Zimmer
MedizinSysteme

Instructions for Use

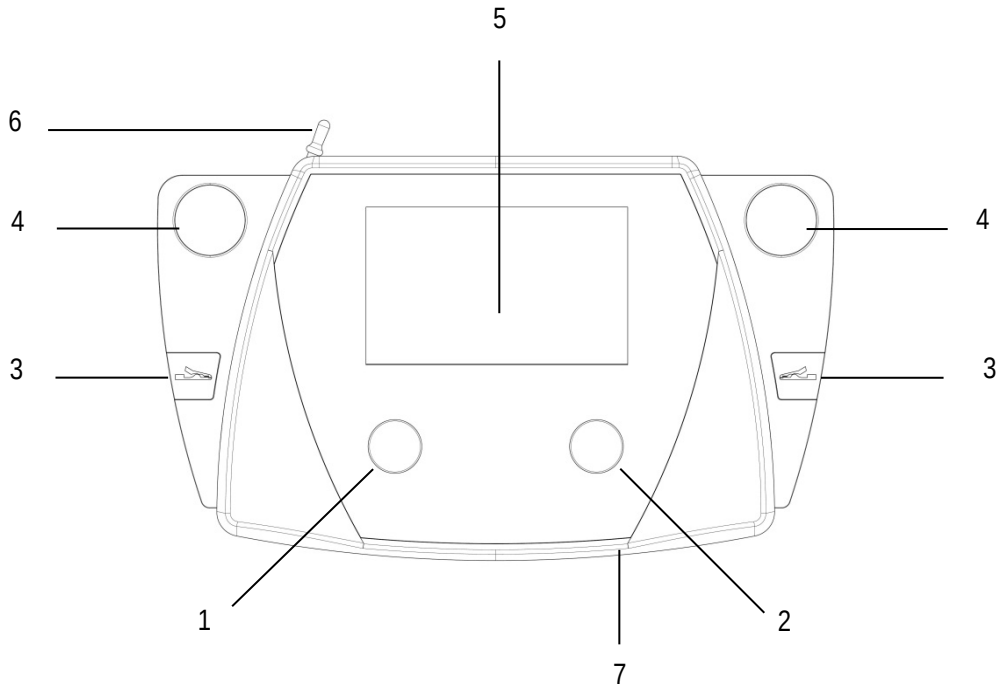
Soleo*line*

Soleo ***SonoStim***, Soleo ***Galva***, Soleo ***VacoS***

EN

Explanation of Symbols
Soleo *SonoStim* / Soleo *Galva*
Front panel

Fig. 1

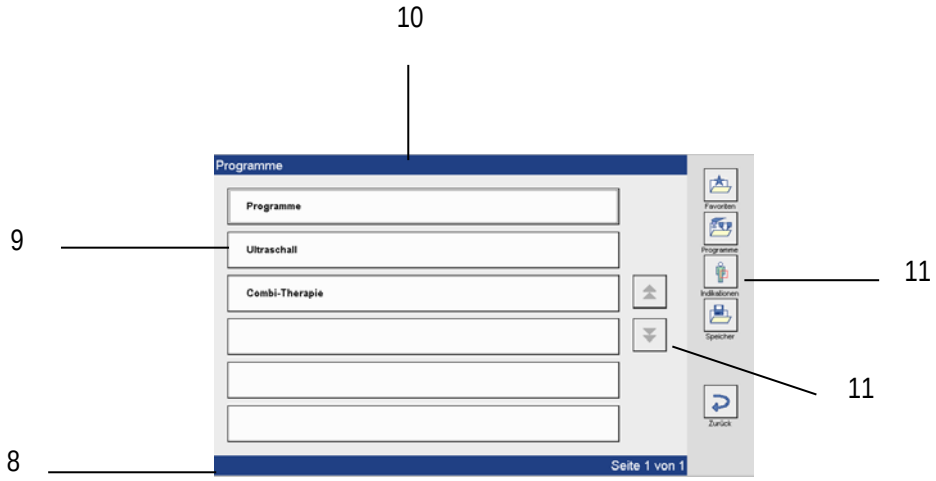


Device and operating elements

1 Intensity controller channel I
2 Intensity controller channel II
3 Alligator clips clipping options
4 Tray mount for ultrasound head
5 Display
6 Touch pen in holder
7 Slot for SD card

Explanation of Symbols
Soleo *SonoStim* / Soleo *Galva*
Display/ Navigation bars

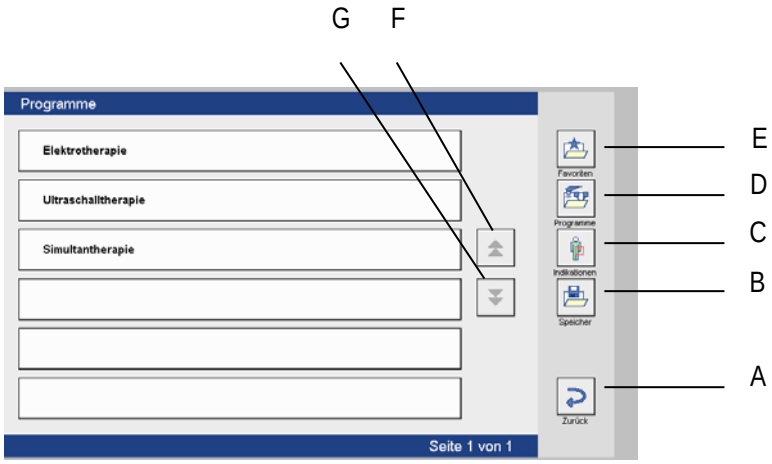
Fig. 2



Displays

8 Status bar
9 Buttons on the screen
10 Title bar
11 Navigation bars

Fig. 3



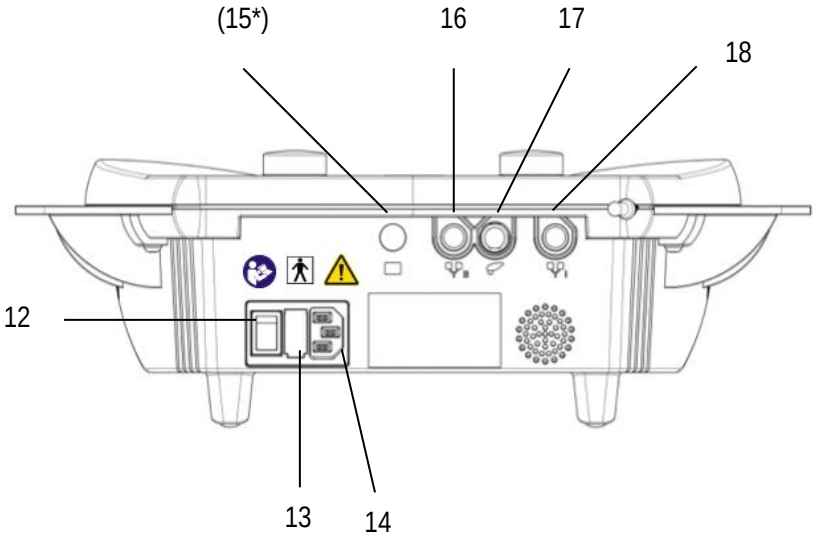
Navigation bar Description of functions			
	(A)	Back	Moves back one step
	(B)	Memory	Switches to the memory area
	(C)	Indications	Switches to the indication menu
	(D)	Programmes	Switches to the programme list
	(E)	Favourites	Switches to the favourites area
	(F)	Scroll backwards	Moves back one page
	(G)	Scroll forwards	Moves forwards one page

Explanation of Symbols

Soleo *SonoStim* / Soleo *Galva*

Rear Panel/Switches and Connector Sockets

Fig. 4



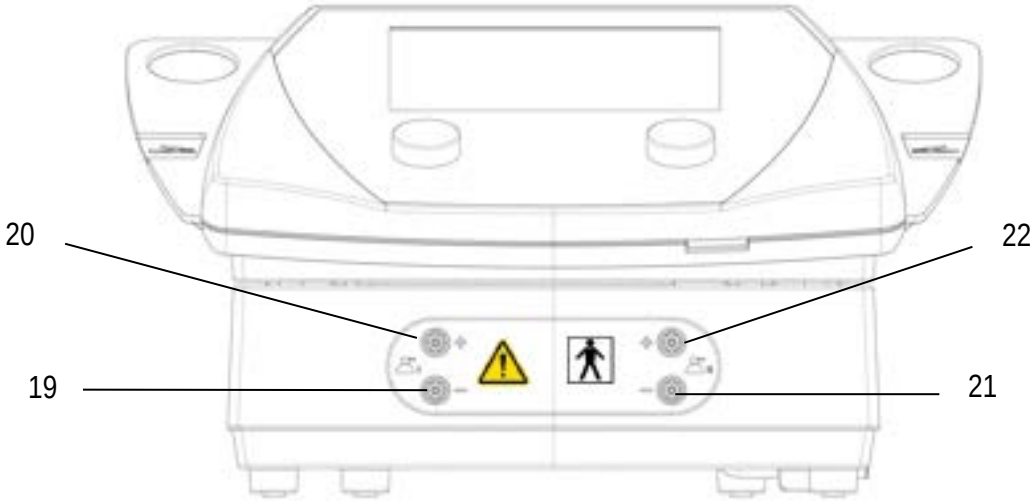
Switches and connector sockets

12 On/off switch
13 Holder for mains fuse
14 Connection for mains cable
16 Socket for electrode cable channel II
17 Connector for ultrasound head 0.8 / 2.4 MHz
18 Socket for electrode cable channel I

Note: The socket (15) has no use for the* Soleo*line.*

Explanation of Symbols
VacoS
Front panel/sockets

Fig. 5

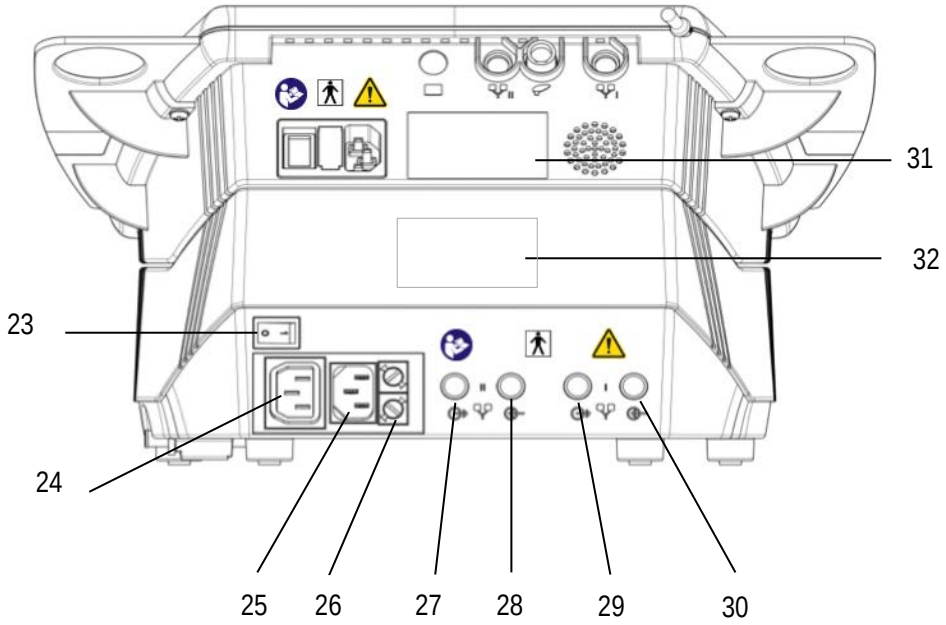


Ports

Group 1
19 Socket for Vaco electrode tube black, cathode
20 Socket for Vaco electrode tube red, anode

Group 2
21 Socket for Vaco electrode tube black, cathode
22 Socket for Vaco electrode tube red, anode

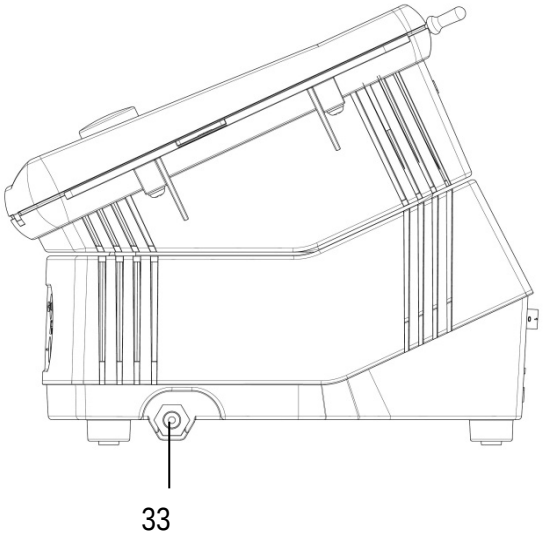
Fig. 7



Switches and connector sockets

23 On/off switch
24 Connection for short mains connection cable
25 Connection for mains cable
26 Bracket for mains backup
27 Socket for electrode cable channel II
28 Socket for connection cable with Sono*Stim*/*Galva* channel II
29 Socket for electrode cable channel I
30 Socket for connection cable with SonoStim/Galva channel I
31 Soleo Sono*Stim* / *Galva* identification plate
32 Soleo Vaco*S* identification plate

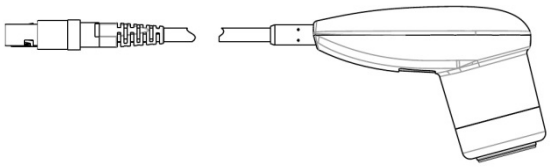
Fig. 8



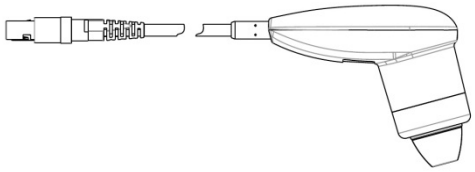
Connections 33 Water separator connector valve

Fig. 9

Ultrasound head, large



Ultrasound head, small



Explanation of Symbols

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

Caution!

In the instructions for use, this symbol represents "Caution" with regard to damage of the device.

Device Type BF

Follow the instructions for use

Instructions for Use

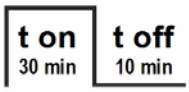
Serial number

Item number

Manufacturer

Date of manufacture

This symbol indicates danger areas on the machine.



Interval operation

Contents

Contents

Contents

Valid for devices Soleo Sono*Stim*, Soleo *Galva* and Vaco*S*.

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

The instructions for use are valid from August 2016.

