BTL-6000

HIGH INTENSITY LASER

(10 W, 20 W, 30 W)

USER'S MANUAL

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1 GENERAL CHARACTERISTICS OF THE DEVICE

1.1 INTENDED PURPOSE

BTL-6000 High Intensity Laser is non-invasive therapeutic device intended to emit energy in the infrared spectrum to provide topical stimulation of the biological tissue. This tissue stimulation results in local acceleration of wound healing, increase of local blood flow and analgesic reaction.

High Intensity Laser can be used for various treatments of muscle, tendon or joint pathologies, e.g., chondral lesions, subacromial impingement syndrome (e.g. calcification of subacromial bursa), carpal tunnel syndrome, presence of musculoskeletal pain (e.g. chronic back pain, cervicobrachial pain syndrome, shoulder pain), tendinitis, epicondylitis, rotator cuff injury; arthrosis (e.g. gonarthrosis), arthritis (e.g. periarthritis humeroscapularis), deep muscle trigger points, calcar calcanei, muscle and tendon ruptures, distortions and sport injuries, paresis, scar, herpes, haematoma.

1.2 USER PROFILE

The device shall be used by medically educated personnel. The user shall be familiar with all safety precautions, operating procedures and maintenance instructions.

1.3 PATIENT PROFILE

The use of the device is intended for adults only, otherwise there is no limitation of gender, weight or height of the patient in general. The patient must not show any signs of contraindications determined for the device. The user should take into account a detailed patient's medical history and examine the patient thoroughly to determine whether or not the application of therapy is suitable for the patient.

1.4 OPERATING ENVIRONMENT

The device is intended solely for professional use in medical facilities. The device is designed for indoor use only, not for use in a location where explosion or water intrusion hazards are present, not for use in dusty or humid environment and not to be exposed to direct sunshine. The device is not intended for home-use.

1.5 DEVICE DESCRIPTION

All models of the device are equipped with a colour touch screen. Horizontal orientation of the device allows the information on the screen to be seen clearly from different servicing positions. The on-screen information will guide the user step-by-step through the entire therapy process. The therapeutic parameters are easily set using the touch screen buttons and knobs/buttons on the device.

The treatment parameters can be manually set using the touch screen buttons. Throughout the therapy the user is informed about the remaining time of the therapy and remaining dose to be applied. These values are automatically calculated from the parameters that can be set by the user: operation mode (continuous or pulsed), frequency, treatment area, dose and power output.

1.6 CONTRAINDICATIONS AND POSSIBLE SIDE EFFECTS

1.6.1 CONTRAINDICATIONS FOR HIGH INTENSITY LASER TREATMENT

- Psychological illness
- Major systemic diseases – e.g. uncontrolled Diabetes mellitus, systemic lupus erythematosus
- Current pregnancy
- Photosensitivity, medications affecting sensitivity to light
- Tattoos and other higher pigmented regions in the treated area
- Corticosteroids or injections of the treated area within the last 3 months, long-term corticosteroids use
- Pacemaker
- Anticoagulant therapy, bleeding disorders
- Hemorrhage in the treated area
- Application over the thyroid or other endocrine glands
- Application within 4 to 6 months after radiotherapy
- Known or suspected malignancy, history of cancer or any type of malignancy
- Febrile conditions, serious illness, chronic infection
- Epilepsy
- Sensory loss in the treatment area
- Deep vein thrombosis
- Application in the periorbital or genital area

1.6.2 POSSIBLE SIDE EFFECTS OF HIGH INTENSITY LASER TREATMENT

- Unpleasant sensation of heating
- Sensation of tingling
- Temporary hyposensitivity
- Temporary hypersensitivity
- Erythema

1.7 GENERAL WARNINGS AND PRECAUTIONS

Use clinical assessment to determine all aspects of the treatment including, but not limited to, the laser treatment protocol, technique, power settings, pulse duration and interval settings and other procedural requirements. Some of the situations where special precautions are required:

 All patients should receive a skin type assessment according to Fitzpatrick (see Chapter 1.7.1). The therapy parameters must to be adjusted based on this assessment.

 It is necessary to keep moving the applicator throughout the whole therapy. Avoid static application.

 Scar tissue is associated with poor circulation and reduced cooling through heat transmission by blood. Power settings may have to be reduced to avoid over-heating.

 Tender or Sensitive Skin: The patient may be hypersensitive to heat. Reduce power as necessary to ensure comfort during treatment.

Swelling/inflammation: Patient may be sensitive to heat. Reduce power as necessary to ensure comfort during use.

 Redness: may be associated with increased temperature and an increase in absorption properties of the skin. Reduce power as much as necessary to maintain comfort during use.

Excessive fat tissue is known to transmit heat without much attenuation. Reduce power as necessary.

 Implants: Different materials will respond differently to the laser energy and heat. Be aware of any implants and location. Avoid direct exposure of the implant site to laser or heat.

 No ointments, creams, lotions or heating lotion patches should be used at the site or on close proximity.

 No therapies that could change body temperature (ultrasound, thermotherapy and electrotherapy) should be used prior to laser treatment.

 No treatment over articles of clothing. Only direct application to the uncovered skin surface is acceptable.

 All persons present in the operatory must wear protective laser eyewear.

 Do not look directly into the beam or at accidental reflections.

 The device shall be operated only by persons cited in chapter 1.2 USER PROFILE.

 All reflective materials and windows in the treatment room must be covered in order to prevent reflection of the laser beam or unwanted irradiation outside.

 Patients must be monitored for pain or discomfort throughout the entire procedure. In case the patient does not tolerate the therapy, discontinue the treatment immediately.

 All Scanning System sensors are optimized to a defined range of therapeutic distances. If the treatment distance is out of the therapeutic range it may not correspond to real values.

⚠ When using the optional Scanning System accessory, output power could be less than the maximum of the unit.

⚠ Patient movement during Scanning System therapy can cause inaccurate temperature readings.

⚠ Do not cover the air vents of the device. This would result in non-functioning of the device.

⚠ Do not operate the device out of temperature ranges between 10 °C to 35 °C.

⚠ Take care while lifting the device to prevent back injury.

⚠ While performing therapy make sure that the there is no threat of strangulation to the patient due to loose fibres.

⚠ Therapy shall not be applied to those body parts which are listed in chapter 1.6 CONTRAINDICATIONS AND POSSIBLE SIDE EFFECTS.

⚠ Therapy shall be applied only to patients cited in chapter 1.3 PATIENT PROFILE.

1.7.1 SKIN TEST EVALUATION ACCORDING TO FITZPATRICK

The Fitzpatrick Scale (Fitzpatrick skin typing test or Fitzpatrick phototyping scale) is a numerical classification schema for the colour of skin.

All patients should receive a classifying skin test assessment according to Fitzpatrick prior to the treatment. The Fitzpatrick Scale:

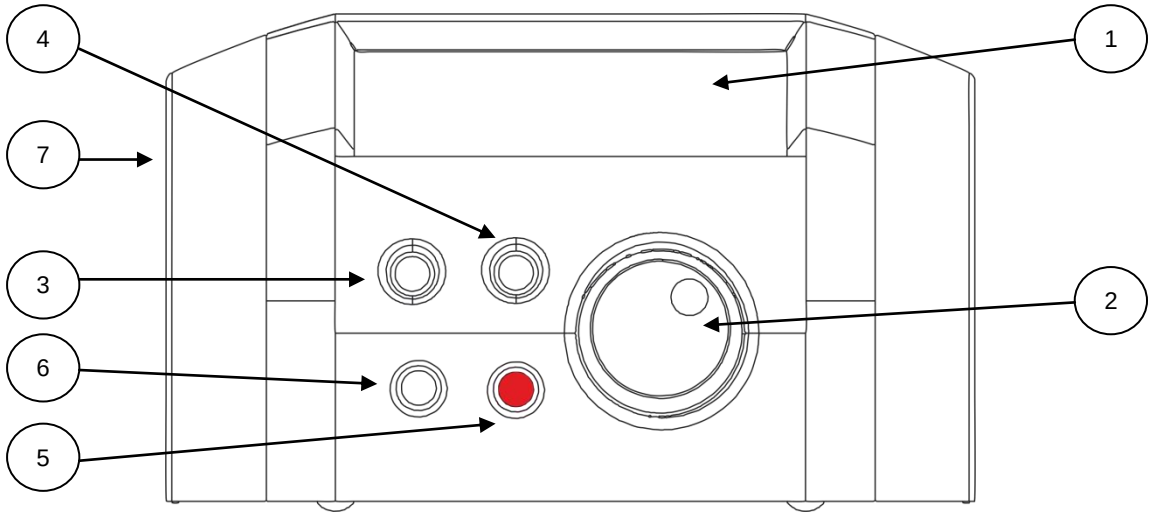
- Type I Skin white; very fair; freckles; typical albino skin. - Always burns, never tans.
- Type II Skin white; fair. - Usually burns, tans with difficulty.
- Type III Skin beige; very common. - Sometimes mildly burns, gradually tans to light brown.
- Type IV Skin beige with a brown tint; typical Mediterranean Caucasian skin. - Rarely burns, tans with ease to moderate brown.
- Type V Skin dark brown - Very rarely burns, tans very easily.
- Type VI Skin black - Never burns, tans very easily, deeply pigmented.

⚠ Patients evaluated as skin type V. and VI. must be treated with special precautions. Any discomfort and any unpleasant sensations of over-heating must monitored during the whole treatment procedure with special care!

2 INSTRUCTIONS FOR OPERATION AND SAFE USE

2.1 THE FRONT PANEL

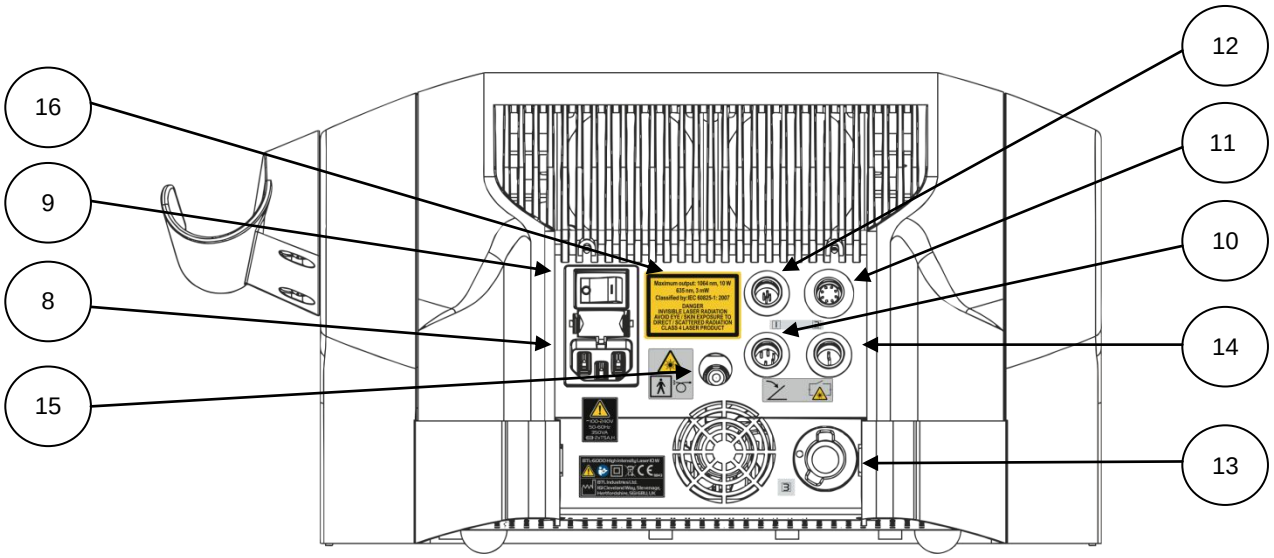
The main unit contains the main microcomputer and software for controlling the entire system. The unit is password secured and a safety interlock must be connected.



