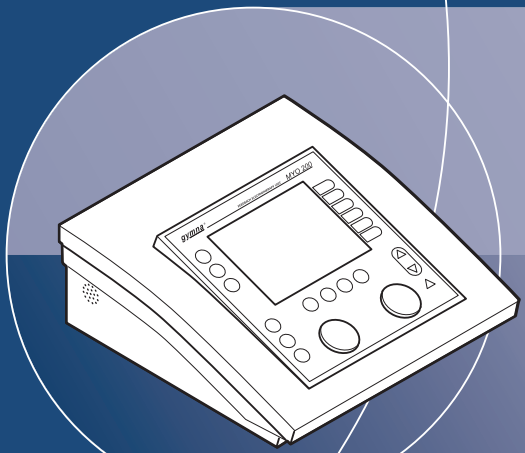
User Manual



Myo 200

User Manual Myo 200

Device for electrotherapy stimulation and feedback

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Abbreviations

AQ	Accomodation Quotient
CC	Constant Current
CP	Courte Période
CV	Constant Voltage
DF	Diphasé Fixe
EL	Electrode
EMC	Electromagnetic Compatibility
EMG	Electromyography
ESD	Electrostatic Discharge
ET	Electrotherapy
FB	Feedback
HAC	Hospital Antiseptic Concentrate
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
P	Pressure
TENS	Transcutaneous Electrical Nerve Stimulation
VAS	Visual Analogue Scale

Symbols on the equipment


Read the manual


Manufacturer

Symbols in the manual


Warning or important information.

TABLE OF CONTENTS

1 SAFETY

1.1 Purpose

The Myo 200 is intended solely for medical applications. You can use the Myo 200 for electrotherapy and re-education. For re-education the feedback signal is measured, if chosen in combination with an electrotherapy stimulation. 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 device 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 §5.1.1*.
- 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.
- Because the Myo200 is intended to measure extreme small potentials, its immunity level for electromagnetic radiation is lower then 3V/m. See *§8.3.1* for detailed information.
- Only use the accompanying accessories that are supplied by GymnaUniphy. *See §7.6 and §7.7*.
  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.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Check the electrode cables, the electrodes and the probes 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.

1.3 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.
The device contains no human or animal tissue, no medical substances, and no blood or blood products from human or animal origin.

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 §7.6 and §7.7*.
   - 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 device 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 §4.8*.
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 ▢ next to **Mains frequency**.
7. If necessary, change the setting with △ and ▽ to the local mains frequency.
8. 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:

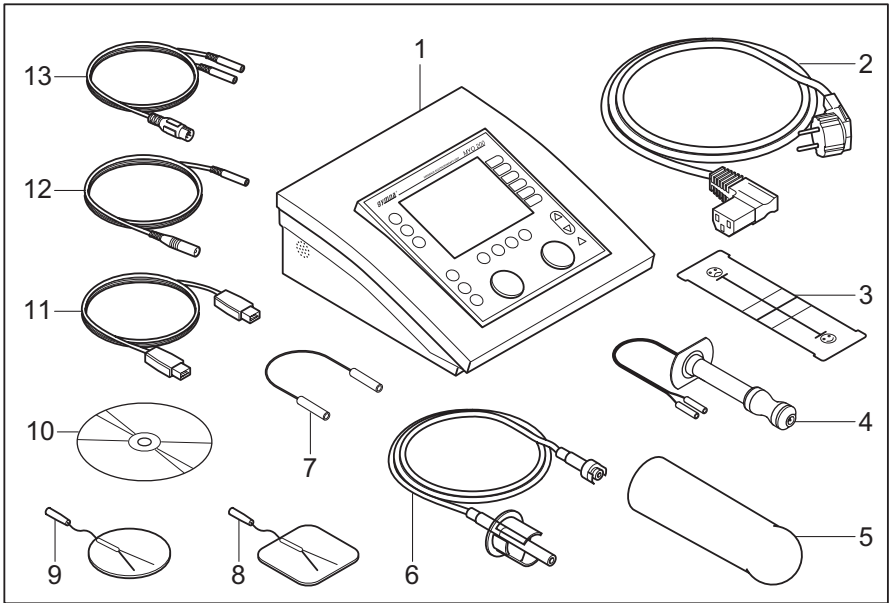
- Transport or store the equipment in the original packaging.
- The maximum period for transport or storage is: 15 weeks.
- Temperature: -20 °C to +60 °C.
- Relative humidity: 10% to 100%.
- Atmospheric pressure: 200 hPa to 1060 hPa.

2.6 Reselling

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

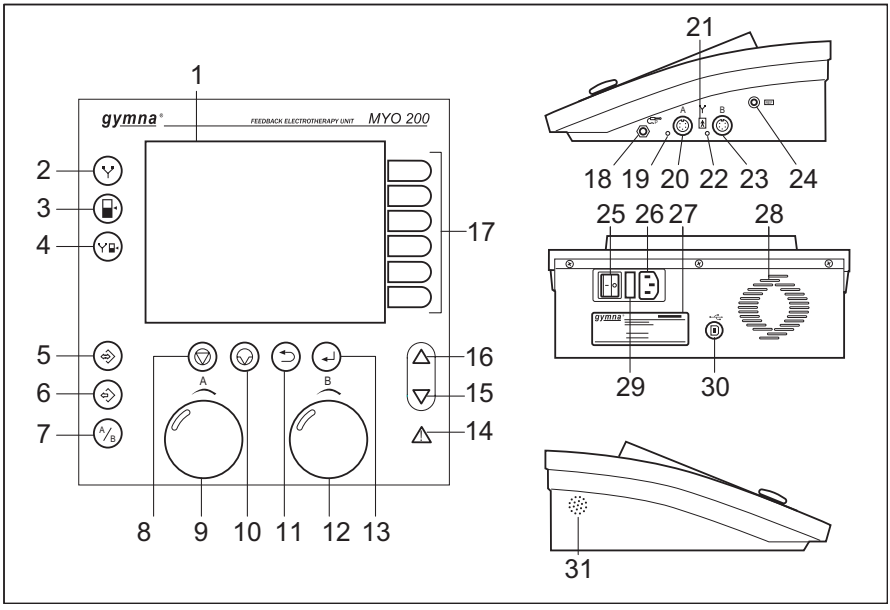
3 DESCRIPTION OF THE EQUIPMENT

3.1 Myo 200 and standard accessories



1. Myo 200. *See §3.2.*
2. Power cord
3. VAS score card
4. Vaginal probe 'Novatys'
5. Vaginal pressure probe
6. Vaginal pressure pipe
7. Test plug
8. Adhensive electrodes (4 pieces)
9. Adhensive electrodes round (4 pieces)
10. CD-ROM with Myo 200 PC-software
11. USB connection cable
12. Reference cable
13. Two-ply EMG electrode cable (2 pieces) and two-ply EMG-incontinence electrode cable

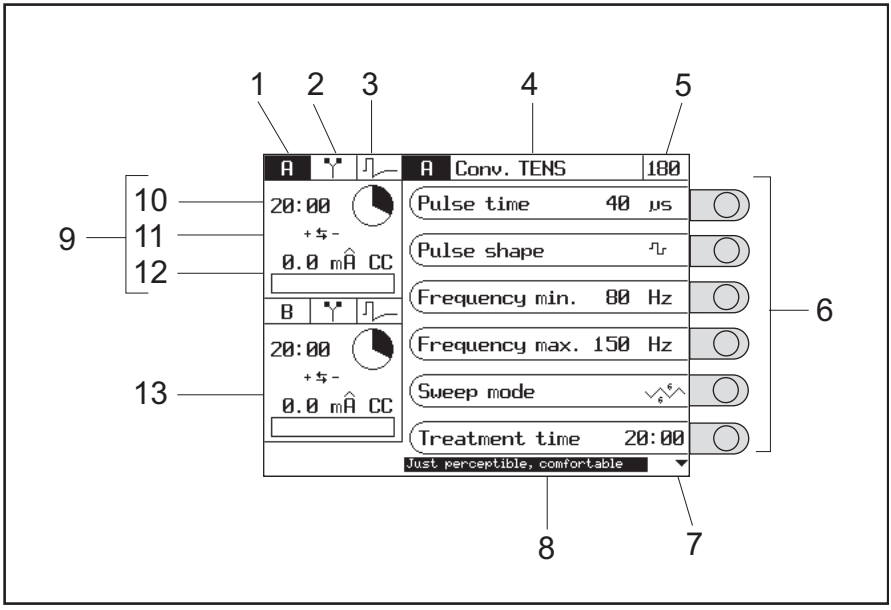
3.2 Components of Myo 200



1. Display. *See §3.3.1*.
2. Electrotherapy stimulation
3. Feedback
4. Electrotherapy stimulation and feedback
5. Memory
6. Start menu
7. Channel selection: A or B
8. Stop
9. Intensity of channel A
10. Pause
11. Return to previous menu
12. Intensity of channel B
13. Enter
14. Indication: Read manual
15. Down
16. Up
17. Select parameter or menu
18. Connector for pressure feedback, channel P
19. Indicator lamp for channel A
20. Connector for electrode, channel A
21. Indication: Type BF applied part
22. Indicator lamp for channel B
23. Connector for electrode, channel B
24. Connector for reference electrode
25. On/off switch
26. Connection to mains supply
27. Type plate
28. Ventilation opening
29. Fuse holder
30. USB connector
31. Speaker grill

