Zimmer
MedizinSysteme

Instructions for Use

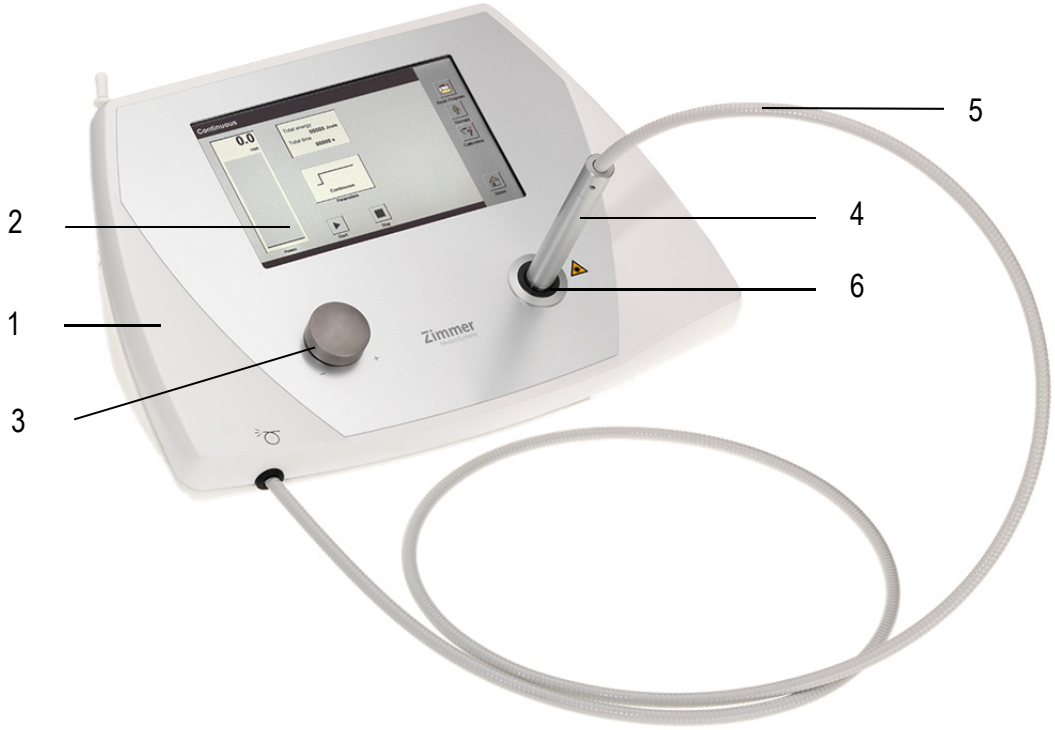
Opton

GB

Figures

Front panel of the device

Fig. 1



Selection and control elements	1	Controller unit
	2	Display
	3	Intensity controller
Applicator with fiber-optic cable	4	Applicator
	5	Fiber-optic cable
Calibration sensor	6	Calibration sensor and holder for applicator

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Rear panel of the device

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Switches and sockets

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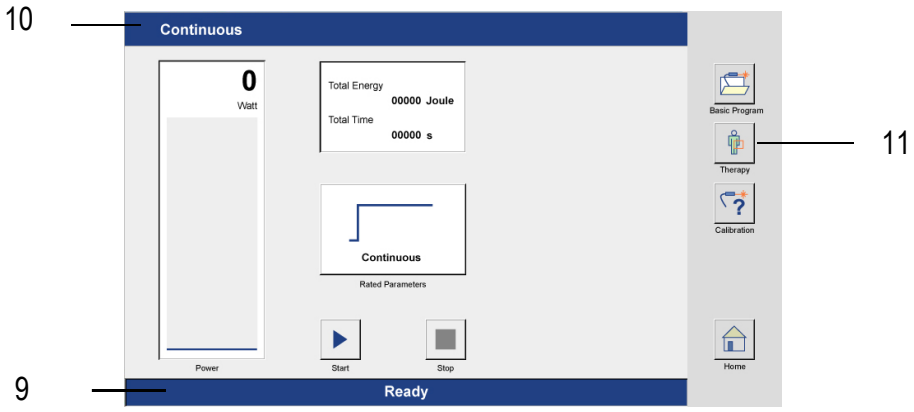
8 Interlock connector socket
9 Socket for mains cable
10 Holder for main fuse
11 Identification plate
12 On/off switch
13 Emergency stop button
14 Touch pen in holder

Figures

Display / Navigation Bars

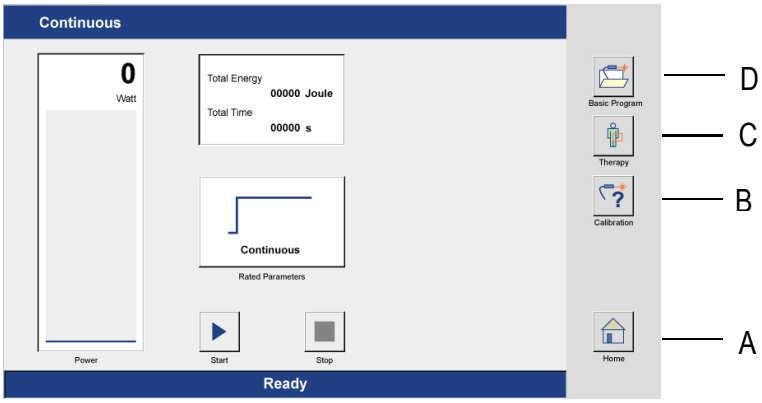
Fig. 3



Display

9 Status bar
10 Title bar
11 Navigation bar

Fig. 4



Navigation bar	(A) Home	Moves back to main page
Description of the functions	(B) Calibration	Switches to the calibration page
	(C) Therapy	Switches to treatment recommendations
	(D) Basic Program	Switches to the base program

Figures

Accessories

14 Footswitch

15 Laser warning sign with laser warning lamp

16 Interlock plug

17 Protective sleeve

18 Laser protection glasses

19 Laser warning sign

Explanation of Symbols

Caution: laser aperture
Note: laser radiation emitted from applicator tip

Turn the emergency stop button clockwise (following the arrows) to unlock

Type Applied BF part

Footswitch socket

Interlock socket

Value of accessible fuses

Instructions for use

Follow the instructions for use

Serial number

Article number

Manufacturer

Date of manufacture

Caution!