Indications / Contraindications

1

1.1 Electrotherapy indications

Circulation promotion treatment

- Functional circulatory disorders
- Angiopathy in diabetes mellitus
- Angioneuropathy (M. Raynaud)
- Acrocyanosis
- Arterial occlusive disease (stage I/IIa)
- Venous vascular disease
- Chronic venous insufficiency
- Sympathetic reflex dystrophy
- Sudeck syndrome (stage II)
- Disruption of trophism
- Lymphedema
- Fascia treatment (as pretreatment)
- Chronically tense muscles
- Disease of the peripheral joints (chronic)
- Radicular syndromes with spinal disorders (subacute and chronic)
- Ligament ruptures
- Tenosynovitis
- Bursitis

Analgesic therapy

- Sprains, contusions, muscle sprains,
- Tendons, joints and bones
- Large myalgia
- Polyarthralgia
- Joint diseases, inflammatory
- Chronic polyarthritis (rheumatoid arthritis), treatment in inflammatory poor intervals
- Diffuse pain in periarthropathy, arthrosis,
- M. Bechterew
- Tendinitis, tenosynovitis
- Local and pseudoradicular spinal disorders
- Radical lesions
- Disc surgery
- Chronic inflammatory spinal diseases
- Chronic pain conditions, pain disorder
- Pelvipathy (so-called adnexitis)
- Pelvipathy (so-called prostatitis)
- Neuralgia
- Neuritis
- Polyneuropathy
- Radicular syndrome
- Nerve compression syndrome
- Allodynia
- Causalgia

Indications / Contraindications

1

1.1 Electrotherapy indications

Trophism promotion treatment

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

Muscle toning therapy

- Muscle weakness
- Voluntary innervation weakness
- Missing muscle feeling

Muscle detoning therapy

- Overloading the muscles
- Painful muscular tension
- Myofascial pain syndromes
- Tendon and muscle rupture
- Contractures

Other indications

- Periarthropathies and insertion tendinopathies (acute, subacute)
- Periarthropathies and insertion tendinopathies (chronic)
- Disease in the peripheral joints (acute, subacute)
- Post-traumatic state images (hematoma, edema)
- Excessive sweating of hands and feet (hyperhidrosis palmarum and plantarum)
- Spinal disorders acquired: post-traumatic, post inflammatory, degenerative
- Posture spinal disorders in childhood and adolescence
- Spinal fractures, spinal fusion
- Joint surgery, arthroscopy, arthrotomy
- Congenital malformations or incorrect settings of the musculoskeletal system to be treated in childhood
- Fecal incontinence
- Urinary incontinence
- Disruption of gut motility
- Chronic constipation
- Secondary lymphedema and lymphoedema
- Pelvic pain
- Polyneuropathy
- Anterior horn of the spinal cord disease
- Peripheral paralysis, brachial plexus
- Non-local, generalised spinal disorders
- Spasticity
- Spastic paresis
- Flaccid paralysis

1.2 Contraindications for electrotherapy

General Contraindications

- Vague pain symptoms
- Acute inflammation (local, systemic)
- Suspected diseases of the cardiovascular system
- (Suspected) epilepsy
- Arterial occlusive disease from stage IIb according to Fontaine
- Purulent processes
- Fever
- General infections
- Tumours of a malignant and benign nature
- Thrombophlebitis
- DVT at risk of embolism
- Pacemakers and other implanted electronic devices
- Transcardial current flow
- Metal implants in the current field when using galvanic or unipolar currents with pulse widths of more than 1 ms
- Psychosis
- Reduced skin sensitivity
- Application on or in the vicinity of open wounds or fractures

The following should also be considered when planning TENS therapy

- Causally repairable pain
- Predominantly psychogenic pain (TENS therapy is ineffective)
- Central pain syndromes, for example thalamic pain syndrome

In addition the following contraindications should be observed

Muscle treatment with swollen group pulses (threshold currents) in case of:

- Unconsciousness, consciousness
- Reflex inhibition (e.g. fractures)
- Muscle inflammation
- Mimetic facial muscles
- If the electric stimulation therapy triggers persistent pain
- Infants, toddlers
- When spasticity increases
- Pregnancy

Particular caution is required:

- With bleeding after acute trauma or fracture
- After surgical procedures when muscle contraction may disrupt the healing process

Precautions for certain current forms

Diadynamic current, trabert current

- A careful electrode technique is necessary to avoid possible skin damage through a high galvanic share of diadynamic currents
- Cautious dosing in case of sensory disturbances

Electroacupuncture

- No needle acupuncture in bleeding disorders

1.3 Indications for ultrasound therapy

Indications from orthopaedics, surgery, traumatology, rheumatology

- Spinal pain syndromes, e.g. cervical spine syndrome
- Ankylosing spondylitis (only in inflammation-free intervals)
- Joint disorders
- Rheumatoid arthritis (if heat treatment is indicated)
- Arthrosis
- Periarthropathies
- Epicondylopathy
- Tendopathies, periostosis, calcaneal spurs
- Achillodynia
- Scars, contractures, Dupuytren's contracture
- Posttraumatic arthritis
- Fractures (particularly in cases of delayed callus formation)

Other indications

- Bronchial asthma
- Rhinopathy
- Persistent symptoms of the cervical spine after whiplash injury with recurrent blockages
- Headache
- Earache
- Post herpetic neuralgia
- Functional disorders of the stomach and duodenum
- Pelvic pain
- Functional disorders of the pelvis

1.4 Contraindications for ultrasound therapy

General Contraindications

- Vague pain symptoms
- Diseases where heat should not be used, for example, acute inflammatory diseases
- Diseases where mechanical impacts are contraindicated, e.g. deep vein thrombosis,
- Restricted blood flow
- Suspected diseases of the cardiovascular system
- Haemorrhagic diatheses
- Cervical vertebrae – do not use ultrasound higher than C 3
- Ultrasound treatment of parenchymatous or heat-sensitive organs (testes, eyes, gravid uterus, liver, kidneys etc.)
- Anaesthetised skin areas
- Temperature sensitivity disorders
- After treatment with ionising radiation
- Epiphyseal plates
- Tumours
- Electronic pacemakers
- Application on or in the vicinity of open wounds
- Impaired reflexes or pain sensitivity
- Application to the abdomen, pelvis, or lumbar area when pregnant or presumed pregnant

Metal implants and endoprostheses

Dynamic ultrasound radiation in low dosage is nowadays no longer a matter for concern.

Side Effects

2

Side effects of electrotherapy	If used correctly, no side effects are known.
Side effects of ultrasound therapy	If used correctly, no side effects are known.

Application Information

3

3.1 General

Prior to the application of the device to the patient, the user should become acquainted with the operating instructions or the individual treatment methods and also with the indications / contraindications, warnings and directions for use. Additional sources of information on ultrasound therapy should also be taken into consideration.

This user manual should always be kept with the device to enable the persons charged with the operation of the device to access it at any time.

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

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

Caution! Magnetic and electric fields can influence the function of the device. Therefore, the device must not be operated in the vicinity of devices that generate strong electromagnetic fields (X-ray or diathermy devices, MRI scanners). Please keep a safe distance of several metres.

Caution! The device is not suitable for use in areas with an explosive, combustible or combustion-promoting atmosphere.

Caution! During use, the device must be placed in such a way that direct access to the device's central power supply is possible, so that it can be disconnected from the mains at any time.
Inspect the device before use. If damaged, it must not be used.

Caution! Only accessories provided by Zimmer MedizinSysteme GmbH are to be used and no other devices must be connected to the VacoS.

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 the realignment or re-arrangement of the device or the shield.

Caution! No change to the device or the medical system may be carried out during the product life of the device.

The entire medical system is suitable for application in the patient environment.

Caution! To safely disconnect the unit from the mains supply, remove the mains plug from the socket housing or socket.

3.2 Electrotherapy

Electrode positioning and choice of treatment parameters should always be adapted to the treatment guidelines.

For currents in which a chemical burn is possible (e.g. galvanic current, diadynamic current, currents with galvanic share), the recommended maximum current density is 2 mA rms/cm² electrode surface.

If the current density exceeds 2 mA eff/cm², an increased attention from the user is required.

Note that with a smaller electrode surface a higher current density is achieved by using different electrodes.

Caution! The Tens treatment should not be used on the head or directly on the eye.

Caution! In simultaneous operation, the ultrasonic head may be used as the dynamic electrode in connection with a stationary electrode, which is connected to the electrode cable. The ultrasonic and electrode channels form an application part. Please note that therapeutic currents flow in this mode via the ultrasound head.

3.3 Ultrasound

Handle the ultrasound head carefully, as rough handling can alter its properties. Do not bring the ultrasound head into contact with sharp or pointed objects, as the aluminium head is susceptible to scratching.

The use of a couplant other than the special Sono plus ultrasound gel can damage the ultrasound head.

Disinfect the ultrasound head after use, using commercially available equipment disinfectants.

Inspect the ultrasound head for damage prior to each use. If damaged, it must not be used.

Caution!

In simultaneous operation, the ultrasonic head may be used as the dynamic electrode in connection with a stationary electrode, which is connected to the electrode cable. The ultrasonic and electrode channels form an application part. Please note that therapeutic currents flow in this mode via the ultrasound head.

Caution!

With regular use of the ultrasound head in the water bath, the user must take protection measures. All body parts of the user immersed in the water must be protected by appropriate measures. Suitable protective measure are so-called "aerated clothes".
This can be neoprene gloves or latex over wool gloves.

Warnings

4

4.1 General

This product is intended for use by medical professionals only.

Very important: Never connect two patients to the device in one treatment session!

The patient must not be left unattended during therapy.

Treatment instructions regarding the treatment location, duration and intensity of treatment require medical knowledge and may only be issued by licensed physicians, therapists and members of the auxiliary medical professions. It is imperative that these instructions are followed.

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

Dispose of the packaging material correctly. Keep out of reach of children.

The use of this product with settings or for applications other than those specified in the user manual may lead to hazards resulting from the uncontrolled release of ultrasonic energy.

In the case of patients with implants or with an implanted electronic device, treatment may only be performed after clarification that no risk is involved.

The simultaneous connection of the patient to a high-frequency surgical device is not permitted. This can lead to burns.

4.2 Electrotherapy

Electrotherapy

Use of electrodes near the thorax may increase the risk of ventricular fibrillation.

When performing an iontophoresis,the drug used may possibly have an analgesic effect and pain sensitivity is then reduced.

Stimulation current can have a stimulating effect on insulin release. In diabetes patients this may therefore lead to hypoglycaemia.

The electrical stimulation or the materials used can cause skin irritation or hypersensitivity in susceptible patients. This can be reduced by the use of alternative electrode material or by changing the electrode system.

Stimulation should not be used:

- above the sinus nerve
- on the throat and mouth
- transthoracically
- transcerebrally
- over swollen, infected, inflamed areas
- over or in cancerous lesions

Vacuum

In patients who are prone to bruising, perform an evaluation of the lack of risks before beginning treatment.

Note: *For electrical therapy in combination with the vacuum unit, the above warnings apply*,

With an intensity regulator, currents above 10 mA eff. or voltages in excess of 10 V at the output terminals are permitted.

Soleo*line* – in brief

What is Soleo*line*?

An ultra-modern innovative product line that provides 3 different device variants.

Soleo *SonoStim*
A state of the art, innovative combination device for electrotherapy and ultrasound therapy, with the option of the additional use of a vacuum unit.
Soleo *Galva*
A state of the art, innovative electrotherapy device, with the option of the additional use of a vacuum unit.
Soleo *Sono*
A cutting-edge, innovative ultrasound therapy device.

Note: *The operation of Soleo Sono is described in a separate manual.*

What does Soleo*line* offer?

The delivery of monophasic, biphasic and medium frequency currents for nerve stimulation and muscle therapy in 1-channel and 2-channel operation and the delivery of therapeutic ultrasound.

Why use Soleo*line*?

A modern, clearly arranged colour display that provides all therapy-related parameters, as well as modern touch operation.
Customisable program start-up settings and a clear, simple menu offer maximum convenience for the user.

The combination of electrotherapy and ultrasound therapy in one system allows proven simultaneous therapy.

The compact design allows space-saving work in the practice room and is ideally suited for use during home visits.

The use of the vacuum unit ensures comfortable electrode application and additionally results in a pleasant massage effect for the patient.

Innovations in Soleo*line*?

Sono*Swing*, innovation in the field of ultrasound therapy:
- an ultrasound head with two frequencies
- selectable penetration depth by the percentage adjustment of the frequency components.

Note: *The application of the device is intended for the medical community (e.g. doctors, therapists and trained medical assistants).*

Intended Use

The Soleo*line* product range includes 3 different device versions:

Soleo *Sono*
Ultrasound therapy device for treatment with therapeutic ultrasound.
Soleo *SonoStim*
Combination device for ultrasonic therapeutic treatment and electrotherapy, with the option of the additional use of a vacuum unit.
Soleo *Galva*
A device for electrotherapy, with the option of the additional use of a vacuum unit.

Note: *The following description of the installation of the cables refers to the operation of Soleo SonoStim/Soleo Galva without VacoS.*

Note: *There are coloured arrows located on the cables as a guide for proper connection to the device.*

Electrotherapy

When connecting the electrode cable, ensure that the green arrow is in the plug below.

- Connect the electrode cable for channel I to the appropriate socket (18).
- Connect the electrode cable for channel II to the appropriate socket (16).
- Insert the red alligator clips to the red connector of the electrode cable.
- Insert the black alligator clips to the black connector of the electrode cable.

Ultrasound therapy

Connect the ultrasound head to the appropriate socket (17).

Connect the mains cable

Connect the mains cable to the appropriate socket (14) and connect the cable to the mains.

Note: *The device may only be connected to power outlets with a protective contact.*

Switch the device on

The device is switched on via the rocker switch (12).

Switch the device off

The device is switched off via the toggle switch (12).
To completely disconnect the device (all-phase) from the network, remove the power cord.

Caution!

All cables must be protected against jamming or other mechanical damage.

Note: *All of the buttons, menus and sub-menus can be activated directly on the screen using your finger or a touch pen.*

7.2 Installation of cables for VacoS

Note: *The control and operation of VacoS is via Soleo SonoStim/Soleo Galva. A stand-alone operation is not possible.*

Preparation

Position Soleo SonoStim/Soleo Galva so that the devices are aligned with each other. The sockets of the Vaco electrodes hoses must be on the front (fig. 4).

Connection of VacoS with SonoStim/Galva

Make sure when mounting the connecting cable that when connecting the cable to Soleo SonoStim/Soleo Galva (16+18), the green arrow is in the plug below.

Make sure when mounting the connecting cable that when connecting the cable to VacoS (28+30), the green arrow is in the plug below.

Channel I
Connect the connecting cable to the intended port on Soleo SonoStim / Soleo Galva (18) and on VacoS (30).

Channel II
Connect the connecting cable to the intended port on Soleo SonoStim / Soleo Galva (16) and on VacoS (28).

Note: *If Soleo SonoStim / Soleo Galva is operated in conjunction with VacoS, the connection is made with the electrode cable on VacoS. The assembly is described below.*

Assembly Electrode cable

Make sure when mounting the electrode cable for VacoS that the green arrow is facing upward in the insertion direction.