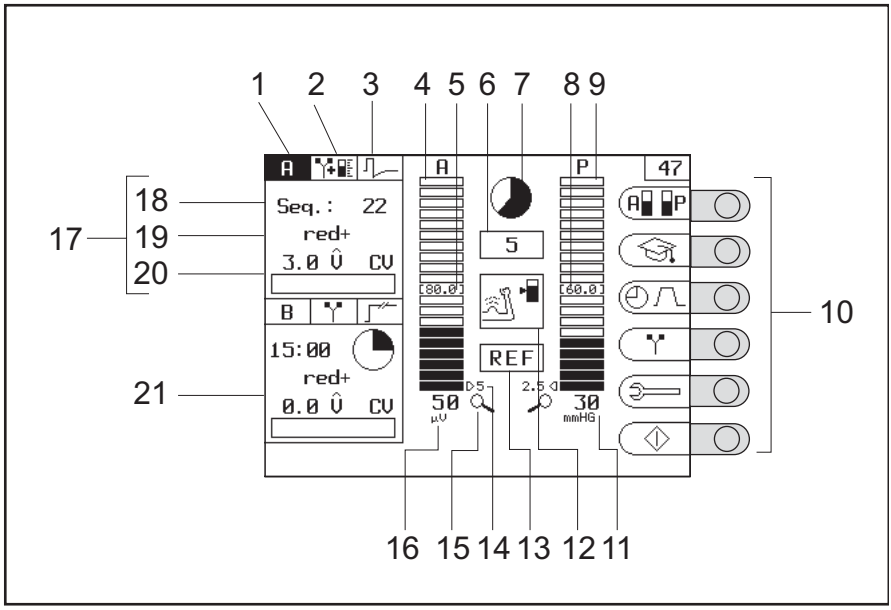
3.3 Display

3.3.1 Display for electrotherapy



1. Channel
2. Electrotherapy
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. *See §4.3.6*.
10. Remaining treatment time
11. Polarity
12. Set intensity
13. Screen for channel B

3.3.2 Display for re-education



1. Channel
2. Therapy (ET, FB or ET-FB)
3. Current shape
4. Bar graph of channel A
5. Target value of channel A
6. Remaining phase time (in seconds)
7. Remaining phase time (diagram)
8. Target value of channel P (B)
9. Bar graph of channel P (B)
10. Settings with selection knobs
11. Feedback value of channel P (B)
12. Phase symbol
13. Warning no reference electrode
14. Resolution, value of one bar graph segment
15. Zoom function active
16. Feedback value of channel A
17. Screen for channel A.
18. Remaining number of sequences or remaining treatment time
19. Polarity
20. Set intensity
21. Screen for channel B

3.4 Display symbols

3.4.1 General

	Electrotherapy stimulation	**A**	Channel A
	Feedback	**B**	Channel B
	Electrotherapy stimulation and feedback	**A + B**	Channel A and B simultaneously
	Treatment time	**P**	Channel P
0:00	Treatment completed	**SEQ**	ET: Sequential current shapes FB: Number of sequences

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

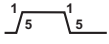
	Random TENS		2-pole medium frequency surge current
CP	CP (diadynamic)		2-pole medium frequency
DF	DF (diadynamic)		4-pole interferential with rotating vector
LP	LP (diadynamic)		Rheobase and chronaxie
MF	MF (diadynamic)		Rheobase and AQ

3.6 Parameter

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 (V_{pk})

Sweep mode

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

3.6.2 re-education

To maintain the overview on the re-education display, the settings symbols disappear after a while. The settings symbols appear again by pressing on a random  .


Feedback channel A


Feedback channel A and B


Feedback channel A and P (pressure)


Feedback P


Start


Phase time menu


Myo settings menu


Expert menu


Capture target menu


Electrotherapy parameters menu

Capture target


Maximum capture target method


Mean capture target method


Minimum capture target method


Time for the automatic capture target


Manual capture target method


Step size target change


Adjust target channel A


Adjust target channel B


Adjust target channel P

Zoom function


Zoom channel A


Zoom channel B


Zoom channel P

State symbols


Stimulation phase


Capture target

Rest phase

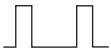
Stimulation assessment


Feedback phase

Warning no reference electrode

3.7 Current shapes

3.7.1 Unidirectional currents


Rectangular pulse current

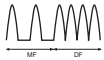

Triangular pulse current

2-5 current (UltraReiz)


Medium frequency rectangular current

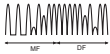
3.7.2 Diadynamic currents


MF



CP


DF



LP

3.7.3 Interferential currents


2-pole medium frequency


4-pole interferential with rotating vector

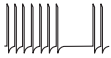

4-pole Interferential

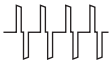
3.7.4 TENS currents

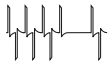

Conventional TENS, asymmetrical


Conventional TENS, alternating symmetrical


Conventional TENS, alternating asymmetrical


TENS burst


Conventional TENS, symmetrical

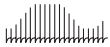

TENS burst, alternating

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 key or with the parameters in the Start menu:

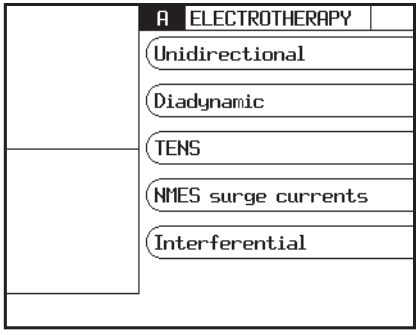
- **Therapy keys**: Quickly select a therapy with therapy keys, and . *See §4.1.1*.
- **Objectives**: Select a therapy on the basis of an objective. *See §4.1.2*.
- **Indication list**: Select a therapy on the basis of a medical indication. *See §4.1.3*.
- **Program number**: Select a certain program 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 electrotherapy. *See §4.1.6*.

Besides this, you can change the system settings. *See §4.8*.

4.1.1 Therapy keys

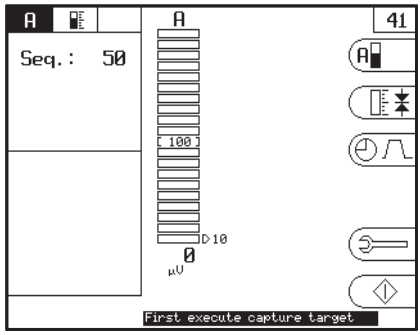
Electrotherapy selection

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



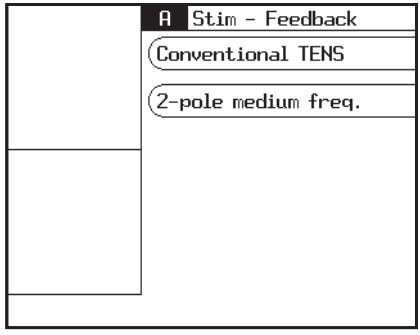
Feedback selection

1. Press : **Feedback**. The **Feedback** screen appears.



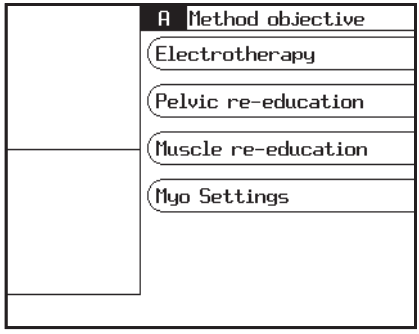
Electrotherapy in combination with feedback selection

1. Press : **Electrotherapy and feedback**.
2. Select the current shape with .



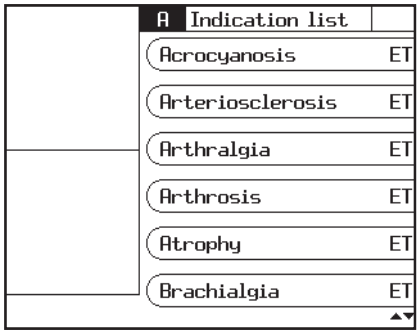
4.1.2 Therapy selection via objectives

1. Press to go to the start menu.
2. Select **Objectives**.
3. Select **Electrotherapy**, **Pelvic re-education** or **Muscle re-education**.
4. Select the desired treatment with .



