Zimmer
MedizinSysteme

Instructions for Use

Opton*Pro*

25 Watt, 15 Watt, 10 Watt

EN

Illustrations

Front of the device

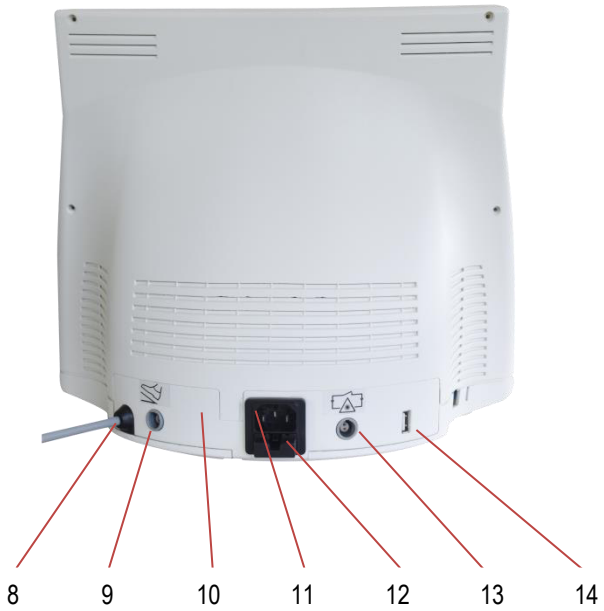
Fig. 1

Selection and operating elements	1	Control Unit
	2	Display
	3	Emergency stop button
	4	On/off Switch
Applicator with light guide	5	Applicator with
	5.1	Hand Switch and
	5.2	Integrated infrared sensor and laser aperture
	6	Optical fibre
Test sensor	7	Test sensor and holder for applicator

Illustrations

Rear of the device / switches and ports

Fig. 2



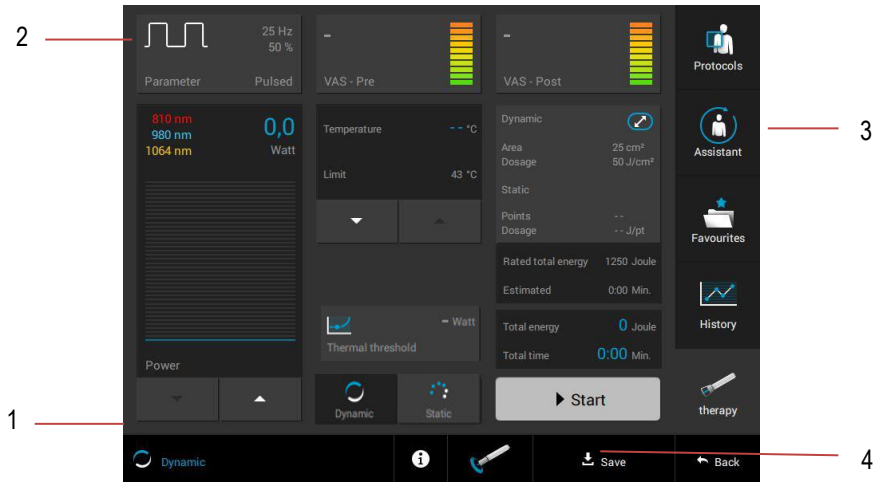
Ports

8 Light guide outlet
9 Connection port for foot switch
10 Identification plate
11 Connection for power cable
12 Holder for mains fuse
13 Connection port for interlock plug
14 Connection port for USB

Illustrations

Screens / display views / navigation menus

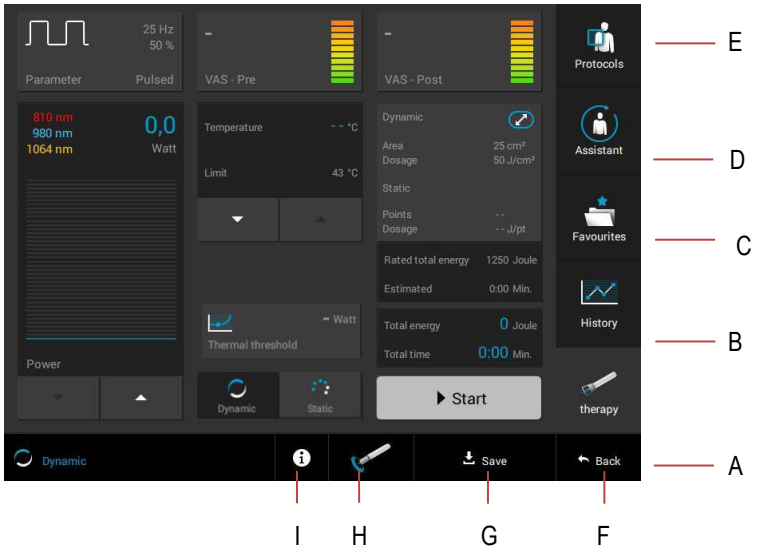
Fig. 3



Display view

1 Status line
2 Buttons on the screen
3 Buttons in the navigation menu
4 Buttons in the status line

Fig. 4



Navigation menu / status bar
Description of the functions

(A) Therapy	Switches to the therapy screen
(B) History	Switches to the VAS history
(C) Favourites	Switches to Favourites
(D) Assistant	Switches to Assistant
(E) Protocols	Switches to Protocols
(F) Back	Switches one page back or to the start-up screen
(G) Save	Switches to Memory
(H) Performance test	Switches to the performance test level
(I) Information	Switches back to therapy recommendations

Illustrations

Accessories

1 Spacer, small

2 Spacer, large

3 Foot switch (optional)

4 Laser warning sign with laser warning light

5 Interlock plug

6 Protective laser glasses

Visible and Invisible Laser Radiation!
Avoid direct or diffuse exposure to eyes and skin!
Class 4 Laser
Wavelengths 810 nm, 980nm, max. 10W CW,
Pilot beam Wavelength 650 nm, max. 5 mW CW
IEC 60825-1:2014

7 Laser Warning Sign up to OptonPro 10 W

Visible and Invisible Laser Radiation!
Avoid direct or diffuse exposure to eyes and skin!
Class 4 Laser
Wavelengths 810 nm, 980nm, 1064nm, max. 25W CW, Pilot beam Wavelength 650 nm, max. 5 mW CW
IEC 60825-1:2014

8 Laser Warning Sign up to OptonPro 25 W

Explanation of symbols

Caution: laser aperture
Note: The laser beam exits at the end of the applicator

Turn the emergency stop button in the direction of the arrow to unlock

Laser Stop button symbol

Connection port for foot switch

Connection port for interlock

Rating of the accessible fuses

Follow instructions for use.

Serial number

Catalogue number

Manufacturer

Date of manufacture

This symbol indicates “Caution” with regard to possible material damage.

This symbol indicates “Danger” with regard to possible risks to people.

USB connection port

IP20

Housing and handpiece protected against solid foreign particle with a diameter of less than 12.5 mm, no protection against ingress of water

Optical fibre applicator

Disposal of electrical and electronic equipment as well as used batteries and accumulators. Products marked with the adjacent symbol must not be disposed of with household waste.

Applied Part Type B

Contents

Contents

Valid for the devices Opton*Pro* 10 W, Opton*Pro* 15 W and Opton*Pro* 25 W.
This instructions for use is valid as of April 2022.

These instructions for use are an integral part of the device, they must be kept with the device in order to allow access at any time to the persons responsible for operating the device. If the instructions for use have become illegible, damaged or otherwise inaccessible to the user, a replacement must be requested from the manufacturer for the safe use of the Opton*Pro* and made available to the user. This includes the information on the labels on the device.

The instructions for use can also be downloaded from our website (https://www.zimmer.de/eifu/).

Indications

1

OptonPro can be applied at the following Indications

The Opton*Pro* is indicated as an adjuvant application for the treatment of the musculoskeletal disorders listed below:

- Knee osteoarthritis,
- Lateral epicondylitis,
- Low back pain,
- Chronic neck pain.

Treatment effects are usually enhanced by a combination with exercise or other state-of-the art therapies.