- Connect the electrode cable for channel I to the appropriate socket (29) on VacoS.
- Connect the electrode cable for channel II to the appropriate socket (27) on VacoS.
- Insert the red alligator clips to the red connector of the electrode cable.
- Insert the black alligator clips to the black connector of the electrode cable.

Mounting the Vaco electrode hose.

Connect the black Vaco electrode hose to the appropriate socket (1) on the front of VacoS
at I - .

Connect the red Vaco electrode hose to the appropriate socket (2) on the front of VacoS
at I .
Connect the black Vaco electrodes hose to the appropriate socket (3) on the front of VacoS
at II - .

Connect the red Vaco electrode hose to the appropriate socket (4) on the front of VacoS
at II + .

Insert the Vaco electrode to the connector on the free end of the Vaco electrode hose.

Assembly Vaco electrodes

Connect each of the 4 Vaco electrode hoses to each Vaco electrode.

Establish network connection

Connect the short mains cable to the sockets provided on *VacoS* (24) and on Soleo *SonoStim* / Soleo *Galva* (14).

Connect the mains cable

Connect the mains cable to the socket provided on *VacoS* (25) and connect the cable to the mains.

Turn the VacoS on

VacoS is switched on via the toggle switch (23).

Note:

Activation of VacoS take place through this window.

The window is only active when VacoS is on.

8.1 General

Note: *The following descriptions always relate to the treatment with one channel and emanate the factory default settings.*

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

start up Screen

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

or

Selecting configuration

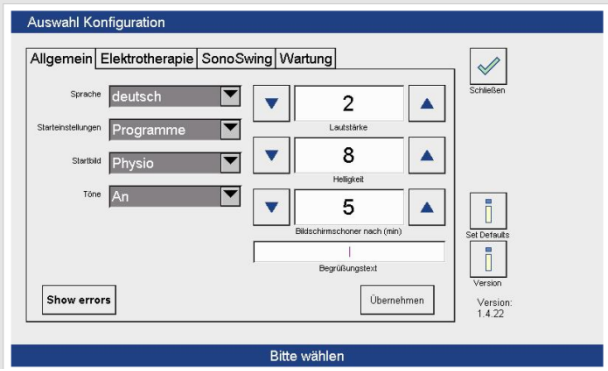
Touching the 

button opens the "configuration menu".

Configuration menu

In the configuration menu, the factory settings can be changed and adjusted individually. After activating the configuration menu, the "configuration selection" screen becomes active.

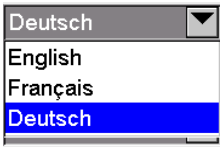
Settings General



The settings options are shown below.
By default, the factory settings are pre-programmed as shown in the screen.

Language

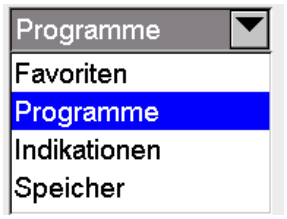
Selecting the language



The selection is made directly in the corresponding row.

Program start up settings

Adjustment of the program start up settings.



The selection is made directly in the corresponding row.

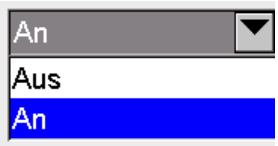
Startup screens

Choice of two start up screens.

The selection is made directly in the corresponding row.

Sounds

Switching the signal tones on and off.



The selection is made directly in the corresponding row.

Volume

Adjustment of the volume from 1 to 4.

The adjustment is made using the two arrow keys.

Brightness

Adjustment of screen brightness from 0 to 10.

The adjustment is made using the two arrow keys.

Screensaver

Adjustment of screen saver start time, from 0-20 minutes.

The adjustment is made using the two arrow keys.

Note: *The screensaver function is disabled when therapy is in progress.*

Welcome text

Option to enter a personalised welcome text.

Activating the field opens the on-screen keyboard for entering a greeting text.

Set Defaults

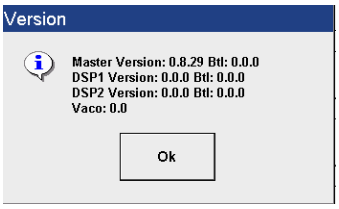
Touching button 

restores the default factory settings.

Version

Touching the 

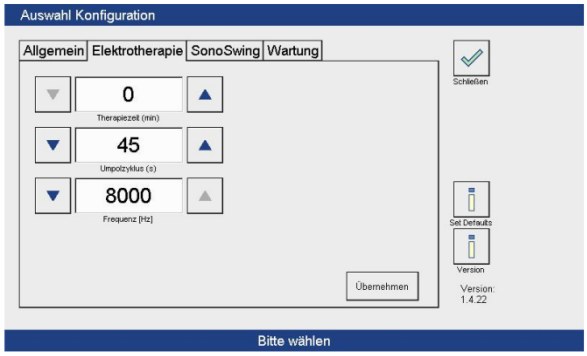
button opens a window with information regarding the current software version.



Touch the OK button to close the window.

Electrotherapy settings

Elektrotherapie



Time

Adjustment of a single treatment time of 1 to 60 minutes for all programmes.

The adjustment is made using the two arrow keys.

Polarity reversal cycle

Adjustment of periods of time from 10 to 120 seconds.

The adjustment is made using the two arrow keys.

Frequency

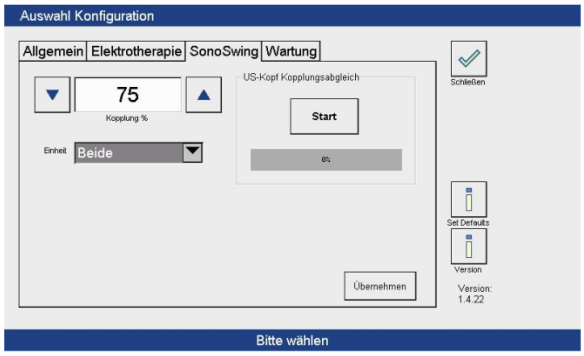
Adjustment of the fundamental frequency in stages 2500 Hz, 4000 Hz and 8000 Hz.

The adjustment is made using the two arrow keys.

Note: *Activation of the "SonoSwing" menu and the associated settings are only active in the Soleo SonoStim version.*

Ultrasound therapy settings

SonoSwing



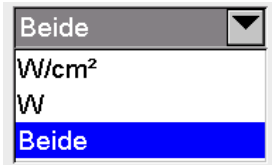
Coupling signal

Adjustment (50 to 95%) of the coupling limits value.

The adjustment is made using the two arrow keys.

Unit

Adjustment of unit intensity on the bar graph.



The selection is made directly in the corresponding row.

Maintenance

Opens the "Maintenance Configuration Selection" screen.

In the maintenance menu, software updates can be performed.

You will receive the latest information about performing a software update when an update is planned.

To open the maintenance menu, enter the password "armin".

Soleo *SonoStim* – Instructions for operation

9

9.1 Electrotherapy

Note: *The following notice applies to all the system therapies.*

If the treatment time is extended individually, there may be a change in the method of operation and the patient must be observed during use with increased attention.

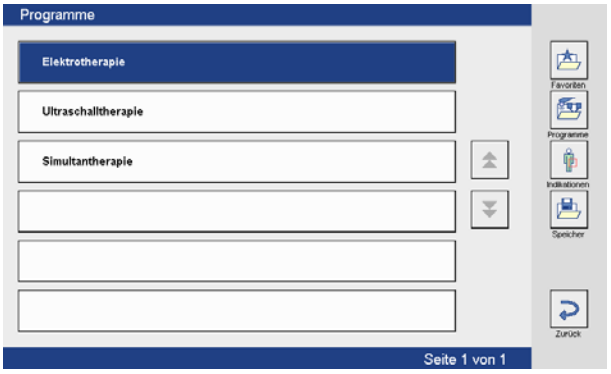
Program start up

Touching button 

opens the programme screen. Here the desired programme may be selected.

SonoStim programme In *SonoStim* , 3 different forms of treatment are available:

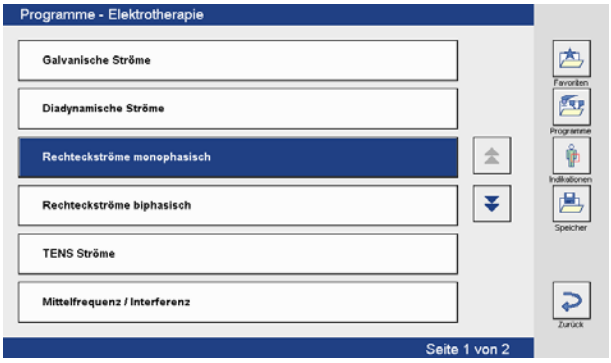
Selecting electrotherapy The electroptherapy selection is made directly in the corresponding row.



The following description refers to the electrotherapy programmes.

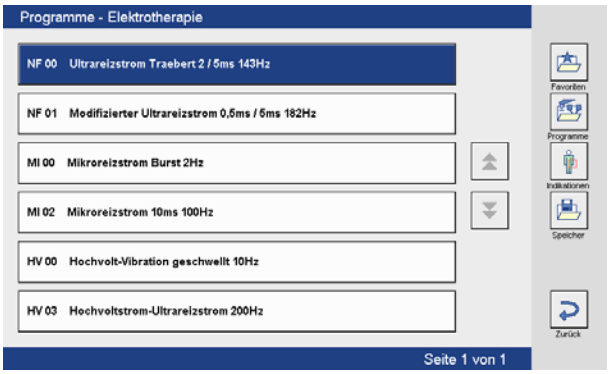
Selecting the current form group The selection of the desired current category is carried out directly in the corresponding row (rectangular monophasic currents here).

9.1 Electrotherapy



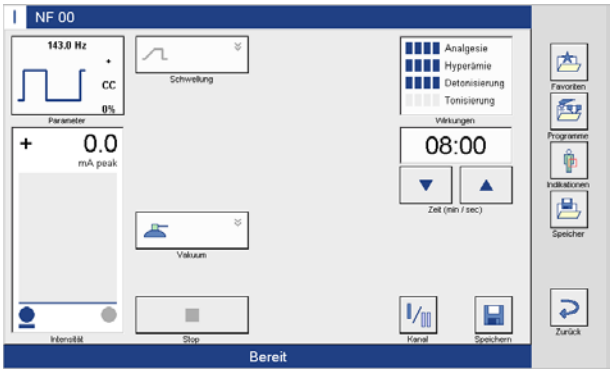
Current form configuration

The current form selection is made directly in the corresponding row. (here NF 00).



Therapy screen

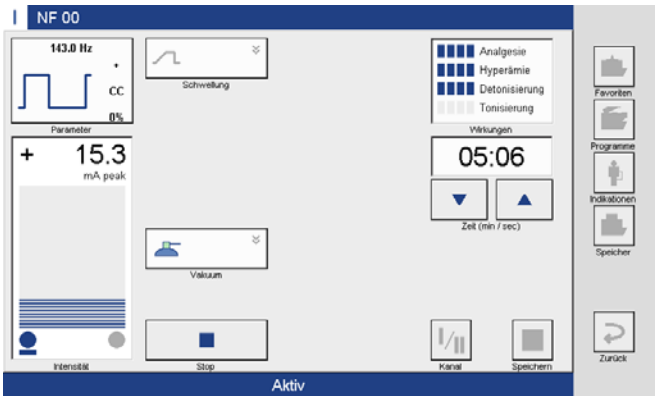
After selection of the current form, the therapy screen opens automatically on channel I.



9.1 Electrotherapy

Therapy startup

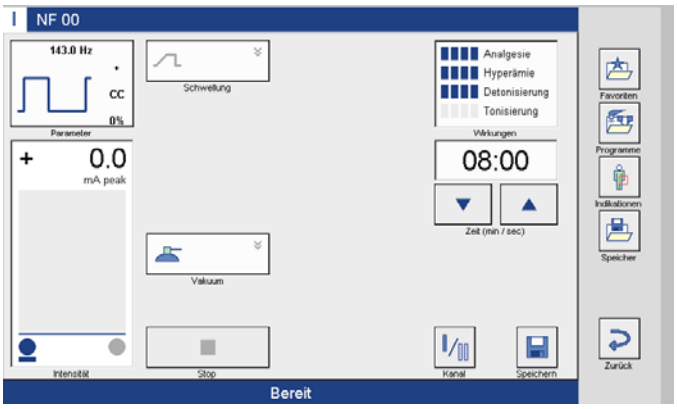
By adjusting the intensity from the left intensity regulator, the display changes in the bottom status line from "ready" to "active" and the therapy is being performed. In the bar graph, the current flow is displayed and the therapy time counts down at one-second intervals.



End of therapy

The end of the treatment period is indicated by an acoustic signal at the end of treatment, the clock is set to 00:00, the intensity automatically goes to zero and the bar graph disappears. The display in the lower status bar changes from "active" to "ready".

The treatment time is activated automatically after the end of therapy.



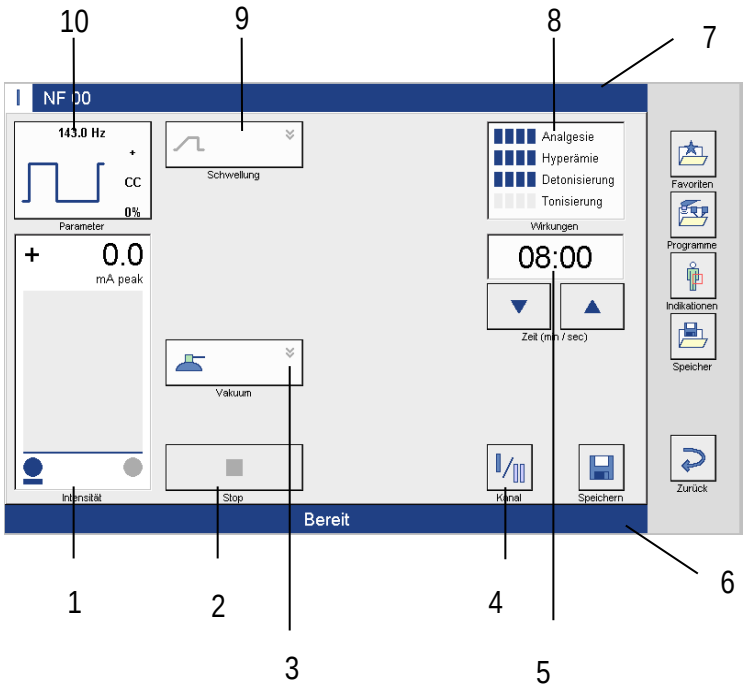
Note:

The vacuum button 

is only visible if *VacoS* is connected to Soleo *SonoStim* / Soleo *Galva* as described in section 7.2 and turned on.

9.1 Electrotherapy

Description of the display elements and buttons



(1) Intensity

The bar graph displays the intensity currently selected.
In the CC mode, the display is in mA eff. or peak.
In the CV mode, the display is in peak volts.
The setting is done with the left intensity controller (Mono Stim) or with two controllers (Duostim).

