Zimmer MedizinSysteme

Instructions for Use

enShock

EN

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2 Display
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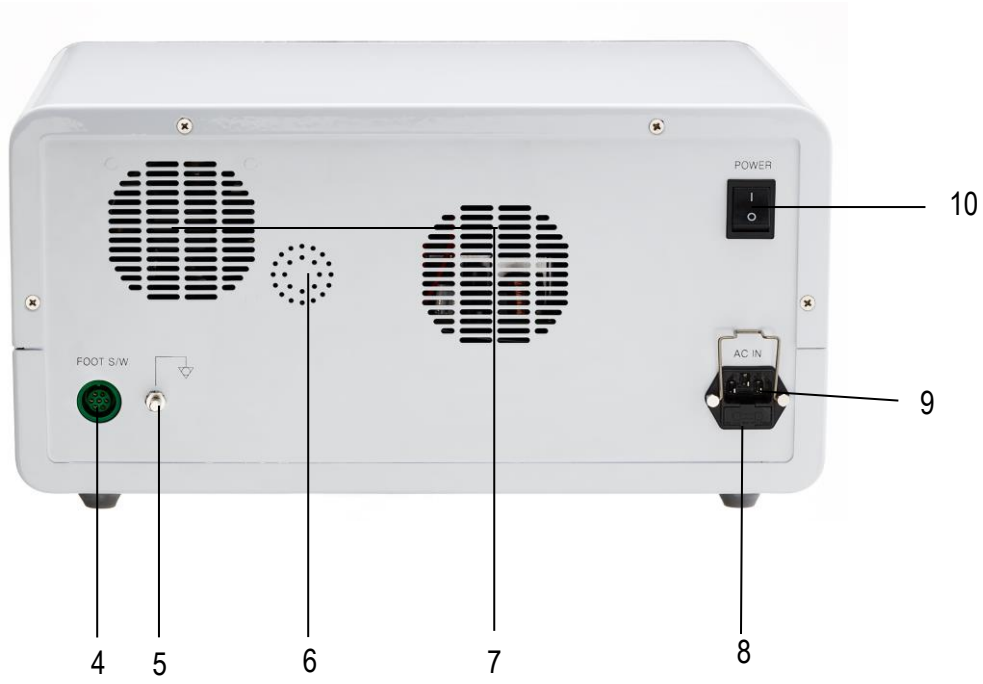

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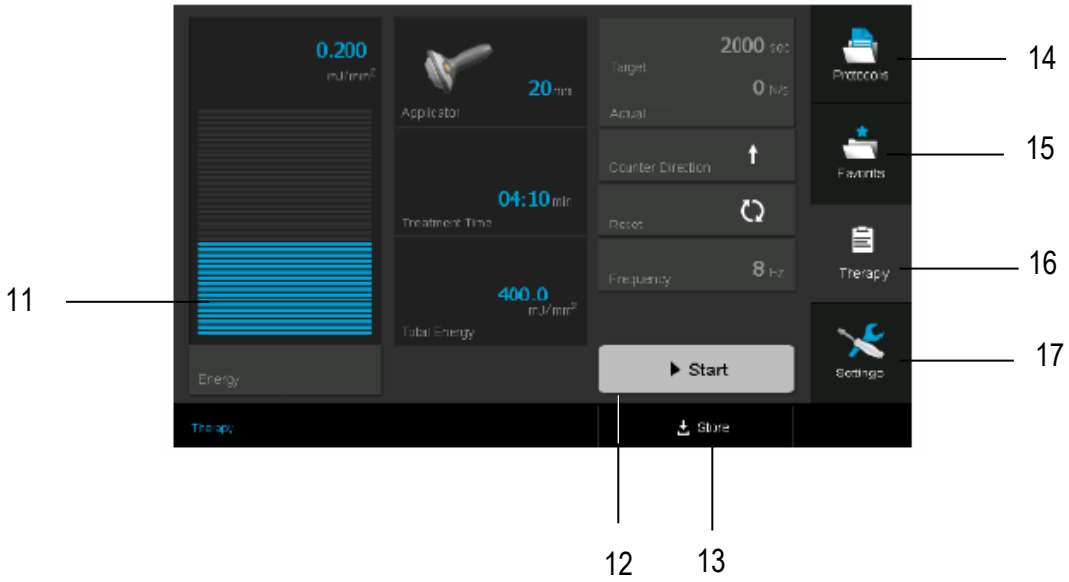

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Gel pads

5 / 10 / 15 / 20 / 25 / 30 / 35 / 40 mm

Foot switch
(optional)

Conductive gel

Power cable

Explanation of symbols

General warning sign: this symbol points out hazards on the device.

In the instructions for use, this symbol indicates “**Dangers and warnings**”.

Caution!

In the instructions for use, this symbol indicates **"Caution" with regard to possible damage to the device.**

Products which are marked with the adjacent symbol may not be disposed of in household waste. The European WEEE Directive applies here.

Note the instructions for use.

Follow the instructions for use.

Switch on/switch off symbol.

Serial number.

Lot number.

Article number.

Manufacturer.

Date of manufacture.

Explanation of symbols

Indication of the quantity contained in the packaging.

Non-sterile.

Device type BF.

CE marking with the number of the notified body.

Medical device.

Protect from heat (sunlight).

Storage and transport temperature range.

Storage and transport air humidity range.

Storage and transport air pressure range.

This side up – indicates top side of the packaging.

Fragile, handle with care.

Protect from moisture.

Recyclable

Explanation of symbols

Unique Device Identification

Maximum stacking height

Contents

Contents

Valid for the device enShock.

