Zimmer
MedizinSysteme

Instructions for Use

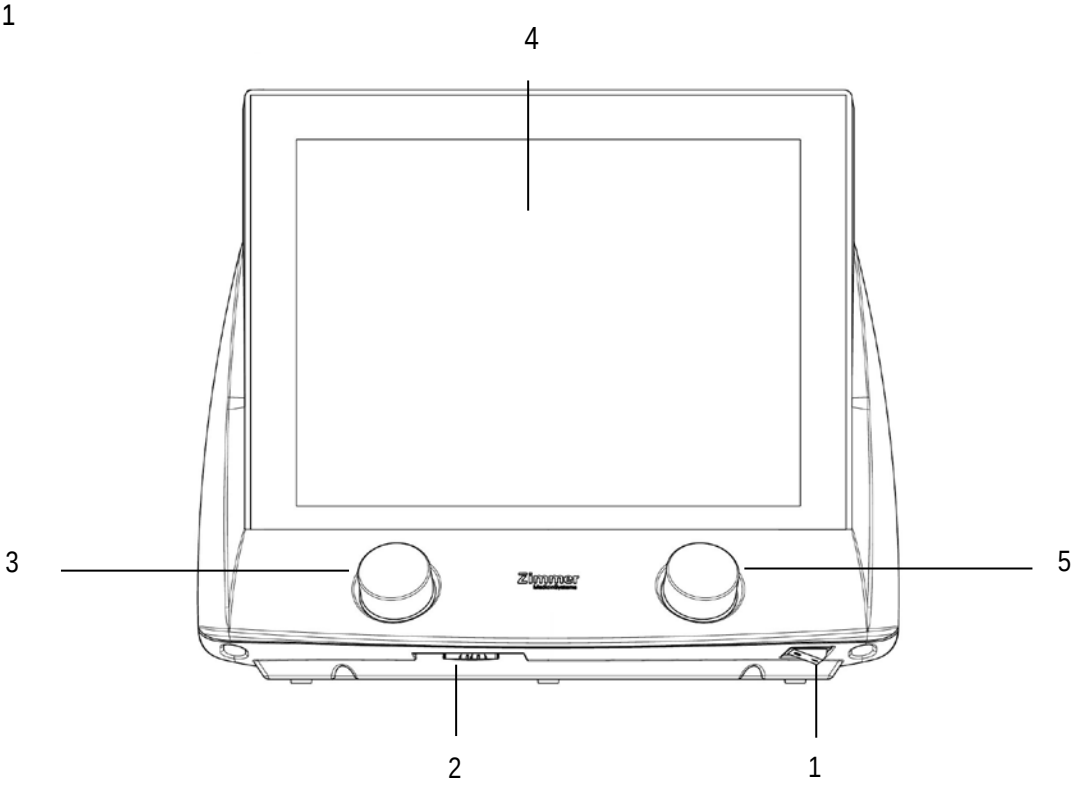
PhySys

EN

Illustrations

Front of the device and transducers

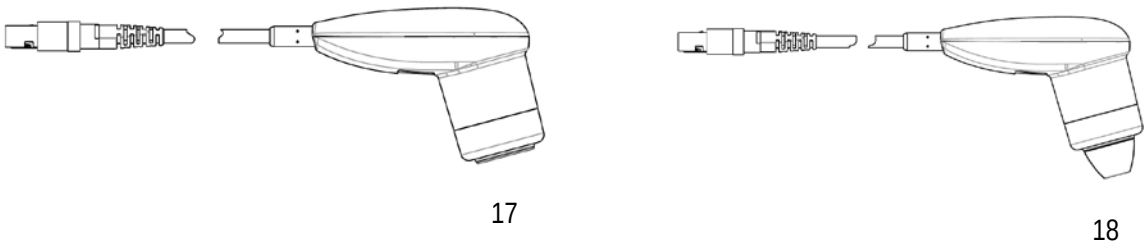
Fig. 1



Selection and operating elements

1 Mains switch
2 Slot for SD card
3 Intensity regulator channel I
4 Display
5 Intensity regulator channel II

Fig. 2



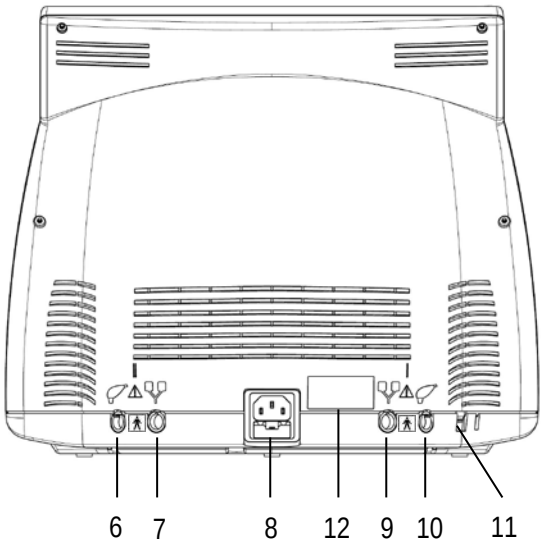
Transducers

17 Ultrasound transducer, large, 5 cm²
18 Ultrasound transducer, small, 1 cm²

Illustrations

Back of the device

Fig. 3



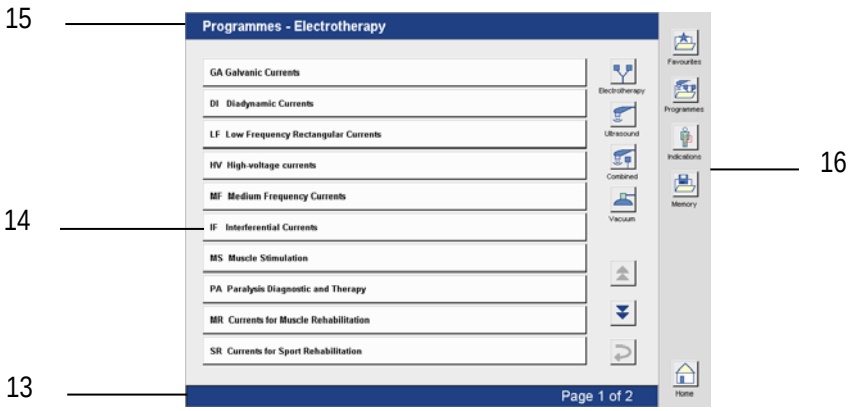
Ports

6 Port for ultrasound transducer 0.8/2.4 MHz
7 Port for patient cable channel II
8 Connection for power cable
9 Port for patient cable channel I
10 Port for ultrasound transducer 0.8/2.4 MHz
11 Port without function
12 Identification plate

Illustrations

Screens / display

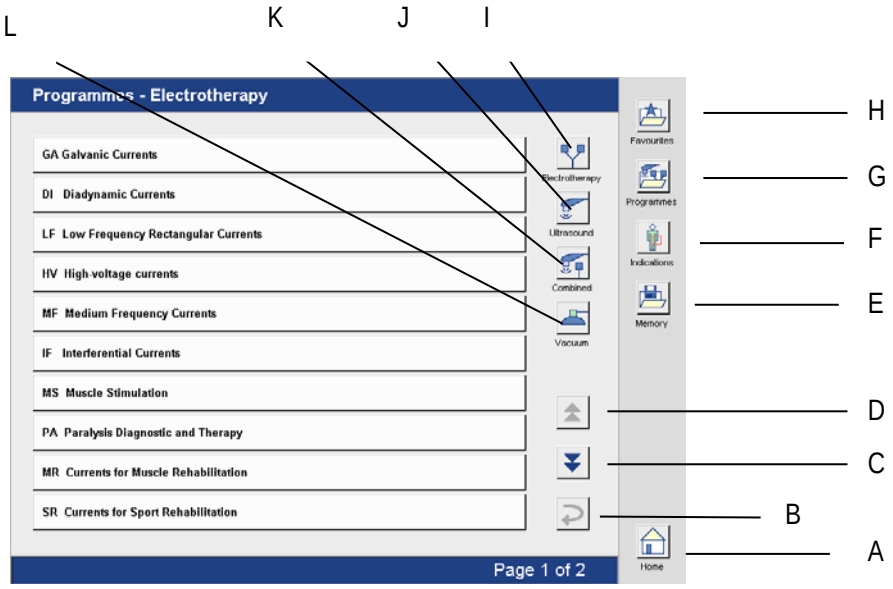
Fig. 5



Display views

13 Status line
14 Buttons on the screen
15 Heading
16 Navigation menu

Fig. 6



Navigation menu

(A) Home	Switch to start-up screen
(B) Back	Moves one step back
(C) Scroll forwards	Goes forward one page
(D) Scroll backwards	Goes back one page
(E) Memory	Switch to memory
(F) Indications	Switch to indication menu
(G) Programmes	Switch to the program list
(H) Favourites	Switch to favourites
(I) Electrotherapy	Switch to electrotherapy program list
(J) Ultrasound	Switch to ultrasound program list
(K) Combined	Switch to combined program list
(L) Vacuum	Switch to the vacuum screen

Explanation of symbols

In the instructions for use this symbol indicates “Danger”.

Caution!

In the instructions for use this symbol indicates “Caution“ with regard to possible damage of the device.

Applied part type BF

Instructions for use

Follow instructions for use.

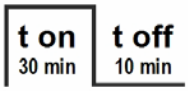
Serial number

Item number

Manufacturer

Date of manufacture

This symbol points out hazardous areas on the device.



Interval operation→30 minutes on, 10 minutes off

Content

Content

Valid for the device Phy*Sys*, SD edition.

These instructions for use are an integral part of the device. They must be stored with the device and kept accessible at all times for anyone authorised to operate this device.

Last updated: July 2017

Indications / Contraindications

1.1 Indications - Electrotherapy

1

Circulation-promoting therapy

- Functional circulatory disorders
- Angiopathy in diabetes mellitus
- Angioneuropathy (Raynaud's disease)
- Acrocyanosis
- Venous vascular diseases
- Chronic venous insufficiency
- Reflex sympathetic dystrophy
- Sudeck's syndrome (stage II)
- Lymphoedema
- Treatment of the facial nerve (as a pre-treatment)
- Chronically contracted muscles
- Peripheral joint disease (chronic)
- Radicular syndrome in the setting of spinal diseases (subacute and chronic)
- Ligament ruptures
- Tenosynovitis
- Bursitis

Analgesic therapy

- Strains, contusions, sprains to muscles, tendons, joints and bones
- Extensive myalgia
- Polyarthralgia
- Joint diseases, inflammatory
- Chronic polyarthritis (rheumatoid arthritis), treatment during the low inflammation interval
- Diffuse pain in periarthropathy, osteoarthritis, ankylosing spondylitis
- Tendinitis, tenosynovitis
- Local and pseudoradicular spinal diseases
- Radicular lesion
- Disc surgery
- Inflammatory spinal diseases, chronic
- Chronic pain conditions, pain disorder
- Pelvic pain (adnexitis)
- Pelvic pain (prostatitis)
- Neuralgia
- Neuritis
- Polyneuropathy
- Radicular syndrome
- Nerve compression syndrome
- Allodynia
- Causalgia (complex regional pain syndrome)

Trophicity-promoting therapy

- Venous ulcers
- Neurotrophic ulcers
- Decubital ulcers
- Delayed wound healing
- Osteoporosis
- Delayed bone healing
- Ligament ruptures

Muscle-toning therapy

- Muscle weakness
- Poor innervation of the skeletal muscles
- Absent muscle sensation

Indications / Contraindications

1.1 Indications - Electrotherapy

1

Muscle-relaxing therapy

- Muscular overload
- Painful muscle tension
- Myofascial pain syndrome
- Tendon and muscle ruptures
- Contractures

Experiences from clinical practice have also shown that there may be a positive effect when treating the following conditions:

- Periarthropathy and insertional tendinopathy (acute, subacute)
- Periarthropathy and insertional tendinopathy (chronic)
- Peripheral joint disease (acute, subacute)
- Posttraumatic conditions (haematoma, oedema)
- Excessive sweating of the hands and feet (Hyperhidrosis palmarum et plantarum)
- Acquired postural disorders of the spine: posttraumatic, postinflammatory, degenerative
- Postural disorders of the spine in childhood and adolescence
- Spinal fractures, spondylodesis
- Joint surgeries, arthroscopy, arthrotomy
- Congenital malformations and deformities or maladjustment of the locomotor organs for treatment in childhood
- Stool incontinence
- Urinary incontinence
- Impaired gut motility
- Chronic constipation
- Secondary lymphoedema and lymphostasis
- Chronic pelvic pain
- Polyneuropathy
- Spinal muscular atrophy
- Peripheral paresis, plexus paresis
- Non-local, generalised spinal diseases
- Spasticity
- Spastic paralysis
- Slack paralysis
- Psoriasis

