: 6 x 8 cm (per 2 pces)	109.959
	1	EL sponge no. 2 for electrode 6 x 8 cm (per 4 pces)	100.658
	4	Elastic fixation bandage - 5 x 60 cm	108.935
	1	US head, 1/3 MHz - ERA 4 cm^2 incl. holder	117.122
	1	Contact gel, 150 ml	100.018
	1	Power cord[1]	100.689
	1	Test connector V/V - 4mm	108.919
	1	VAS score card	115.684
	1	User manual	NL: 326.315 FR: 326.337 EN: 326.326 DE: 326.348 ES: 327.371
	1	ET/US/laser placing diagrams	326.359

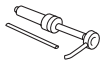
1 This power cord has a CEE 7/7 type plug. For countries with other outlets, a different power cord with the appropriate plug is supplied.

7.8 Optional accessories electrotherapy

	Quantity	Description	Art. no.
	1	Vaginal stimulation probe with 6-pole DIN plug	107.348
	1	Anal stimulation probe with 6-pole DIN plug	107.349
	1	Rectal stimulation probe	112.166
	2	Rubber electrode no. 1 - 4 x 6 cm	109.958
	2	Rubber electrode no. 3 -8 x 12 cm	109.960
	4	EL sponge no. 1 for electrode 4 x 6 cm	100.657
	4	EL sponge no. 3 for electrode 8 x 12 cm	100.659
	4	Adhesive electrode, 3 cm diameter	326.799
	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
	1	Adapter cable for adhesive electrode - 4 > 2 mm	113.334
	1	Pin electrode 15 mm diameter with grip and sponge	109.943
	10	EL sponges for pin electrode	109.944

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

7.9 Optional accessories ultrasound therapy

	Quantity	Description	Art. no.
	1	US head, multi-frequency,1/3 MHz - ERA 1 cm^2, incl. holder	117.123
	1	Contact gel, bottle 500 ml	100.016
	1	Contact gel, can 5 l	100.019
	1	Pump for can, 5 l	100.020

7.10 Optional accessories laser therapy

	Quantity	Description	Art. no.
	1	Mono 200, Monoprobe, incl. holder	326.381
	1	Quad 200, Clusterprobe, incl. holder	326.392
	1	Laser goggles l 800-1000 L2	111.890
	1	Remote interlock for laser	116.227

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

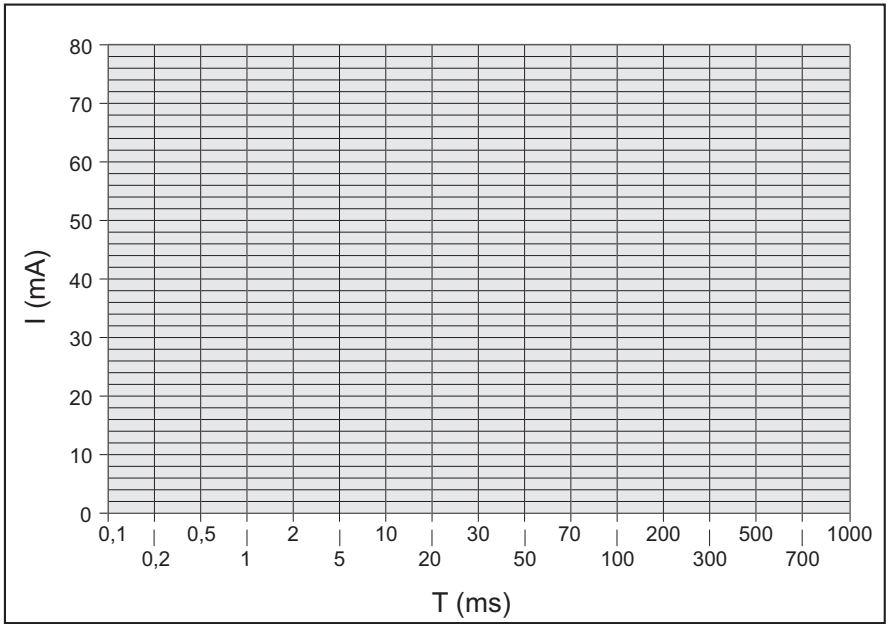
8 APPENDICES

8.1 Agents for iontophoresis

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

8.2 Diagnostic I/T-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 EMC directive

Use only accessories that are specified in this manual. See *§7*. The use of other accessories can have a negative effect on the electromagnetic compatibility of the equipment.
If you use the Combi 200L in the vicinity of other equipment, you must check that the Combi 200L is functioning normally.
The following paragraphs contain information about the EMC properties of the equipment.

