

Instructions for use

Gymna

Acure series



CE 0344



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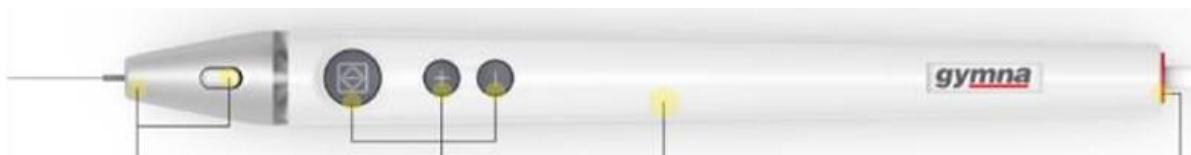
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Symbols on the equipment and accessories

	Manufacturer
 YYYY-MM	Date of manufacturing and country of origin
 0344	CE mark with identification number of the notified body
 SN	Serial number
	Do not dispose of this electrical equipment in domestic waste!
	Caution
	Applied part type BF
	Class II
	Read the instructions for use before using the Acure device and whenever you are unsure about how to use the Acure device correctly.
	USB connection. Attention: put the USB cover cap back on the USB connector after each use.
	Power on / stand-by switch
	Remove battery before equipment disposal
	DC input
	AC-DC adaptor

Symbols on the hand piece (detachable component)



	Start or Stop of action (combined in toggle function)
	Increase the intensity by one step
	Decrease the intensity by one step

General symbols in the manual

	Warning or important information.
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Abbreviations in the manual

General

EMC ElectroMagnetic Compatibility

ESD ElectroStatic Discharge

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1 SAFETY

1.1 General

1.1.1 Intended use

The gymna Acure device series is intended for the application of Percutaneous Electrolysis, a progressive application technique in the field of electrotherapy.

A galvanic current is applied to the patient by the use of an acupuncture needle electrode, functioning as the cathode (negative electrode) in the electrical circuit.

For the anode (positive electrode) a large size rectangular shaped silicone rubber electrode is used, together with a well moistened sponge making direct contact to the skin surface.

It is important that the silicone rubber electrode and well moistened sponge are placed at short distance with respect to the pathological area to be treated.

Making use of the fixation strap allows short interpolar distances, independently of the treatment location.

The needle puncture must be inserted under echography guidance in order to apply the current exclusively to the degenerated/damaged tissue.

The application produces an electrochemical reaction (electrolysis) in the treated area and initiates a local inflammatory response necessary for tissue regeneration leading to tissue recovery.

Galvanic Electrolysis is a possible therapy technique intended for patients (preferred age from 18) suffering from:

- Chronical tendinopathies
- Soft tissue injuries (muscle, tendons, ligaments, fasciae)
- Trigger points (release of trigger point tension by applying dry needling)

The intended users are physiotherapists and medical degree doctors who have the legal competence in the country where they practice to perform this treatment.

The gymna Acure device series may only be operated by health care professionals mentioned above;

- after thoroughly reading and understanding the content of these instructions for use
- after being trained and instructed in the application of the Galvanic Electrolysis technique
- when qualified in applying "ultrasound imaging" specific for musculoskeletal structures, to obtain:
 - precise localization of the pathologic area to be treated
 - correct penetration and verification of the acupuncture needle position
 - correct follow up during the treatment application
 - verification that the electrolysis effect covers the whole intended pathologic area becoming hyperechogenic

The user is responsible for complying with all applicable laws and regulations including applicable safety regulations related to the correct use and maintenance of the gymna Acure device. The gymna Acure device for the application of Percutaneous Electrolysis is designed to be used in the framework of professional healthcare activities in environments like surgeries in residential area, physiotherapists practice, sport facilities, hospitals excluding OR and shielded rooms for MRI.

1.1.2 Principle of Operation

The device consists of a table top control unit with a mains powered external D.C. power supply, a hand piece to manipulate the needle and a return electrode. The control unit contains a battery to allow operation without external power supply. The power supply is medical grade so it can remain connected during a treatment. It is used to charge the battery and to operate the device, e.g. when the battery is low.

Apart from the socket for the power supply there is a socket for the return electrode lead wire and one for the cable of the hand piece with the needle. A holder for that on the control unit is provided, constructed in such a way that the operator is forced to dispose of the used needle before putting the hand piece in it.

A colour display with touch screen provides the graphical user interface of the embedded software. When there is no current flowing it can be set by the operator to deliver the required level of current with a linear ramp up and ramp down during an adjustable time, or the current level can be adjusted via the touch screen or with up and down buttons on the hand piece.

The software controls a D.C. current source that has enough compliance to deliver the required current even with a high resistance of the patient's skin. When the return electrode is attached to the patient and the needle is inserted, an A.C. voltage source delivers a minute current with a frequency beyond 20 kHz. This is detected and enables the start of the current pulse.

The operator attaches the return electrode to the patient near the area where the intervention will be done. A sterile needle is clamped with its handle into the front of the hand piece and pulled out of its packaging. With the transducer of the ultrasound imaging equipment the injury is located and the needle inserted until its tip is in the pathologic area. Pressing the start/stop button on the hand piece starts the D.C. current. Electrolysis will take place when sufficient charge is delivered and the water molecules will be split in hydrogen and hydroxil ions. This is visualized as a full hyperechogenic zone by the ultrasound imaging equipment. This is the signal to stop the current by pressing the start/stop button again. In case it is uncomfortable for the patient the current can be stopped or reduced by the decrement button on the hand piece. Or, when the pain tolerance of the patient is higher, it can be increased by the increment button on the hand piece. So there is no need to let go of the hand piece during the procedure. The device records the amount of the delivered charge which is usually about 30 mC. The user is first made attentive when this value is reached while a warning is issued when this value is seriously exceeded.

For dry needling of trigger points the maximum current is limited to 1 mA. The ultrasound imaging equipment is not needed for this application. A short tiny muscle twitch is observed via the needle when the trigger point tension releases. The A.C. auxiliary current is not used.

The user can log the recordings of current level, duration and applied charge per session in a patient database together with details on the disorder and progress of the treatment. This will be a great source of data for clinical follow up studies (after anonymizing it of course).

1.2 Safety instructions

1.2.1 General



- Only qualified people who are trained in the application of the therapy may use the device.
- For optimum treatment, an anamnesis must first be performed. Based on the findings, a treatment plan with objectives will be formulated. Follow the treatment plan during the therapy. This will limit possible risks, related to the treatment, to a minimum.
- Only treat patients with electrical implants (pacemaker) after obtaining medical advice.
- Only a technician authorized by GymnaUniphy N.V. may open the equipment or the accessories.
- Always keep these user instructions with the equipment.
- Follow the instructions and directions in these user instructions.
- Only make use of standard and optional accessories listed in these instructions for use.
- When the mains adapter is used then do not place the Acure or other equipment in such a way the adapter cannot be easily removed from the mains outlet socket.
- Place the equipment on a horizontal and stable surface.
- Keep the ventilation openings at the bottom and rear of the equipment free.
- Do not place the equipment in the sun or above a heat source.
- Do not place any objects on the equipment.
- Do not use the equipment in a damp area.
- Do not let any liquid flow into the equipment.
- Do not sterilize the equipment or accessories.
- For cleaning and disinfecting the equipment and accessories: see § 5.2
- The Medical Devices Directive 93/42/EEG from the European Commission requires devices to be safe during their service life. Therefore, it is strongly recommended to perform at least each two years a technical safety inspection. See § 5.1.1

1.2.2 Electrical safety



- Only use the equipment in an area with facilities that meet the applicable legal regulations.
- It is strictly forbidden using any external power supply or battery pack that is not specified in this user manual. See § 7.6
- Connect the medical grade power supply to an outlet that meets the locally applicable requirements for medical areas. The device is Class II.
- The output connectors are exclusively for use with the supplied cable of the hand piece and the 1-pole patient cable.

1.2.3 Prevention of explosion



- Do not use the equipment in an area where combustible gases or vapours are present.
- Switch off the device before disinfecting or decontaminating the room where it is placed.
- Switch off the equipment when it is not used.