Contraindications / Side effects

Contraindications

- Fresh hematomas and active haemorrhage
- Tumorous diseases (malignant, semi-malignant and benign), even over areas that are suspicious or contain potentially cancerous tissue, irradiation of malignancies and precancerous growths
- Eye area and its vicinity
- Pregnancy
- Low back and stomach during menstruation
- Epilepsy
- Fever
- On patients suspected of carrying serious infectious disease and or disease where it is advisable, for general medical purposes, to suppress heat or fevers
- Sensitivity on the treatment area
- Placing an active applicator over metal implants, e.g. cochlear implants
- Application on freckles
- Application directly over areas with open wounds or infected areas
- Application on the sympathetic, vagus or cardiac area in patients with heart diseases or pacemakers
- Photosensitive medication or application on photosensitive areas
- Irradiation of endocrine glands
- Sensational deficit in the treatment area
- where analgesia may mask progressive pathology, and where the practitioner would normally avoid the use of any other analgesia to retain the beneficial aspects of pain
- over areas injected with steroids in the past 2-3 weeks
- over the neck (thyroid or carotid sinus region) or chest (vagus nerve or cardiac region of the thorax)
- treatment over sympathetic ganglia
- for sympathetic local pain relief unless ethology is established or unless a pain syndrome has been diagnosed
- on ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result
- Particular caution is required when administering treatment near the ear, nose, mucous membrane and blood vessels. Direct radiation must be avoided.
- If there are skin diseases, metabolic diseases or inflammatory diseases, a physician should be consulted prior to treatment.
- suspected or confirmed neoplasms

Side effects

To avoid possible adverse side effects, pay attention on the precautionary and application instructions. In the event of improper use of laser radiation, the application of radiation can cause damage to skin and equipment. Additional examples for possible adverse side effects are:

- Smoke formation
- Danger of fire and explosion
- Electrical hazards
- Fibre breakage and emission of radiation

The human eye is particularly sensitive. Damage to the eye usually causes irreparable malfunction. Take great care!

Safety information / Warnings

Opton*Pro* is a class 4 laser. The accessible laser beam is very dangerous to the eye and dangerous to the skin. Even diffusely scattered radiation can be hazardous. The laser beam can cause a risk of fire or explosion.
The laser beam emitted from the device is invisible.
Observe all corresponding safety instructions!
Operation of the device is subject to occupational safety regulations and the regulations of professional associations. Corresponding guidelines and regulations must be observed.
The device may be operated only at a properly connected socket with protective conductor (according to VDE 0100 part 710).
The device may only be operated in accordance with these instructions for use. All other applications are the responsibility of the operator.
For maintenance measures, expansions, readjustments or modifications, the provisions of the German Medical Devices Act and the Medical Device Operator Ordinance apply.
If there is visible damage to the device, the light guide or applicator, the device should not be used any further. Call customer service.

Legal regulations according to the Occupational Safety and Health Ordinance on Artificial Optical Radiation (OStrV) (only for the Federal Republic of Germany)

1. The operator must conduct a hazard assessment and display operating instructions.
2. The operator must designate a laser protection officer.
3. The laser protection officer must provide safety-related instruction to persons assigned to use the device. This instruction must be repeated annually.
4. The device may be operated only by the defined user group (see the beginning of chapter 3).
5. The operational area of the laser must be identified with the laser warning sign (for example, on all doors of the treatment room). Warning lights on the doors must indicate the operation of the laser.
6. All doors to the operational area (e.g., treatment room) of the laser should be secured with an interlock device. Other measures to protect against inadvertent radiation are permitted.
7. All objects and materials located in the working area of the laser must have low flammability.
8. Instruments used in the working area of the laser must, through their shape and material, exclude hazardous reflections.

This information is taken from the Occupational Safety and Health Ordinance on Artificial Optical Radiation – OStrV – and are valid at the time of printing. They may be changed at any time without notice.

General

1. The use of flammable anaesthetic gases or oxidising gases such as nitrogen oxide (N_2O) and oxygen should be avoided. Some materials, such as cotton, which are saturated with oxygen, can ignite in the case of high temperatures which develop when the laser device is used as intended. Solvents of adhesives and flammable solutions which are used for cleaning and disinfection should be given time to evaporate before the laser device is used. Attention should also be paid to the fact that gases produced by the body itself can ignite.
2. To avoid skin damage, please observe the therapy guidelines in these instructions for use.
3. Be aware that reflective objects in the treatment area can deflect the laser beam.
4. Ensure that the working area of the laser is free of flammable materials.
5. Be aware that the laser beam can leave the treatment room through windows, glass doors or other openings. Take corresponding precautionary measures.
6. The light guide and the applicator are very sensitive optical systems. Accordingly, treat them with care and protect them from soiling.
7. Never bend the light guide and protect it from tensile stress. Damage to the light guide can lead to undesired beam exposure.
8. Never unscrew the spacer sleeve on the front part of the handpiece. Treatment without the spacer sleeve or with an incorrectly mounted sleeve can lead to increased beam exposure or to burns of the skin.
9. Operation of this device in the vicinity of strong electromagnetic fields (e.g., tomographs, X-ray or diathermy equipment) may interfere with the operation of the device. Please keep a safe distance of several meters.
10. To avoid the risk of electric shock, the plug must be disconnected from the power supply before performing any cleaning or maintenance activities.
11. Inspect the device before use. If there is any damage, it must not be used.
12. Only accessories provided by Zimmer MedizinSysteme GmbH must be used.
13. During operation, the user may not touch the patient and the socket of the footswitch or the interlock connection on the device housing simultaneously!

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

General

User group

The use of the Opton*Pro* is limited to the following criteria:

- Members of authorized/licensed medical profession (e.g. doctors, therapists, medical paraprofessionals) who understand the warnings as well as the contraindications and indications of the accompanying documents
- Expertise: Knowledge of the mode of action of laser therapy
- Health Conditions: The user must have no visual or hearing impairment and no color blindness.

Patient groups

No limitation with regard to gender, nationality, ethics and skin colour types (I Celtic type, II Nordic type, III mixed type, IV Mediterranean type, V dark type, VI black type).
Age: The person to be treated must be older than 18 years and be able to clearly communicate pain perception.
In general, the person to be treated must have intact thermal perception.

Information for the user

The users of the Opton*Pro* must have read the instructions for use prior to the first use of the device, including the treatment methods, indications, contraindications, warnings and application information.

Observation of and feedback from the patient

During the therapy, the patient may not be left unattended. The user must take note of the patient's feedback and react accordingly.

Following treatment instructions

Treatment instructions regarding location, duration and scope of the treatment require medical knowledge and may only be given by authorised physicians, therapists and medical professionals. These instructions are mandatory.

User environment

Application may take place only in closed, dust-free rooms.
Use in wet areas is not permitted and may in case of non-compliance lead to considerable damage and endanger both the patient and the user.

Application Principle

After entering the key switch, the user must enter the laser parameters. He holds a handpiece to the body region to be treated and starts the laser therapy by pressing the foot switch or the button on the handpiece. After the static and / or dynamic treatment, the laser therapy is terminated upon reaching the desired laser power. During the entire therapy, the user is present and responds to the feedback from the patient.

Application duration

The maximum therapy time per patient depends on the size of the treated body area and the laser energy to be applied.

The application duration depends on the applied laser energy. It should be applied up to 6,000 J per treatment.

Application outside of/according to use as intended

The use of the device outside of the settings or applications indicated in the instructions for use can lead to hazards which lead to the uncontrolled release of laser energy. The device

may be used only according to its intended use.

Emergency Stop

In case the software does not stop the emission of laser radiation immediately, push the emergency stop.

General

Pilot beam takes the same path as the therapy beam
Since the pilot beam takes the same path and has the same application area as the therapy beam, this is a good way to check the integrity of the laser transmission system. If the pilot beam does not appear at the distal end of the applicator, if its intensity is low or if it appears to be scattered, this is a possible indication of a damaged or defective laser transmission system.

Risk of explosion and combustion
It's forbidden to use the laser in the presence of combustible materials, solutions or gases or in an oxygen-enriched environment because of fire and explosion hazard.