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

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

Contents

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Display messages / navigation bars
Accessories

Explanation of symbols

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This instructions for use is valide for Opton devices and integral part of the device.
It must be stored with the device and kept accessable at all times for anyone authorized to operate the device.
This manual is valid as of October 2014.

Indications

1

Opton is used to initiate and support healing processes in the body's tissues. The device is suitable for the treatment of the following indications:

Myopathy, tendinopathy
Lower back pain (such as ischialgia)
Arthropathy, arthrosis
Rheumatoid arthritis
Trauma disorders (such as sprains and strains)
Impingement syndromes (such as carpal tunnel syndrome)
Skin diseases (such as acne vulgaris, herpes simplex, verrucas, ano-genital warts, leg ulcers, decubitus ulcers)

The following effects have been demonstrated:
Musculoskeletal disorders
Healing, pain relief

Rheumatoid arthritis
Symptom relief, pain relief, increased mobility

Carpal tunnel syndrome
Pain relief

Tendinopathy
Healing, pain relief, increased mobility

Epicondylitis (tennis elbow)
Healing

Back and neck pain
Pain relief

Chronic joint diseases
Pain relief

Experience has also shown that Opton can have a positive effect in the treatment of the following diseases:

- Periarthropathia humeroscapularis
- Adductor insertion tendinopathy
- Patellar tendinitis
- Greater trochanteric pain syndrome
- Achillodynia
- Plantar fasciitis
- Insertion tendinopathy of the pes anserinus
- Painful muscular tension
- Gonarthrosis
- Rhizarthrosis
- Cervical spondylarthrosis
- Torn muscles
- Morton's neuroma

Contraindications

2

- Fresh haematomas

- Malignant, semi-malignant and benign tumours

- Treatments around the eye

- Pregnancy

- During menstruation in the abdomen or lower back

Particular caution is adviced in applying treatments near the ear, the nose, mucous membranes and blood vessels. Absolutely avoid direct irradiation of these areas.

In the presence of skin diseases, metabolic disorders and/or inflammatory diseases, the treatment should be performed only after consulting a physician.

Side effects

3

When used correctly, no side effects are known.

Safety instructions / warnings

Opton is a Class 4 laser. The accessible laser radiation is very hazardous to the eye and hazardous to the skin. Even diffusely scattered radiation can be dangerous. The laser radiation can cause fires or explosions.
The laser radiation emitted by the device is invisible.

Caution: Use of the controls or settings options in a manner other than those described here may lead to hazardous exposure to radiation!
Observe all relevant safety instructions!

The device must only be operated in accordance with occupational safety regulations and the rules of the relevant professional associations.
Corresponding directives and regulations must be observed.
The device may only be operated via a properly earthed socket with a grounded outlet (according to DIN VDE 0100 Part 710).
The device may only be operated in accordance with these instructions. All other applications are solely at the risk of the operator.
For maintenance, extensions, readjustments or changes, please refer to national regulations.
If there is any visible damage to the unit, the laser cable or applicator, the device must not be operated. Call customer service.

Legal requirements in accordance with the Regulations of the BG regulations (applies only within Germany)

1. Before first use, the operation of the device must be reported to the professional association and the competent authority for occupational safety (such as the trade supervision board).
2. The operator must appoint a laser safety officer.
3. The laser safety officer must provide safety instruction to all persons involved with the use of the device. This training must be repeated annually.
4. The device may only be operated by trained personnel who are at least 18 years of age. All persons within the area where the laser is being used must be briefed on the rules of conduct and safety rules that must be observed.
5. The area where the laser is to be used must be identified with laser warning signage, for example on all doors to the treatment area. There must be warning lights on the doors indicating when a laser is currently in use.
6. All doors to the laser treatment area should be secured with an interlock device. Other measures to protect against accidental irradiation are also allowed.
7. All objects and substances in the laser treatment area must be of low flammability.
8. Any instruments used in the laser treatment area must prevent hazardous reflections in their design and materials.

This information has been taken from BGV B2 and was valid at the time this manual was printed. These regulations are subject to change without notice.

General

1. The device is not intended for use in potentially explosive and/or combustive environments.
2. The use of flammable anaesthetic or oxidising gases such as nitrous oxide (N_2O) and oxygen should be avoided. Some materials such as cotton which are saturated with oxygen can be ignited by high temperature occurring during intended use of the laser device. Glue solvents and flammable solutions used for cleaning and disinfection should be allowed to evaporate before the laser device is used. Attention must be payed to bodily gases which may also ignite.
3. To avoid skin damage, please follow the treatment guidelines in the laser manual.
4. Please note that reflective objects in the treatment area can refract the laser radiation.
5. Ensure that the laser treatment area is free of flammable substances.
6. Please note that the laser radiation can leave the treatment area through windows, glass doors or other openings. Take appropriate precautions.
7. The fiber-optic cable and applicator are very sensitive optical systems. Treat them with appropriate care and protect them from contamination.
8. Never bend the fiber-optic cable and protect it against tensile loads. Damage to the fiber-optic cable can lead to unwanted radiation exposure.
9. Do not unscrew the spacer sleeve on the front part of the applicator under any circumstances. A treatment without the spacer sleeve or with an incorrectly installed sleeve can lead to increased exposure to the laser beam and cause skin burns.
10. When in use, electrical devices emit electromagnetic fields that can interfere with other devices. If in doubt, keep sufficient distance from potential sources of interference or avoid operating such devices simultaneously.
11. The device is to be used only in response to an indication by a physician.
12. Caution - If operating or adjusting devices other than those described here are used or if other procedures are performed, these may result in hazardous radiation influence.
13. The use of the device without spacers and high output settings poses a risk of skin burns.