1.2.4 Electromagnetic compatibility



- Medical electrical equipment requires special precautions for Electro Magnetic Compatibility (EMC). Follow the instructions for the installation of the equipment. See § 2
- Electromagnetic disturbances may cause instability in the output current causing it to exceed the specified tolerances. See the EMC guidance in § 8.1.1 for detailed information.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. This concerns in particular surgical R.F., shortwave, and microwave equipment.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Acure device, including the cables. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories and cables other than those specified or provided by GymnaUniphy, see § 7.6, could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

1.2.5 Therapy application



- Simultaneous connection of a patient to a high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the Acure device.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- It is strictly recommended only to do needling on one body half in one treatment
- Needle puncture in hemiplegic patients on the affected side also is strictly advised against
- It is advised not to exceed the current density of 0.25 mA/cm^2 for galvanic currents. Higher intensities may cause skin irritation or skin burns, specific under the anode electrode.
- Use the large size rectangular silicone rubber electrode as anode (positive electrode) with a well-moistened sponge making direct contact to the skin surface.
- Do not use a self-adhesive electrode as the positive electrode because skin burns are highly likely to occur, independent of the electrode size.
- Use only disposable sterile acupuncture needles with the correct properties. See § 7.3
- Immediately remove and dispose the acupuncture needle after use in a safe way. Place the hand piece always in the holder when it is not used.
- Check the hand piece, electrode cables and the electrodes at least once a month. Check whether the insulation is still intact.
- Replace the hand piece if the cable or the connector are damaged. See § 5
- Check the conductivity of the silicone rubber electrode at least once a week. See § 4.7.1

1.3 Contraindications

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

1.3.1 Contraindications list

- High fever
- Pacemakers
- Heart disease, rhythm disorder
- Severe cardiovascular problems
- Neuro sensory disorders
- Psychological problems
- Prostheses
- Superficially implanted materials
- Cancer with tumor metastasis
- Generalized tuberculosis
- Skin lesions
- Skin infections
- Thrombosis, thrombophlebitis
- Bleeding tissue and increased risk to hemorrhage
- Varices
- Pregnancy
- Menses
- Epiphyseal disc (children)
- Epilepsy (avoid neck electrode positions)
- Electrode positions near sinus caroticus
- Eyes and testis
- Caution at areas close to the endocrine glands
- Fibromyalgia
- Hypersensitivity
- Patients with needle phobia
- Precautions when facing excessive autonomic responses: During the first treatment session, observe whether the patient has an allergic response to galvanism, or if there are excessive general or localized autonomic responses.
- Needle puncture in the affected limb in post-mastectomy patients

1.3.2 Adverse side effects

- Bleeding in the area of needle insertion
- Reddening of the skin surface at the treatment site
- Pain at tolerable level during and after the treatment
- Skin irritation beneath the anode electrodes

1.3.3 Conformity with directives

The Acure device series complies with the requirements of the following directives:

- 93/42/EEC on medical devices (MDD)
- 2006/66/EC on batteries and accumulators (BAD)
- 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2)
- 2012/19/EU on waste electrical and electronic equipment (WEEE)
- 2014/53/EU on radio equipment (RED)

The device contains no human or animal tissue, no medicinal substances, no blood or blood products from human or animal origin, no latex, no DHEP, and no radioactive substances.

It is not intended to administer or transport body fluids.

1.3.4 Liability

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

- an incorrect diagnosis is made
- the user instructions are wrongly interpreted or ignored
- the equipment or the accessories are used incorrectly
- accessories are used other than specified in the instructions for use
- if an external power supply is used other than specified in the instructions for use
- the equipment is badly maintained
- maintenance or repairs are performed by people or organizations that are not authorized by GymnaUniphy.

Neither the manufacturer nor the local GymnaUniphy dealer can be held liable, in any way whatsoever, for the transfer of infections via the needles or any other accessories.

2 INSTALLATION

2.1 Receipt

Procedure

1. Check that the equipment did not get damaged during transport.
2. Check that the accessories are intact and complete. See § 7.6
3. Inform your supplier of any damage or defects by no later than within 3 working days after receipt. Report the damage by telephone, fax, e-mail or letter.

Warning:



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

2.2 Placement of the device

Procedure

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

Warning:



- Keep the ventilation openings at the bottom and rear of the equipment free.
- Do not place the equipment in the sun or above a heat source.
- Do not use the equipment in a wet area.

2.3 Connection to the mains supply

Connect the device to the supply mains with the standard delivered external medical grade power supply. One can use of a power adaptor socket when necessary. See § 7.6
Connect to a mains outlet that meets the locally applicable requirements for medical areas. The power supply is suited for a nominal mains voltage of 100-240 V / 50-60 Hz.

2.4 Mains power or battery operation

The device has an internal Li-ion battery. It is strictly recommended to fully charge the battery before taking into use. The device can operate on the supply mains or on the battery while performing the treatment.

The device has a battery management system that controls charging when connected to the supply mains and warns when the battery gets exhausted.

The actual condition of the battery is visualized in the right upper corner of the LCD-screen. Either;

	Device is connected to the supply mains. (<i>lightning sign in battery</i>) The treatment will be performed while making use of the mains power. The battery management system takes care of recharging the battery.
	Device is disconnected from the supply mains. The treatment will be performed running on the battery. The battery management system takes care that the treatment can only start if the battery is sufficiently charged. (level >10 %)
	The remaining battery charge is too low to start a treatment (level ≤ 10 %)

There's an extra indicator LED, near the Power On button at the backside of the device, if for some reason the condition of the battery is not visible on the LCD.

No light	Device is powered Off
White full	Device is powered On. But not connected to the mains power
Green glowing	Device battery is charging
Green full	Device battery is fully charged 100%
Orange full	Device battery level is < 10%

Attention:

- It is recommended to power the device by the supply mains whenever possible. This will increase the service life of the battery.

2.5 Touchscreen application / save energy modes

The device has a touchscreen. All settings and treatment possibilities can be selected by touching the applicable button.

Attention:

- To save energy this device goes in sleep modes. Bring the device out of sleep modes by just touching the touchscreen. (See § 4.7.1 standby time)
- If there's no response or if the display does not light up, connect the device to the medical grade power supply and switch on the device via the Power On button at the backside.

2.6 A functional device test is automatically performed

- every time the device is switched on with the Power On button

If the self-test was successfully, the device enters the application screen.

If an error was encountered, an error message appears to guide the user on how to proceed.

2.7 Check proper functioning

Observe whether the device is operating normally, especially when other electrical or electronic devices or transmitters are operating nearby. In case the behavior is erratic, try reorienting or repositioning the device to mitigate possible electromagnetic disturbances. See also §8.1.1.

2.8 Shutting down procedure

Press the stop button when the equipment is still generating current.

Discard the needle in the safety container when still in the hand piece.

Press the power off button at the back above the socket for the adapter.

Remove the adapter from the mains outlet socket if charging the battery is not necessary.

3 DESCRIPTION OF THE EQUIPMENT

3.1 Acure device series with standard accessories



- Acure device series
- Hand piece (wired including 5 pole male connector)
- Hand piece holder
During mounting is a mirroring positioning possible, specific for left or right handed users
- external medical grade power supply
- set of power adaptor sockets
- 1-pole patient cable; 4mm M to 2 mm F
- rubber electrode brace, size 6cm x 8cm ; 2 mm
- sponge for electrode brace, size 6cm x 8cm (2x)
- elastic fixation strap, size 60 cm (2x)
- rechargeable battery pack (lithium ion)
- quick start guide
- instructions for use (on USB-stick)
- safety instructions (multi language)

3.2 Components of the Acure device series

Front view:

1. full colour 7 inch display with capacitive touchscreen



Lift side: (no connections)

Right side:

2. connection for the hand piece cable
3. 4 mm banana plug for the 1-pole patient cable (rubber electrode, sponge)



Backside:

4. Power-on device switch.
5. LED indicator. Shows the Power conditions, valuable when the device display is not light up. See § 2.4
6. Inlet connector for external medical grade power supply
7. USB connector (place cover after use)



Warnings:



- Only the use of USB-sticks is allowed!
- Do not connect USB mass storage devices such as USB powered hard disks.
- Do not connect externally powered USB devices or other information technology equipment as this can adversely affect the safety of the patient.

8. Mounting grip for hand piece holder
9. Hand piece holder

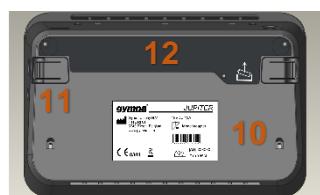
Warnings:



- Store hand piece safely after each use
- Acupuncture needle must be removed from the hand piece before storage

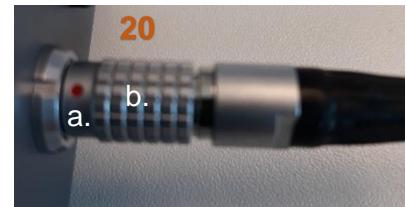
Bottom:

10. Device type shield
11. Inclination feet to improve viewing angle (gives 10% extra angle)
12. Battery pack lid (See §8.3 for replacement & disposal)



Hand piece: (detachable component)

13. Acupuncture needle entrance. See § 7.3 for specifications of the allowed needles
14. Needle fixation/release mechanism knob
15. Multi-colour ring indicating the current state of the device. See § 4.4
16. Start/stop button to perform the treatment
17.  button to increase intensity
18.  button to decrease intensity
19. Hand piece cable
20. Handpiece connector with a lock/unlock function
 - a. red marker must be at the top side
 - b. only push or pull gently on the grip part



3.3 Controls on the touchscreen & hand piece

All device settings and treatment possibilities can be selected by touching the applicable button on the touchscreen. See § 4

The hand piece contains duplicated push buttons and acts as wired remote control to perform the treatment safely. See § 4

Warnings:



- If the touchscreen does not respond correctly, see § 6.1
- If the hand piece does not respond correctly, see § 6.1 and § 4.7.1 hand piece

3.4 Display layout

The display is divided in three vertical panes



left: the menu pane

- contains the direct application buttons, the patient database entry, etc.
- press the desired button to make the selection; scroll vertically for more choices
- the selected button is indicated in full-colour with a pointer

menu pane buttons

enabled	selected	functionality
		Direct treatment application. Will run in μA-level according corresponding parameters. See §4.1.1, §4.1.2. For parameter ranges see § 7.2.3
		Direct treatment application. Will run in mA-level according corresponding parameters. see § 4.1.3; For parameter ranges see § 7.2.3
		Direct treatment application for trigger points treatment. Will run in <u>limited mA-level</u> . See § 4.1.4; For parameter ranges see § 7.2.3
		Body area. Allows guided selections based on anatomic locations and corresponding treatment applications. See § 4.2.1
		Patient database. Allows patients management and storage of the applied treatment application and link it to a patient. See § 4.6
		System settings menu. Allows personalization of the device and displays device info. See § 4.7.1
		Contra indications list. See § 1.3 and § 4.2.3. Treatments should not be given to patients with the listed conditions.
		Anatomical library. See § 4.2.2. Functions as a medical encyclopedia.

right: the option pane

- contains the battery level and shows if the device is connected to the supply mains. This information is kept visible at the top of the option pane.
- contains supporting buttons related to the choice made on the left side in the menu pane. in this example all related to the μ A choice;
- press the desired button to make the selection; scroll vertically for more choices
- the selected button is indicated in full white-colour with a pointer.

middle: the central pane

- the central pane shows the requested information, and is the outcome of selections previously made in the left and right panel;
- in some cases this central pane can contain multiple pages you can navigate through (see for example § 4.6)
- For example in a treatment parameter screen the central pane shows a therapy output window (a dark blue coloured field) containing the effective treatment time together with the automatically recorded administered electrical charge.