(2) Start / Stop

Pressing the button starts or stops the therapy.

(3) Vacuum

The therapy screen indicates the connection of the vacuum unit.
Activation of the button opens the "vacuum" setting and start-up screen

Note:

If there is no vacuum unit connected, this button is completely hidden.

(4) Channel

After activating the button, several channel mode selection possibilities are available.
In group "mode" you can select between mono/twin and duo.
In the "channel" group, the desired channel for the therapy can be activated.
In the "synchronisation" group, specification of the threshold is determined for the modes twin / duostim. Parallel and separated modes are available alternately.
In duostim mode, the current form can be selected for each channel.

(5) Therapy time

Displays the therapy time for the selected program.
Using the arrow buttons, the preset therapy time can be increased or shortened. After the start of therapy, the current remaining therapy time is displayed.

(6) Status line

The status bar shows information regarding the current therapy status. If therapy is not active, the "Ready" display appears; when therapy is in progress the text "Active" appears.

(7) Title bar

In the title bar, the name of the current ultrasound therapy program is displayed.

(8) Effect

Gives an overview of the medical effects of the current flow form.

Note:

If the parameters of the waveform (pulse time or pause) change, the current form's effects will change. Therefore, after a change the window is no longer visible.

(9) Threshold

Represents the threshold parameters of the current treatment programme in the activated state. The parameters of increase time, hold time and break time are displayed.
If there is no threshold activated, the threshold window is shown minimised.
Activation of the "threshold" button opens the "threshold parameters" window. Here threshold can be activated or the parameters can be user-defined.
Changed parameters are taken over by activating the "OK" button and the "Cancel" button aborts the process.

Note:

If no threshold is provided for a programme, the window is completely hidden.

(10) Parameters

Represents the parameters of the current therapy programme.
These are the pulse and pulse pause time (and hence frequency), polarity, CC / CV and galvanic share parameters.
Activation of the "parameters" button opens the "current form parameters" window. The parameters can be user-defined.
Use the arrow keys to change pulse parameters or the values within the current form up and down.
Change the polarity, change CC/CV and galvanic share by activating the corresponding button.

Note:

Modes 1.3 to 1.5 are not useful for all types of current and are therefore not always displayed.

9.2 Ultrasound Therapy

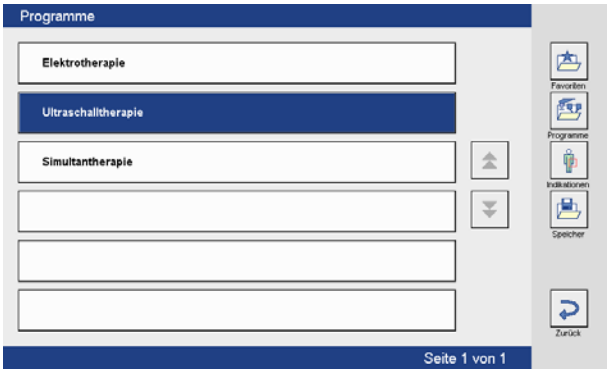
Program start up

Touching button 

opens the programme screen. Here the desired programme may be selected.

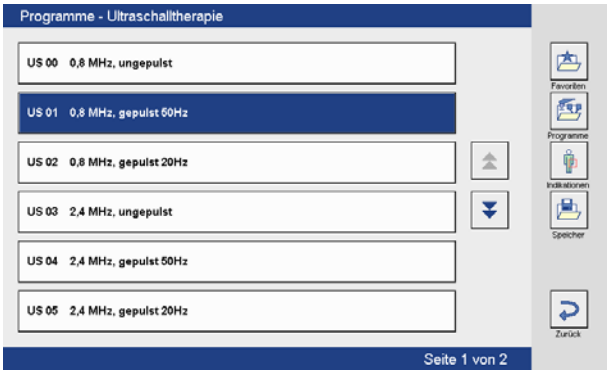
Selecting ultrasound therapy

The ultrasound therapy selection is made directly in the corresponding row.



Programme selection

The desired ultrasonic therapy program is selected directly in the corresponding row (in this case US 01).



9.2 Ultrasound Therapy

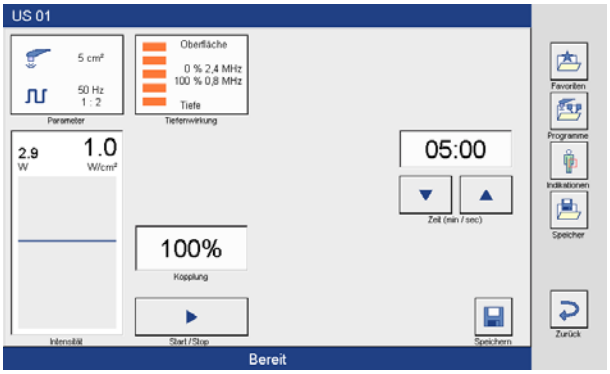
Therapy screen

After selecting the ultrasound therapy program, the therapy screen opens.

Note: *Before starting treatment, check that the data in the parameter window (in this case 5 cm²) corresponds with the connected ultrasound head.*

Adjusting the intensity

Adjust the intensity using the left intensity controller.



Therapy startup

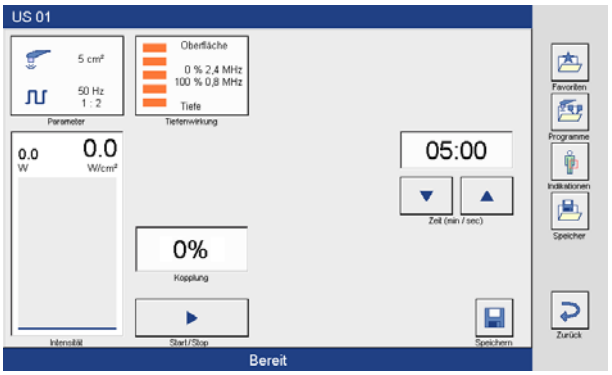
Touching 

starts the therapy. When therapy starts, the display in the bottom status bar changes from "Ready" to “Active "and the "Start" button changes to "Stop". In the bar graph, the configured dose is displayed and the therapy time counts down at one-second intervals. The coupling display is active.

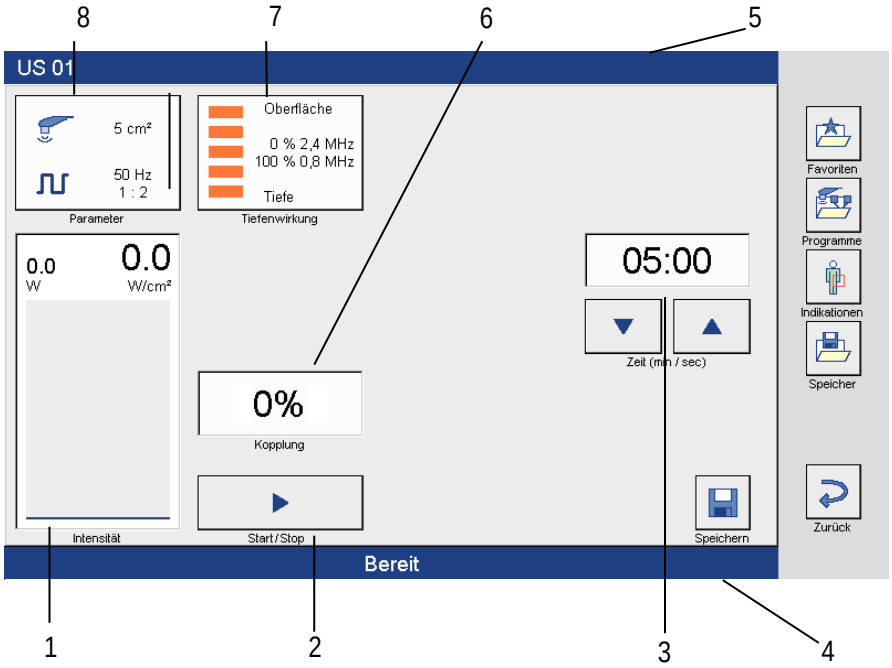
End of therapy

After expiration of therapy time, an acoustic alert signals the end of therapy and the clock reads 00:00. The intensity automatically returns to zero, the bar graph display disappears and the coupling indicator is inactive. The display in the lower status bar changes from "Active" to "Ready".

The therapy time is automatically re-activated after the end of therapy and the "Stop" button will change to "Start".



Description of the display elements and buttons



(1) Intensity

The bar graph displays the currently set intensity. The intensity is adjusted using the left controller.

(2) Start/Stop

Pressing the button starts or stops the therapy.

(3) Therapy time

Displays the therapy time for the selected program.
Using the arrow buttons, the preset therapy time can be increased or shortened. After the start of therapy, the current remaining therapy time is displayed.

(4) Status bar

The status bar shows information regarding the current therapy status. If therapy is not active, the "Ready" display appears. When therapy is in progress the text "Active" appears.

(5) Title bar

In the title bar, the name of the current ultrasound therapy program is displayed.

(6) Coupling

Indicate coupling. The coupling is digitally displayed as a percentage.

(7) Depth effect

The bar graph shows the current frequency ratio, ranging from 0.8 MHz (800 kHz) to 2.4 MHz, as a percentage. The percentage frequency ratio is adjusted using the right controller.

(8) Parameters

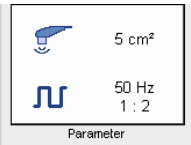
Displays the active ultrasound head.
Activating the window opens the "Ultrasound parameters" window. Here the ultrasonic mode can be selected and the ultrasound head switched to water bath therapy (see Section 9.3).

9.3 Water Bath Treatment

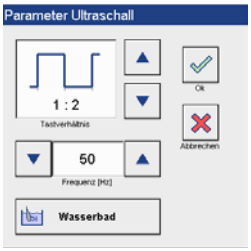
Note: *If ultrasound therapy is performed in a water bath, the temperature monitoring of the ultrasound head must be modified prior to therapy.*

Performance

Activating the parameter button



opens the ultrasound parameters window.



Pressing the water bath button

By touching the water bath button

and confirming with "OK", the temperature monitoring of the ultrasound head is modified to suit water bath therapy.

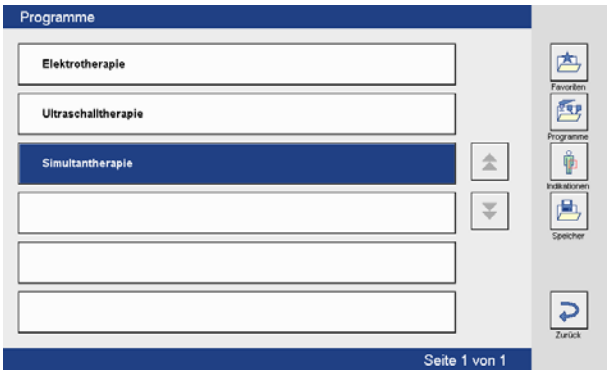
Note: *Upon completion of water bath therapy, it is possible that the temperature of the ultrasound head is too high for therapy outside the water bath.*
This is displayed in the status bar, with the message "Ultrasound head temperature control". Therapy is not possible during this time. Once the ultrasound head temperature control process is complete, the message disappears and therapy can continue.

Program start up

Pressing the button opens the programme screen. Here the desired programme may be selected.

Selecting simultaneous therapy

The simultaneous therapy selection is made directly in the corresponding row.

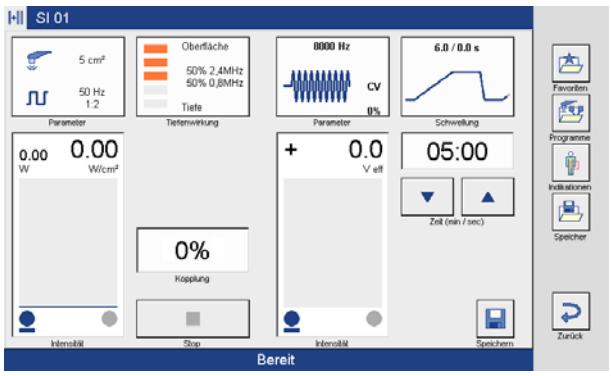


Programme selection

The desired simultaneous therapy programme is selected directly in the corresponding row.

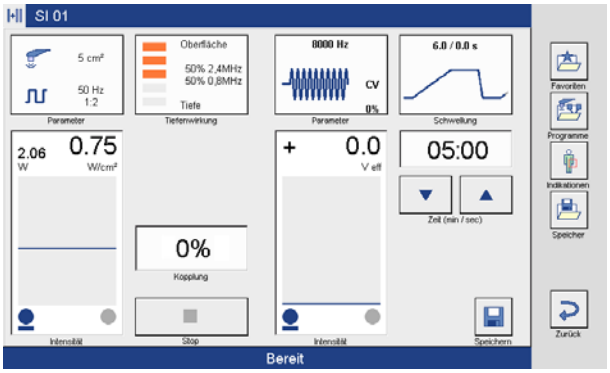
Therapy screen

After selecting the simultaneous therapy programme, the therapy screen opens.



Setting the intensity of the ultrasound

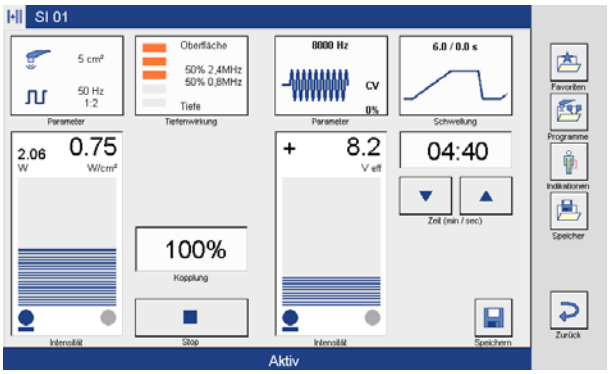
Adjust the intensity using the left intensity controller.



Therapy startup

By adjusting the intensity over the right intensity controller, simultaneous therapy is active.

Adjusting electrical stimulation intensity



The display in the lower status bar changes from "ready" to "active". In the left bar graph, the ultrasonic dose appears and the docking indicator is active. The right bar graph shows the actual current flow. The treatment time is reduced by the second.

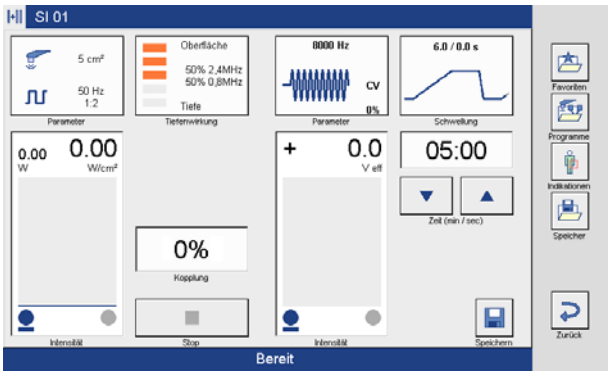
Note:

In simultaneous therapy it is to be noted that the current-carrying electrode cable (anode) is basically only active for channel I.

