

Tamburo Thulium Fiber Laser System

INSTRUCTIONS

FOR USE

Tamburo Premium

Tamburo Pro

Tamburo Lite



menovex
ADVANCED LASER IN

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1. General Information

1.1. Important information – Read before use!

This manual contains information needed to safely operate your Tamburo Thulium Fiber Laser System. The medical staff should carefully read this manual prior to starting any operation with the Tamburo Thulium Fiber Laser System, in order to obtain the best results and operate the system safely. However, this information is not intended to replace training on the system.

In order to attain best results with Tamburo Thulium Fiber Laser Systems and to avoid risks of dangerous faults, please be sure that you carefully and completely read this user manual before starting any operation.

1.2. Introduction

The Tamburo is a Thulium fiber laser device emitting at a wavelength of 1940 nm, which is used by physicians as a tool in surgical procedures.



Type	Model
Tamburo Premium	MIL-TFL-600A
Tamburo Pro	MIL-TFL-600B
Tamburo Lite	MIL-TFL-600C

This manual provides information on the **Tamburo Premium**, the **Tamburo Pro** and the **Tamburo Lite** Thulium Laser System.

All systems provide foldable screen. The Specifications of Tamburo Premium, Tamburo Pro and the Tamburo Lite Thulium Laser System is in Chapter 10.

1.3. Safety instructions

The safety instructions in this manual are intended to prevent possible injuries, material damage and operational faults. Reading carefully through this manual before operating the laser for the first time is also considered a safe operation concerning this product. In this manual a distinction is made between the safety instructions used to warn of possible injuries (WARNING) and instructions warning against operational faults (CAUTION).

WARNING



Risk of injury! This instruction concerns the safety of patients, operators and other persons, who are in the room where the laser is being operated or maintained.
In this manual the following symbol is used to warn the risk of injury from laser radiation.

CAUTION



Danger of operational fault! Failure to follow this instruction can lead to damage of the laser system, the applicator or the laser fiber. In this manual the following symbol is used to indicate a possible operational fault and the damage of the laser system, which might result from it.

1.4. Combined use

We recommend to use fibers distributed by **menovex** in conjunction with the Tamburo Thulium Fiber Laser System.



Caution: Products may be incorrectly combined! Injury of the patient, user or damage to the product is possible. The different products may be only applied jointly if the intended use and the relevant technical data, such as working length, diameter, peak voltage, etc. are suitable. Follow the instruction manuals of the products used in combination with this product.

1.5. Symbols and Abbreviations

Symbol	Description	Symbol	Description
	Serial number		Unique Device Identification
	Quantity		Refer to instruction manual
	Date of manufacture		Use by date
	Do not use if package is damaged		Type BF applied part (Laser Fiber)
	Do not stack		Fragile

Symbol	Description	Symbol	Description
	This way up		Temperature limit
	Keep away from rain		Humidity limitation
	Keep away from sunlight		Atmospheric pressure limitation
	Equipotentiality		Caution
IPX8	Ingress Protection Code — footswitch		WEEE (Waste Electrical and Electronic)
	EU Authorized Representative		Medical Device
CE 0197	Notified body identification number		Caution: Federal (USA) restricts this device to sale or on the order of physician

RFID — Radio Frequency Identification
 NODH — Nominal Ocular Hazard Distance
 MPE — Maximum Permissible Exposure
 OD — Optical Density
 EMC — Electromagnetic Compatibility

2. Clinical Application

2.1. Intended Use

The Tamburo Thulium Fiber Laser System are intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue, with or without an endoscope, in the following indications: urology, lithotripsy gastroenterological surgery and gynecological surgery.

2.2. Treatment Parameters and Instructions

The Tamburo and its accessories are surgical devices that should be used only by physicians or surgeons who have been trained in laser surgery through courses, mentorships, and under the guidance of other physicians or surgeons knowledgeable about laser use. No claim is made about the certainty of treating successfully any medical condition by laser.

All users and support staff must have thorough knowledge of its operation and its effects. Users should get acquainted with this manual and with the device in a non-clinical setting before using it for patient treatment in a clinical situation.

BEFORE operating the laser system, surgeons and all staff operating the laser should carefully read this User Manual. Please use major attention to the General Warning of Section 2 (Laser Safety) and Section 6 (Clinical Applications).

The Tamburo is a Laser System emitting an invisible infrared beam at 1.9 μm wavelength. This laser beam is strongly absorbed by water (chromophore) which is ubiquitous in all tissues. Thus, the speed of cutting and vaporization action will remain relatively constant regardless of tissue vascularization.

2.2.1. Treatment parameters and instructions for endoscopic procedures

Before firing the laser, both aiming beam and fiber tip must be clearly visible through the endoscope. The aiming beam must be directed towards the targeted tissue. Illuminate the tissue you wish to treat with the aiming beam. Never fire the laser unless you can see the aiming beam on the targeted tissue.



Caution: Fiber tip must protrude from endoscope when firing. Fiber or endoscope damage could result when operators do not comply with this provision.

DO NOT START LASING AT MAXIMUM POWER. Begin the procedure with a low power and regulate the output power until the desired tissue vaporization/ablation/coagulation effect is achieved. Do not adjust laser power until the effect of the radiation on the tissue has been evaluated.

In endoscopic surgery within water-filled large environments (as in BPH procedure), it is possible to use the maximum output power (60W). It is possible to use the fiber in contact with the tissue.

If the fiber tip is submerged in water (e.g. endoscopic incision/ablation of soft tissues in urology treatments), it is possible to use the fiber in contact with the tissue. Conversely, if this condition does not apply, some tissue may remain attached to fiber tip upon ablation/cutting when in contact with the tissue. Thus, where/when possible, a near-contact (small distance) approach should be preferable in this case.



Warning: When the fiber is firing in contact with no liquid in between of fiber tip and target tissues or is deepened into that, the user should fire with extreme caution as the interaction between laser and tissue is not (or only partially) visible. Wrong evaluation of ongoing process may result in unwanted tissue damage or perforation.

Depending on the environment where the surgical procedures is being carried out, different treatment recommendations apply:

- o Water-surgery in large cavities: When using the laser in water (as the surgical irrigation solution) within large cavities (as in bladder during BPH treatment) it is recommended to start ablation or cutting at 30W and adjust the power according to the observed effect. If bleedings are found, coagulate the tissue surrounding the bleeders; the surgeon may choose to defocus the laser energy by increasing the distance between tissue and fiber tip or by decreasing the laser power.
- o Water-surgery in small cavities/channels: Conversely, when using the laser in water (as the surgical irrigation solution) within small cavities or narrow channels (as in ureter), it is recommended to start ablation or vaporization at 5-10W and adjust the power according to the observed effect. If bleedings are found, coagulate the tissue surrounding the bleeders; the surgeon may choose to defocus the laser energy by increasing the distance between tissue and fiber tip or by decreasing the laser power.
- o Other endoscopic procedures: When using the laser endoscopically, without any fluid in between of fiber tip and targeted tissue, begin the procedure at a lower power (5-10W) and increase the power until desired tissue effect is achieved. Do not adjust the power of the laser until the effect of the laser on the tissue has been evaluated. It is recommendable to use the fiber in non-contact with the tissue (distance from 1mm). If tissue adheres to the fiber tip, the fiber has to be extracted from the endoscope so that the tissue can be removed. For information and warnings regarding smoke formation, hemostasis and interaction with tissue, the same indications reported for laparoscopic procedures apply.

Damage to Endoscope:

The Tamburo can cause significant damage to the endoscope. Damage will occur if the laser is activated while the laser fiber is aimed towards the endoscope or while the aiming beam is directed towards the inside of the endoscope.

Damage to endoscope's outer sheath may cause rough or sharp sports on the sheath which may be traumatic to tissues. Damage to scope's inner sheath could create sharp points or ridges that may damage the fiber and result in premature fiber degradation or failure.

To avoid damage to the endoscope, please be sure that the shell of the fiber is visible at all times.

2.2.1.1. Clinical Parameters for Soft Tissue in Urology

he thulium wavelength provides effective haemostasis without damaging surrounding or non-targeted tissues. Coagulation can be achieved by reducing the energy or power density over the vascularized tissue or by increasing the distance between fiber tip and point of bleeding.

The following table shows the suggested maximum power and recommended fibers for endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in urological applications:

Application	Average Power (Watts)	Recommended Fiber Size
Bladder Tumours	max 30	365 – 550 µm
Ureteral Tumours	max 15	272 – 365 µm
Incision of Strictures	max 30	272 – 550 µm
Benign Prostatic Hyperplasia	max 60	≥ 550 µm

Note: Laser settings are guidelines only; always start with low settings and increase them progressively to achieve the desired tissue effect.

2.2.1.2. Clinical Parameters for Urinary Lithotripsy

Pre-clinical and clinical testing have demonstrated that urinary calculi can be safely and effectively fragmented from pulsed emission starting with power settings of 0.5 or 0.6 Joules and at a frequency of 5 or 6 Hertz.

The use of high-power output settings requires special attention, especially when the fiber tip is in close proximity to the ureteral walls in order to avoid ureter perforation. Similarly, for lithotripsy in other body areas, the use of high-power output settings requires special attention, especially when the fiber tip is in close proximity to tissues and structures that are particularly thin and fragile and/or must not be perforated/ablated as nerves, vessels and arteries functional membranes.

For effective fragmentation, the tip of the optical fiber should be directly in contact with the stone. Whenever possible, laser energy should be directed at the side of, or at weak points, in the stone.