Different status of keys and buttons

Keys and buttons can behave in different modes

- enabled modes: keys or buttons can be selected
- disabled modes: keys or buttons are momentary not selectable
they have a high gradient transparency in the colour
- selected modes: you have already selected these keys or buttons

4 OPERATION

Attention:



The treatment applications and pre-configured settings are suggestions based on the experiences of medical experts or physiotherapists. They are indicative and can be used as an example, but can also be adjusted to one's own expertise.

This is at the risk of the operator!

4.1 Therapy selection via therapy buttons

4.1.1 Therapy selected in μA - level and in standard modes

In the option pane is already chosen for standard modes  (= traditional parameter design)

Explanation of the central pane:



1. therapy name or application name
2. message rule: contains a clear symbol + explanatory content

Type	Icon	Description
Information		Guideline for the user to perform the next step
Advice Attention		Suggests best way to perform an action Make user attentive while activity can continue
Warning		Indicates immediate action from the user is required before continuing

adjustable parameters:

3. the intensity in μA . For the range § 7.2.3

- the  and  intensity buttons are disabled
- Press the intensity parameter field if you want to adapt the step size of the intensity
- Select one of the defined step sizes
- Sub-window closes automatic and new step size is shown in the intensity parameter field



4. the treatment time in minutes: seconds
push on the enabled  and  buttons to change the timer settings
keep the button pressed to change parameter with higher velocity
5. Pushbutton to confirm the correctness of the pre-adjusted parameters
therapy output window: (still zero values because treatment is not started yet)
6. the effective treatment time in minutes:seconds
7. the administered electrical charge Q in milli-Coulomb (mC)

4.1.1.1 Performing the therapy in standard modes

Below are the necessary actions described that need to be taken in the correct order on both the device and the hand piece to allow performing the treatment application.

For the visual colour feedback of the illuminated ring on the hand piece see § 4.4

Set a therapy

Procedure:

1. Press the intensity parameter field if you want to adapt the step size of the intensity
2. Change treatment time if necessary with the enabled  and  buttons
3. Push the confirm button  if you agree with the intensity step size and treatment time
4. This confirmation  enables the Start button on the hand piece. See  content.
5. *The green illuminated ring on the hand piece flashes very briefly.*



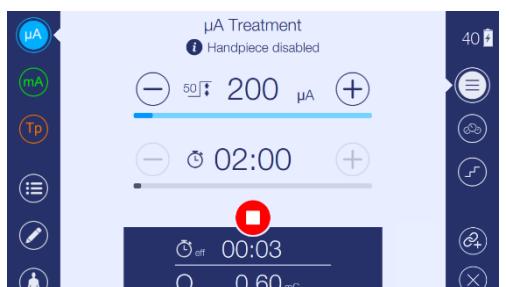
Start and perform a therapy

Procedure:

The hand piece and its buttons function as a wired remote control.

1. Press the Start button  on the hand piece.
2. The intensity on the patient will be equal to the pre-adjusted intensity step size value at the treatment start. (e.g. 200 μA)
3. The effective treatment timer starts running.

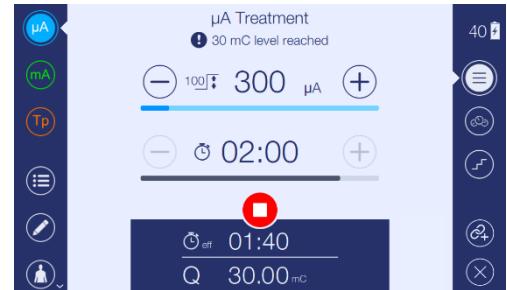
The green illuminated ring on the hand piece lights up continuously.



4. From now on are the  and  buttons on both the hand piece and display enabled to adjust the intensity.
5. Every single push on the  or  changes the intensity by one step, and is made visible on the hand piece by a *short blinking of the green illuminated ring*.

The output window and value bars:

1. *The intensity value bar shows the actual intensity value as a percentage of the maximum allowed intensity value. (e.g. 300/2500)*
2. During the therapy increases the effective treatment timer every second while the initial preset treatment timer stays unaltered.
3. *The time value bar shows the effective treatment time as a percentage of the set treatment time. (e.g. 1:40/2:00)*
4. The administered electrical charge Q in milli-Coulomb (mC) is updated once per second.



Attention:

There will be cases that for a certain treatment the charge to administer is more or less predictable. In that case will the user be advised via a message on the touchscreen (e.g.  30 mC level reached).

Additional the continuous green coloured illuminated ring on the hand piece will shortly interrupt by an orange flashing light.

Nevertheless, the user can still decide to proceed the treatment based on the evaluation of the echographic image.

Stop the therapy

Procedure:

1. Once the user decides the administered electrical charge is sufficient, based on the evaluation of the echographic image, the treatment must be stopped.
2. Press the Start/Stop button on the hand piece . The intensity will fade out to zero.
3. All parameter settings are retained.
4. A Stop trigger on the hand piece can be seen as a kind of pause. Treatment can be continued by pressing again the start button on the hand piece.

Attention:

5. Pressing the stop button  on the touchscreen ends the treatment. The parameters have to be confirmed again on the touchscreen before the treatment can be resumed.
6. This confirmation  enables the Start/Stop button on the hand piece again.

4.1.1.2 Option pane buttons in a therapy screen

Enabled	selected	functionality
		<p>Therapy screen is in standard modes in traditional parameter design. See § 4.1.1 and § 4.1.3.1 and § 4.1.4.1</p> <p><u>Specific behaviour:</u> The intensity starts from 0 and there's no preset intensity value target. The intensity must be increased manual with the  button. For every press increases the intensity only one stepsize. Press  button to decrease the intensity with one stepsize.</p>
		<p>Therapy screen is in advanced modes in dashboard parameter design. See § 4.1.2 and § 4.1.3.2 and § 4.1.4.2</p> <p><u>Specific behaviour:</u> The treatment intensity will increase (fade-in) automatic to the preset intensity value according to a chosen ramp curve once the start button on the handpiece is pressed.</p>
		Show the applied treatment in a graphical representation See § 4.1.1.3
		Further continue the treatment session with a next sequence See § 4.1.1.5
		Close and save the performed treatment application See § 4.1.1.4

4.1.1.3 Show the applied treatment in a graphical representation

Procedure:

- Once the treatment application is stopped it is possible to view it again by selecting the enabled  button in the options pane.
- The line graph represents the performed treatment plotting the current amplitude versus time.
- The treatment results are more detailed shown in in the lower part of the screen.



4.1.1.4 Close and possibly save the performed treatment application

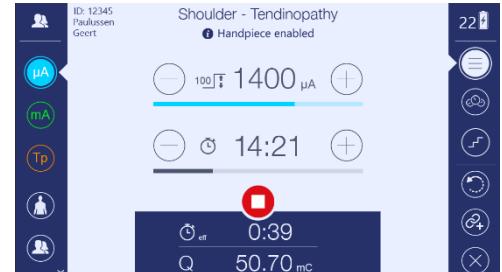
Attention:

Only when this finished treatment session is linked to a selected patient from the patient database it can be saved to the selected patient. The patient identity is visible in the left upper corner.

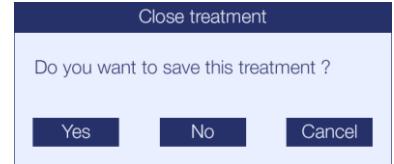
See §4.6 for the behavior of the patient database.

Procedure if a patient is selected:

1. Once the treatment is finished or stopped is it possible to store the applied therapy under the selected patient.
2. Press the close button  in the option pane

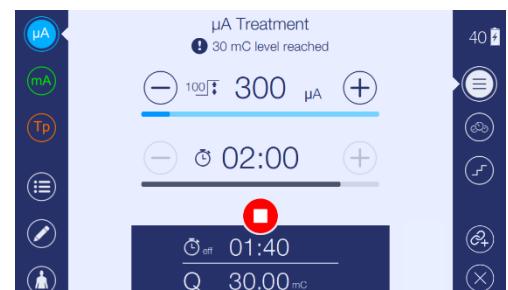


3. The following message box appears
 - Yes: applied treatment is saved behind the selected patient
 - No: the performed treatment session closes and actual parameter screen gets updated with the new kept defaults
 - Cancel: Pop up question box disappears. Actual parameter screen is kept unchanged
4. Be aware that the link to the selected patient is lost from the moment that Yes or No is selected.



