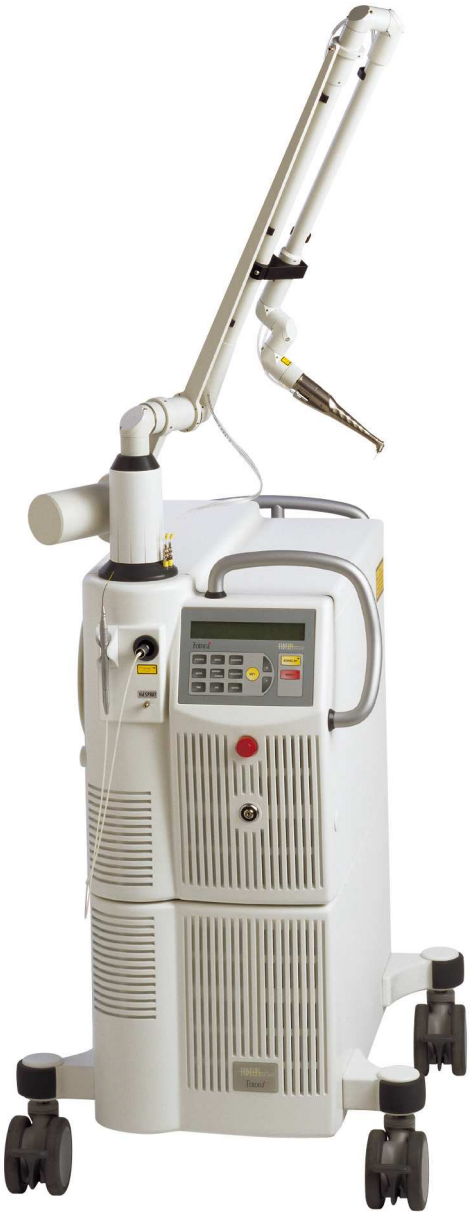


MANUFACTURER:
Fotona d.d.
Stegne 7, PO Box 59
SI – 1210 Ljubljana, Slovenia
phone: + 386 1 500 91 00
fax: + 386 1 500 92 00
www.fotona.si

CE
0123

OPERATOR MANUAL

FIDELIS Er II, FIDELIS Nd II, FIDELIS PLUS II

Model: M002 – 3A, M001 – 13F, M021 – 3AF
Code: 68444, 68447, 66892
68646 CE ENG/08

Please note that while every effort has been made to ensure that the data given in this manual is accurate, the information, figures, illustrations, tables, specifications, and schematics contained herein are subject to change without notice.

Content

Foreword

Dear customer,

Thank you for purchasing a Fotona laser system and placing your trust in our brand. We are certain that your Fotona system will be an asset to your practice and will provide you with significant advantages in many different areas of your daily work. With over 40 years of experience we have a deep understanding of today's modern physicians' needs and aim to provide laser-based solutions that excel in quality and reliability.

Fotona medical laser systems have been developed and are manufactured according to the most stringent international quality and safety requirement and standards. All Fotona laser systems are authorized to carry the CE mark.

Fotona medical laser systems provide the modern physician with the opportunity to offer their patients precise, gentle and effective treatments. We believe the following advantages will benefit your practice:

- Greater patient comfort and satisfaction.
- Quicker, more efficient procedures.
- Higher precision and control.
- Superior clinical results.
- New challenges and procedures.

The purpose of this Operator Manual is to provide regulatory required information on particular characteristics of the laser system and its operation. We strongly recommend to carefully read and study the entire content of this manual before attempting to operate the device. Please take note of the various warnings and notes that are provided to ensure a maximum life-span of your device and to safeguard the safety of the patient, medical personnel and yourself.

In the event you should have any questions or comments regarding the Fotona laser system, we invite you to contact us by email at info@fotona.si . Alternatively, we can be contacted through the contact details provided on the cover page.
To ensure that we can be of optimal service, we kindly recommend to register your Fotona device online at www.fotona.si .

We hope you will enjoy your Fotona laser system and the added value and advantages it will bring to your work.

Fotona Sales &
Marketing Department

INTRODUCTION AND SYSTEM CHARACTERISTICS

1.1 General

The Fotona Fidelis II laser systems range incorporates treatment lasers that operate in the invisible near- and mid-infrared ranges of the electromagnetic spectrum, and an aiming beam laser that operates in the visible range.

The incorporated lasers and their handpieces were developed for therapeutic use in dentistry, for soft and hard tissue surgery. Additionally the Er:YAG laser and its accessories can be used for certain indications in dermatology.
Please refer to Section 2 for more detailed information on indications for use.

The Variable Square Pulse (VSP) Technology implemented in the laser systems allows ultimate control of laser energy and laser pulse length.

The Fidelis II laser systems incorporate the following treatment laser sources:

Fidelis Plus II:
- Er:YAG laser, with a wavelength of 2940 nm
- Nd:YAG laser, with a wavelength of 1064 nm

Fidelis Er II:
- Er:YAG laser, with a wavelength of 2940 nm

Fidelis Nd II:
- Nd:YAG laser, with a wavelength of 1064 nm

The aiming laser is a semiconductor diode laser with a wavelength of 650 nm.

Both treatment laser types are pulsed solid-state lasers and generate high-energy concentrated light, which may cause serious injury if used improperly.
For this reason, the operator must carefully read and comprehend this manual before attempting to operate the device.

The Fidelis II laser systems are equipped with an internal water spray device, therefore no external water or pressurized air connection is needed. All spray adjustments can be done using the system control panel.

CAUTION !

The Fotona Fidelis II laser systems should be used only by physicians trained in the operation of laser devices.

CAUTION !

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

CAUTION !

Portable and mobile RF communications equipment can affect medical electrical equipment.