1.2 Contraindications - Electrotherapy

General Contraindications

- Unclear pain symptoms
- Acute inflammation (local, systemic)
- (Suspected) cardiovascular diseases
- (Suspected) epilepsy
- Peripheral arterial occlusive disease, stage IIb or higher according to Fontaine
- Purulent processes
- Fever
- Generalised infections
- Benign and malignant tumours
- Thrombophlebitis
- Phlebothrombosis with the risk of emboli
- Cardiac pacemaker and other implanted electronic devices
- Transcardial current flow
- Metal implants in the circulation territory when galvanic or unipolar currents are used with pulse widths of more than 1 ms
- Psychoses
- In cases of limited skin sensitivity
- Use on or near open wounds or over fractures

The following should also be borne in mind in the case of TENS therapy

- Pain that can be causally relieved
- Primarily psychogenic pain (TENS therapy is ineffective)
- Central pain syndrome, such as thalamic pain syndrome

Contraindications which should also be borne in mind

Muscle treatment with surged group pulses (surge currents) for:

- loss of consciousness, reduced state of consciousness
- Reflex inhibition (e.g. in the case of fractures)
- Muscle inflammation
- Facial muscles
- If the electric stimulation therapy triggers persistent pain
- Infants, young children
- If spasticity increases
- Pregnancy

Special caution:

- In the case of a bleeding tendency following acute trauma or fracture
- Following surgical procedures if muscle contraction can disrupt the healing process

Precautions for certain current forms

Diadynamic current, Träbert current

- Careful electrode technique is necessary to avoid possible skin injury due to high galvanic component of the diadynamic currents.
- Careful dosing in the case of sensitivity disorders

Electroacupuncture

- No needle acupuncture in the case of coagulation disorders

1.3 Indications - Ultrasound therapy

Indications from orthopaedics, surgery, traumatology rheumatology

- Vertebrogenic pain syndrome, e.g. cervical syndrome
- Ankylosing spondylitis (only during the inflammation-free interval)
- Joint diseases
- Rheumatoid arthritis (if heat treatment is indicated)
- Osteoarthritis
- Periarthropathy
- Epicondylopathy
- Chronic tendinitis, periostitis, heel spur
- Achillodynia
- Scars, contractures, Dupuytren's contracture
- Posttraumatic discomfort
- Fractures (especially with delayed callus formation)

Other indications

- Bronchial asthma
- Rhinopathy
- Persistent discomfort of the cervical spine following whiplash with repetitive blockages
- Headaches
- Earaches
- Postherpetic neuralgia
- Functional disorders of the stomach and duodenum
- Chronic pelvic pain
- Functional discomfort of the lesser pelvis

1.4 Contraindications - Ultrasound therapy

General contraindications

- Unclear pain symptoms
- Diseases for which heat should not be used, such as acute inflammatory diseases
- Diseases in which mechanical influences are contraindicated, such as phlebothrombosis
- Limited blood flow
- Suspected cardiovascular diseases
- Haemorrhagic diathesis
- Do not treat cervically higher than C3
- Ultrasound treatment of parenchymatous or heat-sensitive organs (testes, eyes, gravid uterus, liver, kidney, etc.)
- Anaesthetised areas of skin
- Abnormal temperature perception
- Following treatment with ionising radiation
- Epiphyseal plates
- Tumours
- Electronic pacemakers
- Use on or near open wounds
- Limited reflexes or pain sensitivity
- Use on the abdominal, pelvic or lumbar regions during pregnancy or suspected pregnancy

Metal implants and endoprostheses

Nowadays there are no more concerns against the use of dynamic, low-dose ultrasound.

Side effects

2

Side effects of electrotherapy	No side effects are known if used correctly.
Side effects of ultrasound therapy	No side effects are known if used correctly.

Application information

3.1 General

Prior to using the device on a patient, the user should become familiar with the instructions for use and individual treatment methods to be used as well as the indications / contraindications, warnings and application information. Additional sources of information about the ultrasound therapy should be followed.

These instructions for use must always be stored with the device and kept accessible at all times for anyone authorised to operate this device.

Caution! To avoid the risk of electric shock, the plug must be disconnected from the power supply before performing any cleaning or maintenance activities.

Caution! Before use, ensure that the device is powered via a properly grounded mains socket (electrical installation according to DIN VDE 0100 Part 710). The device must only be operated with the supplied power cable. The power cable must be protected against mechanical stress.

Caution! Magnetic and electrical fields can affect the function of the device. For this reason, do not operate the device in the vicinity of devices which generate strong electromagnetic fields (X-ray or diathermy equipment, MRI machines). Please keep a safe distance of several meters.

Caution! The device is not suitable for use in areas with an explosive, flammable or combustive environment.

Caution! During use, the device is to be located in a position allowing direct access to the device´s central mains supply so that it can be disconnected from the mains at any time.

Caution! Inspect the device before use. If there is any damage, it must not be used.

Caution! Only accessories provided by Zimmer MedizinSysteme GmbH may be used.

Caution! The device may cause malfunctions or may interfere with the operation of equipment in the vicinity. It may be necessary to take appropriate remedial action, such as realignment, re-arrangement of the device or install shielding.

Caution! During the service life of the device, no changes may be made to the device or medical system.

Caution! The complete medical system is suitable for use in the vicinity of the patient.

Caution! To safely disconnect the device from the power supply, pull the mains plug out of the housing socket or outlet.

Electrode positioning and the selection of treatment parameters should always be coordinated to the treatment specifications.

For currents for which there is a risk of chemical burns (for example, galvanic current, diadynamic currents, currents with a galvanic component), the recommended maximum current density is 2 mA eff/cm² electrode surface.

If the current density exceeds 2 mA eff/cm², increased attention on the part of the user is necessary.

When using different electrodes, be aware that in the case of a smaller electrode surface, a higher current density may be reached.

Caution! Stimulation current treatment should not be performed on the head or directly on the eye.

Caution! In combined operation, the ultrasound head can be used as a dynamic electrode in connection with a stationary electrode which is connected via the electrode cable. In such a case, the ultrasound and electrode channel constitute an applied part. Please be advised that in this operation, therapeutic currents flow through the ultrasound transducer.

Handle transducer gently; rough handling can alter its characteristics. Do not allow sharp or pointed objects to come into contact with the ultrasound transducer since the aluminium head can be easily scratched.

The use of coupling agents other than the special Sono plus ultrasound gel can damage the ultrasound transducer.

Disinfect ultrasound transducer after use with conventional equipment disinfectants.

Inspect the ultrasound transducer for damage before each use. If there is any damage, the ultrasound transducer must not be used.

Caution! During combined operation, the ultrasound transducer can be used as a dynamic electrode in connection with a stationary electrode which is connected via the electrode cable. In such a case, the ultrasound and electrode channel constitute an applied part. Please ensure that in this operation, therapeutic currents flow through the ultrasound transducer.

Caution! If the ultrasound transducer is regularly used in a water bath, measures which protect the user must be taken. All user body parts submerged in water must be protected through appropriate measures. Appropriate protective measures include what is known as “aerated clothing.” These can include, for example: neoprene gloves or latex over cotton gloves.

Warnings

4.1 General

4

This device is intended to be used exclusively by medical professionals.

It must always be ensured that two patients are never simultaneously connected to the device during a treatment session!

The patient must not be left unattended during therapy.

Any treatment instructions regarding treatment location, duration and intensity require medical knowledge and should be given by authorised physicians, therapists and medical paraprofessionals. These instructions must be followed.

Use in wet areas is not permitted and may in case of non-compliance lead to considerable damage and endanger both the patient and the user.

Dispose of the packaging material properly. Make sure that it is not accessible to children.

The use of the device out of the settings or applications specified in the instructions for use may lead to hazard by the uncontrolled emission of ultrasound energy.

On patients with implants or an implanted electronic device do not conduct treatment before the risk has been assessed and found negligible.

Patients may not be connected to a high-frequency surgical device at the same time. This can lead to burns.

4.2 Electrotherapy

Electrotherapy

Placing electrodes near the chest can increase the risk of ventricular fibrillation.

When performing iontophoresis, the drug used may have an analgesic effect and pain sensitivity is reduced as a result.

Stimulation current can have a stimulating effect on insulin release. This may result in hypoglycaemia in diabetic patients.

The electrical stimulation or materials used can cause skin irritation or hypersensitivity in sensitive patients. This can be reduced through the use of an alternative electrode material or by changing the position of the electrodes.

Stimulation may not be used:

- over the carotid sinus nerve
- over the neck and mouth
- transthoracically
- transcerebrally
- over swollen, infected, inflamed areas
- over or near cancerous lesions

Vacuum

In patients who tend to develop haematomas, treatment should only be performed after the risk has been assessed and found negligible.

Note: *The above warnings apply to electrotherapy in combination with the vacuum unit.*

When the intensity controller is turned up high, currents above 10 mA eff may flow or there may be voltages over 10 V at the output sockets.

Phy*Sys* – in brief

What is Phy*Sys*?

An ultramodern, innovative combination device for electro- and ultrasound therapy with the option of additionally using a vacuum unit.

What does Phy*Sys* do?

The emission of monophasic, biphasic and medium-frequency currents for nerve stimulation and muscle therapy in single-channel and dual-channel operation as well as the emission of therapeutic ultrasound.

What are the benefits of Phy*Sys*?

A large colour display showing all therapy-related parameters, modern touch operation as well as individual program start settings and a clear, simple menu navigation ensure maximum convenience for the user.

The combination of electro- and ultrasound therapy in one device makes the proven combined therapy possible.

The integration and the use of the vacuum unit ensure convenient electrode application and also create a pleasant massage effect for the patient.

In combination with the column, convenient storage of the accessories is possible.

Phy*Sys* innovations

In the case of SonoSwing, the innovation in the field of ultrasound therapy:

- an ultrasound transducer with 2 frequencies
- freely selectable depth of penetration through the adjustability of the frequency components by percentage

Separately controlled mechanical and thermal effects enable the type of effect to be individually selected.
The user can freely select whether a thermal effect or a mechanical effect is desired.

Note:

The application of the device is reserved for medical professionals (such as physicians, therapists and health paraprofessionals).

Intended use

Intended use

Phy*Sys* is a combination device for therapeutic ultrasound and electrotherapy with the option of a vacuum unit for electrode application and supportive massage.

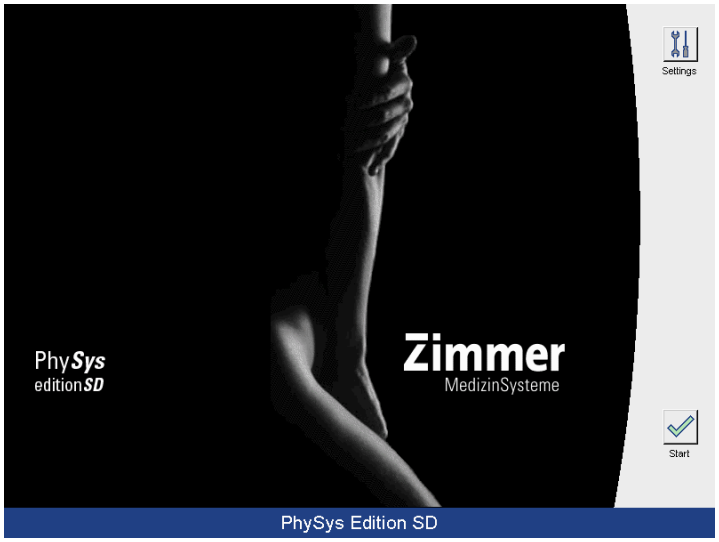
Electrotherapy	Insert the patient cable for channel I in the intended port (9). Insert the patient cable for channel II in the intended port (7). Connect the plug on the end of the electrode cable (red plug in the port marked red, black plug in the port marked black) with the patient cable channel I. Connect the plug at the end of the electrode cable (red plug in the port marked red, black plug in the port marked black) with the patient cable channel II.
SonoSwing	*Connect the transducers to the intended ports (6 and/or 10).*
Note:	*The vacuum unit is integrated in the column as a slide-in module. Please see the separate assembly instructions for securing the PhySys tabletop device to the column and installing the vacuum unit in the column.*
Vacuum unit (Vaco*P*)	Connect the red vacuum suction line to the provided port at the back of the column at “circuit 1, anode”. Connect the black vacuum suction line to the provided port at the back of the column at “circuit 1, cathode”. Connect the red vacuum suction line to the provided port at the back of the column at “circuit 2, anode”. Connect the black vacuum suction line to the provided port at the back of the column at “circuit 2, cathode”. Place the vacuum suction electrodes with the plug on the free end of the vacuum lines.
Connect power cable	Connect the power cable to the provided port (8) and connect the cable to the mains.
Switch device on	Switch on the device at the mains switch (1) on the right below the screen.
Coupling alignment	With the ultrasound transducer connected, the request for coupling alignment appears after the device is switched on.
Performing the coupling alignment	Have a container with water available and carefully follow the instructions on the screen.
Note:	*If both transducers are connected to the PhySys, the displays of both transducers are highlighted in blue and active for the coupling alignment. Perform the alignment for both transducers consecutively. If only one ultrasound transducer is connected, only the button of the connected ultrasound transducer is highlighted in blue and active for the alignment procedure. The second button of the ultrasound transducer which is not connected is highlighted in grey and inactive.*

Note: *The descriptions below always refer to therapy with one channel and are based on the factory default settings.*

Note: *Changes to the default settings can only be made from the start-up screen.*

Start-up screen

After the device has been switched on and the self-test performed, the start-up screen opens.



