# Class IV
# Laser device

# Operator manual

Title – Operator manual Cube (US market)
Date – 20th June 2018
Rev. C

Manufactured by:
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FDA Device FDA 510(K) clearance #K120604, May 25, 2012.

CE The device is manufactured in compliance with the provisions of Council Directive 93/42/EEC and 2007/47/CE concerning medical devices.

**0476**

# 1 Warning and safety information

## *1.1 Highlighting of warning and safety information*

To prevent personal injury and/or material damage, you must observe the warning and safety information provided in the present operating instructions.

All such information is highlighted by signal words as follows:

**Notice**
for additional information;

**Caution**
if there is any risk of damage to the device;

**Warning**
if there is any hazard to the life or health of persons.

➢ This symbol indicates that you have to take action.
↳ This symbol indicates that a certain result will occur.

## *1.2 Intended use*

The devices are designed in different versions and the following parameters are listed:

- Cube 3: 660nm±10nm, 800nm±15nm, 970nm±15nm; ISP peak power 15W;
- Cube 4: 660nm±10nm, 800nm±15nm, 905nm±15nm, 970nm±15nm; ISP peak power 20W;

Each device is indicated for emitting energy in the Infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

The device does not store preset treatments, the operator can set up the parameters manually in order to be able to use the equipment with his specific requirements.

The device can be used in medical practice, in physical therapy centers and in sport facilities. The device can be used in an ambulatory for surgical and medical practice.

**Notice**
The device may be operated only by medical qualified personnel. The applicable occupational safety regulations and accident prevention measures and the current operating instructions must be complied with.

**Notice**
Users are obliged to use only faultless materials, to ensure correct application and to protect themselves, the patient and other persons against hazards.

⚠ Warning

The device must not be used in areas where an explosion hazard exists or in the vicinity of highly flammable materials.

⚠ Warning

Public legal requirements may include special safety regulations concerning protection against laser radiation. These requirements must be fulfilled.

⚠ Warning

Failure to use the settings specified in this manual or perform the actions described here may lead to a dangerous exposure to radiation.

## *1.3 Instructions on use of the laser protective goggles*

Before using the laser protective goggles, please read and observe the instructions for use provided by the manufacturer and attached to the goggles in the case.

Before using the laser protective goggles, please make sure:

- the laser protective goggles are not damaged;
- the laser protective goggles conform to standard EN 208;
- the laser protective goggles are equivalent to the technical features listed in paragraph 4.1.

These instructions apply particularly when using goggles supplied from an outside source that are not included in the scope of delivery of the device.

## *1.4 Interferences caused by mobile wireless phones*

⚠ Caution

To ensure safe operation of medical electrical equipment, the use of mobile wireless phones in practice or hospital environments must be prohibited.

## *1.5 Disposal of main unit*

If you plan to discontinue the use of your device and you intend to dispose of the unit, make sure to observe the applicable legal provisions.

The sign of the barred trash bin displayed on equipment or packaging thereof indicates that upon completion of its life cycle, it should be disposed of separately from other waste.
The separate disposal of dead equipment is the producer's responsibility.
Therefore, the user must contact the authorized service center for the correct disposal.

The proper disposal of this equipment will automatically provide for the recycling and proper processing and disposal of the same which helps to prevent possible negative effects on our environment and health, and encourages the recycling of its parts. The improper or illegal disposal by the user will entail the application of administrative sanctions according to the laws and regulations in force.

## *1.6 Safety precautions*

Each device is manufactured in compliance with the provisions of Council Directive 93/42/EEC (MDD) and 2007/47/CE concerning medical devices.
Always observe the following precautions:

⚠ Caution
The laser unit and accessories are not sterilizable.

⚠ Warning
When disconnecting the optical fiber from the device, always cover the connector with the special protection cap. Make sure that no dust or dirt can enter the optical fiber socket or the optical system. Otherwise the unit may be permanently damaged.

⚠ Caution
Any use of the controls or setting options in a manner other than the one described here may lead to a dangerous exposure to radiation. Manufacturer is not responsible for damages caused to the not correct use of the device or to the disrespect of the instructions and caution indicated in the present manual.

⚠ Caution
Never place your finger or any other objects in the optical connectors. This could cause damage to the optical instrument.

⚠ Caution
Switch the device OFF immediately in case of an emergency. To do this, press the “LASER STOP” button below the touch screen on the front side of the control unit.


⚠ Warning
Observe all labels on the device.

⚠ Warning
Operation of this laser unit by unauthorized persons must be prohibited in order to prevent incorrect or improper use. Laser equipment not in use must be protected against unauthorized access. This can be achieved for example by switching off the laser unit after use, so that the electronic access key must be entered prior to further operation.

⚠ Warning
Never direct the laser beam toward a person’s eye or thyroid gland. All persons present in the room (patient, operator and assistant) must always wear the laser protective goggles delivered along with the device.

⚠ Warning
Never use optical instruments such as microscopes, eye loupes or magnifiers together with the original protective goggles. Otherwise sufficient eye protection can no longer be ensured.

⚠ Warning
Oxygen-saturated materials such as cotton wool can catch fire owing to the high temperature that the unit reaches during operation. Label removers and flammable solutions used for cleaning and disinfecting the device should be allowed to evaporate before using the device. Observe fire hazards caused by flammable gases.

⚠ Warning
The unit is not suitable for use in the presence of anesthetics that are flammable when in contact with air, oxygen or nitrogen monoxide.

⚠ Warning
Never direct the laser beam toward paper, plastics or objects with dark surfaces. They could catch fire due to the high temperatures produced by the laser beam.

⚠ Caution

Avoid interference between the laser emission and any optical sensors of devices operated in the vicinity of the device.

⚠ Caution

Do not place the unit near heat sources. Do not cover the convection openings for air cooling on the sides of the unit.

⚠ Caution

The device may be operated only by trained and qualified personnel. In order to prevent false or improper use, the device must not be used by unauthorized persons. Do not write down the electronic access key somewhere else in order to reduce risk of misuse of the laser by unqualified persons. Please turn off the unit after the use.

⚠ Warning

Set up the laser unit properly and completely before putting it into operation.

⚠ Warning

Make sure that the electrical system is equipped with the required devices for protection against direct and indirect contact (thermomagnetic switches, residual current circuit breakers) and has been set up by a qualified electrician in compliance with the IEC applicable standards. National directives regarding electrical installations must be observed.

⚠ Warning

Verify that the line voltage corresponds to the voltage indicated on the rating plate of the adapter or in the technical specifications.

⚠ Warning

Do not use the device if a visual inspection shows that it has been damaged.

⚠ Warning

If you accidentally spill any liquid on the unit, immediately stop treatment, disconnect the power cable and contact the authorized service center for assistance.

⚠ Caution

Never under any circumstances try to disassemble the device. This is limited exclusively to trained and authorized personnel.

⚠ Warning

It is recommended not to use the handpiece in direct contact to skin of the patient, but to keep distance from the skin and always move it!

⚠ Warning

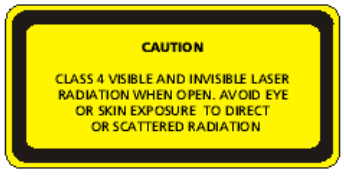
Before starting treatment, please try to treat fix points, keeping a distance of about two centimetres from the skin of the patient, in particular if you are using continuous emissions, in order to check the sensibility of the patient and the energy density, especially if the patient’s skin is particularly brown.

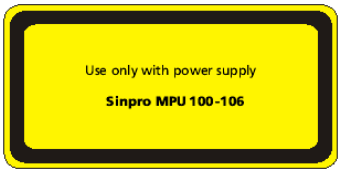
⚠ Warning

It is recommended to verify that the part to treatment not present neo of great dimension or dark zones that could absorb excessive amounts of energy. In this case protect with dioxide of titanium or zinc the treatment part.