Procedure if no patient is selected:

1. Once the treatment is finished or stopped press the close button  in the option pane
2. The performed treatment session closes and actual parameter screen gets updated with the new kept defaults



4.1.1.5 Continue the treatment session with a next sequence

In many cases ends the treatment session with 'Dry needling' to release pathologic related triggerpoints.

By a selection on the next sequence button  the software knows that the next application choice (e.g. ) will become a subpart of the whole treatment session.

In this case becomes a possible pop-up question box to save a sequential treatment session postponed to a later moment.

The benefit is that in just one saving action, all individual sequences gets saved.

Attention:

The next sequence button is not shown if the user has deactivated the use of the "Patient database" in the System settings.

4.1.1.6 Choosing another treatment application in the left menu pane before closing the session

When another treatment application becomes chosen while the previous performed treatment session isn't closed yet, the device behaves in a similar way as if the 'close button' in the option pane is pushed, before the parameter screen of the new selected application opens. See § 4.1.1.4

4.1.2 Therapy selected in μ A- level and in advanced modes

In the option pane is already chosen for advanced modes  (=dashboard parameter design)

Specific behaviour in advanced modes:

- The treatment intensity will increase (fade-in) automatic to the preset intensity value according to a chosen ramp curve once the start button on the hand piece is pressed.

Explanation of the central pane:



1. therapy name or application name
2. message rule: contains a clear symbol + explanatory content

Type	Icon	Description
Information		Guideline for the user to perform the next step
Advice Attention		Suggests best way to perform an action Make user attentive while activity can continue
Warning		Indicates immediate action from the user is required before continuing

adjustable parameters:

3. the intensity circle shows the desired preset intensity value in the middle. The circle contains extra petals to get direct access to the other important parameters and shows the default values directly in the petals. Press a petal and make the desired readjustment. Screen part closes automatic and new value is shown in the petal. For the ranges see §7.2.3 The petal will open as follows:

- a. Step size settings



- b. Ramp curve settings
slow - medium - fast



- c. Preset Intensity settings



4. the treatment time in minutes: seconds

push on the enabled \ominus and \oplus buttons to change the timer settings
keep button pressed to change parameter with higher velocity

5. Pushbutton to confirm the correctness of the pre-adjusted parameters

therapy output window is split in: (*still zero values because treatment is not started yet*)

6. the effective treatment time in minutes:seconds
7. the administered electrical charge Q in milli-Coulomb (mC)

4.1.2.1 Performing the therapy in advanced modes

Beneath describes the necessary actions that need to be taken in correct order on both the device and the hand piece to allow performing the treatment application.

For the visual colour feedback of the illuminated ring on the hand piece see § 4.4

Set a therapy

Procedure:

1. Press on the corresponding petal to get direct access for changing the parameter values of:
 - a. Intensity step size
 - b. Ramp curve
 - c. Preset intensity as the target value
2. Change treatment time if necessary with the enabled  and  buttons
3. Push the confirm button  if you agree with all the presets.
4. This confirmation  enables the Start button on the hand piece. See  content.
5. *The green illuminated ring on the hand piece flashes very briefly.*



Start and perform a therapy

Procedure:

1. The hand piece and its buttons function as a wired remote control
2. Press the Start button  on the hand piece

Attention:

The intensity will increase (fade-in) automatic to its preset value from the moment that the Start button on the hand piece is pressed.

3. *During the fade-in time flashes the green illuminated ring on the hand piece, while it lights up continuously as soon as the preset intensity value is reached.*
4. From the moment that the Preset intensity value is reached can the intensity be fine-tuned with the enabled  and  buttons on either the hand piece or the touchscreen

5. Every single trigger on the  and  intensity buttons is noticeable via a short blinking of the green illuminated ring.

The output window and value bars:

6. The intensity value bar in a circle shows the actual intensity value as a percentage of the maximum allowed intensity value. (e.g. 550/2500)
7. During the therapy increases the effective treatment timer every second while the initial preset treatment timer stays unaltered.
8. The time value bar in a circle shows the effective treatment time as a percentage of the set treatment time. (e.g. 0:08/2:00)
9. Every second becomes the administered electrical charge Q in milli-Coulomb (mC) updated.



Attention:

There will be cases that for a certain treatment application the administering charge level is somehow nearly predictable. In that case will the user be made attentive via a message on the touchscreen (e.g.  30 mC level reached).

Additional the continuous green coloured illuminated ring on the hand piece will shortly interrupt by an orange flashing light.

Nevertheless, the user can still decide to proceed the application based on the evaluation of the echographic image.

Stop the therapy

Procedure:

1. Once the user agrees the administered electrical charge based on the evaluation of the echographic image, the treatment must be stopped.
2. Press the Stop button on the hand piece . The intensity will fade out to zero.
3. All parameter settings are retained.
4. A Stop trigger on the hand piece can be seen as a kind of pause. Treatment can be continued by pressing again the start button on the hand piece.

Attention:

The intensity will increase (fade-in) automatic to its preset value from the moment that the Start button on the hand piece is pressed.

5. Pressing the stop button  on the touchscreen ends the treatment. The parameters have to be confirmed again on the touchscreen before the treatment can be resumed.
6. This confirmation  enables the Start/Stop button on the hand piece again.

Other option pane buttons in the advanced therapy screen

The behaviour of these buttons is exactly the same as for the standard therapy screen

-  Show the applied treatment in a graphical representation See § 4.1.1.3
-  Further continue the treatment session with a next sequence See § 4.1.1.5
-  Save and close the performed treatment application See § 4.1.1.4

4.1.3 Treatment applications in mA –range

4.1.3.1 Performing the therapy in standard modes

The behaviour in mA-level is exactly the same as explained for μ A-level. See § 4.1.1

The only difference is: the set Intensity range. See § 7.2.3

4.1.3.2 Performing the therapy in advanced modes

The behaviour in mA-level is exactly the same as explained for μ A-level. See § 4.1.2

See § 7.2.3 for all different parameter settings.

4.1.4 Treatment applications in Trigger points

4.1.4.1 Performing the therapy in standard modes

The behaviour for trigger points is mainly the same as explained for μ A-level. See § 4.1.1.1

The main differences are:

- the set Intensity range limit
- there is no calculation of the administered electrical charge Q
- the detection on a closed patient circuit is inactive while performing trigger points!

See § 7.2.3 for all different parameter settings.

4.1.4.2 Performing the therapy in advanced modes

The behaviour for trigger points is mainly the same as explained for μ A-level. See § 4.1.2

The main differences are:

- the set Intensity range limit
- the detection on a closed patient circuit is inactive while performing trigger points!
- there is no ramp curve setting
- there is no calculation of the administered electrical charge Q

See § 7.2.3 for all different parameter settings.



4.2 Other therapy selections besides the direct therapy keys

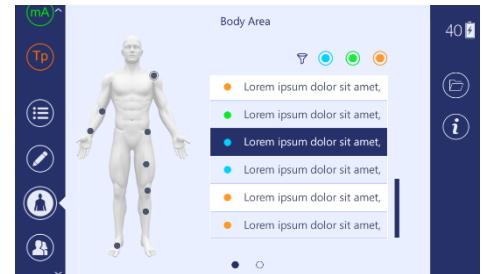
Aside of using the direct therapy keys as , ,  you can also select a therapy via another menu entrie selectable in the left menu pane.

4.2.1 Therapy selection via Body Area

4.2.1.1 Load a protocol with preconfigured settings via Body area

Procedure

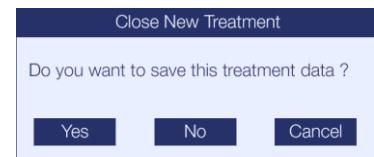
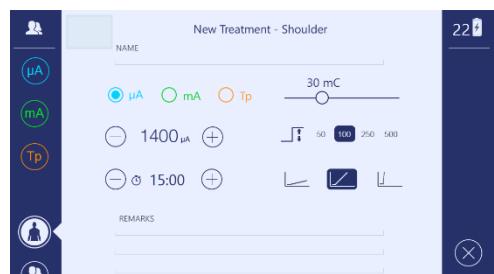
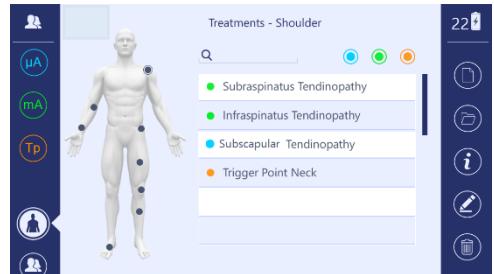
1. Press the Body Area button
2. Press the dot corresponding to the anatomical location you want to choose an application from
3. In the example on the right side is already chosen for an existing treatment application at the Shoulder
4. Press the load button  to open the corresponding parameter screen with the preconfigured settings
5. From here on the treatment can be applied



4.2.1.2 Create an own settings application via Body Area

Procedure

1. Press the Body area button
2. Press the dot corresponding to the anatomical location you want to choose an application from
3. When the list does not contain yet the desired treatment application it is possible to create a new own settings application.
4. Select the new button  to create a new application
5. Enter a name for the new application
6. Make the desired parameter settings
7. Press the close button  to leave the screen
8. A question box appears to save the created treatment application
9. Once saved this created application becomes added in the corresponding list
10. From now on it can be selected as an own settings application



4.2.2 Anatomical library

The library contains anatomical images and clinical information of the musculoskeletal system.