The stone should be progressively reduced in size by slowly removing small fragments.

Continuous irrigation should be used to wash away stone fragments and to provide cooling of the treatment site.

DO NOT START LASERING AT MAXIMUM POWER. Begin the procedure with a low power (e.g. 5-10W in pulsed mode) and increase the output power until the desired effect is achieved.

Application	Average Power (Watts)	Recommended Fiber Size
Bladder Calculi	max 60	≥ 550 µm
Ureteral Calculi	max 15	272 – 365 µm
Renal Calculi	max 20	150 – 272 µm

*pulsed mode only

Note: Laser settings are guidelines only; always start with low settings and increase them progressively to achieve the desired tissue effect.



Warning: The user must understand that the greater the increase of settings, the greater the additional energy released (along with fluid heating risk of injury risk).

Use small pulse energy in order to minimize the size of fragments.

Consider using a shorter pulse duration in case of harder stones.

Use short pulse duration and high pulse energy in order to maximize the speed of fragmentation.

Warning: In general, when performing endoscopic stone lithotripsy, it is recommended to start with a minimum power setup. High power setting (<20-30W) should be used with caution.

2.2.2. Treatment parameters and instructions for open surgery & laparoscopic procedures

Before firing the laser, the aiming beam and fiber tip must be clearly visible and directed towards the targeted tissue. Direct the aiming beam towards the tissue you intend to treat. Never fire the laser unless you can see the aiming beam on the targeted tissue. Use of a surgical handpiece is recommendable when manipulating the fiber.



Caution: when firing, fiber tip must protrude from equipment operative channel (e.g. handpiece cannula). Damage to fiber or device operative channel could result when operators do not comply with this provision.

DO NOT START LASERING AT MAXIMUM POWER. In open surgery or in laparoscopic procedures (with the fiber tip non-submerged in water solution) begin the procedure at a lower power (5-10W) and increase the power until desired tissue effect is achieved. Do not adjust the power of the laser until the effect of the laser on the tissue has been evaluated.

When using the laser in open surgery or in laparoscopic procedures with the fiber tip submerged in water solution, it may be reasonable to increase the output power (with respect to a similar endoscopic situation without irrigant presence) and adjust the power according to the observed effect. Indeed, part of the emitted energy will be absorbed by the liquid in between of fiber tip and targeted tissue.

2.3. General Laser Warnings

The physician or surgeon should become fully acquainted with the unique surgical and therapeutic effects produced by the 1.9 μ m wavelength before using the System Laser in a clinical environment. These effects include coagulation, depth of penetration and cutting intensity.

Caution should be used with power (Watts) and lasing duration until the surgeon is completely familiar with the biological interactions of laser energy with various types of tissue. Unless otherwise stated in the specific application section, the surgeon should begin with the lowest power and use short duration exposures. The surgeon should observe carefully the induced surgical effect and adjust laser settings until the desired surgical effect is obtained.

The following warnings and precautions are applicable for each surgical specialty contained in this manual. For specific application warnings and precautions, see the section specific to a given surgical specialty.



Warnings

- The Tamburo Laser System is a surgical device that should be used only by physicians or surgeons who have been trained in laser surgery through courses, mentorships, and under the guidance of other physicians or surgeons knowledgeable in laser use. No claim is made about the certainty of treating successfully any medical condition by laser.
- BEFORE operating the laser system, surgeons and all staff operating this device should read carefully

Chapter 3 of this manual.

- Surgeons using Tamburo Laser System must understand the laser's unique properties prior using the device.
- Before turning the laser system on, operating room personnel should wear protective eyewear suitable for 1.9 um laser energy.
- Careful assessment of the target and surrounding tissue should be made, and appropriate power and pulse duration should always be used.
- Use extreme caution until the biological interaction between laser energy and tissue is thoroughly understood.
- As with conventional endoscopic surgery, the possibility of complications and adverse events (such as chills, fever, edema, hemorrhage, inflammation, tissue necrosis or infection) may occur following treatment. In extreme cases, death may occur due to procedural complications or concurrent illness. The risk of infection and scarring associated with any surgical procedure has to be taken into account as well. Therefore, appropriate pre- and postsurgical care should always be practiced.
- Tissue perforation may result if excessive laser energy is applied. This could occur through the use of excessive laser power or the application of a correct power for excessive periods, particularly in disease tissue.
- Incorrect treatment settings can cause serious tissue damage; therefore, it is recommended that you use the lowest acceptable treatment settings until you get familiar with the instrument's capabilities.
- Aim and use the laser only on tissues that are fully visible.
- The laser should be used only on tissues that are fully observable. Do not use the laser if the desired target is not visible.
- Extra caution should be used when lasing tissue close to arteries, nerves and veins.
- Use of the laser on anatomical structures in proximity to known critical structures, such as large arteries, veins, nerves, bowel, ureter, bladder, etc., should be performed carefully to avoid inadvertent or unintended treatment of such structures.
- Begin laser treatment at the lowest power, with short duration exposures until fully familiar with effects of the applied wavelength on the tissues.
- Flash fire may occur. Refer to Chapter 3 for more information. A bowl of water should be available in case a fire occurs. Inhalation general anaesthetics must not be used if flammable. Oxygen levels in the direct surgical area must not exceed 50%. The risks of combustion, perforation, and laser-induced haemorrhage, any of which could cause death, must be fully explained to the patient.
- The flammability of methane gas must be considered when treating in or near the perianal area.
- Patients who experience discomfort during laser treatment may require analgesics.
- As with conventional non-laser surgical procedures, there is no guarantee that treatment with the Tamburo Laser System will entirely eliminate the disease. Repeated treatment or alternative therapies may subsequently be required.
- The laser may not be effective for coagulation in massive hemorrhage situations. The surgeon must be prepared to control hemorrhages with alternative non-laser techniques, such as ligature or cautery.
- Alterations in surgical approach or technique may be required to accommodate laser use.
- The surgeon should schedule follow-up visits in the same manner as for any patient undergoing such surgery with other modalities.
- Surgeons should be thoroughly trained and proficient in all aspects of endoscopic surgery prior to using the laser through an endoscope. Depth perception through an endoscope is distorted. The surgeon must

rely on both the visual and tactile feedback of the delivery system.

- If any abnormality in the function of the endoscope and/or endoscopic image is suspected during use, stop the procedures immediately and carefully withdraw the endoscope from the patient.
- Care must be taken to protect endotracheal tubes from laser radiation. Ignition or perforation of endotracheal tubes by the laser beam could result in serious or fatal patient complications.
- A smoke evacuator and in-line filter should be used to capture the smoke plume resulting from laser procedures. The plume should be regarded as a source of active biological material and a possible carcinogen.
- The recommended power settings are less important than the visual tissue effect. Changes in tissue texture and color are the best indicators of laser impact upon the targeted area. Specific pulse duration depends on the tissue and is left to surgeon's preference and best medical judgment.
- The lowest possible power settings required to achieve the desired tissue effect should be used for treatment.
- Higher wattages of power may be necessary to achieve the desired tissue effects if fluid cooling is employed. Excessive power settings may cause damage to the Disposable Laser Fiber Delivery Devices.
- The use of mechanical pressure on the Disposable Laser Fiber Delivery Devices does not increase its cutting or vaporization effects but may induce bleeding, thermal damage and fiber destruction.
- For equal powers emitted from laser source, fibers with smaller diameter generate greater power densities (on the contrary fibers with bigger diameter generate lower power densities). Thus, the operator must regulate the output power (on laser device display) taking into account the fiber diameter.
- There is an increased risk of back-scatter (reflection) and forward scatter (penetration) when using the laser in non-contact mode.
- Different energy densities induce different effects upon tissues, therefore using fibers with different diameters with the same output power could have different outcomes on irradiated tissues. Employed laser power has to be tuned also according to fiber diameter.

2.4. General Laser Precautions

- Use caution with patients who have had difficulty with previous endoscopic procedures.
- Electrocautery and/or suture (ligature) should be easily accessible in the event that a bleeding artery or vein is too large to be coagulated by laser.
- Use caution when treating patients who have recently undergone radiotherapy. Such patients may be at greater risk of tissue perforation or erosion.
- Discontinue laser treatment immediately if the patient develops any cardiopulmonary problem.

2.4.1. Urology precautions and warnings

- Care should be exercised so as not to over distend the bladder when using the laser endoscopically. Excessive bladder distension could result in coagulative necrosis of the superficial and inner muscular region of the bladder wall.
- Extra precautions should be taken when radiation therapy and laser therapy have to be carried out concurrently, including more stringent post-operative monitoring. Clinical studies have shown that patients who have undergone radiation therapy present a greater risk of perforation or tissue erosion.
- To avoid the potential risk of endoscope ignition or damage from the treatment beam or treatment beam backscatter, it is recommended that the fiber protrudes 4 to 6 mm beyond the distal port of the endoscope

so it is fully in the visual field.

- Use of lower power levels and shorter exposure times are required in order to prevent thermal damage to underlying structures (e.g. to thin-walled structures such as the bladder).

2.4.2. Precautions and warnings in other medical specialties

Lithotripsy

- The laser should be used with a laser fiber delivery system in direct view and in direct contact with the targeted ureteral stone. To minimize the potential migration up to the ureter, laser energy should be directed to the side of the stone, if possible, rather than the leading edge. Maintaining low energy levels and repetition rates will reduce the potential for possible stone migration.
- Be aware of edematous folds of epithelium that may lie between the laser fiber and the stone.
- Basketing may be used with larger stone fragments that are relatively hard or tend to escape to the ureter in a retrograde fashion.
- Baskets, guide wires, and other endoscopic accessories may be damaged by direct contact with the laser beam.
- The use of irrigation is recommended throughout the lithotripsy procedure to absorb any produced heat, to carry stone fragments out of the urinary system, and to enhance direct visualization. The rate of irrigation should be carefully adjusted to avoid flux of calculi into the kidney.