# 2 Symbols and abbreviations

## *2.1 Symbols on the device*

| Symbol | Description |
|---|---|
|  | Class II unit according to IEC 60601-1. |
|  | Type B applied part according to IEC 60601-1. |
| CE<br>0476 | CE mark in accordance with Council Directive 93/42/EEC and 2007/47/CE, stating the manufacturer's Notified Body. |
|  <br>20XX-XX-XX | Date of manufacture (year-month-day). |
|  | Please refer to manual first. |
|  | Do not dispose with domestic waste. |
| DC IN | Connection socket for DC input from the power supply. |
|  | Connection socket for interlock. |
|  | Connection socket for USB. |
|  | Laser radiation warning. |
|  | Specification of laser output power and wavelength of IR and aiming beam (see also Chapter "Technical data").<br>Verifies the compliance of the device with IEC 60825-1. |
|  | Warns of potential laser radiation hazards when opening the laser unit. |

| | |
|---|---|
|  | Warns of Class 4 laser radiation hazards when using the unit. |
|  | “LASER STOP” button: Press this button in case of an emergency. |
|  | Operate the unit exclusively with the MPU100-106 power supply. |
|  | Pairing button of the wireless footswitch (optional). |

## 2.2 Glossary

| | |
|---|---|
| **Continuous emission** | Continuous laser emission; |
| **Pulsed emission** | Pulsed laser emission (Chopped Mode); |
| **Frequency** | Number of laser pulses per second; |
| **Hertz** | Unit of measure for frequency; |
| **Interlock** | Safety device that stops laser radiation when the door of the treatment room is opened; |
| **Joule** | Unit of measure for emitted energy; |
| **Watt** | Unit of measure for laser power. |

## 2.3 Abbreviations

| | |
|---|---|
| **$cm^2$** | Square centimeter; |
| **Hz** | Hertz; |
| **s** | Seconds; |
| **W** | Watt; |
| **mW** | Milliwatt (one thousandth of a watt); |
| **J** | Joule; |
| **nm** | Nanometer; |
| **V** | Volt; |
| **IR** | Infrared diode; |
| **NOHD** | Nominal ocular hazard distance according to IEC 60825-1. |

# 3 Technical Data

## *3.1 Specification*

According to the applicable standards, each device is classified as follows:

- Class II, Type B according to IEC 60601-1 of electrical safety;
- Class IIb according to Council Directive 93/42/EEC;
- Class A according to IEC 60601-1-2 of the electromagnetic compatibility;
- Class IV laser product according to IEC 60825-1 of laser product;
- Degree of protection according to IEC 60601-1 medical unit IP20 (enclosure not water-proof), IPX5 for footswitch.

## *3.2 Device specification*

| Specification | Cube 3 | Cube 4 |
|---|---|---|
| **Laser type** | Diode GaAlAs | |
| **Laser system** | Class IV (according to IEC 60825-1) | |
| **Device classification** | Class IIb (according to Council Directive 93/42/EEC) | |
| **Wavelength (nm ± 15 nm)** | 800, 970 | 800, 905, 970 |
| **(660nm ± 10 nm)** | 660 | 660 |
| **ISP peak power (W)** | 15 | 20 |
| **ISP average power (W)** | 8 | 12 |
| **CW power (W) ±20%** | 12 | 15 |
| **Max power 660 nm (mW)** | 120 | |
| **Emission mode** | CW (continuous wave), modulated 1 Hz to 20 kHz, ISP | |
| **IP degree of protection** | Laser unit: IP20; footswitch (cover not waterproof): IPX5 (according to IEC 60601-1) | |
| **Insulation class** | Class II, type B (according to IEC 60601-1) | |
| **Aiming beam** | 660 nm ± 10 nm, max. 1mW | |
| **NOHD** | 1.65 m max | |
| **Start** | Finger switch with electronic access key, footswitch (optional) | |
| **Power supply** | Sinpro MPU100-106, 100 - 240 VAC, 47 - 63 Hz | |
| **Display** | Full color, graphical LCD touchscreen | |
| **Dimensions (W x L x H)** | 180 x 200 x 190 mm | |
| **Weight** | approx. 1300 g (incl. handpiece and rechargeable battery) | |

## 3.3 Wireless footswitch specification

| | |
|---|---|
| **Model designation** | NanoLOC AVR |
| **Frequency** | 2.4 GHz – 2.4835 GHz (ISM band) |
| **Transmitting power** | < 2 mW (short-range device) |
| **Modulation type** | Multi Dimensional Multi Access (MDMA) |

## 3.4 Transport and storage

The device comes in a box that ensures proper and easy transport.
In its original transport packaging, the device can withstand the following ambient transport conditions

- Temperatures from - 40°C to + 70°C;
- Relative humidity from 10% to 90%;
- Atmospheric pressure from 800 hPa to 1060 hPa.

⚠ Caution

Do not leave the device in a vehicle parked in the sun. The inside temperature of the car could thus heat up to a point where individual components may be damaged.

Notice

The rechargeable battery must be fully charged regularly. After 6 months of no charging (storage) the rechargeable battery might lose its loading capacity and might not be rechargeable anymore.

## 3.5 Operating conditions

The device may be operated in the following environmental conditions:

- Temperatures from + 10 °C to + 33 °C;
- Relative humidity from 10% to 95%;
- Atmospheric pressure from 800 hPa to 1060 hPa.

⚠ Caution

Following transport and storage, let the device adapt to room temperature for about one hour prior to operation to reduce the risk of malfunctions caused by condensation.

# 4 Installation

Any national or local regulations stipulating that the device may be installed only by trained personnel must be strictly observed.

## *4.1 Scope of supply*

| Part Description | Qnt | DJO Part Number |
|---|---|---|
| Cube 3 Unit Only | 1 | 3079-USA |
| Cube 4 Unit Only | | 3080-USA |
| Cube 4 PLUS Unit Only | | 3081-USA |
| Cube Goggles: 780-<790 DIR LB6 (OD6+); 790-<808 D LB6 +IR LB7 (OD7+); 808-1070 D LB6 + ILB8 + R LB7 (OD8+); 650-680 0.01W 2x10E-6J RB1 (OD1-2) | 1 | PF002P-USA |
| Cube Dark Goggles: 620-<650 DIR LB1 (OD1+);650-<680 DIR LB2 (OD2+); 755-1090 D LB6 + IR LB7 (OD7+); 620-635 0,01W 2x10E-6J RB1 (OD1-2); 650-665 0,1W 2x10E-5J RB2 (OD2-3) | 1 | MP503-USA |
| Cube Warning sign | 1 | MP130GC-USA |
| Cube Power supply: SINPRO MPU100-106 | 1 | E6254473-USA |
| Cube Power cord, USA/Canada | 1 | MP111B-USA |
| New packaging KIT, Cube Laser | 1 | MP500-USA |
| Cube Operating manual MED | 1 | 13-00170-US |

## *4.2 Spare parts and optional*

| Part Description | DJO Part Number |
|---|---|
| Zoom optical without distal, Cube3/4 | MP486-USA |
| Cube Distal Piece MED | MP513-USA |
| Cube Goggles | PF002P-USA |
| Cube Dark Goggles | MP503-USA |
| Cube Child Goggles MED | MP478-USA |
| Cube Warning sign | MP130GC-USA |
| Cube Operating manual MED | 13-00170-US |
| Cube Power supply | E6254473-USA |
| Cube Power cord, USA/Canada | MP111B-USA |
| Optical fiber, all Cube | MP443-USA |
| Cube ENT hand piece | MP041P |
| Cube Optical PLUS 40mm MED | MP475 |
| Cube 4 wireless foot pedal | PF067-USA |
| Cube Trolley | PF094-USA |
| Cube Extend PLUS | PF115-USA |
| Cube Transport Case | IM017A-USA |
| New packaging KIT, Cube Laser | MP500-USA |
| Interlock Connector | E6254481 |
| Battery | 6239243CUBE |
| White sock, Chattanooga | MP542-USA |
| Black sock, Chattanooga | MP543-USA |
| Zoom Optical with distal MED | MP041M-USA |

| Part Description | DJO Part Number |
|---|---|
| Distal piece 40 mm MED | MP474-USA |
| Optical Plus 40mm (without distal) | MP553-USA |
| Optical part of zoom PLUS (without distal) | MP554-USA |
| Optical part of zoom PLUS with distal MED | MP555-USA |
| Class 4 label, visible/invisible - if open | MP263-USA |
| Class 4 label, visible/invisible | MP264-USA |
| Label, use Sinpro MPU100-106 | MP473-USA |
| Label, power and wavelength C4 | MP355-USA |
| Label, power and wavelength C3 | MP354-USA |

## *4.3 Power supply*

➢ Connect the power cable to the DC IN socket at the back of the device.


### ⚠ Caution

The device may only be operated with the Sinpro MPU100-106 power supply. Operation with other power supplies may result in failure or destruction of the laser unit. If any power supply other than the one recommended is used, the approval of the entire unit automatically becomes void and the warranty expires.

### ⚠ Warning

The use of any power supplies other than the one recommended may cause overheating and failure of the laser unit or damage of batteries.

The device is supplied with a rechargeable battery and therefore can be used without connected power cable. The status of the rechargeable battery and whether the power cable is actually connected will be always displayed on the touch screen.

### ⓘ Notice

There is a warning if the rechargeable battery reaches a low level of capacity.

### ⓘ Notice

While operating, should the charge level of the battery be below 5%, the green led will flash at 5 “ intervals to remind the user to plug in the unit.

The device is fully functional and can be run while charging the battery.

➢ Charge the battery completely.

### ⓘ Notice

The rechargeable battery must be fully charged regularly. After 6 months the rechargeable battery might lose its loading capacity. If left discharged for longer than 6 months, it may not be rechargeable anymore.

### 4.3.1 Replacing the rechargeable battery

If the rechargeable battery does not charge more than 30% even by charging it overnight, the battery needs to be replaced.