You can't access the library during the time that the treatment is applied.

Procedure

1. Press the Anatomical library button in the menu pane
2. Select the body part you want to display information of and choose an item from the list
 - if necessary scroll vertically in the list
 - or follow the on screen options to select the desired item
3. The anatomical information is displayed



4.2.3 Contra Indications list

All contra indications are listed behind this button.

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

Additional they are also listed in this instructions for use. See § 1.3

4.3 Placing and connecting the accessories

warning:



- Be sure that before you start treatments you completely understand everything explained in § 1.1.1

Make always use of an echography-imaging device to identify the injury and to define the precise location of the pathologic area. Disinfect the skin surface at the pathologic area.

Once the treatment location is defined you need to place the surface electrode & sponge as close as possible to the pathologic zone.

Connect the easy fix rubber electrode and sponge to the 1-pole patient cable which functions as the positive electrode in the electrical circuit. See § 4.3.1 for preparations.

Verify that the accessories are correctly connected to the device.

warning:



- Do not use adhesive electrodes because the applied current has a galvanic component that might cause skin etching and burns under the electrode area.

warning:



- Check the patient's reaction. Repeat this check regularly during the treatment.
- When with the guidance of the echography-imaging device, during the treatment is verified that the electrolysis effect covers the whole intended pathological area becoming hyperechogenic, the treatment must be stopped
- Remove the needle safely and take care of proper disposal
- Place the hand piece immediately in the hand piece holder after use
- Remove the rubber electrode & sponge from the patient
- For maintenance and cleaning see § 5

4.3.1 Prepare the easy fix rubber electrode & sponge

warning:



- Prior to initial use thoroughly rinse the sponge pads in warm tap water to remove the impregnating agent.
- Moisten the sponges thoroughly with water. In case of poor conduction, use water with a saline solution to improve the conductivity of the sponges.

Procedure

1. Fixate the wet sponge on the black side of the rubber electrode
2. Braid the fixation strap on the rubber electrode to get an easy fix combination
3. Fasten the easy fix combination with the wet sponge directly on the patients' skin.
4. It is advised to place it as close as possible to the treatment location to shorten the interpolar distance.

4.4 The coloured illuminated ring on the hand piece

The illuminated rings on the hand piece provides the following information.

The colours can be green (normal operation), orange (point to be attentive), red (warning) which points that an immediate response of the operator is required.

Indication light	Situation
no light	<ul style="list-style-type: none"> hand piece is NOT yet in operate modes or hand piece is no longer detected by the device <ul style="list-style-type: none"> no reactions on any key presses
green very briefly flashing	<ul style="list-style-type: none"> parameter settings are confirmed  hand piece is detected by the device and in operate modes <ul style="list-style-type: none"> waiting state for the Start button 
green blinking	<ul style="list-style-type: none"> hand piece operates in 'advanced modes' Start button  <ul style="list-style-type: none"> the light blinks <u>during the ramp up-time</u> until the Set intensity value is reached; or; the light blinks <u>during the ramp down-time</u> until the intensity is zero.
green continuous light	<ul style="list-style-type: none"> Hand piece is in operate modes <ul style="list-style-type: none"> patient is currently treated with the Set Intensity
green short interruption	<ul style="list-style-type: none"> Hand piece is in operate modes <ul style="list-style-type: none"> each press on the intensity up or intensity down button is short visible
green slowly switching by orange	<ul style="list-style-type: none"> Hand piece is in operate modes <ul style="list-style-type: none"> signal to be attentive for the applied charge, although user can decide to proceed the action without harm
orange continuous light	<ul style="list-style-type: none"> Hand piece is just stopped delivering the set intensity <ul style="list-style-type: none"> there is an open patient circuit detected during the therapy
green rapidly switching by orange	<p>Hand piece is in operate modes</p> <ul style="list-style-type: none"> signal to warn the user for the actual situation. It is advised to thoroughly check this situation, and finish the treatment as soon as possible.
red continuous light	<ul style="list-style-type: none"> hand piece is still detected by the device <ul style="list-style-type: none"> immediate response from operator required points to a failure modes hand piece buttons do NOT react when pressed!

4.5 Patient circuit not closed detection

There is an integrated detection to monitor if the electrical patient circuit is closed during the application.

The detection will work over the whole amplitude range in both μ A-level and in mA-level.

This detection is not activated for trigger point applications.

The user will be warned auditory and visually via a warning message on the display and a colour change of the illuminated ring in the hand piece.

- audio: see § 4.7.1 the sound parameter
- warning:  open patient circuit detected
- colour illuminated ring on hand piece: Orange continuous light. See § 4.4

4.6 Patient database

4.6.1 Administer the Patient database



This menu allows to administer the patient database.

Only via the patient database it is possibility to store, reopen or manage performed treatment applications which are directly linked to the patient.

Attention:



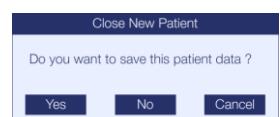
If you do not want to make use of the benefits of the Patient database you can hide the patient database button in the menu pane. Go to System settings menu and change the parameter; Patient database use to Off-mode See § 4.7.1

If the Patient database setting is switched to the Off-mode, then there is no possibility to save the performed treatment sessions at all.

Be aware that the Patient database button in the left menu pane will disappear as long as this setting is in Off-mode.

Procedure to create a new patient file:

1. Press the Patient database button in the menu pane
2. The patient list appears in alphabetic order
 - if necessary scroll vertically in the list
 - or perform a search to find the name
3. Select the new button to create a new patient file
4. Enter the New patient details
5. The mandatory fields * are on the first page
6. Swipe to the next page to enter more details
7. Press the close button to leave the screen
8. A question box appears to save the new patient file



Other keys in option pane when patients list shown:

Press if you want to read info of the selected patient

Press if you want to edit info of the selected patient

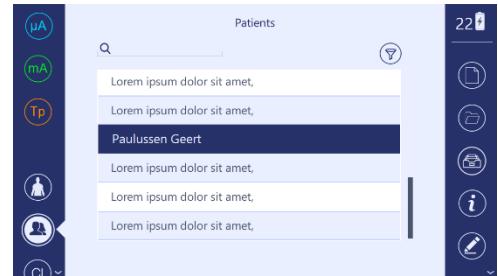
Press if you want to delete the selected patient



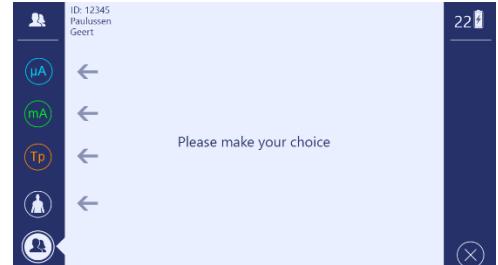
4.6.2 Load an existing therapy application via the patient database

Procedure

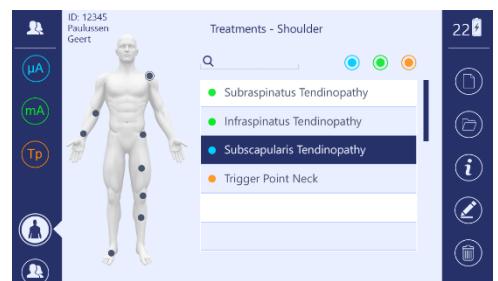
6. Press the Patient database button  in the menu pane
7. The patient list appears in alphabetic order
 - if necessary scroll vertically in the list
 - or perform a search  to find the name
8. Select the desired patient



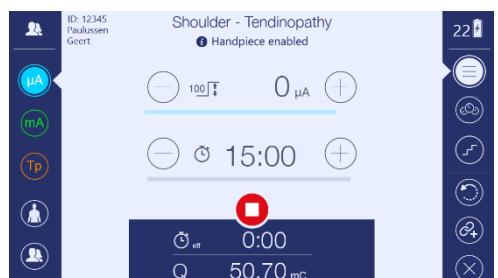
9. Select the load button  to choose a therapy application for the selected patient
10. A new screen appears from which you can select a new therapy application for the selected patient
11. Patient ID is visible in left upper corner
12. Choose one of the direct therapy keys or make a selection via the Body area entry



13. In the example on the right side is already chosen for an existing treatment application for the Shoulder via the Body area entry.



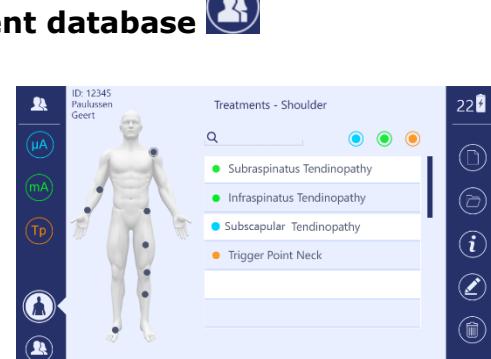
14. Press the load button  to open the corresponding parameter screen.
15. From here on the treatment can be applied



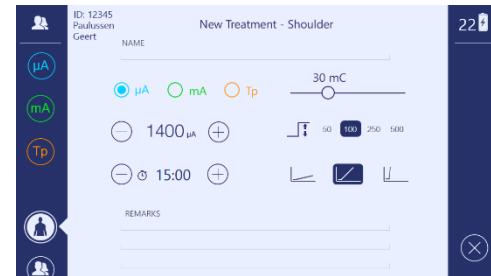
4.6.3 Create a new therapy application via the patient database

Procedure

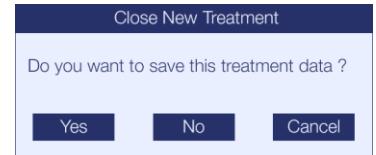
11. Perform the same steps 1 until 6 as explained in the above § 4.6.2
12. Make a selection via the Body area entry and choose the desired location. (e.g. shoulder)
13. When the list does not contain yet the desired treatment application it is possible to create a new one.