2.5. General Laser Complications

The potential complications encountered in endoscopic laser surgery are the same as those normally encountered in conventional endoscopic surgery.

- Acute pain may occur immediately following laser therapy and may persist for as long as 48 hours.
- Immediately following laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These issues generally resolve without treatment.
- Laser ablated tissue may become necrotic or infected after treatment. In case of any concern about possible infection, appropriate treatment should be carried out.

2.5.1. Complications for Urology

As with other endoscopic urologic procedures, there may be urine leakage following the laser procedure.

- The use of flexible endoscopes carries a risk of stricture formation; these rates may improve with further advances in ureteroscope design. □ Although rare, loss of a kidney may occur as a result of the procedure or because of the stone itself.
- Complications following endoscopic BPH management (and other endoscopic treatments for urinary soft tissues) may include UTI, AUR, urethra stricture, BNS, TUI and haematuria.

2.5.2. Complications in other medical specialties

Complications for Lithotripsy

- The use of flexible endoscopes carries a risk of stricture formation; these rates may improve with further advances in ureteroscope design.
- For other complications related specifically to a certain medical specialty, further refer to the relevant section.

Complications for Gastroenterology Surgery

- Patients may experience gastrointestinal distension or pneumothorax during or after therapy.
- Swallowing may be worsened, rather than immediately improved, following esophageal procedures due to secondary tissue edema. This potential problem should be explained to the patient prior to the therapy.

2.6. Contraindications

The use of a laser instrument for an application is at the physician's discretion except in cases where the indication has been contraindicated.

- Inability to receive endoscopic or laparoscopic treatment
- Intolerance to anesthesia
- Resection or excision of large, highly vascularized organs
- Carcinoma of the prostate
- Septic peritonitis
- Intestinal obstruction
- Septic shock
- Resection or excision of large, highly vascularized organs

3. Safety Information

3.1. General safety

- Operation of this system should be performed by specialized medical staff only, who are compliant with applicable national regulations.
- Adequate training on laser safety standards should be obtained by all operators and support personnel prior to operation of the laser.
- Precautions must be taken by users to prevent exposure of laser energy to the eyes and skin from direct and reflected laser beams, except as a therapeutic application as described in this chapter.
- Additional precautions must be taken to prevent fire, electrical injury, and explosion.
- The laser device is provided with an operating room door interlock connection, which must be set up by the hospital personnel.

3.2. Working Area

This device is a laser of Class 4 and must be used in a specific working area defined and delimited following the international standards IEC 60825-1.

IMPORTANT!

This device is certified to be used in the operating room.

The device shall be used in a position such that the mains switch and the other controls are easily accessible.

Rules of Access to the Restricted Working Area by external staff and visitors include:

- Be guided by staff

- Goggles should always be worn in the working area when the laser is switched on.
- Awareness of electrical hazards and other risks associated with the operation of the laser within the working area (laser radiation, electric shock, etc.).

IMPORTANT!

This device is certified to be used in the operating room.

The device shall be used in a position such that the mains switch and the other controls are easily accessible.



Warning: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

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

3.3. Eye and skin exposure

The laser beam emitted by the Tamburo can cause vision loss. The laser operates at different wavelengths, visible and invisible. Any energy transmitted by the laser system entering the eye will be focused directly on the retina. Direct absorption of laser energy by retina can result in temporary clouded vision, retinal lesion, long term scotoma and long term photophobia.

A danger exists in any case of:

- Direct laser radiation
- Reflected laser radiation
- Diffused laser radiation



Warning: All the personnel present in the laser working area must wear all the protective devices.

Use protective goggles with the following minimal specifications: 1940 D LB4 for laser source Thulium at 1920 - 1960 nm.

In addition, do not look directly at the laser beam, even when wearing protective goggles.

IMPORTANT

Within the range of the laser, every person must wear laser goggles. Check the laser goggles for perfect condition before each use. The goggles must not be mechanically damaged in any way. Before wearing goggles, make sure that the goggles are in a good condition

The skin is generally able to withstand higher levels of laser radiation but can also be burned to a greater or lesser degree depending on the duration and intensity of exposure. If necessary, wear suitable protective clothing.

3.3.1. Nominal Ocular Hazard Distance

The laser system must be used in a closed area that does not allow the escape of direct, reflected or

transmitted laser radiation.

Following the Standard IEC / EN 60825-1, the MPE (Maximum Permissible Exposure), NOHD (Nominal Ocular Hazard Distance) and OD (Optical Density) have been calculated.

- The MPE level represents the maximum level to which an eye, or skin, can be exposed without consequential injury, immediately or long-term. The MPE is related to radiation wavelength, pulse duration or exposure time, the tissue at risk and, for visible and near infrared radiation in the 400- 1400 nm range, to the size of the retinal image.
- The NOHD is the distance at which the beam irradiance or radiant exposure equals the appropriate corneal maximum permissible exposure.
- The OD of the protective goggles to be worn is defined as: $OD = \log_{10} (H_0/MPE)$ Where H_0 is the expected unprotected eye exposure level.

Results of MPE, NOHD and OD calculations are reported in Chapter 10.

3.4. Environmental conditions



Caution: The working area must be marked with the laser warning labels, so as to prevent accidental entry into the area. All windows, mirrors, metal and other reflective objects (clocks) should be covered, so as to avoid distortions of the laser beam. All staff in the working area should

know how to turn off the laser system in case of emergency.

The use of mobile phones is prohibited in the working area while using the device, because it could interfere with its proper operation.

Be careful that the laser system key is in a safe place when not in use.

3.4.1. Electrical connection requirements

The device must be connected to the electrical system in compliance with electrical safety regulations. The device can be supplied with a cable with different plugs suitable with the electrical standard requirements of the country where the laser system is going to be installed.



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

3.4.2. Temperature and humidity

Appropriate values of temperature and humidity are required for the proper device functioning. This Laser Device has to operate in ambient condition according to the parameters in the Technical Specification Chapter.

3.4.3. Minimum space requirements

To ensure proper device ventilation there must be at least 50 cm of free space on both sides. The Laser device can be easily moved from room to room. Make sure that adequate space and appropriate electrical socket are available in the room. Place the device in such a way to have easy access when disconnecting it.

3.5. Fire hazard

The laser radiation of this LASER device is able to melt, burn or vaporize almost all materials. The use of this LASER device is limited to the applications specified in this manual.

Fire hazard can occur due to the nature of the laser treatment. The absorption of emitted laser energy, no matter the duration, may raise the temperature of any material.

When this LASER device is used, the following precautions should be taken:

- Do not use any flammable substance, such as alcohol or acetone, in the preparation of the skin for treatment. Use soap and water if necessary.
- Anaesthetics administered either by inhalation or topically must be approved as non-flammable.
- Use particular care in the use of oxygen, do not use the laser device in oxygen rich environment, as it may lead to explosion.
- Avoid using combustible materials, such as gauze and drapes, in the treatment area. When required, these materials must be made fire-retardant by keeping them moist with water. Clothing should be kept away from the treatment area.
- Cotton wool and similar materials, when saturated with oxygen, can catch fire due to the high temperature emitted by laser.
- Before using the laser, let solvents, glues or flammable solutions evaporate if they are used to clean or disinfect.
- Attention: endogenous gases can catch fire or explode.

3.6. Emission of toxic gas or vapor

The radiation of this LASER device is able to melt, burn or vaporize almost all materials. Vapors or emitted gases resulting from laser operation may be dangerous to both patient and medical personnel in the surgical area. The use of this LASER device is limited to the applications specified in this manual.

3.7. Safety features for the electromagnetic compatibility (EMC)

The LASER device does not include any type of direct connection with other external devices.

The LASER device can be disturbed by the interference with external electromagnetic fields generated by other electrical devices installed near it.



Warning: Turn off mobile phones and similar devices while operating the device.

This LASER device must be installed and used according to EMC information described in the tables reported in Chapter 11.

3.8. Warning and instructions for the device disposal

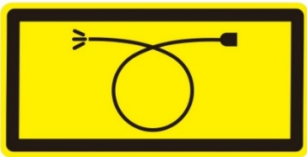
At the end of its lifetime, the device has to be handled according to the National or Local regulations for the disposal of waste electrical and electronic equipment.

The device is subject to national standards which regulates the disposal of waste such as electrical equipment.

It is forbidden to dispose of the device as municipal waste, instead it has to be collected separately according to the WEEE Directive (Waste Electrical and Electronic Equipment).

The penalties for violating law requirements are severe.