No unauthorized modification
WARNING: No modification of this equipment is allowed.

No maintenance during the laser therapy
No maintenance work may be performed during the laser therapy.

No reflective and scattering objects
The user and the patient may not wear any reflective and scattering objects in the treatment field, for example, rings, piercings, etc.

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

No therapy if pain relievers or mind-altering substances are taken
Since taking these substances can lead to a change in pain perception, no therapy should be performed. In the worst case, this can lead to burns.

Use of protective laser glasses
All persons in the treatment room must wear protective laser glasses. Use only protective glasses with an optical density OD > 3 (protection level at least LB 3) at 650/810/980/1064 nm for operating mode D (continuous wave) and a light transmission of at least 20% in the visible range. The glasses must be both heat- and UV-resistant and meet the requirements of EN 207. The protective glasses must be designed for power up to 25 W.

No connections of devices with their own power supply
No devices with their own mains power (e.g., plug-in power supply) must be connected to the USB interface and to the connection for the interlock/foot switch. Note that the USB connection via USB stick is only used for data transfer of laser parameters and VAS data.

No operation in case of wearable implants etc.
In the case of patients with implants or implanted electronic devices, only carry out a treatment after the risk has been clarified.

No use in connection with a high-frequency surgical device
A simultaneous connection of the patient with a high-frequency surgical device is not permitted. This can lead to burns.

No use of liquids during normal use

During normal use, the handling of liquids near or during laser therapy is forbitten.

No simultaneous touching
It is forbidden for the user to touch the pins of the footswitch (9) /the interlock (13) and the patient simultaneously.

No touching of metal tip after long treatment
Please don't touch the metal tip of the handpiece after long treatment. The tip can get warm (see chapter 9).

Application information

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

Before use, make sure that the device is operated via a standard socket with protective contact (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.

The device is not suitable for use in areas with an explosive, flammable or combustion-promoting 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 do this, pull the mains plug out of the socket.

The device may be opened only by service technicians authorised by Zimmer MedizinSysteme GmbH. The device does not contain any parts to be maintained by the user. To disconnect the device from the power supply, disconnect the mains plug from the socket.

This instructions for use should always be kept with the device to enable the persons charged with the operation of the device to access it at any time

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

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

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

Potential contact components (spacers, applicator) must be cleaned and disinfected after each use.

Handle the optical fibre carefully and do not expose it to any strong tensile, pressure or bending stress. The optical fibre can be damaged if it is bent excessively. To prevent this, the bending radius should never be less than a minimum of 60 mm.

The laser light can be activated and deactivated using the foot switch or the manual switch on the applicator. The mechanism activated first is always the one applied.

In the event of danger, the mains plug can be disconnected from the socket to bring the unit into a safe condition.

When using the spacers, do not apply pressure to the patient's skin with them.

High-power laser applications lead to intense heating of the laser unit, for technical reasons. When applying very large amounts of high-power energy (>6000 Joule), a cooling phase is automatically initiated by the device during which no laser radiation is emitted.
This is shown by the message “Excessive temperature. The laser is being brought to operating temperature. Ready to use again in XX:XX min:sec.” (see chapter 15).

The application duration depends on the applied laser energy. It should be applied up to 6000 Joule per treatment.

Applicator

The applicator is at the end of the light guide. The laser beam exits from the front end of the applicator. The aperture is protected by a lens from dirt and damage.
Direct the applicator only on the area of the patient to be treated. Never lay it down outside of the test sensor.

Manual switch

The manual switch is used to trigger the laser beam. Operate the manual switch only when you have directed the applicator beforehand at the patient’s body area to be treated. An acoustic signal can be heard while the laser beam is being emitted.

Emergency stop button

The emergency stop button makes it possible to immediately interrupt operation of the device by interrupting the power supply.
To interrupt operation, press the emergency stop button until it clicks into place and the device switches off.
To resume operation, return the button to the original position by turning the red button in the direction of the arrow.

Test sensor

The test sensor makes it possible to measure and balance the laser power emitted.
The test sensor is also used to store the applicator after the treatment and during periods in which the device is not in use. In this way, the applicator is protected from dirt and damage.

Protective glasses

All persons present in the treatment room (patient, therapist, support staff) must wear suitable protective glasses. Only use protective glasses with an optical density OD > 3 at 810 nm and 980 nm and a light transmission of at least 20 % in the visible range. The glasses must be heat and UV resistant and comply with the specifications of EN 207. The glasses must be designed for power of up to 25 W.

Spacers

Two spacers with different lengths and therapy areas are available which hold the laser head at a defined minimum distance from the skin. Be aware that there may be high power densities, particularly when the handpiece is used without a spacer and when the output power is set to a high level. There is a risk of thermal skin damage. Use without a spacer is not recommended.

Opton*Pro* – in brief

Intended use of Opton*Pro*

Opton*Pro* is a medical therapy device for the generation of a laser beam from three wavelengths for the thermal initiation and support of tissue healing processes for external application.
In principle, direct contact of the skin with or without spacers is not intended during therapy.

If necessary, the spacers can be placed on the skin.

The laser radiation of the working beam and pilot beam is generated in the basic unit by laser diodes and directed at the back of the device via the permanently connected laser fibre to the laser hand piece. Here, the laser radiation on the applicator head is emitted. Working and pilot beams are routed via the same optics, both of which have the same beam path.

What are the benefits of Opton*Pro*?

The simultaneous application of laser light from two – depending on the model – or three wavelengths (810/980 and 1064 nm) opens up a broad field of treatment options for the user.

The modern microprocessor control and the accurate device for power measurement enable simple and low-risk use.

The modern, clear colour display showing all therapy-related parameters and the modern touch operation ensure enjoyment and motivation during treatment.

Individual program start settings and clear, simple menus offer the user maximum convenience.

Residual risks
If the device is used within its intended purpose, no other unacceptable residual risks are known besides the side effects and the warnings already mentioned.

Note: *The application of the device is reserved for the defined user group*

System set-up

6.1 Safety measures

6

Safety measures

Affix a laser warning sign including light to each door to the treatment room.

Remove the laser warning sign sticker from the sheet enclosed with the device and affix it visibly to the device.
Select a sticker in a language which can be understood by all employees.

The laser protection officer must ensure proper application of safety features.

When not in use, the device should be protected against unauthorised use by operating the code button.

Note:

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

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

Ensure that the applicator (5) is fully pushed into the test sensor (7).

Power cable assembly	Connect the power cable to the provided port (11) on the device and connect the cable to the mains.
Interlock plug	Connect the interlock plug (5) to the provided port (13) on the device.
Switch device on	Switch on the device using the mains switch.
Select programme	Press the “Start” button, and select a program.
Enter code	The code must be entered after each time the device is switched on. Enter the code 1234 and confirm with “OK”. If an incorrect code is entered, this is displayed by a message. After activating the “OK” button, the entry can be repeated.
Select therapy screen	Activate the “Therapy” button.
Adjust intensity	Adjust the desired output.
Attach spacer	Place the spacer (1/2) on the applicator.
Activate laser	Activate the laser by pressing the “Start” button.
Applicator	Place the applicator in the correct position in the treatment area.
Patient preparation	In addition to your standard practice procedures, we recommend that the area to be treated must be free of clothing. Please observe the warnings.
Start of therapy	The therapy begins by pressing the manual switch on the applicator.
End of therapy	Releasing the manual switch interrupts or terminates the therapy. Remove the spacer from the applicator after the therapy and insert the applicator into the test sensor.
Note:	*The foot switch is not included in the standard scope of delivery of OptonPro.*
Operation using the foot switch	Connect the foot switch to the port provided (9) and put it on the floor. Activating the foot switch starts the therapy. Deactivating the foot switch interrupts or terminates the therapy.