1.2 System Characteristics

Laser system

Laser type	Nd:YAG laser	Er:YAG laser
Wavelength	1064 nm	2940 nm
Max. pulse energy	n/a	1,5 J
Max. pulsewidth	320 µs	1000 µs
Max. frequency	100 Hz	50 Hz
Max. power	15 W	20 W

Laser Beam Delivery Unit

	Nd:YAG laser	Er:YAG laser
Beam delivery type	Fiber-optic; fiber diameters of 200 µm and 300 µm	7-mirror articulated arm

Compatible Handpieces for the Er:YAG laser source

(Note: Applicable for Fidelis Er II and Fidelis Plus II laser systems)

Model	**Description**
R02-F	Dental, non-contact, 90°-angled handpiece, 0.9 mm spot size at the focal point, with removable air/water spray nozzle. Recommended for removal of hard dental tissues.
R04-F	Dermatological, straight handpiece, with 3 different spacers for 3, 5 and 7 mm spot sizes. Recommended for skin resurfacing, removal of skin lesions and scars.
R05-F	Surgical, 90°-angled handpiece for cutting, 0. 45 mm spot size at the distance indicated by the spacer. Recommended for cutting in skin and mucosa.
R06-F	Multi-functional, straight, fiber-optic tip handpiece, 0.9 mm spot size. Different lengths of fiber-optic tips are possible. Recommended for cutting of hard tissues, e.g. bone.
R07	Dental, fiber-optic tip, 90°-angled handpiece, 0.9 mm spot size, with removable air/water spray nozzle. Recommended for the removal of hard dental tissues.

R08	Surgical, straight handpiece, 0.45 mm spot size at the distance indicated by spacer. Recommended for cutting in skin and mucosa. Special spacer available for hair transplant procedures.
R09-2	Multi-functional, collimated straight handpiece, 4 mm spot size for a 2 to 10 cm distance from the target. Recommended for skin resurfacing and removal of leukoplakia.
R09-3	Multi-functional, collimated straight handpiece, 5 mm spot size for a 2 to 10 cm distance from the target. Recommended for skin resurfacing and removal of leukoplakia.
R09-2G	Multi-functional, collimated straight handpiece with a tube for gynaecology. Recommended for the removal of genital warts.
R11	Dermatological, straight collimated handpiece with variable focus. Recommended for skin resurfacing and removal of skin lesions and scars.
R14-A	Dental, fiber-optic tip, 90° degrees handpiec e, 0.9 mm spot size, with integrated air/water spray nozzle. Recommended for the removal of hard dental tissues.
R14-B	Dental, fiber-optic tip, 105° degrees handpie ce, 0.9 mm spot size, with integrated air/water spray nozzle. Recommended for the removal of hard dental tissues.

Please note that the information given in the table above can be subject to change without notice and is dependent of the lasertherapy parameters chosen on the laser system for specific applications. It is recommended to carefully read the respective Handpiece Operator Manuals before attempting to use the handpieces and/or contact the Fotona distributor for further information regarding the specific applications and specifications for handpieces.

Compatible Handpieces for the Nd:YAG laser source

(Note: Applicable for Fidelis Nd II and Fidelis Plus II laser systems)

Model	**Description**
R21/R22	Dental, contact 200 and 300 µm fiber-optic handpiece. Recommended for disinfection in endodontics and periodontics, and soft tissue surgery.
R24	Dental, collimated fiber-optic handpiece, 6 mm spot size. Recommended for bleaching.

Please note that the information given in the table above can be subject to change without notice and is dependent of the lasertherapy parameters chosen on the laser system for specific applications. It is recommended to carefully read the respective Handpiece Operator Manuals before attempting to use the handpieces and/or contact the Fotona distributor for further information regarding the specific applications and specifications for handpieces.

INDICATIONS FOR USE

2.1 Intended use

In **dentistry** the Er:YAG laser, and its accessories, are intended for incision, excision, vaporization, ablation and coagulation of intra-oral soft and hard dental tissue.
The procedures include caries removal, cavity preparation and enamel etching.

In **dermatology** the Er:YAG laser, and its accessories, is intended for surgical incision/excision, vaporization and coagulation of soft and hard tissue. All soft tissue is included, such as skin, subcutaneous tissue, striated and smooth tissue, cartilage meniscus, muscle, mucous membrane, lymph vessels and nodes, organs and glands.

In **dentistry** the Nd:YAG laser, and its accessories, are intended for incision, excision and coagulation of intra-oral soft tissue, including the marginal and interdental gingiva.
This includes incising, excising and coagulating the epithelium lining, the free or marginal gingiva, and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket).

CAUTION !

Avoid treating any lesion that seems not benign; biopsy (multiple biopsies) any suspicious lesions.
Consult a specialist for skin cancer screening before initiating ablative laser therapy.

2.2 Dentistry: Indications, Contra-indications and Side effects

Er:YAG Laser in Dentistry	*Nd:YAG Laser in Dentistry*
Indications • Removal of enamel • Removal of dentin • Removal of caries lesions • Removal of filling materials (composite resin, GIC,…) • Fissure sealing • Modification of enamel and dentine • Root and bone resection • Soft tissue surgery • Removal of superficial oral lesions (leukoplakia, lichen panus, keratosis of all variations, various hyperkeratotic growths,…) • Removal of fibroma • Removal of granulation tissue • Desensitization of hypersensitive teeth • Calculus removal	**Indications** • Frenectomy • Removal of fibroma and hyperplasia • Removal of granulation tissue • Implant release after healing • Aphthae and herpes • Reduction of bleeding • Gingivectomy • Gingivoplasty • Reduction of interdental papilla • Crown lengthening • Periodontics – closed curettage • Desensitization of hypersensitive teeth • Endodontics – debris removal, closing of lateral dentin tubules and bacteria reduction of the root canal • Gutta-percha removal

Er:YAG Laser in Dentistry	*Nd:YAG Laser in Dentistry*
Contra-indications (relative and absolute) • Histologically demonstrated malignant carcinoma • Irradiation of the neck region in hyperthyreosis • Epilepsy • Fever and infectious diseases • Heavy blood loss • Neuropathies • Amalgam fillings	**Contra-indications (relative and absolute)** • Thin dentine walls • Histolocally demonstrated malignant carcinoma • Irradiation of the neck region in hyperthyreosis • Epilepsy **Possible side effects** • External root resorption • Thermally associated pain • Dentinal charring