Removing and replacing the battery:

- Extract the handpiece and unroll completely the fiber;
- Remove the 5 cross head screws of the grey battery cover;
- Pull out the battery by the appropriate strap;

Mount the new battery.

- Replace the battery cover taking care the fiber lock is in the proper position and screw gently. Do not screw too firmly.
- Plug in the power supply connector and switch on the device;
- Enter in setup menu, select battery calibration.

A message screens asks to confirm the battery calibration process.

- Press OK to confirm;
- Unplug the power supply connector and wait until the device switches off automatically;
- Then plug in the power supply connector and charge for 2 hours.

**⚠ Caution**

Only use the specific battery pack provided (see chapter spare parts and optional).

## *4.4 Optical fiber and zoom optical with distal*

The optical fiber is supplied ready to be used. The operator is able to perform needed treatment simply plugging the zoom optical with distal.

The handpiece has different distal parts:

Optical fiber (including handpiece body)

Zoom optical with distal.

**ⓘ Notice**

For the use of optional opticals, please read carefully the specific instructions and the attached warnings.

**⚠ Caution**

Always cover the optic of the handpiece body with the zoom optical. Make also sure that no dust or dirt enter the optical fiber socket or the handpiece optical system. Otherwise the unit may be permanently damaged. Use a soft cloth to clean the lens.

Detach

Attach

**Notice**

The user can attach the part, simply connecting it to the handpiece body.
When attaching or detaching the parts, we recommend to slightly rotate the two parts. The rotation of the two parts makes the operation easier.
The user must hear a sound (click) locking the distal. This guarantees a correct connection.

**Notice**

The device is able to detect the correct connection of the zoom optical and to warn the operator in case of wrong assembly.

**Notice**

Before starting the treatment, the device remembers the operator to be sure that the optical to be used is the correct one.

**Notice**

Clean the lens of the optical with a dry, soft cloth. Please proceed carefully not to scratch and damage the foil on the lens.

### 4.4.1 Zoom optical

The zoom optical is supplied assembled and ready to be used. The operator is able to manage the energy density by turning the ring. On the ring a spot size regulator is present and allows you to select a different treatment diameter and thus a different power density.

**Warning**

There is a locking system in the ring and a warning symbol advising the operator to pay attention to the use. A small treatment spot increases the power density, and thus the potential thermal hazard.

**Warning**

During laser therapy use, the zoom optical is not applied in a single and fixed point, but is applied all around the part to be treated.
During treatment, always move the handpiece!

**Warning**

Be careful because the power density is very high if you choose the smaller part of the spot size regulator.
**The power of the laser should be no greater than 500 mW with this small position.**

Spot size regulator

| Spot size regulator | Max beam diameter, mm | Approx. treatment area, $cm^2$ |
|---|---|---|
|  | 11 | 1 |
| | 16 | 2 |
| | 20 | 3 |
| | 22 | 4 |
| | 25 | 5 |

**⚠ Warning**

Should any treatment utilize an average power ≥ 8W, enlarge the spot diameter to its maximum. This action will avoid excessive power density to be delivered over the treated area.

**⚠ Caution**

The distal can be removed for cleaning. Do not force overly the tailspin of the distal on the handpiece body, this could damage the optic part.

**ⓘ Notice**

All the parts can be removed for cleaning. See paragraph 7.2 for cleaning instruction.

**⚠ Warning**

Do not use the device if the aiming beam is not visible.

**⚠ Warning**

The aiming beam must not be aimed at anyone's retina. It comprises an intensive light source even when set to a low power level. Always wear protective goggles.

**⚠ Warning**

Before and during the emission laser verify that the aiming beam is present and that it projects a regular shape. If it does not come projected some shape, or if it is much irregular, the optical fiber or the device could be damaged. In this case, proceed as follows:

- Switch off the laser and check the optical fiber as well as the fiber connection for mechanical damage;
- If the optical fiber is damaged;
- If you cannot detect any damage on the optical fiber and the signal of the aiming laser is not visible, switch off the laser and contact Authorized Service Center.

**⚠ Caution**

Always cover the connector of the optical fiber with one of the special protection caps if the fiber is dismounted in order not to damage optic parts. Make sure that no dust or dirt can enter the optical fiber socket or the optical system. Otherwise the unit may be permanently damaged.

### 4.4.2 Care of the optical fiber

The optical fiber comes with a metal hose with a coating to protect it from damage.
For proper functioning and upkeeping, it must be handled with care, especially when winding and unwinding in its proper seat about the device.

**⚠ Warning**

Do not unwind once the yellow sticker on the fiber appears.
Unwinding beyond the yellow sticker may damage the optical fiber irreparably!

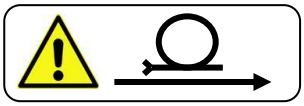
Marker of optical fiber's end.

**⚠ Warning**

The fiber must be wound around the device counter clockwise.
Should it be wound differently will damage the fiber irreparably!

**⚠ Warning**

The arrow of the label shows the correct winding of the fiber.



**⚠ Caution**

The optical fiber may be damaged if it is seriously bent, pitched or improperly routed.

**⚠ Caution**

Bear in mind the maximum bending radius of the optical fiber:

- 2 cm: Short-term (during treatment): 100 x radius of optical fiber;
- 3 cm: Long-term (during storage): 600 x radius of optical fiber.

**ⓘ Notice**

The unit detects the electric fiber connections.

## 4.5 Interlock

As foreseen by the normative the device is supplied with connector interlock for the automatic interruption of the emission laser at distance.
Such connector is normally connected to a switch which interrupts the functioning of the laser in case a person enters in the room in which it is used.


**Notice**
The installation must be performed by a qualified electrician who is also responsible for the installation and maintenance of the electrical system to which the device is connected.

**Notice**
Please request the technical data sheet with wiring diagram for the installation of the interlock device.

**Notice**
Additional or different safety precautions required by the applicable national or local regulations for the protection of operators, assistant personnel, or patients must also be observed.

## 4.6 Wireless footswitch (optional)

The device can be operated using the fingerswitch (which is integrated in the handpiece) as well as by using the optional wireless footswitch.

**Caution**
Touch a grounded metal part before opening the housing to prevent damage to the PC board due to electrostatic discharge.

**Caution**
Prior to changing the batteries, switch the device off at the main switch. This prevents accidental triggering.

Removing and replacing the batteries:
- Remove the screws from the bottom of the footswitch.
- Remove the cover and replace the battery (2 AA type cells).

Be careful to insert it with the correct polarity (minus pole facing spring).
- Place the battery holder back again in the compartment and close it with the cover.
- Screw the screws at the bottom of the footswitch.

**Notice**
After changing the batteries, switch the device on and check the complete functionality of the footswitch. It is not needed to register again the footswitch again at the device after changing batteries.

# 5 Operation

## *5.1 Start the device for the first time*

**Notice**

Touchscreen functionality: When the touchscreen is touched by the finger the touch field is highlighted. As soon as the finger leaves the touchscreen the action will be activated.

**Notice**

Symbols/Icons on the LCD:

| Name | Explanation | Symbol |
|---|---|---|
| Battery state | Information concerning the battery status.<br>Press the icon to check the battery percentage. |  |
| Connected/charging battery | Battery is connected to power supply and charging. |  |
| Information | Press it to see device information. |  |
| OK | Operator confirms and activates action. |  |
| Back | Operator goes back one screen. |  |
| Clear | Press it to delete in case of wrong typing. |  |
| New | Operator wants to generate a new application. |  |
| Save | Operator saves an application. |  |
| OK (Laser) | Laser is being activated. |  |
| ‘Plus’ and ‘Minus’ | Operator is able to count up and down numerical value. |  |
| ‘Forward’ and ‘Backward’ | Operator is able to scroll forward and backward the pages of a list. |  |
| Delete | An application will be deleted. |  |

## *5.2 Switch on/off power*

After starting the device by switching on the on/off button on the backside of the control unit the yellow LED will be on.


**Notice**

Remember to switch on also the power supply, in case the switch is present.

**Notice**

While the device is booting, a screen will remember the user to carefully read the manual before unit use.

During or after treatment the laser can be switched off by switching on the on/off button on the backside of the unit. Here the laser diode is permanently disconnected from power supply.

In case of emergency press the laser stop button. Note that the laser is interrupted and restarted in a safe mode but not switched off.

**Notice**

The device can be switched off in two ways:

- Keep pressed the on/off button on the backside of the unit;
- Press the battery icon and then confirm the action.

**Notice**

The laser main switch on/off does not disconnect the battery loading circuit, i.e. the batteries are loaded even if the laser is off.

## 5.3 Enter pin code

The device may be operated only by authorized personnel. So for security purposes the device has an electronic key. After boot, the device will ask to digit the pin code, which consists of a sequence of 4 keys.


The code is **0 0 0 0**.


Press it to delete in case of wrong typing.


Press it to confirm the pin code.


Press it to see device information.