End of therapy

After expiration of the treatment time, an acoustic alert signals the end of therapy and the clock reads 00:00. The intensity automatically returns to zero, the bar graph display disappears and the coupling indicator is inactive. The display in the lower status bar changes from "Active" to "Ready".

The treatment time is activated automatically after the end of therapy.



Description of the display elements and buttons

The individual buttons are described in the preceding chapters.

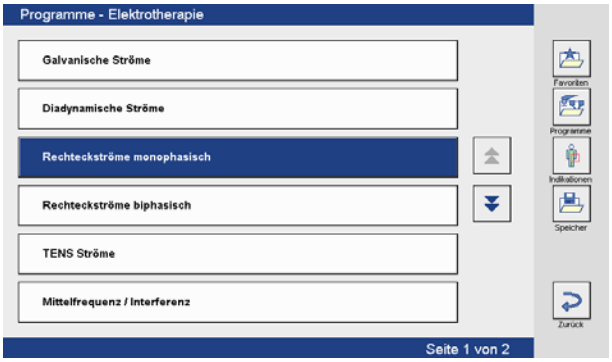
Program start up

Activation of button 

opens the electrotherapy programme window.

Selecting the current form group

The selection of the desired current category is carried out directly in the corresponding row (rectangular monophasic currents here).

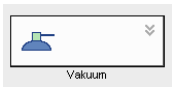


Note: *The next steps for the implementation of the therapy are described in detail in chapter 9.1.*

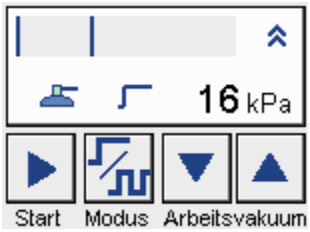
Note: *For the therapy screen, the procedure is described similar to chapter 9.1 electrotherapy.*

Note: *If there is no vacuum unit available, the "vacuum" button does not appear. This is also true if the data transfer or the connection of the vacuum unit to Soleo SonoStim/Soleo Galva is disturbed or interrupted.*

Opening the vacuum menu

Clicking on the button 

opens the vacuum menu.

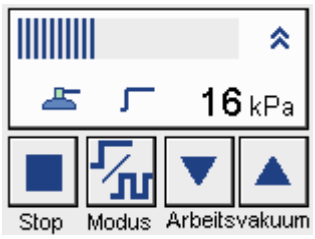


Activating the basic vacuum

A basic vacuum of 16 kPa is set at the factory.

Pressing the button 

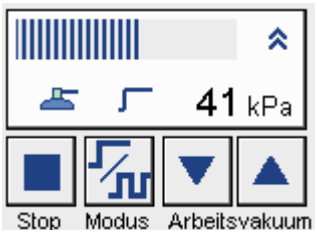
activates the basic vacuum for sucking the Vaco electrodes.



With activation of the basic vacuum, the vacuum is active. The bar graph shows the value of the basic vacuum.

Note: *Pulsed mode is set in the factory. Pressing the "mode" button opens the "vacuum" entry field to adjust the pulsed mode.*

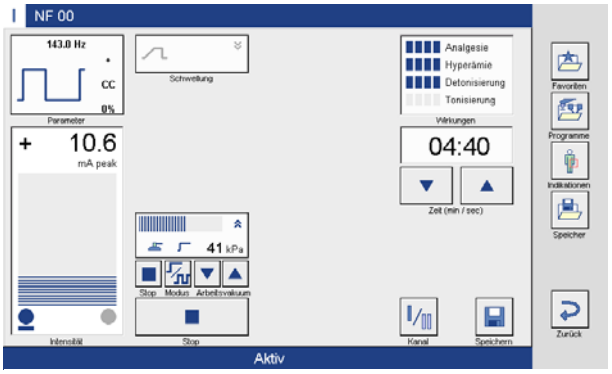
Selecting the working vacuum



The intensity of the working vacuum is set via the two arrow keys.
The bar graph shows the current value of the working vacuum.

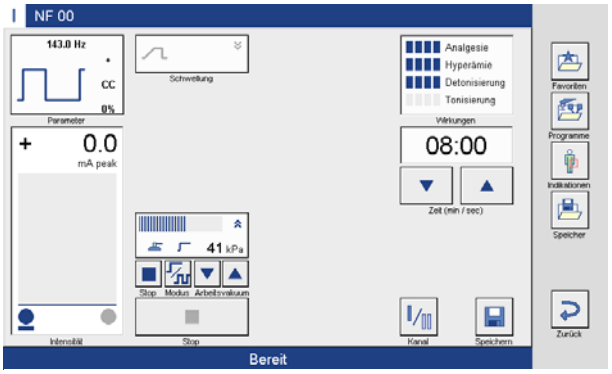
Starting electrotherapy

By adjusting the intensity from the left intensity regulator, the display changes in the bottom status line from "ready" to "active" and the therapy is being performed. In the bar graph, the current flow is displayed and the therapy time counts down at one-second intervals.



Electrophysiology therapy end

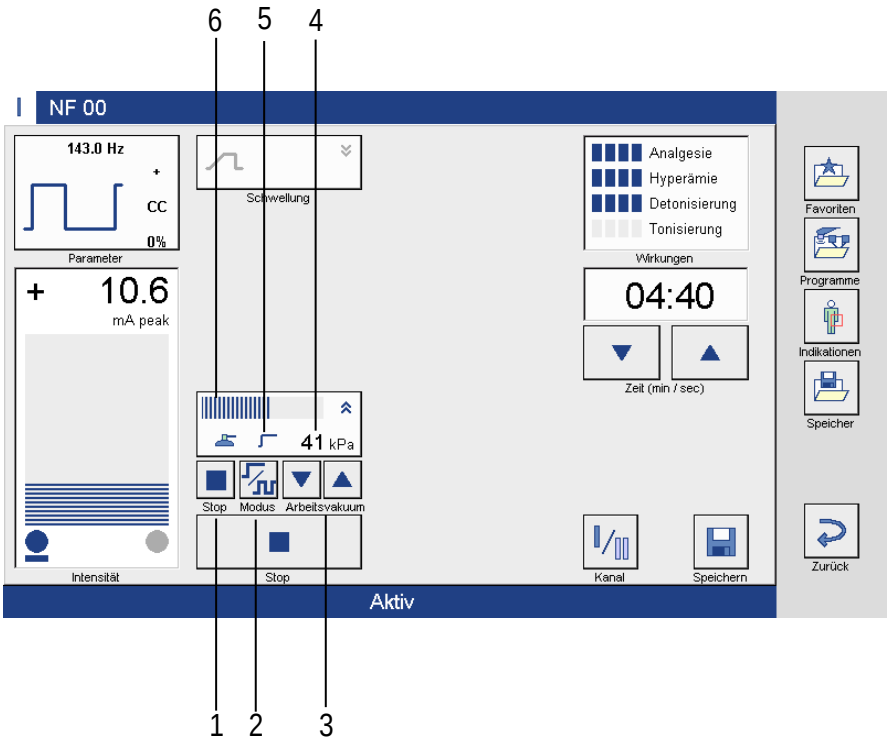
The end of the treatment period is indicated by an acoustic signal at the end of treatment, the clock is set to 00:00, the intensity automatically goes to zero and the bar graph disappears. The display in the lower status bar changes from "active" to "ready".
The treatment time is activated automatically after the end of therapy.



Note:

The vacuum must be manually stopped using "stop" after the time has ended. The "stop" button changes to "start".

Description of the display elements and buttons



Note: *After pressing the "vacuum" button, the parameter window opens.*

(1) Start/Stop — Activation or deactivation of this button starts and stops the suction of the electrodes with the basic vacuum.

(2) Mode — Activation of the button opens the "vacuum" entry field for setting the parameters.

(3) Working vacuum — The working vacuum can be adjusted using the arrow keys.

(4) Vacuum display — Indicates the current vacuum in kPa.

(5) Operating mode — Display of the currently selected mode.

(6) Bar graph — Display of the intensity set.

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

Water separator

Vaco*S* includes an integrated water separator that collects the moisture released from the sponges and thereby protects the vacuum unit from calcification.

If the water separator is full, a message appears on the display "empty water separator".

Note:

If the water separator is not emptied, no therapy can be started.

Empty the water separator as described in chapter 22.

SD card

Custom settings and the list of indications are saved on the SD card.

Note:

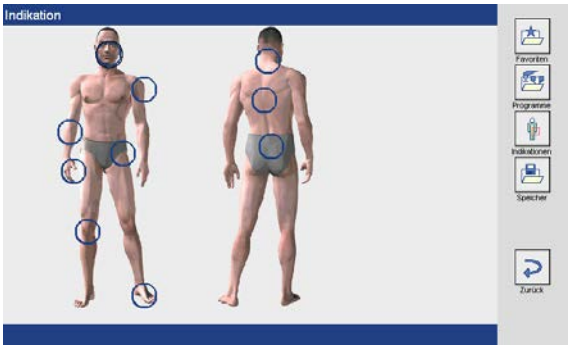
If the SD card is not inserted, the message "No SD card found" will appear when you press the "Indications", "Favourites" and "Memory" buttons.

Deactivate the message as described in chapter 22.

The indication menu is used to assist in the choice of therapy.

Selecting a region of the body

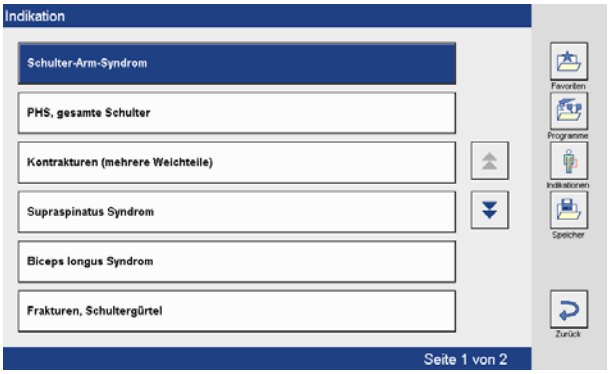
A region of the body is selected by clicking the blue circle.



Selecting a symptom

After selecting the desired region of the body (here shoulder), an indications window opens with various disorders in the shoulder area.

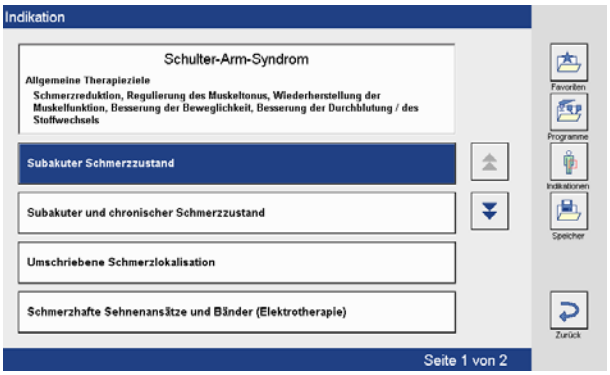
The symptom is selected directly in the respective row (in this case shoulder-arm syndrome).



Selecting a differentiated clinical picture

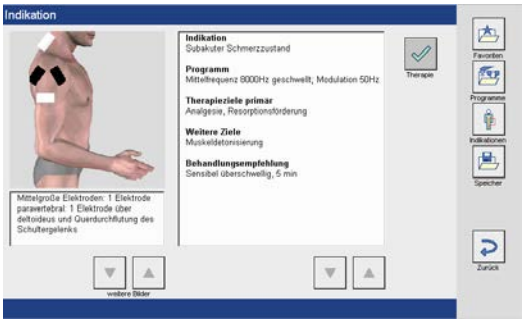
After selecting the symptom, another window opens with differentiated clinical pictures.

The selection of the differentiated disease is carried out directly in the corresponding row (subacute pain here).



Therapy information

After selecting the differentiated clinical picture, another window opens with detailed therapy information and a program recommendation.



Selecting the therapy program

Touching button 

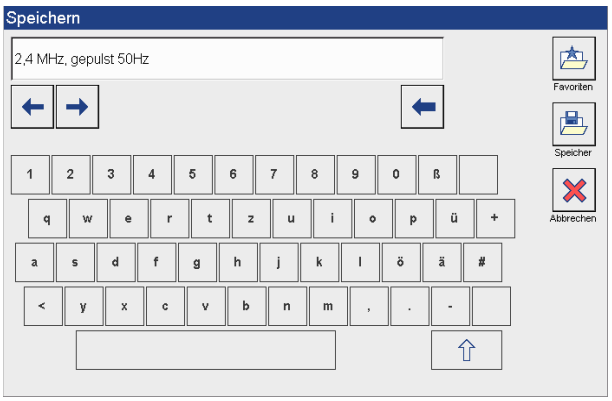
opens the therapy screen with the corresponding programme.

Note: *In order to save programs, the SD card must be properly inserted into the SD card slot. If this is not the case, it is not possible to save programs.*

Opening the memory list and naming a program

Touching button 

opens the keyboard to enable the entry of the programme name.



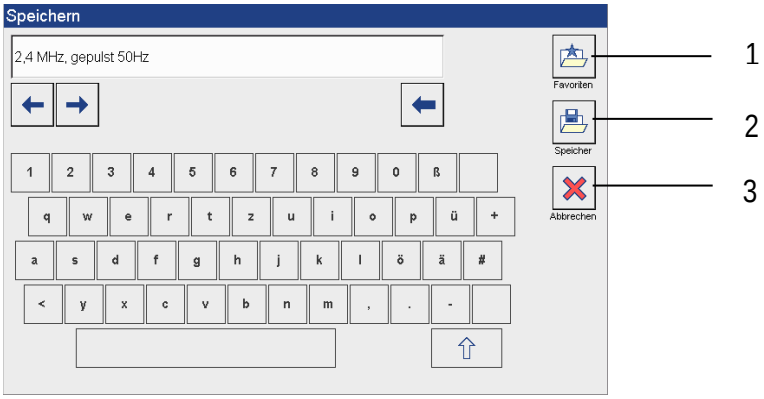
There are 2 available options for the programme name:

1. Acceptance of the program name from the input field.
2. Entry of a personal program name. Entry of a personal program name is carried out using the keyboard.

Note: *When entering a personal program name, the program name in the input field must be deleted first.*

Note: *The programs can be saved in the favourites list or in the memory list. There are 120 memory slots available.*

Saving to the Favourites list / Memory list



Touching button (1) opens the favourites list and automatically saves the program in the favourites list.

Pressing button (2) opens the memory list and saves the program in the memory list.

Touching the "OK" button closes the "Save" screen and moves the program to the corresponding list.

The program is always stored in the first available slot on the list.