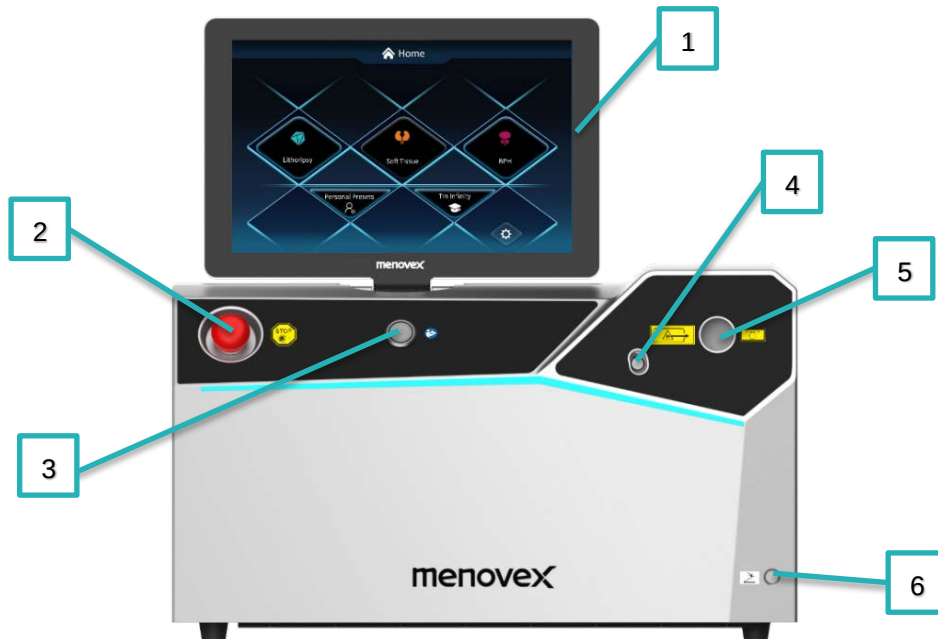
3.9. Labeling of safety indicators

	Laser Explanatory and Certification Model: Tamburo Premium/Pro
	Laser Explanatory and Certification Model: Tamburo Lite
	Laser aperture
	Fiber applicator
	Remote interlock connector
	Footswitch connector
	Emergency laser off

4. Device Description

4.1. General description of the device

Front View



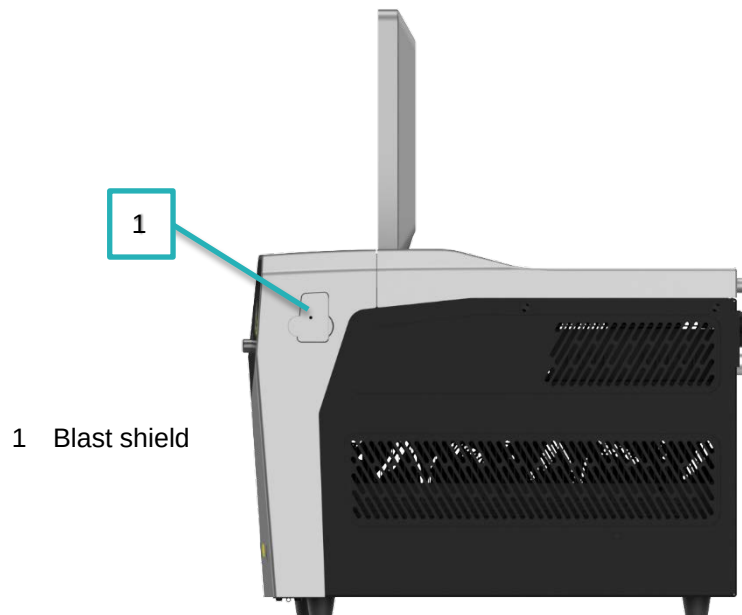
- | | |
|-----------------------------|-------------------------------|
| 1 Touch screen Display | 4 External protection shutter |
| 2 Emergency red push button | 5 Laser Fiber connector |
| 3 Power Button | 6 Footswitch connector |

Rear View



- | | |
|---------------------------|----------------------|
| 1 Interlock connector | 3 Power cable socket |
| 2 Equipotential connector | |

Side view



1 Blast shield

4.2. System Components

Main Components	Description
Thulium Laser System	Qyt:1
Thulium Laser Fiber	Optional
Fuse	Qyt:2
Footswitch	Qyt:1
Protective Goggles	Qyt:3
Blast shield	Qyt:2
Power Cord	5 m, Qyt:1
Interlock connector	Qyt:1
Ground wire	Qyt:1
"Laser in Use" Signage	Qyt:1

5. System Installation

5.1. Device installation

Device installation requires that safety precautions are followed, including power requirements and environmental conditions in the working area.

The installation of the laser device must be performed by qualified technical personnel authorized by the manufacturer. This person should also carry out tests on the operation of the device after installation in the designated working area.



Caution: Do not start using the laser device before reading this manual. The warranty does not cover any damage occurred prior to installation.

5.2. Transportation

While transporting the laser, the fittings, fiber, power cord, the pedal and remote locking must be disconnected from it. Finally, the laser and the accessories should be stored in slots inside the packaging.



Caution: In order to transport the laser device, it must be gripped on both sides using the bottom grooves, by at least two people, and positioned on a trolley.

5.3. Packaging

The laser system is normally shipped in a specific cardboard on wood pallet. Upon the container arrival, it will be a client responsibility to review the packaging.

If you find any of the following situations, please contact sales personnel.

- Damaged packaging
- Packaging deformation
- Packaging is damp

5.4. Inspection

It is important that the received material is inspected immediately upon arrival on the following terms:

- Administrative check:
 - Number of packages
 - Sizes and weights
- Technical check:
 - Packaging condition

These checks must be made visually, with the greatest possible care and in the presence of the carrier.

5.5. Labelling check

Verifying the integrity and readability of the security labels placed on the device is responsibility of the user. If

labels are damaged, they must be replaced immediately with the labelling.

5.6. Installation procedure

The installation procedure must be performed each time the device is installed for the first time or after being transported by means of cars, elevators, trucks, air cargo, etc.

During installation the device must be checked for proper operation and possible malfunctions after transportation of the laser device must be corrected. The installation procedure includes also a training course from the distributor to the user concerning the use of the medical device.

The first procedure step typically takes several hours, during this time the access to the installation site is forbidden. The case is normally shipped to the distributor.

It is extremely important that the packed materials are checked immediately upon their arrival, if possible, in the presence of the shipping agent's employee, as follows:

- Open the packaging and put the laser device in a proper site for a general check
- Execute the following operations for the general check:
 - Check the labels of the device
 - Connect the remote door interlock
 - Connect the footswitch
 - Connect the laser device to the power supply
 - Turn on the system
 - Enter the password to enter the treatment interface.
 - Check the screen display for any damage.
 - Turn off the system
- After the general check:
 - Remove the laser fiber
 - Remove the footswitch
 - Remove the interlock
 - Remove the key

5.7. Mains connection

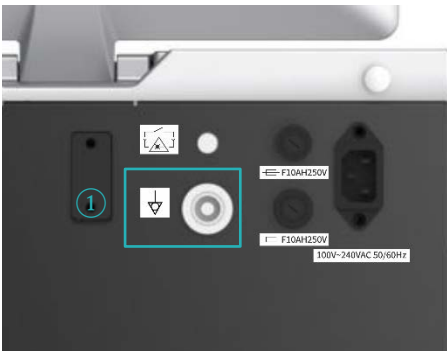
Once all the checks have been made and after placing the laser device in its final position in the working area, you can connect the device to the mains. Use the cable provided. Such cable can suffer wear over time. The operator or anyone involved in the ordinary maintenance of the device after the installation must take care of monitoring the maintenance status of the power cable.

The device must be connected to the mains in compliance with electrical safety regulations.



Caution: Before starting to use the device, be sure that the cable lock is fixed and the cable cannot be removed.

5.8. Equipotential connector connection



- ① equipotential connector connection location

The device, in compliance with IEC 60601-1, is provided with an equipotential connector that can be connected to the equipotential line of the room where the device is used.

5.9. Remote interlock connection

According to IEC 60825-1 all laser devices must be equipped with a remote block connector, connected to the room access door, which prevents laser emission when the door is opened.

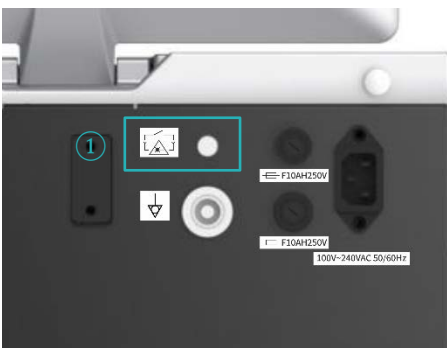


A suitable switch shall be prepared by the client on the room access door where the device will be installed. In case of multiple access doors, each door should have its own switch, whose contacts have to be connected in series.

The remote interlock cable must be connected to a lamp mounted at the entrance of the working area (as shown in the picture). When the door is closed, the switch will enable laser emission with a dedicated electrical signal.

The connection, or the sequence of connections, has to be wired with a suitable cable to the interlock connector during the device installation.

The interlock connector is wired on the laser side in the following way:



- ① remote interlock connection location
- The remote interlock has to be connected to pins A and B. The circuit is conductive, indicating that the working area interlocking door has been closed.

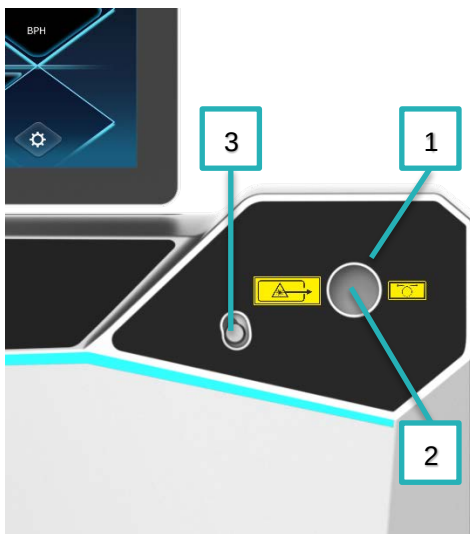
5.10. Footswitch connections

The footswitch is used to start the laser emission and press middle button to switch from Ready to Standby status and vice versa. To connect the footswitch, plug its connector into the dedicated device socket (on the frontal panel).