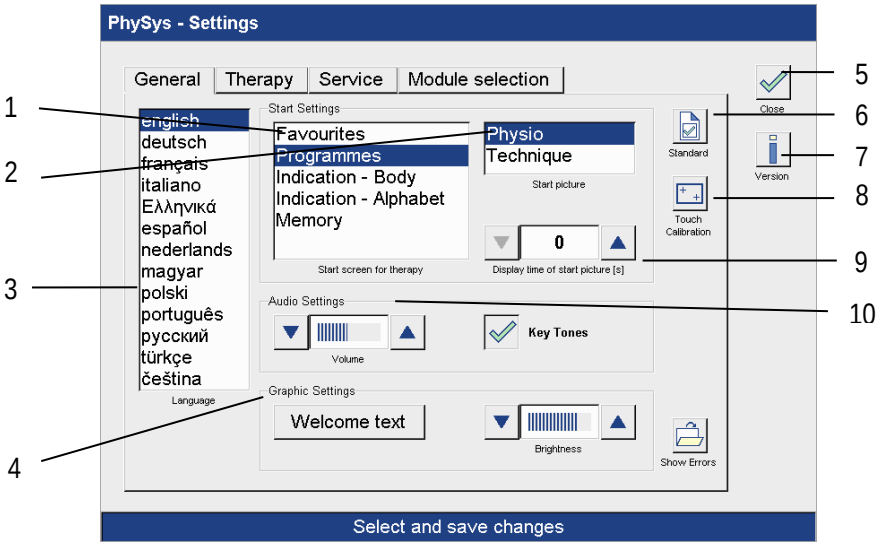
Select settings

Activating the "*Settings*" button opens the settings menu.

Settings menu

Factory settings can be changed and individually adjusted in the settings menu.
After activating the settings menu, the "General settings" screen is active.

Settings – General



The setting options are described below.
The default settings are pre-programmed in the factory as shown on the screen.

(1) Start Settings

Options to individually select the start settings.

(2) Start picture

Option to select from two start pictures.
The selection is made directly in the corresponding line.

(3) Language

Language selection.
The selection is made directly in the corresponding line.

(4) Graphic Settings

1. Welcome text:
Activating the “Welcome text” field opens a window with an alphabetical keyboard to enter an individual welcome text in the start-up screen.
Activating the “Save” button saves the text entered.
Activating the “Cancel” button leads back to the settings menu.

2. Brightness:
Option to adjust the brightness of the screen illumination.

(5) Close

Activating the “Close” button switches immediately to the start screen.

(6) Standard

Activating the “Standard” button restores the factory default settings.

(7) Version

Activating the “Version” button opens a window with information on the current software version.

(8) Touch Calibration

Activating the “Touch calibration” button opens the screen to perform a touch calibration. This can lead to an improvement in the event of insufficient accuracy during touch input.
The left knob must be briefly pushed for the touch calibration. It is important not to touch the screen while doing so.

In addition, a switch can be made directly from the start screen to the calibration menu. To do this, the right knob must be held down for 5 sec. The touch calibration menu then opens and the touch calibration can be performed as previously mentioned.

(9) Display time of start picture

Display time setting option for the start screen using both arrow buttons.
After the start time has elapsed, a switch is automatically made to the start screen.

In the setting “0 seconds” the start screen remains visible until the “Immediate start” button is activated.

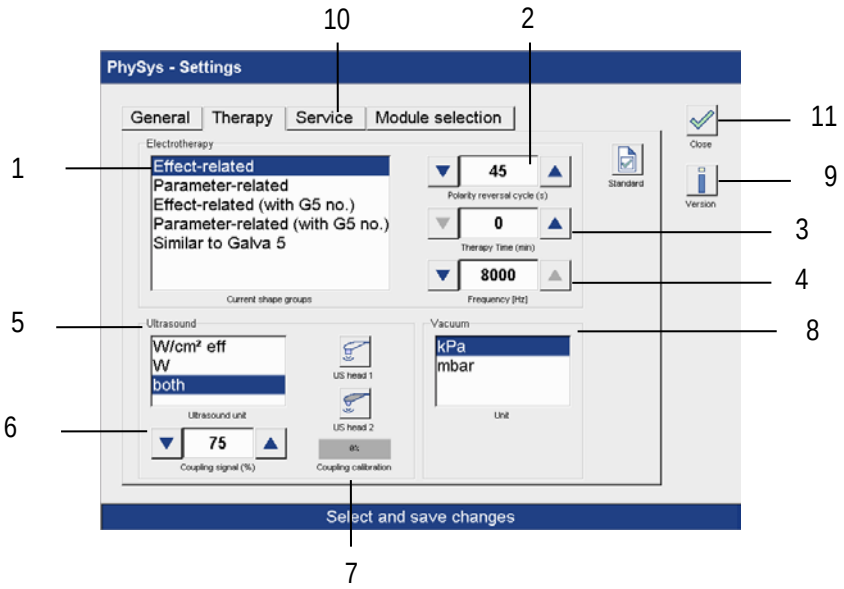
(10) Audio settings

1. Volume:
The volume of the signal sounds can be adjusted by activating the control panels.
The adjustment can be made using the two arrow buttons.

2. Key tones:
The key tones are activated or deactivated using the “Key tones” selection box.

Settings – therapy

Activating the “Therapy” field opens the “Therapy settings” screen.
Therapy-related settings can be applied here.



(1) Electrotherapy

The display mode of the electrotherapy programs can be set.
The selection is made directly in the corresponding line.

(2) Polarity reversal cycle

The polarity can be adjusted using the two arrow buttons.

(3) Therapy time

A uniform therapy time for all programs can be set using the two arrow buttons.

(4) Frequency

Option to adjust the basic frequency at the levels of 2500 Hz, 4000 Hz and 8000 Hz. The adjustment can be made using the two arrow buttons.

(5) Ultrasound

Option to adjust the intensity unit on the bar graph. The selection is made directly in the corresponding line.

(6) Coupling signal

The threshold value of the coupling can be adjusted using the two arrow buttons.

(7) Coupling calibration

To compensate for possible misalignments of the transducers caused by multiple hours of operation, coupling alignment can be performed. To do this, the ultrasound transducer to be calibrated is selected using the “US head 1” and “US head 2” buttons.
For information on performing the coupling calibration, see section 7 “Set-up”.

(8) Vacuum

Option to adjust the intensity unit of the vacuum. The selection is made directly in the corresponding line.

(9) Version

Activating the “Version” button opens a window with information on the current software version. Activating the “OK” button closes the window.

(10) Service

The “Service” menu is not relevant for the user. The points listed here are only used in the event of service by customer service.

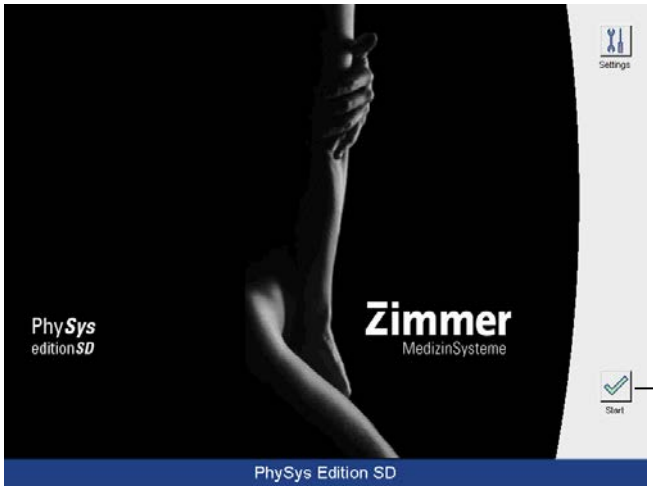
(11) Close

Activating the “Close” button opens the window to save the settings. Activating the “Yes” button saves the modified settings and returns to the start screen. Activating the “No” button leads back to the start screen without saving the modified settings. Activating the “Cancel” button interrupts the process.

Note:

The following information applies for all forms of therapy available in the system.
If the therapy times are individually extended, this may cause a change in the mode of action and the patient must be observed more closely during the application.

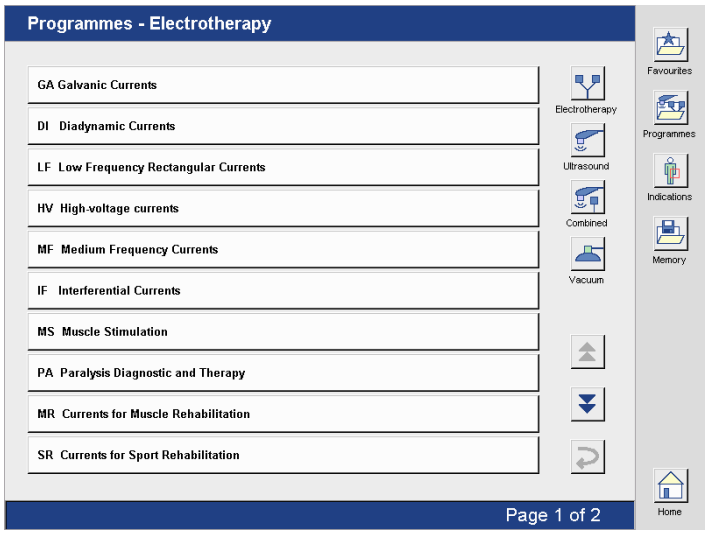
Program start



Using the button (1), the “Programmes - Electrotherapy” window opens.

Electrotherapy programs

In “Programmes – Electrotherapy“ the current forms are divided according to current form group (when the setting “parameter-related” was selected during configuration).

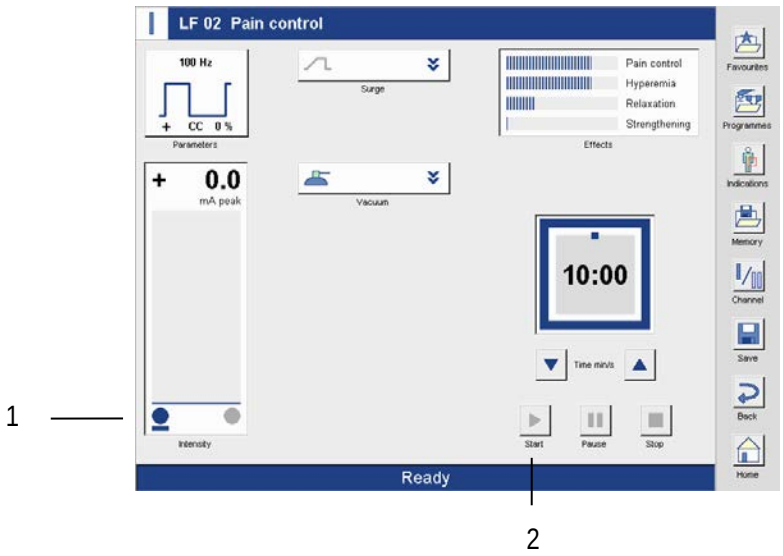


Current form group / Select current form

The desired current form group as well as the current form are selected directly in the corresponding line.

Therapy screen

After selecting the current form, the therapy screen automatically opens on channel I.



Start of therapy

By adjusting the intensity using the left intensity regulator, the display in the lower status line changes from “Ready” to “Active” and therapy proceeds. The present current flow is shown in the bar graph (1) and the therapy time decreases every second.

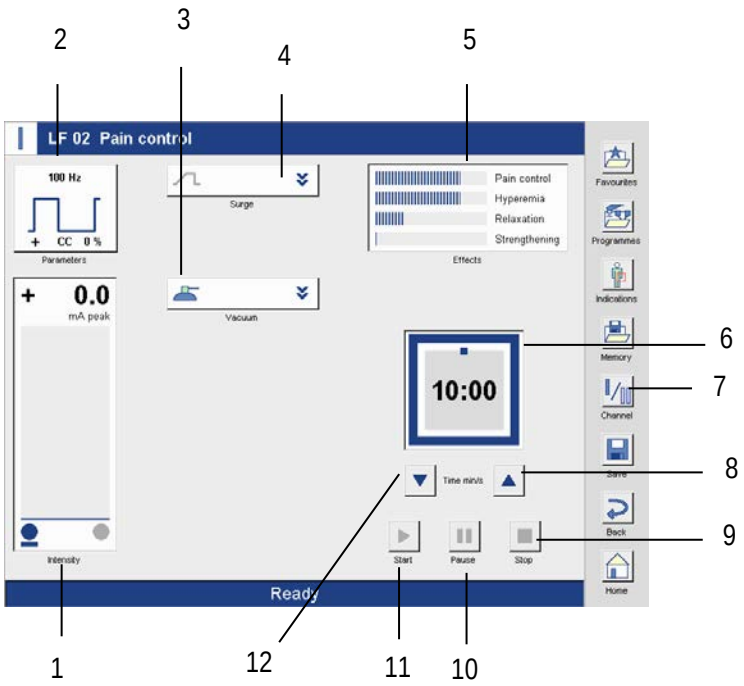
End of therapy

After the therapy time has elapsed, an acoustic signal indicates the end of the therapy, the clock is at 00:00, the intensity automatically goes to zero and the bar graph display goes out. The display in the lower status line changes from “Active” to “Ended”.