2.3 Dermatology: Indications, Contra-indications and Side effects

Er:YAG Laser in Dermatology

Indications

- Ablation of superficial benign pigmented lesions:
  - Lentigines
  - Chloasma
  - Café-au-lait
  - Warts
  - Hipertrophic scars and keloid
  - Acne scars
  - Xanthelasme
  - Millia
  - Seborrheic keratosis
  - Pigmented actinic keratosis
  - Benign papilloma and dermatofibroma
  - Dermal photo-aging
- Ablative skin resurfacing

Possible side effects

- Scarring (hypertrophic, atrophic)
- Delayed healing, persistent ulcerated areas
- Hypopigmentation
- Hyperpigmentation
- Infections

Contra-indications (relative and absolute)

- History of abnormal (keloid) scarring.
- Active infection in the treatment area.
- History of Herpes Simplex infection in the treatment area.
- Excessive sun exposure (tanned skin).
- Use of iron supplements or an anticoagulant therapy
- A history of a photosensitivity disorders.
- Use of medication that may cause photosensitivity.
- Pregnancy
- Irradiation in the region of the gonads
- Diabetes

SAFETY AND REGULATORY COMPLIANCE

WARNING !

Severe and/or permanent eye damage may occur.

Never look directly into the treatment or aiming laser beam or scattered laser light from reflective surfaces.

Never look directly into the laser aperture, optical fiber tip, articulated arm exit aperture or handpiece exit when power is applied to the laser, even when laser safety eyewear is worn.

3.1 Ocular Protection

- Appropriate eye protection (see below) must be worn by the patient and all operating personnel to prevent inadvertent exposure to the eyes.
- The treatment room door should be kept closed at all times while operating the laser system.
- Warning signs in prominent places at all entrances to the laser treatment room should alert all personnel they are entering a controlled area.
- The use of door interlocks that automatically disable the laser, when the treatment room door is opened, is recommended

Safety eyewear

- Ensure that all personnel wear appropriate safety eyewear whenever the laser system is switched on.
- Never look directly into the laser beam even when wearing protective eyewear.
- Never allow the laser beam to be directed at anything other than the target area.

Er:YAG wavelength
Laser safety eyewear is required with Er:YAG 2940 nm wavelength.
The laser safety eyewear recommended for use with the Er:YAG wavelength laser should have an optical density according to I,RL 5 (for Europe) or OD 5 (elsewhere)

Nd:YAG wavelength
Laser safety eyewear is required with Nd:YAG 1064 nm wavelength.
The laser safety eyewear recommended for use with the Nd:YAG wavelength laser should have an optical density according to I,RL 7 (for Europe) or OD 7 (elsewhere).

Aiming beam
A low power visible aiming beam is used to aim the treatment beam at the target tissue. The aiming beam shines coaxial with the treatment beam.
The power of the visible aiming beam, with a wavelength of 650 nm, does not exceed 1 mW, and therefore additional ocular protection for this laser is not needed.

Nominal Ocular Hazard Distance (NOHD)

The following table specifies the minimum distances at which laser light emitted from the Fotona laser systems are not considered harmful (NOHD – Nominal Ocular Hazard Distance).

Er:YAG Laser

Handpiece	Divergence (mrad)	NOHD (m)
Articulated arm exit	7	21.6
R02-F	80	1.9
R04-F	160	1.18
R05-F	192	0.7
R06-F	200	0.61
R07	200	0.61
R08	192	0.85
R09	14	11.32
R11	20	7.83
R14	92	1.33

Nd:YAG Laser

Handpiece	Divergence (mrad)	NOHD (m)
R21/R22 with 200 µm fiber	220	11
R21/R22 with 300 µm fiber	334	17.5
R24	40	135

3.2 Electrical Hazards

- Never attempt to open the laser system's protective housing due to the realistic risk of being exposed to high voltage components and excessive laser exposure.
  Only qualified service personnel, authorized by Fotona, should perform work inside the laser system console.
- Fotona strongly recommends that the area around the laser system and footswitch is kept dry.
- Do not place fluid filled containers on the top of the laser system console.
- Do not operate the laser system if any of the cords are considered faulty or frayed.
- The laser system should undergo routine inspection and maintenance according to Fotona's recommendations and institutional standards.

3.3 Explosion and Fire Hazards

WARNING !

Fire and explosion hazard.

Do not use the laser in the presence of flammables or explosives, such as volatile anesthetics, alcohol, certain surgical preparation solutions, and other such substances.

Do not use the laser system before ensuring that surgical drapes and gowns made of flame-retardant material and towels or gauze sponges moistened with a sterile saline solution or sterile water are available in the operating field.

WARNING !

Do not use the laser system with the attached fiber-optic delivery unit, if you cannot see the red aiming beam.

The fiber-optic delivery unit's optical fiber may be damaged.

Using a damaged fiber may result in accidental laser exposure to operating room personnel or the patient and/or may cause fire in the operating room.

3.4 Protecting Non-Target Tissues

WARNING !

The system should always be kept in STANDBY mode except during actual treatment to minimize the risk of accidental laser exposure if the footswitch is inadvertently pressed.

- Before removing the laser-optic delivery unit or the handpiece, always put the device in STANDBY mode.
- Do not place hands or other objects in the laser beam path.
- Only the operator of the device, directing the laser beam at the target tissue, should have access to the laser footswitch.
- Use caution pressing the laser footswitch, when it is in proximity to footswitches for other equipment. Always ensure that the pressed footswitch is the correct one, to avoid accidental laser exposure.

3.5 Safety Features

Emergency-Off Push Button

The laser system shuts down immediately, when the red emergency-off push button (located on the front panel) is pressed.

Keylock Switch

The correct key must be inserted into the keylock switch to be able to switch on the laser system.

The key can only be removed in the OFF position and the laser can only operate with the key in the ON position.