Warning: Do not wrap the footswitch with any plastic (or other material) film or cover bag, unless authorized by the manufacturer. The unauthorized use of wrapping bags/films may block the pedal in pressed position and cause unwanted laser emission.

5.11. Laser fiber connection



The fiber is connected to the device through the cable connector on the front.

The device accepts fiber with a handle and with RFID Recognition System (only with Tamburo System internal code).

Furthermore, this handle enables the automatic detection of fiber status (present / absent), its diameter and its type (single use / reusable). If the fiber is not connected to the device, an error message is displayed when the device is switched on.

Component description:

- 1 RFID Antenna
- 2 Laser fiber connection location
- 3 External protection shutter



Caution: It is very important to tighten the fiber nut to the device by hand until it is firmly fixed. Improper connection may cause a low output power.

5.12. Laser fiber check

Please see Section 7.4.

5.13. Installation or removal of fuses

The fuse is located next to the power socket on the rear panel. When replacing a fuse, the user needs to use a flat screwdriver to rotate and remove the protective cover. The fuse will automatically pop out and can be replaced with the same model fuse.

6. Instructions for use



Warning: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

6.1. Start-up procedure

Before proceeding with the start-up procedure of the device, verify the proper connection of the following accessories:

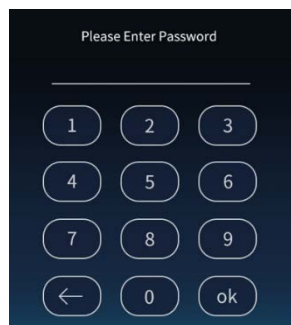
- Power supply cable
- Interlock connector
- Footswitch

Also, make sure that the emergency red button is not pushed.

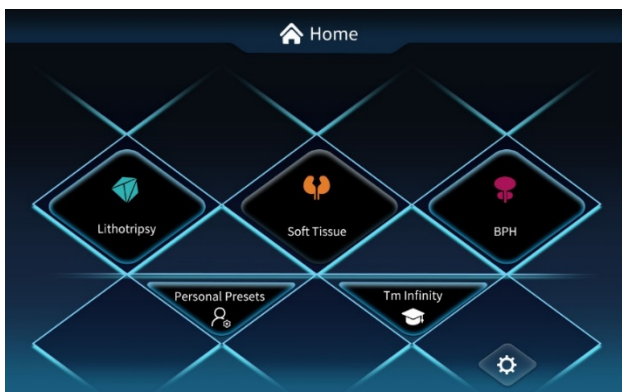


To turn the device ON:

Press the main switch on the rear panel. At the start-up, the screen display is shown in the left.



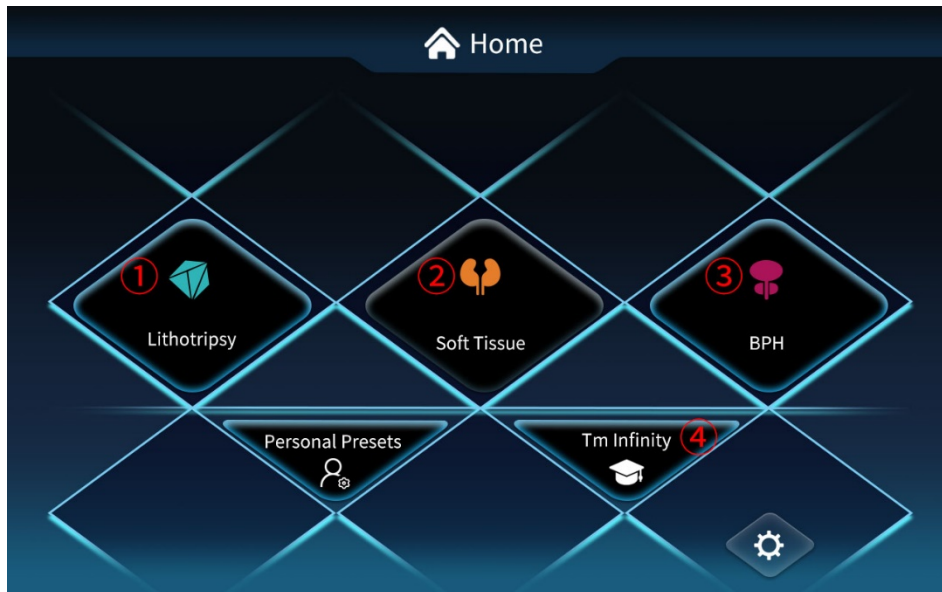
Enter the device usage authorization password, and then enter the device's operation interface.



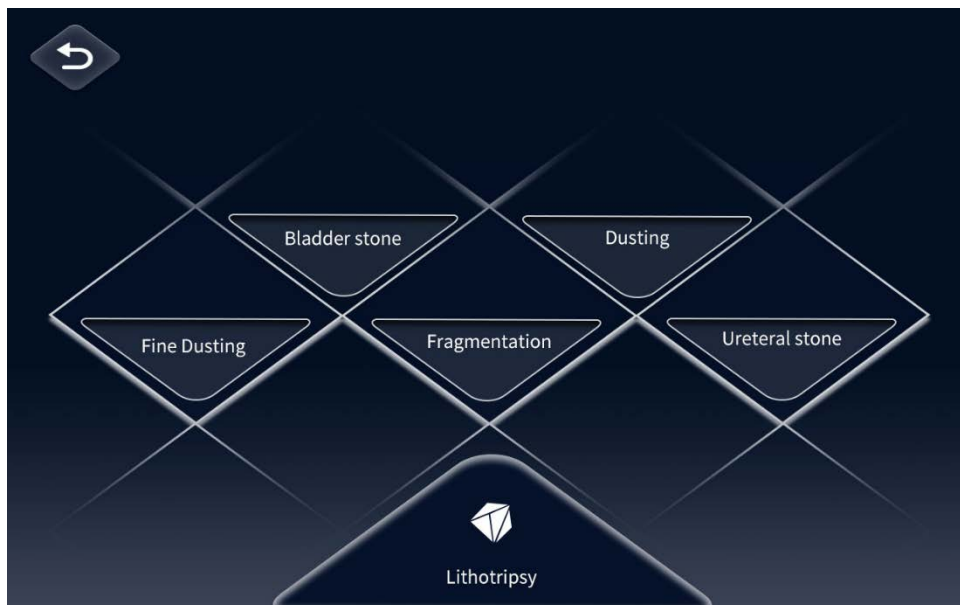
The left figure is the main interface for operation, where treatment indications can be selected, such as Lithotripsy, Soft tissue and BPH, etc.

6.2. Operating instructions

6.2.1. Main Screen

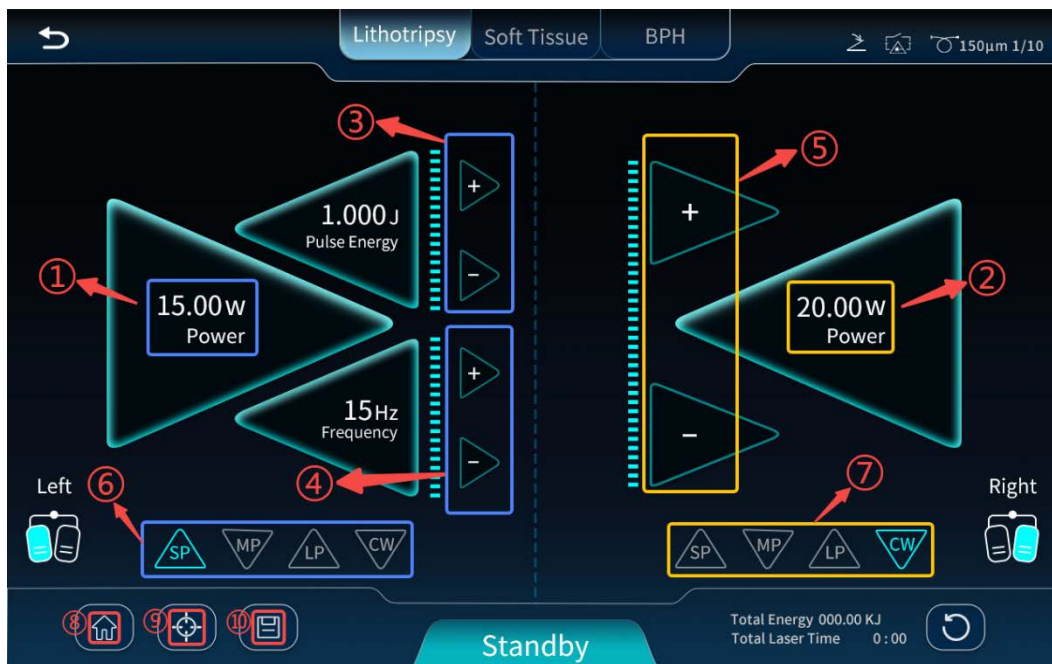


On the main interface, you can choose according to the treatment purpose, as shown in Figure ①, ②, ③, and ④. For example, if you click ①, the device interface will guide further selection, as shown in the following figure:



Clicking on any specific usage scenario in the above image will redirect you to the "Treatment Interface", as shown in Chapter 5.2.2.