Activating the therapy time

Using the button (2), the therapy time is reactivated after the end of therapy.

Description of the display elements and buttons



(1) Intensity — Displays the intensity adjusted.

(2) Parameters — Shows the parameters of the current therapy program.
The following parameters are displayed:

- Impulse and impulse pause time and thus the frequency
- Polarity, CC/CV, galvanic proportion

Activation of the “Parameters” button opens the “Current form parameters” window.
Here the parameters can be modified in a user-defined way.
The impulse parameters to be changed are selected using arrow buttons.
The arrow buttons can be used to modify the values up or down within the limits specified in the current form definition.
The polarity is changed and the CC/CV and galvanic proportion are switched by activating the corresponding button.

(3) Vacuum — Indicates in the therapy screen that the vacuum unit is connected. Activation of the “Vacuum” button opens the “Vacuum” settings and start screen.

(4) Surge — When activated, this shows the surge parameters of the current therapy program.
The following parameters are displayed:
Rise time, hold time, pause time.

If no surge is activated, the surge window is shown in minimised form.
Activation of the “Surge” button opens the “Surge parameters” window. Here a surge can be activated or the parameters can be changed in a user-defined manner.

Note: If no surge is intended for a program as a default, the window is completely hidden.

Note: When parameters are changed, activating the “OK” button applies the changes. Activating the “Cancel” button interrupts the process.

(5) Effects — Gives an overview of the effects associated with the present current form.

Note: If the waveform parameters (pulse time or pulse pause) are changed, the mode of action of the current form also changes. For this reason, the window is no longer visible after a change.

(6) Therapy time — Displays the therapy time.

(7) Channel — Switch to channel mode.

(8) Time min/s — Activating the button increases the therapy time.

(9) Stop — Activating the button ends the therapy before the therapy time has elapsed.

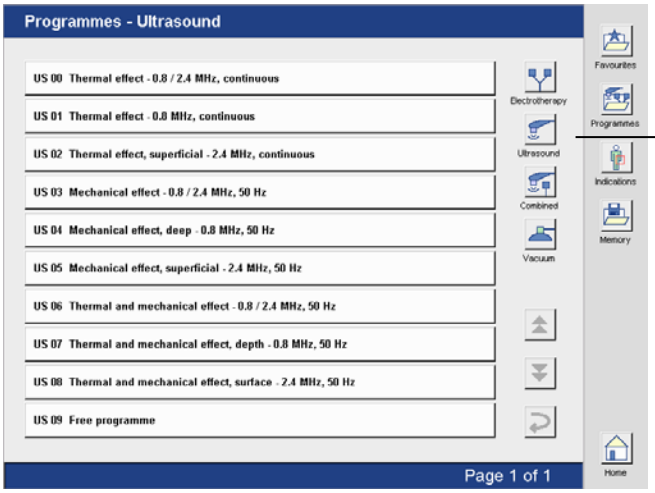
(10) Pause — Activation of the button stops the therapy time and interrupts the therapy.

(11) Start — Activation of the button in pause mode continues the therapy.
Activation of the button after the therapy time has elapsed resets the therapy time to the preset value.

(12) Time min/s — Activating the button decreases the therapy time.

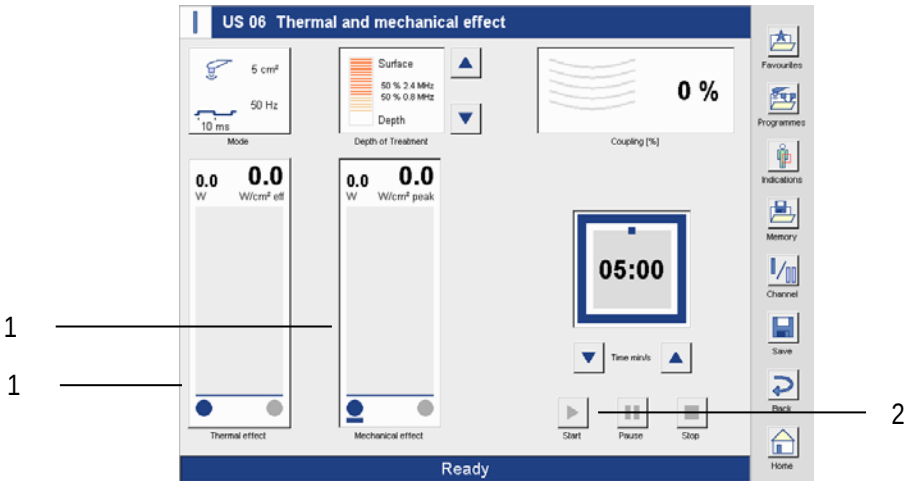
Program start Using the “Start” button, the “Programmes – Electrotherapy” window opens.

Ultrasound programs Using the button (1), the “Programmes - Ultrasound” window opens.



Select program The desired ultrasound therapy program is selected directly in the corresponding line.

Therapy screen After the ultrasound therapy program has been selected, the therapy screen opens.



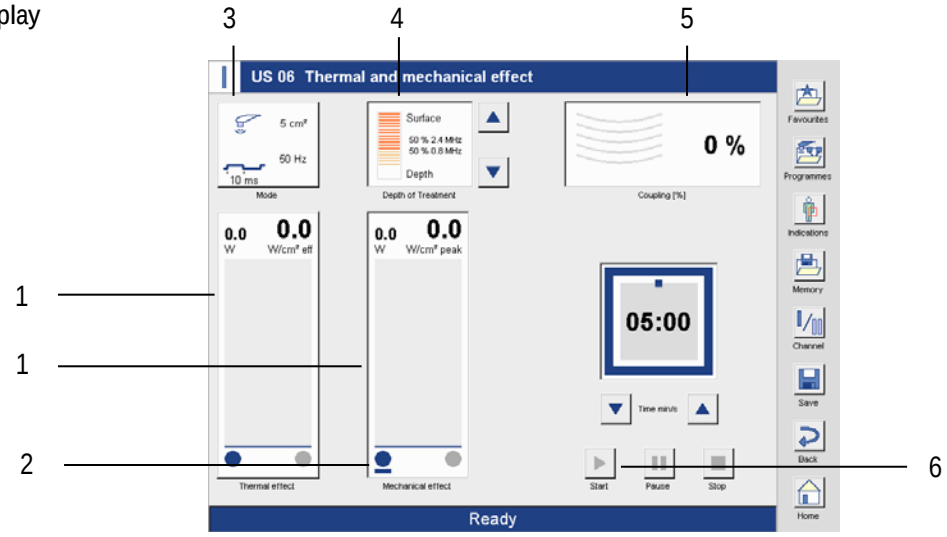
Adjust intensity The intensity is adjusted using the left intensity regulator.

Start of therapy Activating the (2) button starts the therapy. The display in the lower status line changes from “Ready” to “Active” upon the start of therapy. The dose set is shown in both bar graphs (1) and the therapy time decreases every second. The coupling display is enabled.

End of therapy After the therapy time has elapsed, an acoustic signal indicates the end of therapy and the clock is at 00:00. The intensity automatically goes to zero, the bar graph display disappears and the coupling display is disabled. The display in the lower status line changes from “Active” to “Ended”.

Activating the therapy time Using the button (2), the therapy time is reactivated after the end of therapy.

Description of the display elements and buttons



(1) / (2) Thermal effect / Mechanical effect

The bar graph displays (1) indicate the set intensity.
The programs US 00, US 01, US 02 and US 09 emit the unpulsed ultrasound output and therefore exclusively have a thermal effect. In the therapy screen, only the thermal effect bar graph is shown and can be adjusted. In the case of the pulsed programs, the option for separately controlled thermal and mechanical effects can be used to individually select whether the ultrasound therapy should focus on the thermal effect or on the mechanical effect. To individually change the ratio specified by default, the bar graph is activated directly in the bar graph display. The blue bar in the lower part of the bar graph display (2) indicates that the bar graph is activated.

Note:

The separately controlled mechanical and thermal effects enable an individual selection as to whether the ultrasound therapy is to focus on the heat effect or the mechanical effect.
To individually change the specified ratio, activate the desired bar graph directly in the bar graph display.
The blue bar under the blue dot indicates which bar graph is activated.

(3) Mode

Shows the parameters of the current therapy program.
The following parameters are displayed:
Data from the active ultrasound transducer, operating mode, pulse time, pulse frequency.
Activation of the “Mode” button opens the “Ultrasound parameters” window. Here the other ultrasound transducer can be activated and the parameters can be changed in a user-defined manner.
The ultrasound transducer, change in the operating mode, pulse frequency and the associated pulse time are selected by activating the corresponding button.

Note

If the ultrasound therapy is performed in water, the temperature monitoring of the ultrasound transducer must be modified prior to the therapy.
Activating the “Water bath” button modifies the ultrasound transducer for water bath treatment.

(4) Depth of Treatment

The bar graph shows the frequency ratio from 0.8 MHz to 2.4 MHz in percent. The individual setting is adjusted using the two arrow buttons to the right of the display window.
Additional information can be found in the therapy manual.

(5) Coupling

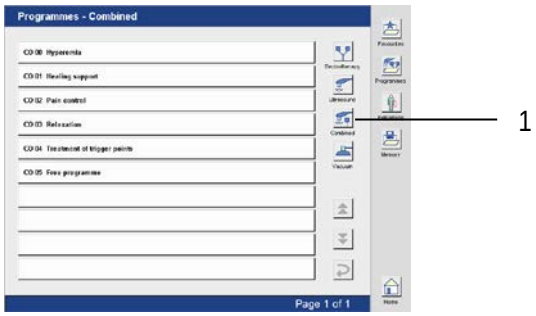
Coupling display. The coupling is displayed graphically, in different colours depending on the coupling level, as well as digitally in percent.

(6) Start

Activating the button starts the therapy.

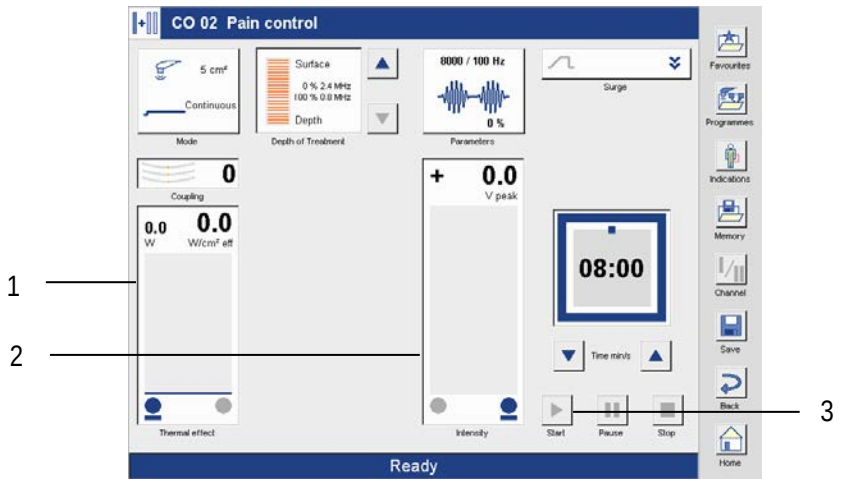
Program start Using the “Start” button, the “Programmes – Electrotherapy” window opens.

Programmes - Combined Using the button (1), the “Programmes - Combined” window opens.



Select program The desired combined therapy program is selected directly in the corresponding line.

Therapy screen After the combined therapy program has been selected, the therapy screen opens.



Adjust ultrasound intensity Adjust the heat effect using the left intensity regulator.

Adjust intensity of stimulation current / Therapy start The combined therapy is active when the stimulation current is adjusted with the right intensity regulator.
The display in the lower status line changes from “Ready” to “Active”. The set ultrasound dose is shown in the left bar graph (1) and the coupling display is active. The present current flow is shown in the right bar (2) graph. The therapy time decreases every second.

Note: *During combined therapy, it should be noted that the live electrode cable (anode) is fundamentally only active on channel I.*

End of therapy After the therapy time has elapsed, an acoustic signal indicates the end of therapy and the clock is at 00:00. The intensity automatically goes to zero, the bar graph display disappears and the coupling display is disabled. The display in the lower status line changes from “Active” to “Ended”.

Activating the therapy time Using the “Start” button (3), the therapy time is reactivated after the end of therapy.

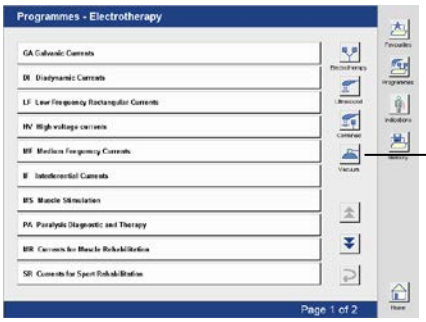
Description of the display elements and buttons The display elements and buttons are described in detail in sections 8.1 and 8.2.