To prevent unauthorized use of the laser system, always remove the key from the keylock switch when the treatment session has been completed.

Laser Emission Indicator

The message “EMISSION” is displayed on the control panel display in READY mode and during laser operation. Additionally, the red led light in the upper left hand corner of the READY key will be lit.

An audio signal indicates laser emission when the laser is activated by pressing the footswitch.

Doorswitch Interlock

A remote interlock outlet (doorswitch) is provided to disable the laser system, if the operating room door has been opened.

When the doorswitch is activated, the laser stops immediately, the shutter closes, and the system reverts to STANDBY mode.

To resume treatment, the operating room door must be closed and the operator must press the READY key again.

If the doorswitch interlock plug is removed from the system, the system becomes inoperable.

Protective Housing

The protective housing of the instrument prevents unintended access/exposure to laser radiation above Class I limits.
The protective housing can only be opened using special tools and should only be attempted by qualified service personnel, authorized by Fotona.

Safety Interlocks

(Note: Applicable for the Fidelis Nd II and Fidelis Plus II laser systems)

If the Nd:YAG fiber-optic delivery unit is removed from its port on the device, the laser is disabled and the shutter closes.

The message "USER INTERVENTION ATTACH FIBER" is shown on the control panel display.

The system cannot deliver a treatment beam unless the fiber-optic delivery unit is properly attached to its port on the system.

The Nd:YAG handpiece must be in rest position in its holder on the laser console in order to use the Er:YAG laser.

Location of Controls

All the controls of the laser system are located on the front panel of the device for easy and safe access during operation.

Safety Shutter

Each treatment laser incorporates a safety shutter of which the positions are monitored by the system.

The safety shutter for the corresponding treatment laser is open during laser treatment only.

Manual Reset

If the laser treatment is interrupted externally (for example opening the operating room doors), the system will stop the laser immediately and revert to STANDBY mode, the safety shutter will close, and the message "DOOR OPEN INTERLOCK" appears on the control panel display.

To resume laser operation, close the operating room door and press the READY key.

Microprocessor Controlled Fault Detection

The laser system is a computer-controlled device with several built-in monitoring and fault detection circuits and procedures.

If the system detects any fault, which it cannot correct, it will immediately disable the laser, close the safety shutter, block the footswitch and keyboard, and issue an advisory or system error code message on the display. Additionally, it will switch off the power supply and discharge the energy storing capacitors.

The operator can remedy certain advisory messages like footswitch, doorswitch, fiber, overheating coolant related failures.

In case the system is blocked and displays a "System Error XX" message, immediately notify the technical service.

Digital On-line Laser Output Energy/Power Regulation

The laser system incorporates a sophisticated double channel safety structure for energy regulation. Each laser pulse is measured and energy is regulated according to a prescribed algorithm in the microprocessor.

The laser output energy is constantly regulated by a signal from a feedback energy meter. A second energy meter also monitors the energy of the laser. Should the readings of both energy meters differ for more than a prescribed value; the system will shut down, the laser will disable, the safety shutter will close, and an appropriate error message will be displayed.

3.6 Regulatory Compliance

The Fotona Fidelis II laser systems fully comply with all requirements of the MDD 93/42/EEC.

List of standards

The following standards and their requirements as well as regulatory issues have been used and implemented in the Fotona laser systems:

EN 60601-1/1990+A1:1993+A2:1995+A13:1996
- Medical electrical equipment
  Part 1: General requirements for safety

EN 60601-1-2/2001
- Medical electrical equipment
  Part 1: General requirements for safety.
  Part 2: Collateral standard: Electromagnetic compatibility – Requirements and tests.

EN 60601-1-4/1996
- Medical electrical equipment
  Part 1: General requirements for safety.
  Part 4: Collateral standard: Programmable electric medical systems.

EN 60601-2-22/1996
- Medical electrical equipment
  Part 2: Particular requirements for safety diagnostic and therapeutic laser equipment.

EN 60825-1/2001
- Safety of laser products.
  Part 1: Equipment classification, requirements and user′s guide.

EN ISO 14971/2000
- Medical devices – Application of risk management to medical devices

3.7 Electro-Magnetic Compliance Statement

The Fidelis medical electrical equipment needs special precautions regarding EMC and needs to be installed and put in service according to the EMC information provided bellow.

ELECTROMAGNETIC EMISSION		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The Fidelis II laser system uses RF energy only for its internal function. Therefore the RF emissions are very low and are not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	Class B	The Fidelis II laser system is suitable for use in all establishments, including domestic establishments 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	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

ELECTROMAGNETIC IMMUNITY			
Immunity test	**IE 61000 test level**	**Compliance level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a typical commercial hospital environment.
Surge	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial hospital environment. If the operator of the Fidelis II laser system requires continuous operation during power mains interruption, it is recommended that the system be powered from an uninterruptible power supply or battery.
NOTE U_T *is the ac mains voltage prior to application of the test level*			

ELECTROMAGNETIC IMMUNITY			
Immunity test	**IE 61000 test level**	**Compliance level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 1.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Fidelis II laser systems, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = (3.5/V1)\sqrt{P}$ $d = (3.5/E1)\sqrt{P}$ 80 MHz to 800 MHz $d = (3.5/E1)\sqrt{P}$ 800 MHz to 2.5 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 meters (m) Field strength from fixed RF transmitters, as determined by an electromagnetic 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: 
NOTE 1: At 80 MHz and 800 MHZ, the higher frequency range applies. NOTE 2: These guidelines not apply in all situations. Electromagnetic propagation is affected by absorption, reflection from structures, objects and people.			
[a] Field strength 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 measured field strength in the location in which the above mentioned Fotona laser systems are used exceeds the applicable RF compliance level above, the laser systems should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the laser device. [b] Over the frequency range 150 kHz to 80 MHz, field strength should be less then (V_1) V/m.			