6.2.2. Treatment Interface

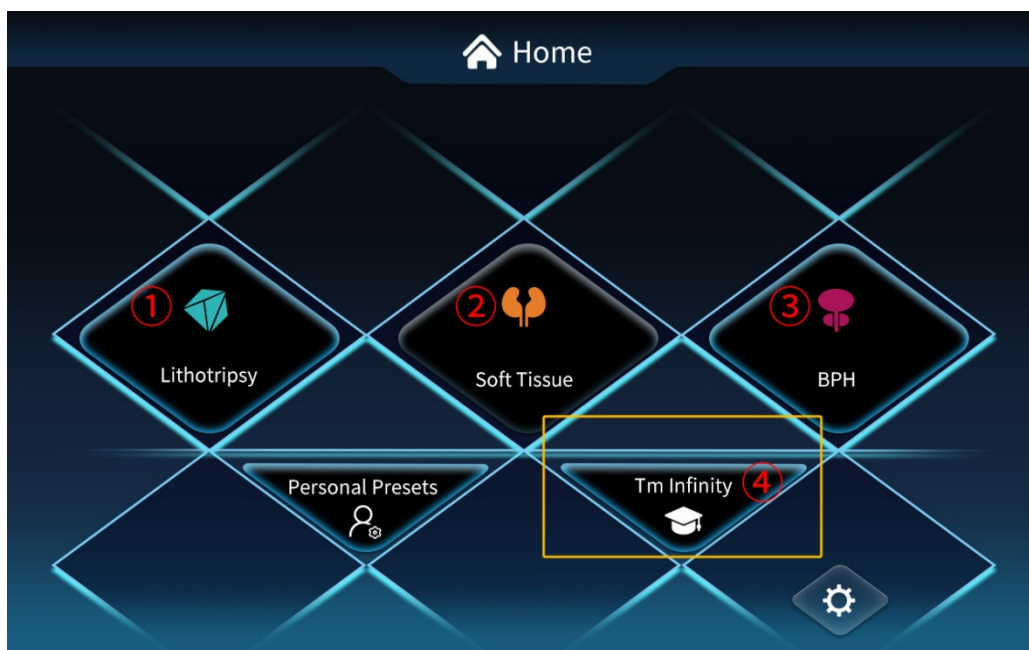


NO.	Description	NO.	Description
1	Output power for left footswitch	6	Pulse width for left footswitch
2	Output power for right footswitch	7	Pulse width for right footswitch
3	Pulse energy Adjustment	8	Return to the main interface
4	Frequency Adjustment	9	Enter the aiming light control interface
5	Output power Adjustment	10	Save current laser parameters

Special Note:

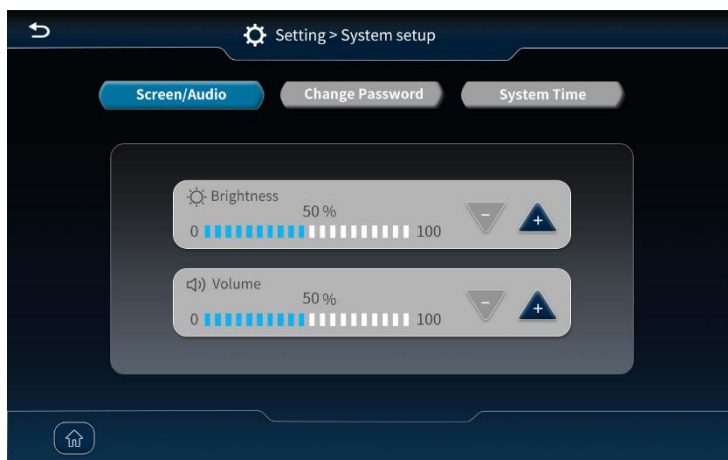
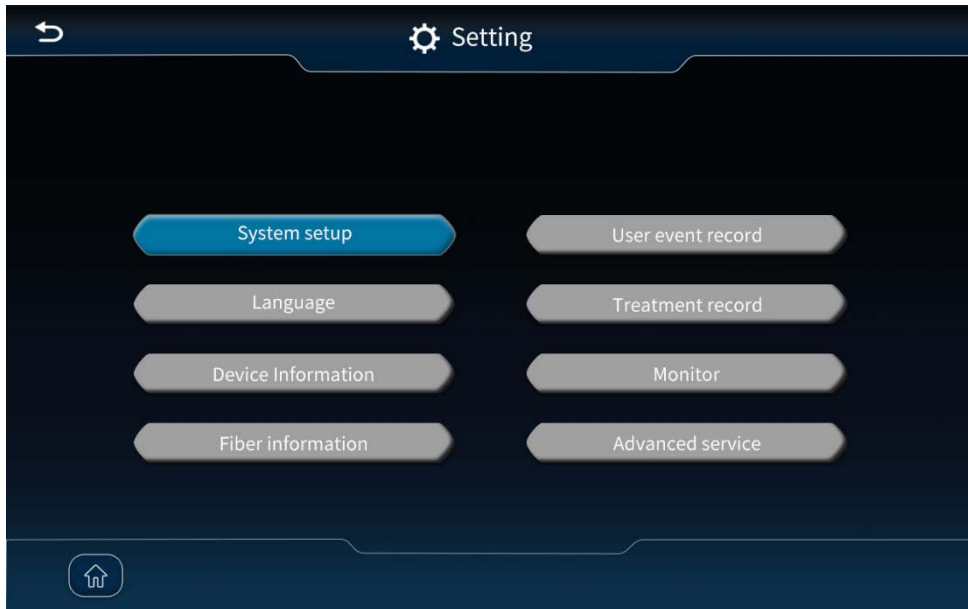
Press ④ on the main interface to enter the free setting mode.

Users can set any laser parameters supported by this laser without any power limitations.

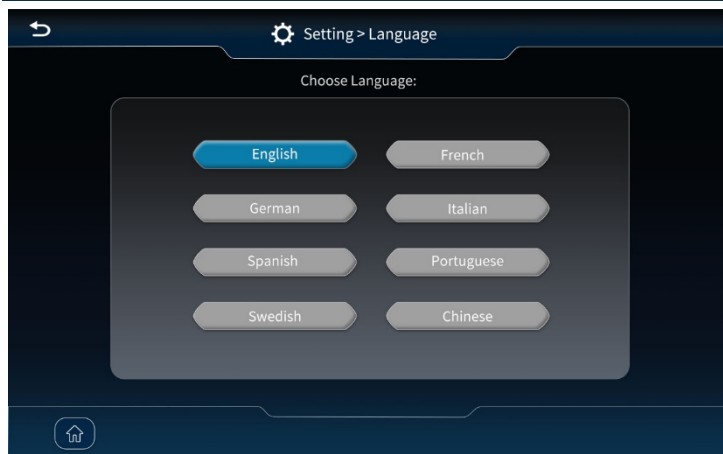


6.2.3. Settings interface

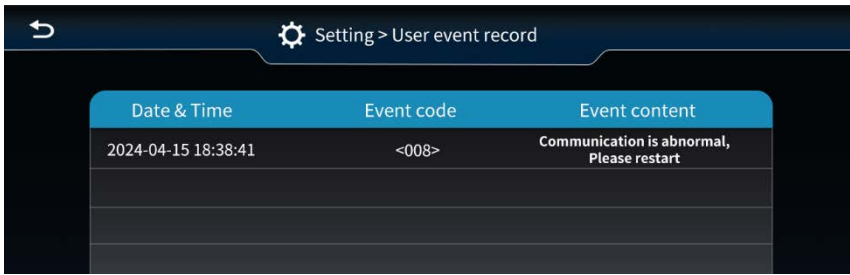
Click  on the main interface to enter the system settings interface. You can modify various parameters of the system, as shown in the following figure:



Set brightness and sound



Set language



Date & Time	Event code	Event content
2024-04-15 18:38:41	<008>	Communication is abnormal, Please restart

View record



Date & Time	Pulse Energy	Power	Frequency	Pulse Duration	Fiber type	Total energy	Total time
2024-04-15 19:04:06	0.025	2.00	80	LP	150μm	000.05	0000:25
2024-04-16 19:04:06	0.025	2.00	80	LP	272μm	000.05	0000:25
2024-04-17 19:04:06	0.025	2.00	80	LP	550μm	000.05	0000:25

6.3. Laser emission

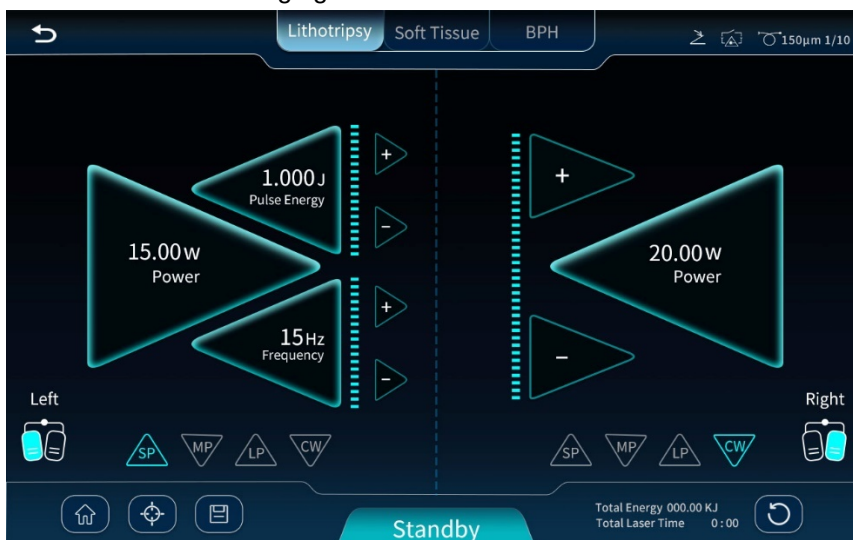
After setting the working parameters with suitable values, the user can start the laser emission as follows.