1. Touch screen
2. **Select** knob (to select individual parameters)
3. **Enter** button
4. **Esc** button
5. **Laser stop:** emergency laser stop button
6. **ON/OFF** switch (backlit, in blue, when the control unit is ‘’on’’)
7. USB located in the device’s grip for use only in compliance with IEC 60950-1.

The USB port serves only for service purposes such as the uploading of firmware; it is not designed for therapy use!

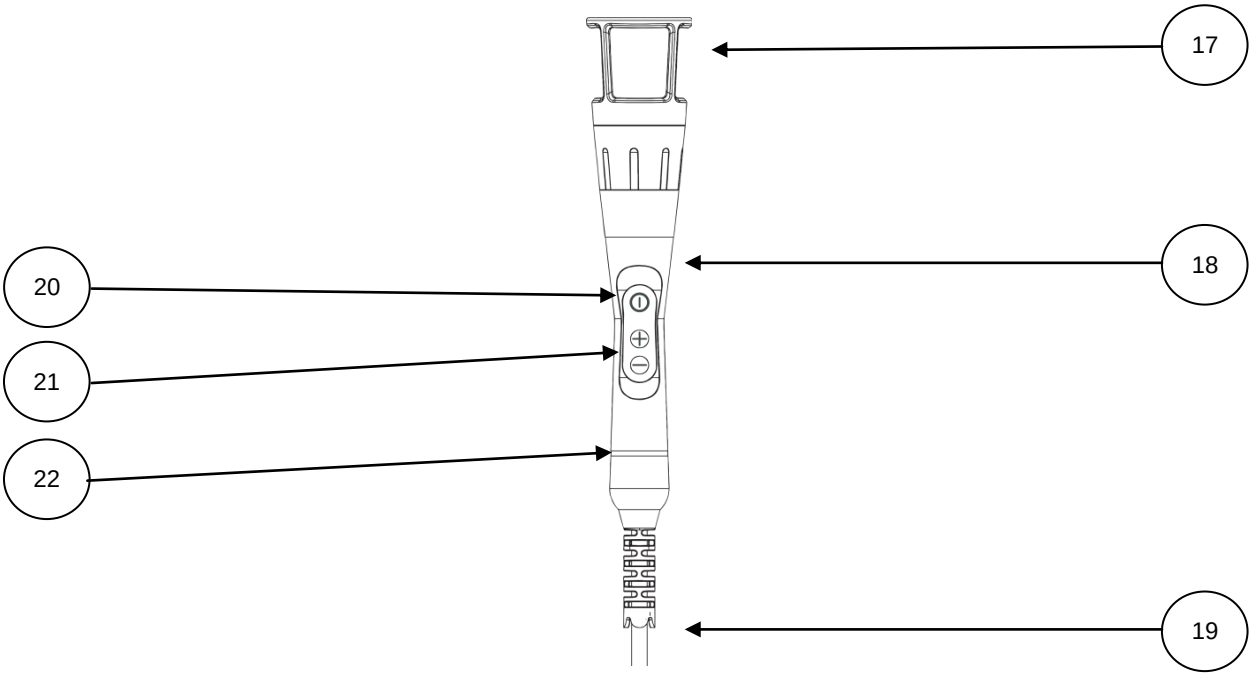
2.2 THE REAR PANEL



8. Connector for the power cable
9. Power ON/OFF switch
10. Footswitch connector
11. Scanning System cable connector
12. Patient emergency switch connector
13. Fibre checking sensor window
14. Safety interlock/door lock sensor connector
15. Connector for applicator – applicator is permanently attached
16. Type and safety labelling

2.3 THE LASER APPLICATOR

Applicator with optical zoom attachment for precise adjustment of the therapeutic spot in the range of 10 mm to 30 mm. The laser light is delivered to the applicator from the main unit using a permanently attached optical fibre. Take care while attaching the optical zoom attachment to prevent any pinch to the fingers.

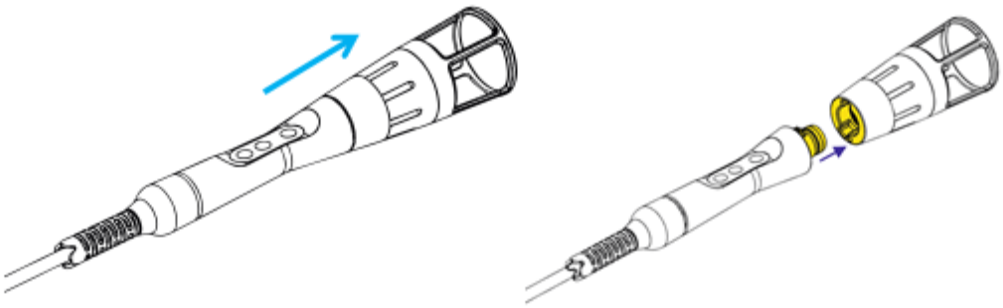


17. Optical zoom attachment
18. Main body of the applicator
19. Optical fibre
20. Therapy On/Off button
21. Intensity +/- button
22. Indication light ring

Do not remove the attachment while therapy is in progress.

Make sure that the hand-piece is always properly secured in the hand-piece holder when not used.

2.3.1 ATTACHING AND DETACHING OF THE OPTICAL ATTACHMENT



Optical zoom attachment can be attached and detached to the applicator as shown in the picture and make sure that the slots in the zoom attachment is coincide with the main body of applicator. If the zoom attachment is disconnected while performing therapy, the therapy will be terminated.

2.4 SCANNING SYSTEM

Scanning System is an optional accessory designed to perform automatic laser application in a defined therapeutic distance from 10 cm up to 50 cm. Laser output is located in the bottom of the device. The device is equipped with a batch of sensors. An ultrasonic distance sensor is used for precise Scanning system positioning.

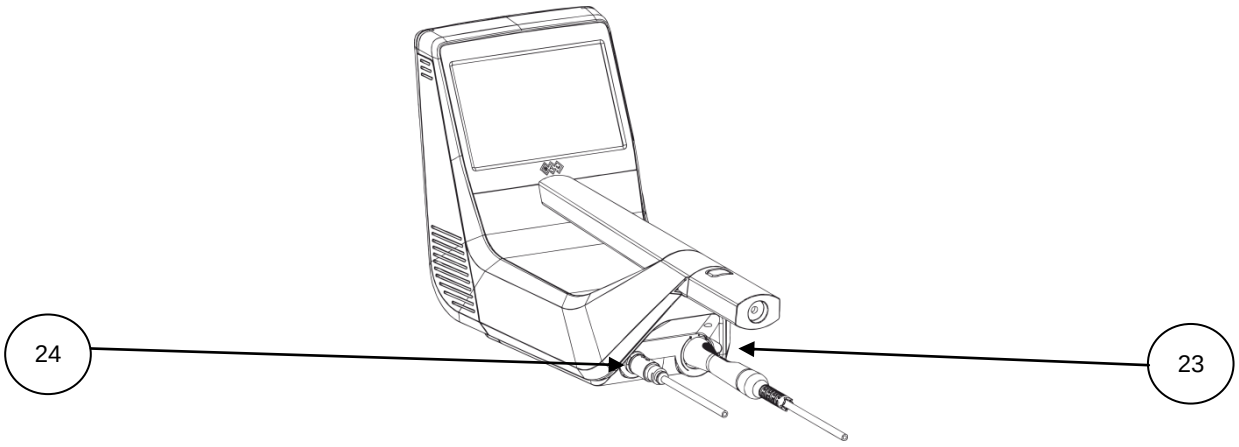
The Scanning System Elite is equipped with an IR camera. Device labels are placed on the bottom of the device. Connection is provided by the communication cable (No. 24) which is near the applicator connection.

⚠ There could be a mismatch in the ultrasonic distance sensor values when using the Scanning System over areas with significant body hair and over the materials with high absorption of mechanical waves (e.g. towels)

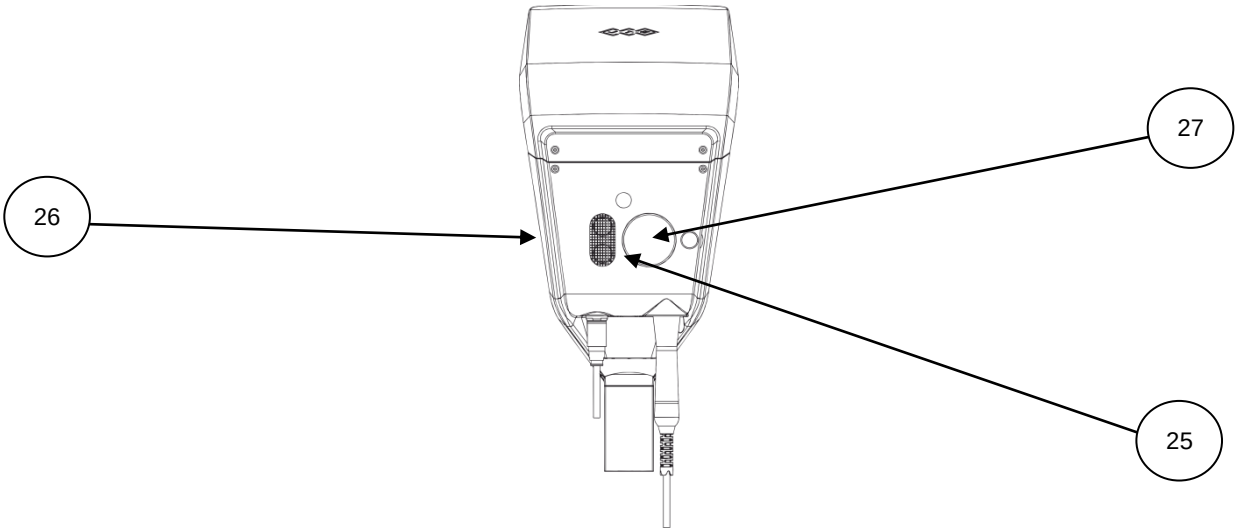
⚠ A graph of delta temperature values should only be used for informative reasons. Not for diagnostic evaluation.

⚠ IR camera values could be unstable during the first minutes after starting the device due to thermal stability of the camera.

⚠ Do not disconnect Scanning System cable when device is running.