14. Select the new button  to create a new application
15. Enter a name for the new treatment application
16. Make the desired parameter settings
17. Press the close button 



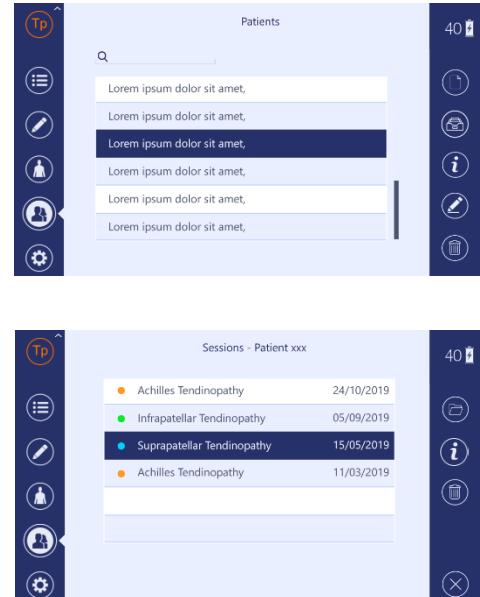
18. A question box appears to save the new created treatment application
19. Once saved this created application becomes added in the corresponding list
20. From now on it can be selected as a treatment application



4.6.4 Reselect an earlier saved treatment session via the patient database

Procedure

1. Press the Patient database button  in the menu pane
2. The patient list appears in alphabetic order
 - if necessary scroll vertically in the list
 - or perform a search  to find the name
3. Select the desired patient
4. Press the Sessions button 
5. A new screen appears showing all saved sessions of the selected patient with the most recent on top
6. Select the desired session
7. press the load button  to open the treatment parameter screen of the selected session



Session	Date
Achilles Tendinopathy	24/10/2019
Infrapatellar Tendinopathy	05/09/2019
Suprapatellar Tendinopathy	15/05/2019
Achilles Tendinopathy	11/03/2019

Other keys in option pane:

Press  if you want to view the results of the selected program

The graphical presentation of this saved treatment session appears

Press  if you want to delete the selected treatment session

Press  to close this screen. Automatic Go back to previous screen



4.7 System settings

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

Procedure

1. Press the System settings button  in the menu pane
2. Select the desired system setting in the detail pane
 - if necessary scroll vertically in the list
 - or follow the on screen options to select or re-adjust the setting
 - screen layout of individual setting can differ somehow

4.7.1 System settings description

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

Date & Time: Set the date and time.

Energy savings of the battery:

- Reduce brightness automatic:

the brightness of the color LCD will reduce to 30% after a delay of 5 minutes, counting from the moment that the device doesn't behave any longer in operating modes.

Just one click on the touchscreen brings the brightness back to the normal level

- Standby time:

User can select a delay time either 10 or 20 minutes before the device gets in sleep modes.

Just one click on the touchscreen brings the device back to full performance.

- Power Off automatic:

After a delay of 30 minutes, counting from the moment that the device doesn't behave any longer in operating modes.

Push the Power switch at the back to switch on the device again.

Keyboard: (QWERTY or AZERTY) . Set the desired keyboard for the editable screens

Sound: Activate or deactivate the sound settings for specific situations.

- they function as audio feedback to be attentive or as a warning.
- they are not meant to function as alarm signals!

Parameter	range	default
Volume	1 .. 5	3
Disabled key pressed	On ; Off	On
Confirmation sound	On ; Off	On
Start button pushed	On ; Off	On
Stop button pushed	On ; Off	On
Open patient circuit detected	On ; Off	On
mC thresholds reached	On ; Off	On

Patient database use: default in On-modes

If the Patient database setting is switched to the Off-modes, then there is no possibility to save the performed treatment sessions at all. And there is no "add-sequence button" available in the options pane.

Additional the Patient database button in the left menu pane will disappear as long as this setting is put in Off-modes.

System information: view the system information of the device.

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

Hand piece:

- **Hand piece information:** information of the hand piece. (act as read only screen)
- **Hand piece buttons**  ,  use default in On-modes
By default all 3 buttons on the hand piece are enabled.
But it is possible to switch this parameter to the Off-modes. In that case it is not possible to adjust the set intensity by using the  and  buttons on the hand piece.
- **Hand piece test:** allows to check the proper functionality of the buttons and the coloured illuminated ring
Procedure to **check the hand piece buttons**
 1. Select: Hand piece test
 2. Follow the on screen instructions
 3. Press one hand piece button at the time
 4. The guided hand piece picture shows directly the corresponding result of the test activityAttention: complete test performed of all 3 buttons, independent of certain system settings.

Procedure to check the coloured illuminated ring

- 1. Select: Illuminated ring test**
2. Follow the on screen instructions
3. The guided hand piece picture shows directly the corresponding result of the test activity

Rubber electrode test:

With this test is the condition of the silicone rubber electrode tested.

Follow the on screen instructions to perform the test.

Error history: view the total number of errors and details about the last 10 errors reported. Always have this information available when you contact the technical service department.

Screen saver info: allows entering your specific message that is displayed during a possibly screen saver phase.

You can set your own text. For example, a welcome message, your specific expertise or some practice based info.

Procedure

1. Select: Screen saver info.
2. Follow the on screen instructions
3. A keyboard will appear to enter the desired information
4. Save the information or leave it unchanged.

Access key code: Personalize your key code to get secured access to certain protected device functionality; as for example entering the Patient database.

The factory value of the key code = 1234

Restore the direct therapy programs: The content of the μ A, mA, Tp programs in the left menu pane are restored to the default settings of the manufacturer.

Restore to default factory settings

When this restore action is applied are all previous customized settings, and all data stored in the patient database immediate deleted, and is the device totally reset. The device will from now on operate with the default factory settings.

5 INSPECTIONS AND MAINTENANCE

5.1 Inspections

Component	Check	Frequency
<i>hand piece:</i> cable, connector	'damage' insulation intact PINS in connector	at least 1x per month
<i>hand piece:</i> buttons & coloured Illuminated ring	'functionality' see § 4.7.1	at least 1x per month
electrode cable & rubber electrode	'damage' insulation intact	at least 1x per month
electrode cable & rubber electrode	'conductivity' see § 4.7.1	at least 1x per month
main device	'technical safety inspection' see § 5.1.1, § 8.2	at least 1x per year

5.1.1 Technical safety inspection

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

Note:

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

Inspection points

The technical safety inspection contains the following tests:

Test 1: General: Visual inspection and check on the operating functions

Test 2: Electro therapy

Test 3: Handpiece

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

Inspection result

1. A registration must be maintained of the technical safety inspections. Use the inspection report in the appendix for this purpose. See § 8.2
2. Copy this appendix.
3. Complete the copied appendix.
4. Keep the inspection reports for at least 10 years.

The inspection is successful if all inspection items are passed.

Repair all faults on the equipment before the equipment is put back into operation.

By comparing the registered measurement values with previous measurements, a possible slowly-deteriorating deviation can be ascertained.

5.2 Maintenance

Component	Check	Frequency
hand piece, cable, connector	'cleaning' See § 5.2.3	after every treatment
electrode cable & rubber electrode	'cleaning' See § 5.2.3 & § 5.2.4	after every treatment
electrode sponge	'cleaning' see § 5.2.5	after every treatment
fixation bandages	'cleaning' see § 5.2.6	at least 1x per week
main device	'cleaning'" see § 5.2.1 & § 5.2.2	at least 1x per week
acupuncture needle	'disposable' single use	dispose safely after each use in special container

Caution:



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

5.2.1 Cleaning the main unit

Caution:



- Do not sterilize the unit
- Do not use chloride based agents as these may affect the casing parts of the device

General cleaning:

1. Remove dust with a soft micro fiber cloth
2. If necessary, remove stains or dirt with a damp micro fiber cloth
3. If required, clean the device with a small amount of mild household detergent

Surface disinfection:

4. Use a non-alcoholic disinfection solution or any other agent suitable for surface disinfection that does not harm the material (housing is from lacquered ABS).
5. Or make use of a commercial product specific for surface disinfection and cleaning of non-invasive medical devices. (e.g. Clinell)

5.2.2 Cleaning the touch screen (glass plate)

Caution:



- Do not use abrasive cleaners.
- Cleaner must be neither acid nor alkali (neutral pH).
- Use of incorrect cleaners can result in optical impairment of touch panel and/or damage to functionality.
- Do not use organic chemicals such as: paint thinner, acetone, toluene, xylene, propyl or isopropyl alcohol, or kerosene

General cleaning:

1. Use a soft micro fiber cloth to clean the panel
2. If necessary, use a non-abrasive commercial glass cleaning agent
3. Do not apply the cleaning agent directly to the touchscreen, but instead apply a small amount of this cleaning agent to the soft microfiber cloth and wipe the glass plate gently.