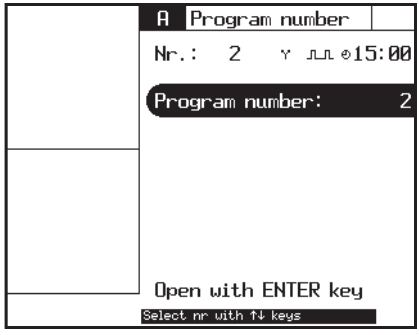
4.1.3 Therapy selection via indication list

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



4.1.4 Program number selection

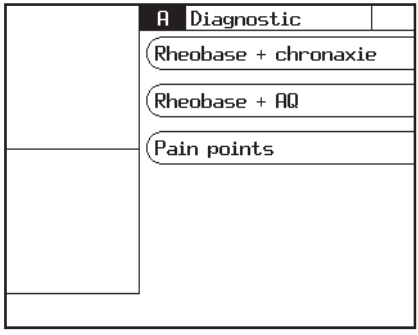
1. Press ⏻ to go to the start menu.
2. Select **Program number**.
3. Select the desired program with △ or ▽. *See §9.1.*
4. Press ↵. *See §4.7.*



4.1.5 Diagnostic program selection

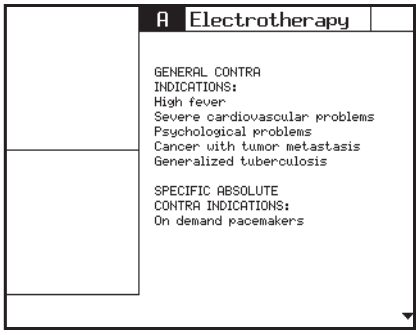
With the diagnostic programs, you can localise and treat pain points, etc.

1. Press ⏻ to go to the start menu.
2. Select **Diagnostic programs**.
3. Select the desired diagnosis with ◯. *See §4.6.*



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 Channel settings

The Myo 200 has the possibility to select a therapy individual or in combination. The following channel settings are possible.

Channel A	**Channel B**	**Channel P**	*See*
ET	-	-	*§4.3.1 and §4.3.2*
-	ET	-	*§4.3.1 and §4.3.2*
ET	ET	-	*§4.3.1, §4.3.2 and §4.3.5*
FB	-	-	*§4.4.1*
-	-	FB (pressure)	*§4.4.2*
FB	FB	-	*§4.4.1* and *§4.4.3*
FB	-	FB (pressure)	*§4.4.1, §4.4.2* and *§4.4.3*
FB	ET	-	*§4.4.1, §4.3.1* and *§4.3.2*
FB	ET	FB (pressure)	*§4.4.1, §4.3.1, §4.3.2, §4.4.2* and *§4.4.3*
ET+FB	-	-	*§4.5.1*
ET+FB	FB	-	*§4.5.1, §4.4.1, §4.4.3* and *§4.5.3*
ET+FB	-	FB (pressure)	*§4.5.1, §4.4.2, §4.4.3 and §4.5.3*
ET+FB	ET+FB	-	*§4.5.1 and §4.5.3*

Channel A	Channel B	Channel P	*See*
ET+FB	ET	-	*§4.5.1*, *§4.3.1*, *§4.3.2 and §4.5.3*
ET+FB	ET	FB (pressure)	*§4.5.1*, *§4.3.1*, *§4.3.2*, *§4.5.3*, *§4.4.2* and *§4.4.3*

4.2.2 Set parameters

1. Select the desired parameters with ▭ after the therapy is selected. See *§4.1*. You can only change the outlined parameters. In the re-education display the small outlined parameters disappear during treatment after a while to keep the overview on the screen. Press a random ▭ first to see the parameters.
2. 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.

4.2.3 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.

4.2.4 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.

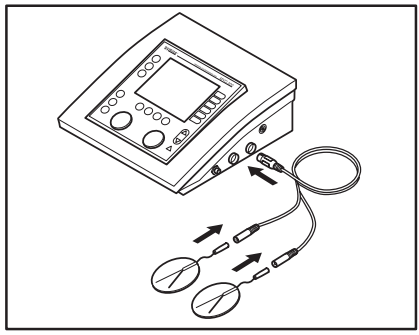
4.3 Electrotherapy

4.3.1 Performing electrotherapy with electrodes

1. Select the desired electrotherapy program. See *§4.1*.
2. Place the electrodes. *See page 28: Placing rubber electrodes* and page *28: Placing 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 *§4.1.2*.
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.

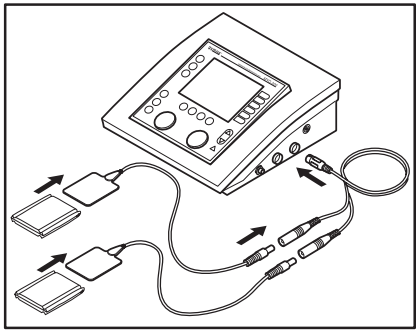
Placing adhesive electrodes

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 two-ply EMG electrode cable (black and red connector).
4. Connect the two-ply EMG electrode cable to connector Y_A or Y_B of the Myo 200.

Placing rubber electrodes



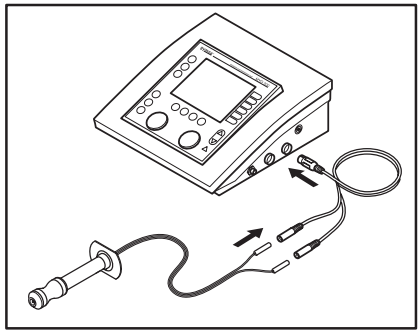
1. Moisten two EL sponges. Use water with a saline solution to improve the conductivity of the EL sponges.
2. Slide a rubber electrode into each sponge.
3. Place the sponges on the part of the body that must be treated.
4. Fasten the sponges to the part of the body with the elastic fixation straps.
5. Connect the red connector of the rubber electrode to the red connector of the two-ply (EMG) electrode cable (4 mm).
6. Connect the black connector of the rubber electrode to the black connector of the two-ply (EMG) electrode cable (4 mm).
7. Connect the two-ply (EMG) electrode cable to connector Y_A or Y_B of the Myo 200.

4.3.2 Performing electrotherapy with a probe

- Considering the hygiene and 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. *See §5.2.4*.
2. Select the desired electrotherapy program.
3. Make sure the intensity is zero.
4. Place the probe. *See page 29: Placing a vaginal or an anal probe* and page *30: Placing a rectal probe*.
5. Rotate intensity knob A or B to start the treatment and to set the desired intensity.
6. Check the patient's reaction. Repeat this check regularly during the treatment.
7. The equipment stops the treatment and indicates that the treatment is completed.
8. Make sure the intensity is zero.
9. Remove the probe.
10. Clean the probe. See *§5.2.4*.

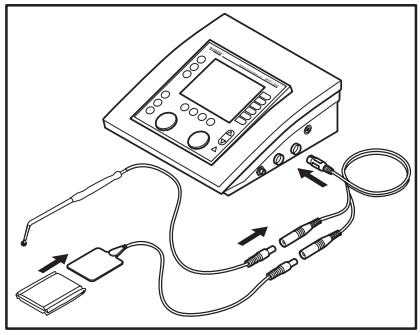
Placing a vaginal or an anal probe



1. Connect the probe to the two-ply EMG-incontinence electrode cable (white connectors).
2. Connect the two-ply EMG-incontinence electrode cable to connector Y_A or Y_B of the Myo 200. The probe is 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.
3. Apply, if necessary, an antiseptic lubricant to the probe.
4. Place the probe.

Placing a rectal probe

1. Connect the rectal probe to the red connector of the two-ply EMG electrode cable (4 mm).
2. Connect a rubber electrode to the black connector of the two-ply EMG electrode cable (4 mm).
3. Connect the two-ply EMG electrode cable to connector Y_A or Y_B of the Myo 200.



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, if necessary, an antiseptic lubricant to the probe.
5. Place the probe.

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:

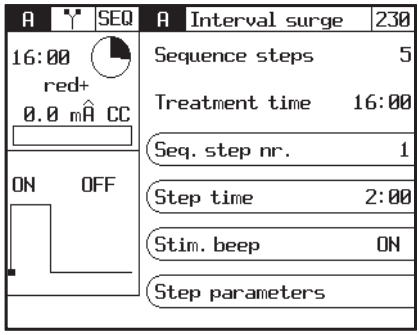
- In one electrotherapy, you can realise several objectives.
- In a treatment with one objective, you can place different accents in the objective.
- You can distinguish between different phases in a treatment, for example preparation, core effect and cooling.