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE FOTONA LASER SYSTEMS

The Fidelis II laser system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The operator can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the laser system as recommended bellow, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz d=(3.5/V1)√P	**80 MHz to 800 MHz** d=(3.5/E1)√P	**800 MHz to 2.5 GHz** d=(7/E1)√P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at maximum output power not listed above, the recommended separation distance d is 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.

THE LASER SYSTEM IN OPERATION

4.1 Preparations for Use

- Inspect and assure yourself that the device's cooling air inlet and outlet are not blocked or hindered in any way, for efficient cooling.

  The device should be placed in the laser treatment room so that a minimum 1 meter distance is left between the rear side of the device and any obstacle (e.g. wall, other devices, etc.).
- Inspect and assure yourself that the device's power cord is properly inserted in the mains electrical supply outlet.
- Inspect and assure yourself that the main switch (located at the rear of the device) is switched off.
- Verify that the mains electrical power supply is switched on.
- Check the spray water level.
  Switch the laser system off. Open the lower front panel on the Fidelis II console, with a sharp, quick push. Pull (swing) the reservoir out of the console to check the water level.

4.2 Footswitch and Interlock Connection

- Connect the footswitch connector to its respective port at the rear of the device.

  If the footswitch is not properly connected, the message "USER INTERVENTION ATTACH FOOTSWITCH" appears on the system display after switching on the system.

  The message will remain and the laser will be inoperable, until the footswitch is properly connected.
- A remote interlock plug is supplied with the laser system.
  If the plug is removed, the laser will not operate and the message "USER INTERVENTION ATTACH DOORSWITCH" will appear on the system display after switching on the system.

  To set up the doorswitch interlock, please consult your dealer for assistance.

  The doorswitch interlock port, designated as "DOORSWITCH", is located at the rear of the device. When properly set-up, the interlock will disable the operation of the laser immediately, if the operating room door is opened. The system closes the safety shutter, and reverts to STANDBY mode. The message "DOOR OPEN…INTERLOCK" appears on the display. To resume operation, close the door and press the READY key.

4.3 Laser Beam Delivery Systems and Handpiece Connection

CAUTION !

Since the aiming beam passes down the same laser beam delivery systems as the treatment beam it provides a good method of checking the integrity of the laser beam delivery system.

If in READY mode, the aiming beam spot is not visible at the distal end of the delivery unit, its intensity is reduced or it appears diffused, then this could be an indication of damage to the laser delivery system.

Er:YAG Laser Beam Delivery System and Handpiece Connection

(Note: Applicable for the Fidelis Er II and Fidelis Plus II laser systems.)

The laser system is equipped with a 7-mirror articulated arm, which is permanently attached to the laser system.

The articulated arm must be attached and aligned during installation of the laser system onsite. Only skilled and trained personnel, authorized by Fotona, may perform the attachment and alignment procedure.

A variety of handpieces can be attached to the articulated arm (see the list of compatible handpieces in the “Specifications” section).

WARNING !

Do not switch on the laser system without attaching a handpiece to the articulated arm.

WARNING !

Carefully inspect the Er:YAG handpiece for any eventual damage before attaching it to the articulated arm.

The exit window or fiber tip and the proximal input lens must be clean.

Do not use a damaged handpiece. This may result in accidental fracture of the lens or exit window, lead to excessive laser exposure to the operating room personnel and/or patient, and cause fire in the operating room.

Before switching the system on, select and attach the most appropriate handpiece considering the intended therapeutic application.

Follow the instructions contained in the handpiece’s Operator Manual to assemble and connect the handpiece before use. Additionally, follow the instructions to set the handpiece type on the control panel before use (see the "Selecting the Laser Treatment Parameters" section).

NOTE

The balancing weight located on the arm should be readjusted for each handpiece type. To adjust arm balance, turn the adjusting knob under the balancing weight.

Nd:YAG Laser Beam Delivery System and Handpiece Connection

(Note: Applicable for the Fidelis Nd II and Fidelis Plus II laser systems.)

The Nd:YAG laser incorporated into the laser systems can be coupled to different fiber-optic delivery units with different fiber diameters. Each fiber-optic delivery unit has a SMA905 fiber connector at its proximal end. The fiber connector is placed in an adapter, specially designed by Fotona, for easier attachment to the fiber-coupling port on the system.

Before switching the system on, select and attach the most appropriate handpiece considering the intended therapeutic application.

Before switching on the system, make sure that the fiber-optic delivery unit is properly attached to the fiber-coupling port on the system console. The laser system automatically detects the attached fiber. The laser system disables the laser and displays the message "USER INTERVENTION ATTACH FIBER", in the event that no fiber is attached to the fiber-coupling port.

CAUTION !

Note that the supplied fiber-optic delivery units are not sterile.

They should be sterilized before use according to the instructions in the handpiece's Operator Manual.

CAUTION !

The distal end of the fiber-optic delivery unit is a bare optical fiber.

Only use the supplied tools to strip (remove the protective fiber jacket) and scribe (cut) the fiber.

The fiber's distal end should be scribed before each treatment.

The red aiming beam emerging from the distal fiber end should be a regular, homogenous illuminated circular shape.

Do not use the fiber until it is properly scribed if the shape of the red aiming beam is irregular.

Do not use the fiber-optic delivery unit, if after properly performing the scribing procedure, the red aiming beam is not visible even at the highest aiming beam intensity setting.

Assemble the fiber-optic delivery unit with the handpiece according to the handpiece's Operator Manual.

Do not kink, step on, pull or catch the fiber on any equipment.

Any damage to the fiber beam delivery unit can cause accidental laser exposure to operating room personnel and/or the patient or may cause fire in the operating room.

Follow the instructions to select the laser beam delivery type (see the "Selecting the Laser Treatment Parameters" section).

4.4 Switching the System On and Off

Switching the System On

- Inspect and verify that the "Laser in Use" warning sign has been switched on outside the treatment room.
- All personnel present in the treatment room must wear appropriate laser safety eyewear (see the "Ocular Protection" section).
- Switch on the main power switch located at the rear of the device.