23. Applicator connector
24. Scanning System cable connector

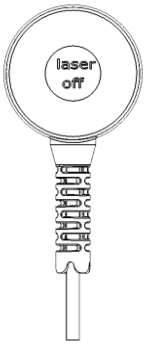


25. Laser output
26. Ultrasonic distance sensor
27. IR camera

2.4.1 PATIENT EMERGENCY BUTTON

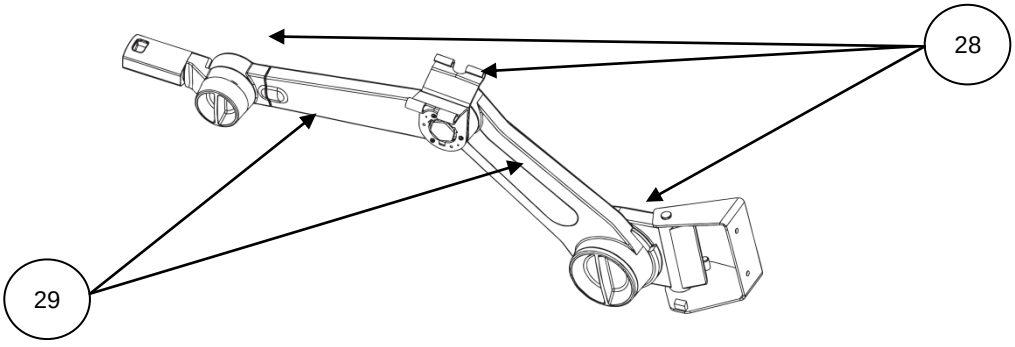
When therapy is provided by the automatic applicator Scanning System, it is necessary to connect the Patient emergency button to the main unit which can stop the therapy. Without the Patient emergency button the Scanning System device will not work.

⚠ Ensure that the Patient emergency button is in the patient's hand while performing therapy.



2.4.2 APPLICATOR ARM

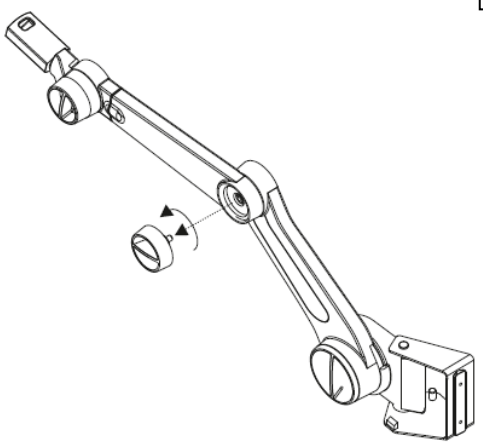
The applicator arm comprises of 3 knobs for adjusting and fixing the arm position (28, 2 rotary joints (360°) for adjusting the applicator position (29), 1 rotary joint (1cover° on the middle knob) for adjusting the arm position and cable holder.



2.4.2.1 Assembly and Set-Up of applicator arm

Installation of the cable holder

1.



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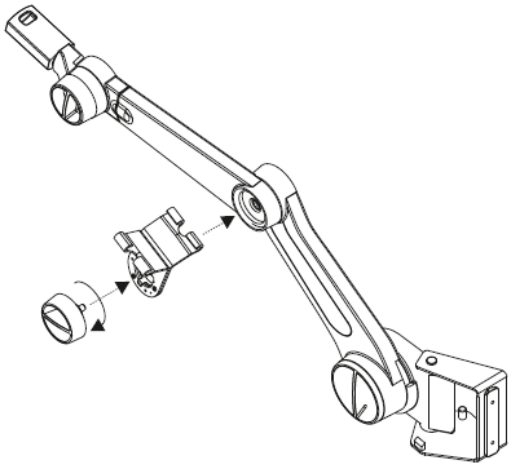


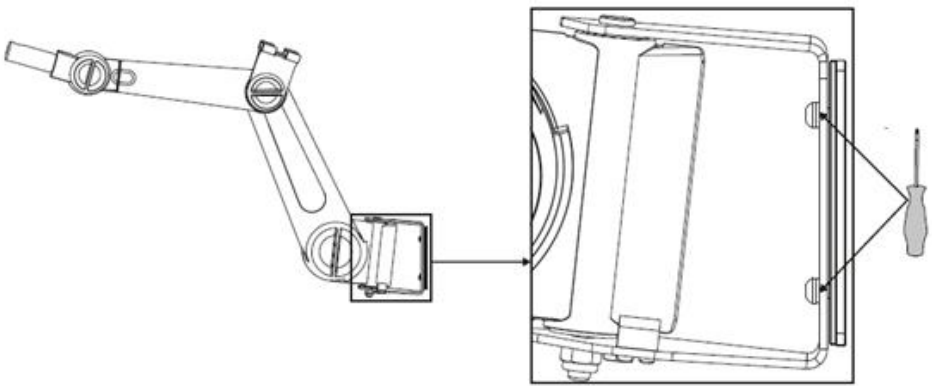
1. Release the whole knob (1) and put the applicator holder in between the knob and the joint it.
2. Tighten the knob in clockwise direction to attach the cable holder.

Installation of arm

Application arm has to be installed before main unit is attached to the trolley.

1. Before the installation, loosen the applicator arm holder screws 3 to 4 times.
2. Application arm shall be installed on to the left side of the trolley from the front view.
3. Application arm holder has to be attached maximal 5 mm below the edge of the side profile. To fix the application arm holder tighten the application arm screws
4. When needed adjust turning force of last joint using tube wrench

1.



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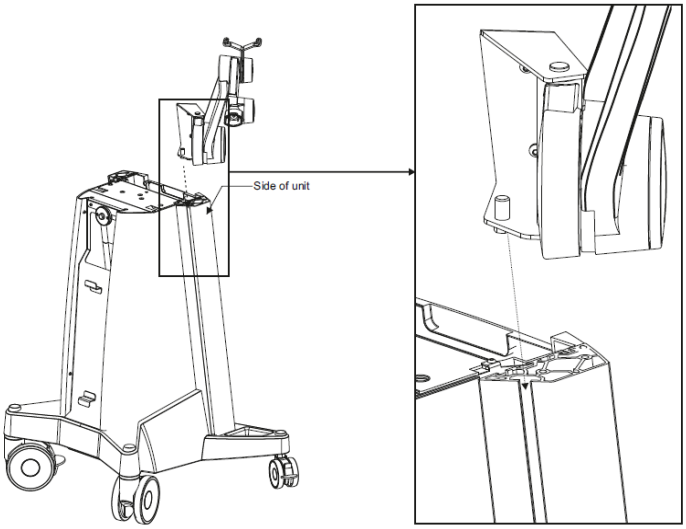

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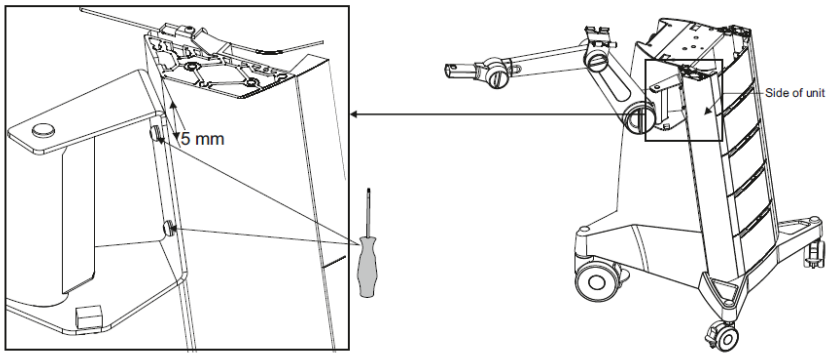

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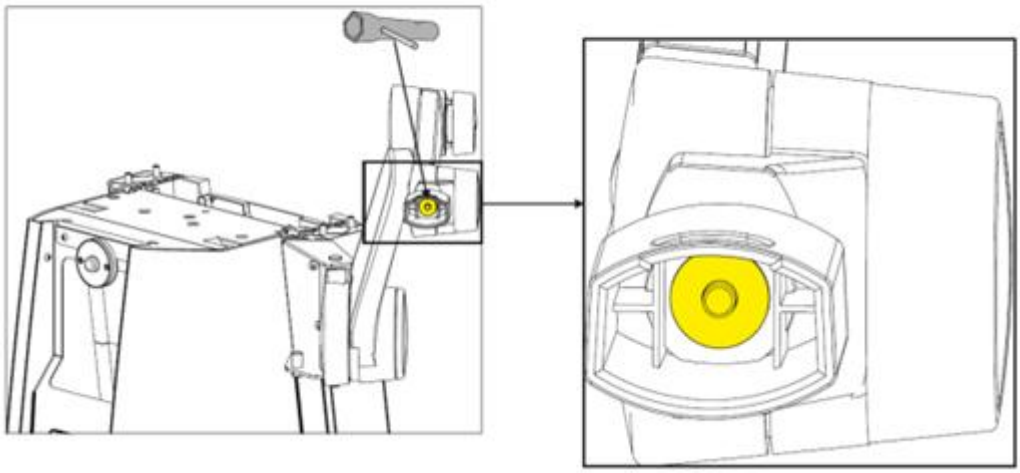
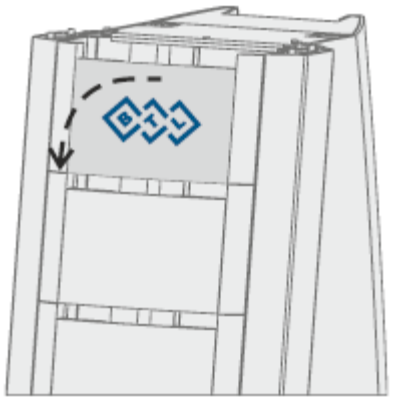


2.4.3 HIGH INTENSITY LASER MOUNTING ON THE TROLLEY

1. Open the drawer
2. Put the BTL-6000 High Intensity Laser unit on the trolley
3. Fasten the screw
4. Close the drawer

1.



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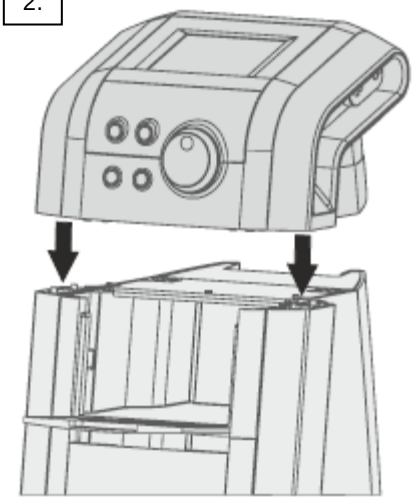

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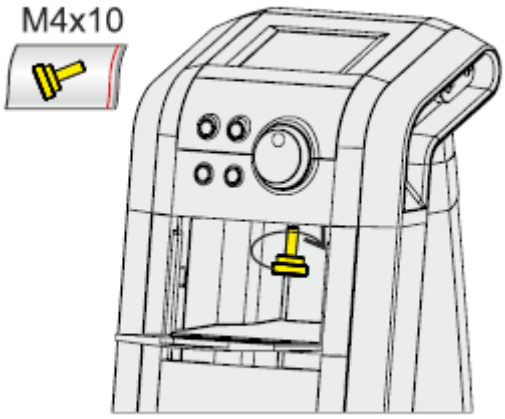

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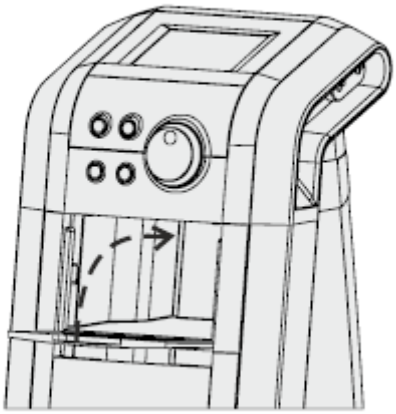
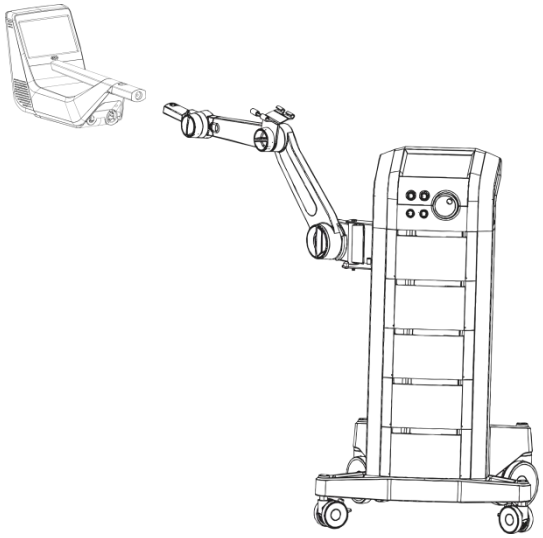


2.4.4 SCANNING SYSTEM INSTALLATION AND CONNECTION

1.