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

The instructions for use are valid as of May 2021.

Intended purpose, indications, contraindications and side effects

1

Intended purpose

The enShock is intended to deliver focused shock waves for the treatment of various indications of the musculoskeletal system.

Indications

The enShock provides focused shock wave therapy for people with musculoskeletal disorders and other conditions as considered appropriate by the health care professionals providing treatment.

The enShock is indicated for:

- Myofascial trigger points and the effects they have on back pain, neck pain and myofascial pain syndrome
- Calcifying tendinitis of the shoulder and calcifying tendinopathy, calcific tendinitis and rotator cuff disease with or without calcification
- Subacromial pain syndrome
- Lateral epicondylitis (lateral epicondylopathy of the elbow/tennis elbow/mouse elbow/mouse arm), medial epicondylitis (golfer's elbow)
- Patella tip syndrome (jumper's knee, patellar tendinopathy)
- Achilles tendinopathy
- Plantar fasciopathy and plantar fasciitis
- Pseudoarthrosis and bone non-union, delayed union and its causes, osteochondritis dissecans and its causes, avascular necrosis (femoral head necrosis, knee)
- Medial tibial stress syndrome
- Greater trochanteric pain syndrome
- Stress fractures

Contraindications

- Local infections
- Local tumour diseases
- Coagulopathy (analysis of coagulation status is necessary before use)
- Use of anti-coagulation medications
- Pregnancy
- Lung tissue or other hollow or air-filled organs in the treatment area
- Children with open epiphyses
- Epiphyseal plate in the treatment area
- Treatment area in the region of the brain or spine
- Treatment area in the region of the eyes/face

Caution is indicated in the case of persons:

- With sensory disturbances
- With strong autonomic dysfunction
- With osteoporosis
- Who are under the influence of drugs and/or alcohol

The device may not be used on injured skin or mucous membranes.

Side effects

Common side effects include:

- (Transient) increased pain, radiating pain
- Skin irritation, skin reddening, local skin damage such as skin erythema, petechial skin bleeding, hematoma, local swelling, transient numbness
- Nausea
- Headaches/migraines
- Nerve irritation, nerve injury

Rare adverse events include:

- Bone injury or fracture occurring post-treatment
- Tendon rupture occurring post-treatment
- Vascular injury
- Exacerbation of the condition
- Worsening symptoms
- Local soft tissue damage.
- Absence of bony connection (in the case of stress fractures)
- Pseudathrosis

Intended user

enShock is intended for health care professionals, such as physiotherapists, doctors and medical assistants.

Target patient population

enShock should not be used on infants and young children.
enShock should not be used on patients who have any of the contraindications listed.
Patients must be physically and mentally able to consciously perceive and express the perception of pain stimuli.

Mode of action/functional principle

Piezoelectric crystals produce pressure waves when they are electrically activated. The crystals are mounted in an array, so that the pressure waves emitted by each crystal meet in a focal point. The penetration depth is determined by the chosen gel pad spacer.

Application information

2

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

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

Caution! enShock should not be placed and used in hygienically critical medical areas such as operating rooms, intensive care units or emergency departments.

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

Caution! Medical electric devices are subject to special precautionary measures with regard to electromagnetic compatibility (EMC) and must be installed according to the EMC information in the accompanying documentation. For more information, see chapter 17 “Manufacturer's EMC declaration”.
Operation of this device in the vicinity of strong electromagnetic fields (e.g., tomographs, X-ray or diathermy equipment) may interfere with its operation. Please keep a safe distance of 5 metres.

enShock is not suitable for use in areas with an explosive, flammable or combustive environment.

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

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

Inspect the device and applied parts before use. If there is any damage, the device must not be used.

Caution! Only accessories provided by Zimmer MedizinSysteme GmbH that are intended for this device may be used. The enShock should not be combined with any other medical or non-medical device.

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

The consistency of the gel in the gel pads changes due to heat, cold, direct sunlight, mechanical damage or natural aging. Therefore, protect the gel pads from natural environmental influences.

In order to achieve a uniform gel consistency and thus consistent success with the treatment, always store the gel pads away during breaks in treatment and, likewise, store away any gel pads not used during therapy. They should be stored in the intended storage box, protected from direct sunlight and extreme cold or heat, in a dry environment and not below 1°C and at a maximum of 30°C).

Only use gel pads for therapy that have been stored at room temperature for at least 2 hours before the therapy.

Do not use visibly damaged gel pads. Replace the gel pads if they are mechanically damaged or if the consistency has noticeably changed. The gel pads should be replaced after one year of use, at the latest.

Remove any excess conductive gel from the gel pads and applicator immediately after therapy has ended.

The applied parts may only come into contact with the patient's uninjured skin.

Only use the conductive gel that is provided for this purpose and included in the scope of delivery.

Do not perform therapy without conductive gel and an inserted gel pad. Otherwise, no focused shock wave will be able to be applied to the patient. The conductive gel is absolutely necessary for uniform energy transfer.

If the enShock is placed on a foreign equipment trolley or other storage surface, care must be taken to ensure that it is designed for the maximum device weight, with accessories, and that the device is positioned stably so that it does not fall down, including during transport. The handpiece must also be secured against falling.

Warnings

Treatment instructions regarding the location, duration and intensity of the treatment require medical knowledge and should only be given by medical professionals. These instructions must be followed.

The patient must not be left unattended during therapy.

Performing intracranial, transcardiac and cervical-occipital treatments is prohibited. Failure to follow this instruction may lead to hazards to the patient.