Pressing button (3) cancels the save operation.

Individually saved programs are listed in the favourites list.

Here these can be

1. called up in order to implement therapy or
2. edited (the sequence altered or deleted).

Note: *The steps to retrieve and editing the favourites / memory list are identical; therefore only the retrieve and editing of the favourites list is described.*

Selecting the favourites list

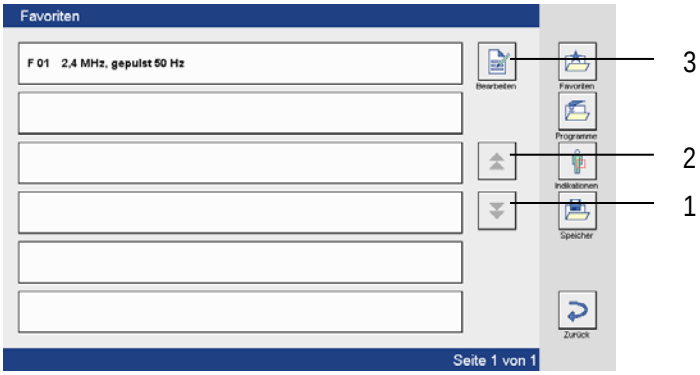
Touching button 

opens the favourites list.

Calling up a program

The desired program is selected directly in the corresponding row.

Editing the favourites list

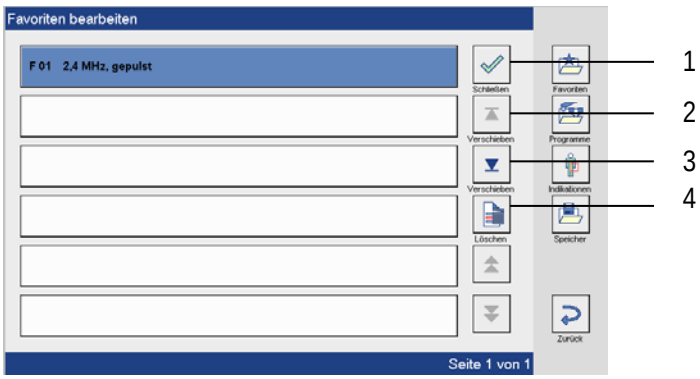


By pressing buttons (1) and (2), the individual favourite pages can be viewed. Button (1) scrolls forwards, and button (2) backwards.

Pressing button (3) opens the "Edit Favourites" screen.

Editing favourites

The programme to be processed is selected directly in the corresponding row.



Touching button (1) returns you to the favourites list.
Touching button (2) scrolls the program up.
Touching button (3) scrolls the program down.
Touching button (4) deletes the program.

Note:

Touching button (4) triggers a confirmation prompt:

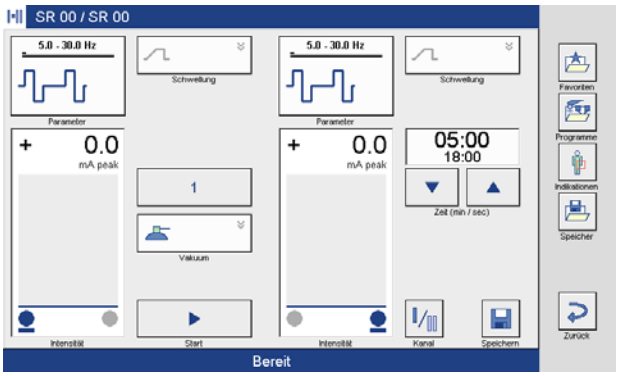
"Do you really want to delete the program?"

Touching the "Yes" button deletes the program.
Touching the "No" button cancels the delete routine.

Sequence programmes are a combination of up to three electrotherapy programmes that are launched in direct succession one after another automatically. In the programme family "currents for sports rehabilitation", various programmes are predefined at the factory. They usually comprise warming, training or toning and relaxation phases.

Furthermore, there is a freely programmable programme.

Therapy screen Preset programme

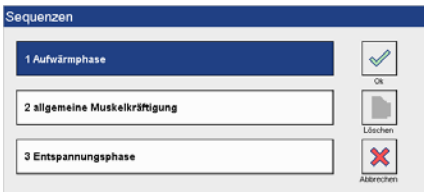


Note: *Since different pulse shapes and frequencies provide a different current feel, the intensity levels for individual sequences are set in advance of the therapy.*

Activating the sequence window

By activating field 

this opens the "sequences" window.



Here the intensity thresholds of the individual sequences are defined in advance of sequential therapy.

The sequence selection is made directly in the corresponding row.

Setting intensities

Determining the intensity using the intensity adjuster.

The intensity adjustment is performed according to the sequences 2 and 3.

Note:

By determining the intensity, the treatment time runs for each sequence.
By selecting the next sequence the preset intensity of the preceding sequence will be saved automatically.

With activation of sequence 1, the treatment time becomes active again for the default values and resets the start button.

Therapy startup

Activation of button 

starts the therapy.

The 3 sequences take place in succession. The sequence change is indicated by an acoustic signal.

End of therapy

After the treatment period, this is indicated by an acoustic signal at the end of treatment.

Paralysis diagnosis and therapy

12

12.1 Overview

In Soleo SonoStim / Soleo Galva, there are special programmes for the diagnosis and treatment of paralysis and flaccid paralysis.

With the diagnostic programmes, clues for assessing the severity of flaccid paralysis can be obtained, making it possible in a simple manner to individually set the parameters necessary for the treatment.

Diagnostic programmes

PA 00 Medium frequency innervation test according to Lange
PA 01 Faradic test
PA 02 Chronaxie / accomodation quotient
PA 15 Gold standard test

For therapy, different programmes are available with the pulse shapes appropriate for paralysis therapy.

The parameters can be individually adjusted according to the disease.

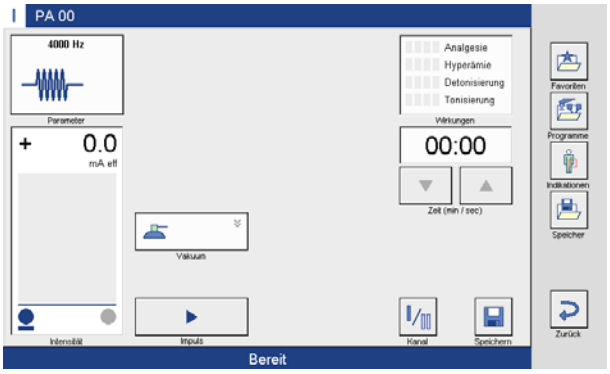
Treatment programmes

PA 06 Paralysis Treatment with delta currents (alternating)
PA 07 Paralysis, medium degeneration
PA 08 Paralysis, low degeneration
PA 10 Intentional exercises (biphasic)
PA 11 Muscle rehabilitation force (biphasic)
PA 12 Muscle rehabilitation endurance (biphasic)

12.2 Medium frequency test by Lange

The medium frequency test according to length gives a rough indication of whether a muscle is partially or completely denervated. The electrodes are placed in the centre of the muscle to be examined.

Display screen



Note: *When using full intensity, the "pulse" button is active.*

Performance

Turn on at an appropriate intensity and activating the button 

triggers a single pulse.

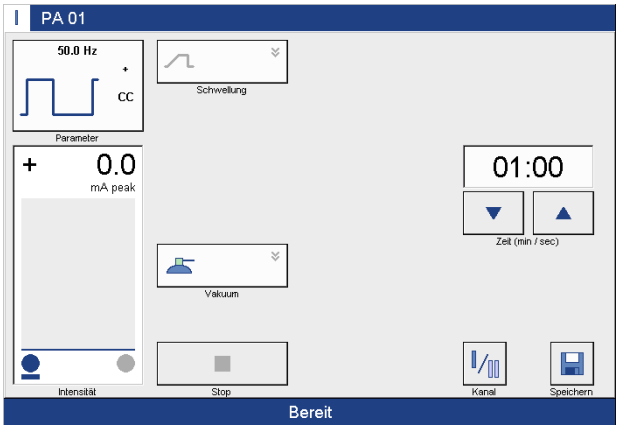
Subsequently, the test is carried out on healthy muscle. If the two muscles show an approximately equal excitability to the single pulse triggering, the examined muscle is innervated.
If significant differences in the response of muscles to high stimulus intensities are observed, the examined muscle is partially denervated.

12.3 Neofaradic test

The faradic test tells you whether a muscle is innervated normally.

A muscle is normally innervated when it reacts during a stimulation time of 1 minute with an equally long-lasting contraction.
Innervation is to be assumed if no or only short-term contractions are observed.

Display screen



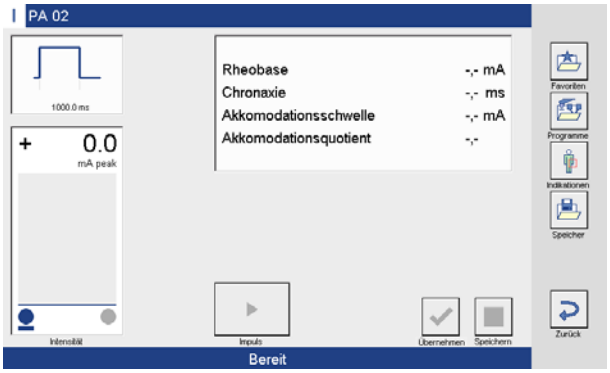
Performance

After selecting the intensity, the stimulus time of 1 minute is started.

12.4 Chronaxy/accommodation quotient

This programme is used to perform a simple and rapid diagnosis.
It consists of 3 programme steps in which rheobase, chronaxie and the accomdation thresholds are measured and the accompdation quotient determined.

Display screen



Rheobase

Threshold current to induce a minimal muscle twitch with a rectangular pulse of 1000 ms.

Identifying/assuming rheobase

Step 1: Set to a low intensity
Step 2: Trigger a single pulse

Repeat steps 1 and 2 with increasing intensity until a minimum muscle twitch is visible. With the first minimal muscle twitch, the rheobase value is determined.

Step 3: Accepting the rheobase value

With the acquisition of the detected pulse, the intensity is automatically set to twice the rheobase value. The intensity cannot be changed in this programme step.

Chronaxie

Pulse duration to induce a minimal muscle twitch at a threshold current value, which corresponds to twice the rheobase value.

Identifying/assuming chronaxie

Step 1: Increase (or possibly) decrease the pulse time gradually by activating the arrow keys
Step 2: Trigger a single pulse

Repeat steps 1 and 2 until a minimum muscle twitch is visible. With the first minimal muscle twitch, the chronaxie value is determined.

Step 3: Accepting the chronaxie value

Accomodation threshold

Threshold current to induce a minimal muscle twitch with a triangular pulse of 1000 ms.

Accommodation quotient

$$\frac{\text{Intensity threshold (mA) of DIC at 1000 ms}}{\text{Intensity threshold (mA) of RIC at 1000 ms (Rheobase)}}$$

DIC
Triangular impulse response
RIC
Rectangular impulse response

Identifying/assuming the accomodation threshold

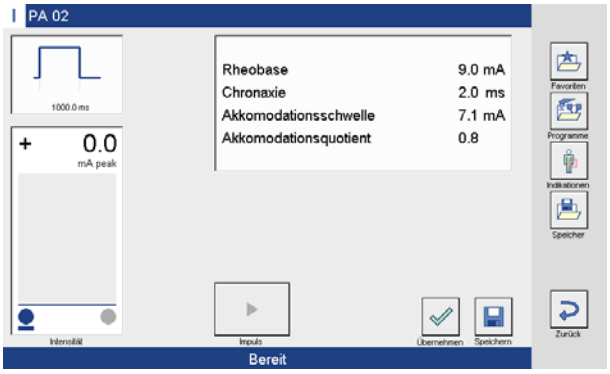
Step 1: Set to a low intensity
Step 2: Trigger a single pulse

Repeat steps 1 and 2 with increasing intensity until a minimum muscle twitch is visible. With the first minimal muscle twitch the accommodation threshold is determined.

Step 3: Accepting the accomodation threshold value

Accommodation quotient

With acceptance of the value of the accommodation threshold, the accommodation quotient is automatically calculated. The measured values are displayed in a window.



12.4 Chronaxy/accommodation quotient

Chronaxie assessment

<0.05 ms hyperexcitability
0.05 to 1 ms normal excitability
1 - 20 ms partial degeneration
> 20 ms full degeneration

Normal chronaxie value (according to Edel)

Anterior muscles (front of the body)
Proximal: 0.08 to 0.16 ms
Distal: 0.16 to 0.32 ms
Posterior muscles (back of the body)
Proximal: 0.16 to 0.32 ms
Distal: 0.44 to 0.72 ms

Assessment of the accommodation quotient according to Edel

6 - 3: normally functioning neuromuscular system
3 - 2: minor/partial degeneration
2 - 1: serious/severe degeneration

12.5 Fisch Gold Test

This programme is used to perform a simple and rapid diagnosis.

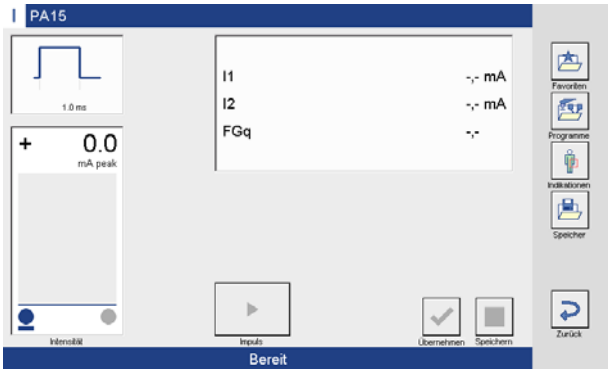
The measurement is carried out in 2 phases:

In phase 1, the intensity I1 of the first muscular contraction is determined at a square pulse of 1 ms pulse width.

In phase 2, the intensity I2 is determined with the first muscle twitch in a square pulse of 100 ms.

As a result, the quotient FGQ = I1 / I2 is shown.

Display screen



Performing measurement phase 1

Step 1: Turn on adequate intensity
Step 2: Trigger a single pulse

Repeat steps 1 and 2 with increasing intensity until a minimum muscle twitch is visible.

Step 3: Copy the reading

After the acquisition of the measured value, the parameters are automatically applied to measurement phase 2.

Performing measurement phase 2

Measurement phase 2 is similar to measurement phase 1.

After performing the measurement, the measured values are shown in the top right of the screen.

Assessment of the quotients

< 1.7: normally functioning neuromuscular system
> 1.7: partial degeneration

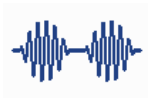
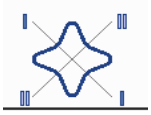
Should one of the two intensities not be determined, the degeneration is complete.