  The system performs a Power On selftest of the built-in microprocessor. The message “TEST PROGRAM CRC” appears on the display

  A “FOTONA LASERS” message appears on the display after completing the selftest.
- Insert the key in the keylock switch and turn it to the ON position.
  The message “RUNNING SELFTEST, PLEASE WAIT” appears on the display. In this mode the system checks the complete device for proper operation.

  After completing the selftest, the system enters the handpiece selection and confirmation menu for the laser type, which was last in use prior to switching off the system.

If during the system selftest any faulty conditions are encountered, any error codes or advisory messages appear on the display, please refer to the "Troubleshooting" section.

Switching the System Off

- *If the laser system is in READY mode, indicated by a red led light in the top right corner of the READY key, press the STANDBY key on the control panel to put the system into STANDBY mode.*
- When the system is in STANDBY mode, turn the key in the keylock switch to the OFF position.
- Remove the key to prevent unauthorized use of the laser system.
- Switch off the main switch.

Emergency Off-Switch

To switch off the laser system in an emergency situation:

- Press the Emergency Stop push button (located on the front panel of the device).
- The message "EMERGENCY STOP" will appear on the display.
- Turn the key in the keylock switch to the OFF position and switch off the main switch.

Restarting the System After an Emergency Stop

To restart the laser system:

- Wait at least 1 minute after having performed an Emergency Off Switch procedure.
- Rotate the Emergency Stop push button to the left to release.
- Switch on the main switch.
- When the “FOTONA LASERS” message appears on the display, turn the key in the keylock switch to the ON position.

4.5 Selecting the Treatment Settings

Selecting the Treatment Laser Source

(Note: Applies to the Fidelis Plus II laser system)

❖ **Selecting the laser source**

When the laser system has performed the selftest, it enters the selection menu of the laser source that was last used.

- Press the SOURCE key.
- Press the “+” or “-“ key to change the laser source.
- Press the SET key to confirm the intended laser source and to enter the handpiece and fiber selection menus.

❖ **Selecting the laser source during treatment**

- Press the SOURCE key twice.
  The system will revert to STANDBY mode, if it is in READY mode.
- Press the “+” or “-“ key to change the laser source.
- Press the SET key to confirm the intended laser source and to enter the handpiece and fiber selection menus.

CAUTION !

After selecting the laser source, select and confirm the fiber-optic delivery unit or handpiece as described below.

Selecting the Er:YAG Laser Treatment Parameters

(Note: Applicable for the Fidelis Er II and Fidelis Plus II laser systems.)

Because different applications can be performed with the laser system's Er:YAG laser source, it is important to select the appropriate handpiece for the intended application.

The various handpieces transmit the treatment laser beam differently. When using the Er:YAG laser, the handpiece attached to the articulated arm and the handpiece type selected on the control panel must match.

Once a handpiece has been selected and attached to the articulated arm, it is important to select and confirm the corresponding handpiece type on the laser system control panel. The handpiece type is engraved on the handpiece body (e.g. R02, R04, R07, etc.).

The display appearances, for dental and dermatological applications, of the Er:YAG laser is shown in Fig. 1a and Fig.1b respectively:

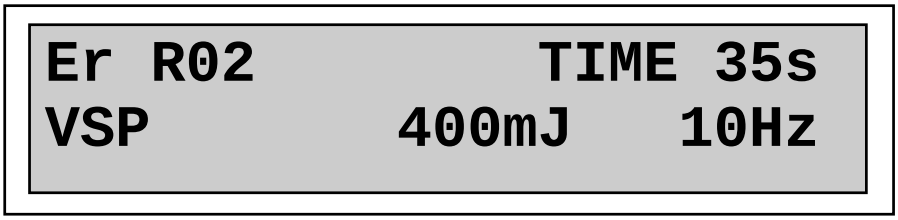


Fig. 1a. Fidelis II Er:YAG display appearance for dental applications

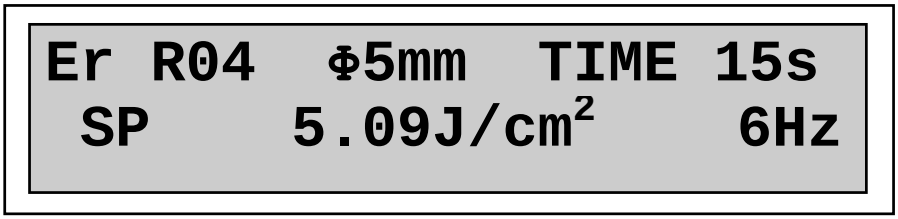


Fig. 1b. Fidelis II Er:YAG display appearance for dermatological applications.

NOTE

Some handpieces are designed for lower maximum output settings. Damage to the handpiece may occur if the handpiece attached to the laser beam delivery system does not correspond with selected handpiece type on the control panel.
While changing the selected handpiece type, the laser parameters (energy and frequency) will change automatically to the parameters last used with the selected handpiece type.

WARNING !

The operator is solely responsible for properly selecting and confirming the handpiece on the system console, according to the intended application.

The delivered energy per pulse can differ significantly from the intended energy per pulse, and can potentially damage the handpiece or optical fiber, if an incorrect handpiece is selected on the control panel.

❖ **Selecting and confirming the handpiece type on the control panel after switching on the system**

Once the selftest is completed, after switching on the system; the system waits for the selection of the handpiece type.

- Press the “+” or “-“ keys until the desired handpiece type (R02, R07, etc.) is displayed.
  The handpiece type selection on the console has to match the handpiece intended for use.
- Attach the corresponding handpiece to the articulated arm.
- Press the SET key to confirm the selected handpiece type. The laser system then enters STANDBY mode and displays the parameters and the selected handpiece type, which were last used before the device was switched off.

The system automatically adapts the transmission of the handpiece for accurate output energy, after confirming the handpiece type.

This procedure assures that the energy of the treatment beam emerging from the handpiece matches the energy value shown on the display.