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

Never use the handpiece without an appropriate gel pad or with a damaged gel pad. Failure to follow this instruction may lead to hazards to the patient.

Patient body parts which contain (metal) implants (for example, a bone nail, pacemaker, ICD, IUD, etc.) must be excluded from the treatment.

Cables leading to the applicator should be guided in such a way that contact with the patient or with conductive or energy-absorbing objects is avoided.

Ensure that the handpiece and gel pad are never directed towards the eyes during operation.

Ensure that the handpiece and gel pad are not directed at metallic surfaces (such as a couch, washbasin, device housing, etc.).

Ensure that the device is not opened.

Ensure that the power cable is immediately disconnected from the mains if liquid or foreign bodies penetrate the housing.
Ensure that the device is inspected by an authorised service employee before it is put back into operation.

To completely disconnect the device from the mains, pull the power cable out of the socket.

Ensure that the ventilation slots are not covered. Do not cover the ventilation slots with objects.

enShock – in brief

What is enShock?

An ultramodern, innovative therapy system for applying focused extracorporeal shock waves.

What does enShock do?

enShock is used to apply electrically activated pressure waves.
The individual pressure waves meet in a focal point. The penetration depth is determined by the chosen gel pad.

What are the benefits of enShock?

The modern, clear colour display shows all therapy-related parameters and offers modern touchscreen operation; combined with the optional foot switch, this ensures motivation on the part of the user and efficient patient treatment.

The compact design enables space-saving work in an office and is ideally suited for mobile use.

The low-noise handpiece guarantees no disruptive side-effects for the practitioner, even in the case of intensive use.

Note:

Use of the device is reserved for medical professionals (such as physiotherapists, doctors and medical assistants).

Ensure that the device is placed on a stable surface.

No special training or instruction is required in order to use the device. However, the device may only be used by medical professionals who have previously familiarised themselves with the device and the instructions for use and understand the intended use, application and warning notes outlined therein.

Make sure that the power switch of the device is set to “0”.

Connect power cable Connect the power cable to the provided port (9) on the device, and connect the cable to the mains.

Note: *The device may only be connected to power outlets with an earthing contact.*

Connect handpiece Connect the handpiece to the handpiece connector (1).

Install gel pad Only use the gel pads if they have been stored for at least 2 hours at room temperature before therapy.

Rotate the gel pad fixation ring (18) anti-clockwise to remove it.

Select a gel pad and apply sufficient conductive gel to the back side of the pad.

Place the back side of the gel pad into the handpiece, and put the gel pad fixation ring (18) back on the handpiece

Fix the gel pad fixation ring (18) in place by rotating it clockwise.

Make sure to use sufficient conductive gel on the front side of the gel pad as well as when performing a treatment.

Connect foot switch The optional foot switch must be connected to the foot switch connector (4) The foot switch has 3 buttons. The white button (left side) is used to apply the set power. The middle button adjusts the energy downwards (blue). The yellow button (right side) is used to adjust the applied energy upwards.

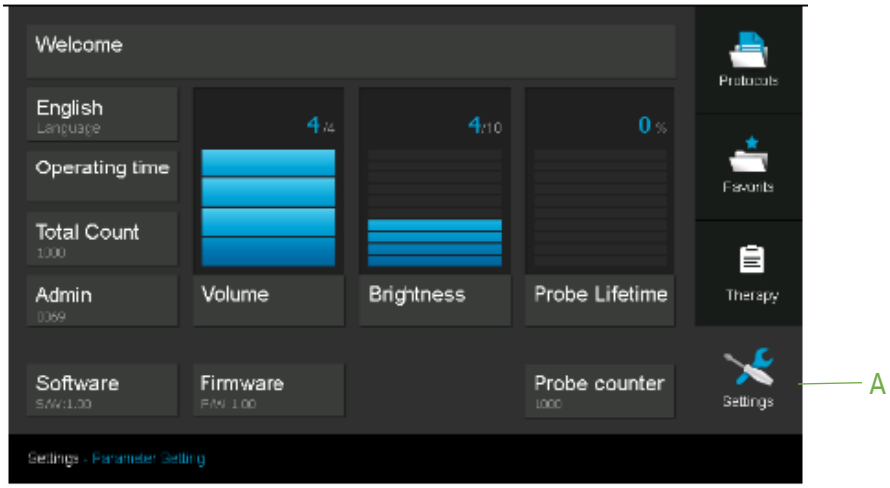
Switching device off The device is switched off using the on/off switch (10).
In order to fully disconnect the device from the mains, the power cable must be disconnected.

Caution! All cables must be protected from pinching or other mechanical damage.

Note: *The following descriptions are based on the factory settings.*

Settings menu Factory settings can be changed and individually adjusted in the “Settings” menu.

Select settings Activating the “Settings” button (A) opens the “Configuration" screen.



Welcome text Activating the “Welcome” button opens the alphabetical keyboard, with which you can enter a welcome text for the start-up screen.

Language Activating the “Language” button opens a selection window with different languages. Use the arrow buttons to scroll through the list. You can select your desired language directly in the corresponding line.

Operating time Displays the total operating time of the device.

Total count Total number of shock waves generated by the device.

Admin Button to enter “Admin” mode (password-protected).

Software Displays the version of the currently installed software.

Firmware Displays the version of the currently installed firmware.

Probe counter Total number of shock waves generated by the currently connected handpiece.

Volume Button to adjust sound volume.