Surface disinfection:

4. Make use of a commercial product specific for surface disinfection and cleaning of non-invasive medical devices.

5.2.3 Cleaning the hand piece and patient cable

Surface disinfection:

1. Remove the acupuncture needle and be careful to dispose the needle safely.
2. Avoid that any liquid directly enters into the needle holder. Therefore, do not immerse the front side of the needle holder neither the cable connectors into any cleaning or disinfecting liquids.
3. Disinfect the hand piece and cables with a 70% alcohol solution.
4. Or make use of a commercial product specific for surface disinfection and cleaning of non-invasive medical devices.
5. Never disinfect the hand piece or any other accessories in an autoclave. They will damage by the extreme temperature.

5.2.4 Cleaning the silicone rubber electrode

General cleaning:

1. Clean the electrodes in a non-aggressive soap solution. Do not immerse the connector.
2. Rinse the electrodes thoroughly with water and dry the electrodes.

Surface disinfection:

3. Disinfect the electrodes with a 70% alcohol solution. This can cause the black colour to be stained, but this does not affect the operation of the electrodes.
4. Or make use of a commercial product specific for surface disinfection and cleaning of non-invasive medical devices.

5.2.5 Cleaning the sponges

General cleaning:

1. Wash the sponges thoroughly after each use, using a mild household cleaning agent and warm water.
2. Rinse the sponges thoroughly with clear water and let them dry if not put to use immediately after cleaning.

Surface disinfection:

3. Sponges can be disinfected by immersing them with a 70% alcohol solution.
4. Immediate replace damaged sponges.
5. Replace the sponge the latest every 6 months.

5.2.6 Cleaning the fixation bandages

1. Clean the bandages in a non-aggressive soap solution, rinse thoroughly and let dry.
2. Or disinfect the bandages in a 70% alcohol solution and let dry.

6 MALFUNCTIONS, SERVICE AND WARRANTY

6.1 Malfunctions

Component	Problem	Solution
Device	Device cannot be switched on	See § 6.1.1
	Device does not react to commands or a fault report appears	See § 6.1.2
	Device does not react to triggers performed on the hand piece	See § 6.1.3
	Foreign language on the screen	Change the language. See § 4.7.1
sponges	Furring	Replace the sponges
	Bad conduction	Replace the sponges

6.1.1 Device cannot be switched on

Procedure

1. Check if the mains voltage has failed
2. Check if the external power supply is correctly connected
3. Check if the power on switch at the backside is switched on.
See § 2.4 for the color definition in all circumstances
4. Contact your dealer if the device still cannot be switched on.

6.1.2 Device does not react to commands or an error message appears

The safety system of the device has ascertained a fault. You cannot continue to work.

An instruction usually appears on the screen.

Procedure

1. Disconnect the patient from the device
2. Switch the power switch at the backside off
3. Wait 5 seconds and switch the power switch on again
4. Contact your dealer if the device still does not react to commands

6.1.3 Device does not react to triggers performed on the hand piece

Procedure

1. Disconnect the patient from the device
2. Select via the System settings menu the hand piece test to check the proper working of the hand piece. See § 4.7.1

3. Contact your dealer if the hand piece malfunctions

6.2 Service

Caution:



- Only a technician authorised by GymnaUniphy N.V. may open the equipment or the accessories to perform repairs. The equipment does not contain any components that may be replaced by the user.
- If possible, open the screen with the system settings before you contact the technical service department. See § 4.7.1

Service and warranty are provided by your local GymnaUniphy dealer. The conditions of delivery of your local GymnaUniphy dealer apply. If you have qualified technical personnel that are authorised by GymnaUniphy to perform repairs, your dealer can provide diagrams, spare parts lists, calibration instructions, spare parts and other information on request, for a fee.

6.3 Warranty

GymnaUniphy and the local GymnaUniphy dealer declares itself to be solely responsible for the correct operation when:

- all repairs, modifications, extensions or adjustments are performed by authorised people;
- the electrical installation of the relevant area meets the applicable legal regulations;
- the equipment is only used by suitably qualified people, according to these user instructions;
- the equipment is used for the purpose for which it is designed;
- maintenance of the device is regularly performed in the way prescribed. See § 5
- the technical life time of the equipment and the accessories is not exceeded;
- the legal regulations with regard to the use of the equipment have been observed.

The warranty period for the equipment and hand piece is 2 (two) years, for the battery it is 6 (six) months beginning on the date of purchase. The date on the purchase invoice acts as proof.

This warranty covers all material and production faults. Consumables, such as patient cables, rubber electrodes, sponges, needles... do not fall under this warranty period.

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

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

6.4 Technical lifespan

The expected lifespan of the device is 6 years counting from the production date. Please refer to the identification plate. GymnaUniphy N.V. will provide service, spare parts and accessories for 6 years after the production date except in case of force majeure.

7 TECHNICAL DATA

7.1 General

Dimensions Unit (wxdxh)	210 x 160 x 90 mm
Weight	~ 0,85 kg
Weight incl. accessories	~ 1,00 kg
Supply voltage	12 VDC
Maximum current rating	2 A
Class Electrical	class II
Dimensions hand piece (wxdxh)	175 x 16 x 16 mm
Weight hand piece	~ 0,060 kg
Weight power supply	~ 0,17 kg
Mains voltage	100-240 V, 50-60 Hz
Current rating	0.6 A - 0.3 A
Maximum power rating	24 W
Operation mode	suited for continuous operation

7.2 Electrotherapy performance

Specifications put forth in this manual were in effect at the time of publication. However, due to the GymnaUniphy policy of continuous improvement to keep up with the most recent clinical evidence, the applications and protocols may change at any time without obligations on the part of GymnaUniphy.

7.2.1 General

Applied part safety	Type BF (floating patient circuit)
Treatment time	0 - 60 min.
Current waveform	Direct current
Output stage type	Constant current source
Limitation	+150% of the set value at 10% of the maximum range decreasing to +110% of this maximum
Accuracy	Load 500-1000 Ω \pm 10%
Polarity	The acupuncture needle is always the negative pole
Patient circuit closed detection	Active during percutaneous electrolysis treatments. Turned off for dry needling. 150 μ A, 148 kHz

7.2.2 Bluetooth

Operating frequency band	2402-2480 MHz
Receiving bandwidth	2402-2480 MHz
Modulation	GFSK
Effective radiated power	0.066W

7.2.3 Parameter properties

Intensities and time:

Therapy method	Treatment time	Intensity step sizes	Preset intensities in advanced modes	Intensity maximum range
	<u>02:00 min</u>	50- <u>100</u> - 250- 500 (μA)	300- 500- 1000- 2000 (μA)	2500 (μA)
	<u>00:30 min</u>	0.5 - 1.0 (mA)	2.0- <u>3.0</u> - 4.0 - 6.0 (mA)	8.0 (mA)
	<u>05:00 min</u>	0.5 (mA)	0.5- 1.0 (mA)	1.0 (mA)

Factory defaults are underlined

Rampcurve values in advanced modes:

low medium high	Ramp curve	Ramp time
	low	8 sec
	medium	4 sec
	high	2 sec

Ramp time:

is the time needed to automatic increase from zero to the Preset intensity value

goal:

The sensory sensitivity level in the human body has the capability to adapt itself for slow changes; as for example a slow increase of the intensity. Based on this we may say that at a treatment start, the patient comfort will increase the longer it takes in time before the higher preset intensity value is reached.

7.3 Acupuncture needle

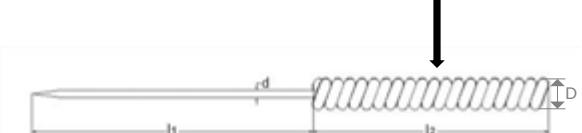
Attention:



- We recommend to purchase the acupuncture needles from a local distributor, who strictly complies according the applicable local legislation.
- Immediately remove and dispose the acupuncture needle after use in a safe way.
- Place the hand piece always in the holder without needle when it is not used.

7.3.1 Properties of the acupuncture needle

- High quality, single use, sterilized, acupuncture needle
- The needle needs to be compatible with Percutaneous electrolysis
- Needle is made of a single thread uncoated stainless steel with braided steel handle without a head.



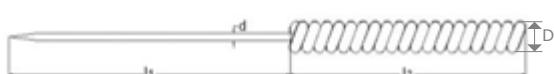
7.3.2 Dimensions of the acupuncture needle

Attention:



Select the correct needle thickness and length for the type of injury to be treated.

- Needle diameter (d): between 0.30mm - 0.35mm
- Handle outer diameter (D): between 1.25 mm - 1.45 mm
- Handle length (l_2): between 25mm - 30mm
- Needle body lengths (l_1): between 20mm - 100mm



7.4 Environmental conditions

Ambient temperature	+10 °C to + 35 °C
Relative humidity	30% to 75%
Atmospheric pressure	70 kPa to 106 kPa

7.5 Transport and storage

Transport weight device	~1,00 kg
Storage and transport temperature	-40 °C to +60 °C
Relative humidity	10% to 100%, including condensation
Atmospheric pressure	20 kPa to 106 kPa
Transport classification	Single piece, by post

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

7.6 List of standard and optional accessories

Check for the article numbers in the most recent datasheet or ask your local dealer.