Application information

5

Prior to using the device on the 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 sences of information about the treatment should be followed.

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

Caution! Operating of this device in the vicinity of strong electromagnetic fields (such as tomography, x-ray or diathermy equipment) may interfere with the operation of the device. Please keep a safe distance of several metres.

Opton is not suitable for use in explosive, flammable or combustive environment.

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

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

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

Caution! Only accessories from Zimmer MedizinSysteme GmbH must be used.

By electromagnetic effects the device may cause malfunctions or interfere with the operation of other equipment in the surrounding area. It may be necessary to take appropriate remedial action, such as realigning or reassembling the device or install electromagnetic shielding.

Caution! The device may only be opened by authorised service technicians from Zimmer MedizinSysteme.

Application information

Applicator

The applicator is located at the end of the fiber-optic cable. The laser beam is emitted from the front tip of the applicator. The outlet is protected against dirt and damage with a lens.
Point the applicator only on the area to be treated. Never place it down outside the calibration sensor.

Foot switch

The foot switch is used to initiate the laser beam. Press the foot switch only if the applicator is already pointed on the part of the patient's body that is to be treated. An acoustic signal sounds while the laser beam is being emitted.
Locate the foot switch in such a way, that it cannot be operated accidentally or by unauthorised persons.

Emergency stop button

The emergency stop button enables the immediate interruption of device operation by disconnecting the power supply.
To interrupt operation, press the emergency stop button until it clicks and the device shuts down.
To resume operation, return the button to its original position by turning the red knob in the direction shown by the arrows.

Calibration sensor

The calibration sensor enables the amount of laser output to be measured and adjusted.
The calibration sensor is also used for the applicator to be placed after treatment and when not in use. This protects the applicator from dirt and damage.

Safety glasses

All persons present in the treatment room (patient, therapist, support staff) should wear proper protective eyewear.
Only use goggles with an optical density OD > 3 at 810nm and 980nm and a translucence of at least 20% in the visible range. The glasses must be heat- and UV-resistant and comply with the requirements of EN 207.

Spacer (optional)

There are two spacers of different lengths and treatment surfaces available that will hold the laser head at a defined distance from the skin.

Protective sleeves

Protective sleeves are available when using the device without the spacers. They can be placed on the applicator to enhance patient comfort.

Silicone spacer (optional)

For the treatment of skin diseases, optional spacers made of silicone are available; these must be placed on the applicator to avoid contamination.

Note:

For more additional instructions on the use, cleaning and disinfection of the space, please refer to the spacer instruction manual.

Target beam

Opton has a target beam that provides information about the direction of the laser beam.
The target beam is not the same diameter as the laser beam and is not an indicator of the surface area being treated.

Opton – in brief

What is Opton?

A medical high-power laser therapy device for treatment with laser radiation.

What does Opton do?

Opton delivers laser beams to provide photochemical and thermal stimulation of parts of the musculoskeletal system requiring physical therapy.

Why Opton?

The simultaneous use of laser beams of two wavelengths (810 and 980nm) provide the user with a wide array of treatment options.

The modern microprocessor controls and the precise instrument for power measurement make the device easy to use at low risk use.

The modern, clearly understandable colour display shows all parameters relative to the treatment and the modern touch-screen controls provide fun and motivation during treatment.

Individual program start-up settings and clear, simple menu navigation provide maximum comfort to the user.

Note:

The device may only be used by healthcare professionals, such as physicians, therapists and trained medical assistants.

Device set-up

7

7.1 Safety precautions

Safety measures

Place a laser warning sign and a warning light on each door to the treatment room.

The laser safety officer must ensure that all safety measures have been correctly followed.

The device should be protected against unauthorised use by activating the key button when not in use.

Note:

Make sure that the main switch on the device is set to "0".

Ensure that all persons in the treatment room are wearing safety glasses.

Make sure that the applicator (4) is fully inserted into the calibration sensor (6).

Assembling the mains cable	Connect the mains cable to the corresponding socket (9) on the device and connect the cable to the mains.
Interlock plug	Connect the interlock plug (16) to the corresponding socket on the device (8).
Connect the footswitch	Connect the footswitch (14) to the corresponding socket on the device (7) and place it on the floor.
Switch on the device	Turn on the device at the main switch (12).
Key code	4 seconds after switching on, the "key" window will open automatically. Enter the key code: 1234.
Note:	*Each time the device is switched on via the main switch, the key code must be entered.*
Treatment screen	Confirm the key code with "OK"; this takes you directly to the treatment screen.
Setting the beam intensity	Set the desired intensity with the intensity controller (3).
Activate the laser	Activate the laser by pressing "Start".
Applicator	Place the applicator (4) on the correct area of the body to be treated.
Start treatment	Treatment starts once the foot switch is activated.
End treatment	By de-activating the foot switch, the application is interrupted or terminated. Place the applicator back into the calibration sensor after treatment.

Settings

8

Note:

The following descriptions are based on the factory default settings.

All buttons, menus and sub-menus can be activated directly on the screen with the touch pen or by a touch of the finger.

Ensure that all persons in the treatment room are wearing safety glasses.

To prevent unauthorised persons from using the laser,
Opton must be activated by entering a key code each time it is switched on.
Only once the code has been entered, can the laser beam output be set and delivered.