6.3.1. RFID fiber connection

When the user approaches the RFID handle of the fiber to the external protective shutter, it will automatically open. If it does not automatically open, users can also move the sliding knob to open it

The system recognizes immediately fiber type and number of reuses, showing this information on the upper right corner of the treatment interface.

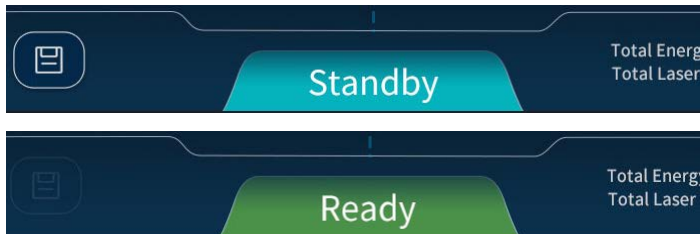
Special note: The working parameters of the laser can only be set in Standby mode, as shown in the "Standby" interface in the following figure:



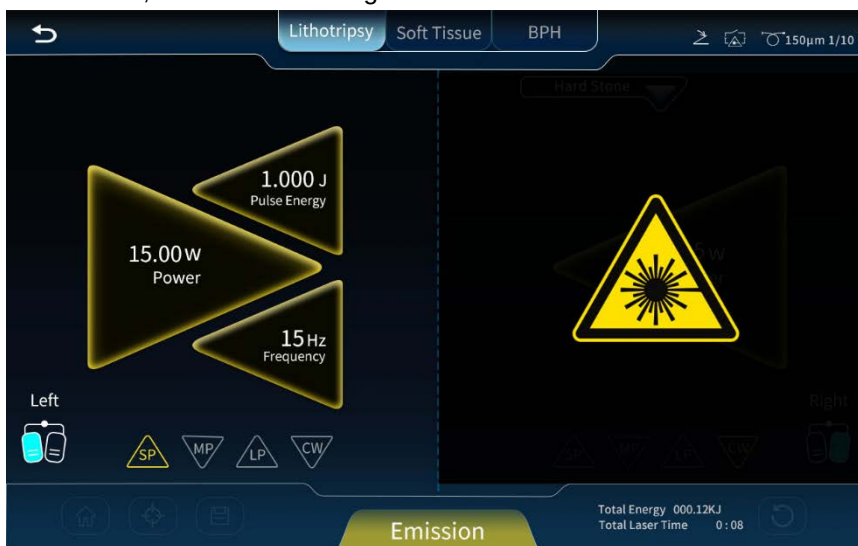
6.3.2. Ready / Standby

When the user taps on the Ready/Standby area, the system will be set respectively in the Ready or Standby mode.

In Standby mode the laser is not firing and the system cannot emit energy. In the Ready mode, the laser is firing and ready to emit energy. The status area shows the current status of Laser System:



If the left footswitch is pressed, the laser device will emit according to the parameter configuration on the left-side screen, as shown in the figure:



If the right footswitch is pressed, the laser device will emit according to the parameter configuration on the right-side screen.



Warning: While keeping the fiber tip inside of patient body, user should switch from Ready to Standby status when performing provisionally any procedure other than lasing.



Warning: Before removing the fiber from patient body, user MUST switch from Ready to Standby status (both when treatment is completed and when performing provisionally any procedure other than lasing).

6.3.3. Laser Parameters

A wide range of combination of pulse energy (Joules, J) and frequency (Hertz, Hz) is available. The laser output power (Watt, W) for each possible combination is calculated (max 60 W) as follows:

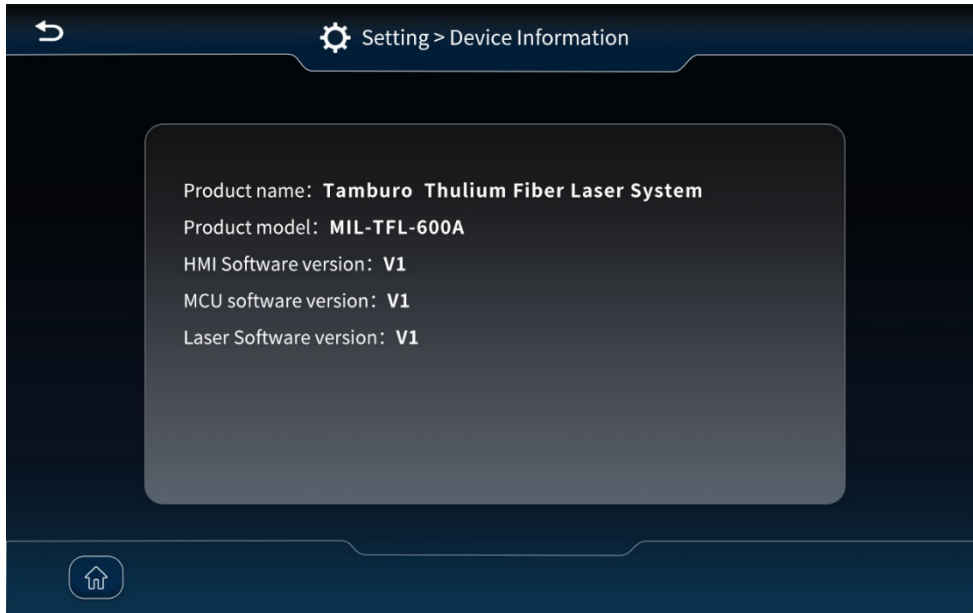
$$\text{Power (W)} = \text{Energy (J)} \times \text{Frequency (Hz)}$$

The diameter, type and number of uses of the connected fibers are automatically detected. Laser fibers with

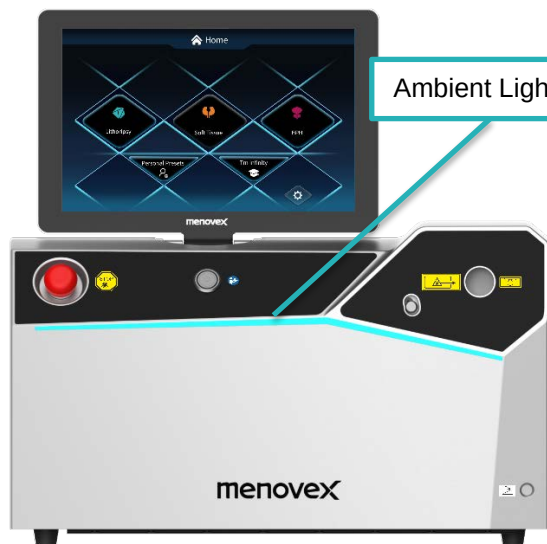
diameter $\leq 200\mu\text{m}$ may have limitations in the output power settings (energy / frequency) due to their technical features.

6.4. Software Version

Click the Device Information button to view the Software information controlling the laser system.



6.5. Ambient Light



The Ambient Light indicators on the device represent the following statuses:

- **Purple (Flashing):** Self-test without fiber connected
- **Blue (Flashing):** Self-test with fiber connected
- **Blue (Steady):** Standby status
- **Green (Steady):** Ready status
- **Yellow (Steady):** Laser emission
- **Red (Steady):** Fault detected

6.6. Error and warning description

Different errors may be displayed on the control panel. Every time an error occurs, a message appears at the right top of the screen specifying the error type.

When an error occurs, the System behavior is different depending on the issue level of severity:

- **ERROR Status:** In the "ERROR" status power electronics are cut off through a suitable switch and the device starts running in a safe mode or gets restarted.
- **STANDBY Status:** Some error/warnings force the system in "STANDBY" status, preventing to enter in Ready mode till the cause of the error has been solved.

A complete list of all the possible errors types is provided below.

Error message	Issue related	System behavior
	Footswitch not present/connected	Force STANDBY status
	The remote interlock contacts are open	Force STANDBY status
	Equipment malfunction	Force STANDBY status Press  to see the fault code. For specific fault code meanings and troubleshooting methods, please refer to Chapter 8.
	Fiber not present/connected	Force STANDBY status
	Fiber not identified by RFID	Force STANDBY status

6.7. Shutdown procedure and protection against unauthorized use

Once device operation is accomplished and the laser is in Standby mode, one can proceed with its shutdown procedure as follows:

- Disconnect the fiber from the device and cover the laser device output connector with its dedicated protection shutter
- Press the frontal ON/OFF button
- Turn off the main switch on the rear panel and unplug the power cable
- Disconnect the remote interlock
- Disconnect the footswitch
- In order to disconnect the device from the mains it is necessary to detach the supply cable plug from the mains.
- Keep the device and its accessories in a dry and safe place

In order to avoid improper use of the device, device shall be turned off when the device is not being used.

7. Maintenance and cleaning

This section contains mainly user information regarding the care and cleaning of the device. Should you require any assistance concerning maintenance or technical intervention, please contact **menovex** Customer service.

7.1. Device cleaning

The laser device does not need special maintenance by the user. Switch off the device before starting the cleaning procedure. Clean the visible surfaces with a damp cloth, taking care not to let the water enter the device (in particular attention must be paid in not spilling any drop on monitor frame interstice and monitor itself). Do not use alcohol or disinfectant solutions, because they are highly flammable. While cleaning, be careful not to let the cleaning solution leak in the fiber connection port. Use the supplied caps to close the fiber connection port after each use. Do not use any alcohol solution to clean the display.