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 28: Placing rubber 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 Set channels A and B

The Myo 200 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 §4.8*.
2. If necessary, change the parameter Copy parameters to OFF.
3. The selected channel has a black background. If desired, press A/B to change the first channel.
4. Select an electrotherapy treatment. *See §4.1*.
5. Set the parameters for the first channel. *See §4.2.2*.
6. Press A/B to select the other channel.
7. Select an electrotherapy treatment for the second channel. *See §4.1*.
8. Set the parameters for the second channel. *See §4.2.2*.
9. Place the electrodes or a probe and start the treatment. *See §4.3.1* and *§4.3.2*.

Both channels are selected simultaneously and automatically in case of:

- 4-pole current shapes

Copy channel

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

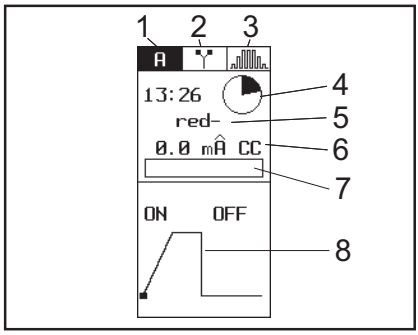
1. Press ⏎ for 5 seconds. The System setting menu appears. *See §4.8*.
2. If necessary, change the parameter Copy parameters to ON.
3. Select a treatment. *See §4.1*.
4. Set the parameters for the first channel. *See §4.2.2*.
5. Press A/B to select the other channel. The treatment including the settings are copied to the other channel.
6. If desired you can change the parameters or the treatment of the selected channel.
7. Place the electrodes or a probe and start the treatment. *See §4.3.1* and *§4.3.2*.

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.

4.3.6 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.

4.3.7 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 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 *§3.7*.

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.

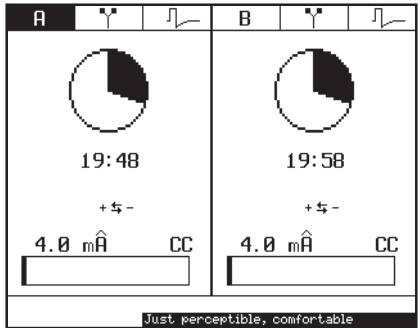
Stimulation beep (on, off)
Switch stimulation beep on or off.

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.

4.3.8 Opening the intensity screen

1. Press ↵ after the treatment is started. The intensity screen appears.
   The left part of the screen shows channel A. The right part of the screen shows channel B.
2. Press ↩ to return to the setting menu.

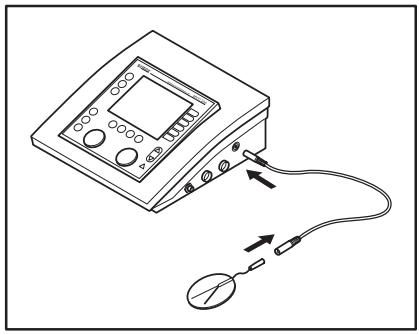


4.4 Feedback

4.4.1 Measure feedback with electrodes

1. Select the desired feedback treatment on channel A. *See §4.1*.
2. Place the electrodes or the probe. *See page 28: Placing adhesive electrodes*, *page 28: Placing rubber electrodes and page 29: Placing a vaginal or an anal probe*. Only the EMG electrode cable and the EMG-incontinence electrode cable are suitable for feedback measurement.
3. Place the reference electrode for a reliable measurement. *See page 38: Placing adhesive reference electrode*.
4. Determine the target value via capture target. *See §4.4.4*.
5. If desired, select menu ◴⎍ with ◯ to change phase time parameters. *See §4.2.2*.
6. Select ◇ with ◯ to start the treatment.
7. Guide the patient through the treatment phases.
8. If necessary, change settings during the treatment. *See §4.4.5*.
9. The equipment stops the treatment and indicates that the treatment is completed. Remove the electrodes or probe.

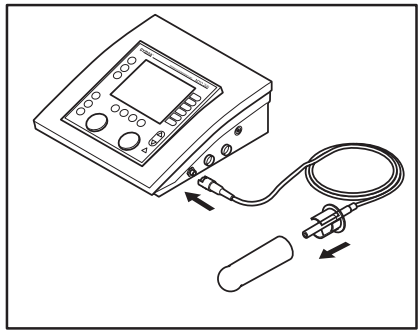
Placing adhesive reference electrode



1. If possible, disinfect the part of the body where the adhesive reference electrode is to be placed.
2. Place the adhesive reference electrode near to the location of the feedback measurement.
3. Connect the adhesive reference electrode via the reference cable to connector REF of the Myo 200. Replace or reconnect the reference electrode, if the warning REF appears on the display. The reference electrode is not detected by the equipment.

4.4.2 *Measure feedback with vaginal or anal pressure probe*

- Considering the hygiene and 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 a feedback treatment on channel A. *See §4.1 and §4.5*.
3. Connect the probe to the appropriate pressure pipe (vaginal or anal).
4. Connect the pressure pipe to connector P of the Myo 200.
5. Select the feedback treatment on channel P. *See §4.4.3*.
6. Apply an antiseptic lubricant to the probe.
7. Place the probe.
8. Determine the target values via capture target. *See §4.4.4*.
9. If desired, select menu with to change phase time parameters. *See §4.2.2*.
10. Select with to start the treatment.
11. Guide the patient through the treatment phases.
12. If necessary, change settings during the treatment. *See §4.4.5*.
13. The equipment stops the treatment and indicates that the treatment is completed. Remove the electrodes and the probe.
14. Clean the probe. *See §5.2.4*.

4.4.3 *Set channels B or P*

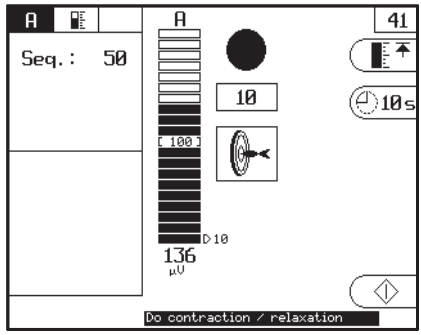
A feedback treatment for channel A is selected.

1. Select the parameter A with .
2. Change the parameter to A B, A P or P with △ and ▽. The feedback treatment is selected on respectively channel A and B, channel A and P or only channel P.

4.4.4 *Capture target*

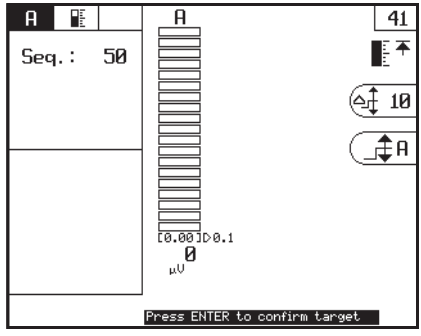
The target value for stimulation or relaxation for feedback phase is determined via capture target.

Perform automatic capture target



1. Select with . The **Capture target menu** screen appears.
2. Set the automatic capture target method. Select the methode parameter with and change with △ and ▽.
   - Select : Calculates the target value as the average of the highest measurements during the capture time.
   - Select : Calculates the target value as the average of the mean measurements during the capture time.
   - Select : Calculates the target value as the average of the lowest measurements during the capture time.
3. If necessary, select the time s with and change with △ and ▽.
4. Select with to start the capture target.
5. Guide the patient through measurement. The scale of the bargraph changes according to value of the feedback signal during the capture time.
6. The equipment stops the measurement and shows the calculated target value. The position of the target value depends on the automatic selected scale.
7. Press ↵ to confirm the target value or fine-tune the target value. *See page 40: Fine-tune target*.

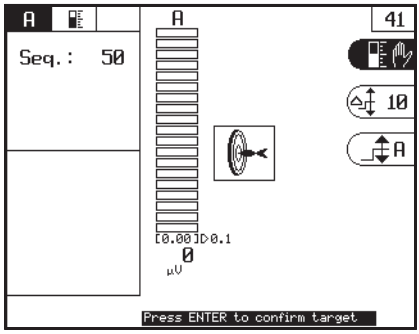
Fine-tune target



1. If necessary, select the with and change with △ and ▽.
2. Select the A, B or P with .
3. Change the value of the target with △ and ▽.
4. If necessary, repeat the previous steps for the other channel.
5. Press ↵ to confirm the target. The position of the target value depends on the automatic selected scale.