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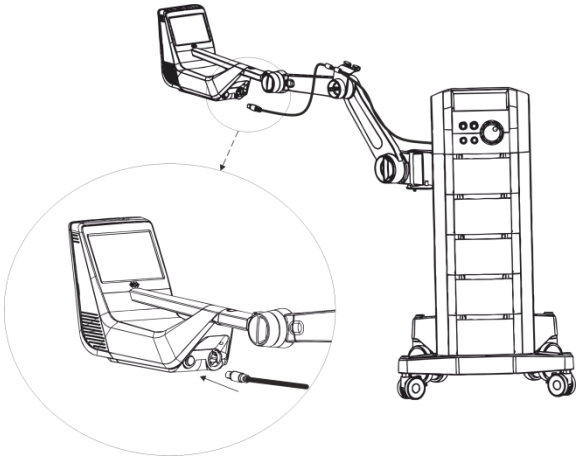

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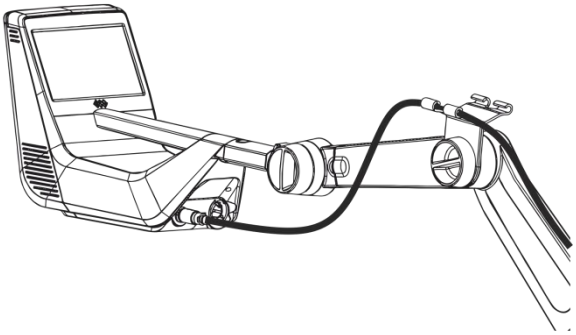

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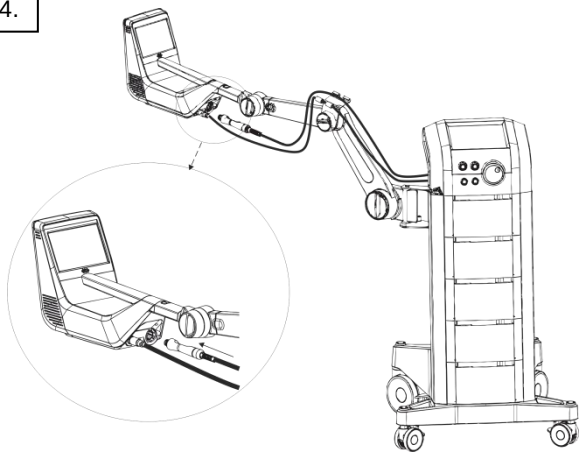

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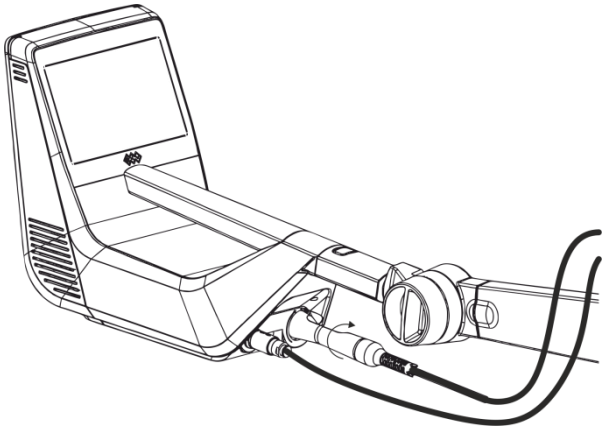
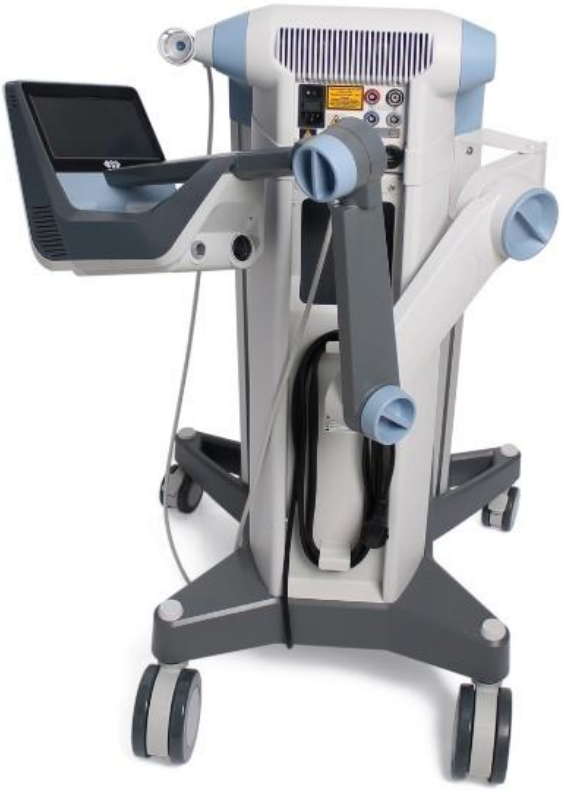


1. ⚠ Connect the Scanning System to the arm, it is fully locked in once the click sound is heard.
2. ⚠ Completely engage and make sure that the Scanning System head adaptor is completely inserted and the button is in the slot.
3. ⚠ Connect the Scanning System with the main unit using the Scanning System cable.
4. Disconnect the optical zoom attachment from the applicator and put it into the holder.
5. Insert the applicator into the Scanning System and rotate clockwise to lock the applicator.

2.4.5 TRANSPORTING THE SCANNING SYSTEM DEVICE ON THE TROLLEY

The Scanning System device shall be transported only in the orientation shown below.



⚠ While moving the device with the trolley make sure that it is properly secured.

It is recommended that the device is stored in the transportation position to make sure that the device only takes up the required amount of space.

3 BASIC DISPLAYS AND OPERATION OF THE DEVICE

3.1 UNBOXING THE DEVICE

Inspect the box for damage and report any damage to the transport carrier and the distributor. Do not proceed with assembly and set-up if the box is damaged. Keep the original box and packaging to ensure safe future transport of the device.

When bringing the device from a cold environment into a warm one, do not plug it into the power source until the device has had to equilibrate to room temperature (minimum 2 hours).

Unpack the device and place it on a stable horizontal surface which is suitable for its weight. Always position the device out of direct sunlight. During operation, the control unit and the Scanning System get warm, so it must not be positioned near direct heat sources. The device is self-cooled by forced air circulation. The cooling vents are located on the rear panel and on the bottom of the control unit and on the sides of the Scanning System. Do not cover or block these vents or try to insert fingers inside the device through the vents. Allow a minimum of 4 inches (10 cm) clearance behind the rear panel. Do not place the device on a soft surface (such as a towel) which may obstruct airflow to the bottom cooling vents. Do not put any heat-producing devices or any objects containing water or other liquids on the device. Do not place the device close to appliances producing strong electromagnetic, electric or magnetic field (diathermy, Xrays, etc.), otherwise it could be undesirably influenced.

In the event of any questions, please contact an authorized service of BTL devices.

Procedure:

1. First connect the device to the mains supply using power cord cable, which you will connect to the connector on the rear panel of the device and to 100 V – 240 V mains socket. Plug the device directly into the mains socket. Do not use any multi-connection extension cables or two-socket adaptors.
2. Connect the safety interlock to the connector in the rear panel.
3. Connect the footswitch control cable to the connector in the rear panel. (Optional accessory)
4. Then switch on the power switch in the rear panel of the device.
5. Press the **on/off** switch located on the front panel of the device.

Note:

After switching the device on, the device will run a self-diagnostic of its internal circuits and its functions for about 10 to 15 seconds. If any fault is detected, the screen will display a warning message. If necessary; the control unit will lock itself into a “secure” mode. If this situation occurs, please contact your authorized BTL distributor.

3.2 DEVICE STARTUP / SHUTDOWN

Plug the power cord (supplied with the device) into the connector of the device and into the mains. Plug the device directly into the mains; do not use extension cords with multiple sockets or multi-socket adaptors.

Switch the power ON/OFF switch on the rear panel to position “**I**”.

Press the **on/off** button on the front panel.

Turn off the device by pressing the **on/off** button**.** A great deal of thermal energy is accumulated in the applicator at the end of the therapy, thus the automatic applicator cooling process must be completed before the device is turned off. The cooling process can be interrupted by pressing the **esc** button. The unit turns off automatically after the cooling process is completed (when the ambient and applicator temperatures are equal).

3.3 NAVIGATION CONTROLS

The top part of the touch-screen contains a basic navigation toolbar:

	LIST	displays the list of available user protocols
	QUICK	displays the screen with the quick** choice of user protocol
	MANUAL	displays the screen with therapy parametres
	MENU	enables setting the device functions
	HOME	enables returning back to screen which is configured as Home (reconfigurable by the user, welcome screen by default)

3.3.1 DEVICE MENU

By pressing the **menu** button on the touch screen you can browse the through following menus of function settings and information screens:

- user settings / database
- unit settings
- specific settings

3.3.2 USER SETTINGS / DATABASE

This item displays a menu referring to the data saved by the user:

- clients
- user protocols
- recent therapies

3.3.2.1 Clients

This item enables setting up, editing and deleting client information. It is possible to assign therapies from the list of user protocols to any client and to run these therapies after pressing the **load** button.

3.3.2.2 User Therapeutic Protocols

This option enables running user protocols after pressing the **load** button and editing or deleting their names, program numbers and descriptions. Every generator tab shows only the therapies that have been created on that tab.

3.3.2.3 Recent Therapies

This option displays the list of last performed therapies on the selected tab and enables starting a therapy again after pressing the **load** button.

3.3.3 UNIT SETTINGS

The submenu allows setting the following parameters:

- language
- date & time
- sound settings
- colour schemes
- screen saver and auto switch-off
- password
- unit information
- accessories information
- advanced settings

3.3.3.1 Language

Selection of the language for displayed texts on the display. English is set by default.

3.3.3.2 Date & Time

Setting the date and time of the device.

3.3.3.3 Sound Settings

This option allows setting the sound volume and modifying the acoustic signals of key pressing, touching the screen and some processes (start of therapy, interruption of therapy, end of therapy etc.). Standard default sounds are preset at the factory. Sounds can be muted completely or customized in the standard sounds editing.