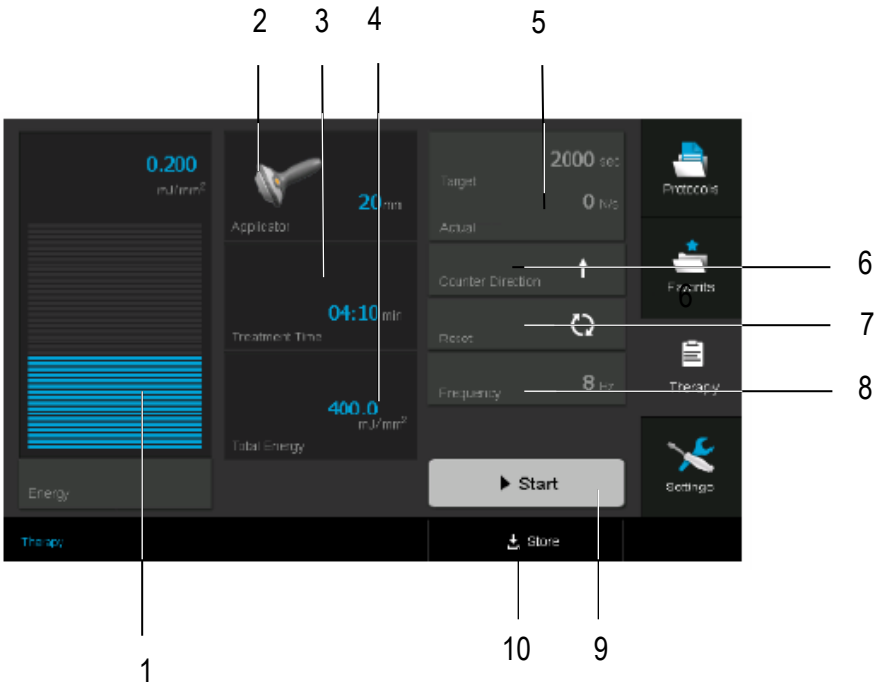
Brightness Button to adjust screen brightness.

Probe lifetime Displays the lifetime of the currently connected handpiece in %.

Note:	*The following recommendations are only guidelines and must, of course, be adapted to the patient's individual situation.*
Gel pads	enShock comes with 8 gel pads to ensure an optimal penetration depth. The penetration depth in human tissue depends on the gel pad used. The diameter of the gel pads reflects the penetration depth. Example: a gel pad with a diameter of 20 mm leads to a maximum energy level at a depth of 20 mm. The diameter of the gel pad can be read on the gel pad in question.
Note:	*For a longer service life, we recommend storing the gel pads out of direct sunlight and at a temperature of between 1°C and 30°C.*
Conductive gel	Optimal energy transfer can only be guaranteed when conductive gel is used.
Treatment time:	Depending on the size of the treatment area and the disease status, the recommended treatment time is between 5 and 20 minutes.
Dosage:	It is recommended to start with a low dose and to increase it until the patient develops a clear perception of the shock waves.
Note:	*The patient should be carefully monitored during therapy.*

Note:	*The following descriptions are based on the factory settings.*
Note:	*All buttons, menus and sub-menus can be activated directly on the screen by pressing with the finger.*
Open therapy screen	Activating the “Therapy” button opens the therapy screen.
Select gel pad	Select the appropriate gel pad and place this correctly into the handpiece.
Note:	*To guarantee optimal energy transfer, use sufficient conductive gel between the handpiece and the gel pad.*
Adjust parameters	Adjust the desired energy level, number of shocks and frequency by selecting the parameter in question and adjusting the value using the central control knob. If the optional foot switch is connected, the “-” and “+” pedals can be used for adjustment as well.
Apply conductive gel	Apply the conductive gel to the treatment area and spread the gel evenly over the entire surface of the treatment area
Start of therapy	Start a treatment by selecting the “Start” button, immediately followed by clicking the orange button on the handpiece (19) or pressing the “Shock” pedal on the optional foot switch.
Note:	*If the "Start" button is not activated, no power will be emitted.*
Note:	*The energy level and frequency can be increased or decreased during therapy by selecting the parameter in question followed by using the central control knob or the optional foot switch.*
End of therapy:	An acoustic signal will sound after the therapy time has elapsed.
Note:	*If the volume is set to “0” in the “Settings” menu, no acoustic signal will sound.*

Description of the display elements and buttons



(1) Energy Displays the energy level and allows it to be adjusted from 0.005 to 0.500 mJ/mm^2 in increments of 0.005 mJ.

(2) Gel pad Displays the recommended gel pad.

(3) Treatment time Displays the treatment time remaining. This time is not adjustable and depends on the set number of shocks and frequency.

(4) Total energy Displays the sum of all energy. This value is not adjustable and is the result of the set energy level multiplied by the number of shocks.

(5) Number of shocks Displays the number of shocks set (target) and allows this to be adjusted, and displays the number of shocks generated (actual). The maximum number of shocks is 10,000 and can been adjusted in increments of 100 shocks.