Perform manual capture target

1. Select with . The **Capture target menu** screen appears.
2. Select the capture target method parameter with .
3. Change the parameter to with △ and ▽.
4. Change the target value manual. *See page 40: Fine-tune target.*
5. Press to confirm the target value. The position of the target value depends on the automatic selected scale.



4.4.5 Settings during treatment

Expert mode

1. Select with . The **Expert** menu appears.
2. If necessary, fine-tune the target value or activate the zoom function. *See page 40: Fine-tune target or §4.4.6.*

Phase time

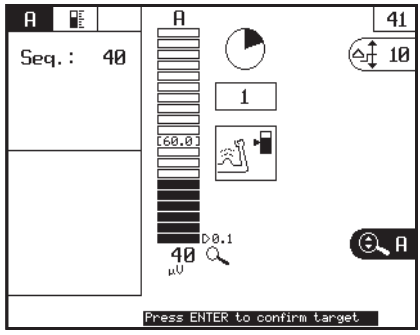
1. Select with . The **Phase time** menu appears.
2. If necessary, change a phase time parameter. *See §4.2.2.*

Myo settings

1. Select with . The **Myo settings** menu appears. *See §4.4.7.*
2. If necessary, change a myo setting parameter. *See §4.2.2 and §4.4.7.*

4.4.6 Zoom function

The zoom-in function makes small variations in the measured feedback signal visible when the feedback signal is relative high.



1. Select A, B or P with ◯ in the expert menu.
2. Press △ to activate the zoom-in function. The target value positions in the middle of the bar graph and 🔍 appears. A message appears if the zoom action is not possible.
3. Press ▽.to zoom-out. Note: The fine tune function is impossible as long as the zoom function is active. Zoom-out fully to deactivate the zoom function, 🔍 disappears.
4. Press ↩ to leave the expert menu.

4.4.7 Myo settings parameters

The **Myo settings** menu is reached via selection of 🔧 with ◯ and contains the following parameters.

Customize Myo screen

The posibility to change the default settings of the screen

- **Feedback (A, A+B, A+P, P)** : The default channel view.
- **Target value (10, 25, 50, 100, 250, 500 µV or mmHg)** : The default target value before performing capture target.
- **Capture target** : The default capture target method. *See §4.4.4.*
- **Capture time (1 - 20 s)** : The default capture time in the automatic capture target method.
- **Target step (0.1, 1, 10, 100 µV)** : The default step size for fine-tune of the target.

Myo sounds

- **Volume (1 - 10)** : The volume settings.
- **Audio (continuous, pulsed, off)** : The sound signal settings.
- **Target (below, around, above)** : The sound setting for the measured feedback value in relation to target value.
- **Sound on channel (A, B/P)** : The channel on which the sound is active.
- **Beep on phase**
  - **Stimulation phase (on, off)** : On: A sound at the start of the stimulation phase.
  - **Feedback phase (on, off)** : On: A sound at the start of the feedback phase.
  - **Rest phase (on, off)** : On: A sound at the start of the rest phase.

Filter (low, medium, high)
The degree of filtering the data for a graphical view.

Time (treatment time, sequence number)
The visualisation of the treatment duration via number of sequences or via treatment time.

Blank Channel (none, A, B, P)
The possibility to hide the channel view and the channel sounds for the concentration of the patient to one channel. The measurement is done in the background.

Calibrate pressure
Calibrate the pressure channel to compensate temperature influences. Disconnect the pressure pipe before the start of the callibration.

Copy Stimulation (on, off)
On: Copy the combination treatment parameters from channel A to channel B. See *§4.5.3*.
Off: Set channel B indepented.

4.5 Electrotherapy stimulation in combination with feedback

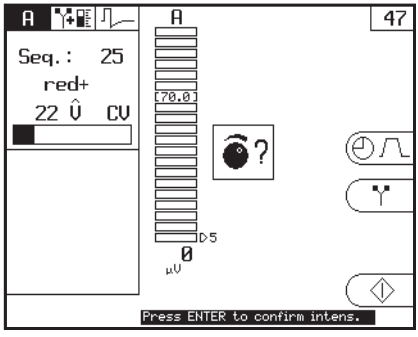
4.5.1 Perform electrotherapy stimulation and measure feedback

1. Select the desired combination treatment of electrotherapy and feedback on channel A. Select the therapy via **Objectives**, **Program number** or therapy key (Y/ü). *See §4.1.2, §4.1.4 and §4.1.1.*
2. Place the electrodes or the probe. *See page 28: Placing adhesive electrodes, page 28: Placing rubber electrodes, page 29: Placing a vaginal or an anal probe and page 30: Placing a rectal probe.* Only the EMG electrode cable and the EMG-incontinence electrode cable are suitable for feedback measurement.
3. Place the reference electrode for a reliable measurement. *See page 38: Placing adhesive reference electrode.*
4. Determine the target value via capture target and set the stimulation intensity via stimulation assessment. *See §4.4.4 and §4.5.2.*
5. Select ◊ with ▭ to start the treatment.
6. Guide the patient through the treatment phases.
7. If necessary, rotate intensity knob A or B during the stimulation phase to change the intensity of the electrotherapy stimulation.
8. If necessary, change feedback settings during the treatment. *See §4.4.5.*
9. The equipment stops the treatment and indicates that the treatment is completed. Remove the electrodes or probe.

4.5.2 Stimulation assessment

After the target value is determined via capture target the **Stimulation assessment** screen appears. During the stimulation assessment the intensity of the electrotherapy signal for the stimulation phase is set.

1. Rotate intensity knob A or B to set the desired intensity of the electrotherapy stimulation.
2. Press ↵ to confirm the intensity value. The intensity fades out and the **Feedback** screen appears.



4.5.3 Set channels

A combination treatment of electrotherapy and feedback for channel A is selected. The parameters A, AB, AP or P determine the selection of the treatment on channel B

Set an electrotherapy treatment on channel B

1. Select the parameter A with .
2. If necessary, change the parameter to AP with △ and ▽.
3. Press A/B to select the channel B. The **Start menu** appears.
4. Select an electrotherapy treatment for channel B. *See §4.3.*

Set a feedback treatment on channel B

1. Select the parameter A with .
2. Change the parameter to AB with △ and ▽.
3. Select with . The **Myo settings** menu appears. *See §4.4.7.*
4. Set the parameter **Copy stimulation** to **OFF**.
5. Press A/B to select the channel B. A feedback treatment is selected on channel B.
6. Press A/B to set the feedback settings for channel A and B.

Set a combination treatment on channel B

1. Select the parameter A with .
2. Change the parameter to AB with △ and ▽.
3. Select with . The **Myo settings** menu appears. *See §4.4.7.*
4. Set the parameter **Copy stimulation** to **ON**.
5. Press A/B to select the channel B. The combination treatment including the settings are copied to the channel B.
6. Set the electrotherapy parameters for the channel B. *See §4.2.2.*
7. Press A/B to set the feedback settings for channel A and B.

4.6 Diagnostic programs

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

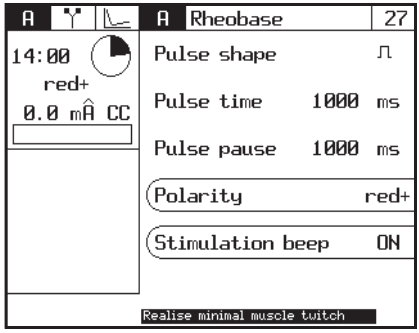
- Rheobase and chronaxie. See *§4.6.1.*
- Rheobase and AQ. See *§4.6.2.*
- Manually determine an I/T curve. See *§4.6.3.*

Besides this, there are diagnostic programs for localisation:

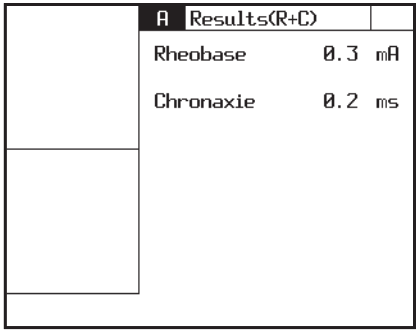
- Pain points. See *§4.6.4.*

4.6.1 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 *§4.7.1*.



4.6.2 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 *§4.6.1*.
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 *§4.7.1*.

4.6.3 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.