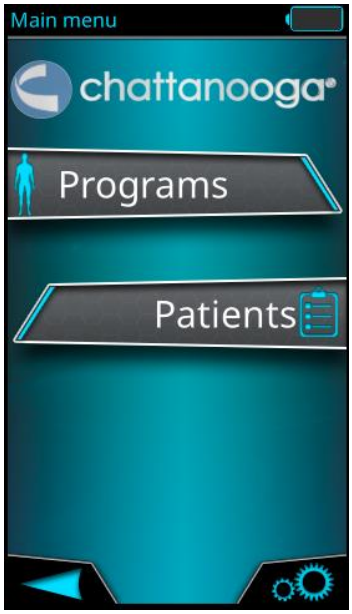
⚠ Warning

The device may be operated only by qualified personnel. Do not give the access to unauthorized third parties.

Do not write down the electronic access key somewhere else to reduce the risk of misuse of the laser by unqualified persons. Please turn off the unit after the use.

## 5.4 Main menu screen

After entering the pin code, the device shows the main menu.



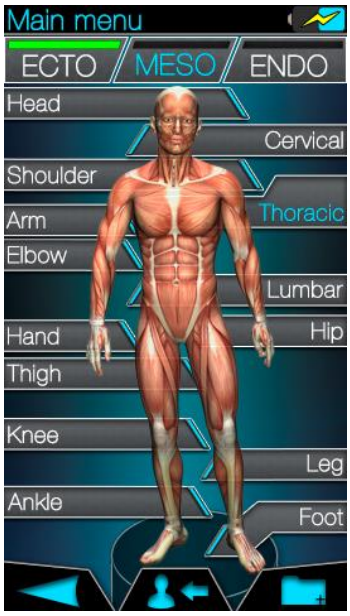

Press it to go to Programs.

Press it to go to Patients.

Press it to go back one screen.

Press it to go to Set-up.

After choosing Programs, you can enter in the following screen.





Body types are the following:
**Ectomorph:** typical skinny body;
**Mesomorph:** athletic body.
**Endomorph:** solid and generally soft body;

**Head, Cervical, Shoulder, Thoracic, Arm, Elbow, Lumbar, Hip, Hand, Thigh, Knee, Leg, Foot**

Body parts. The operator can select one of the listed treatment areas.

Press it to go back one screen.

Press it to enter in Patient list.

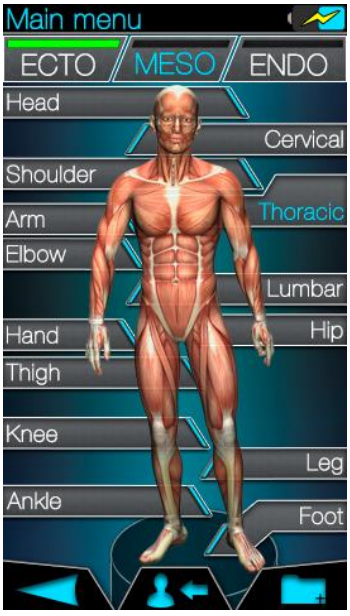
Additional treatments. Press it to go to the treatments not related to any anatomical body part.

## Notice

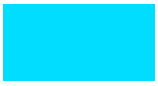
The device is able to store all the steps performed by the operator during the device use. In particular the operator can set as default the body mass and always know the performed choice.

The following scheme describes how to set the default value and how to visualize the performed steps.


Keeping pressed the body mass for 3 seconds, it becomes as default option.
Blue: default body mass.
Green: currently selected body mass.




The body part can have 2 different modalities:



Blue: selected body part (only in a selected Patient).

Grey: Not selected body part.

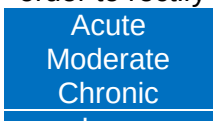
After the selection, the device will ask the operator to select the patient skin type on the basis of the Fitzpatrick scale.


**I** White, very fair, red or blond hair, blue eyes, freckles
**II** White, fair, red or blonde hair, blue hazel, or green eyes.
**III** Cream white, fair with any eye or hair color, very common.
**IV** Brown, typical Mediterranean Caucasian skin.
**V** Dark brown, mid-eastern skin type.
**VI** Black.

The selected area is highlighted in green.

After that, the following screen is displayed.


On the upper part of the screen, the device shows the already selected body type and treatment area. These are modifiable in order to rectify a wrong choice.




Chronicity of the treatment.


Pain level of the treatment.

Each square into the grid is editable and it corresponds, to each skin type, chronicity and pain level combination.

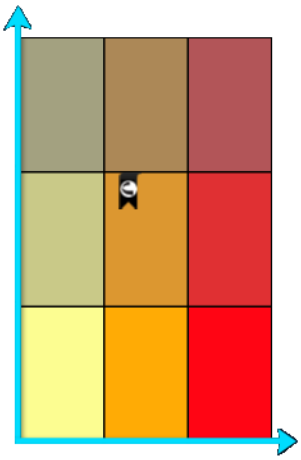
Skin type based on Fitzpatrick tone scale.
The blue point shows the selected skin type.

Press it to go back one screen.

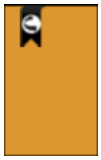
## Notice

The device is able to remember the already selected matrix position (only in a selected Patient).

In particular:



Each square of the matrix can be visualized in the following ways:



Cell with check: last selected treatment.

Cell without check: not selected treatment.

## Notice

The "  " check is active only inside a Patient.

After that, the *treatment area* will be shown.

### 5.4.1 Treatment creation from additional

After the selection of  from the main menu the device will show the following screen. These treatments are not strictly connected to the body part of the human body.


Pressing the desired treatment, it will be highlighted.

Rename treatment.

Delete treatment.

Press it to go back one screen.

New: Press it to create a new treatment.


Arrows used to scroll forward and backwards, if more than one page on the list is present.
The first number shows the current page, the second one the total number of pages.

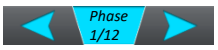
For a new treatment press  . After that treatment area will be shown.

The following screen shows how to create a new treatment.

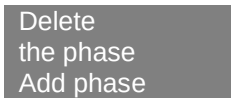

Select the field to be modified.

Green: selected field.
Black: not selected field

Press it to count up and down numerical value.




Press it to scroll forward and backward the phases. The first number shows the current page, the second one the total number of pages.




Press it to delete or add a phase.


ISP (Intense super pulse) modality can be selected.

Press it to enter in the Keyboard.


Selectable wavelengths.
Green: selected field.
Blue: not selected field.

Press it to go back one screen.

Press it to save a treatment.

**Notice**

In ISP modality, the device is able to automatically manage the wavelengths and the operator cannot select them.

**Notice**

Peak power is delivered only in pulsed mode and it is called ISP (Intense Super Pulse). It is a pulsed mode which delivers the following average power:

- Cube 3: average power 0.1 – 8 W;
- Cube 4: average power 0.1 – 12 W;

**Notice**

In ISP modality, frequency values are defined between 1–20000 Hz. In particular, in case of CW frequency is automatically converted into 20000 Hz.

The following steps allow the operator to set parameters.

- Select **Add phase** to create a new phase for the treatment;
- Select the needed parameters.

To manage the parameters select the field that will be highlighted with a green square and then press:

 Minus / Plus key or  to enter in a Keyboard to implement the modification.

If device is in ISP modality, the operator

| can modify | cannot modify |
|---|---|
| **Average power** | **Power** |
| **Frequency** | **Wavelength** |
| **Phase time** | |

If device is not in ISP modality, the operator

| can modify | cannot modify |
|---|---|
| **Power** | **Average power** |
| **Wavelength** | |
| **Frequency** | |
| **Phase time** | |

**Notice**

Treatment time and Total Joule are automatically calculated by the device, and cannot be set by the user.

To manage the parameters select the field that will be highlighted with a green square and then press:

 Minus / Plus key or  to enter in a Keyboard to implement the modification.

**Treatment time**

Treatment total time. This value is automatically calculated by the device.

**Total Joule**

The device automatically calculates the energy used during treatment (in J) from the power values and the selected laser activation time. Total energy during application is displayed.

**Power**

It is adjustable between 0.1 W and max value. In 0.01 W increments by typing in the numbers or by touching  .
The following power:

- Cube 3: CW power 0.1 – 12 W;
- Cube 4: CW power 0.1 – 15 W;

**Notice**

In ISP modality power emission is automatically set.

**Average power**

The device calculates the average power from the power values and duty cycle.

**Notice**

In ISP modality average power can be set in base of model.

**Frequency**

Frequency is adjustable between CW, 1 - 20000 Hz or ISP.
It is adjustable by typing in the numbers or touching 
Increments are adjustable as follows:

- from 1 to 20000 Hz – step of 1 Hz.

**Phase time**

Time of the each phase is adjustable between 1 to 999 s.
It is adjustable by typing in the numbers or by touching 

**Wavelength**

Wavelengths are adjustable based on the model, they can be selected in single or combined modality.

- ➢ Set the parameters for a phase and proceed for the maximum number of 12 phases.
- ➢ To delete completely a phase, select it and then press delete phase.
- ➢ To confirm the personal treatment press the save button and enter the name.
- ➢ After name's confirmation, the device will store the treatment.