Some handpieces (e.g. R04, R09 and R11) require the spot size be selected according to the intended application. Press the “+” or “-“ keys and the SET key to confirm the selection (see Figures 1a and 1b).

❖ **Selecting and confirming the handpiece during operation**

If the handpiece type needs to be changed during operation, the handpiece selection on the control panel must be repeated.

- Press the SOURCE key
- Press the “+” or “-“ keys until the desired handpiece type (R02, R07, etc.) is displayed.
- Attach the corresponding handpiece to the articulated arm.
- Press the SET key to confirm the selected handpiece type.

The system itself automatically compensates the transmission of the handpiece for accurate output energy, after confirming the handpiece type.

This procedure assures that the energy of the treatment beam emerging from the handpiece matches the energy value shown on the display.

Some handpieces (e.g. R04, R09 and R11) require the spot size be selected according to the intended application. Press the “+” or “-“ keys and the SET key to confirm the selection (see Figures 1a and 1b).

❖ Selecting the mode of operation

There are six modes of operation available with the Er:YAG laser:

- **SSP** (Super very Short Pulse)
- **MAX** (Maximum Speed Mode)
- **VSP** (Very Short Pulse)
- **SP** (Short Pulse)
- **LP** (Long Pulse)
- **VLP** (Very Long Pulse)

See the “Specifications” section for information on laser pulse length in each mode of operation.

- Press the MODE key
- Press the “+” or “-“ keys to select the desired mode of operation.
- Press the SET key to confirm the selection.

NOTE

While changing the mode of operation, the laser parameters (energy and frequency) will change automatically to the laser parameters last used in the selected mode.

❖ Selecting the energy per pulse

- Press the ENERGY/POWER key
- Press the “+” or “-“ keys to select the desired energy per pulse.
- Press the SET key to confirm the selection.

For handpieces that require spot size selection, pressing the ENERGY key alternates between energy and fluence selection. The basic selection is an energy value; fluence is the energy density value for a chosen spot size.

❖ Selecting the frequency (pulse repetition rate)

- Press the FREQUENCY key
- Press the “+” or “-“ keys to select the desired frequency (pulse repetition rate).
- Press the SET key to confirm the selection.

NOTE

If the system is already in READY mode, changing the energy, frequency, mode of operation or handpiece type (SOURCE) will automatically revert the laser system into STANDBY mode and the safety shutter will close.

The aiming beam power level and water spray settings can also be selected in READY mode without reverting to STANDBY mode.

❖ **Selecting the treatment duration**

- Press the TIME key.
- Press the "+" or "-" keys to select the treatment duration.
- Press the SET key to confirm the selection.

After pressing the footswitch, the laser delivers pulses for the selected duration. To start a new treatment sequence release and press the footswitch again.

The TIME function is enabled, if the green led light is lit. By pressing the TIME key again, the green led light switches off and the TIME function is disabled, meaning that the treatment duration is not limited.

❖ **Checking the laser pulse counter**

Press the COUNTER key. The display shows "Er SESSION" followed by the number of pulses emitted during the last session.

To reset (clear) the pulse counter, press the "-" key.

To check the total number of all Er:YAG pulses, press the COUNTER key again.

The display shows "Er TOTAL" followed by the cumulative number of all Er:YAG laser pulses.

The cumulative laser pulse counter cannot be reset.

Selecting the Nd:YAG Laser Treatment Parameters

(Note: Applies to Fotona laser systems that incorporate an Nd:YAG laser source.)

The display appearance of the Nd:YAG laser is shown in Fig. 2.

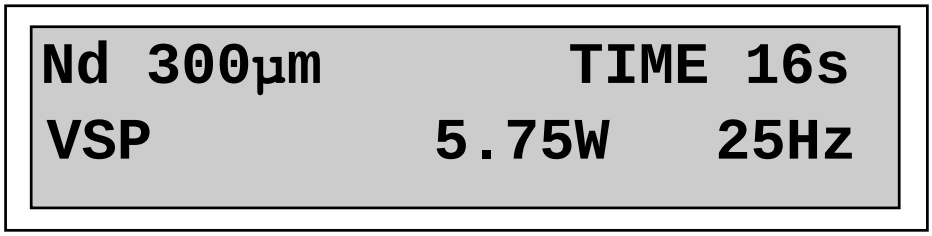


Fig. 2. Fidelis II Nd:YAG display appearance

❖ **Selecting and confirming the fiber-optic delivery unit**

There are three different types of fiber-optic delivery units available with the laser system: 200 µm, 300 µm and R24, it is important to select the appropriate fiber-optic delivery unit according to the intended application.

Once a fiber-optic delivery unit has been selected and attached to the articulated arm, it is important to select and confirm the corresponding fiber-optic delivery type on the laser system control panel.

❖ **Confirming the beam delivery type after switching on the system**

After the selftest has been completed and the Nd:YAG laser source is selected, the system waits for confirmation of the fiber-optic delivery type.

- Press the "+" or "-" keys to select the desired fiber-optic delivery type on the display (200 μm, 300 μm or R24).
- Press the SET key to confirm the fiber-optic delivery type.

The system automatically compensates the transmission of the selected fiber-optic delivery type to provide accurate output power, after confirming the fiber-optic delivery type.

CAUTION !

While selecting the fiber-optic delivery type, assure yourself that the corresponding fiber-optic delivery unit is attached to the system.

The operator is solely responsible for correctly selecting and attaching the corresponding fiber-optic delivery unit according to the selected fiber-optic delivery type and treatment requirements.

For example should the 300 μm fiber-optic delivery type be selected on the system display, with the 200 μm fiber-optic delivery unit attached to the system, serious damage may occur at power levels higher than 5 W.

❖ **Selecting and confirming the fiber-optic delivery type during operation**

If the fiber-optic delivery unit needs to be changed during operation, the fiber beam delivery type selection on the control panel must be repeated.

- Press the SOURCE key to change the fiber beam delivery type.
- Press the "+" or "-" keys to select the desired beam delivery type (200 μm, 300 μm or R24).
- Plug the corresponding fiber-optic delivery unit into the fiber-optic delivery port on the system console.
- Press the SET key.