7.2. Laser Maintenance and technical check

The Laser device is designed for maximum safety and performance. Under normal operating conditions and when respecting a careful use, the manufacturer recommends a check-up of the device by a qualified technician every 12 months. The intensive use, dust, or continuous movement of the laser in different places may require a more frequent monitoring.

7.3. Safety labelling check

The user must regularly verify the integrity and readability of the security labels placed on the device. If labels are damaged, they must be replaced immediately in accordance with the labeling described in Chapter 3.9.

7.4. Laser fiber maintenance



Warning: Be sure that fiber sterilization is not expired (expiration date is reported on fiber label). Please read carefully the instruction manual of the laser fiber before use to assure a proper and safe use.

7.4.1. Fiber management (application cycles)

The number of application cycles of a laser fiber is mentioned on the label or in the instruction manual of the laser fiber. The RFID system keeps record of the number of uses (correlated with the required sterilization cycles) that the fiber undergoes.

Only the use of RFID Tamburo Laser Fibers is allowed with the Tamburo Laser System.



Caution: A disposable laser fiber cannot be used a second time after the first use!
A single-use laser fiber, even if new, in any case cannot be re-sterilized a second time!

After the use of a disposable laser fiber or at the end of the application cycles of a re-processable laser fiber, change the old fiber with a new one.

While fiber records indicate the number of uses for single-use and reusable fibers, the user should be aware of the expiration date and not use a surgical fiber that has passed its expiration date. Prior to use, the user should check both the number of uses of a surgical fiber as well as the expiration date of each fiber.

Laser emission will not be possible until a fiber is connected. The fiber must have at least 1 use left.

7.4.2. Check the laser fiber before operation



Caution: Before each use, check the shape of the aiming beam to verify the effective quality of the beam pattern. This check can be done by placing the fiber perpendicularly to a surface with the aiming beam activated.

If the laser fiber connection is damaged, replace the optical fiber immediately. If optical fiber tip is dirty or damaged, renew it by following the instructions reported inside fiber user manual.

If you want to inspect the quality of the connected fiber in a safe way (Standby mode), you could activate the pilot laser without entering the Ready mode and evaluate its output profile.

7.5. Blast Shield Replacement



Warning: This operation must be carried out with clean hands and extreme caution to avoid optical damage of the device. Failure to follow the below instructions may result in insufficient laser energy being delivered to the treatment site.

The blast shield replacement must be executed in the following way:

1. Turn the device off, disconnecting the equipment from mains.
2. Use a small eject tool to press the small circle in the head of the blast shield (located on the side panel of the laser system)
3. The blast shield will pop out partially
4. Pull the blast shield straight out of the laser system
5. Insert a new blast shield (taking care not to touch the lens) into the port.
6. Press until a tactile click is felt.

8. Troubleshooting

Code	Fault	Possible Causes	Recommended Actions
000	No Fault	/	/
001	Laser module fan error	Foreign objects blocking the air inlet and outlet Fan blocked	Check the fan
002	Emergency stop switch error	Emergency LASER STOP activated	Deactivate Emergency LASER STOP switch
003	Startup error	Initialization error	Call service
004	Pedal not connected	Wrong pedal connections	Check connections
009	Energy error	Fluctuation of energy parameter during laser radiation	Wait a few seconds for stabilization. Call the service
010	Fiber not present/connected	Wrong fiber installation	Check the fiber connection
011	Fiber not identified by RFID	Wrong fiber installation Wrong fiber type	Check the fiber connection Change fiber

Code	Fault	Possible Causes	Recommended Actions
012	The remote interlock contacts are open	The ext. Interlock is not connected or is poorly connected	Control ext. Interlock connection
016	Shutter error	Incorrect shutter position	Call service
041	Blast shield wrong installation	Wrong blast shield installation	Check Blast shield Call service
042	Internal temperature fault	The temperature is too high or low	Enter standby mode Lower the ambient temperature to cool down the device. Operating temperatures, please refer to Chapter 10
043	Air inlet temperature fault	The temperature is too high or low	Enter standby mode Lower the ambient temperature to cool down the device. Operating temperatures, please refer to Chapter 10
044	Air outlet temperature fault	The temperature is too high or low	Enter standby mode Lower the ambient temperature to cool down the device Operating temperatures, please refer to Chapter 10.
045	Energy output fault	The emission is too high or low	Call service
046	Energy output fault	The emission is too high or low	Call service
047	Laser operating temperature fault	The temperature is too high or low	Enter standby mode Lower the ambient temperature to cool down the device. Operating temperatures, please refer to Chapter 10

9. Disclaimer

menovex shall not be liable for any medical expense or any direct, incidental or indirect loss arising from misuse (including reuse), improper selection, misoperation or any other man-induced accident of the product and purchase of the product from any illegal source, any risk unable to be identified under the current technological level or any potential adverse event or risk listed herein, regardless of whether the claim is based on warranty, contract, tort or any other theory of law.

10. Technical Specifications

10.1. General Specifications

Specification	Description
Product category	Surgical laser for medical use
Classification of Medical Device Directive 93/42/EEC	Class IIb
Electrical Requirements	100 – 240V~ at 980VA 50/60 Hz
Type of protection against electric shock	Class I
Degree of liquid ingress protection	IPX8 for the footswitch
Degree of electric shock protection	Type BF
Mode of operation	Continuous
Dimension	48 X 29 X 40 cm
Weight	≤ 43 kg
Operating temperature	10° C – 30° C
Storage/ Transport temperature	-20° C – 55° C
Operating humidity	≤ 75%
Atmospheric pressure	800-1060hPa
Cooling system	Air cooling system
Max noise	≤ 70 dB
Shelf life	7 years

10.2. Laser Specifications

Specification	Description		
	Premium MIL-TFL-600A	Pro MIL-TFL-600B	Lite MIL-TFL-600C
Laser Classification IEC/EN 60825-1	Class 4		
Aiming beam classification IEC/EN 60825-1	Class 3R		
Laser Type	Thulium Fiber Laser		
Wavelength	1940 nm±20 nm		
Average power	2 – 60W	2 – 60W	2 – 40W
Pulse Energy	0.025 – 6J	0.025 – 6J	0.025 – 4J
Operating mode	Pulsed / CW	Pulsed	Pulsed
Pulse duration	200µs – 50ms	200µs – 50ms	200µs – 33ms
Repetition rate	1 – 2400Hz	1 – 2400Hz	1 – 1600Hz
Aiming Beam Pulse Frequency	Green, 510 – 530 nm, power ≤5 mW		
Beam divergence	16°		
MPE (Maximum Permissible Exposure)	1000 W/m ²		
NOHD (Nominal Ocular Hazard Distance)	1.08m	0.61m	0.50m
OD (Optical Density)	5		
Glasses specification	LB4		

Note 1: The expanded uncertainty of the measurement result is: Beam divergence $U_{rel}=2\%$, $k=2$; Pulse duration $U_{rel}=0.16\%$, $k=2$; Max power $U_{rel}=2\%$, $k=2$;

Note 2: The device is provided with internal measuring system to control the actual emission of the laser energy. The device does not require calibration by the user.

11. EMC Information

According to the EMC information and technical notes, special precautions for electromagnetic compatibility (EMC) are required, and installation and operations must be done in accordance with the EMC information provided in this IFU.



Warning: Use of accessories and cables other than those specified or provided by the MANUFACTURER of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment.



Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



Warning: 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 Tamburo Thulium Fiber Laser System, including cables.

Otherwise, degradation of the performance of this equipment could result.

Guidance and manufacturer's declaration – Electromagnetic emissions		
The DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of the DEVICE should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The DEVICE 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. The DEVICE 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.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Class A	

Guidance and manufacturer's declaration – Electromagnetic immunity			
The DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of the DEVICE should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm 6\text{kV}$ contact $\pm 2,4,8,15\text{kV}$ air	Same as left	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	$\pm 2\text{kV}$ for power supply lines $\pm 1\text{kV}$ for input/output lines	Same as left	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 1\text{ kV}$ line(s) to line(s) $\pm 2\text{ kV}$ line(s) to earth	Same as left	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% U_t for 0.5 cycle 0% U_t for 1 cycle 70% U_t for 25/30 cycles (50/60 Hz) 0% U_t for 250/300 cycles (50/60Hz)	Same as left	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DEVICE requires continued operation during power mains interruptions, it is recommended that the DEVICE be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Same as left	If image distortion occurs, it may be necessary to position the DEVICE further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of the DEVICE should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the DEVICE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80\text{MHz} \sim 800\text{MHz}$ $d = 2.3\sqrt{P} \quad 800\text{MHz} \sim 2.7\text{GH}$ 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 meters (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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	
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.			
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 Model 006 is used exceeds the applicable RF compliance level above, the DEVICE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DEVICE. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the DEVICE			
The DEVICE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DEVICE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DEVICE 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
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 meters (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 1 At 80 MHz and 800 MHz, the separation distance for 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.			

12. Wireless Equipment Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 25 cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This statement applies only to the wireless portions of the device:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Wireless Equipment Compliance — RFID Reader

RFID Reader	
FCC ID	2BNAH-MILTFL600
Frequency Band North America	917.4MHz~927.2MHz
Frequency Band EU	866.20MHz~867.80MHz
Modulation Type	PR-ASK
Effective Radiated Power (max) for EU	688.7 mW

Manufacturer:

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