3.3.3.4 Colour Schemes

This option allows selecting one of the pre-set colour layouts of the device and changing the colour representation of the elements displayed on the screen.

3.3.3.5 Screen Saver and Auto Switch-off

The option enables setting the type of screen saver. It is also possible to set the idle time after which the screensaver shall be activated, the screen shall be switched off or the entire device turned off.

3.3.3.6 Password

This menu allows changing the password which is required after switching the device on. Without entering the password no further work with the device is possible.

3.3.3.7 Unit Information

Some information about the unit is displayed – the serial number, type of the device, multifirmware ID version, HW key etc. If the device function is time-limited, this item shows the date by which the device will be fully functional.

3.3.3.8 Accessories Information

This option displays information about the connected accessories.

3.3.3.9 Advanced Settings

This option allows setting less frequent functions of the device:

- **HOME** screen mode (setting the type of the screen after selection of therapy type)
- **QUICK** screen mode (displaying of quick user protocols)
- **LIST** screen mode (displaying of the list of protocols or body parts)
- user accounts

- time of use
- touch panel calibration
- display contrast
- buttons backlight
- service functions
- dialog history
- setting of HW key

3.3.4 SPECIFIC SETTINGS

3.3.4.1 QUICK Screen Protocols

The option enables setting protocols on the QUICK screen and additional functions referring only to the selected generator.

3.3.4.2 Therapy Settings

The option enables setting protocols on the pauses between sections and phases.

3.3.4.3 Sound During Therapy

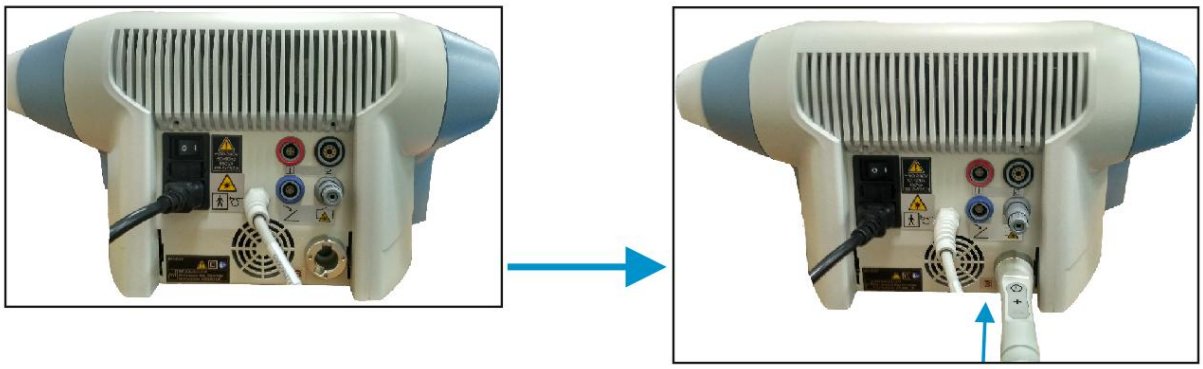
This menu allows changing the sound during therapy and its volume.

3.3.4.4 Handpiece power check

It is recommended that the laser source be calibrated every 3 months. The process is automatic and takes about 10 seconds. Calibration must be performed without any attachment. The procedure is as follows.

<u>Procedure for calibration of the applicator:</u>

1. Place the end part of the applicator without the attachment into the calibration window in the back of the unit.



2. Choose “applicator calibration” in the “specific settings” menu.
3. Choose “start power check”.

4 THERAPY

4.1 THERAPY SETUP STEP BY STEP GUIDE

4.1.1 GENERAL GUIDELINES FOR SETTING UP THERAPIES

- Set the therapy parameters according to the patient's conditions and skin type.
- Select appropriate size of the therapeutic spot.
- During the therapy keep the applicator perpendicular to the patient's skin.
- Always keep moving the applicator to avoid overheating tissue. Avoid static application.

Ask for feedback from the patient whilst the therapy is in progress.

It is recommended that protection eye cups are used instead of protective goggles in case of facial application.

4.1.2 SETTING THE THERAPY BY SELECTING A USER PROTOCOL – LIST SCREEN

The list of all user protocols is displayed after the **LIST** button is pressed.

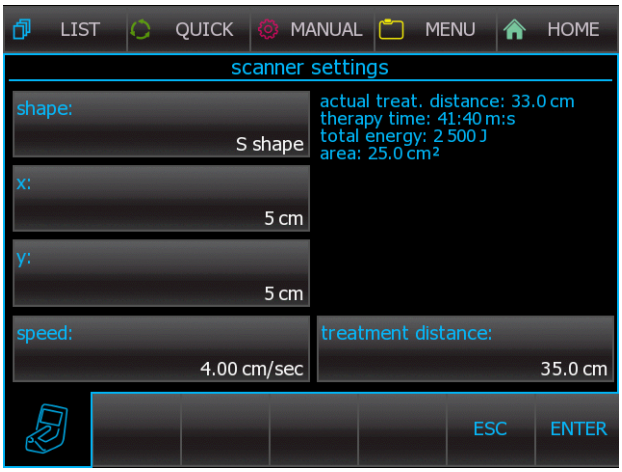
Once desired protocol is found, its selection can be made by pressing the selected protocol row or the **enter** button on the touch screen or the front panel.

4.1.2.1 BODY CONDITIONS – ADJUSTING THERAPEUTIC PROTOCOLS ACCORDING TO THE PATIENT

The BTL-6000 High Intensity Laser offers a function for adjusting the therapeutic protocols according to the patient body conditions which is only for therapeutic protocols.

4.1.3 SCANNER SETTINGS – ADJUSTING THERAPEUTIC AREA AND TREATMENT DISTANCE

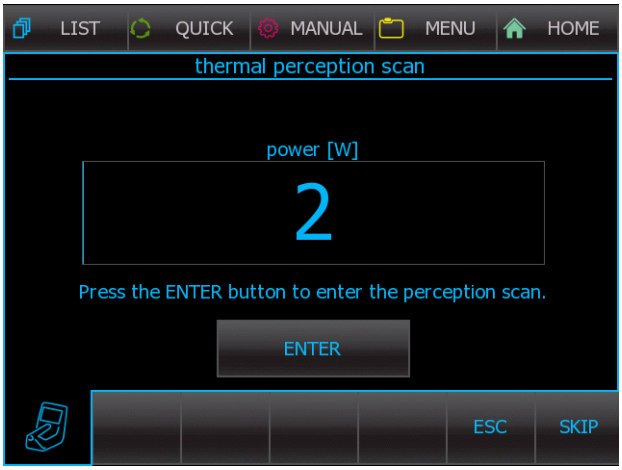
The BTL-6000 High Intensity Laser in combination with the Scanning System Elite or Easy optional accessory offers a function for adjusting the therapeutic area and treatment distance setting. After adjusting therapeutic protocol using the **SCANNER SETTING** screen, the device displays the screen with parameters overview.



⚠ These settings are available only when using the Scanning System Elite or Scanning System Easy optional accessory.

4.1.3.1 THERMAL PERCEPTION SCAN

The BTL-6000 High Intensity Laser in combination with the Scanning System offers a thermal perception scan function, which offers therapy parameter adjustment based directly on patient feedback. The test is connected only with Scanning System therapeutic protocols and follows the area setting screen. The test is provided on the therapeutic area dimension and consists of a continuous power increment. The test can be stopped by the patient using an emergency button, or operator via the unit GUI. The test should be stopped before the patient perceives an uncomfortable heat level.



⚠ Wearing protective goggles during the Thermal perception scan is mandatory.

4.1.4 QUICK THERAPEUTIC PROTOCOL SELECTION – QUICK SCREEN

After **QUICK** button pressed on the navigation toolbar is the device displays the user protocol quick-selection screen.

The **QUICK** screen serves for fast start of the therapy without the need to browse through the entire list of user protocols. To select a protocol just press the respective button. The list of quick screen protocols can be fully customized (*menu – specific settings – setting of the **QUICK** screen protocols*).

Additional to the QUICK screen and the user protocols it is possible to display the screen for the selection of therapy by the program number; this option can be set in the device menu (*menu – unit settings – advanced settings – QUICK screen mode*).. To set the program value, press the required element on the touch screen and then use the **select** knob or the numerical keyboard. The screen for the selection of therapy by the program number can also be displayed by pressing the **list** button twice.

To start the therapy using the selected therapeutic protocol from the therapy parameters screen (see below – MANUAL screen), press **start** on the touch screen or **start/stop button** on the front panel of the device.

4.1.5 MANUAL SETTINGS OF THERAPY PARAMETERS – MANUAL SCREEN

After the **MANUAL** button from the navigation toolbar is pressed, the device displays the **MANUAL** therapy parameters screen where the full range of therapy parameters can be set and the therapy can be started immediately.

This screen also appears always before the start of therapy when one of the pre-set therapeutic protocols from the **LIST** or **QUICK** screens is selected.

	Press the edit button on this screen to edit the therapy parameters. The screen with advanced therapy parameters will be displayed.
	Press the save button to save current therapy setting. The therapy is saved as a user-defined therapeutic protocol and can be assigned to a specific client.

The following parameters can be set:

Therapy

Mode of the laser light emission.

Power

Output power of the emitted laser light in Watts (W). This parameter is available in all therapy modes.

Dosage

Therapeutic dosage in joules per cm^2 (J/cm^2). This parameter is available in all therapeutic modes except the single pulse.

Area

Therapeutic area in square centimetres (cm^2). This parameter is available in all therapeutic modes except the single pulse.

Frequency

Frequency of the pulsed laser light in Hertz (Hz). This parameter is available in all therapeutic modes except the single pulse and continuous mode.

Pulse width

Width of the single pulse emitted in milliseconds (ms). This parameter is available only in single pulse therapy mode.

The following parameters are indicated:

Total energy

Automatic calculation of the total energy in joules (J) to be delivered during the therapy. The total energy is calculated using the Dosage and Area. This parameter is available in al therapeutic modes except the single pulse.

Therapy time

Automatic calculation of the therapy time in minutes and seconds (m:s). The therapy time is calculated using the Total energy and Power. This parameter is available in all therapeutic modes except the single pulse.

NOTE: The maximum Therapy time is limited to 99 minutes 59 seconds.

Energy per pulse

Automatic calculation of the energy in joules (J) delivered by a single emitted pulse. This parameter is indicated only in the single pulse therapy mode.

4.1.5.1 Setting the Therapy mode

The following therapy modes can be set:

- **CW (Continuous mode)**: continuous laser emission;
- **PW (Pulsed mode)**: repetitive pulsed laser emission with adjustable duty cycle and frequency;
- **ISP (Superpulse mode)** : superpulse laser emission with 10% fixed duty factor;
- **TMP (Triangular mode)** : triangular laser emission with 100 Hz fixed frequency;
- **sequence (Sequence mod)** : up to 99 sections;
- **SP (Single pulse mode)**: single pulse laser emission with adjustable pulse width;

⚠ When using an optional accessory Scanning System Single Pulse therapy mode is not available.

4.1.5.1.1 Therapy settings for sequence mode

This mode enables creating a therapy sequence by setting therapy parameters for each section in the sequence. The sequence can consist of up to 99 sections.