The following picture shows the *treatment area* coming from main menu or additional.


Images of the selected body part can be seen.


Body mass and position of Chronicity/pain level matrix.


Treatment phases are shown. In particular for each phase emission modality is shown (CW, Hz o ISP). The current phase will be highlighted.

Laser armed. After a delay of 2 seconds by this button pressure, the aiming beam is switched on and the laser is ready to be used.

Press it to go back one screen.

Press it to the main menu.

Press it to change screen in order to modify parameters.

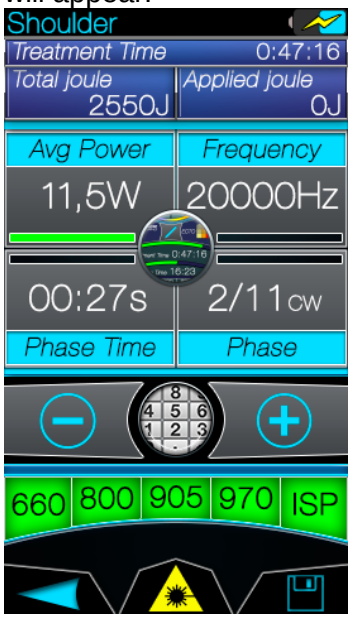
## ⚠ Warning

All persons present in the room must wear the laser protective goggles as soon as it is advised during use.

## ⓘ Notice

Before starting a laser treatment in battery operation please reconfirm the battery status.

The user can modify parameters and if needed the user can press  and the following screen will appear.




Select the field to be modified and then press the key to count up and down numerical value

Green : selected field.
Black: not selected field.

Press it to count up and down numerical value.

Press it to come back to the start area.

Press it to enter in the Keyboard.

Selectable wavelengths and ISP modality.


Green: selected field.
Blue: not selected field.

ISP (Intense super pulse) modality can be selected.

Laser armed. After a delay of 2 seconds by this button pressure, the aiming beam is switched on and the laser is ready to be used.

Press it to go back one screen.

Press it to save a treatment.

## ⚠ Warning

All persons present in the room must wear the laser protective goggles as soon as it is advised during use.

## Notice

Before starting a laser treatment in battery operation please reconfirm the battery status.

The following fields allow the operator to manage the treatment parameters.

| | |
|---|---|
| **Power/ Avg power Frequency Phase time** | Press one of the fields and the numeric keyboard. It allows the operator to set the desired value. Press OK to confirm the choice. |
| **Phase** | Pressing this field and then the keyboard is possible to add a new phase (+ icon) (the new one is created and it is positioned after the selected one) or delete the current one. The treatment is composed up to twelve phases. |
| **800nm** | Selectable wavelengths and ISP modality. Green: selected field. Blue: not selected field. |
| **ISP** | ISP (Intense super pulse) modality can be selected. |

For each treatment phase, the device keeps trace of the performed modifications. The followings images show the colors used for the status identification.



The operator is working in this phase.
No modifications have been performed respect to the already present values.


The phase is present but not currently used.
No modifications have been performed respect to the already present values.


The phase is present but not currently used.
At least one parameter has been modified respect to the already present values.

The parameters management is in detailed described.

**Notice**
In ISP modality, the device is able to automatically manage all the wavelengths and the operator cannot select them.

**Notice**
Peak power of 660 nm is 0.1 W.

**Notice**
Peak power is delivered only in pulsed mode and it is called ISP (Intense Super Pulse). It is a pulsed mode which delivers the following average power:

- Cube 3: average power 0.1 – 8 W;
- Cube 4: average power 0.1 – 12 W;

**Notice**
In ISP modality, frequency values are defined between 1–20000 Hz. In particular, in case of CW frequency is automatically converted into 20000 Hz.

The following steps allow the operator to set parameters.

- Press the  from the *treatment area* and select the phase to be modified;
- Select the needed parameters.

To manage the parameters select the field that will be highlighted with a green square and then press:

 Minus / Plus key or  to enter in a Keyboard to implement the modification.

If device is in ISP modality, the operator

| can modify | cannot modify |
|---|---|
| **Average power** | **Power** |
| **Frequency** | **Wavelength** |
| **Phase time** | |

If device is not in ISP modality, the operator

| can modify | cannot modify |
|---|---|
| **Power** | **Average power** |
| **Wavelength** | |
| **Frequency** | |
| **Phase time** | |

**Notice**

Treatment time and Total Joule are automatically calculated by the device, and cannot be set by the user.

To manage the parameters select the field that will be highlighted with a green square and then press:

 Minus / Plus key or  to enter in a Keyboard to implement the modification.

**Treatment time**

Treatment total time. This value is automatically calculated by the device.

**Total Joule**

The device automatically calculates the energy used during treatment (in J) from the power values and the selected laser activation time. Total energy during application is displayed.

**Power**

It is adjustable between 0.1 W and max value. In 0.01 W increments by typing in the numbers or by touching  .
The following power can be set:

- Cube 3: CW power 0.1 – 12 W;
- Cube 4: CW power 0.1 – 15 W;

**Notice**

For the use of other optional distals, please read carefully the specific instructions and the attached warnings.

**Notice**

In ISP modality power emission is automatically set.

**Average power**

The device calculates the average power from the power values and duty cycle.

**Notice**

In ISP modality average power can be set in base of model.

**Frequency**

Frequency is adjustable between CW, 1 - 20000 Hz or ISP.
It is adjustable by typing in the numbers or touching 
Increments are adjustable as follows:

- from 1 to 20000 Hz – step of 1 Hz.

**Phase time**

Time of the each phase is adjustable between 1 to 999 s.
It is adjustable by typing in the numbers or by touching 

**Wavelength**

Wavelengths are adjustable based on the model, they can be selected in single or combined modality.

- Set the parameters for a phase and proceed for the maximum number of 12 phases.
- To delete completely a phase, select it and then press delete phase.
- To confirm the personal treatment press the save button and digit the name.
- After name's confirmation, the device will store the treatment.

Press  to arm the laser.

- ↳ Device warns to wear protective goggles.
- ➢ After acknowledging the advice the green LEDs start flashing.
- ↳ After a delay of 2 seconds, the aiming beam is switched on.
- ↳ The laser is now ready for operation.

## Notice

Before the laser emission starts, the device will ask the operator to verify the optics in use. Please, select the icon corresponding to the optics used for the treatment.
In the case optional optics are used, the max average power will automatically be adapted.

When you actuate the switch the laser starts emitting. At the same time, two yellow LEDs at the upper right and left end of the device control unit light up as well as the laser active bar on the touch screen and the audible alarm sounds. When you release the switch to interrupt treatment, the laser is deactivated, but remains ready for operation.

## Notice

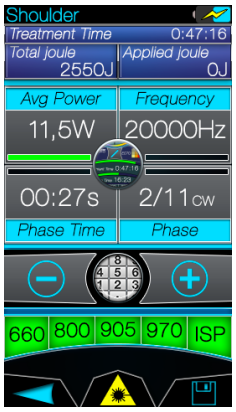
In case the operator needs to disable the laser emission sound only for the treatment currently in use, after the pressure of laser arming icon, it is necessary to press the sound icon. Thanks to this option, during laser emission, the laser will be disabled only for the treatment to be performed.

## Notice

In base of the selected frequency (CW, chopped or ISP modality), the aiming beam emits in a different way, as described:

- **CW**: the aiming beam is fixed, not flashing;
- **Modulated**: the aiming beam is slowly flashing;
- **ISP**: the aiming beam is quickly flashing.

The following explanation describes how to perform the treatment and the patient folder storing:

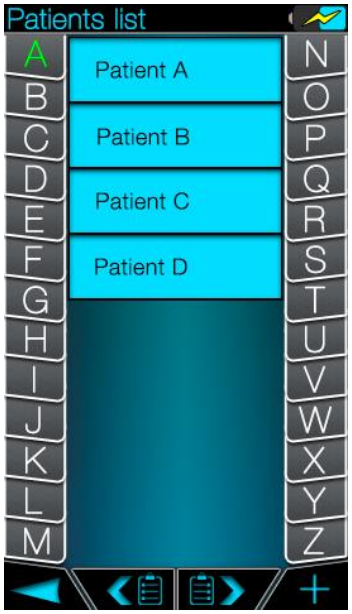



Before performing a treatment, the operator can memorize it in the patient folder. Press the saving button and digit the patient name on the alphanumeric keypad.
In this way, every time that the operator needs to access the patient folder, the device will immediately show the chronicity / pain level matrix related to the last performed treatment.
Moreover it is always possible to modify the parameters in order to customized the treatment.
At the pressure of the saving button the device will store modifications.

At the pressure of the saving button on already performed treatment and not belonging to a patient folder, the device will ask you to introduce on alphanumeric keypad the new patient name.

### 5.4.2 Patients

After choosing Patients, you can enter in the following screen.