Note:	*The following descriptions are based on the factory settings.* *All buttons, menus and sub-menus can be activated directly on the screen with finger pressure.* *Ensure that all persons present in the treatment room are wearing protective laser glasses.* *Changes to the default settings can only be made in the configuration menu from the start-up screen.*
Configuration menu	Factory settings can be changed and individually adjusted in the configuration menu.
Configuration information	Activation of the “Configuration” button in the start-up screen opens the “Configuration general” screen.
Welcome text	Activating the “Welcome text” button opens the alphabetical keyboard to enter an individual welcome text in the start-up screen. Activating the “OK” button saves the text entered. Activating the “X” button leads back to the “Configuration general” screen.
Language	Activating the “Language” button opens the window to select the language. The selection is made directly in the corresponding line.
Start settings	Activating the “Start-up settings” button opens the window to select the individual start-up settings. The selection is made directly in the corresponding line.
Colour scheme	Activating the “colour scheme” button switches between two screen settings. The bright or dark screen can be selected.
VAS values	Activating the “VAS values” button activates/deactivates the VAS scale in the therapy screen.
Volume	The volume of the signal sounds can be adjusted by activating the control panels. The adjustment can be made using the two arrow buttons.
Brightness	Option to adjust the brightness of the screen illumination. The adjustment can be made using the two arrow buttons.
Set to default	Activating the “Set to default” button restores the factory default settings.
Version	Activating the “Version” button opens a window with information on the current software version.
Opton	Activating the “Opton” button opens the “Configuration Opton” screen.
Code	The laser is access-protected by a code.
Note:	*If access is deactivated, only the parameters can be set.* *Activation of the laser, power settings and conducting a performance test are not possible.*
Enter individual code	Activating the “Code” button opens a numeric window to enter the code. In the first step, the old code is entered in the “Old code” field. In the second step, activate the “New code” button by directly selecting it and enter the new code in the numeric window. Activating the “OK” button accepts the entry and closes the numeric window. Activating the “Cancel” button interrupts the process.

Deactivation of the code

Option to adjust the deactivation time period.
The adjustment can be made using the -/+ buttons.

The access is deactivated after the set time has passed, if no settings have been made on the screen within this time.
The code must then be re-entered.

If actions are carried out within the set time, the deactivation time period automatically resets back to 10 minutes.

The "deactivated" setting overrides the default or individually set activation time.

Temperature

Activation of the "Temperature" button activates/deactivates the temperature measurement in the therapy screen.

Manual switch

Activation of the "Manual switch" button offers various options for operating the manual switch.

1. Continuous: To emit the laser beam, the manual switch must be continuously held down. When the manual switch is released, the emission of the laser beam is interrupted.
2. Double click: To emit the laser beam, the manual switch is set with a double click so that the laser beam can be emitted without continuously pressing the manual switch. When the manual switch is pressed once, the emission of the laser beam is interrupted.
3. Deactivated: Deactivates the function of the manual switch.

Pilot beam

Activating the "Pilot beam" button enables the emission of the pilot beam to be set to "Pulsed" or "Continuous" while the laser beam is emitted.

Note:

The aiming beam provides information on the direction of the laser beam.
It corresponds to the diameter and position of the laser beam.

Thermal threshold

Activation of the "Thermal threshold" button activates/deactivates the thermal threshold test in the therapy screen.

Skin temperature limit

Option to enter a skin temperature limit.
The upper skin temperature limit is restricted to 43°C.

General

Activation of the "General" button leads back to "Configuration general".

Maintenance

Activation of the "Maintenance" button opens a window in which the date and time can be set to meet country-specific requirements.

Export VAS / Favourites

Enabled the VAS data and Favourites saved in the device to be saved on a USB stick. This is used to backup or transfer the data to an additional/another Opton*Pro* (10 W/15 W/25 W) device.

Import VAS / Favourites

Via a USB stick, the data from another Opton*Pro* (10 W/15 W/25 W) can be transferred to this device.

Performing Import / Export VAS / Favourites

Procedure: Insert USB stick into the port provided.
The data are transferred by activating the desired button.

Save settings

Activating the "OK" button saves the modified settings and returns to the start-up screen.

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

Open therapy screen Activating the “therapy” button in the start-up screen opens the therapy screen.

Adjust power The power is adjusted in the “Power” bar graph.

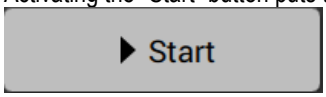
Two options are available for adjusting the power:

1. Using the arrow buttons underneath the bar graph, the power can be adjusted in 0.1-W increments.

If the arrow buttons are held down, the adjustment process is accelerated.

2. Activating the bar graph opens a numeric field. The selection is made by activating the button with the desired power. The adjustment is made in 0.1-W increments. Activating the “OK” button accepts the selected power. Activating the “Cancel” button interrupts the process.

Activate laser Activating the “Start” button puts the laser in an operational state.



The “Start” button becomes inactive and the “Stop” button becomes active.
The “foot off the switch” symbol indicates that the laser is ready for use.

Pilot beam appears The pilot beam is activated to throw light on the treatment area. Safety instruction in chapter 3 has to be observed.

Laser Ready to use indicator The following symbol indicates that the laser is in the ready to use state:

Start of therapy The laser power is emitted by activating the manual switch/foot switch.

When laser power is emitted, an acoustic signal sounds and the symbol changes to “foot on the switch”.

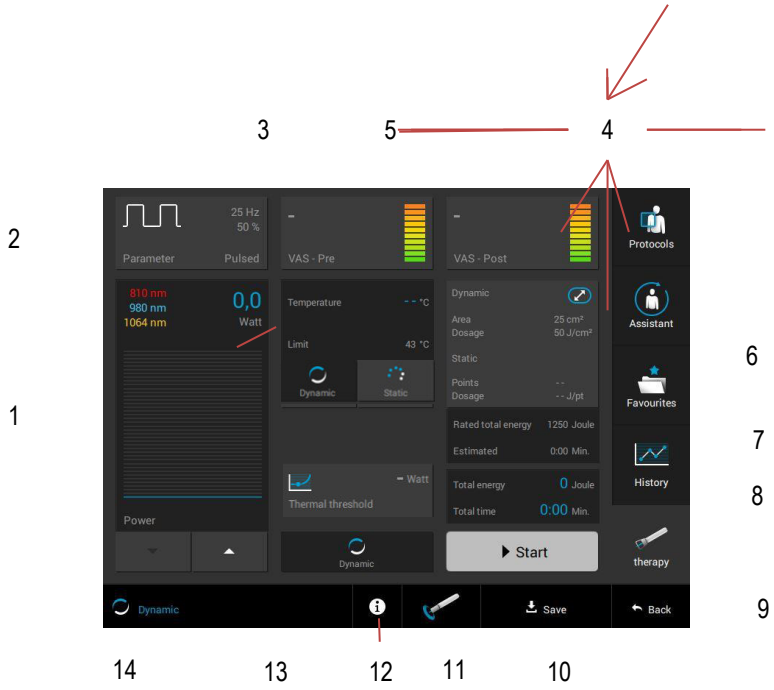
The currently emitted power is displayed in watts in the bar graph.

Note: *The patient should be monitored carefully during therapy and if necessary, the therapy should be adapted or discontinued if problems occur.*

End of therapy The power emission ends by deactivating the manual switch/foot switch or when the total energy has been reached.
The acoustic signal ends. The symbol changes to “foot off the switch”. The laser is ready for use.
By reactivating the manual switch, the laser therapy can be continued as desired.

Note: *Interrupting the laser emission using the “Stop” button ends the operational state of the laser. After the end of the treatment, remove the spacer from the applicator. Insert the applicator into the test sensor.*

Description of the display elements and buttons



Note:

The following description relates to the therapy screen which is provided through the selection of "Protocols" and "Assistant".
If the selection is made directly via "Therapy", the display (6) is not available. Instead of this, a "Thermal threshold" button at this site is preset as a default.
The function of the "Start" button is described in chap. 8.1.

Note: Thermal threshold test

To determine the individually correct laser output, especially in the case of high power and dark skin types, it is recommended that a thermal threshold test be performed prior to each treatment. This is described in Chap. 8.5.