8.3.1 Guidance and declarations

Guidance and manufacturer's declaration - electromagnetic emissions		
The 200-series devices are intended for use in the electromagnetic environment specified below. The customer or the user of a 200-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 200-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 200-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 200-series devices are intended for use in the electromagnetic environment specified below. The customer or the user of a 200-series device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact / ±8 kV air No loss of performance	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV power / ±1 kV I/O No loss of performance	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV diff. / ±2 kV comm. No loss of performance	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	U_T - 100% (0,5 period) No loss of performance U_T - 60% (5 periods) No loss of performance U_T - 30% (25 periods) No loss of performance U_T - 100% (5 seconds) Device resets to a safe state. (60601-1 § 49.2)	Mains power quality should be that of a typical commercial or hospital environment. If the user of a 200-series device requires continued operation during power mains interruptions, it is recommended that the 200-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 200-series devices are intended for use in the electromagnetic environment specified below. The customer or the user of a 200-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 200-series device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 V_{rms} AM 1 kHz 80% 150 kHz to 80 MHz	10 V.....0,15-80 Mhz 51 V.....6,78 Mhz 54 V.....13,56 Mhz 50 V.....27,12 Mhz 45 V.....40,68 Mhz	$d = 0{,}35\sqrt{p}$ $d = 0{,}07\sqrt{p}$ $d = 0{,}06\sqrt{p}$ $d = 0{,}07\sqrt{p}$ $d = 0{,}08\sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m AM 1 kHz 80% 80 MHz to 2,5 GHz	10 V/m..0,08-1,0 Ghz 26 V/m....1,4-2,0 Ghz 30 V/m...433,92 Mhz 30 V/m.....915 Mhz	$d = 0{,}35\sqrt{p}$ 80 MHz to 800 MHz $d = 0{,}70\sqrt{p}$ 800 MHz to 2,5 GHz $d = 0{,}12\sqrt{p}$ $d = 0{,}23\sqrt{p}$
Radiated RF ENV 50204	3 V/m CW 200 Hz d.c. 50% 895 MHz to 905 MHz	30 V/m.895-905 Mhz	$d = 0{,}23\sqrt{p}$
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
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 200-series device is used exceeds the applicable RF compliance level above, the 200-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 200-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 200-series device

The 200-series device is intended for use in the electromagnetic environment in which radiated RF disturbances are contolled. The customer or the user of a 200-series device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 200-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.

8.4 Technical safety inspection

Combi 200L with serial number ..... is / is not[1] in good working order		
	Inspection performed by:	Owner:
Location:	Name:	Name:
Date:	Initials:	Initials:

1 Cross out what does not apply.

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

8.4.1 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.	☐	☐	☐

8.4.2 Test 2: Electrotherapy

		Yes	No
1.	Connect loads of 500 Ω to both normal electrode pairs. Connect an oscilloscope to these pairs (black to ground).		
2.	Select channel A, program 4: MF constant.		
3.	At maximum intensity, the output currents correspond within 10% with the values on the display.	☐	☐
4.	The output signals correspond with figure 1.	☐	☐
5.	The polarity changes to negative if "RED(-)" is selected.	☐	☐
6.	The warning "Bad contact with the patient" is given if the load is disconnected.	☐	☐
7.	Select channel B, program 4: MF constant. Select CC.		
8.	At maximum intensity, the output currents correspond within 10% with the values on the display.	☐	☐
9.	The output signals correspond with figure 1.	☐	☐
10.	The polarity changes to negative if "RED(-)" is selected.	☐	☐
11.	The warning "Bad contact with the patient" is given if the load is disconnected.	☐	☐
12.	Remove the load, so that the unloaded output voltage can be measured.		
13.	Select channel A, program 23: 2-pole medium frequency. Select CV.		
14.	At maximum intensity, the output voltage corresponds within 10% with the values on the display.	☐	☐
15.	The output signals correspond with figures 2 and 3.	☐	☐
16.	The yellow lamp next to the output connectors lights if the intensity is not 0.	☐	☐
17.	Select channel B, program 23: 2-pole medium frequency. Select CV		
18.	At maximum intensity, the output voltage corresponds within 10% with the values on the display.	☐	☐
19.	The output signals correspond with figures 2 and 3.	☐	☐
20.	The yellow lamp next to the output connectors lights if the intensity is not 0.	☐	☐