Changes to the basic settings are only possible from the start-up screen.

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Start-up screen

Note:

If no button is pressed within 4 seconds after turning on the device, the key code screen automatically appears. During this initial 4 seconds, the user can also press the "Start" button (2) or press "Settings" (1). Pressing the "Start" button before the 4 seconds are up, immediately opens the window for entering the key code.

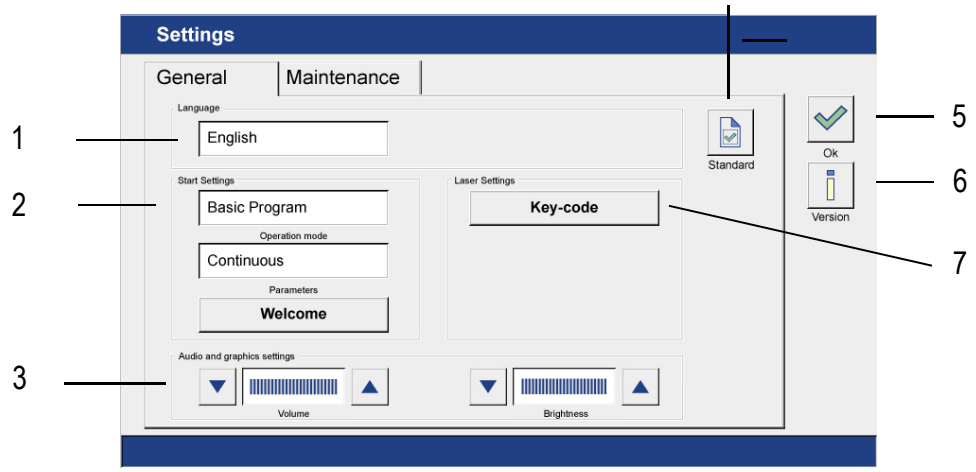
If the home screen is activated, it automatically switches after 4 seconds to the menu you have selected in the start-up settings (either basic program or treatment recommendations).

Selecting settings

Pressing the "Settings" button (1) opens the "Settings" screen.

Configuration menu

The configuration menu allows changes and individual adjustments to the factory settings to be made.



The setting options are shown below.

(1) Language

Press the "Language" button to open the window for selecting the language. The selection is made directly on the corresponding line.

(2) Start-up settings

1. Individual options for start-up settings.
1.1 Basic program in serial pulses, non-pulsing and single pulse modes.
1.2. Treatment recommendations
2. Welcome:
Pressing the "Welcome" button opens a window with an alphabetic keyboard to enter a welcome message for the start-up screen. Press "Save" to store the text that you have entered. Press "Cancel" to return to the configuration menu.

(3) Audio and graphics settings Volume

1. Brightness:
Allows the screen brightness to be adjusted.

2. Volume:
Allows the volume of the signal tones when touching the control panels to be adjusted. The adjustment is made using the two arrow keys.

(5) OK

Press the "OK" button to return to the start-up screen.

(6) Version

Press the "Version" button to open a window with information about the current software version.

(7) Key

Allows individual key codes to be set.
Pressing the "key" button opens a number pad for entering the code.
To specify a custom key code, the previous key code must first be entered on the keypad. Then you can enter the new key code.
Press "OK" to accept and close the keypad. Press "Cancel" to cancel the operation.

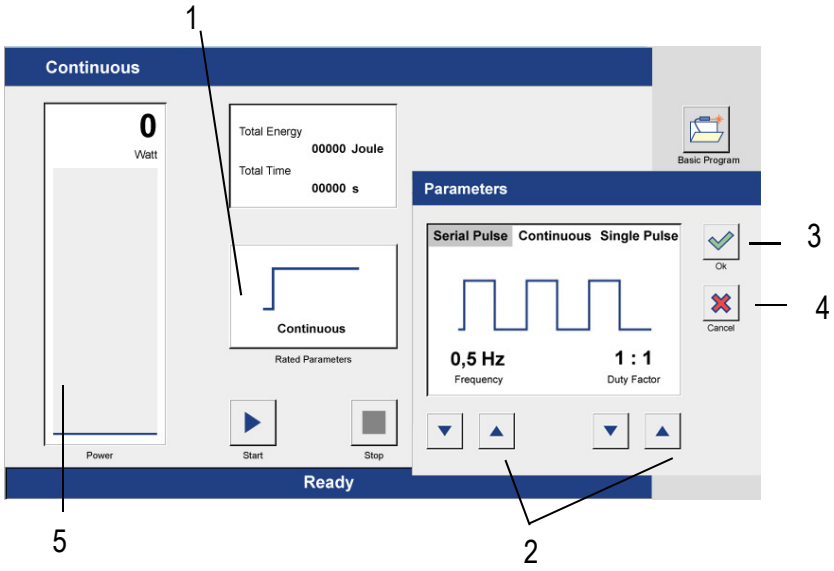
Note:	*The key code must be entered each time the Opton is switched on.*
(8) Default	Press "Default" to restore the default factory settings.
Note:	*The "Maintenance" menu is only accessible to service technicians.*
Save settings	Press "OK" to save the changed settings and return to the home screen.

Starting the program

The treatment screen will open automatically after the home screen has displayed for four seconds or by pressing the "Start" button.

Set operating modes

Press "Parameters" (1) to open the "Parameters" window.
Here you can select options for the different operating modes.



Set the values using the arrow buttons (2).

Press the check mark (3) to accept the changed settings.
Press the X (4) to cancel the changes.