Sequence editor is controlled by the following buttons:

	Shift to the left position in the sections list.
	Shift to the right position in the sections list.
	Add a new section (with default values)
	Delete the current section
	Create a copy of the current section.
	Cut the current section.
	Place the chosen section before the current one.
	Place the chosen section behind the current one.
current section	Displays the current section number and number of sections
section time	Displays the duration of the current section.
dosage	Sets the parameters of amplitude modulation
power	Sets the parameters of frequency modulation.
type	Sets the type of current section.
total energy	Indication of energy time for whole sequence.
total time	Indication of total time for whole sequence.
total dose	Indication of total dose for whole sequence.

4.1.5.2 Setting the Output power

The output power can be set on the therapy parameters screen, even during the course of therapy. After pressing the “power” button it is possible to set the intensity either by means of the numeric keypad, preset values written on the buttons or by the select knob. During therapy, the intensity value can be changed by means of the select **knob** or **applicator keypad**.

4.1.5.3 Setting the Dosage

A crucial therapeutic parameter of High Intensity Laser therapy is the dosage in joules per one centimetre square of the treatment area. The dosage (J/cm^2) is set on the therapy parameters screen. Setting is enabled when any therapy modes are active with the exception of single pulse.

4.1.5.4 Setting the Treatment Area

Appropriate treatment area can be set on the therapy parameters screen. Set the value accordingly to the expected size of the area to be treated. Setting is enabled when either all therapy modes are active except the single pulse.

4.1.5.5 Setting the Frequency

The optimum frequency of the pulsed laser light emitted can be set on the therapy parameters screen. The frequency of the laser pulses can be set in the range from 1 Hz up to 20 kHz. Setting is enabled when pulsed, triangular and super pulsed therapy mode is active.

4.2 COURSE OF THERAPY

4.2.1 START, INTERRUPTION AND END OF THERAPY

For safety reasons the therapy can be only started by performing two subsequent steps.

First, press the **start** button on the screen and the “therapy” window will open. The device will start emitting a red aiming beam from the applicator and an indicator light will start blinking. The aiming beam approximately marks the treatment area and indicates to the user that the device is ready to start the therapy.

 Abort the therapy if the aiming beam is not present.

Note that the footswitch must be released and the safety interlock must be connected while pressing the **start** button.

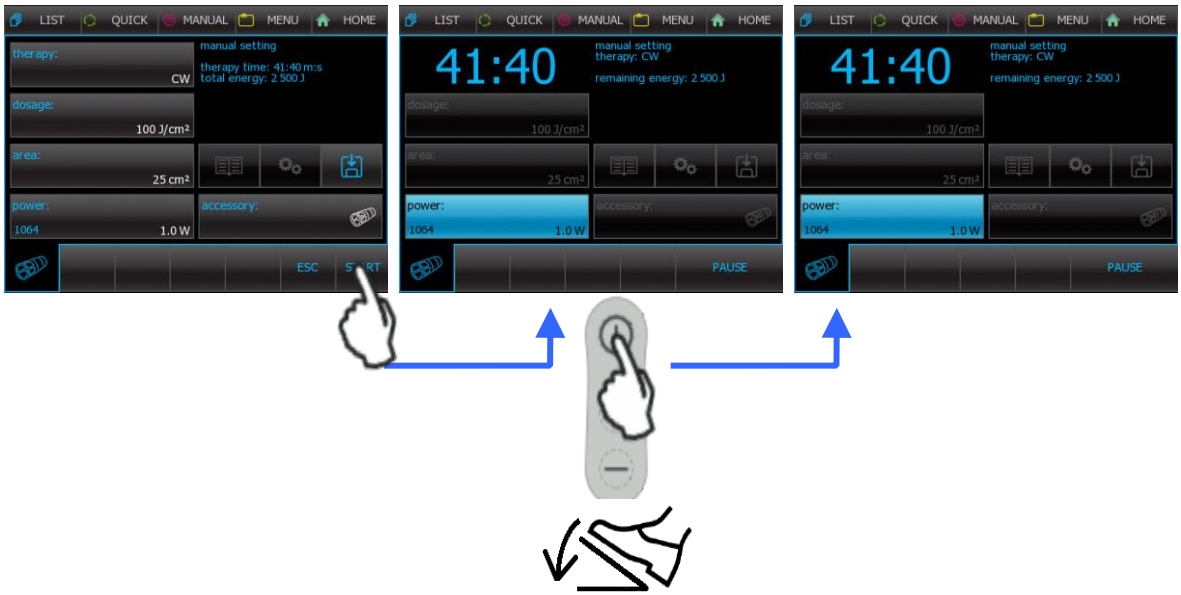
In the second step, emission of the laser light is activated by pressing the on/off control on the Applicator. When the on/off control is pressed, the therapy laser light is emitted:

- In **all modes except for single pulse mode** the laser light will be emitted until the on/off control is pressed again. Therapy in progress is indicated using a yellow circular light around the **laser stop** button, a beeping sound and continuous light of the indicator stripe.
- In **single pulse mode** by pressing the on/off control, the device will emit one laser light pulse. During pulse generation, the backlight around the **laser stop** button is yellow and the device makes a beeping sound. Hold the on/off control until the pulse generation is complete. For another emission the on/off control must be pressed again.

During the therapy the device continues to emit the red aiming beam.

It is possible to adjust power using applicator controls.

The therapeutic laser is invisible to the human eye.



To stop laser emission before the therapy is over, press the on/off **control.** To interrupt/pause the therapy press the **pause** button on the therapy screen or on/off **control**. To resume the interrupted – paused – therapy press the **continue** button on the screen or on/off **control**. To stop the therapy, press esc.

The laser power can also be changed during therapy by turning the select **knob** to the right to increase the intensity or to the left to decrease the intensity or by using the **applicator keypad**.

To immediately stop laser unit activity in case of emergency, press the red **laser stop** emergency button on the front panel of the unit.

In **all modes** except the single pulse mode**,** the therapy will end automatically when the calculated therapy time/total energy decrease to zero.

To stop laser emission before the therapy is over, press the on/off **control.** To interrupt/pause the therapy press the **pause** button on the therapy screen or on/off **control**. To resume the interrupted – paused – therapy press the **continue** button on the screen or on/off **control**. To stop the therapy, press esc..

In **single pulse mode** by pressing the on/off control, the device will emit one laser light pulse. During pulse generation, the backlight around the **laser stop** button is yellow and the device makes a beeping sound. Hold the on/off control until the pulse generation is complete. For another emission the on/off control must be pressed again.

To immediately stop laser unit activity in case of emergency, press the red **laser stop** emergency button on the front panel of the unit.

4.3 SAVING A THERAPY

The BTL-6000 High Intensity Laser offers a function for user protocols saving. The user protocol can be saved (after setting therapy parameters) exclusively on the **MANUAL** screen by pressing the **save** button on the touch screen. During the protocol saving the following data must be inserted: name of therapeutic protocol (this will be displayed in the list of user protocols under the **list** button), the program number and an additional description of the protocol (this will be displayed in the device database). The protocol can also be assigned to a specific client.

User therapeutic protocols may be displayed on the **QUICK** screen. The list of protocols displayed on the **QUICK** screen can be modified in the device menu (*menu – specific settings – **QUICK** screen protocols*).

4.4 SETTING OF THERAPY WITH THE SCANNING SYSTEM (OPTIONAL ACCESSORY)

4.4.1 GENERAL GUIDELINES FOR THERAPY SETTING

1. Set the patient into the therapeutic position.
2. Set the therapy parameters according to the patient's conditions and skin type.
3. Place the Scanning System at the defined treatment distance.
4. Make sure that the Scanning System is oriented in such way that the distance sensor is directed at the patient's body.
5. Set the treatment distance and treatment area.
6. Check the output pattern before starting the therapy
7. Start the therapy.
8. It is necessary for the patient emergency switch to be held by the patient during the therapy.

 Do not perform scanning system therapy on the head.

 Do not perform Scanning System therapy out of therapeutic distance range

 Check the visual laser pattern dimensions before starting the therapy and if there is any abnormality compared to the expected therapy pattern, do not perform the therapy.

 Ensure that the arm joints are tightened properly before starting therapy.

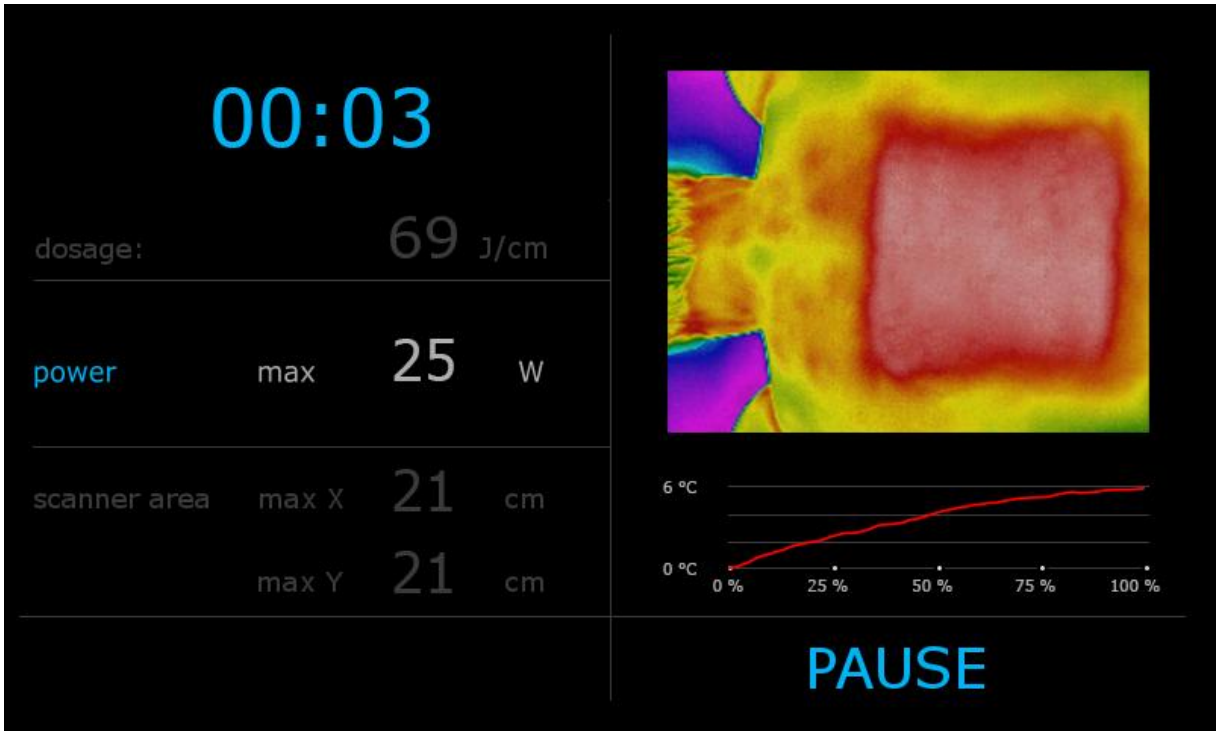
 There could be a mismatch in the ultrasonic distance sensor values when using materials with a high absorption of mechanical waves.

 The graph of delta temperature values should only be used for informative reasons. Not for diagnostic evaluation.