Figure 1

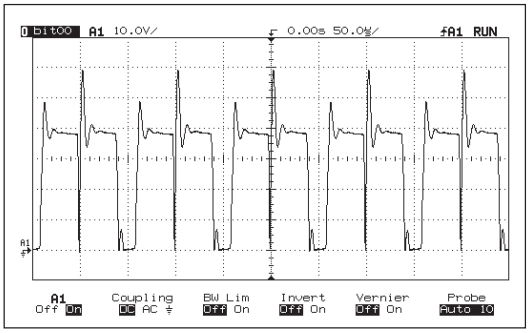


Figure 2

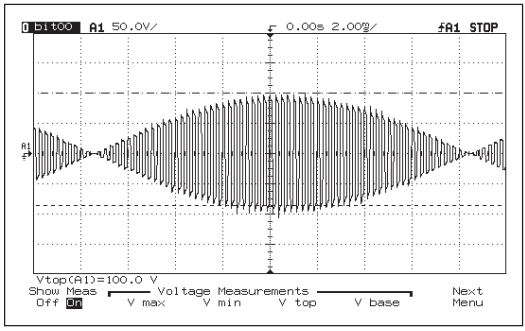
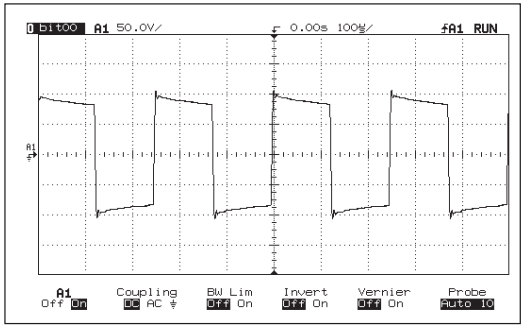


Figure 3



8.4.3 Test 3: Ultrasound

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

8.4.4 Test 4: Laser therapy

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

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

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

	Test A: The monoprobe	**Yes**	**No**
1.	Connect the monoprobe to the Combi 200L. See *§4.6.1*.		
2.	Press ⊛ to select the laser therapy. The green indicator light lights up.	☐	☐
3.	Press the black knob on the laser probe. The yellow indicator light lights up and the green indicator light goes out.	☐	☐
4.	Release the black knob. The green indicator light lights up and the yellow indicator light goes out.	☐	☐
5.	Start the laser therapy to measure the E_p value with the laser radiation measurement device. The measured E_p value is .....µJ. Stop the laser therapy.		
6.	The measured E_p value corresponds within ±20% with the E_p value of the test protocol of the laser probe.	☐	☐

	Test B: The clusterprobe	**Yes**	**No**
1.	Connect the clusterprobe to the Combi 200L. See *§4.6.1*.		
2.	Press ⊛ to select the laser therapy. The green indicator light lights up.	☐	☐
3.	Press the black knob on the laser probe. The yellow indicator light lights up and the green indicator light goes out.	☐	☐
4.	Release the black knob. The green indicator light lights up and the yellow indicator light goes out.	☐	☐
5.	Start the laser therapy to measure the E_p values with the laser radiation measurement device. The measured E_p value from laser diode 1 is .....µJ. The measured E_p value from laser diode 2 is .....µJ. The measured E_p value from laser diode 3 is .....µJ. The measured E_p value from laser diode 4 is .....µJ. Stop the laser therapy. The sum of the four measured E_p value is .....µJ.		
6.	The sum of the measured E_p values corresponds within ±20% with the total E_p value of the test protocol of the laser probe.	☐	☐

Test C: Calibration of the laser test eye	**Yes**	**No**
1. Connect a calibrated monoprobe to the Combi 200L. See *§4.6.1*.		
2. Select Laser energy measurem. in the System settings menu. See *§4.9.8*.		
3. Place the laser probe output perpendicular on the laser test eye ✹⊢. Start the laser energy measurement. Move the probe a bit to-and-fro to obtain the maximum value. The measured E_p value is .....µJ. Stop the laser energy measurement.		
4. The measured E_p value corresponds within ±5% with the E_p value of the calibrated laser probe.	☐	☐
5. If not, contact the service department of your local dealer.		

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

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

Notes:

8.5 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 Function overview

9.1.1 Therapy keys

The numbers refer to the program numbers.

Electrotherapy

Unidirectional currents

Diadynamic currents

TENS currents

NMES surge currents

Interferential currents

Ultrasound therapy

Combination therapy

Laser therapy

9.1.2 System settings

Press ⟲ for 5 seconds

Contrast
Language
Sound settings
Text start up screen
Copy parameters
System information
Plate electrode test
Cable test
Laser energy measurement
Error history
Counter working hours
Reset menu
Stop time if bad US

9.1.3 Objectives

The numbers refer to the program numbers.

Electrotherapy

Pain relief

Muscle detonising

Muscular training

Ultrasound therapy

Condition trophic

Increase extensibilty

Improve cell function

Laser therapy

Improve cell function

Pain relief

9.1.4 Indication list

ET: Electrotherapy, US: Ultrasound therapy, CO: Combination therapy, LA: Laser therapy

The numbers refer to the program numbers.

9.1.5 Diagnostics

9.1.6 Contra indication

Electrotherapy

General

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

Specific absolute

On demand pacemakers

Specific relative for monophasic pulses

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

Specific for relative biphasic pulses

Skin infections
Thrombosis, thrombophlebitis
Heart disease, rhythm disorder
Decreased sensibility
Locat. near sinus caroticus
Pregnancy

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

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

Specific relative for pulsing ultrasound
Pacemaker
Pregnancy

Combination therapy
See contra indications
Electrotherapy and US

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

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

9.2 Literature

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

9.3 Terminology

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

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

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

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

antalgic: The pain is reducing.

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

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

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

durability: Being able to frequently repeat a muscle contraction.

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

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

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 program.

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.

10 INDEX

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