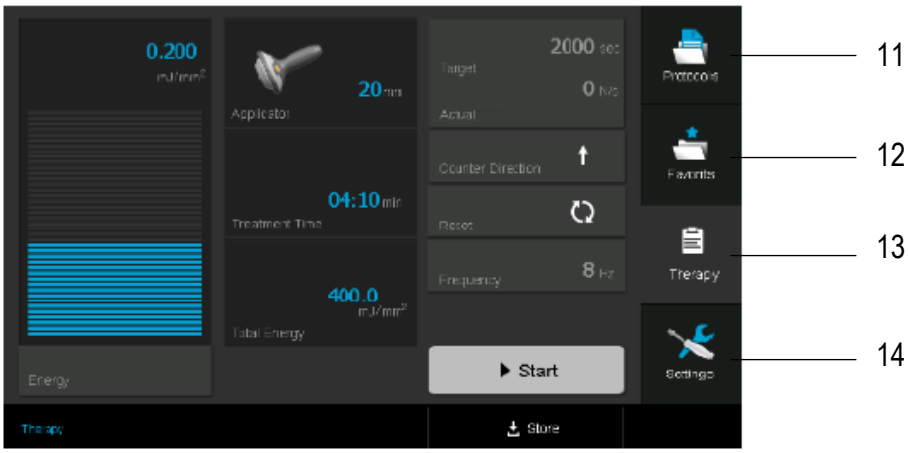
(6) Counter direction Is used to set the shock calculation method, count up/count down.

(7) Reset Resets the value of actually generated shocks.

(8) Frequency Displays the frequency and allows it to be adjusted from 1 to 12 Hz in increments of 1 Hz.

(9) Start Treatment start button

(10) Store Button to add the currently set protocol to “Favourites”



(11) Protocols Switches to Protocols

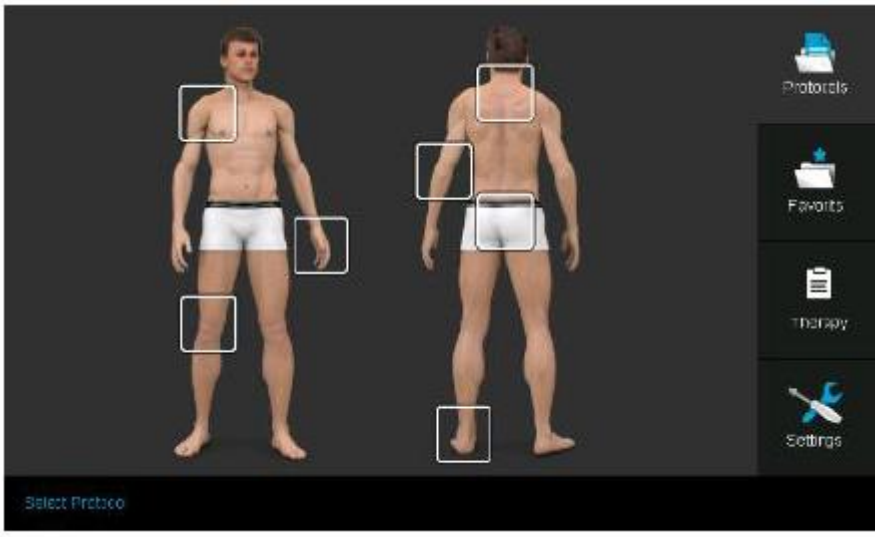
(12) Favourites Switches to Favourites

(13) Therapy Switches to Therapy

(14) Settings Switches to Settings

Protocols

The "Protocols" menu is used for support when selecting the therapy and provides information about the application.



Selecting the body region

The desired body region is selected by activating the white square. After selecting the desired body region, the window with corresponding indications will open.

Select indication

Select the appropriate indication and press the “Confirm” button.

Therapy information

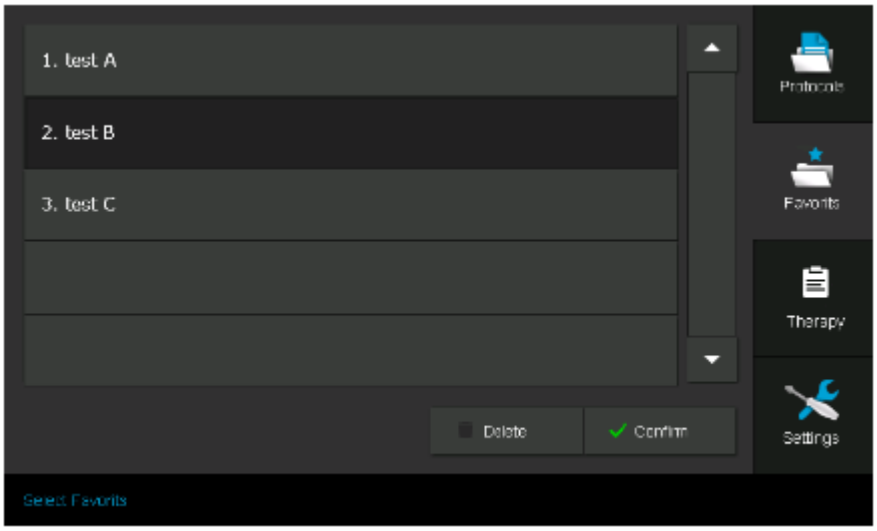
The therapy screen will open with the corresponding treatment recommendations. All parameters can be changed according the instructions in chapter 7.3.

Start treatment

Start the treatment by selecting the “Start” button, immediately followed by clicking the orange button on the handpiece or pressing the “Shock” pedal on the optional foot switch.

Favourites

When changes are made to programmes in the therapy screen, these are automatically listed in Favourites when saved.



Favourites list

In the Favourites list, the programmes can be:

1. Accessed for therapy:
To do this, select the desired programme directly in the corresponding line and then click the “Confirm” button.