A quick touch of the chosen patient, allows you to enter in the multi choice screen (treatment repetition, view history and delete).

Press it to go back one screen.

Arrows used to scroll forward and backwards, if more than one page on the list is present.

Press it to create a new patient.
Select body mass, skin type and write the patient's name. Press OK to confirm the patient's folder creation.

**Notice**

The device is able to store all the steps performed by the operator during the device use.

**Notice**

The device stores body mass and the skin type of all the patients. After patient's creation, these parameters are no longer required. However they can always be modified if needed.

**Notice**

At the selection of an already created patient, the device will show the main menu. In this way the operator can select the body part to be treated. After that the operator can set the treatment from the patient's chronicity / pain level matrix.

**Notice**

At the selection of an already created patient with an already performed treatment, the device will directly show the patient's chronicity / pain level matrix.

**Notice**

In order to have the history of the performed treatments, the patient must be created before the treatment execution. For instance, if a treatment is performed before the patient creation, at the save button pressure, the device will limit to only the patient creation.
On the contrary, the patient creation and the following treatment execution, will allow the device to memorize the history of the performed treatment.

After the matrix selection, the device will show the following screen.


*A first pressure* allows the operator to come back to patient's matrix.
*A second pressure* allows the operator to come back to the patient's main menu.

Press it to the main menu.

## 5.5 Set-up

The following area allows the operator to personalize the device. Select the interested area to enter in the following screen and so set the function.


Set date and time of the device.
Date format (dd/mm/yy or mm/dd/yy).
Time format (24hours notation): hh:mm.
See related paragraph for further explanation.

Choice of different preset languages.
Language will be automatically applied after confirmation.

Set level of display brightness by using ◄►.

Set personal pin code.
See related paragraph for further explanation.

Select volume level of warning sound and press button sound by using ▼▲.

Battery calibration process.
Follow the instruction displayed on screen.

Configure the switch emission modalities:

- **Single touch**: laser active if fingerswitch is kept pressed.
- **Double touch**: laser is active at the first pressure of the fingerswitch. Second pressure enables the emission.
- **RRT**: Remote Restart Control.

Software update.
Follow the instruction displayed on screen.

⚠ Caution

Use only USB memory devices with authorized software updates.

ℹ Notice

Remember to connect the power supply before performing software update

History. View and download the performed treatments.

Press it to go back one screen.

### 5.5.1 Date&Time

The key allows the operator to set date and time.


Press it to increase and decrease the Date.

Press it to increase and decrease the Time.


Press it to confirm date and time.

Press it to go back one screen.

### 5.5.2 Change P.I.N.

The key allows to modify the pin code of the device.


Digit the new pin code. Confirm by pressing OK.
The numeric pad always displays the used key code.


Press it to confirm the new P.I.N.

Press it to go back one screen.

**Warning**

The device may be operated only by qualified personnel. Do not give the access to unauthorized third parties.

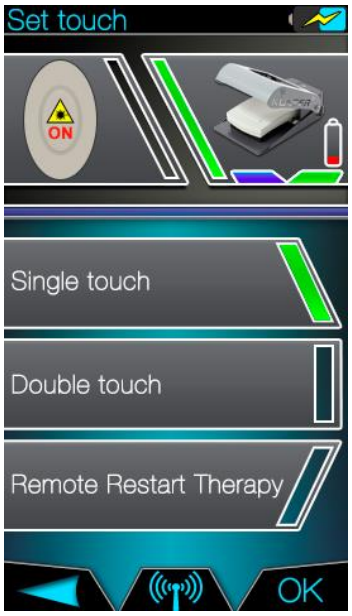
Do not write down the electronic access key somewhere else in order to minimize the risk of misuse of the laser by unqualified persons. Please turn off the unit after the use.

**Notice**

In case the operator forgets the pin code, digit the super pin code **2974**. It cannot be modified.

### 5.5.3 Set touch

This key allows the operator to set the switch modality.




| | |
|---|---|
| Single touch | Laser active if fingerswitch is kept pressed. |
| Double touch | Laser is active at the first press of the fingerswitch. Second press terminates the emission. |
| Remote Restart Therapy | Remote Restart Control. Perform a treatment again by using the hands button on the handpiece. |
|  | Press it to select the finger switch. |
|  | Press it to select the wireless footswitch. (It is present only if footswitch enabled). |
|  | Operator goes back one screen. |
|  | Press it and follow the instruction on screen to set the pairing to the footswitch. (It is present only if footswitch enabled). |
|  | Press it to confirm the switch modality. |

**Notice**

The green bar shows the selected modality.

**Notice**

**Single touch.** If the switch is kept pressed, the message “LASER ON” appears and at the same time, yellow LEDs light up, audible alarm sounds and laser starts emitting. At the switch release, the laser is deactivated, but remains ready for operation.

**Notice**

**Double touch**. At the first pressure of the switch, the message “LASER ON” appears, at the same time, yellow LEDs light up, audible alarm sounds and laser starts emitting. At the switch release, the laser is still active. Press the switch a second time to deactivate the laser.

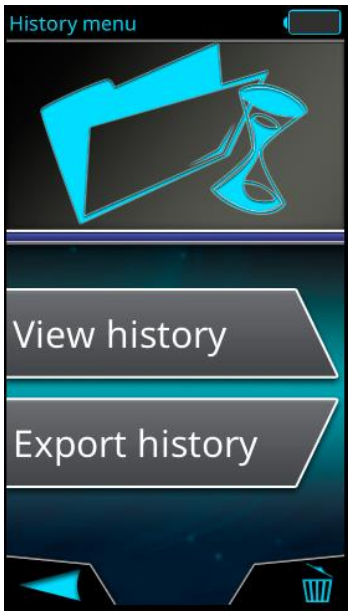
**Notice**

The **RRT** (**R**emote **R**estart **T**herapy) modality allows to perform again a complete treatment without removing the hands from the handpiece. It is sufficient to press the fingerswitch one time to close the “completed therapy” window.

- In **Double touch**, the second pressure of the fingerswitch enables the termination of the laser beam.
- In **Single touch** modality excludes **RRT** and vice versa.

### 5.5.4 History

The history stores the performed treatments and allows the operator to download them onto a USB stick.




| | |
|---|---|
| View History | View history. Press the button to check data of the performed treatments. |
| Export history | Save history. Press the button to download data of the performed treatments. Proceed as instructed on the screen. |

Press it to go back one screen.

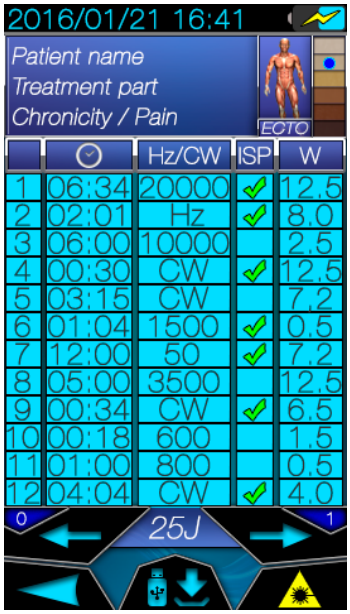
Press to delete history.

**Notice**

The whole treatment list can be deleted from the History file by pressing the proper key to confirm the action. The operation is irreversible.

Press **View history** to visualize the screen to set year and month to be consulted. Use the arrows to scroll the date.

Confirming the choice with OK, the device will show the treatment's parameters as in the following screen.




Press it to go back one screen.

Press it to export performed treatments into the USB stick.

Laser armed to perform the screened treatment. After a delay of 2 seconds by this button pressure, the aiming beam is switched on and the laser is ready to be used.

**Warning**

All persons present in the room must wear the laser protective goggles during use.

At the end of each application the device stores the following parameters in the History file.

In the upper part of the screen date&time and treatment's parameters are shown.


Number of the treatment phases (in case the operator performs more than 12 phases, the device will show only the last 12).


Single phase time.

Emissive modality (modulated (1-20000 Hz) or continuous (CW)).

ISP modality. If active this symbol  is displayed.

Average power.

Patient name (if selected).

Total emitted energy (even in case the operator performs more than 12 phases, the device calculates the total emitted energy).


Arrows used to scroll treatments and number of pages to be scrolled.

The device allows the user to choose the following different file formats:

| | |
|---|---|
| **TXT** | Format available on any text program. |
| **CSV** | Format used to exchange data between spreadsheets. |

There are two different kinds of history:

**- Global history**, that shows a complete list of performed treatments.

Press **Export history** or  to export the treatments directly into the USB stick Class 2.0.

Notice

The file name of the complete list has the following structure: "history-global-2013-07-10-083042" and the numbers indicate date & time of the file with ".txt", ".csv" extension.

**- Single patient history**, that shows only treatments of the selected patient.

From the patient menu select "View history". The screen allows to export the patient's treatments directly into the USB stick Class 2.0.

Notice

The file name of the patient's treatments has the following structure: "history-Patient name-2013-07-10-083042" and the numbers indicate date & time of the file with ".txt", ".csv" extension.