Operating modes

The following operating modes can be selected:
- no pulsing
- single pulse
- serial pulsing

Available options in the various operating modes

Single pulse: Pulse time 0.5 – 5 seconds

	Frequency	Duty cycle
Serial pulsing:	0.5 Hz, 0.6 Hz, 0.7 Hz, 0.8 Hz, 0.9 Hz, 1 Hz, 2 Hz, 3 Hz, 4 Hz, 5 Hz, 10 Hz, 25 Hz, 50 Hz	1:1–1:8

Setting the intensity

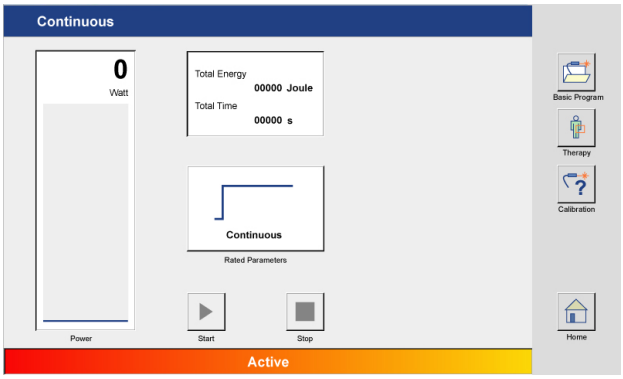
By turning the intensity controller, you can select the level of the desired output (5). The setting is in increments of 0.1 W.

Activate the laser

Pressing the "Start" button makes the laser ready to operate.
This is indicated with the message "Ready" in the footer. If the "Start" button is no longer lit up (because it has already been pressed), the "Stop" button becomes active.

Start treatment

By pressing the foot switch, the laser beam is delivered and the "Ready" message switches to "Active".

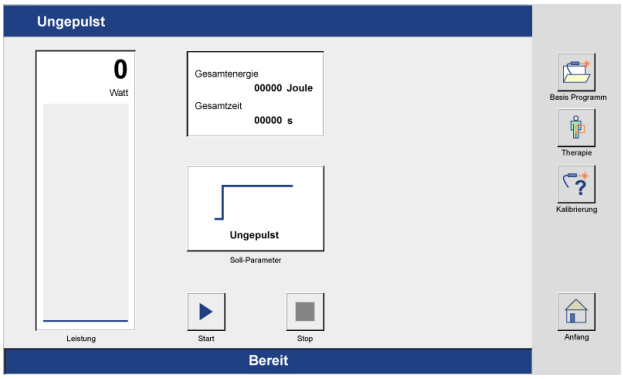


Note:

During use, the patient must be monitored carefully and the treatment should be adjusted or terminated as necessary if any issues arise.

End treatment

De-activating the foot switch cuts off the laser beam.
The message in the footer switches from "Active" back to "Ready".



The output must be manually reset to 0.0 W. Use the controller to set the output level.

Note:

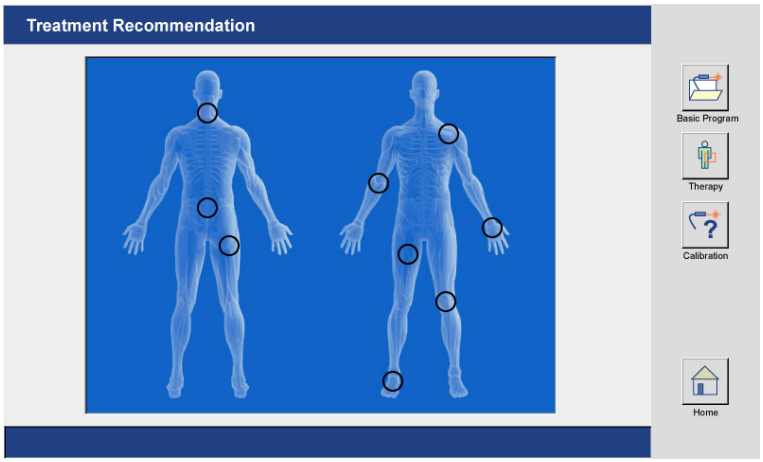
If output is terminated with the "Stop" button, both the "Start" button and the foot switch must be activated to restart treatment.

Place the applicator back into the calibration sensor once treatment is complete.

The "Treatment Recommendations" menu helps users select appropriate treatment options.

Treatment

Press the "Treatment" button in the navigation bar to open the "Treatment Recommendations" menu.

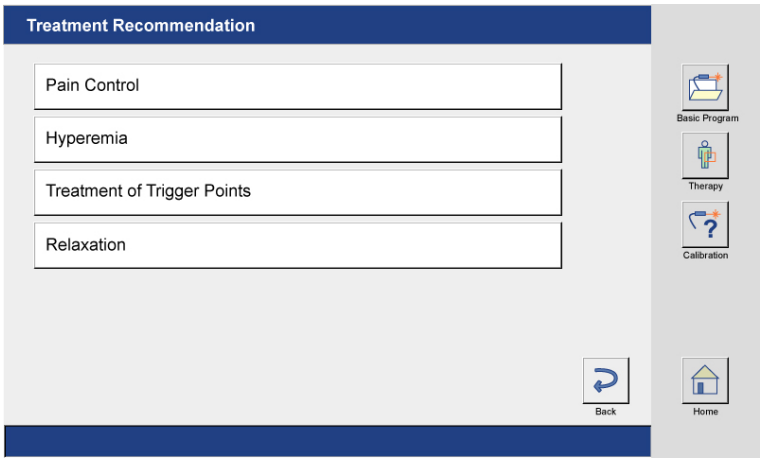


Selecting treatments by body region

Select the body region by clicking on the black circles shown.