Program start

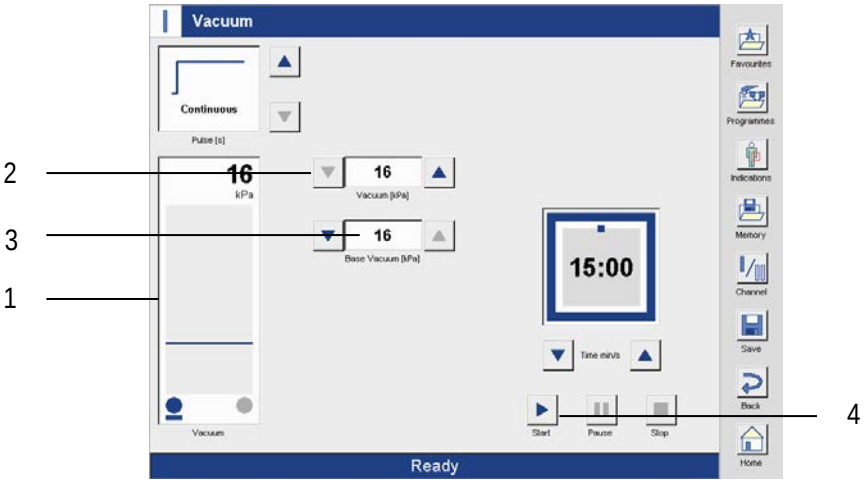
Using the “Start” button, the “Programmes – Electrotherapy” window opens.

Vacuum window

Using the “Vacuum” button, the Vacuum window opens.



Vacuum screen



Activate base vacuum

A base vacuum of 16 kPa is set as a default (3).

The drawing in of the vacuum electrodes is activated using the “Start” button (4). The display in the lower status line changes from “Ready” to “Active”.

The level of the base vacuum is shown in the bar graph (1) and the therapy time decreases every second.

Adjust vacuum

The vacuum is adjusted using the right and left arrow buttons next to the window (2) or using the left intensity regulator.
After adjusting the vacuum, the current vacuum level is displayed in the bar graph.

End of therapy time

After the therapy time has elapsed, an acoustic signal indicates the end of the therapy, the clock is at 00:00, the vacuum level automatically goes to zero and the bar graph display goes out.
The display in the lower status line changes from “Active” to “Ended”.

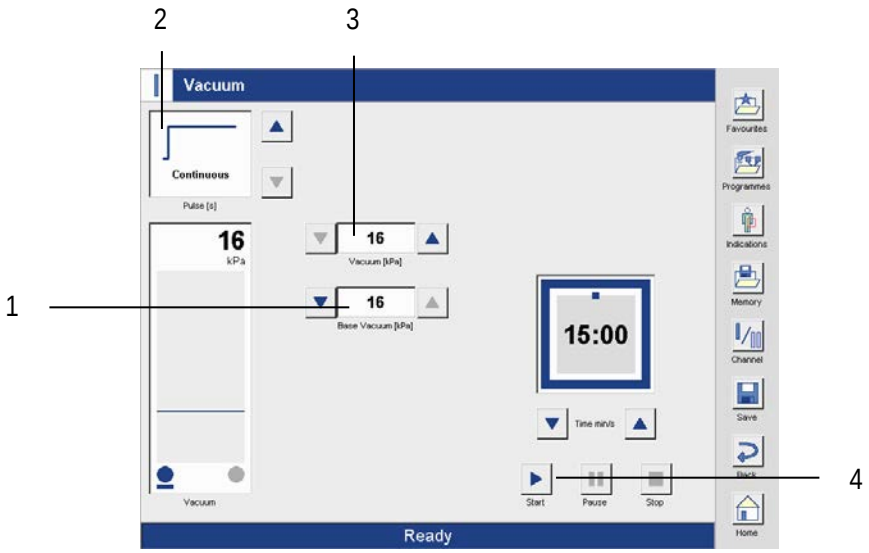
Activating the therapy time

Using the “Start” button, the therapy time is reactivated after the end of therapy.

Note:

Since the vacuum unit is used in most cases in connection with electrotherapy, the “Pause” button is not active during solo operation.

Description of the display elements and buttons



(1) Base Vacuum

Displays the base vacuum set as default.
The base vacuum can be increased or decreased up to 12 kPa using the two arrow buttons.

(2) Pulse

Shows the parameters of the current program.

The following parameters are displayed:
Operating mode, unpulsed or pulsed, showing pulse time.

In pulsed operation, the pulse duration is set using the two arrow buttons next to the display window.

(3) Vacuum

Shows the set vacuum. The vacuum is adjusted using the right and left arrow buttons.

(4) Start

Activating the button activates the base vacuum to draw in the electrodes.

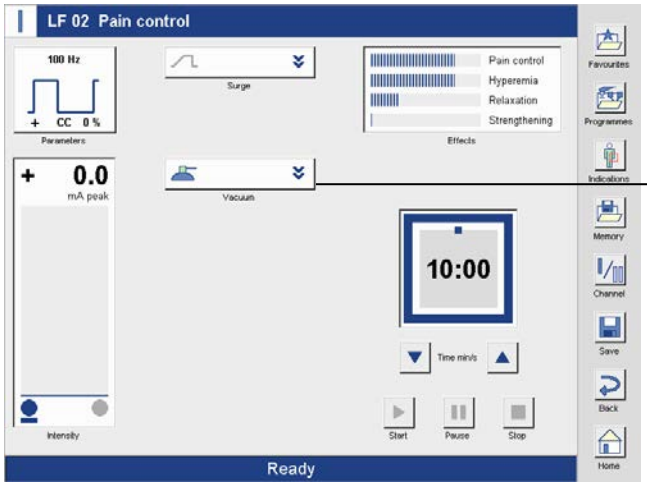
Note:

The procedure up to the therapy screen is analogous to the procedure described in section 8.1 “Electrotherapy”.

Note

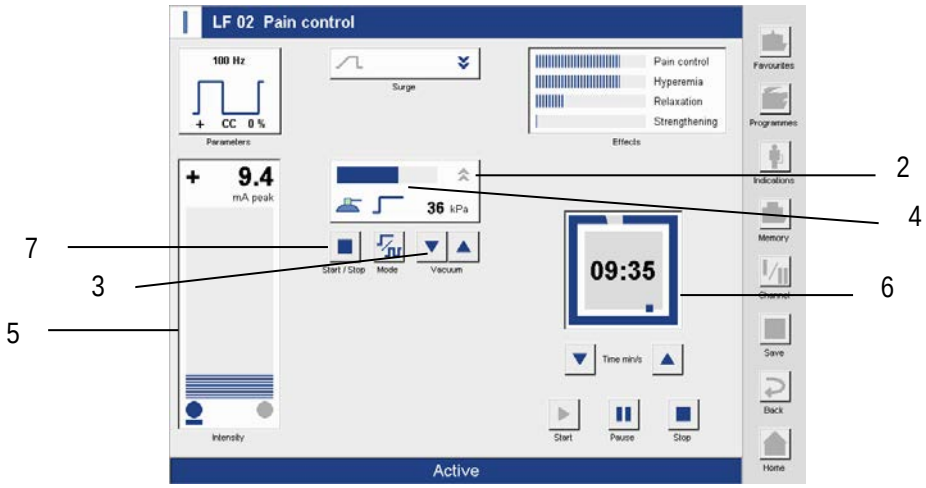
Pulsed operation is only possible with the large vacuum electrodes.

Open Vacuum menu



Activating the field (1) opens the Vacuum menu (2).

Therapy screen



Select vacuum

The vacuum is adjusted using the two arrow buttons (3).

After adjusting the vacuum, the current vacuum level is displayed in the bar graph (4).

Therapy start – Electrotherapy

By adjusting the intensity using the left intensity regulator (5), the display in the lower status line changes from “Ready” to “Active” and therapy proceeds. The present current flow is shown in the bar graph and the therapy time (6) decreases every second.

Therapy end – Electrotherapy

After the therapy time has elapsed, an acoustic signal indicates the end of the therapy, the clock is at 00:00, the intensity automatically goes to zero and the bar graph display goes out. The display in the lower status line changes from “Active” to “Ended”.

Note:

After the therapy has elapsed, the vacuum unit must be manually deactivated by pressing “Start / Stop”.

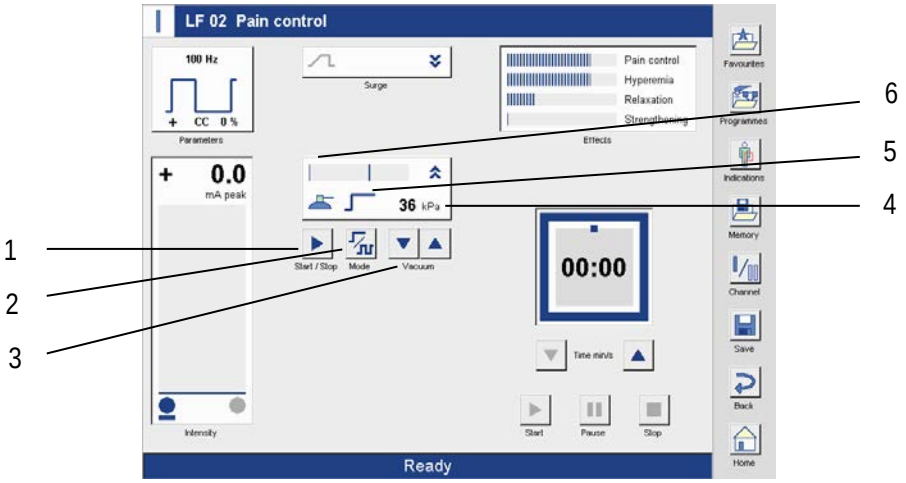
Deactivating the vacuum unit

The vacuum unit is deactivated using the “Start / Stop” button (7).

Activating the therapy time

Using the “Start” button, the therapy time is reactivated after the end of therapy.

Description of the display elements and buttons



Note: *After the "Vacuum" button is activated, the parameter window opens.*

(1) Start / Stop — Activating the button activates the base vacuum to draw in the electrodes. Activating the button deactivates the vacuum.

(2) Mode — Activating the button opens the "Vacuum" entry field to adjust the parameters.

(3) Vacuum — The vacuum adjustment is made using the two arrow buttons.

(4) Display (kPa) — Numeric display of the set vacuum.

(5) Operating mode — Displays the set operating mode.

(6) Bar display — Displays the intensity adjusted.

Note: *Pulsed operation is only possible with the large vacuum electrodes.*

The Vaco*P* integrated in the column contains a water separator which collects moisture emitted from the sponges and thus protects the vacuum unit from calcification.

Note: *Before you empty the water separator, remove any Vaco electrode from the tube.*

Emptying the water separator

Empty the water separator by opening the discharge tap.
The discharge tap is located on the underside of the Vaco*P*.
Close the discharge tap afterwards.

We recommend emptying the water separator daily.

Note: *After closing, ensure that the discharge tap is at an angle of 90° to the flow direction (see Fig.).*

VacoP and "DuoStim separate" mode

In the "DuoStim separate" mode, a dual circuit vacuum application is not possible.

In the "DuoStim separate" mode, only channel I is active for vacuum application. Channel II cannot be operated with vacuum application.

The indication menu is used for support during therapy selection.

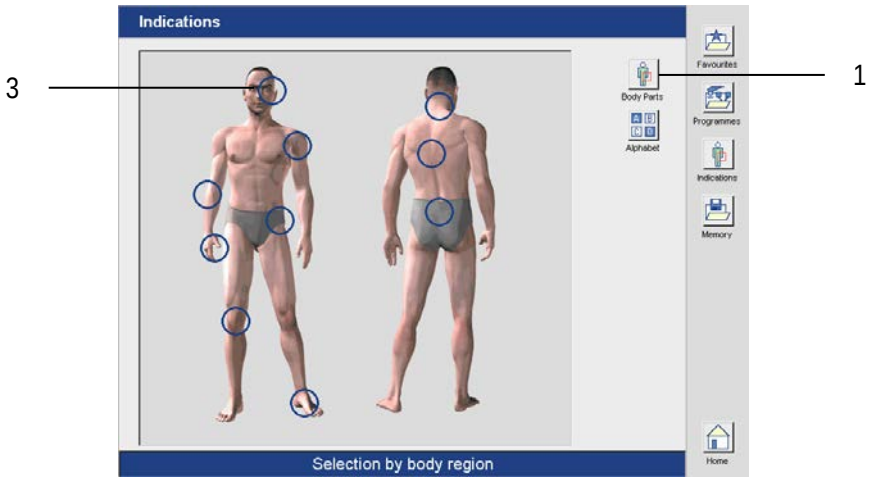
Indications

Activating the “Indications” button opens the “Indications” menu.