2. Deleted:
To delete a favourite, select the corresponding treatment and click the “Delete” button.

Technical information

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Mains voltage	220 V AC; 60 Hz 230 V AC; 50 Hz
Power consumption	Max. 300 VA
Fuse	T5AL/250 VAC
Output energy	0.05–0.500 mJ/mm^2 ± 20%
Operating mode	Single Pulse or Continuous Pulse
Output frequency	1–12 Hz ± 20%
Expected lifetime of handpiece	5,000,000 shocks
Protection class	I
Application part type	BF
Applied part	Handpiece with gel pads (diameter)
Protection against ingress of particles and water	Device: IPX 0 Foot switch: IPX 1
Dimensions	W 405 mm x H 207 mm x D 424 mm
Weight	23 kg (control unit without accessories)
Operation	10–40°C, 30–85% relative humidity, without condensation, at 700–1060 hPa
Transport/storage	-10–50°C, 20–85% relative humidity, without condensation, at 700–1060 hPa Gel pads should be stored at the customer's premises in a dry environment, protected from sunlight and at temperature (1–30°C).

Note: *The device may only be stored and transported in its original packaging.*

Subject to technical changes!

Reprocessing cleaning, disinfection

9

Warning notice

Before starting cleaning and maintenance measures, the device must always be switched off using the main switch and the power plug must be pulled.

Please note the information for the cleaning agent and disinfectant you are using regarding application, material compatibility, application time, precautions and the spectrum of action.

Please ensure you are wearing the appropriate personal protective equipment (protective goggles, protective gloves, etc.) for all cleaning and disinfection measures.

It is important to ensure that no moisture enters the system/handpiece during cleaning. The device and handpiece are not protected against the ingress of liquids. Therefore, sprays should not be used.

If liquid gets into the system during cleaning/disinfection, put the device out of service, protect it from being recommissioned and inform the service team.

Make sure that cleaning/disinfection does not damage the device's labels (e.g., warnings, labelling, type plate). If a label comes loose or gets damaged, contact the service team and request a replacement.

Please do not use sharp-edged objects for cleaning and disinfection.

Only use the device and accessories in a hygienic, dirt- and dust-free environment.

Reprocessing restrictions

enShock and all its accessories do not need to be sterilised and are not intended for this purpose. enShock and all its accessories are not suitable for machine cleaning and disinfection.

Initial treatment on the place of use

All parts of the device that may come into contact with the patient must be cleaned during initial commissioning and before coming into contact with the patient for the first time in order to remove residues from production and packaging.
The device housing and its power cable should not come near the patient.

Preparation before cleaning and disinfection/ pre-cleaning

- Disconnect the device from the mains.
- After each application, remove any excess contact gel from the applicator and gel pad immediately after use (the gel should not be allowed to dry for a prolonged period) using commercially available paper towels.

Machine: cleaning

enShock and all its accessories are not intended to be cleaned by machine.

Manual cleaning

In case of visible contamination, the housing and all accessories can be cleaned with a commercially available non-alcoholic plastic cleaning agent, or tap water, without any chemical cleaning agents. To do this, wipe the surfaces with a non-drip cloth that has been soaked in cleaning agent according to the manufacturer's specifications until the dirt is removed.

The gel pads and fixation ring on the handpiece can also be cleaned under tap water.

When cleaning, make sure that no liquid enters the cables of the connectors and the housing of the control unit or applicator.

Machine disinfection:

enShock and all its accessories are not intended for disinfection by machine.

Manual disinfection:

Always clean before each disinfection!

Housing and foot switch:
Disinfection of the enShock housing is not required insofar as it is outside the patient environment. Nevertheless, we recommend disinfecting the housing at least once a week by means of wipe disinfection using a commercially available non-alcoholic plastic and metal disinfectant that is suitable for medical devices (e.g., Mikrozid sensitive liquid, alcohol-free, by Schülke).
The foot switch is protected against vertically falling dripping water.

Applicator and cable:
Disinfect the applicator and cable after each time they come into contact with the patient using a commercially available non-alcoholic plastic and metal disinfectant that is suitable for medical devices (e.g., Mikrozid sensitive liquid, alcohol-free, by Schülke). When using disinfection wipes, you should wipe 3 times. Do not use disinfectant spray as the housing is not protected against the ingress of liquids.

Gel pads:
Disinfect the used gel pads after each time they come into contact with the patient using a commercially available non-alcoholic plastic and metal disinfectant that is suitable for medical devices, either in spray form or wetted onto disinfectant wipes (e.g., Mikrozid sensitive liquid, alcohol-free, by Schülke). When using disinfection wipes, you should wipe 3 times. If you use disinfectants in spray form, ensure the entire surface is uniformly wetted.

Please rinse the gel pads under tap water after disinfection to completely remove all residues of the disinfectant.

Failing to disinfect a contact part can lead to cross infection!

Drying

All accessories can be dried in room conditions without special equipment.

Maintenance, control and testing

Please check the accessories for visible mechanical damage after cleaning and disinfection measures; replace accessories in case of visible mechanical damage or wear. No functional test or calibration needs to be performed after preparation.

Packaging

The enShock device and accessories do not need to be packaged after cleaning and disinfection, but they should be protected from dust, moisture and direct sunlight.

Reprocessing cleaning, disinfection

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Sterilisation

enShock and all its accessories are not intended for sterilisation and are not suitable for this process.

Storage

enShock and all its accessories should be stored in a dry and dust-free environment at room temperature, protected from direct sun light.

Additional information

The device and its accessories are considered uncritical within the specified intended use as this entails use on uninjured, healthy skin and application in an uncritical hygienic environment.

The instructions listed above have been approved by the medical device manufacturer as suitable for reprocessing a medical device for reuse. The reprocessor is responsible for ensuring that the reprocessing as actually performed, using equipment, materials and staff in the treatment facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the procedure.