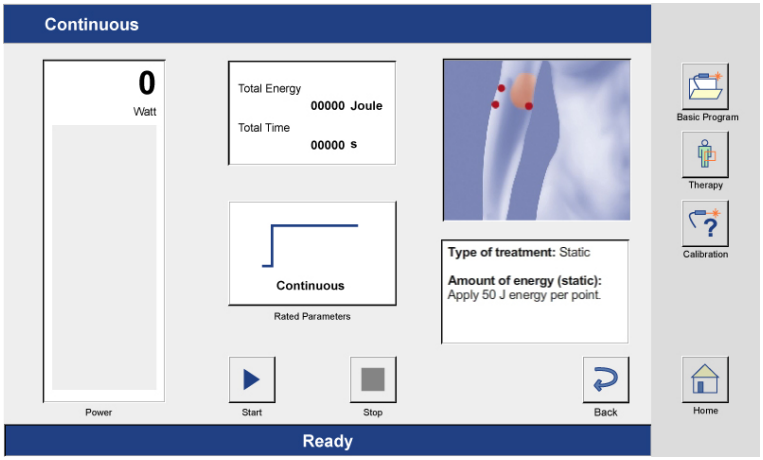
Selecting the body region

After selecting the desired region of the body, a window listing the recommended applications is displayed.
The selection is made directly by touching the corresponding row.



Treatment program

Once the selection menu is closed, the treatment program opens with recommendations for the kind of treatment and recommended amount of energy output.

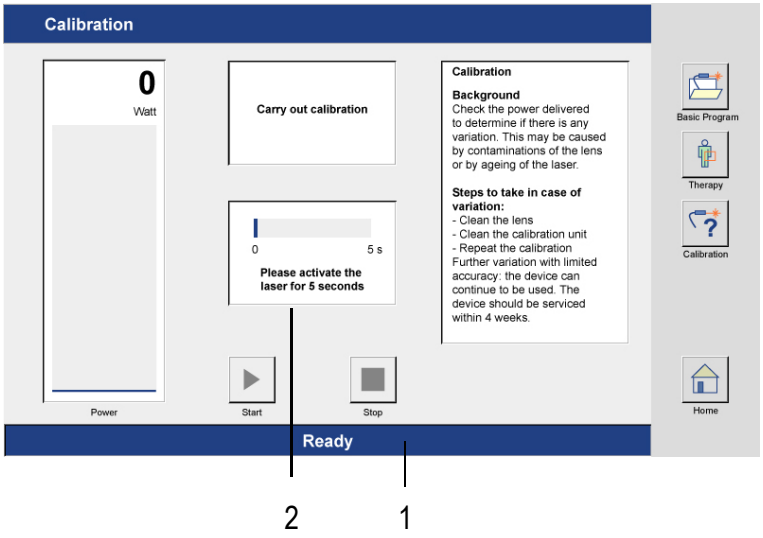


The parameters for the pre-defined programs can be individually modified and saved.

Note:

If the predefined program parameters in the treatment recommendations are changed, the treatment recommendations are no longer valid.
The following message will appear:
"Parameters have been changed: no treatment recommendation possible."

Calibration is used to control the amount of laser beam emitted. It should be performed each day before the first use of the laser.



Calibration procedure

1 Close the doors of any interlock plug that has been installed.
2. Make sure that the laser wand is in the calibrator.
4. Activate the laser by pressing the "Start" button.
5. The maximum laser power is automatically entered.
6. Press the foot switch for the specified duration.

During calibration, the elapsed time is shown in the bar graph in window (2).

Calibration results

The status bar (1) will display the calibration results.

1. Calibration OK:
Laser is operating normally
2. Limited accuracy:
There is a deviation in the laser output.
This suggests contamination or age-related changes to the laser system. The device can continue to be used, but maintenance should be performed within 4 weeks.
3. Calibration failed:
The laser output is outside the allowable range.
The device must not be used. Put the device out of operation and contact your service representative.

A repeat of the calibration can be performed. Before calibration can be repeated, the calibrator must first cool down. This will be indicated in the status bar.

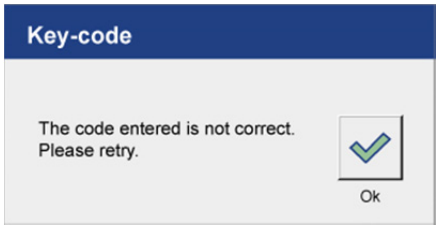
Key code

11

The laser is protected by a key code that must be entered each time the device is switched on.

Correctly entering the key code

If an incorrect key code is entered, this will be indicated by the following message.



After pressing "OK", you may attempt to enter the key code again.

Note: *In the configuration menu, you can set your own key code.*

Technical data

Wavelength	810 nm and 980 nm
Power supply	100-240V~, 50 Hz / 60 Hz 220 V~ / 60 Hz
Power consumption	max. 100 VA
Mains fuse	2 x T2A
Protection class	I
Applied part	Type BF per EN 60601-1
Laser system	3 semi-conductor diode lasers, optical fibres
Treatment area	min. Ø 10 mm
Power output	max. 4W
Repetition frequency	0.5 to 1 Hz, 2 Hz, 3 Hz, 4 Hz, 5 Hz, 10 Hz, 25 Hz, 50 Hz (CW mode)
Pulse duration	0.5 to 5 sec. (pulse mode)
Accuracy	±20%

	Without spacers	Optional Small spacers	Optional Large spacers
Treatment distance	0 cm	1.2 cm	4.5 cm
Treatment area	min. Ø 10 mm / 0.8 cm²	min. Ø 20 mm / 3.1 cm²	min. Ø 34 mm / 9 cm²
Output density	max. 5W / cm²	max. 1.3 W / cm²	max. 0.45W / cm²

Dimensions	322 x 234 x 130 mm (HxWxL)
Laser class	4
Safety distance	NOHD (Nominal Ocular Hazard Distance) 2.2 m
Beam divergence	35°
Interlock device	Door contact switch, open when door is opened, load up to 12V, 10mA, series circuit with several doors
Display	LCD
Weight	total: 2.5 kg

Technical data

Environmental conditions

Operation:
Temperature: 10° to 40°C
Humidity: 30% to 90% relative humidity, no condensation
Air pressure: 700 to 1060 hPa

Storage and transport:
Temperature: -10° to 50°C
Humidity: 10% to 90% relative humidity, no condensation
Air pressure: 500 to 1060 hPa

Storage and transport

Please keep all packaging. The device may only be shipped and stored in the original packaging.