Note:

In the “Indications” menu there are two options available to select the desired application:

- *through selecting a body region*
- *through a list.*

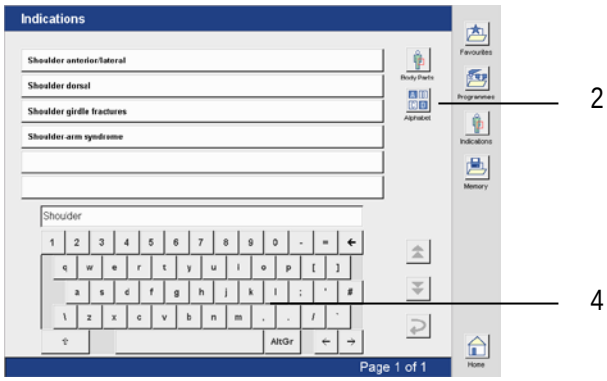


Selecting the application by body region

Activating the button (1) opens the “Selection by body region” menu.
The body region is selected by clicking on the blue circle (3).

Selecting the application by list

Activating the button (2) opens a menu in which the treatment regions are listed in alphabetical order.



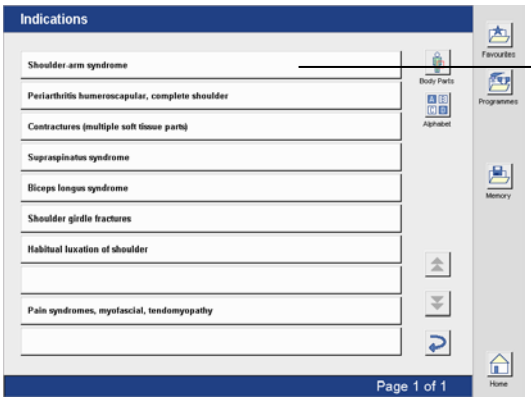
The selection is made through an entry via the keyboard (4).

Note:

Regardless of whether the application is selected using body regions or the list, the program steps are identical here and are therefore described only once below.

Select clinical picture

After selecting the desired body region or making a selection via the list (here: “Shoulder”), the window (5) opens with various indications in the shoulder region.

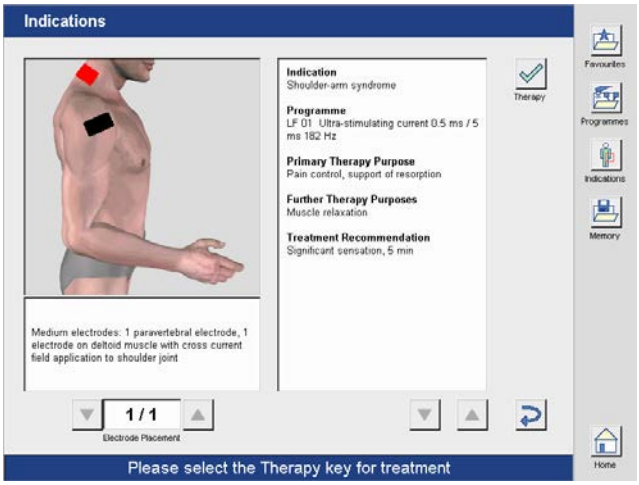


The desired clinical picture is selected directly in the corresponding line (here: Shoulder-arm syndrome).

Additional selection options can be made depending on the application. The selection is made directly in the corresponding line.

Therapy information

If the selection is completed, a window with detailed therapy information and a program recommendation opens.



Select therapy program

Activating the “Therapy” button opens the therapy program.

Note: *The parameters of the predefined programs can be individually modified and saved.*

Note: *To save programs, the SD card must be correctly inserted in the SD card slot. Otherwise it will not be possible to save programs.*

The programs can also be saved unchanged.

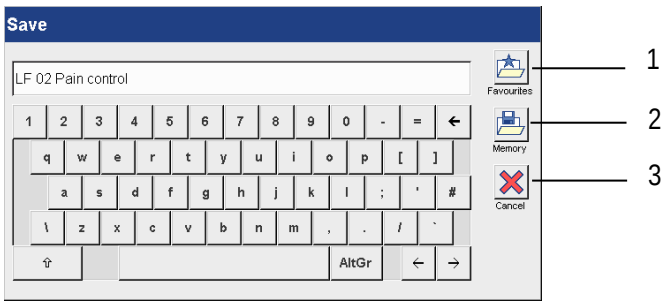
The procedure for saving is the same for all forms of therapy. The procedure for saving an electrotherapy program is described below.

The program parameters can be changed and saved in the therapy screen.

Note: *In addition to saving programs, the I/T curve data can be saved in the I/T curve screen (paralysis diagnostics). These data can be exported and read into Excel and individually processed, for example.*

Open memory list and name program

Activating the “Save” button opens the keyboard to enter the program name.



Two options are available for naming programs:

1. Acceptance of the program name stored in the entry field.
2. Entry of an individual program name. In the case of an individual program name, entry is performed using the keyboard.

Note: *Before entering an individual program name, the program name stored in the entry field must be deleted.*

Note: *The programs can be saved in the Favourites list or Memory list. There are 120 storage locations available in each case.*

Saving in the Favourites list / Memory list

Activating the button (1) opens the Favourites list and automatically saves the program in the Favourites list.
Activating the button (2) opens the Memory list and saves the program in the Memory list.
Activating the “OK” button closes the “Save” screen and adds the program to the corresponding list.

The program is always saved in the first open space in the list.

Activating the “Cancel” button (3) interrupts the save procedure.

The individually saved programs are listed in the Favourites and Memory list.
Here these can be:

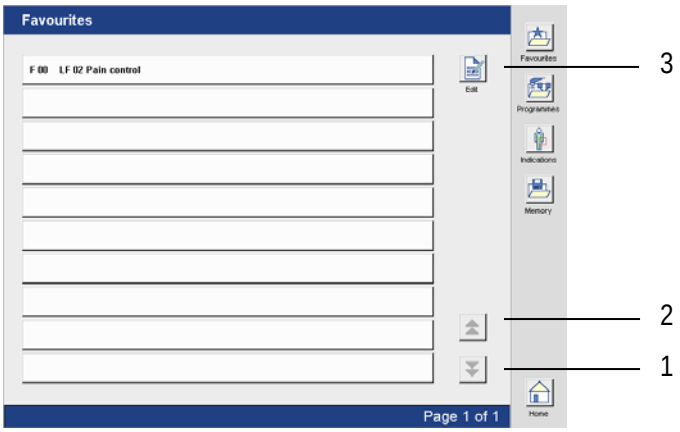
1. retrieved for therapy or
2. edited (moved in the sequence and deleted).

Note: *The steps to retrieve and edit the Favourites / Memory list are identical, so only the retrieving and editing the favourite list is described.*

Select Favourites list Activating the “Favourites” button opens the favourites list.

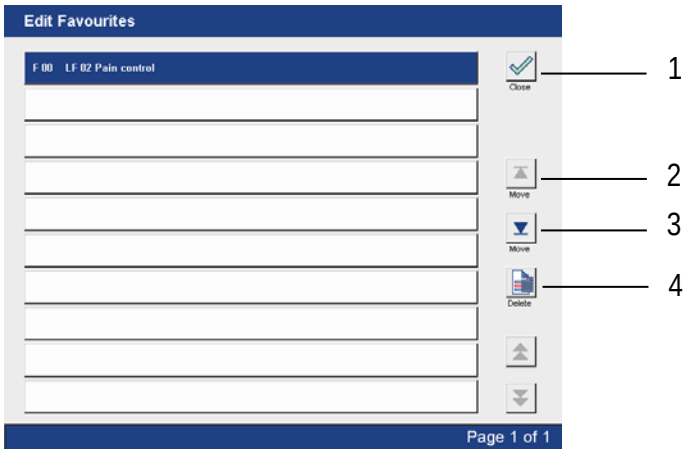
Retrieve program The desired program is selected directly in the corresponding line.

Edit Favourites list By activating the buttons (1) and (2), the individual pages in Favourites can be viewed. Button (1) scrolls forward, button (2) scrolls backward.



Activating the button (3) opens the “Edit Favourites” screen.

Edit Favourites The program to be edited is selected directly in the line.



Activating the button (1) leads back to the Favourites list.
Activating the button (2) moves the program up.
Activating the button (3) moves the program down.
Activating the button (4) deletes the program.

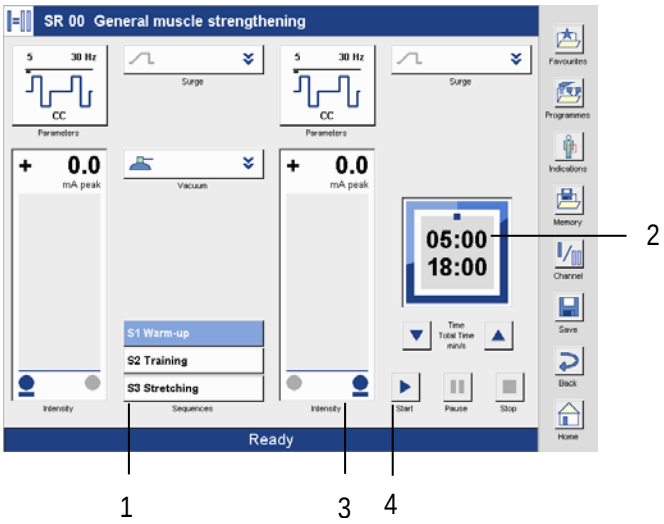
Note: *Activating the button (4) triggers a confirmation prompt:*
“Do you really want to delete the program?”
Activating the button “Yes” deletes the program.
Activating the button “No” interrupts the deletion process.

9.10 Sequence programs

Sequence programs are a compilation of up to three electrotherapy programs which are run consecutively in sequence. In the program family “currents for sports rehabilitation”, a variety of default programs are predefined. They generally consist of the warm-up, training or strengthening and stretching phases.

A freely definable program is also available.

Therapy screen for pre-programmed program



Sequence list

Display of the three phases of the sequence program. The active phase is shown in blue (1).

Therapy time

A therapy time (2) is specified for all three phases. The upper time shows the remaining time of the current phase. The lower time shows the remaining total time.

Note:

Since different pulse forms and frequencies involve different current perception, the intensity thresholds for the individual sequences are defined prior to therapy.

Sequence 1
Warm-up

Sequence 1 is highlighted in blue and thus active.
Use the two intensity regulators to set the intensity for sequence 1.

Sequence 2
Training

Sequence 2 is selected directly in the list (1).
Following the selection, sequence 2 is highlighted in blue and thus active.
Use the two intensity regulators to set the intensity for sequence 2.

Sequence 3
Stretching

Sequence 3 is selected directly in the list (1).
Following the selection, sequence 3 is highlighted in blue and thus active.
Use the two intensity regulators to set the intensity for sequence 3.

Note:

Once the intensities have been defined, the therapy time of the individual sequences proceeds. When the next sequence is selected, the pre-set intensity of the previous sequence is automatically saved.

Activation
Sequence 1

Activation of the sequence 1 in the list (1) after the intensities for all 3 sequences have been defined. At the same time, the therapy time returns to the pre-set values and the start button becomes enabled.

Start of therapy

Activating the “Start” button (4) starts the therapy.
The 3 sequences run consecutively. The sequence switch is indicated by an acoustic signal.

End of therapy

After the therapy time has elapsed, an acoustic signal indicates the end of therapy.

In the “currents for sports rehabilitation” program family, an individual sequence program can be defined by selecting “SR 07“.

Note:

Sequence programs can be performed in monostim as well as in twinstim mode. The freely definable sequence program is defined in monostim mode as default. For programming a twinstim program, twinstim must be activated in channel mode.

Define sequence program screen

Select sequence

As a default, the first sequence is active upon selection of the program (1). The desired sequence is selected directly in the corresponding line and is highlighted in blue after activation. The “Current form groups” screen opens upon selection of the sequence to be programmed.

Select current form group

Selection of the desired current form group.

Select current form

Selection of the desired current form.

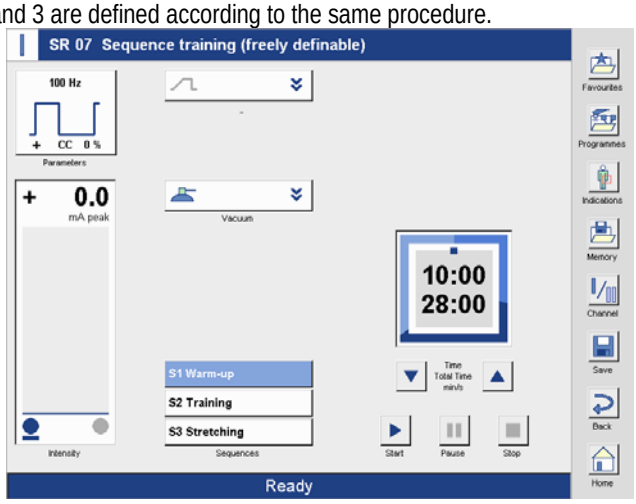
Save sequence 1

When the desired current form is selected, it is added to the sequence program and saved on the activated sequence place.

Define sequence 2 and 3

Sequences 2 and 3 are defined according to the same procedure.