4.6.4 Pain points

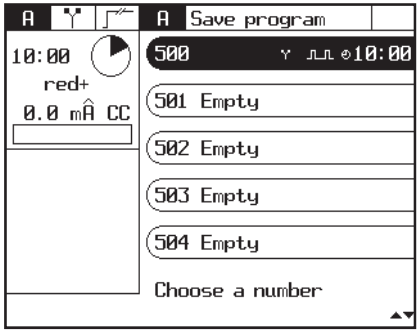
1. Press ⏎ to go to the start menu.
2. Select Diagnostic programs.
3. Select Pain points.
4. Select the diagnostic program for pain points.

4.7 Programs

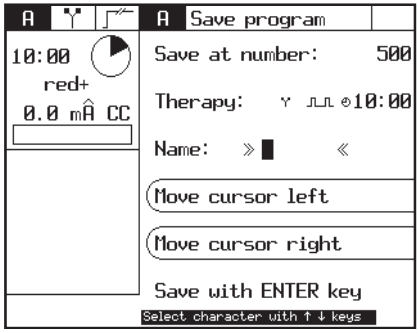
You can save 20 of your own programs for later use: programs 500 up to and including 519. You can modify these programs for much-used or specific current shapes for a certain patient.

4.7.1 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 ▽.



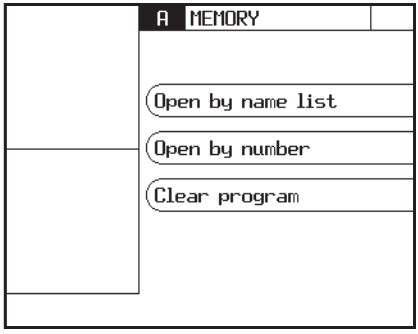
6. Enter the name of the program. Use the name or the number of the patient, for example.
   - Select a character with △ and ▽.
   - Select **Cursor to left/right** to move the cursor.
7. Press ↵ to save the program.



4.7.2 Selecting a saved program

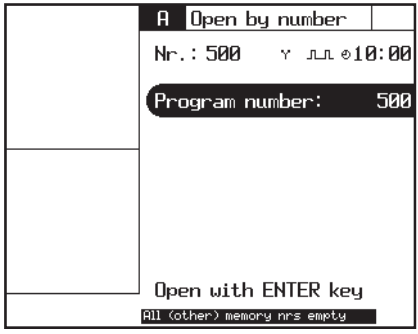
Selecting a program by the name list

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



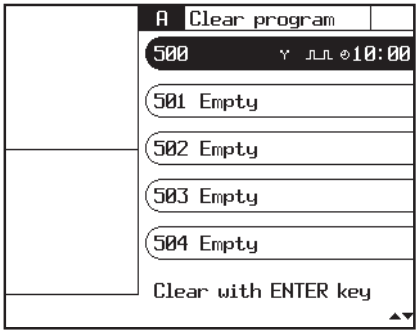
Selecting a program by the number

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



4.7.3 Clear a program

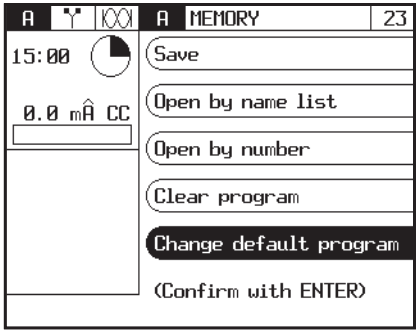
1. Press ⊛.
2. Select **Clear program**.
3. Select the program that must be deleted with ◯.
   If desired, go to the following programs with △ or ▽.
4. Press ↵ to clear the program.



4.7.4 Editing a standard program

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

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 *§4.7.1*.

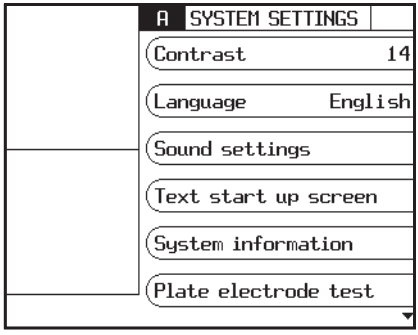
You can reset the standard settings of the standard programs with **Reset Menu**. See *§4.8.2*.

4.8 System settings

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

4.8.1 Changing the system settings

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



4.8.2 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 *§4.8.3*.

Text start up screen
The text that appears in the top of the start up screen, after the equipment is switched on. See *§4.8.5*.

Copy parameters (on, off)
On: In ET-mode the ET-parameters of the first channel will be copied in the other channel when pressing A/B. See *§4.3.5*.

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 *§4.8.6*.

Cable test
Test the cables. See *§4.8.6*.

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 have been in use. For this, the output of the channel must have been higher than zero.

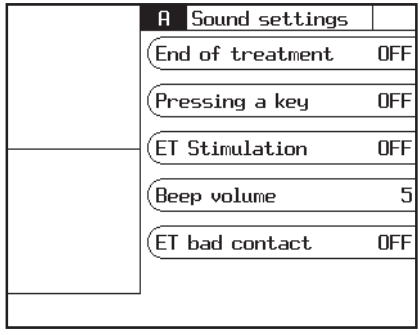
Reset menu
- Reset working hours: Set the number of working hours of a plate electrode to zero.
- Reset programs 1-50: This restores the standard settings of the standard programs. See *§4.7.4*.
- Erase total memory: Restores the standard settings of the standard programs and of the edited programs.

Press ▢ again to confirm.

Mains frequency (50, 60 Hz)
The setting must be the same as the local mains frequency.

4.8.3 Setting the sound

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



4.8.4 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.

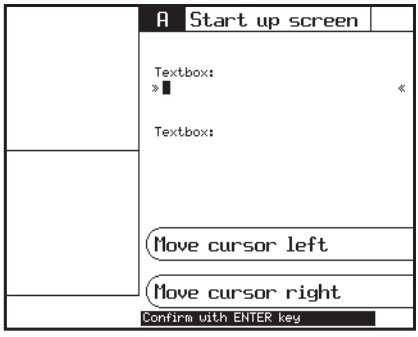
Beep volume (min.1, standard 5, max.10)
The volume of the sound signals.

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

4.8.5 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.



4.8.6 Cable test

1. Press ⮌ for 5 seconds. The System settings screen appears.
2. Select Cable test,
3. Connect the electrode cable to channel A.
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 ⮌.

4.8.7 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.

5 INSPECTIONS AND MAINTENANCE

5.1 Inspections

Component	Check	Frequency
Electrode cables and electrodes	Damage Insulation intact Pins in connector straight	At least 1x per month
Vaginal, anal and rectal probe	Dents, cracks or other damage	At least 1x per month
Vaginal and anal pressure probe	Cracks or other damage	At least 1x per month
Vaginal and anal pressure pipe	Damage Blockage	At least 1x per month
Equipment	Technical safety inspection. See *§5.1.1*.	At least 1x per year

5.1.1 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: Feedback
4. Test 4: Electrical safety inspection: measurement of the earth leakage current and patient leakage current according to IEC 62353.

Inspection result

1. A registration must be maintained of the technical safety inspections. Use the inspection report in the appendix for this purpose. See *§8.4*.
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 probe	Cleaning and disinfecting. See *§5.2.4*.	After each use
Vaginal and anal pressure probe	Cleaning and disinfecting. See *§5.2.4*.	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 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.

Clean before and after each use:

1. Clean the probe thoroughly with soap and water.

Make sure that the probe connectors do not get into the water.

2. If necessary, desinfect the probe.

- Use a bactericidal and virucidal cold soaking solution.
- Follow the manufacturer's instruction and the descriped time to soak.
- Make sure that the probe connectors do not get into the soaking solution.

3. Rinse the probe thoroughly with water.
4. Dry the probe with a clean towel.
5. Store the probe in a plastic bag that is provided with the name of the patient.

6 MALFUNCTIONS, SERVICE AND GUARANTEE

6.1 Malfunctions

Component	Problem	Solution
Myo 200	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 *§4.8*.
	Permanent feedback signal	Check the mains frequency and change if necessary. See *§4.8*.
	No pressure	Check the pressure pipe and the coupling for leakage
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 equipment still does not react to commands.

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 *§4.8*

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 Myo 200 (w x h x d)	266 x 275 x 100 mm
Weight Myo 200	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 mÂ

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 mÂ
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 mÂ

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 mÂ

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 mÂ

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 mÂ

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 mÂ

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 Feedback

Pressure	0 - 1000 mmHg (1332 hPa) absolute input 0 - 750 mmHg (1000 hPa) relative input
Resolution pressure	≥ 0,25 mmHg
Absolute tolerance pressure	10 %
EMG	0 - 2500 μV_{rms}
Resolution EMG	≥ 0,25 µV/division
Bandwidth	8 - 1500 Hz
Mains hum suppression	≥ 40 dB
Absolute tolerance EMG	8 %

7.4 Environmental conditions

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

7.5 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.