Cleaning and disinfection

– Before starting any maintenance or cleaning measures, the device must be switched off with the main switch and the mains cable unplugged.

– Ensure that the cleaning and disinfection does not damage any labels on the device (such as warnings, labels of control devise, identification plote).

– During cleaning or disinfection, ensure that no liquid enters the device, foot switch or applicator. Do not use sprays.

– If liquid does penetrate the device or applicator during cleaning or disinfection, please put the unit out of service, protect it from being used and contact your service department.

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

Housing / Foot switch

Cleaning: In the event of visible contamination the housing, the foot switch and all cables can be cleaned using commercially available alcohol-free plastic cleaning agents. Wipe the surface with a soft cloth soaked in the cleansing agent according to its manufacturer's instructions but not dipping wit until the dirt is removed.

Disinfection: We recommend that disinfecting is to be carried out at least once a week as well as if there is any indication of contamination. Please consult your hygiene professional in this regard.
Always clean the device prior to disinfection.

The housing, foot switch and cables can be disinfected with disinfectant wipes. Use a commercially available alcohol-free disinfectant for metal and plastics which has a bactericidal, virucidal and fungicidal effect. Observe the application instruction of the manufacture. Wipe all surfaces with a soft cloth soaked, but not dripping wet, according to the specifications of the manufacturer in the disinfectant or with cloths pre-impregnated with disinfectant (wipes).
Follow any instructions for drying or post-cleaning.

Applicator / spacers

Cleaning: Remove the spacer from the applicator before cleaning. Then proceed as indicated under "Housing / Foot Switch". Use a cotton swab to clean the applicator lens.

Disinfection: We recommend disinfecting the device at least once a week as well as if there is any indication of contamination. Please consult your hygiene professional in this regard.
Always clean the device before disinfecting it.

Remove the spacers from the applicator before cleaning. Use a standard

alcohol-free disinfectant for metal and plastics which has a bactericidal, virucidal and fungicidal effect. Then proceed as indicated under "Housing / Foot Switch".
Use a cotton swab to clean the applicator lens.

Absolutely no residual cleaning or disinfectant agent must be left on the applicator lens! Any contamination will change the optical properties of the lens. Contact the service department in this case.

Caution: *If flammable solutions are used for cleaning and disinfection, enough time must be allowed for them to evaporate before using the device. Otherwise, it may catch fire!*

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

CE-mark

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The product bears the CE marking

CE 0123

according to EC Directive 93/42/EEC concerning medical devices.

Scope of delivery and accessories

Delivery includes:

Article no.	
4651	1 basic unit 1 mains cable 1 foot switch 1 interlock plug 2 sets of safety glasses 1 laser warning sign for door incl. warning light 25 protective sleeves 2 touch pen 1 user manual

* see also accessories

Accessories

Article no.	
117	Mains cable
94062522	Foot switch
98072210	Door sensor
68072310	Interlock plug
87450240	Safety glasses (2 pcs)
95730012	1 laser warning sign for door incl. warning light
65730310	Protective sleeves (25 pcs)
65071610	Silicone spacer
50400240	Small spacer
50400250	Large spacer
65800410	Touch pens (2 pcs)
10102170	Instruction manual

Device combinations

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For Opton no combination devices are provided by the manufacturer.

Anyone who contrary to these specifications combines devices and thus operates a medical system does so at its own risk.

Safety and maintenance

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Opton is manufactured according to the safety regulations in DIN EN 60601-1.

Zimmer MedizinSysteme GmbH can only be held responsible for the device's safety and reliability if

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

The device contains no parts that can be repaired by the operator.

Calibration

Before each treatment, calibrate the laser system (Chapter 10). This will ensure that the laser system is operating properly, the laser cable is intact and the applicator is fully functional.

Functional tests

Note *Ensure that all persons in the treatment room are wearing safety glasses.*

Functional test

1. Make sure that the applicator is fully inserted into the calibration sensor.
2. Turn the device on.
3. Enter the key code.
4. Press the "Calibration" button.
5. Activate the laser by pressing "Start".
6. Perform the calibration as described in Chapter 10. The message "Calibration OK" in the status line confirms that the laser unit is in good condition.
7. Press the emergency stop button. The appliance must switch off immediately. Return the button to its original position by turning the knob in the direction shown by the arrows.

Safety checks
Metrological control

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For the device Opton neither a Safety check (STK) nor a Metrological Control (MTK) is required in Germany.

In Germany, among others, the Medical Devices Operator Ordinance (MPBetreibV) and the BG regulation to electrical systems and equipment (BGV A3) apply in their current version.

Note: *These requirements apply to the operation of the unit in Germany. Please observe the national regulations in your country.*

Device does not function

No response to the main switch, display remains dark

Possible cause 1:
Mains connection
Remedy for cause 1:
Check if the mains cable is properly plugged into the electrical outlet and that the plug is firmly inserted into the socket on the device.
Check the mains cable for damage.
Check the electrical circuit and outlet.

Possible cause 2:
Mains fuse
Remedy for cause 2:
Check the mains fuse.
Replace the fuse only with exactly the same or equivalent fuse.
Before restoring electricity, check for any possible faults.

If the fault occurs again, inform customer service immediately.