(1) Bar graph power / wavelength

Displays the set power in W on the right in the upper half.
Adjusting the power is described in chap. 8.1.
Displays the selected wavelengths in the upper half on the left.

(2) Parameters

Displays the set operating mode. Activating the "Parameter" button opens a selection window with the various operating modes as well as the "Wavelengths" button.

The following operating modes can be selected: Continuous, pulsed, single pulse, duty cycle.

To change the operating mode, this is directly activated and is then highlighted in blue.

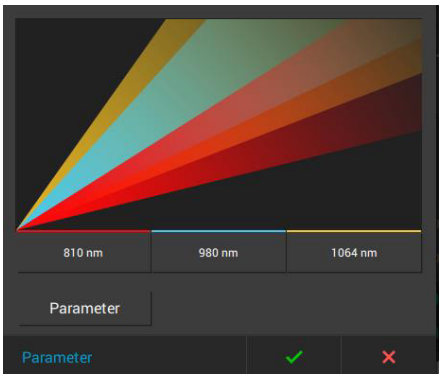
Setting options of the various operating modes:
Serial pulse: 0.1 Hz to 20,000 Hz
Single pulse: 0.1 to 5 seconds
Duty cycle: 10% - 90%.

To change the parameters, this is directly activated and is then highlighted in blue. The change is made using the two arrow buttons.

Wavelength

Activation of the "Wavelengths" button opens the selection window in which the wavelengths can

be activated or deactivated.



Activation/deactivation is carried out using the 810 nm, 980 nm and 1064 nm buttons.

Activating the “OK” button accepts the entry and returns to the therapy screen.

Activating the “X” button interrupts the process and returns to the therapy screen.

Activating the “Parameter” button returns to the “Parameter” selection window.

Note: *The setting of 25 W is only possible if all 3 wavelengths are activated.*

Information on VAS

Opton*Pro* has a visual analogue scale, also called a pain scale. The pain scale is often used in pain therapy.
It measures the patient's subjective pain intensity.

The patient rates the current pain on a scale of 0–10, whereby 0 = "no pain" and 10 = "worst pain imaginable".

The measurement is carried out before and after each treatment.

When documented repeatedly, this method gives an overview of the time course and success of a therapy.

Activating the “VAS - Pre”/“VAS - Post” field in the therapy screen opens the “Patient" screen.

VAS list

In the VAS list,
1. New patients are entered for measurements
2. Patients that have already been entered are called up for further measurement
3. Data are processed (moved in the sequence or deleted)

Enter new patient

Activation of the “New” button opens an alphabetical keyboard to enter the patient name. Enter the patient's name.
The data are accepted using the “OK” button and the screen with the pain scale screen opens.
Activating the “X” button interrupts the process.

(3) Perform VAS Pre

The patient marks his/her current pain perception on the scale from 1-10.
This is accepted in the scale and shown by a blue arrow as well as the value displayed. Activating the “OK” button accepts the value and returns to the therapy screen.

(4) Perform VAS Post

The perception of pain after therapy is determined by activating the “VAS - Post” button.

Note: *Performing VAS - Post is identical to performing VAS - Pre and therefore not described again.*

Repeat measurement

Patients that have already been entered are activated in the VAS list directly on the corresponding line. Once the line has been activated, the screen opens automatically with the pain scale so that a new measurement can be performed.

Note: *Up to 40 measurements per patient can be stored.*
Once this number has been reached, the following information appears: “The maximum number of measurements that can be saved per patient has been reached. A maximum of 40 measurements can be stored.”

To perform more measurements on this patient, the patient must be entered again.

VAS history

Activating the “History” button in the screen leads directly to the history of the patient currently selected.

Activating the “History” button in the navigation bar opens the list with the patients created.
The patient to be assessed is selected directly in the line. Once the line has been activated, the screen opens automatically with the progression curve of the therapy.
Activating the “Table” button displays the progression of therapy in tabular form.

Editing the VAS list

Activating the “History” button opens the “Patient” screen.
Activating the “Edit” button opens the screen to edit the data. The patient to be edited is selected directly in the line and is shown marked in blue; the “Delete” button becomes active. By selecting and pressing the bar on the right side of the line, the patient can be moved elsewhere.
Activating the “Delete” button deletes the program.

Note:

Editing the list is also possible in the “Patient” screen after activating the “VAS - Pre” and “VAS - Post” buttons. The procedure is described in the previous paragraph.

(5) Temperature / limit

The applicator is equipped with an infrared sensor which enables skin temperature measurement.
The skin temperature measured is shown in blue in the upper part of the display window.
The limit is shown in the lower part. The limit can be changed using the two arrow buttons.
If the skin temperature set has been reached, an acoustic signal can be heard
and the power emission is interrupted.
Once the skin temperature has cooled below the limit, the therapy can be continued by activating the manual switch.

(6) Therapy information

Display of therapy information determined through “Assistant” or “Protocols”.

Note:

If the path to the therapy screen is selected directly by activating the “Therapy” button, no therapy information is shown.

(7) Rated total energy / estimated

Rated total energy:
Display of joule number to be applied determined through “Assistant” or “Protocols”.
Estimated:
Displays an estimation of the duration of therapy after the power is entered.

Note:

If the path to the therapy screen is selected by activating the “Therapy” button, no joule number is determined and indicated for rated total energy.

(8) Total energy / total time

Total energy:
Indicates the total energy in joules during laser beam emission.
Indicates the total duration of the therapy.

Note:

The laser beam emission is only automatically stopped when the total energy is reached if a joule number is saved in the case of rated total energy.

Note:

The values are reset by activating the “Back” button after leaving the therapy screen.

(9) Back

Activating the “Back” button in the therapy screen returns to the start-up screen or scrolls one page back.

(10) Save

Activation of the “Save” button opens an alphabetical keyboard to enter an individual name of the program.
Activating the “OK” button accepts the saved data.
Activating the “X” button interrupts the process.

(11) Performance test

The performance test is used to check the laser power emitted.
It should be performed before each treatment.

Activating the “Performance test” button opens the screen to perform a performance test.

Sequence of the performance test

1. With interlock device installed, close door
2. Ensure that the applicator is in the test sensor
3. Activation of the laser and manual switch for the time period indicated

During the performance test, the time elapsed is shown in seconds.

Results of the performance test

The result of the performance test is shown in the “Pulsed” display.

1. Performance test OK:
Laser is working properly.
2. Limited accuracy:
The laser shows a deviation in the laser power.
This suggests soiling or deviations of the laser system related to ageing. The device can continue to be used, however maintenance should be performed within the next four weeks.
3. Performance test failed:
The laser power is outside of the permitted range.
The device must no longer be used. Take the device out of service and contact customer service.

The “Last performance test” display shows the implementation of the last performance test.

(12) Information

Activating the “ⓘ” button in the therapy screen leads back to the “Protocols” screen with therapy recommendations.

Note:

The button is only active if the path to the therapy screen is selected via “Protocols”.

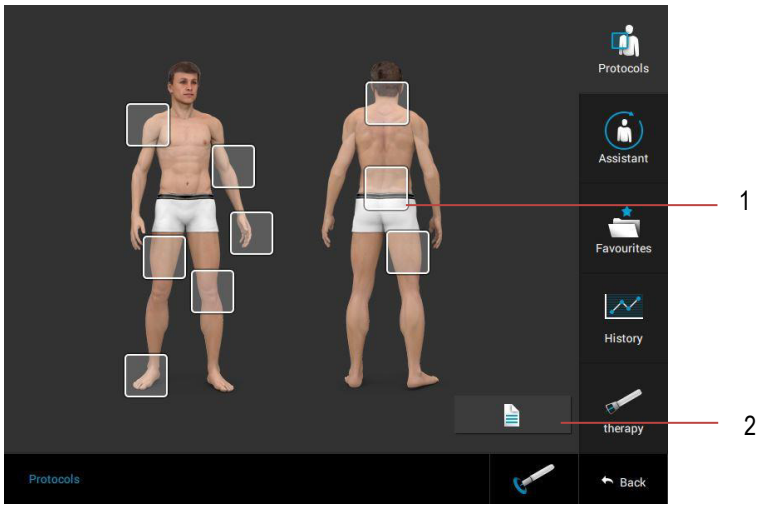
(13) / (14) Treatment types

The laser power can be applied statically and dynamically.
In doing so, trigger and primary pain points are treated statically and the remaining area of pain is treated dynamically (combined treatment).