Sequence training screen freely definable



Note:

The specification of the intensities and therapy start are described in detail in the previous section.

Technical information

10.1 General

10

Mains power Phy*Sys*	220 – 240 V~ / 50/60 Hz 220 V~ / 60 Hz
Mains power Vaco*P*	220 – 240 V~ / 50/60 Hz 220 V~ / 60 Hz
Power consumption	max. 150 VA
Power consumption Vaco*P*	max. 50 VA
Protection class	I
Mains fuse	2 x 2.0 A T (Phy*Sys*) 1 x T 200 mA (Vaco*P*)
Applied part	Type BF
Operating mode	Interval operation- 30 minutes on, 10 minutes off
Dimensions	
Phy*Sys* with column	H 138 x W 53 x L 52 cm
Phy*Sys*	H 30 x W 35 x L 20 cm
Column	H 109 x W 53 x L 52 cm
Weight	
Phy*Sys* with column and Vaco*P*	10.9 kg
Phy*Sys* with column without Vaco*P*	8.9 kg
Column and Vaco*P*	7.8 kg
Phy*Sys*	3.1 kg
Column	5.8 kg
Vaco*P*	2.2 kg
Note:	*Storage and transport only in original packaging.*
Operation	+10 to +35°C, 30 to 75% relative humidity without condensation, at 700 to 1060 hPa
Storage and transport	-10 to +50°C, 10 to 90% relative humidity without condensation, at 700 to 1060 hPa
	Subject to technical changes!

Emitted output (max.)	At a load resistance of 500 Ohm
Galvanisation (mA eff)	80
Diadynamic currents (mA eff)	20
High voltage currents (mA peak)	250
Medium-frequency currents (mA peak/mA eff)	140/100
Interference currents (mA eff)	100
Microstimulation current (mA peak)	2
Low-frequency square-wave currents (mA peak/mA eff)	80/80
Accuracy	± 20%
Applied part	Stimulation current electrodes
Polarity of the currents	If currents have a polarity: Red = positive (+), Black = negative (-)
Note:	*Please note that the amperages emitted decreased with increasing patient impedance. This can be read on the bar graph.*

Transducers	
Frequency	0.8 MHz and 2.4 MHz
Ultrasound transducer, small	1 cm^2 , ERA = 0.67 cm^2 at 0.8 MHz, 0.65 cm^2 at 2.4 MHz
Maximum output	1.0 W at 0.8 MHz, 0.6 W at 2.4 MHz
Intensity levels	0.1 to 1 W/cm^2 eff. in intervals of 0.1 W/cm^2
Ultrasound transducer, large	5 cm^2 , ERA = 2.30 cm^2 at 0.8 MHz, 2.38 cm^2 at 2.4 MHz
Maximum output	6.9 W at 0.8 MHz, 7.1 W at 2.4 MHz
Intensity levels	0.1 to 3 W/cm^2 eff. in intervals of 0.1 W/cm^2
Accuracy	± 20%
Ultrasound types	1. Continuous ultrasound 2. Pulsed sound, adjustable pulse frequencies 20 Hz, 50 Hz, 100 Hz Duty cycle 1:10.....9:10
Interchangeability	Ultrasound transducers are calibrated ex works and can be interchanged without any problems.
Applied part	Transducer oscillator

10.4 Vacuum

Underpressure	12 – 60 kPa
Pulsed operation	Period duration 1 to 8 s can be adjusted in intervals of 0.5 seconds; duty cycle 1:1
Accuracy	± 20%
Applied part	Vacuum suction cups and sponges

– Before starting any maintenance and cleaning measures the device must always be switched off at the main switch and the mains cable must be disconnected.

– Make sure that during cleaning or disinfection no liquid penetrates the device. Do not use sprays.

– If during cleaning or disinfecting liquid penetrates the device, please put the device out of service, protect it from being used again and contact your service representative.

– Make sure that when cleaning and disinfecting the labelling of the device (such as warnings, labels of control devices, identification plate) is not damaged.

– The device and its applied part are considered as uncritical in relation to hygiene due to the use on non-injured and healthy skin.

Housing / cables

Cleaning: In the event of visible contamination, the housing and all cables can be cleaned using commercially available alcohol-free plastic cleaners. Wipe the surface until the dirt is removed, using a soft cloth soaked according to the specifications of the manufacturer of the cleaning agent but not dripping wet.

Disinfection: We recommend that disinfection is to be carried out at least once a week, as well as if there is any indication of contamination. Consult with your hygiene specialist when doing so. Always perform cleaning prior to disinfection.

Housing and all cables can be disinfected using disinfectant wipes. Use a commercially available alcohol-free disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties. Observe the instructions for use of the respective manufacturer. Wipe all surfaces using a soft cloth soaked according to the specifications of the manufacturer of the disinfectant, but not dripping, or with cloths pre-impregnated with disinfectant (wipes).
Also observe requirements for drying or post-cleaning, where applicable.

Transducers

Cleaning: Follow the procedure described under “Housing”.

Disinfection: Follow the procedure described under “Housing”.

Cleaning
Disinfection

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Vaco electrodes

Cleaning: In the event of visible contamination, the Vaco electrodes can be cleaned using commercially available alcohol-free plastic cleaners. Unplug the Vaco electrodes from the electrode tube and turn the suction cup completely inside out. Immerse the Vaco electrode in a cleaning solution according to the information from the manufacturer of the cleaning agent and clean the electrode thoroughly using a hard brush. Ensure that the gap underneath the metal plate is also completely clean. Rinse with fresh water afterwards.

Disinfection: We recommend that disinfection is to be carried out at least once a week, as well as if there is any indication of contamination. Consult with your hygiene specialist when doing so. Always perform cleaning prior to disinfection.

The Vaco electrodes can be disinfected using a conventional, alcohol-free disinfectant for metal and plastic which has a bactericidal, virucidal and fungicidal effect. Observe the instructions for use of the respective manufacturer. Completely immerse the Vaco electrodes into the disinfectant and move them gently. Ensure that the inner and outer surfaces are completely wetted with disinfectant.
Also observe requirements for drying or post-cleaning, where applicable.

Sponges / sponge pockets

Cleaning: Rinse the sponges / sponge pockets thoroughly with water. The use of cleaning agents is not recommended, since components remain in the sponges and can cause skin irritation during use. This can also lead to damage of the material.

Disinfection: For thermal disinfection, boil the sponges / sponge pockets for 10 minutes or wash them (water temperature min. 95°C) in pure water without additives. The use of disinfectants is not advised since ingredients which remain in the sponges can lead to skin irritation during use. In addition, the material may become damaged.

If flammable solutions are used for cleaning and disinfecting, sufficient time must be allowed for the solution to evaporate before using the device. Otherwise, it may lead to inflammation.

Note: *Use the device only in a hygienic environment.*

Electrodes
Information on the use of different types of electrodes

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General information

The electrodes must be selected and applied with care. During constant current operation, ensure good, even contact with skin. A decrease in the area of contact can cause the patient to have paraesthesias.
Prior to treatment, the skin should be inspected and cleaned, if necessary, for example if the patient is sweaty or if ointments have been applied to the skin. Inflamed areas of skin, small wounds or fissures are covered with Vaseline or zinc paste. Particular caution is also required in the case of fresh scars.

Disposable electrodes

The self-adhesive disposable electrode enables convenient, quick application. Their one-time use ensures hygienic application. Three therapeutically useful sizes enable individual therapy that is adapted to the patient's medical condition.
Disposable electrodes are particularly suitable for therapy with bipolar currents; for therapy with monopolar pulse currents or currents with a galvanic component, a moist sponge should additionally be used with the disposable electrodes as padding.
All conventional electrotherapy electrodes can be connected to the Phy*Sys* using an insulated cable clip.

Note:

The disposable electrode is for one-time use only and can be disposed of with household waste without any problems.
Use of the disposable electrode several times can be hazardous to the patient.

For applications over particularly large areas, plate and rubber electrodes are available, in addition to the disposable electrodes.

The electrical connection is made using the clips of the electrode cable, just as in the case of the disposable electrode. Secure clips to the plate electrode which is fully inserted into the sponge pocket.

Rubber electrodes

Rubber electrodes are suitable for therapy with bipolar currents; when using a purely galvanic current, currents with galvanic components or a longer pulse length, it should be noted that there is a decrease in conductivity through the withdrawal of carbon, which is the normal result of use.

Tin plate electrodes

For therapy with a purely galvanic current (galvanisation, iontophoresis), large tin plate electrodes are suitable.

Sponge pockets and sponges

Rubber and tin plate electrodes must always be padded with a moist intermediate layer. The use of sponge pockets is recommended for rubber electrodes; sponges which should be at least 1 to 2 cm thick are recommended for tin plate electrodes. Tap water is recommended for moistening the sponges; distilled water is not suitable due to its poor conductivity.
In contrast to the convenient, self-adhesive disposable electrodes, rubber and tin plate electrodes must be secured. Velcro or elastic straps are suitable for this purpose.

Insert the electrodes all the way into the sponge pockets and apply with gentle pressure until they properly sit closely against the body. The securing straps should not leave behind any furrows.

CE mark / manufacturer

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The devices have a CE mark

CE 0123

in accordance with the EC directive on medical devices 93/42/EEC.

Manufacturer

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Scope of delivery

Complete Phy*Sys* system, consisting of:
Electro-ultrasound therapy unit, Vaco*P* and column

Item no.*

2 pc. patient cable
1 pair electrode cables, grey, incl. 1 black and 1 red crocodile clamp
1 pair electrode cables, white, incl. 1 black and 1 red crocodile clamp

1 ultrasound transducer 28 mm

1 pair Vaco electrode tubes, red, 2.10 m long
1 pair Vaco electrode tubes, black, 2.10 m long
2 pairs Vaco electrodes, ø 90 mm, with sponges, self-closing
2 pairs Vaco electrodes, ø 60 mm, with sponges, self-closing

1 accessory tray for column

1 power cable, angled

1 instructions for use

Scope of delivery

Phy*Sys* tabletop device, consisting of:
Electro-ultrasound therapy unit

Item no.*

2 pc. patient cable
1 pair electrode cables, grey, incl. 1 black and 1 red crocodile clamp
1 pair electrode cables, white, incl. 1 black and 1 red crocodile clamp

1 ultrasound transducer 28 mm
1 transducer holder

1 power cable, angled

1 instructions for use

* See also following pages for article numbers

Scope of delivery

Column

Item no.*

1 accessory tray
3 shelves

Scope of delivery

Vaco*P* (only possible as a slide-in module in column)

Item no.*

1 pair Vaco electrode tubes, red, 2.10 m long
1 pair Vaco electrode tubes, black, 2.10 m long
2 pairs Vaco electrodes, ø 90 mm, with sponges, self-closing
2 pairs Vaco electrodes, ø 60 mm, with sponges, self-closing

* See following pages for article numbers

Accessories

Item no.	
95800610	Swivelling base, rotatable
117*	Power cable, angled, 3 m
10101821	Instructions for use

Note: *Information on the use and operation of the paralysis diagnostics and therapy programs are available in a separate document.*
You may order this any time from your sales representative.

Electrotherapy

155	Patient cable PhySys SD
124	1 pair electrode cables, grey, incl. 1 black and 1 red crocodile clamp
150	1 pair electrode cables, white, incl. 1 black and 1 red crocodile clamp
31100146	Crocodile clip, red
31100147	Crocodile clip, black
87200120	Single-use electrodes, small
87200140	Single-use electrodes, medium
87200130	Single-use electrodes, large
87200110	Single-use electrodes, round
43	Plate electrode made of pure tin, 90 x 120 mm
96	Iontophoresis sponge, 160 x 120 x 19 mm
212	Membrane film for iontophoresis, 180 x 120 mm, 1000 pc.
44	Rubber electrode, 50 x 50 mm, 1 pair
97	Sponge pocket, 70 x 75 mm, 1 pair
46	Rubber electrode, 100 x 50 mm, 1 pair
98	Sponge pocket, 89 x 125 mm, 1 pair
232	Rubber band, 60 cm
233	Rubber band, 120 cm
230	Velcro strap, 60 cm long
231	Velcro strap, 120 cm long

* Standard cable. Other country-specific plug variants available.
If needed, contact your distributor.

Accessories Item no.	
	Ultrasound therapy
4200	Transducer 0.8 and 2.4 MHz, white, ø 28 mm, SD edition
4220	Transducer 0.8 and 2.4 MHz, grey, ø 13 mm, SD edition
65801010	Transducer holder Phy*Sys* tabletop shelf
6	Sonogel, Sono Plus 0.5 L bottle
	Vaco*P*
95*	Sponge for Vaco electrode, large, 90 mm
94*	Sponge for Vaco electrode, small, 60 mm
72	Vaco electrode, ø 90 mm, self-closing
71	Vaco electrode, ø 60 mm, self-closing
164	Vaco electrode tube, red, 2.1 m long
165	Vaco electrode tube, black, 2.1 m long
	PhySys column
66890317	Shelf plate for transducer made of glass, Phy*Sys* column
66890010	Glass plate, top, Phy*Sys* column
66890110	Glass plate, middle, Phy*Sys* column
66890210	Glass plate, bottom, Phy*Sys* column
80400756	Roll of plastic, double, ø 75 mm, grey 11 x 22 mm

* Minimum order per size: 4 pieces

For safety reasons only use original accessories, as proper functioning cannot otherwise be guaranteed.