Contact details of manufacturer

Zimmer MedizinSysteme GmbH
Junkersstr. 9
89231 Neu-Ulm
Germany
Tel: +49 (0)731 97610

CE marking

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The device bears the CE marking

CE 0123

Accords with the EC Directive on Medical Devices 93/42/EEC and meets the essential requirements of Appendix I of this directive.

The device is classified in class IIa according to Appendix IX of the directive.

Manufacturer

Zimmer MedizinSysteme GmbH
Junkersstraße 9
89231 Neu-Ulm, Germany

Scope of delivery and accessories

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Item no.	Scope of delivery
5440	1 enShock control unit
5445	1 Handpiece
54201000	1 Set of gel pads
54202500	1 Bottle with conductive gel
54201020	1 Power cable
10105114	1 Instructions for use

Item no.	Accessories
5445	1 Handpiece
54201000	1 Set of gel pads
54202500	1 Bottle with conductive gel
54201010	1 Foot switch
5446	1 Equipment trolley
54201020	1 Power cable
10105114	1 Instructions for use

Device combinations

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enShock is not intended by the manufacturer to be combined with other devices or connected to other medical or non-medical devices.

Anyone who combines devices against these guidelines, thereby creating a medical system, does so on his/her own responsibility.

enShock is manufactured and tested according to currently valid standards for medical devices.

Zimmer MedizinSysteme GmbH can only consider itself to be responsible for safety and reliability if:

- the device is operated using a proper power outlet with an earth contact and the electrical installation complies with DIN VDE 0100 part 710 or a comparable standard;
- the equipment is operated in accordance with the instructions for use;
- extensions, readjustments or modifications are carried out only by persons authorised by Zimmer MedizinSysteme GmbH;
- the user has ascertained functional safety, a proper operating condition and mechanical integrity before using the device and accessories;
- the device is operated only by medical professionals;
- the device is not operated in hazardous areas and/or a combustive atmosphere; and
- the device is immediately disconnected from the mains when penetrated by liquid.

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

Fuses and other spare parts may only be replaced by trained service staff.

The device may only be serviced by trained staff. All information required for servicing can be found in the enShock service manual or can be requested from the manufacturer. Upon request, Zimmer MedizinSysteme will provide wiring diagrams, lists of components, descriptions, calibration instructions or other documents.

Before starting any cleaning and maintenance measures, the device must always be switched off using the main switch, and the mains plug must be disconnected.

Handpiece

Inspect the connector, cable and surface of the handpiece regularly for cracks and other damage. If the surface is damaged, the part must be replaced.

The handpiece has a life span of 5,000,000 shocks.
After 4,500,000 shocks, the user will get a message to replace the applicator before reaching 5,000,000 shocks.
It is not possible to exceed the life span of 5,000,000 shocks.

Gel pads

Inspect the surface regularly for cracks and other damage. If any surface is damaged, the gel pad must be replaced.

Foot switch (optional)

Regularly check the connector, cable and foot switch for cracks and other damage. If there is any damage, the foot switch must be replaced.

Functional testing

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Functional test

Regularly check the functionality of the handpiece and the optional foot switch.
Regularly check the handpiece, gel pads and foot switch for any damage.

Perform the test as described below:

- Connect the handpiece to the device.
- If available, connect the foot switch to the device.

No message: functionality is guaranteed.
“Handpiece not detected” message: check whether it is correctly attached to the device.

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

Safety checks/ metrological checks

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In Germany, it is not necessary to perform either a safety check or a metrological check for the enShock device.

In Germany, the MPBetreibV (Medical Device Operator Ordinance) and DGUV V3 (Accident Prevention Regulation – Electrical Systems and Equipment), among others, apply in their respective current versions.
These are to be followed when operating the device.

Note: *These requirements apply to operation of the device in Germany. Please consider any divergent national regulations in your country.*

Malfunction of the handpiece/ no power output

Possible cause 1:
Handpiece is not correctly connected to the device.
Remedy for cause 1:
Check whether the handpiece is correctly connected to the device.
The plug must be fully engaged.
Check the cable of the handpiece for damage or kinks.

No power transfer

Possible cause 1:
No conductive gel was used between the handpiece and he gel pad.
Remedy for cause 1:
Ensure that conductive gel is used.

Possible cause 2:
No conductive gel was used between the gel pad and skin.
Remedy for cause 2:
Ensure that conductive gel is used.

Possible cause 3:
Internal cable defect.
Remedy for cause 3:
Check this by performing the "Cable control" test.
In the event of an error message, inform the service department/customer service.

No response when using the main switch/display remains dark.

Possible cause 1:
Mains connection.
Remedy for cause 1:
Check that the mains plug is correctly plugged into the socket and that the device plug is firmly inserted in the port of the device.
Check the power cable for damage.
Check the mains and socket.

Possible cause 2:
Fuse.
Remedy for cause 2:
Please inform the service department. Fuses may only be replaced by a service technician.

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

Error messages/ troubleshooting

Check SD card
Check whether the SD card is fully inserted and correctly positioned.

Applicator disconnected
Connect the handpiece to the device via the white connection (8 pin).

Excessive temperature
Discontinue the power output until the system has cooled.

Occasionally, device errors can be corrected by switching the system off, waiting 5 seconds, and switching the system back on.

Repairs and services should only be performed by persons authorised by Zimmer MedizinSysteme.

Customer service

It is essential that you notify technical support/customer service of any problems that occur frequently or cannot be resolved.
You may get in touch with them via your sales representative or via the main office in Neu-Ulm.