Treatment types:
Static, Dynamic, Combined

In the “Protocols” and “Assistant” menus, programs with 2 phases are recommended.

The changeover between phases is performed by activating the two buttons (13) “dynamic” and (14) “static”.



Protocols

There are 2 options available for selecting the desired therapy:
- (1) Body regions
- (2) List

Selection via body regions

The desired body region is selected by activating the white square.

Select the clinical picture directly in the corresponding line.
If offered, select the treatment type directly in the corresponding line.
The screen with therapy recommendations opens.
Activating the “therapy” button opens the therapy screen.

Note:

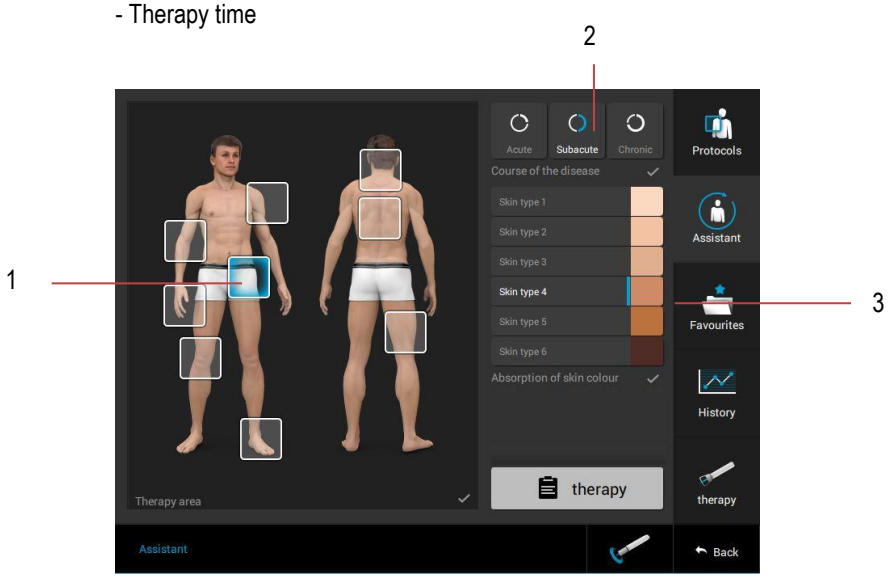
Independent of whether the selection is made via “Body region” or “List”, the program steps are analogous up to the therapy screen.

8.4 Assistant

Assistant

Individual therapy parameters can be determined via the assistant function.

By determining the therapy area, the course of the disease and the skin type, the following information is automatically saved:
- Program parameters
- Amount of energy to be applied
- Therapy time



Determine therapy parameters

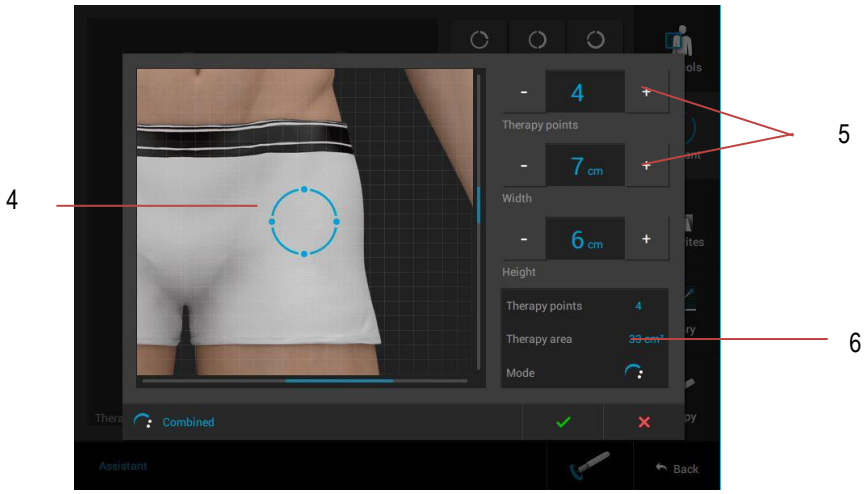
1. Select body region
The desired body region is selected by activating the white square (1).

Note:

The software-controlled calculation of the therapy area is based on a guideline, using an average person of medium height and weight.

When determining the therapy area, please take the patient's height and weight into account.

2. Determine therapy area (2 options)
- By dragging the anchor points (4)
- By activating the -/+ buttons of the "Height" and "Width" display (5)



3. Trigger points
If treatment of trigger points is planned, the number of trigger points to be treated is set by activating the -/+ buttons on the “Therapy points” display.

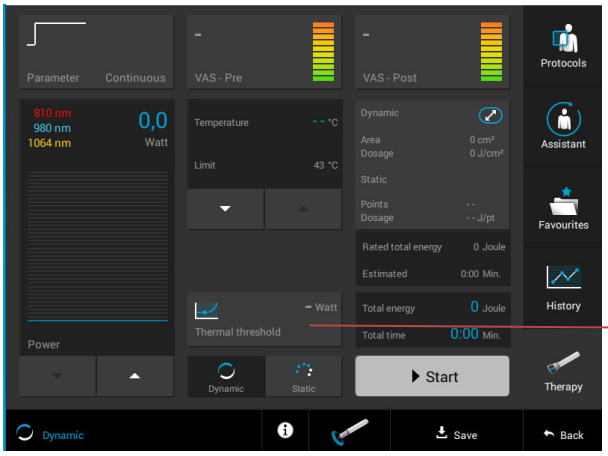
In the window (6), the data determined as well as the mode of treatment are shown.

Activation of the “OK” button accepts the data determined and returns to the “Assistant” screen.
Activation of the “X” button interrupts the process and returns to the “Assistant” start-up screen.

4. Select course of the disease
Select course of the disease directly on the corresponding button (2).

5. Define skin type
Select skin type directly on the corresponding button (3).

Note: *The therapy recommendations as described in Chap. 8.2 are now shown in the therapy screen.*



Note:

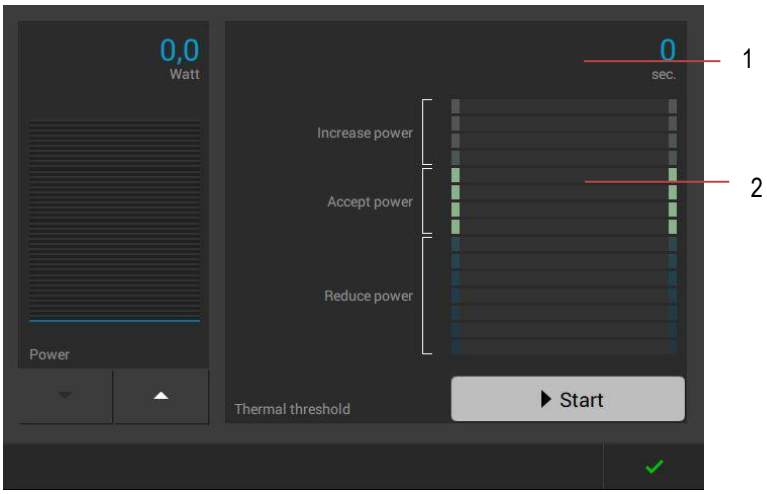
A precondition for the thermal threshold test is intact thermal sensitivity.
If this is locally disrupted, the test should be performed at a heat-sensitive site.

To do this, the laser beam is applied until the patient perceives the heat. If the application time is in the range of 7 to 11 seconds, the correct laser power is determined.

The activation of the laser, the setting of the power and start/stop of the laser emission is analogous to the description in Chap. 8.1.
Setting the power via a numeric field is not possible during the thermal threshold test.

Implementation Thermal threshold test

Activating the “Thermal threshold” button (1) opens the screen to perform the thermal threshold test.