Subject to technical changes.

Device combinations

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The device can be used in combination with Vaco*P*. Please refer to the instructions for use of the device.

Anyone who combines devices against these guidelines and thus creates a medical system does so under his / her own responsibility.

When combining devices, observe the specifications of standard DIN EN 60601-1.

Phy*Sys* is manufactured according to the EN 60601-1 safety regulations.

As the manufacturer, Zimmer MedizinSysteme GmbH can only consider itself to be responsible for safety and reliability if

- the device is operated using a proper power outlet with earth contact and the electrical installation complies with DIN VDE 0100 part 710,
- - the equipment is operated in accordance with the instructions for use,
- extensions, readjustments or modifications are carried out only by persons authorised by Zimmer MedizinSysteme GmbH,
- the user has confirmed the functional safety and the proper operating condition for him-/herself before use,
- prior to each use, the ultrasound transducer, cables and plugs are inspected for damage (such as cracks) which could impair the safety of the device,
- the device is operated only by properly trained personnel,
- the device is not operated in hazardous areas and / or a combustive atmosphere,
- the device is immediately disconnected from the mains when penetrated by liquid.

The device does not contain any parts that can be serviced or repaired by the operator.

Fuses and other spare parts may be replaced only by trained service staff.
Changing the lithium battery by untrained persons can result in a hazard.

Device service may only be performed by trained staff. All descriptions required for service can be seen in the Phy*Sys* service manual or can be requested from the manufacturer. Upon request, Zimmer MedizinSysteme will provide wiring diagrams, lists of components, descriptions, calibration instructions or other documents.

After being switched on, Phy*Sys* performs a self-test which checks all internal components.

If an error occurs, an error message will appear.

In addition, an enhanced function test can be performed for all three operating modes.

These tests should be performed monthly or if the proper functioning of the device is in doubt.

Stimulation current	Select program GA 00. Connect crocodile clips with dummy. If maximum intensity is used, the bar graph display must be completely filled in. Perform the test with both channels consecutively.
Ultrasound	Select ultrasound transducer and cover the surface of the ultrasound transducer with coupling gel. In the event of low intensity and at the start of therapy, the coupling display must indicate over 90%. Perform the test with both transducers consecutively. Then clean the ultrasound transducer.
Vacuum	Remove the suction electrodes from the Vaco tubes. Connect the Vaco tubes to the dummy. Select Vaco and establish base vacuum. Visible display in the bar graph must be present.
Vaco electrodes	Turn the Vaco electrodes inside out so that the electrode surface is no longer surrounded by the rubber lip and generate a vacuum. Vaco*P* must sustain a vacuum.

Note: *Switch off PhySys after the function tests ends.*

If therapy is to be performed immediately afterwards, adjust the desired treatment parameters and proceed as described in section 8.

The Phy*Sys* device and the optionally available Vaco*P* are listed in attachment 1 of the MPBetreibV (Medical Device Operator Ordinance). Please observe the measures which are necessary as a result.

The devices are not listed in attachment 2 of the MPBetreibV.

In Germany, the German Social Accident Insurance (DGUV) (Regulation 3 – Electrical systems and equipment), as amended, must also be observed.

Note: *This information applies to the operation of the devices in Germany. Please consider divergent national regulations in your country.*

Device malfunction

No response to the main switch / display remains dark.

Possible cause 1: Mains connection
Remedy for cause 1: Check whether the mains plug is correctly plugged into the socket and the device plug is firmly inserted in the port of the device.
Check the mains cable for damage; if necessary, replace cable with an equivalent cable.
Check the mains and socket; if necessary, have fault at mains or socket repaired by a professional (electrician).

Possible cause 2: Mains fuse (Phy*Sys)*
Remedy for cause 2: Check the mains fuse.
Replace the fuse only with one with the exact same name / equal rating.
Before doing so, check the power supply thoroughly for possible faults.

If the error recurs, immediately inform the service department / customer service.

Ultrasound transducer is not detected

Possible cause 1: No ultrasound transducer connected
Remedy for cause 1: Check ultrasound transducer connection; if necessary, plug in ultrasound transducer.

Possible cause 2: Ultrasound transducer defective
Remedy for cause 2: Please inform the service department / customer service.

No emission of ultrasound

Possible cause 1: Wrong ultrasound transducer selected (in the case of two transducers connected)
Remedy for cause 1: Check which ultrasound transducer is active. If necessary, switch to the desired ultrasound transducer (see section 8.2.).

No DuoStim application possible

Possible cause 1: Vaco electrodes connected to channel II.
Remedy for cause 1: In “DuoStim separate” mode, no dual circuit vacuum application is possible; only channel I is active. Use channel I for the application of the Vaco electrodes.

No vacuum (VacoP) – System not airtight

Possible cause 1: Suction electrode not properly placed
Remedy for cause 1: Check electrode placement and reposition, if necessary.

Possible cause 2: Discharge tap of water separator not closed
Remedy for cause 2: Check discharge tap on water separator. The discharge tap has to be closed again after emptying.

Possible cause 3: Vaco tube blocked.
Remedy for cause 3: Check patency of the Vaco tube. To do this, remove the Vaco electrode and close tube opening with finger. If no vacuum is created, remove and replace the tube.

In addition to the errors described above, the following error messages may also be displayed by the device.

Cable check

The error message “Cable check” appears on the display.

In the case of electric stimulation therapy in constant current mode, this means:
a break in the patient electrical circuit.
In general, this message refers to electrodes which have fallen off, dirty electrode clips, a defective patient cable or a defective patient fuse. After eliminating the cause, delete message with “OK” confirmation.

Overcurrent

The error message “Overcurrent! (Patient protection)” appears on the display.

This refers to an increase in the maximum permitted current. An increase in current during constant operation generally indicates a device defect, while an increase in current during constant voltage mode can occur when there is a change in the patient resistance (for example, wet skin).

Delete message with “OK” confirmation.
If the error message appears again, please contact Customer Service.

SD card

The error message “Error when opening a file” appears on the display.

This message appears when files stored on the SD card are to be accessed. Insert the card and confirm with “OK”.

The error message “No SD card found” appears on the display.

This message appears

- when programs are to be saved in the Favourites or Memory list and no SD card is inserted,
- when the Favourites or Memory list is to be opened and no SD card is inserted.

Insert the card and confirm with “OK”.

Malfunction

The error message “Error during self-test” appears on the display.

Occasionally, the error can be corrected by switching the device off, waiting 5 seconds, and switching the device back on. Otherwise please inform Customer Service.

You may get in touch with them via the sales representative or via the main office in Neu-Ulm.

The device may only be returned to the factory in its original packaging.

Main office

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Disposal

The device may only be returned to the factory in its original packaging. It must be disposed of by the factory in Neu-Ulm.

In foreign (European) countries please refer to national regulations for disposal. Contact your distributor if necessary.

Medical electrical devices, such as Phy*Sys*, are subject to special precautionary measures with regard to EMC (electromagnetic compatibility) and must be installed and put into operation according to the EMC information in the instructions for use or accompanying documentation.

Portable and mobile HF communication devices (such as mobile phones, cell phones) can affect medical electrical devices.

Phy*Sys* may only be operated with the original power cable indicated in the list of the scope of delivery and accessories. Operation of the device with a different power cable can lead to increased emissions or reduced interference immunity of the device!

Guidelines and manufacturer's declaration – Electromagnetic emissions		
The Phy*Sys* device is intended to be operated in an electromagnetic environment as indicated below. The customer or user of the Phy*Sys* should ensure that it is operated in such an environment.		
Interference emission measurements	Compliance	Electromagnetic environment - Guideline
HF emissions according to CISPR 11	Group 2	The Phy*Sys* device uses HF energy only for its internal functioning. This means that its HF emissions are very low, and it is very unlikely that adjacent electronic devices would suffer interference.
HF emissions according to CISPR 11	Class B	The Phy*Sys* device is suitable for use in all facilities, including those in a residential area, and in those which are connected directly to the public grid which also supplies buildings used for residential purposes.
Harmonic emissions according to IEC 61000-3-2	Class A	
Voltage fluctuations / flickers according to IEC 61000-3-3	Complies	

Table 201 according to EN 60601-1-2:2006-10

The device should not be used in the direct vicinity of or stacked with other devices. If operation near or stacked with other devices is necessary, the device should be observed to check its proper operation in the arrangement used.

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The Phy*Sys* device is intended to be operated in the electromagnetic environment as indicated below. The customer or user of the Phy*Sys* device should ensure that it is used in such an environment.			
Immunity tests	IEC 60601- test level	Compliance level	Electromagnetic environment - Guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or should be covered with ceramic tiles. If the floor is covered with synthetic material, the relative air humidity must be at least 30%.
Rapid transient electrical disturbances / bursts according to IEC 61000-4-4	± 2 kV for power cables ± 1 kV for input and output cables	± 2 kV for power cables Not applicable for input and output cables	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges according to IEC 6100-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, brief interruptions and fluctuations in the supply voltage according to IEC 61000-4-11.	<5% U_T (>95% dip in the U_T for ½ cycle) 40% U_T (60% dip in the U_T for 5 cycles) 70% U_T (30% dip in the U_T for 25 cycles) <5% U_T (>95% dip in the U_T for 5 seconds)	<5% U_T (>95% dip in the U_T for ½ cycle) 40% U_T (60% dip in the U_T for 5 cycles) 70% U_T (30% dip in the U_T for 25 cycles) <5% U_T (>95% dip in the U_T for 5 seconds)	The quality of the supply should correspond to that of a typical business or hospital environment. If the user of the Phy*Sys* requires continued function even if interruptions in the power supply occur, it is recommended to power Phy*Sys* from an uninterruptible power supply or a battery.
Magnetic field at power supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should correspond to the typical values found in a business or hospital environment.
Note: U_T is the a.c. supply voltage prior to application of the test level.			

Table 202 according to EN 60601-1-2:2006-10

The major performance characteristics of the Phy*Sys* are: trouble-free emission of stimulation current and ultrasound, also underpressure in connection with the vacuum unit with the set parameters, as well as trouble-free operation of all functions.

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The Phy*Sys* device is intended to be operated in the electromagnetic environment as indicated below. The customer or user of the Phy*Sys* device should ensure that it is used in such an environment.			
Immunity tests	IEC 60601- test level	Compliance level	Electromagnetic environment - Guidelines
Conducted HF disturbances according to IEC 61000-4-6 Radiated HF disturbances according to IEC 61000-4-3	3 $V_{Effective\ value}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 $V_{Effective\ value}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile radio equipment should not be used at a distance away from the Phy*Sys*, including the cables, that is less than the recommended safety distance which is calculated according to the equation applicable to the transmission frequency. Recommended safety distance: $d = 1.17 \sqrt{P}$ $d = 0.35 \sqrt{P}$ for 80 MHz to 800 MHz $d = 0.7 \sqrt{P}$ for 800 MHz to 2.5 GHz with P as the rated output of the transmitter in watts (w) according to the information of the manufacturer of the transmitter and d as the recommended safety distance in meters (m). At all frequencies, the field strength of stationary radio transmitter should be less than the compliance level[b] according to on-site testing[a]. In the environment of devices which bear the following symbols, interferences are possible: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is influenced by absorption and reflection from buildings, objects and people.			

[a] The field strength of stationary transmitters, such as base stations for radio telephones and land mobile radios, amateur radio stations, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment with regard to the stationary transmitters, an electromagnetic site survey is to be recommended. If the measured field strength in the location in which the Phy*Sys* device is used exceeds the above compliance level, the Phy*Sys* device must be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Phy*Sys* device.

[b] Above a frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Recommended safety distances between portable and mobile HF telecommunication devices and the Phy*Sys* device

The Phy*Sys* device is intended to be operated in an electromagnetic environment in which the HF disturbances are controlled. The customer or user of the Phy*Sys* device can help avoid electromagnetic interference by maintaining a minimum distance between portable and mobile HF telecommunication devices (transmitters) and the Phy*Sys* device – depending on the output power of the communication device as indicated below.

Rated output of the transmitter W	Safety distance depending on the transmission frequency m		
	150 kHz to 80 MHz d= 1.2 √P	80 MHz to 800 MHz d= 0.35 √P	800 MHz to 2.5 GHz d= 0.7 √P
0.01	0.12	0.035	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.70
10	3.8	1.1	2.2
100	12	3.5	7

For transmitters whose maximum rated output is not listed in the table above, the recommended safety distance d in metres (m) can be determined using the equation applicable to the respective column, where P is the maximum rated output 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 be applicable in all cases. The propagation of electromagnetic variables is influenced by absorption and reflection from buildings, objects and people.

Phy*Sys*

Instructions for Use

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