## 5.6 Error messages and warnings

| | |
|---|---|
| **Laser Stop** | The laser has been deactivated by pressing “Laser Stop” button. |
| **Interlock open** | Please wait until the interlock is closed. Check interlock plug on back of machine. |
| **Wear protective goggles** | Before proceeding it is advised to put the laser safety goggles. |
| **Pin code not correct** | Wrong pin code was entered. Please try again. |
| **Delete treatment?** | Confirmation if the treatment shall be deleted. |
| **Error. Wrong USB device.** | Software update : The USB device was not accepted. Please plug it in again or try another USB device. |
| **Insert USB** | Software update procedure: before going on please plug the USB device into USB connector. |
| **Battery low. Estimated power for 180 s.** | The battery level is very low (remaining power for 180 seconds) and needs to be charged. |
| **Battery low** | The battery level is low and needs to be charged. |
| **Fan not working. Switch off the device** | Cooling fan is not working. To avoid damage please switch off the device and let it cool down for a while. |
| **Wait laser source cooling** | To avoid damage of the laser source please wait and let the device cool down. |
| **Missing finger switch** | The fiber switch could not be detected. |
| **Please release the switch** | Release the switch. |
| **Connect plug to the DC-IN** | Connect the DC-IN connector to the device. |
| **Check the connection of the optic** | Check the correct connection of the handpiece distal part. |
| **Insert the correct distal part** | Insert the proper distal part before treatment. |
| **Name already in use** | The name is already present in the list. |
| **Error Contact service** | A malfunction has occurred. Please contact an authorized service center. |

# 6 Indications, contraindications and medical precautions

## *6.1 Indications*

Each device is indicated for emitting energy in the Infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

## *6.2 Contraindications*

⚠ Warning

Do not treat directly over cancer or tumor.

⚠ Warning

Do not treat on gravid uterus.

⚠ Warning

Never direct the laser beam toward a person's eye or thyroid gland. All persons present in the room (patient, operator and assistant) must always wear the laser protective goggles delivered along with the device.

## *6.3 Precautions*

⚠ Warning

It is recommended not to use the handpiece in direct contact to skin of the patient, but to keep distance from the skin and always move it!

⚠ Warning

Before starting treatment, please try to treat fix points, keeping a distance of about two centimetres from the skin of the patient, in particular if you are using continuous emissions, in order to check the sensibility of the patient and the energy density, especially if the patient's skin is particularly brown.

⚠ Warning

If any dark spots or moles are present cover area with titanium, zinc oxide or put a cloth over area to prevent any heat associated with absorption of excessive energy.

# 7 Post treatment cleaning

⚠ Warning

Following treatment, switch off the device and disconnect the power cable from the power supply.

⚠ Warning

Unit and accessories are not sterilizable.

## *7.1 Cleaning of the unit*

Clean the device and the accessories with a dry, soft cloth to remove dust from the device. More stubborn spots can be removed with a damp cloth.

You can disinfect the device using any of the products that are commonly used to disinfect medical electrical equipment, e.g. MinutenWipes from Alpro and Caviwipes TM.

Observe the instructions provided by the manufacturers of these disinfectants.

ℹ Notice

Use only disinfectants that comply with the requirements of your national authorities and whose bactericidal, fungicidal and virucidal properties have been tested and properly certified.

ℹ Notice

Please proceed carefully not to scratch and damage the foil on the touchscreen.

ℹ Notice

The device may be disinfected only by wiping it.

ℹ Notice

Optical fiber can be damaged easily if it suffers excessive flexion or is used in an incorrect way. This fact can compromise the usefulness of the treatment.

ℹ Notice

Clean the lens with a dry, soft cloth. Please proceed carefully not to scratch and damage the foil on the lens.

⚠ Caution

Spray disinfection may allow liquids to penetrate into the device! Do not use spray disinfection for the device! Use only wet cloth.

## *7.2 Cleaning of the zoom optical with distal*

This part can be removed for cleaning. Unscrew the part and clean it with the products that are commonly used to disinfect medical electrical equipment, e.g. MinutenWipes from Alpro and Caviwipes TM.
Observe the instructions provided by the manufacturers of these disinfectants.

ℹ Notice

Use only disinfectants that comply with the requirements of your national authorities and whose bactericidal, fungicidal and virucidal properties have been tested and properly certified.

# 8 Maintenance and service

## *8.1 Maintenance*

The device does not require special maintenance. In case of malfunctioning, see chapter Technical support, repair and testing. However, it is recommended to take the following actions at regular intervals:

| **Action** | **Frequency** | **Responsible** |
|---|---|---|
| Check of the optical fiber | Before each treatment session | Operator |
| Safety checks | Every 2 years | Authorized Service Center. |

**Notice**

If national or local legal regulations require additional safety checks for your laser unit, these regulations must be complied with and the corresponding checks must be performed.

The manufacturer accepts responsibility for the safety of the laser unit only if the following requirements are fulfilled:

- Modifications of the laser unit or repair work may be performed only by authorized personnel.
- The electrical installations in the rooms where the device is used must fulfill the applicable legal requirements.
- The unit must be used in compliance with the instructions provided in the present manual.

## *8.2 Troubleshooting of simple defects*

In case of malfunctioning, proceed as follows:

First of all, be sure that operation steps have been carried out correctly.

The touchscreen of the device remains dark after switching it on.

- Check the connection of the power cable and/or check the rechargeable battery.

When using an interlock device the laser will not be stopped and blocked after interrupting the circuit.

- Check the connection of the interlock device.

There is no aiming beam or it does not project a uniform circular pattern.

- Check to see if the optical fiber is damaged. If the optical fiber is damaged, replace it with a new one.
- Check the connection of the optical fiber to the zoom handpiece is damaged.

Wireless foot control is not working.

- Check the battery of the wireless footswitch.
- Check the registry of the wireless footswitch.
- Check if the wireless footswitch is chosen in the set-up submenu.

If you cannot solve the malfunctioning, switch off the laser and contact an Authorized Service Center.

## *8.3 Safety check*

The following safety checks must be performed every 24 months by a qualified service engineer.

- Visual inspection of the unit and its accessories for mechanical damage that might impair operation;
- General function check;
- Check of the visual and audible indicators;
- Check the electrical power;
- Check the power emission of the laser.

## *8.4 Technical support, repair and testing*

In case technical support, contact the following address:

UNITED STATES:
T: 1-800-494-3395 USA
Email: ChattProductSupport@djoglobal.com

Before sending the device to the Service Center, it is required to disinfect the device and accessories as written in the present manual.
The device may be sent in for repair or for safety inspection only in its original packaging, including all accessories.

This is the only provider of technical service for its products, unless otherwise indicated by the Company. This is to guarantee the product's safety and for the preservation of the product's characteristics.

# 9 Manufacturer's declaration on electromagnetic compatibility

## *9.1 Definitions*

Notice

The device complies with all requirements for electromagnetic compatibility according to IEC 60601-1-2.

### 9.1.1 Emission (electromagnetic)

When electromagnetic energy is emitted by a source.

### 9.1.2 Interference immunity

The ability of a device or system to work without errors even if there is electromagnetic interference.

### 9.1.3 Immunity level

The maximum level of a certain electromagnetic interference that affects a particular device or system, where the device or system remains operative with a certain level of performance.

| **ELECTROMAGNETIC EMISSION** | | |
|---|---|---|
| EMISSION TEST | COMPLIANCE | ELECTROMAGNETIC ENVIRONMENT - GUIDANCE |
| RF emissions<br>CISPR 11 | Group 1 | The unit uses RF energy only for its internal function. The RF emission is therefore very low and it is improbable that nearby electronic devices might be disturbed |
| RF Emission<br>CISPR 11 | Class A | The unit is suitable for use in all establishments, excluded domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.<br>**Warning:** The equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location. |
| Harmonic emissions<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions<br>IEC 61000-3-3 | Complies | |