7.6 Standard accessories

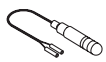
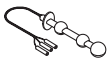
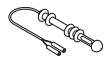
	Quantity	Description	Art. no.
	4	Adhesive electrode, 3 cm diameter	326.799
	4	Adhesive electrode, 5 x 5 cm	326.821
	1	Vaginal pressure probe	109.981
	1	Vaginal pressure pipe	111.917
	1	Vaginal probe 'Novatys' with 2 mm plugs (for EMG and stimulation)	329.978
	2	Two-ply EMG electrode cable with 2 mm plugs. Use the cable in combination with adhesive electrodes.	329.945
	1	Two-ply EMG-incontinence electrode cable with 2 mm plugs. Use the cable in combination with probes.	329.956
	1	Reference cable, 4 mm - 2 mm plugs	329.967
	1	Test plug F/F - 2mm	330.803
	1	Power cord[1] with right angle	112.451
	1	VAS score card	115.684
	1	CD-ROM with Myo 200 PC-software	330.011
	1	USB connection cable Myo - PC	330.000
	1	User manual	EN: 329.637
	1	CD-ROM User manuals Gymna Devices	311.872

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

Quantity	Description	Art. no.
1	ET placing diagrams	117.276
1	Safety instruction	323.011

7.7 Optional accessories

7.7.1 Probes

	Quantity	Description	Art. no.
	1	Vaginal probe 'V2B+' with 2 mm plugs (for EMG and stimulation)	330.594
	1	Vaginal probe 'Optima 3' with 2 mm plugs (for EMG and stimulation)	330.572
	1	Vaginal probe 'Perisize 4+' with 2 mm plugs (for EMG and stimulation)	330.583
	1	Anal probe 'Analia' with 2 mm plugs (for EMG and stimulation)	329.989
	1	Anal probe 'Analys+' with 2 mm plugs (for EMG and stimulation)	330.561
	1	Rectal probe (for EMG and stimulation)	112.166
	1	Anal pressure probe	111.919
	1	Anal pressure pipe	111.918
	1	Vaginal pressure pipe with valve	330.814
	1	Anal pressure pipe with valve	330.825

7.7.2 Electrodes

	Quantity	Description	Art. no.
	1	Elastic fixation bandage - 5 x 30 cm	108.934
	1	Elastic fixation bandage - 5 x 60 cm	108.935
	1	Elastic fixation bandage - 5 x 120 cm	108.936
	2	Rubber electrode no. 1 - 4 x 6 cm	109.958
	2	Rubber electrode no. 2: 6 x 8 cm	109.959
	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. 2 for electrode 6 x 8 cm	100.658
	4	EL sponge no. 3 for electrode 8 x 12 cm	100.659
	4	Adhesive electrode, 2,5 x 5 cm	326.810
	4	Adhesive electrode, 5 x 10 cm	326.832
	1	Pin electrode 15 mm diameter with grip and sponge	114.142
	10	EL sponges for pin electrode	109.944
	1	Adhesive kit	328.504

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

7.7.3 Connectors and general

	Quantity	Description	Art. no.
	1	Test plug F/F - 4mm	108.919
	1	Reference cable, 4 mm - 4 mm plugs	330.781
	1	Two-ply EMG electrode cable with 4 mm plugs. Use the cable in combination with rubber electrodes and rectal probe.	330.792
	1	Two-ply electrode cable with 4 mm plugs. Use the cable in combination with rubber electrodes (not suitable for feedback).	108.725
	1	Myo stand for Mobil700	330.033
	1	Carrying case for 200-series	302.955

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

7.7.4 User manuals

Quantity	Description	Art. no.
1	User manual	NL: 329.615 FR: 329.626 DE: 329.648 ES: 329.659 PT: 329.670

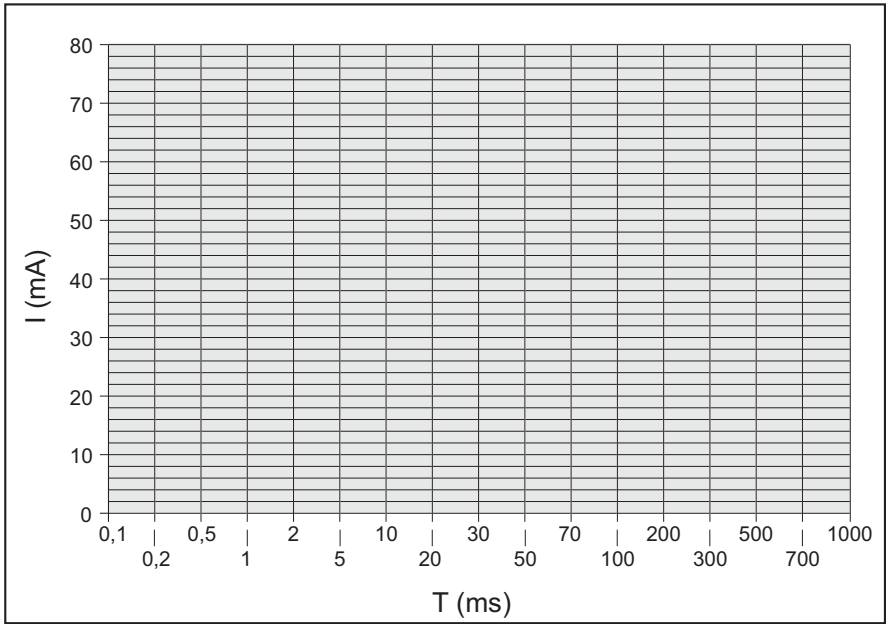
8 APPENDICES

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 cables, electrodes and probes 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 Myo 200 in the vicinity of other equipment, you must check that the Myo 200 is functioning normally.
The following paragraphs contain information about the EMC properties of the equipment. Because this information is intended for technicians, the information is given in English.

8.3.1 Guidance and declarations

Guidance and manufacturer's declaration - electromagnetic emissions		
The Myo 200 device is intended for use in the electromagnetic environment specified below. The customer or the user of a Myo 200 device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Myo 200 device uses 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 Myo 200 device is suitable for use in all establishments, including domestic establishments and those directl connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Myo 200 device is intended for use in the electromagnetic environment specified below. The customer or the user of a Myo 200 device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level [c])**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact / ±8 kV air No loss of performance	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV power / ±1 kV I/O No loss of performance	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV diff. / ±2 kV comm. No loss of performance	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity			
The Myo 200 device is intended for use in the electromagnetic environment specified below. The customer or the user of a Myo 200 device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level [c])**	**Electromagnetic environment - guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	U_T - 100% (0,5 period) No loss of performance U_T - 60% (5 periods) No loss of performance U_T - 30% (25 periods) No loss of performance U_T - 100% (5 seconds) Device resets to a safe state. (60601-1 § 49.2)	Mains power quality should be that of a typical commercial or hospital environment. If the user of a Myo 200 device requires continued operation during power mains interruptions, it is recommended that the Myo 200 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.
			Portable and mobile RF communications equipment should be used no closer to any part of a Myo 200 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration - electromagnetic immunity

The Myo 200 device is intended for use in the electromagnetic environment specified below. The customer or the user of a Myo 200 device should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level [c])**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V_{rms} AM 2 Hz 80% 150 kHz to 80 MHz	3 V.....0,15-80 Mhz 20 V.....6,78 Mhz 20 V.....13,56 Mhz 20 V.....27,12 Mhz 20 V.....40,68 Mhz	$d = 1,17\sqrt{p}$ $d = 0,175\sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m AM 2 Hz 80% 80 MHz to 3,0 GHz	3 V/m.....0,08-3,0 Ghz except: 2 V/m.....433,92 Mhz 10 V/m.....915 Mhz 20 V/m.....2,54 GHz	$d = 1,17\sqrt{p}$ 80 MHz to 800 MHz $d = 2,33\sqrt{p}$ 800 MHz to 3,0 GHz $d = 1,75\sqrt{p}$ $d = 0,70\sqrt{p}$ $d = 0,35\sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m CW 200 Hz d.c. 50% 895 MHz to 905 MHz 1,88 GHz to 1,90 GHz	2 V/m.....895-905 Mhz 3 V/m....1,88-1,90 GHz	$d = 3,50\sqrt{p}$ $d = 2,33\sqrt{p}$
			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 Myo 200 device is used exceeds the applicable RF compliance level above, the Myo 200 device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Myo 200 device.
b Over the frequency range 150 kHz to 80 MHz, field strengths must be less than 3 V/m.
c The standard makes an exception for this kind of equipment if the lower immunity levels are specified.