 If two or more Scanning Systems are used at the same time it shall be separated by a distance of at-least two meters. Violating this distance, might abort the therapy

4.4.1.1 Scanning System running therapy screen

During the running therapy the Scanning System* screen shows buttons with the power and treatment distance, similarly to the MANUAL therapy parameters screen. However, only the power button is active. During the running therapy the pictures from the IR camera and graph of automatic calculation are provided.



4.5 UNIT SETTINGS: THE ‘MENU’ BUTTON

Please refer the unit 3.3 Navigation Controls.

5 LIST OF STANDARD AND OPTIONAL ACCESSORIES

The device is not designed for use with other accessories or other medical equipment other than those stated in this manual.

Standard accessories:

- 1x optical zoom attachment
- 1x interlock
- 2x safety eyewear,
- 1x applicator holder
- 1x power cord
- 1x user's manual
- 1x touch pen
- 1x dust cover
- 1x laser warning label
- 2x fuse T2AH/250 V

Optional accessories:

- Transportation case
- BTL-6000 Trolley
- Scanning System Easy
- Scanning System Elite
- Footswitch
- Patient emergency button
- Safety eyewear
- Patient cups for facial treatment

6 MAINTENANCE AND SAFETY INSTRUCTIONS

The recommended intervals for inspection of the device are 24 months after installation, subsequently each 12 months. The intervals may differ according to the local regulations. The inspection shall be performed according to the procedure authorized by BTL.

To keep the device clean, do not store or use it in an extremely dusty environment for a long time. Do not immerse it in any liquid. Before each use, check that the device and its accessories (especially cables) are not mechanically or otherwise damaged. Do not use the device if it is damaged!

Maintenance and cleaning of the protective window on the applicator:

Check the window that protects the optical fibre outputs in the applicator. If the window is damaged, contact an authorized BTL service department.

Keep the protective window clean. Avoid touching the window with bare hands. Clean the protective window regularly to remove any accumulated dust and finger marks.

 A damaged and/or dirty protective window will result in lower laser power efficiency, excessive heating of the applicator above 41 °C, and may damage the device permanently.

 The protective window shall only be cleaned by using the supplied cleaning cloth. Under no circumstances touch the window with bare hands.

 Use the applicator with most care to prevent damage.

Maintenance and cleaning of the protective windows on the Scanning System :

Check the window that covers the optical output system of the Scanning System and the window that covers the Applicator insertion point. If the window is damaged, contact an authorized BTL service department.

Keep the protective window clean. Avoid touching the window with bare hand. Clean the protective window regularly to remove any accumulated dust and finger marks. Use a soft cloth slightly moistened with water or with a 2% soap solution to clean the window

Exterior cleaning of the device:

Use a soft cloth slightly moistened with water or with a 2% detergent solution to clean the exterior of the device and its parts. Never use cleaning agents containing alcohol, ammonia, benzine, thinners, etc. Never use abrasive cleaning materials which will scratch the device's surfaces. No parts of the device require sterilization. Care should be given to prevent water or other liquids from getting inside the device.

Cleaning and maintenance of accessories which come into contact with the patient:

The accessories that come into direct contact with the patient’s body shall be cleaned after each use with disinfectants approved for use in health service. Do not use solvents!

 Always turn off the device before disinfecting the applicator and accessories. The disinfectant must not reach the optical elements.

After disinfection, it is necessary to wipe the accessories with a soft cloth slightly moistened with clean water so as to prevent any undesirable allergic reaction!

Fuse replacement:

The fuses are placed in the box between the power switch and the power socket in the rear panel. During replacement, check the correctness of the fuses being inserted. This action should only be done by a person acquainted with this procedure!

Before replacement, make sure that the main power switch of the device is in the “0” position and the power cord is unplugged from the unit. Use a flathead screwdriver to release the fuse box. Insert new fuses and plug the fuse box back in the rear panel.

 Do not use fuses other than those listed next to the fuse box!

Plugging the device into an electrical outlet:

The device is equipped with automatic voltage detection, so it can be used for voltages within the 100–240 V range.

 Position the device with care to allow easy access to all connectors.

Transport and Storage:

Keep the shipping container and all packaging materials. Transport the unit in its original box to ensure maximum protection. Unplug the main power cable and all accessories including the applicator holder. Note that the optical fibre with the applicator are permanently attached to the device and cannot be unplugged. Make sure the optical fibre is not twisted during transportation. The optical fibre must not be coiled up to diameters smaller than 15 cm. Take care to avoid shocks or jarring movements to the device during transportation. This device should only be transported and stored under the conditions defined in the Chapter **Technical Parameters**.

Safety Precautions Related to the Trolley:

The trolley is designed for BTL-6000 devices. Do not place any others devices on the trolley!

Use of any other devices than the above mentioned or BTL approved on the trolley, may endanger the health of the patient and/or the operator.

To prevent the damage of the cables, keep all device´s mains and accessories cables attached to the trolley during the moving with the trolley.

The wheels of the trolley must be unbraked during the moving with the trolley. When relocating of the trolley is finished, fix the wheels to prevent spontaneous or accidental movement of the trolley. When fixing or releasing the wheels, use your foot – there is danger of pinching fingers, when releasing the wheel by hand.

To prevent breaking the opened doors, keep the doors of the drawers closed when not putting in or out the storing material. The doors of drawer can be removed by releasing it from the pins in the bottom part. Do not place anything on the opened doors.

Do not tilt the trolley or lean on the trolley! It may cause the release, fall and damage of the devices and accessories that are placed on the trolley or in the drawers. Heavy accessories store inside the lower drawers.

In case of any damage or deviation from the normal function (appearance) is observed, stop using the trolley immediately and contact the authorized BTL service. If the trolley is used in spite of the presence of discrepancies and/or defects, the user is solely responsible for any damage caused by the trolley.

The device is designed for indoor use only.

The trolley must be operated and stored in safe distance from heat sources (such as radiators, stoves) and out of the impact of radiation from heat sources (such as direct sunlight, infrared heaters).

The trolley must be tempered when is transported from cold location to room temperature at least 1 hour.

Do not store any flammable, toxic, highly acidic, alkaline and volatile materials inside the trolley. There is risk of spontaneous combustion, fire and inspiration of dangerous substances.

Maintenance of the Trolley:

Before any maintenance of the trolley turn off all devices on the trolley and unplug all cables from the mains!

All parts of the trolley are designed so that there is not necessary to take care of them during its lifetime (for example greasing, impregnating, etc.).

6.1 GENERAL SAFETY PRECAUTIONS

Before turning on the device for the first time, read this manual carefully.

- All operatory entrances must be marked with the appropriate laser warning sign included with shipment.
- Protect the device against unauthorized use. The device can be protected by switching the device off (a password is required to switch on the device) or by removing the supplied safety interlock from the connector on the back of the unit.
- Do not operate in the presence of explosive or flammable materials. Flammable anaesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided. Solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate the before laser is used. Attention should also be paid to the danger of ignition of endogenous gases.
-  All persons present in the operatory must wear protective laser eyewear. Use only protective eyewear designed for the BTL-6000 High Intensity Laser. Periodically inspect the protective eyewear for any damage. Do not use damaged protective eyewear!
- For replacement or additional protective laser eyewear, please use only eyewear from your authorized dealer.
-  Do not look directly into the beam or at specular reflections.
-  All reflective materials and windows in the treatment room must be covered in order to prevent reflections of the laser beam or unwanted radiation outside the room.
-  Do not aim the laser at metallic or reflective surfaces, such as surgical instruments. If aimed directly at these surfaces, the laser beam will reflect and create a potential hazard.
-  Use only accessories supplied by the manufacturer. Use of unauthorized accessories may result in increased electromagnetic emission and/or decreased electromagnetic immunity of the device.
-  Portable and mobile high-frequency communication devices (such as mobile phones) may affect the function of the device.
- Check whether the parameters of the mains power supply correspond to the requirements of the device according to the Chapter **Technical Parameters**.
- The device requires the environmental conditions that are stated in the Chapter **Technical Parameters**. It must not be used in an environment where there is a danger of explosion or of water penetrating the device. The device cannot be used in connection with flammable anaesthetics or oxidizing gases (O_2, N_2O, etc.).

- Do not place the device in direct sunlight or near strong electromagnetic fields to prevent mutual functionality influence. If this happens, move the device further away from the source of interference or contact an authorized BTL service department.
- Do not sharply twist or bend the optical fibre leading to the applicator. It might damage the optical fibre.
- Inspect the device thoroughly before each use. Look for loose cables, cracked cable and/or fibre cable insulation, cracks in the laser hand-piece's housing and functional behavioural differences in the display or the operating elements. If any anomalies or inconsistencies are found, stop using the device and contact an authorized BTL service department. If the behaviour of the device shows any divergences from the functionality procedures described in this user's manual, stop using the device and contact an authorized BTL service department.
- If the device shows any defects or if there are any doubts concerning its correct and safe functioning, terminate the therapy immediately. If the source of the concern can be determined after a thorough study of the user's manual, then contact an authorized BTL service department immediately.
- As the aiming beam passes down the same delivery system as the therapy laser light, it provides a good means of checking the integrity of the optical fibre. If the aiming beam is not present at the output of the applicator or its intensity is reduced, this is a possible indication of a damaged or malfunctioning optical fibre.
-  No user modification of this device is allowed. Do not try to open the device, remove protective covers, or dismantle the device for any reason. There is a danger of electrical shock and/or serious injury. Replacement of any part, even of the lithium battery, must be performed by an authorized BTL service department only!
- The connectors for accessories, as well as the other connectors, must not be used for connecting anything else other than what they are designed for. There is a danger of electrical shock and/or serious damage to the device.
- Before starting therapy make sure that all set parameters comply with your requirements.
-  To terminate operation, do not use the main power switch! Instead, press the "on/off" button. In case of emergency, use the "laser stop" button for immediate stop of laser emission and device shutdown.
- The time interval between turning off the main power switch and turning it back on must be at least 3 seconds.
- If it is necessary to discard the device, the lithium battery must be removed. The removed battery must be disposed according to local hazardous waste disposal requirements. Do not place the device in municipal waste containers. The device itself does not contain any toxic materials which could harm the environment when disposed of ecologically.
- The device and its accessories must be used in compliance with this manual.
- The device must be placed out of the reach of children.
-  The device does not contain any components, except for the fuse, which can be repaired or replaced by the user. Do not remove the cover from the control unit. All repairs must be performed by an authorized BTL service department.
-  Use of controls or adjustments or performance of procedures other than those specified in this manual may result in hazardous radiation exposure.
- During therapy the operator must not touch other electrical equipment.
- While performing therapy take care that the fibre jacket does not hurt the patient.
-  Do not pull/drag the device with the optical fibre cable.
-  Do not leave the patient unattended during Scanning System therapy.
- Do not use the device without connecting the remote interlock/door switch.

-  Do not open the device with the power cord connected to mains.
-  Do not connect any device other than the recommended ones.
-  It is recommended that the user should not move up towards the Scanning System while performing therapy.
-  Do not perform laser therapy on eyes.
-  Do not lift the device using the Applicator holder.

6.2 TROUBLESHOOTING

The table below shows the list of error messages which can be fixed by the user in most cases.