13.1 Soleo *SonoStim* / Soleo *Galva*

Power supply	100 - 240 V / 50 Hz / 60 Hz 220 V / 60 Hz
Mains fuse	2 x T2AL, 250 V, 5x20 mm
Electrical energy consumption	max. 60 VA
Protection class	I
Operating mode	Intermittent operation: 30 minutes on, 10 minutes off
Applied Part	Type BF
Dimensions	322mm x 234mm x 130mm
Weight	2.1 kg
Operation	+10°C to +35°C, 20 % to 80 % relative humidity without condensation, 700 hPa – 1060 hPa
Storage and transport	-10 °C to +50 °C, 10 % to 90 % relative humidity without condensation, at 700 hPa - 1060 hPa
Note:	*Storage and transport in original packaging only.*
	Subject to technical modifications!

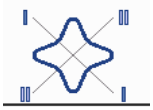
13.2 Stimulation

Output power

		200 Ω	500 Ω	1000 Ω	2000 Ω
Galvanisation GA xx	CC CV	80 mA 14 V	80 mA 40 V	80 mA 60 V	80 mA 60 V
					
Diadynamic currents DD xx	CC CV	6 mA 3 V	20 mA 8 V	20 mA 16 V	20 mA 40 V
					
High-voltage currents HV xx	CC CV	250 mA_{peak} 40 V_{peak}	250 mA_{peak} 140 V_{peak}	250 mA_{peak} 200 V_{peak}	250 mA_{peak} 200 V_{peak}
					
Medium frequency currents MF xx	CC CV	56 mA 10 V	56 mA 25 V	56 mA 60 V	56 mA 60 V
					
Interferential currents IF xx	CC CV	56 mA - V	56 mA - V	56 mA - V	56 mA - V
					
Micro stimulation currents MI xx	CC CV	1 mA_{peak} 0.3 V_{peak}	1 mA_{peak} 0.6 V_{peak}	1 mA_{peak} 1 V_{peak}	1 mA_{peak} 2 V_{peak}
					
Low-frequency rectangular currents NF xx	CC CV	10 mA_{peak} 12 V_{peak}	80 mA_{peak} 40 V_{peak}	80 mA_{peak} 80 V_{peak}	80 mA_{peak} 160 V_{peak}
					

Polarity of the currents	If currents have a polarity: red = positive (+), black = negative (-)
Accuracy	±20 %
Appliance	Stimulation electrodes

Parameters of current forms

Current forms	Programme name	Max. Current (CC)	Frequency	Max. voltage (CV)	Pulse
Galvanisation GA xx 	GA	80 mA_{eff}	--	60 V_{eff}	--
Diadynamic currents DD xx 	DD	20 mA_{eff}	DF: 100 Hz, MF: 50 Hz, CP, LP: 50/100 Hz	60 V_{eff}	7.5 ms
High-voltage currents HV xx 	HV	250 mA_{peak}	1-1961 Hz	128 V_{peak}	10 us-0.1 ms
Medium frequency currents MF xx 	MF	80 mA_{peak}	8000/3-200 Hz	80 V_{peak}	1 ms-50 ms
Interferential currents IF xx 	IF	100 mA_{peak}	8000/10-120 Hz	--	125 us-0.4 s
Micro stimulation currents MI xx 	MI	2 mA_{peak}	2Hz, 100 Hz	20 V_{peak}	20 us-1s
Low-frequency rectangular currents NF xx 	NF	80 mA_{peak}	1-1923 Hz	180 V_{peak}	20 us-1s

All listed parameters are valid for a load resistance of 1 KOhm.
(Pulse duration: 20 us - 1 s, pulse repetition frequency: 1-1923 Hz, pulse repitition amplitude: 80 mA_{peak}, DC voltage: 50 V. These values are for a load resistance of 500 ohm)

13.3 Ultrasound

Ultrasound heads	
Frequency	0.8 MHz and 2.4 MHz
Ultrasound head, small	1 cm^2, ERA = 0,67cm^2 at 0.8 MHz, 0.65 cm^2 at 2.4 MHz
Maximum power	1.0 W at 0.8 MHz, 0.6 W at 2.4 MHz
Intensity levels	0.1 to 1 W/cm^2 eff. at intervals of 0.1 W / cm^2
Ultrasound head, large	5 cm^2, ERA = 2.30 cm^2 at 0.8 MHz, 2.38 cm^2 at 2.4 MHz
Maximum power	6.9 W at 0.8 MHz, 7.1 W at 2.4 MHz
Intensity levels	0.1 to 3 W/cm^2 eff. at intervals of 0.1 W/cm^2
Accuracy	± 20 %
Sound forms	1. Continuous ultrasound 2. Impulse ultrasound, adjustable pulse frequencies: 20 Hz, 50 Hz, 100 Hz Duty ratio: 1: 1, 1: 2, 1: 3, 1: 5, 1: 10
Interchangeability	Ultrasound heads are calibrated ex works and can be easily replaced.
Applied Dart	Transducer ultrasound head

Mains voltage	100 – 120 V / 50 Hz / 60 Hz (1) 230 – 240 V / 50 Hz / 60 Hz 220 V / 60 Hz (2)
Mains fuse	2 x T 0.4 AL, 100 – 120 V, 5 x 20 mm 2 x T 0.2 AL, 230 – 240 V, 5 x 20 mm
Electrical energy consumption	max. 50 VA
Protection class	I
Appli**ed Part**	Type BF
Operating mode	Intermittent operation: 30 minutes on, 10 minutes off
Dimensions	322mm x 234mm x 130mm
Weight	3.0 kg
Operation	+10°C to +35°C, 20% to 80% relative humidity without condensation, 700 hPa – 1060 hPa
Storage and transport	-10 °C to +50 °C, 10% to 90% relative humidity without condensation, at 700 hPa - 1060 hPa
Negative pressure	12-60 kPa
Pulse operation	Period adjustable to 1 to 8 seconds in steps of 0.5 seconds, ratio 1: 1
Accuracy	± 20%
Appli**ed Part**	Vacuum suction cups and sponges
Note:	*Storage and transport in original packaging only.*
	Subject to technical modifications!

- Before starting any cleaning and maintenance measures, the device must always be switched off at the main switch and unplugged.

- Make sure that during cleaning and disinfection no liquids penetrate the device. Do not use sprays.

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

- Make sure that when cleaning and disinfecting the labels of the device (such as warning, labels of control devices, indication plate) are not damaged.

- The device and its applied part are not considered critical in relation to hygiene when used on non-injured and healthy skin.

Housing

Cleaning: The housing and all cables can be cleaned using commercially available, alcohol-free cleaning agents designed for plastics. Wipe the surface until the dirt is removed using a soft cloth soaked according to the specifications of the manufacturer of the cleaning agent so it is not dripping.

Disinfection: We recommend disinfecting the device at least once a week or upon signs of contamination. Consult with your health professional when doing so. Always perform cleaning prior to disinfection.

Housing can be disinfected using disinfectant wipes. To do so, use a commercially available alcohol-fee disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties. Observe the application instructions of the manufacturer. Wipe all surfaces using a soft cloth soaked according to the specifications of the manufacturer of the disinfectant, but not dripping, or use pre-impregnated disinfectant wipes (so called wipes). If applicable, also observe requirements for drying or post-cleaning.

Ultrasound heads

Cleaning: Proceed as described under "housing".

Disinfection: Proceed as described under "housing".

Vaco electrodes

Cleaning: The Vaco electrodes can be cleaned of any visible dirt with commercially available soft plastic cleaners. Unplug the Vaco electrode from the electrode hose and invert the suction cup completely. Dip the Vaco electrode into a cleaning solution prepared according to the manufacturer of the detergent and clean the electrode thoroughly using a stiff brush. Make sure that the gap underneath the metal plate is cleaned completely safely. Rinse with clear water.

Disinfection: We recommend disinfecting the device at least once a week or upon signs of contamination. Consult with your health professional when doing so. Always perform cleaning prior to disinfection.

The Vaco-electrodes can be disinfected with a commercial alcoholic disinfectant for metal and plastic, which is bactericidal, virucidal and fugicidal. Observe the application instructions of the manufacturer. Dip the Vaco electrodes fully in the disinfectant, and move around a little. Make sure that the inner and outer surface is completely covered with disinfectant.
If applicable, also observe requirements for drying or post-cleaning.

Sponges/sponge bags

Cleaning: Rinse the sponge/sponge bags thoroughly with water. The use of cleaning agents is not recommended as components remain in the sponges and can cause skin irritation during application. Furthermore, it may lead to damage of the equipment.

Disinfection: For thermal disinfection, heat the sponges/sponge bags for 10 minutes or wash (water temperature> 95°C) in pure water without additives. The use of disinfectants is not recommended because the elements that remain in the sponges may result in skin irritation during application. In addition, the equipment may be damaged.

If, however, flammable solutions are used for cleaning and disinfection, enough time must be allowed for them to evaporate before using the device. This may otherwise result in ignition.

Note: *Only use the device in a perfectly hygienic environment.*

Electrodes
Information about the use of different types of electrodes

15

General note:

Selection and application of the electrodes must be done with care. In constant-current operation, ensure good and uniform contact with the skin. A reduction in the contact area can lead to discomfort for the patient.

Before treatment, the skin should be inspected and cleaned if necessary, for example if the patient is sweaty or ointments have been applied. Inflamed skin, small wounds or cracks are to be covered with Vaseline or zinc paste. Exercise extreme caution with recent scars.

Single-use electrodes

The self-adhesive disposable electrode allows for convenient and rapid application. Through one-time use, it is hygienic to use. Three therapeutically useful sizes allow individual therapy tailored to the clinical picture.

Single-use electrodes are particularly suitable for treatment with bipolar flows. For therapy with monopolar pulse currents or currents with a galvanic component, the disposable electrodes should be additionally padded with a damp sponge.

For the Soleo SonoStim/Soleo Galva, all electrodes standard in electrotherapy must be connected by means of an insulated cable clamp.

Note:

The disposable electrode is reserved for one-time use and can easily be disposed of as household waste.
Repeated use of the disposable electrode can be dangerous for the patient.

For particularly large-scale applications in addition to the disposable electrodes, plate and rubber electrodes are also available.

The electrical connection is made as in the disposable electrode to the terminals of the electrode cables. Attach clips to the plate electrode fully inserted into the sponge bag.

Rubber electrodes

Rubber electrodes are suitable for therapy with bipolar currents. In the application of pure galvanic current flows with electrical component or long pulse duration, it is important to note that through normal use conditional removal of carbon results in a reduction of the conductivity.

Tin plate electrodes

For the treatment with pure galvanic current (galvanisation, iontophoresis) large tin plate electrodes are suitable.

Sponge bags and sponges

Both rubber and tin plate electrodes must always be backed by a wet liner. For rubber electrodes, the use of sponge bags is recommended for tin plate electrodes, which should be at least 1 to 2 cm thick. To moisten the sponges, tap water is recommended. Distilled water is not suitable, because of its poor conductivity.

In contrast to the convenient self-adhesive properties of single-use electrodes, rubber and tin plate electrodes must be fixed. For this purpose, Velcro or rubber bands are suitable.

Fully insert the electrodes into the sponge bags and fit using slight pressure until they rest properly on the body. The straps should not leave any constrictions.

The products bear the CE marking

CE 0123

in accordance with EC Directive 93/42/EEC concerning medical devices.

Manufacturer

Zimmer MedizinSystems GmbH
Junkersstraße 9
89231 Neu-Ulm, Germany
Tel. +49 731. 9761-291
Fax: +49 731. 9761-299
www.zimmer.de

Scope of delivery item no.	Soleo Sono*Stim*
5302	1 basic device Soleo *SonoStim*
(see below)	2 pairs of electrode cables with twist protection and magnetic clip, incl. 2 red and 2 black alligator clips, 2.90 m long
	1 ultrasound head 0.8 and 2.4 MHz, ø 28 mm
	1 tray mount, right
	1 tray mount, left
	1 mains cable*
	2 touch pens
	2 test resistors
	1 instructions for use

Accessories item no.	
65800410	Touch pen
118	Mains cable*
65910321	Tray mount, right
65910311	Tray mount, left
87054001	Pocket for Soleo*line*
87053000	Case for Soleo*line*
10101393	Instructions for use
	Electrotherapy
154	1 pair of electrode cable with twist protection and magnetic clip, incl. 1 red and 1 black alligator clip, 2.90 m long
68910911	1 pair of electrode cables with twist protection and magnetic clip, 2.90 m long
31100146	Alligator clip, red
31100147	Alligator clip, black
87200120	Box single-use electrodes, small, 32 x 40 mm, 200 pairs
87200140	Box single-use electrodes, medium, 56 x 56 mm, 100 pairs
87200130	Box single-use electrodes, large, 56 x 128 mm, 50 pairs
87200110	Box single-use electrodes, round, ø 100 pairs
43	Electrode plate of pure tin, 90 x 120 mm
96	Sponge for electrode plate 120 x 160 mm
212	1000 films for iontophoresis, 130 x 180 mm
44	Rubber electrode 50 x 50 mm, 1 pair
97	Sponge pocket 70 x 75 mm for # 44, 1 pair
46	Rubber electrode 50 x 100 mm, 1 pair
98	Sponge pocket 115 x 80 mm for # 46, 1 pair
232	Rubber strap 60 cm, with button
233	Rubber strap 120 cm, with button
230	Velcro tape, 60 cm long, 10 cm wide
231	Velcro tape, 120 cm long, 10 cm wide
65920310	Test resistor
	Ultrasound therapy
Art. No.	
4200	Ultrasound head 0.8 and 2.4 MHz, ø 28 mm
4220	Ultrasound head 0.8 and 2.4 MHz, ø 13 mm
6	Sono plus, 1 bottle

Scope of delivery Art. No.	Soleo *Galva*
5330	1 basic device Soleo *Galva*
(see below)	2 pairs of electrode cables with twist protection and magnetic clip, incl. 2 red and 2 black alligator clips, 2.90 m long 1 tray mount, right 1 tray mount, left 1 mains cable* 2 touch pens 2 test resistors 1 instructions for use

Accessories Art. No.	
65800410	Touch pen
118	Mains cable*
65910321	Tray mount, right
65910311	Tray mount, left
10101393	Instructions for use
154	1 pair of electrode cable with twist protection and magnetic clip, incl. 1 red and 1 black alligator clip, 2.90 m long
68910911	1 pair of electrode cables with twist protection and magnetic clip, 2.90 m long
31100146	Alligator clip, red
31100147	Alligator clip, black
87200120	Box single-use electrodes, small, 32 x 40 mm, 200 pairs
87200140	Box single-use electrodes, medium, 56 x 56 mm, 100 pairs
87200130	Box single-use electrodes, large, 56 x 128 mm, 50 pairs
87200110	Box single-use electrodes, round, ø 100 pairs
43	Electrode plate of pure tin, 90 x 120 mm
96	Sponge for electrode plate 120 x 160 mm
212	1000 films for iontophoresis, 130 x 180 mm
44	Rubber electrode 50 x 50 mm, 1 pair
97	Sponge pocket 70 x 75 mm for # 44, 1 pair
46	Rubber electrode 50 x 100 mm, 1 pair
98	Sponge pocket 115 x 80 mm for # 46, 1 pair
232	Rubber strap 60 cm, with button
233	Rubber strap 120 cm, with button
230	Velcro tape, 60 cm long, 10 cm wide
231	Velcro tape, 120 cm long, 10 cm wide
65920310	Test resistor

* Standard cable. Other country-specific plug types are available. If necessary, contact your dealer.