Possible Cause 3:
Emergency stop button pressed.
Remedy for cause 3:
Check that the emergency stop button has been released.

Laser emits no power

Possible cause 1:
Interlock
Remedy for cause 1:
Check that the interlock plug has been correctly installed.

If a door sensor has been installed, check whether the door is open or not closed properly.

Possible cause 2:
Foot switch
Remedy for cause 2:
Check if the foot switch is correctly installed.

Applicator temperature too low

The unit is too cold. Wait until the operating temperature has been reached as indicated by a message on the display.

Applicator temperature too high

The device has become overheated by extended periods of high laser output. Wait until the operating temperature has been reached as indicated by a message on the display.

Errors
Troubleshooting
Disposal

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Malfunction

Internal device malfunctions are indicated by an error message on the display. Sometimes malfunctions can be fixed by switching off the device, waiting five seconds and then switching the device back on.
If this does not work, please contact customer service. You can reach the service department via your sales representative or by calling our Neu-Ulm office.

Customer service

If there are frequent malfunctions or they cannot be resolved as described above, inform customer service right away.
You can reach the service department via your sales representative or by calling our Neu-Ulm office.

Headquarter

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Disposal

The device must be returned to the factory in its original packaging. It must be disposed of by Zimmer MedizinSysteme GmbH.

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

Manufacturer's EMC declaration

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Electric medical devices such asOpton are subject to special precautions with respect to electromagnetic compatibility (EMC) and must be installed and operated according to the user manual or EMC instructions included with the device.

Portable and mobile RF communications equipment (such as mobile telephones) can affect electrical medical devices.

Opton may only be operated with the original parts specified in the list of items included in the delivery and available OEM accessories. The operation of the device with other parts may result in increased emissions or likelihood of malfunctions!

Guidelines and manufacturer's declaration concerning electromagnetic emissions		
The Opton device is intended for use in the electromagnetic environment specified below. The customer or user of Opton should ensure that it is used in such an environment.		
Emissions measurements	**Conformity**	**Electromagnetic environment guidelines**
RF emissions per CISPR 11	Group 1	The Opton device uses RF energy only for its internal function. Therefore, its RF emissions are very low and it is unlikely that nearby electronic equipment will be impaired.
RF emissions per CISPR 11	Class B	The Opton device is suitable for use in all facilities, including residential ones, that are directly connected to the public mains that also supplies residential structures.
Emissions of harmonics per IEC 61000-3-2	Class A	
Emissions of voltage fluctuations / flickers per IEC 61000-3-3	Conforms	

Table 201 per EN 60601-1-2

The device must not be used adjacent to or stacked directly on other devices. If it must be used in the vicinity of or stacked directly on other devices, the device should be monitored to verify that it is operating properly in this set-up.

Guidelines and manufacturer's declaration of electromagnetic immunity			
The Opton device is intended for use in the electromagnetic environment specified below. The customer or user of the Opton device should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 - Test Level**	**Compliance level**	**Electromagnetic environment guidelines**
Electrostatic discharge (ESD) per IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative air humidity must be less than 30%.
Electrical fast transient/bursts per IEC 61000-4-4	±2 kV for mains ± 1 kV for input and output lines	±2 kV for mains Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge voltages per IEC 61000-4-5	± 1 kV line-to-phase conductor ± 2 kV line-to-earth	± 1 kV line-to-phase conductor ± 2 kV line-to-earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations per IEC 61000-4-11	< 5% U_T (> 95% dip in U_T for ½ term) 40% U_T (60% dip in U_T for 5 periods) 70% U_T (30% dip in U_T for 25 periods) < 5% U_T (> 95% dip in U_T for 5 seconds)	< 5% U_T (> 95% dip in U_T for ½ term) 40% U_T (60% dip in U_T for 5 periods) 70% U_T (30% dip in U_T for 25 periods) < 5% U_T (> 95% dip in U_T for 5 seconds)	Mains power quality should be that of a typical commercial or hospital environment. If the user of Opton requires operation to continue even after the energy supply is interrupted, using an uninterruptible power supply (UPS) or battery is recommended. It may cause the device to reset.
Note: U_T is the AC mains voltage prior to applying the test level.			

Table 202 per EN 60601-1-2

The key features of Opton include: delivering laser radiation for therapeutic purposes, as well as trouble-free operation of all functions.

Guidelines and manufacturer's declaration of electromagnetic immunity			
The Opton device is intended for use in the electromagnetic environment specified below. The customer or user of the Opton device should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 - Test Levels**	**Conformity level**	**Electromagnetic environment guidelines**
Conducted RF interference per IEC 61000-4-6 Radiated RF disturbances per IEC 61000-4-3	3 V_{RMS} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{RMS} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Opton, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P}$ for 80MHz to 800 MHz $d = 2.33 \sqrt{P}$ for 800 MHz to 2.5 GHz P is the nominal rating of the transmitter in watts (W) according to the transmittermanufacturer and d is the recommended separation distance in metres (m). The field strength of stationary radio transmitters measured on-site for all frequencies[a] should be less than the conformity level.[b] In the vicinity of devices marked with the following symbol, errors may occur: 
NOTE 1 At 80 Hz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all cases. The 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 land 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 should be considered. If the measured field strength in the location in which the Opton device is used exceeds the applicable RF compliance level given above, the Opton device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Opton device. [b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 204 per EN 60601-1-2

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

The Opton device is intended for use in the electromagnetic environments where RF disturbances are controlled. The customer or the user of the Opton device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Opton device as recommended below, according to the maximum output power of the communications devices listed below.

Nominal capacity of the transmitter W	**Separation distance according to frequency of transmitter M**		
	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.67	11.67	23.33

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

Table 206 per EN 60601-1-2

Opton

Instructions for Use

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