The laser output is set by the user according to his/her discretion.
During emission of the laser power, the time elapsed is shown in seconds in the upper right above the bar graph (1).

If the patient feels a warming effect, the laser power emission is stopped.
If the emission lasts for more than 11 seconds, the following message appears:
“The power is set too low. Please repeat the test.”
The power is automatically increased by 0.5 W.

8.5 Thermal threshold test

If the emission lasts for less than 7 seconds, the following message appears:
“The power is set too high. Please repeat the test.”
The power is automatically decreased by 0.5 W.

If the patient perceives a feeling of warmth between 7 and 11 seconds (2), the recommended power is determined. The message “The power is set correctly” appears.

Activating the “OK” button saves the power determined and automatically accepts this in the “Power” bar graph in the therapy screen.

Note: *If the thermal threshold is determined between 0.5 and 0.1 W and the warming effect is reached in less than 7 seconds, the power is reduced by 0.1 W.*

8.6 Favourites

Favourites

The programs changed and saved in the therapy screen are filed in Favourites through the save procedure.

Edit

In the Favourites list, these can be

1. called up for therapy
To do this, the desired patient is selected directly in the corresponding line.

2. edited, moved in the sequence and deleted
Activating the “Edit” button opens the screen to edit the data. The patient to be edited is selected directly in the line and is shown marked in blue; the “Delete” button becomes active. By selecting and pressing the bar on the right side of the line, the patient can be moved elsewhere.
Activating the “Delete” button deletes the program.
Activating the “Confirm” button ends the editing mode.

Wavelengths Opton*Pro* 10 W	810 nm and 980 nm
Wavelengths Opton*Pro* 15 W /25 W	810 nm, 980 nm and 1064 nm

Output power

Opton*Pro* 10 W	max. 10 W, CW mode
Opton*Pro* 15 W	max. 15 W, CW mode
Opton*Pro* 25 W	max. 25 W, CW mode

Current consumption

Opton*Pro* 10 - 25 W	1.0 A – 1.8 A

	Without spacer	**Spacer, small**	**Spacer, large**
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

	Opton*Pro* 10 W	**Opton*Pro* 15 W**	**Opton*Pro* 25 W**
Power density without spacer	max. 12.5 W/cm²	max. 18.7 W/cm²	max. 31.2 W/cm²
Power density with spacer, small (1.2 cm)	max. 3.2 W/cm²	max. 4.8 W/cm²	max. 8.0 W/cm²
Power density with spacer, large (4.5 cm)	max. 1.1 W/cm²	max. 1.6 W/cm²²	max. 2.7 W/cm²

Technical information

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Note:	*The following data apply to all 3 models.*
Wavelength pilot beam	650 nm
Output power Pilot beam	Max. 5 mW CW
Power supply	100-240 V~, 50 Hz / 60 Hz
Mains fuse	2 x T 2.5 AH, 250 V
Protection class	I
Potential contact component	applicator
Applied part	Spacer small/large, Type B
Potential Contact part	Handpiece (< 10 min), optical fibre (< 10 min), housing and display (< 10 s)
Operating mode	Continuous operation
IP protection class	Device IP20; Footswitch minimum IPX5
Laser system	4 semiconductor diode laser, optical fibre
Treatment area	min. Ø 10 mm
Repetition frequency	0.1 to 20,000 Hz (CW-mode)
Pulse width (single pulse)	0.1 s to 5 s (pulse operating mode)
Accuracy **Accuracy skin temperature measurement**	±20% ±2°C
Maximum temperature of metal tip of handpiece and spacer	Normal condition: 41,7°C @ t_{amb} 40,0°C. with Laser output: 25W, 25% duty cycle (50Hz) Single fault: 43,8°C @ t_{amb} 40,0°C with laser output in constant wave.
Contact time of spacer to patient's skin	Lower than 10 min
Spacer, small **Spacer, large**	L 1.2 cm L 4.5 cm
Dimensions	Device with SysCart H 138 x W 53 x L 52 cm Device H 30 x W 35 x L 20 cm SysCart H 109 x W 53 x L 52 cm
Laser class	4
Safety distance	NOHD (Nominal Ocular Hazard Distance) 3 m MPR (maximum permissible radiation) of skin below limit at 17 cm
Beam divergence	32°
Interlock device	Door contact switch, opening when the door is opened, capacity 12 V, 10 mA, series

connection in the case of multiple doors

Display Liquid crystal display (LCD)

Weight 3.8 kg (with Handpiece and Fiber)
Handpiece with Fiber: 130 g
SysCart: 5,8 kg

Environmental conditions

Operation:

Temperature:	0°C - 40°C
Air humidity:	20% - 80% relative humidity without condensation
Air pressure:	800 hPa - 1030 hPa

Storage and transport:

Temperature:	-10°C - +50°C
Air humidity:	10% - 90% relative humidity without condensation
Air pressure:	700 hPa - 1060 hPa

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

Cleaning / disinfection

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- Before starting any maintenance and cleaning measures the device must always be switched off at the mains switch and the mains cable must be disconnected.
- After cleaning and disinfection, make sure that the labelling of the device (such as warnings, labels of control devices, identification plate) is not damaged.
- Make sure that during cleaning or disinfection no liquid penetrates the device, foot switch or applicator. Do not use sprays.
- If during cleaning or disinfecting liquid penetrates the device or applicator, please put the device out of service, protect it from being used again and contact your service representative.
- The device and its potential contact components are considered as uncritical in relation to hygiene due to the use on non-injured and healthy skin.

Housing / foot switch

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

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

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

Applicator / spacer

Cleaning: Remove the spacers from the applicator prior to cleaning. Then follow the procedure described under "Housing/foot switch". Use a cotton swab to clean the lens in the applicator.

Disinfection: We recommend that disinfection is to be carried after each application, as well as if there is any indication of contamination. Consult with your hygiene specialist when doing so. Always perform cleaning prior to disinfection.

Remove the spacers from the applicator prior to disinfection. Use a commercially available alcohol-free disinfectant for metal, plastic and applied parts which has bactericidal, virucidal and fungicidal properties (we recommend mikrozid® sensitive wipes by schülke). Carefully clean the entire surface, taking care of critical areas such as edges and grooves.
For the applicator: Use a cotton swab to disinfect the lens in the applicator.
No residues of the agent used should remain on the output lens of the applicator! Dirt changes the optical properties of the output lens. In this case, contact the service department.

Protective laser glasses

Cleaning/Disinfection: We recommend to clean and/or disinfect the glasses after each usage, as well as if there is any indication of contamination. For reprocessing instructions, please follow the insert sheet provided by the manufacturer of the protective laser glasses.

Note:

Use the device only in a hygienic environment.

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

Preparation:

Visible contaminants must be removed by manual cleaning with warm water and, if necessary, a detergent before cleaning / disinfecting (e.g. mikrozid® sensitive wipes by schülke). Avoid

strong mechanical influences which could lead to tearing of the material.

CE mark / Manufacturer

The device has a CE mark

CE 0123

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

Manufacturer

Zimmer MedizinSysteme GmbH
Junkersstraße 9
89231 Neu-Ulm, Germany
Tel. +49 (0)731. 9761-0
Fax +49 (0)731. 9761-118
www.zimmer.de

Scope of delivery / Accessories

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Scope of delivery

Item no.*	
4686	1 basic device OptonPro 10 W or
4685	1 basic device OptonPro 15 W or
4684	1 basic device OptonPro 25 W
	1 power cable
	1 interlock plug
	2 protective laser glasses
	1 laser warning sign for door, including warning light
	1 spacer, small
	1 spacer, large
	1 Instructions for use

** see accessories*

Accessories

Item no.	
118*[2]	Power cable
6825410022	Interlock plug
87450250	Protective laser glasses
95730013	Laser warning sign for door, including warning light for Opton*Pro* 10 W
95730016	Laser warning sign for door, including warning light for Opton*Pro* 15 W/25 W
93070620	Spacer, small
93070630	Spacer, large
94119057 / 1250420	Foot switch
9161-D02	SysCart
10102767	Instructions for use

**[2] standard cable. Other country-specific plug variants available. If needed, please contact your distributor.*

Device combinations / Safety and maintenance / Functional test

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Device combinations

For Opton*Pro* no combination devices are provided by the manufacturer.