| **INTERFERNCE IMMUNITY** | | | |
|---|---|---|---|
| The unit is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment. | | | |
| Immunity test | EN 60601-1-2 test level | Compliance level | Electromagnetic environment – guidance |
| Electrostatic discharge (ESD)<br>EN 61000 - 4 - 2 | +/- 6 kV contact discharge<br>+/- 8 kV air discharge | +/- 6 kV contact discharge<br>+/- 8 kV air discharge | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% |
| Electrical fast transient/ burst<br>EN 61000-4-4 | +/- 1 kV for input and output lines<br>+/- 2 kV for power supply lines | +/- 1 kV for input and output lines<br>+/- 2 kV for power supply lines | The quality of the line power supply should be that of a typical commercial or hospital environment |
| Surge<br>EN 61000-4-5 | +/- 1 kV differential mode | +/- 1 kV differential mode | The quality of the line power supply should be that of a typical commercial or hospital environment |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>EN 61000-4-11 | < 5% Ut<br>(> del 95% dip of Ut)<br>for 0,5 cycles<br><br>40% Ut<br>(60% dip in UT)<br>for 5 cycles<br><br>70% Ut<br>(30% dip in UT)<br>for 25 cycles<br><br>< 5% Ut<br>(> del 95% dip of UT)<br>for 5 seconds | < 5% Ut<br>(> del 95% dip of Ut)<br>for 0,5 cycles<br><br>40% Ut<br>(60% dip in UT)<br>for 5 cycles<br><br>70% Ut<br>(30% dip in UT)<br>for 25 cycles<br><br>< 5% Ut<br>(> del 95% dip of UT)<br>for 5 seconds | The quality of the line power supply should be that of a typical commercial or hospital environment.<br><br>If the user of the unit requires continued operation during power mains interruptions, it is recommended that the unit be powered by an uninterruptible power supply or a battery. |
| Power frequency magnetic field<br>EN 61000-4-8 | 3 A/m | 3 A/m | N.A. The unit does not contain devices susceptible to magnetic fields. |

| **RF IMMUNITY** | | | |
|---|---|---|---|
| The unit is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment. | | | |
| Immunity test | EN 60601-1-2<br>Test level | Compliance level | Electromagnetic environment – guidance |
| Conducted RF<br>EN 61000-4-6 | 3 Vrms from<br>150 kHz a 80 MHz | 3 Vrms from<br>150 kHz a 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>d=1,2 . √P from 150 kHz to 80 MHz<br>d=1,2 . √P from 80 MHz to 800 MHz<br>d=2,3 . √P from 800 MHz to 2,5 GHz where “P” is the maximum output power rating of the transmitter manufacturer and “d” is the recommended separation distance in meters. |
| Radiated HF<br>EN 61000-4-3 | 3 Vrms from<br>80 MHz to 2.5 GHz | 3 Vrms from<br>80 MHz to 2.5 GHz | |
|  | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol : | | |

| **RECOMMENED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE UNIT** | | | |
|---|---|---|---|
| The model is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and unit as recommended below, according to the maximum output power of the communications equipment. | | | |
| Rated maximum output power of transmitter (in watts) | Separation distance according to frequency of transmitter (in meters) | | |
| | From<br>150 kHz a 80 MHz<br>D= 1,2 . √P | From<br>80 MHz a 800 MHz<br>D= 1,2 . √P | From<br>800 MHz a 2 GHz<br>D= 2,3 . √P |
| 0,01 | 0,12 | 0,12 | 0,23 |
| 0,1 | 0,38 | 0,38 | 0,73 |
| 1 | 1,2 | 1,2 | 2,3 |
| 10 | 3,8 | 3,8 | 7,3 |
| 100 | 12 | 12 | 23 |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance “d” in meters can be determined using the equation applicable to the frequency of the transmitter, where “P” is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer<br><br>**Notice**<br>At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br>These guidelines may not apply in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

# 10 Appendix

## *10.1 Appendix A – Certification*

The unit is manufactured in compliance with the provisions of Council Directive 93/42/EEC and 2007/47/CE concerning medical devices.

### DECLARATION OF CONFORMITY
### Manufacturer's declaration of conformity
### (directive 93/42 EEC and 2007/47/CE)

**The product:**

**Medical class: IIB**

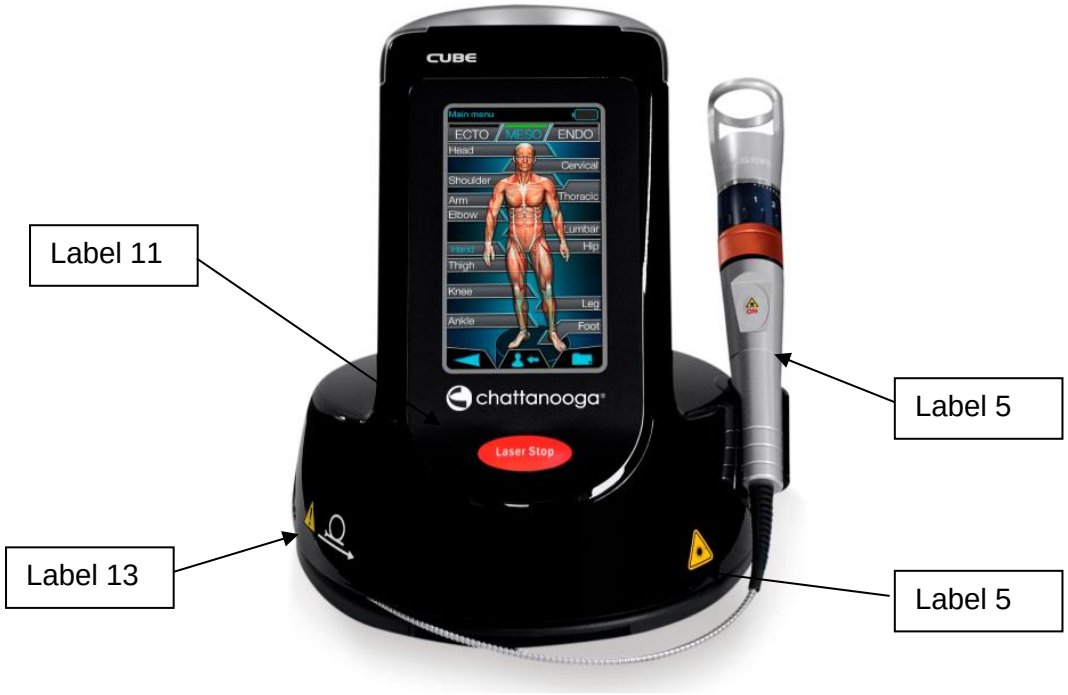
**Type: Laser diode**

Is manufactured in compliance with the standards of Council Directive 93/42/EEC and 2007/47/CE concerning medical equipment in application to the annexes I and II (except point 4) as per certificate MED 21017 released from the Notified Body N° 0476, Kiwa Cermet (Via Cadriano, 23 - 40057 Granarolo dell'Emilia (BO), Italy) and commercialize them according to the Dlgs N.46 dated 27 February 1997 and further modifications and integration, the product has been designed and manufactured according to the following standards:

| | |
|---|---|
| IEC 60601-1:2012 | Electro-medical equipment - General requirements for safety. |
| IEC 60601-1-2:2007 | Electro-medical equipment - General requirements for safety - Secondary standard: Electromagnetic compatibility - Prescriptions and tests. |
| IEC 60601-1-6:2010 + A1:2013 | Medical electrical equipment- Part 1: General requirements for basic safety and essential Performance. Collateral standard: Usability. |
| IEC 60601-2-22:2007 | Medical electrical equipment - Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment. |
| IEC 60825-1:2007 | Safety of laser products: - Part 1: Equipment classification, requirements and user's guide. |
| EN ISO 14971:2012 | Medical devices - Application of risk management to medical devices. |
| IEC 62304:2006 + A1:2015 | Medical device software - Software life-cycle processes. |

## *10.2 Appendix B – Label positions*

The following figures show the positions of the labels on the device.




Picture 1: front side

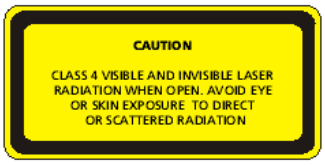
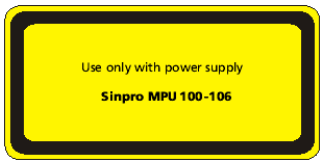

Picture 2: rear side

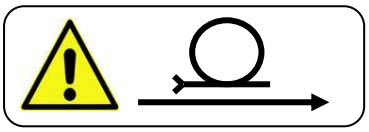

Label 6

Picture 3: inner side


Label 2
Label 3
Label 10
Label 12

Picture 4: bottom

| LABEL | EXPLANATION |
|---|---|
|  | Label_1: Warns of exposure to class 4 laser radiation hazards when using the laser unit. |
|  | Label_2: Warns of potential laser radiation hazards when opening the laser unit. |
|  | Label_3: use only with power supply Sinpro MPU 100-106. |
|  | Label_4: for Cube 3. Specification of laser output power and wavelength of diode and aiming beam. |
|  | Label_4: for Cube 4. Specification of laser output power and wavelength of diode and aiming beam. |
|  | Label_5: Laser radiation warning. |
|  | Label_6: Fingerswitch. |
|  | Label_7: DC in for power supply. |
|  | Label_8: socket for Interlock. |

| | |
|---|---|
|  | Label_9: socket for USB. |
|  | Label_10: Cube 3. Identification serial number of the device. |
|  | Label_10: Cube 4. Identification serial number of the device. |
|  | Label_11 Laser stop. |
| ONLY FOR USA<br>Complies with FDA performance standards for lsaser products except for deviations pursuant to Laser Notice No.50 dated June 24, 2007 | Label_12: FDA clearance.<br>(Only for Us market) |
|  | Label_13: Correct fiber winding |
|  | Label_14: On/off the device |