Scope of delivery Art. No.	*VacoS*
5320	1 basic device Vaco*S* 1 pair Vaco electrode tubes red, 2.10 m 1 pair Vaco electrode tubes black, 2.10 m 2 pairs Vaco electrodes ø 90 mm, self-closing with sponges 2 pairs Vaco electrodes ø 60 mm, self-closing with sponges 2 connection cables for Soleo *SonoStim* / Soleo *Galva* 1 mains connection cable, 50 cm 4 pieces sorting combs for Vaco lines incl. magnetic clip 1 water bottle

Accessories Art. No.	
95	Sponge for Vaco electrode, large, for # 72
94	Sponge for Vaco electrode, small, for # 71
72	Vaco electrode, ø 90 mm, self-closing
71	Vaco electrode, ø 60 mm, self-closing
164	Vaco electrode tube, red, 2.10 m
165	Vaco electrode tube, black, 2.10 m
68910210	Connection cable for Soleo *SonoStim* / Soleo *Galva*
119	Mains connection cable, 50 cm
65350110	Sorting comb for Vaco lines incl. magnetic clip
95920000	Water bottle

Device Combinations

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Soleo *SonoStim* and Soleo *Galva* can be used with *VacoS*.

If you combine the devices and therefore operate a medical system, you are solely responsible for the accuracy of the connection.

Soleo *SonoStim* / Soleo *Galva* are manufactured according to EN 60601-1 safety regulations.

As the manufacturer, Zimmer MedizinSysteme can only be considered responsible for safety and reliability if

- the equipment is operated using a proper power outlet with an earthing contact and the electrical installation complies with DIN VDE 0100 Part 710,
- the device is operated in accordance with the user manual,
- extensions, readjustments or modifications are only carried out by persons authorised by Zimmer MedizinSysteme,
- the user is satisfied regarding the functional safety and the proper condition prior to using the device,
- the ultrasound head, cables and connectors are inspected for any damage that may affect the safety of the device (e.g. cracks) prior to use,
- the equipment is only operated by properly trained personnel,
- the device is immediately disconnected from the mains in the event of the penetration of liquids,
- the device is not operated in hazardous areas and / or a combustive atmosphere.

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

Fuses and other spare parts may be only be exchanged by trained service personnel. Replacement of the lithium battery by untrained persons may cause risks.

Servicing of the device must be performed by trained personnel. All information necessary for service is provided in the Soleoline service manual or can be obtained from the manufacturer. On request, Zimmer MedizinSysteme provides circuit diagrams, component lists, descriptions, calibration instructions or other documents.

Soleo *SonoStim* / Soleo *Galva* performs a self-test after turning on, which checks all internal components.

In the event of a fault, an error message appears.

In addition, an extended function test can be performed as described below for all 3 modes.

These tests should be performed monthly or in case of any doubt regarding the correct function of the device.

Electrical muscle stimulation	Selecting programme GA 00. Connecting the test adapter. At maximum intensity, the display in the bar graph must be full. Run the test with both channels, one after the other.
Ultrasound	Select the ultrasound head and cover the ultrasound head surface with coupling gel. In the case of starting therapy with low power, the coupling display must show more than 90%. Run the test with both ultrasound heads, one after the other. Then clean the ultrasound heads.
Vacuum	Select vacuum and create a basic vacuum. Short circuit the Vaco electrode and set the maximum vacuum. In non-pulsed operation, the bar graph must be full.
Vaco electrodes	Vaco electrodes evert outwardly so that the electrode area is no longer enclosed by the rubber-lip and a vacuum is created. *VacoS* must suction permanently.

The Soleo *Galva*, Sono*Stim* and optionally available Vaco*S* devices are listed in Annex 1 of MPBetreibV (Medical Device Operating Directive). Please observe the measures stipulated therein.

The devices are not listed in Annex 2 of MPBetreibV (Medical Device Operating Directive).

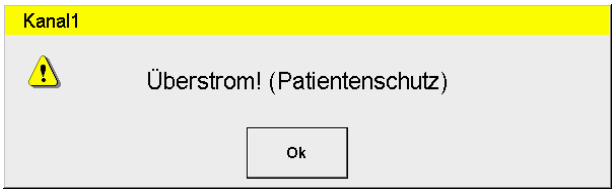
In Germany, the DGUV regulation 3 (Electrical Systems and Equipment) in its current version must also be observed.

Note: *These notes apply to the operation of the device in Germany. If applicable, observe any divergent national regulations that apply in your country.*

Cable inspection

Means with the current stimulation therapy in constant current mode:
Interruption of the patient circuit.
As a rule, this message concerns disconnected electrodes, dirty electrode terminals, a defective patient cable or defective patient safety. Clear message by confirming "OK".

Overcurrent



This refers to an increase in the maximum allowable current. An indicated increase in current in constant operation usually indicates a fault in the device, while increasing the current in constant voltage mode by changing the patient's resistance may occur (e.g. wet skin).

Clear message by confirming "OK".
If the error message occurs again, please contact customer service.

No SD card found

If the SD card is not inserted, the message "No SD card found" will appear when you press the "Indications", "Favourites" and "Memory" buttons.

Insert card and confirm with "OK".

VacoS

No vacuum

If the *VacoS should* not reach the set vacuum, there may be a leak in the system.

Check the following in this case,

- whether all four Vaco connected electrode hoses are closed and connected to a Vaco electrode
- whether the Vaco electrodes are applied to the patient properly.

Vacuum button disabled

Should the vacuum button be disabled, a transmission error may be present.

Check the following in this case,

- whether Soleo *SonoStim* / Soleo *Galva* is connected correctly to *VacoS*
- whether Soleo *SonoStim* / Soleo *Galva* is connected to *VacoS* via the connecting cable
- whether *VacoS* is turned on.

Note:

VacoS and Duostim mode isolated

In "isolated Duostim" mode, a double-circuit vacuum application is not possible. In "Duostim mode", only channel I is active for the vacuum application. Channel II cannot be operated with vacuum application.

VacoS

Water separator full

If the water separator is full, a message appears on the display "empty water separator".
The water is emptied by means of a water bottle that comes with Vaco*S* . Close the message "empty water" by pressing "OK".

Note:

If the water separator is not emptied, no therapy can be started.
We recommend emptying the water separator daily.

Empty the water separator

Mounting the bottle

The connection valve (33) for draining the water separator is on the right side of Vaco*S*. On the water bottle hose, there is a quick-release lock which is connected to the connection valve on the device.

Empty the water

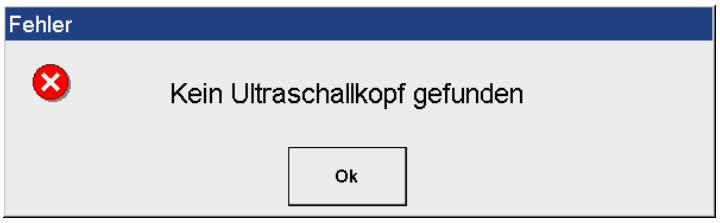
Squeezing the bottle creates a vacuum, which empties the water separator.
Under certain circumstances, a repeated structure of the negative pressure is necessary to empty the water separator.

Dismantling/emptying the bottle

By squeezing the sides of the quick connector on the tube of the water bottle and simultaneously removing the terminal, the bottle is removed from the valve connection.
The lid of the bottle is removed by turning so that the bottle can be emptied.

Error messages

A message regarding the error that has occurred appears on the display, e.g.:



Some errors are also displayed with a corresponding error number (e.g. "Self test error X/XX/X").

In some cases, the error can be corrected by switching off, waiting for five seconds and then switching the device on again.

Otherwise, please contact customer service.
You can reach the service via your assigned sales representative or our headquarters in Neu-Ulm.

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

For questions or equipment malfunctions, please contact the address listed:

Headquarters

Zimmer MedizinSysteme GmbH
Junkersstraße 9
89231 Neu-Ulm, Germany
Tel. +49 731. 9761-291
Fax: +49 731. 9761-299
www.zimmer.de

Disposal

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

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

Medical electrical equipment such as the Soleo SonoStim/Soleo Galva are subject to special precautions with regard to EMC (electromagnetic compatibility) and must be installed and commissioned in accordance with the EMC information contained in the user manual or the accompanying documents.

Portable and mobile RF communications equipment (e.g. mobile phones) can affect electrical medical equipment.

Soleo SonoStim / Soleo Galva may only be operated with the original parts specified in the list of the delivery and accessories. The operation of the device with other parts may result in increased emissions or in the device's decreased interference immunity.

<table>
<tr><th colspan="3">Guidelines and Manufacturer's Declaration - Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The Soleo SonoStim / Soleo Galva device is designed for operation in the electromagnetic environment specified below. The customer or the user of the Soleo SonoStim/Soleo Galva must ensure that it is operated in such an environment.</td></tr>
<tr><th>Emissions measurements</th><th>Compliance</th><th>Electromagnetic environment - guidelines</th></tr>
<tr><td>RF emissions in accordance with CISPR 11</td><td>Group 2</td><td>The Soleo SonoStim/Soleo Galva device must emit electromagnetic energy in order to ensure its intended function. Nearby electronic equipment may be affected.</td></tr>
<tr><td>RF emissions in accordance with CISPR 11</td><td>Class B</td><td rowspan="3">The Soleo SonoStim/Soneo Galva device is suitable for use in all establishments, including domestic establishments and those directly connected to the public supply network that also supplies buildings used for domestic purposes.</td></tr>
<tr><td>Emissions of harmonics in accordance with IEC 61000-3-2</td><td>Category A</td></tr>
<tr><td>Emissions of voltage fluctuations / flickers in accordance with IEC 61000-3-3</td><td>Compliant</td></tr>
</table>

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

The device must not be used in direct proximity to or stacked directly on top of another similar device. If operation near to or stacked on top of another device is unavoidable, the device should be monitored to verify its proper operation within this setup.

Guidelines and manufacturer's declaration - electromagnetic immunity			
The Soleo SonoStim/Soleo Galva device is designed for operation in the electromagnetic environment specified below. The customer or the user of the Soleo SonoStim/Soneo Galva 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) in accordance with IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made from wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient / burst in accordance with IEC 61000-4-4	± 2 kV for mains cables ± 1 kV for input and output cables	± 2 kV for mains cables Not applicable	The supply voltage quality must correspond to that of a typical commercial or hospital environment.
Surges in accordance with IEC 6100-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The supply voltage quality must correspond to that of a typical commercial or hospital environment.
Voltage dips, short-term interruptions and voltage variations in accordance with	< 5% U_T (> 95% dip in U_T for ½ period) 40% U_T (60% dip in U_T for 5 periods) 70% U_T (30% dip in U_T for 25 periods) < 5% U_T (> 95% dip in U_T for 5 seconds)	< 5% U_T (> 95% dip in U_T for ½ period) 40% U_T (60% dip in U_T for 5 periods) 70% U_T (30% dip in U_T for 25 periods) < 5% U_T (> 95% dip in U_T for 5 seconds)	The supply voltage quality must correspond to that of a typical commercial or hospital environment. If the user of the Soleo SonoStim/Soneo Galva requires continued operation, even in the case of interruptions in the power supply, it is recommended that the Soleo SonoStim/Soneo Galva be powered from an uninterruptible power supply or a battery.
Magnetic field of the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at mains frequency should have the typical values found in a business or hospital environment.
Note: U_T is the mains AC voltage before application of the test level.			

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

Main features of the Soleo SonoStim / Soleo Galva (only electrical stimulation) are: trouble-free delivery of electrical stimulation and ultrasound, in conjunction with the vacuum unit and vacuum with the set parameters and trouble-free operation of all functions.

Guidelines and manufacturer's declaration - electromagnetic immunity			
The Soleo SonoStim/Soleo Galva device is designed for operation in the electromagnetic environment specified below. The customer or the user of the Soleo SonoStim/Soneo Galva device should ensure that it is used in such an environment.			
Immunity tests	IEC 60601 – Test Level	Compliance level	Electromagnetic environment - Guidelines
Conducted RF disturbance variables in accordance with IEC 61000-4-6 Radiated RF disturbance variables in accordance with IEC 61000-4-3	3 V_{RMS} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{RMS} 150 kHz to 80 MHz 10 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should not be used any closer to the Soleo SonoStim/Soneo Galva, including cables, than the recommended separation distance calculated using the equation relevant for the transmission frequency. Recommended separation distance: $d = 1.17 \sqrt{P}$ $d = 0.35 \sqrt{P}$ for 80MHz to 800 MHz $d = 0.7 \sqrt{P}$ for 800 MHz to 2.5 GHz where P is the power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). In accordance with an on-site investigation[a] , for all frequencies, the field strength of a stationary radio transmitter should be less than the coincidence level[b]. Errors may occur in the vicinity of devices marked with the following symbol: 
NOTE 1: At 80 Hz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a]The field strengths of fixed transmitters e.g. base stations of mobile telephones and mobile radio devices, amateur radio, AM and FM radio broadcasting, and TV broadcasting cannot be accurately predicted. In order to assess the electromagnetic environment with regard to fixed RF transmitters, a study of the electromagnetic phenomena at the location should be considered. If the measured field strength in the location in which the Soleo SonoStim/Soleo Galva device is used exceeds the above compliance level, the Soleo SonoStim/Soleo Galva device must be monitored to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as the realignment or relocation of the Soleo SonoStim/Soleo Galva device.

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

Recommended separation distances between portable and mobile RF communications equipment and the Soleo SonoStim/Soleo Galva device

The Soleo SonoStim/Soleo Galva device is intended for use in an electromagnetic environment in which RF disturbances are controlled. The customer or the user of the Soleo SonoStim/Soleo Galva device can thus help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Soleo SonoStim/Soleo Galva device – depending on the output power of the communications equipment as indicated below.

Rated power of the transmitter W	Separation distance depending on the frequency of transmitter m		
	150 KHz to 80 MHz $d = 1.17 \sqrt{P}$	80–800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.7
10	3.70	1.11	2.21
100	11.67	3.5	7.0

For transmitters for which the maximum nominal output is not specified in the above table, the recommended separation distance d in metres (m) can be determined using the equation given for the corresponding column, where P is the maximum rated power of the transmitter in watts (W) in accordance with the manufacturer of the transmitter.
NOTE 1: At 80 and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Soleo*line*

Instructions for Use

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