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

Safety and maintenance

Opton*Pro* is manufactured according to IEC 60601-1 safety regulations.

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

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

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

Fuses and other spare parts (such as battery) may only be replaced by trained service personnel according to the instructions in the service manual.

Replacement of the lithium battery by untrained persons can lead to dangers.

The device service may only be carried out by trained personnel.

All descriptions necessary for the service can be found in the service manual of the LTG-01 or can be requested from the manufacturer.

Zimmer MedizinSysteme provides on request circuit diagrams, component lists, descriptions, calibration instructions or other documents.

Legal information

- The device is not listed in Annex 2 of the MPBetreibV (Medical Device Operator Ordinance)
- In Germany, the DGUV regulation 3 (Electrical systems and equipment) must be observed in its current version
- When using OptonPro, the regulations for laser protection (OSTrV) must be observed
- These instructions apply to the operation of the device in Germany. If applicable, observe deviating national regulations in your country

Performance test

It is recommended to carry out a performance test of the laser system before each treatment. In this way, you can be certain that the laser system is working properly, the light guide is intact, and the applicator is functional.

Calibration

The calibration of the device may only be performed by service technicians authorized by Zimmer MedizinSysteme GmbH.
This calibration must be performed if the performance test returns a fail (see chapter 8.2).

Functional test

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

Implementation

1. Conduct a performance test. The procedure for conducting a performance test is described in chapter 8.2.

2. Press the emergency stop button. The device must immediately switch off. Bring the head of the button back into the starting position by rotating in the direction of the arrow.

Safety check
Metrological control

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In Germany, it is not necessary to perform either a safety check or a metrological control for the Opton*Pro* device. The device cannot be allocated either to annex 1 or annex 2 of the Medical Device Operator Ordinance (MPBetreibV).

In Germany, the MPBetreibV (Medical Device Operator Ordinance) as well as the DGUV (German Social Accident Insurance) regulation 3 (electrical systems and equipment), among others, apply in their respective current versions.

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

Reporting

All serious incidents associated with the product are to be reported immediately to the manufacturer and the competent authority of the state in which the user and/or the patient is located.

Device malfunction

No response to the mains switch; display remains dark.

Possible cause 1: Mains connection
Remedy for cause 1: Check whether the power cable is correctly plugged into the socket and 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: Mains fuse
Remedy for cause 2: Check the mains fuse.
Replace the fuse only with one with the exact same name/equal rating.
Before doing so, check the power supply thoroughly for possible faults.

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

Possible cause 3: Emergency stop button pressed.
Remedy for cause 3: Check whether the emergency stop button is unlocked.

Laser does not emit any power

Possible cause 1: Interlock
Remedy for cause 1: Check whether the interlock plug is correctly installed.

With the door monitoring installed, check whether the door switch is open or whether the door is not properly closed.

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

Applicator temperature too low

The device is too cold. Wait for a message in the display indicating the operating temperature has been reached.

Laser unit - temperature too high

The device has become very hot due to a long, high power emission.
Wait for a message in the display indicating the operating temperature has been reached.

Fault

Internal device errors are shown by an error message in the display.
Occasionally, the error can be corrected by switching the device off, waiting five seconds, and switching the device back on.
If that does not resolve the matter, please contact customer service. You may get in touch with them via your sales representative or via the main office in Neu-Ulm.

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
89231 Neu-Ulm, Germany
Tel. +49 (0)731. 9761-291
Fax +49 (0)731. 9761-299
www.zimmer.de

Disposal

The device may only be returned to the factory in the original packaging. It must be disposed of by the factory in Neu-Ulm.
In foreign (European) countries please refer to national regulations for disposal. Contact your distributor if necessary.

EMC declaration

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

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

The Opton*Pro* is exclusively intended and has been tested for professional healthcare facilities, such as hospitals.

The Opton*Pro* 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 Opton*Pro* device was tested on the original device with the handpiece, foot switch and interlock.

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 Opton*Pro* device does not contain any exchangeable components or other parts which lead to worsening of the EMC.

WARNING: Portable RF 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 Opton*Pro* device; this includes cables indicated by the manufacturer. There may otherwise be a loss of performance of this device.

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

The Opton*Pro* 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		
Guidance and Manufacturing Declaration- Electromagnetic Emissions		
The device Opton*Pro* is intended for use in the electromagnetic environment specified below. The customer or user of the device Opton*Pro* should ensure that it is used in such environment.		
Emission Measurement	**Compliance**	**Electromagnetic Environment-Guidelines**
RF Emissions in accordance with CISPR 11	Group 1	The device Opton*Pro* must emit electromagnetic energy in order to ensure its intended function. Nearby electronic equipment may be affected.
RF Emissions in accordance with CISPR 11	Class B	The device Opton*Pro* is suitable for use in all establishments, including domestic establishments and those directly connected to the public supply network that also supplies buildings used for domestic purpose.
Emissions of Harmonics in accordance with IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/ flickers in accordance with IEC 61000-3-3	Compliant	

Table 2			
Guidance and Manufacturing Declaration- Electromagnetic Immunity			
The device Opton*Pro* is intended for use in the electromagnetic environment specified below. The customer or user of the device Opton*Pro* should ensure that it is used in such environment.			
Immunity Tests	**IEC 60601- Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidelines**
Electrostatic Discharge (ESD) in accordance with 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 from wood, concrete or ceramic tiles. If floor are covered with synthetic material, the relative humidity must be at least 30 %
Electrical fast transient/ burst in accordance with IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	The supply voltage quality must correspond to that of a typical commercial or hospital environment.
Surges in accordance with IEC 6100-4-5 -Line-to-Line-	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV	
Surges in accordance with IEC 6100-4-5 -Line-to-Earth-	± 0,5 kV, ± 1 kV, ± 2 kV	± 0,5 kV, ± 1 kV, ± 2 kV	
Voltage dips in accordance with IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The supply voltage quality must correspond to that of a typical commercial or hospital environment. If the user of the device Opton*Pro* requires continued operation, even in the case of interruptions in the power supply, it is recommended that the device Opton*Pro* be powered from an uninterrupted power supply or a battery.
	0 % U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°	0% U_T; 1 Periode und 70% U_T; 25 Perioden Einzelphase: bei 0°	
Voltage interruptions accordance with IEC 61000-4-11	0% U_T; 250/300 cycle	0% U_T; 250/300 cycle	
Magnetic filed of supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m 50 Hz oder 60 Hz	30 A/m 50 Hz	Magnetic fields at mains frequency should have the typical values found in a business or hospital environment.
Note: U_T is the mains AC Voltage before application of the test level			

Table 3			
Guidance and Manufacturing Declaration- Electromagnetic Immunity			
The device Opton*Pro* is intended for use in the electromagnetic environment specified below. The customer or user of the device Opton*Pro* should ensure that it is used in such environment.			
Immunity Test	**IEC 60601-Test Level**	**Compliance Level**	**Electromagnetic Environment - Guideline**
Conducted Disturbances induced by RF fields according IEC 61000-4-6	3 V 0,15 MHz to 80 MHz 6 V in ISM Band between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz to 80 MHz 6 V in ISM Band between 0,15 MHz und 80 MHz 80% AM bei 1 kHz	In the vicinity of devices, bearing the following symbol, interference is possible: 
Radiated RF EM fields according 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 communication equipment						
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum Energy (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380-390	TETRA 400	Pulse Modulation 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM ± 5kHz Derivation 1kHz Sine	2	0,3	28
710	704-787	LTE Band 13, 17	Pulse Modulation 217Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18Hz	2	0,3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900;	Pulse Modulation	2	0,3	28
1845						

Table 4						
Electromagnetic immunity to HF radio communication equipment						
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum Energy (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
1970		GSM 1900; DECT; LTE Band 1,3, 4, 25; UMTS	217 Hz			
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						

Opton*Pro*

Instructions for Use

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