Fault	Possible cause	Corrective actions
System does not work	Power failure	Check the power supply.
Display and/or button backlights not lit	Defective mains fuse	Replace the fuses.
	Defective mains plug	Replace the mains cable.
	Device malfunction	Switch the device off using the mains switch and contact an authorized service of BTL devices.
Door open	Safety interlock not connected	Plug in and tighten the safety interlock into the corresponding socket in the back panel of the instrument.
	Safety interlock not plugged in properly	Unplug and re-plugthe safety interlock and tighten it.
	Safety interlock damaged	Contact an authorized service of BTL devices.
Pressing footswitch does not start therapy	Footswitch not connected	Connect the footswitch to the corresponding connector on the instruments back panel.
	Footswitch damaged	Contact an authorized service of BTL devices.
Temperature alarm	Instrument is too hot	Switch the instrument off completely and let it cool down for 20 min.
Calibration failed	Applicator not inserted properly in the calibration window	Check the placement of the applicator in the calibration window in the back of the instrument and repeat the calibration.
	Footswitch released before the calibration is finished	Repeat the calibration procedure. Release the footswitch only after the device indicates that the calibration is finished.
	Calibration procedure not completed successfully	Switch the instrument off and on again. Repeat the calibration. If the calibration fails again, contact an authorized service of BTL devices.
Error message	System exception	Follow the displayed instructions.
Firmware compatibility error	Incompatible firmware version of accessory	Contact an authorized service of BTL devices.

6.3 USED SYMBOLS

	Warning: The values of laser light energy used during therapy can be potentially hazardous.
	Warning
	Caution
	Type BF applied part
	Class II equipment
	Follow instructions for use (User's Manual)
	Separate collection for electrical and electronic equipment
	Optical fibre applicator
	Foot operated switch
	Fuse
	No pushing
	Name and address of the manufacturer
	Date of manufacture
	Serial number
	Batch code
	Catalogue number
	CE mark

6.4 TECHNICAL PARAMETERS

Model	**BTL-6000 High Intensity Laser 10 W**	**BTL-6000 High Intensity Laser 20 W**	**BTL-6000 High Intensity Laser 30 W**
Laser specifications			
Laser classification	Class 4	Class 4	Class 4
Wavelength	1064 nm ±25 nm	1064 nm ±25 nm	1064 nm ±25 nm
Maximum output power	10 W	20 W	30 W
Power accuracy	±20 %	±20 %	±20 %
Beam divergence - 10 mm spot	0.13 Radians	0.13 Radians	0.13 Radians
Nominal Optical Hazard Distance (NOHD) - 10mm spot	5 m	7.5m	10 m
Spot size			
Spot diameter - zoom accessory	10 mm (-20 %, +30 %) Beyond 10 mm up to 30 mm (±30 %)		
Spot area - zoom accessory	0.79 cm^2 to 7.1 cm^2		
Power density - zoom accessory	12.7 W/cm^2 at 10 mm spot 1.4 W/cm^2 at 30 mm spot	25.5 W/cm^2 at 10 mm spot 2.8 W/cm^2 at 30 mm spot	38.2 W/cm^2 at 10 mm spot 4.2 W/cm^2 at 30 mm spot
Spot size marking	10 mm, 15 mm, 20 mm, 25 mm, 30 mm		
Aiming beam specifications			
Aiming beam laser classification	Class 3R		
Wavelength	620–670 nm		
Maximum output power	< 5 mW		
Operation modes			
CW (continuous wave)			
Power	0.5 W – 10 W ±20 %	0.5 W – 20 W ±20 %	0.5 W – 30 W ±20 %
Dosage	1 J/cm^2 – 1000 J/cm^2 default: 100 J/cm^2		
Treatment area	1 cm^2 – 500 cm^2 default: 25 cm^2		
PW (pulse wave)			
Power	1 W – 10 W ±20 %,	1 W – 20 W ±20 %	1 W – 30 W ±20 %
Frequency	From 1 Hz to 20 kHz ± 10 %		
Duty cycle	< 3W: 50% – 75%, step 1 %, ± 10 % ≥ 3W: 25% – 75%, step 1 %, ± 10 %		
Dosage	1 J/cm^2 – 1000 J/cm^2 default: 10 J/cm^2		
Treatment area	1 cm^2 – 500 cm^2 default: 25 cm^2		
ISP			
Power	1 W up to 10 W ±20 %	1 W up to 20 W ±20 %	1 W up to 30 W ±20 %

Frequency	From 1 Hz to 1 kHz ± 10 %, step 1 Hz		
Duty-cycle	10 % ±10 %		
Dosage	1 J/cm^2 – 1000 J/cm^2 default: 10 J/cm^2		
Treatment area	1 cm^2 – 500 cm^2 default: 25 cm^2		
SP (single pulse)			
Power	0.5 W up to 10 W ±20 %	0.5 W up to 20 W ±20 %	0.5 W up to 30 W ±20 %
Pulse duration	2 ms – 2000 ms, ±10 %		
TMP (triangular mode)			
Power (peak)	1 W up to 10 W ±20 %	1 W up to 20 W ±20 %	1 W up to 30 W ±20 %
Frequency	100 Hz Fixed, ±10 %		
Shape	Symmetrical triangular wave		
Sequence			
Modes	CW, PW, ISP, TMP		
Number of sections	99		
Scanning System output characteristics			
Scanning System model	Scanning System Easy or Scanning System Elite	Scanning System Easy or Scanning System Elite	Scanning System Easy or Scanning System Elite
Maximum nominal therapy output power	9 W ±20 %	18.5 W ±20 %	28 W ±20 %
Power density	11.5 W/cm^2 at 10 mm spot size 5.1 W/cm^2 at 15 mm spot size	23.6 W/cm^2 at 10 mm spot size 10.5 W/cm^2 at 15 mm spot size	35.7 W/cm^2 at 10 mm spot size 15.9 W/cm^2 at 15 mm spot size
Divergence Angle (Milli Radians)	17.2	17.2	17.2
NOHD (S- Shape 1 cm/s speed)	28 m	41 m	50 m
Laser Spot Size			
Spot size at 10 cm Treatment Distance	10 mm ± 30 %		
Spot size at 30 cm Treatment Distance	12 mm ± 30 %		
Spot size at 50 cm Treatment Distance	14 mm ± 30 %		
BTL-6000 High Intensity Laser and Scanning System accessory interface Spec			
Treatment distance			
Recommended	10 cm (±3 cm) to 50 cm (±3 cm)		

treatment distance	
IR camera (Not available for Scanning System Easy)	
FOV coverage for IR camera	51° (+2.75°, -2°) x 38.55° (+2.25°, -1.62°)
Scanning patterns	
S-Shape	
Min. scanning speed	1 cm/s
Max. scanning speed	60 cm/s
Min. number of loops	3
Max. number of loops	19
Line	
Min. scanning speed	1 cm/s
Max. scanning speed	60 cm/s
Spiral	
Min. static time	1 s
Max. static time	3 s
Min. dynamic time	2 s
Max. dynamic time	10 s
Min. number of loops	2
Max. number of loops	5
Min. diameter	5 cm
Max. diameter	15 cm
Classification	
Applied part type	BF, Applicator, Patient emergency button
Electrical Protection class	II
Power supply	
Mains voltage	100–240 V AC +/-10 %
Mains frequency	50–60 Hz
Equipment protection class	Class II
External exchangeable fuses	2x T2AH/250 V, tube safety fuse 5×20 mm, IEC 60127-2
	On the back of device, positions 0 (off) and I (on). To disconnect from the mains, unplug main power cable from the mains socket outlet

Display elements	
Graphic colour touch screen	10 W model: diag. 5.7" / 14.5 cm, resolution 640x480 pixels 20 W and 30W models: 8.4”, 21.36 cm,
Indicators	1x orange, 4x blue, 1x yellow
Graphic colour touch screen for scanning device diag. 7" / 17.78 cm, resolution 800x480 pixels (Not available for Scanning System Easy)	
Operating conditions	
Ambient temperature	+10 °C to +35 °C
Relative humidity	30 % to 75 % RH Non condensing
Atmospheric pressure	700 hPa to 1060 hPa
Position	horizontal on legs
Type of operation	permanent
Transport and storage conditions	
Ambient temperature	-10 °C to +55 °C
Relative humidity	10 % to 85 % RH Non condensing
Atmospheric pressure	650 hPa to 1100 hPa
Position of the main unit	horizontal
Additional conditions	transport only in the original container
Design	
Weight of the main unit including the applicator	max. 8 kg
Weight of the main unit including scanning device and trolley	max. 36 kg
BTL-6000 High Intensity LaserMain unit dimensions (w × h × d)	320 × 190 × 280 mm
Scanning System dimensions (w × h × d)	200 x 250 x 400 mm
IP code according to EN 60 529	IP 20
Standard Accessories	
Power cord	3 m
Optional Accessories	
Footswitch	2 m
Patient emergency button	1.5 m

Storage or Usage of the device beyond the recommended levels will affect the safety and efficacy of the device.

6.5 SAFETY EYEWEAR

Use only eyewear with a suitable protection level (according to EN 207:2009):

- protection level at least L6 for wavelength λ = 1064 nm
- transparent for λ = 635 nm

6.6 ELECTROMAGNETIC COMPATIBILITY (EMC)

The BTL-6000 High Intensity Laser needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document. Portable and mobile RF communications equipment can affect the BTL-6000 High Intensity Laser.

Guidance and manufacturer's declaration – electromagnetic emissions		
The BTL-6000 High Intensity Laser is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-6000 High Intensity Laser should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The BTL-6000 High Intensity Laser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The BTL-6000 High Intensity Laser is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

The BTL-6000 High Intensity Laser should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BTL-6000 High Intensity Laser should be observed to verify normal operation in such configuration.

Recommended separation distances betweenportable and mobile RF communications equipment and the BTL-6000 High Intensity Laser			
The BTL-6000 High Intensity Laser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BTL-6000 High Intensity Laser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BTL-6000 High Intensity Laser as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	***Separation distance according to frequency of transmitter (m)***		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	***150 kHz to 80 MHz*** $d = 2.34\sqrt{P}$
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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BTL-6000 High Intensity Laser, including cables. Otherwise, degradation of the performance of this equipment could result."

Guidance and manufacturer's declaration – electromagnetic immunity			
The BTL-6000 High Intensity Laser is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-6000 High Intensity Laser should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	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 IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25 cycles @ 0° 0 % UT; 250 cycle	0 % UT; 0,5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25 cycles @ 0° 0 % UT; 250 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer’s declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The BTL-6000 High Intensity Laser is intended for use in the electromagnetic environment specified below. The customer or the user of the BTL-6000 High Intensity Laser should ensure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6
Radiated RF
IEC 61000-4-3</td><td>3 V_{rms}
150 kHz to 80 MHz
3 V/m
80 MHz to 2.7 GHz</td><td>3 V_{rms}
3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the BTL-6000 High Intensity Laser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1.17\sqrt{P}$
$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.34\sqrt{P}$ 800 MHz to 2.7 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
Interference may occur in the vicinity of equipment marked with the following symbol  </td></tr>
<tr><td colspan="4">NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BTL-6000 High Intensity Laser is used exceeds the applicable RF compliance level above, the BTL-6000 High Intensity Laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BTL-6000 High Intensity Laser.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

If the BTL-6000 High Intensity Laser device malfunctions/degrades due to Electromagnetic interference the device can be switched off using the power ON/OFF switch on the back panel.

6.7 MANUFACTURER

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For service, please contact our service department at service@btlnet.com.

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