Description	Quantity	Standard Optional
external medical grade power supply; cable length 1.50 m	1	S
set of power adaptor sockets for other EU countries	1	S
rechargeable battery pack 7,4V 5200mAh (li-ion)	1	S
Handpiece ; cable length 2.10m	1	S
hand piece holder	1	S
1-pole patient cable; 4mm M to 2 mm F; cable length 2.50 m	1	S
rubber electrode brace, size 6cm x 8cm ; 2 mm	1	S
rubber electrode brace, size 8cm x 12cm ; 2 mm	1	O
sponge for electrode brace, size 6cm x 8cm	2	S
sponge for electrode brace, size 8cm x 12cm	2	O
elastic fixation strap, size 30 cm	2	O
elastic fixation strap, size 60 cm	2	S
elastic fixation strap, size 120 cm	2	O
quick start guide	1	S
safety instructions	1	S
USB-stick with instructions for use, multi language	1	S

Note:

Replace sponge and electrode brace the latest every 6 months.

8 APPENDICES

8.1 EMC directive

Use only cables, electrodes and hand pieces that are specified in this manual. See § 7.6. The use of other accessories can have a negative effect on the electromagnetic compatibility of the equipment. If you use the Acure device in the vicinity of other equipment, you must check that the device is functioning normally. The following paragraphs contain information about the EMC properties of the equipment.

8.1.1 FCC and IC statement

FCC Statement:

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 cm between the radiator and a human body.

IC Statement:

This device complies with Industry Canada license-exempt RSS standard(s).

Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence.

L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

8.1.2 Guidance and declarations

Guidance and manufacturer's declaration - electromagnetic emissions		
The Acure device is intended for use in the electromagnetic environment specified below. The customer or the user of a Acure device should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	The device use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-3	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Acure device is intended for use in the electromagnetic environment specified below. The customer or the user of a Acure device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2/4/8/15 kV air	± 8 kV contact / ± 2/4/8/15 kV air No loss of performance	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV / 100 kHz for power supply lines ± 1 kV for input/output lines	± 2 kV / 100 kHz power supply/ ± 1 kV I/O is not applicable No loss of performance	Mains power quality should be that of a typical domestic or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV diff. / No loss of performance ± 2 kV comm. is not applicable	Mains power quality should be that of a typical domestic or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° with $U_T = 100/240$ V	U_T - 100% (0.5 period) No loss of performance	Mains power quality should be that of a typical domestic or hospital environment. If the user of a device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
	0% U_T for 1 cycle at 0° with $U_T = 100/240$ V	U_T - 100% (1 period) No loss of performance	
	70% U_T for 0.5 s with $U_T = 100/240$ V	U_T - 30% (0.5 s) No loss of performance	
	0% U_T for 5 s with $U_T = 100/240$ V	U_T - 100% (5 seconds) No loss of performance	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
			<p>Electromagnetic RF energy emitting equipment should be used no closer to any part of a device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distances d in meters (m) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Conducted RF IEC 61000-4-6	AM 1 kHz/80% 3 V _{rms} 0.15-80 MHz 6 V _{rms} 1.8-2.0, 3.5-4.0, 5.3-5.4, 6.765-6.795, 7.0-7.3, 10.10-10.15, 13.553-13.56 7, 14.0-14.2, 18.07-18.17, 21.0-21.4, 24.89-24.99, 26.957- 27.283, 28.0-29.7, 40.66-40.70,	10 V _{rms} 0.15-80 MHz 30 V _{rms} 26.957-27.283 MHz	$d = 0.35\sqrt{P}$ 0.15-80 MHz $d = 0.12\sqrt{P}$ 26.957-27.283 MHz

	50.0-54.0 MHz		
Radiated RF IEC 61000-4-3	AM 1 kHz/80% 10 V/m 0.08-2.7 GHz	10 V/m 0.08-2.7 GHz	$d = 0.35\sqrt{p}$ 80 MHz to 800 MHz $d = 0.70\sqrt{p}$ 800 MHz to 2.7 GHz
RF proximity fields IEC 61000-4-3	CW 18 Hz/50% 27 V/m 380 - 390 MHz, 28 V/m 800-960 MHz FM 1kHz/ ± 5 kHz 28 V/m 430-470 MHz CW 217 Hz/50% 9 V/m 704-787 MHz, 28 V/m 1.70-1.99 GHz, 28 V/m 2.40-2.57 GHz, 9 V/m 5.10-5.80 GHz	27 V/m 380 -390 MHz 28 V/m 430-470 MHz 9 V/m 704-787 MHz 28 V/m 800-960 MHz 28 V/m 1.70-1.99 GHz 28 V/m 2.40-2.57 GHz 9 V/m 5.10-5.80 GHz	$d = 0.22\sqrt{p}$380-390 MHz $d = 0.22\sqrt{p}$ 430-470 MHz $d = 0.67\sqrt{p}$704-787 MHz $d = 0.22\sqrt{p}$ 800-960 MHz $d = 0.22\sqrt{p}$1.70-1.99 GHz $d = 0.22\sqrt{p}$2.40-2.57 GHz $d = 0.67\sqrt{p}$5.10-5.80 GHz
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey can be considered. If the measured field strength in the location in which a device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.			

8.2 Technical safety inspection

device with serial number is / is not ⁴ in good working order		
	Inspection performed by:	Owner:
Location:	Name:	Name:
Date:	Initials:	Initials:
⁴ Cross out what does not apply.		

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

8.2.1 Test 1: General

		Yes	No	NA
1.	The results of earlier safety inspections are available.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	The logbook is present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	The type plate and the supplier's label are legible.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	The housing, connectors and display are undamaged.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	The power supply and connection cord are undamaged.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	The electrode connectors and cables are undamaged.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	The cables and connector of the hand piece are undamaged.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	The hand piece does not have any cracks or other damage that could compromise the insulation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	The automatic self-test at switch-on does not give an error message. See §2.7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	The display does not show any defective points or lines.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8.2.2 Test 2: Patient circuit

		Yes	No
1.	Connect a load of 1000Ω between the hand piece needle entry and the 1-pole patient cable. Connect an oscilloscope to the 1000Ω load. (Needle side is the negative pole)	<input type="checkbox"/>	<input type="checkbox"/>
2.	Select current in mA-level and adjust to maximum intensity.	<input type="checkbox"/>	<input type="checkbox"/>
3.	At maximum intensity, the output currents corresponds within 10% with the values on the display.	<input type="checkbox"/>	<input type="checkbox"/>
4.	The output signals correspond with Figure 1.	<input type="checkbox"/>	<input type="checkbox"/>
5.	The warning 'Patient circuit is not closed' is given if the load is disconnected.	<input type="checkbox"/>	<input type="checkbox"/>

Figure 1.

8.2.3 Test 3: handpiece

		Yes	No
1.	Go to the system settings menu and select the item hand piece. Select the item: check the hand piece buttons.	<input type="checkbox"/>	<input type="checkbox"/>
2.	Follow the on screen instructions. Press one hand piece button at the time. Is pressing of all 3 buttons on the hand piece correctly shown in the hand piece picture?	<input type="checkbox"/>	<input type="checkbox"/>
3.	Go to the system settings menu and select the item hand piece. Select the item: check the coloured illuminated ring	<input type="checkbox"/>	<input type="checkbox"/>
4.	Follow the on screen instructions. Verify the illuminated ring has the same color as selected on the screen.	<input type="checkbox"/>	<input type="checkbox"/>

8.2.4 Test 4: Electrical safety test (IEC 62353)

		Yes	No
1	The touch current is less than 1000 µA	<input type="checkbox"/>	<input type="checkbox"/>
2.	The patient leakage current is less than 5000 µA	<input type="checkbox"/>	<input type="checkbox"/>

Notes:

8.2.5 Used test equipment

Measurement	Equipment name	SN or identification	Calibration due date
Safety test			
Electrotherapy			
Hand piece			

8.3 Decommissioning

8.3.1 Disposal

Take account of the following environmental aspects when disposing of the equipment and the accessories:

- The power supply, main device, hand piece, the cables and the electrodes are waste electrical and electronic equipment. They components contain tin, copper, iron, various other metals and various plastics, etc. Dispose of them according to national regulations.

The device contains a battery-pack.

- A replacement of the battery-pack during the service life of the device is considered to be maintenance and is therefore only allowed by a qualified / trained technician.
- Be aware that at the end of life of the device it is the responsibility of the owner to take care of the correct dispose of the battery-pack.
- Unscrew the battery holder plate and pull the battery out of the compartment. The battery holder plate is fixated with 3 small screws. Only one is visible while the other 2 are positioned under the rubber feet.
- Sponges, contain only organic material and do not require any special processing.
- Packaging materials and manuals can be recycled. Deliver them to the appropriate collection points or include them with the normal household waste. This depends on the local organization of the waste processing.

Notify your dealer about the disposal.

8.3.2 Reselling

This medical equipment must be traceable. The equipment as well as the hand piece do have a unique serial number. Provide the dealer with the name and address of the new owner.

The device contains a patient database.

Before reselling it, you must delete all stored content. Reset the device back into its default factory settings. See § 4.7.1 on how to do this.

9 REFERENCE

Literature

A literature list will be provided on request. Please contact GymnaUniphy.

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