Recommended separation distances between portable and mobile RF communications equipment and the Myo 200 device

The Myo 200 device is intended for use in the electromagnetic environment in which radiated RF disturbances are contolled. The customer or the user of a Myo 200 device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Myo 200 device 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 $d = 1{,}17\sqrt{p}$	80 MHz to 800 MHz $d = 1{,}17\sqrt{p}$	800 MHz to 3,0 GHz $d = 2{,}33\sqrt{p}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in 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

Myo 200 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. Before starting the tests the PC must be disconnected, if present.

Before starting the tests the PC, if present, must be disconnected. If the PC is connected the keys of the Myo 200 are locked.

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 automatic self-test at switch-on does not give an error message.	☐	☐	☐
9.	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

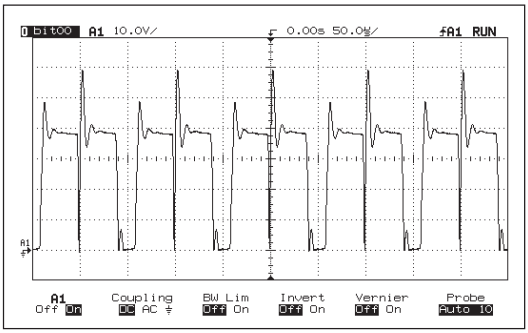


Figure 2

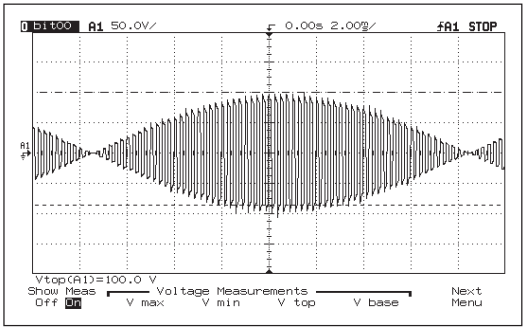
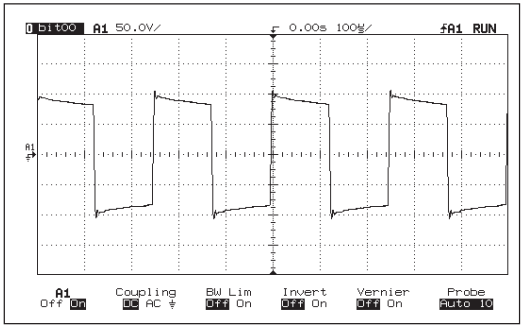


Figure 3



8.4.3 Test 3: Feedback

Feedback channel A **Pass** **Fail**

1. Press ⓕ to select feedback only.
2. Connect circuit both treatment electrodes to the REF input. The reading must be < 5 µV. ☐ ☐

Feedback channel A **Pass** **Fail**

3. Apply a sine of 1 mV_{rms} / 1 kHz between one of the treatment electrodes and the REF input. Tie the other one to the REF input. The reading must be 1000 µV ±10%. ☐ ☐
3. Apply a sine of 1 mV_{rms} / 1 kHz between the other treatment electrode and the REF input and tie the first one to the REF input. The reading must be 1000 µV ±10%. ☐ ☐
4. Change the frequency to the local line frequency. The reading must be < 5 µV. ☐ ☐

Feedback channel B **Pass** **Fail**

1. Select A with ◯ and press △ to activate channel B.
2. Connect circuit both treatment electrodes to the REF input. The reading must be < 5 µV. ☐ ☐
3. Apply a sine of 1 mV_{rms} / 1 kHz between one of the treatment electrodes and the REF input. Tie the other one to the REF input. The reading must be 1000 µV ±10%. ☐ ☐
3. Apply a sine of 1 mV_{rms} / 1 kHz between the other treatment electrode and the REF input and tie the first one to the REF input. The reading must be 1000 µV ±10%. ☐ ☐
4. Change the frequency to the local line frequency. The reading must be < 5 µV. ☐ ☐

Pressure Feedback & Audio **Pass** **Fail**

1. Press ⚙ to access the settings menu.
2. Select **Myo sound** and set **Audio** to **continuous** and **Sound on channel** to **B/P**.
3. Press ↩, select **Customize Myo screen** and set **Target value** to **100**.
4. Press ↩ twice to return to the main feedback screen.
5. Select A B with ◯ and press △ to activate the pressure channel.
6. Disconnect the pressure probe if it is attached. The reading must be 0 mmHg (0 kPa). ☐ ☐
7. Connect the pressure vessel via the vaginal pressure pipe to connector P. Apply a pressure of 760 mmHg (100 kPa). The reading must be 760 mmHg ±15%. ☐ ☐
8. Keep the pressure on without running the pump to check for leaks. The Reading must remain stable for more than 30 s. ☐ ☐

Pressure Feedback & Audio	**Pass**	**Fail**
9. A tone is produced while pressure is applied.	☐	☐

USB connection	**NA**	**Pass**	**Fail**
1. If the Myo 200 is used with a PC, connect the PC and start the Myo program.			
2. Parameter screen of the Myo 200 shows PC mode.	☐	☐	☐

Required equipment

- Sinusgenerator for line frequency and 1 kHz with 1 mV_{rms} output and 600 Ω impedance.
- Small pressure vessel with pump and air pressure meter for 100 kPa without leakage.

8.4.4 Test 4: Electrical safety test (IEC 62353)

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

Notes:

8.5 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 key

The numbers refer to the program numbers.

Electrotherapy

Unidirectional currents

Diadynamic currents

TENS currents

NMES surge currents

Interferential currents

Feedback

Electrotherapy and feedback

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
Error history
Counter working hours
Reset menu

9.1.3 Objectives

The numbers refer to the program numbers.

Electrotherapy

Pain relief

Muscle detonising

Muscular training

Circulatory disorders

Pelvic re-education

Proprioception **Program level 1 - 2 - 3 .**

Patients with normal sensitivity (50 Hz)
- Stimulation / Rest 370-371-372
- Stimulation + Feedback 373-374-375
- Feedback / Rest (1/2) 376-377-378

Patients with high sensitivity (50 Hz)
- Stimulation / Rest 379-380-381
- Stimulation + Feedback 382-383-384
- Feedback / Rest (1/2) 376-377-378

Stress-incontinence **Program level 1 - 2 - 3 .**

Specific twitch (20 Hz)
- Stimulation / Rest 385-386-387
- Stimulation + Feedback 388-389-390
- Feedback / Rest (1/1) 391-392-393

Slow twitch (35 Hz)
- Stimulation / Rest 394-395-396
- Stimulation + Feedback 397-398-399
- Feedback / Rest (1/2) 376-377-378

Fast twitch (70 Hz)
- Stimulation / Rest 400-401-402
- Stimulation + Feedback 403-404-405
- Feedback / Rest (1/4) 406-407-408

Urge-incontinence **Program level 1 - 2 .**

Classic method
- Stimulation (Preferential program) ..... 409 - xxx
- Stimulation / Rest (Alternative program) ..... 410 - xxx

Lindström
- Stimulation / Rest ..... 414 - xxx

Ohlsonn
- Stimulation / Rest ..... 415 - 416

Eriksen
- Stimulation / Rest ..... 417 - xxx

AMD
- Stimulation: 2 blocks ..... 418 - xxx

Mixed incontinence **Program level 1 - 2 - 3 .**
Classic method
Stimulation: 2 blocks..... 411-412-413
AMD
Stimulation / Rest..... 419-448-449

Pelvic floor muscle & Urethral sphincteric insufficiency **Program level 1 - 2 - 3 .**
PFM: Classic method
Stimulation / Rest - Clear atrophy..... 450-xxx-xxx
Stimulation / Rest - Slight atrophy..... 451-xxx-xxx
PFM: Perisize probe
Stimulation / Rest (both channels)..... 452-xxx-xxx
USI
Stimulation / Rest..... 453-454-xxx
PFM & USI
Stimulation / Rest..... 455-456-457

Over activity bladder
Over active bladder..... 196

Muscle re-education

Detonising
Stimulation
Upper body..... 420
Lower body..... 421

Relaxation
Feedback / Rest (2/1)..... 422

Training **Program level 1 - 2 - 3 .**
Slow twitch (35 Hz)
Stimulation + Feedback..... 423-424-425
Feedback / Rest (1/2)..... 426-427-428
Fast twitch (70 Hz)
Stimulation + Feedback..... 429-430-431
Feedback / Rest..... 432-433-434

9.1.4 Indication list

ET: Electrotherapy
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

Feedback
Pregnancy
Vaginal infections and/or injuries
Menses

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.

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