Main office

Zimmer MedizinSysteme GmbH
Junkersstraße 9
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Tel. +49 731. 9761-291
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www.zimmer.de

Disposal

The device and handpiece may only be returned to the factory in their original packaging. They may only be disposed of by the factory in Neu-Ulm.

The gel pads can be disposed of in standard waste. They do not contain substances of concern.

In foreign (European) countries, disposal is handled by distributors authorised by Zimmer MedizinSysteme.

Packaging materials must be kept out of the reach of children as there is a risk of suffocation!

Manufacturer's EMC declaration

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The enShock device was developed according to the recognised rules of engineering; the information on use as intended of the components was taken into account.

enShock should not be operated near active HF surgical devices or magnetic resonance imaging devices which can cause significant electromagnetic interference.

enShock is exclusively intended and has been tested for professional healthcare facilities, such as hospitals.

enShock does not have any key performance features which could be impaired through electromagnetic interference.

WARNING: The use of this device next to or stacked with other devices should be avoided since this could lead to faulty operation. If such use is necessary, the device as well as the other devices should be continuously observed to ensure that they are working normally.

The electromagnetic compatibility of the enShock device was tested on the original device with the specified original accessories.

WARNING: The use of accessories, converters and cables which are not specified or provided by the manufacturer of this device can lead to increased electromagnetic interference emissions or decreased electromagnetic immunity of this device, resulting in improper operation.

The enShock device does not contain any exchangeable components, cables or other parts which lead to worsening of the EMC.

WARNING: Portable HF communication devices (including peripheral devices such as antennas) should be used at a distance of at least 30 cm (12 inches) from any part of the enShock device; this includes cables indicated by the manufacturer. There may otherwise be a loss of performance of this device.

The device was tested for HF immunity with selected frequencies only. Transients with other frequencies occurring in the vicinity can lead to malfunctions. The tested frequencies are listed in Table 4.

The enShock device does not contain any components which can age during the life of the device or which can lead to worsening of the electromagnetic compatibility. Thus no maintenance is necessary during the service life of the device to ensure basic safety.

All tests according to standard IEC 60601-1-2 Ed. 4.0 were performed. Other standards and regulations on electromagnetic compatibility were not applied.

Table 1

Guidelines and manufacturer's declaration – Electromagnetic emissions		
The enShock **device is intended to be used in the electromagnetic environment indicated below. The customer or user of the** enShock **device must ensure that it is used in such an environment.**		
Interference emission measurements	**Compliance**	**Electromagnetic environment – Guidelines**
HF emitted interference according to CISPR 11	Group 2	The enShock device must emit electromagnetic energy to guarantee its intended function. Electronic devices located in the vicinity may be impaired.
HF emitted interference according to CISPR 11	Class A	The enShock device is suitable for use in all establishments, including domestic establishments, and in those which are connected directly to the public grid which also supplies buildings used for residential purposes.
Harmonic emissions according to IEC 61000-3-2	Class A	
Voltage fluctuations/flickers according to IEC 61000-3-3	met	

Table 2

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The enShock **device is intended to be used in the electromagnetic environment indicated below. The customer or user of the** enShock **device must ensure that it is used in such an environment.**			
Immunity tests	**IEC 60601 – test level**	**Compliance level**	**Electromagnetic environment – Guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	Floors should be made of wood, concrete or ceramic tiles. In the case of plastic coverings, the relative humidity must be at least 30%.
Rapid electrical transients/bursts according to IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	The quality of the supply voltage must correspond to that of a typical business or hospital environment.
Surges according to IEC 61000-4-5 (external conductor – external conductor)	± 0.5 kV, ± 1 kV	± 0.5 kV, ± 1 kV	
Surges according to IEC 61000-4-5 (external conductor – ground)	± 0.5 kV, ± 1 kV, ± 2 kV	± 0.5 kV, ± 1 kV, ± 2 kV	
Voltage dips according to IEC 61000-4-11	0% UT; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% UT; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The quality of the supply voltage must correspond to that of a typical business or hospital environment.
	0% UT; 1 cycle and 70% UT; 25/30 cycles	0% UT; 1 cycle and 70% UT; 25/30 cycles	

	Single phase: at 0°	Single phase: at 0°	When the user of the enShock device needs further operation even in the case of interruptions in the power supply, it is recommended to operate the enShock device from an uninterruptible power supply or a battery.
Voltage interruptions according to IEC 61000-4-11	0% UT; 250/300 cycles	0% UT; 250/300 cycles	
Magnetic field at power supply frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	Magnetic fields at mains frequency should correspond to the typical values found in business or hospital environments.
Note: U_T is the a.c. supply voltage prior to application of the test level.			

Table 3

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The enShock **device is intended to be used in the electromagnetic environment indicated below. The customer or user of the** enShock **device must ensure that it is used in such an environment.**			
Immunity test	**IEC 60601 – test level**	**Compliance level**	**Electromagnetic environment – Guidelines**
Conducted disturbances by HF fields according to IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM band between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM band between 0.15 MHz and 80 MHz 80% AM at 1 kHz	**In the environment of devices which bear the following symbol, interferences are possible:** 
Radiated electromagnetic HF fields according to IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM to 1 kHz	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	

Table 4

Electromagnetic immunity to HF radio equipment						
Test frequency (MHz)	Band (MHz)	Service	modulation	Maximum energy (W)	Distance (m)	Test level immunity (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sinus	2	0.3	28
710	704 – 787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

en*Shock*

Instructions for Use

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