The selected beam delivery type is shown on the display.

Select other treatment parameters (MODE, POWER, FREQUENCY and TIME), lift the handpiece from the resting place, and press the READY key.

❖ Selecting the mode of operation

There are three modes of operation available with the Nd:YAG laser:

- **VSP** (Very Short Pulse)
- **SP** (Short Pulse)
- **LP** (Long Pulse)

See the "Specifications" section for information on laser pulse length in each mode of operation.

- Press the MODE key
- Press the "+" or "-" keys to select the desired mode of operation.
- Press the SET key to confirm the selection.

❖ Selecting the average power

- Press the ENERGY/POWER key
- Press the "+" or "-" keys to select the average power.
- Press the SET key to confirm the selection.

NOTE

If the system is in READY mode, changing the energy, frequency, mode of operation or beam delivery type (SOURCE) will automatically revert the system to STANDBY mode and the safety shutter will close.

The aiming beam power level and water spray settings can be selected in READY mode without reverting to STANDBY mode.

❖ Selecting the frequency (Pulse Repetition Rate)

- Press the FREQUENCY key
- Press the "+" or "-" keys to select the frequency (Pulse Repetition Rate).
- Press the SET key to confirm the selection.

❖ Selecting the treatment duration

- Press the TIME key
- Press the "+" or "-" keys to select the treatment duration.
- Press the SET key to confirm the selection.

After pressing the footswitch, the laser delivers pulses for the selected duration. To start a new treatment sequence release and press the footswitch again.

The TIME function is enabled, if the green led light is lit. By pressing the TIME key again, the green led light switches off and the TIME function is disabled, meaning that the treatment duration is not limited.

❖ **Checking the laser pulse counter**

Press the COUNTER key on the control panel.

The display shows “Nd SESSION” followed by the number of pulses emitted during the last session.

The pulse counter can be reset by pressing the DOWN key.

To check the total number of all Nd:YAG pulses, press the COUNTER key twice.
The display shows “Nd TOTAL” followed by the cumulative number of all Nd:YAG laser pulses.
The cumulative laser pulse counter cannot be reset.

Selecting the MENU Options

Additional setting options can be reached by pressing the MENU key. Press the MENU key again to select a different MENU setting mode.

To leave any menu setting mode, press the SET key.

❖ **Selecting the aiming beam power level (PILOT).**

- Press the MENU key once to enter the PILOT setting menu.
- Press the “+” or “-“ keys to select the aiming beam power level (visibility).
- Press the SET key to confirm the selection.

Power levels between 0 and 7 can be selected. Level 0 corresponds to no aiming beam and level 7 corresponds to maximum intensity of the aiming beam.

❖ **Selecting the MELODY of the audio signal during treatment**

- Press the MENU key twice to reach the MELODY menu.
- Press the“+” or “-“ keys to select the melody.
- Press the SET key to confirm the selected melody.

Selecting the Water Spray Parameters

❖ **Changing the air and water flow**

- Press the AIR or WATER key to enter the spray setting mode.
  The spray setting mode is activated as shown in Fig.3.
- Press the “+” or “-“ keys to change the air or water flow parameters.
  When the footswitch is pressed in the spray setting mode, the spray is activated without laser action to allow unhindered tuning of the spray.
- Press the SET key to confirm the spray setting.
  The system returns to the laser parameters selection mode

The flow valve is closed completely when the corresponding value is 0. The lit green led light on the AIR or WATER key indicates that the air or water flow is activated, for all other values.

NOTE

By pressing the AIR or WATER keys twice, the AIR or WATER flows can be instantly disabled. In this case the green led light is switched off but the originally selected AIR and WATER values will remain on the screen.

After pressing the AIR or WATER keys again, the green led light will be lit again and the originally selected AIR and WATER values will be valid again, thus enabling AIR and WATER flow.

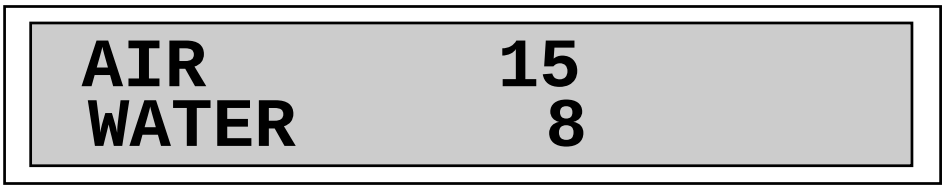


Fig. 3. Fidelis II spray mode display appearance

❖ **Water and air spray offset adjusting mode**

Note that the optimal spray settings for different types of handpieces may differ. When a different handpiece is selected and attached to the system the originally selected optimal spray settings may need adjusting; this is especially noticeable at low spray value settings. In this case the operator has the possibility to change the spray offset, thus unifying the optimal spray values for the different handpieces.

- Press the AIR or WATER key to enter the spray setting mode.
- Press the MENU key twice
- Press the SET key to activate the water and air regulation valves.
- Press the WATER key to calibrate the water spray offset
- Press the “+” or “-“ keys to increase or decrease the water value. Increasing the water value will increase the water flow at the same setting in the spray setting mode.
- **Repeat the same procedure for the air valve.**
- Press the SET key, to activate the water spray setting mode.

Spray Water Refilling

It is advisable to check the spray water level before switching the Fidelis II system on. A low spray water level is indicated by a blinking green led light on the WATER key and an audio beep signal (only in READY mode) when the system is switched on.

- Switch the laser system off.
- Open the lower front panel on the Fidelis II console, with a sharp, quick push.
- Pull (swing) the reservoir
- Press the air relief button on top of the reservoir to reduce the air pressure in the reservoir.
- Unscrew the reservoir
- Clean and disinfect the reservoir.
- Fill the reservoir with fresh water
- Screw the reservoir back tightly to prevent air leakage.
- Return reservoir to the original position in the console.
- Close the lower front panel on the system console.

CAUTION !

It is advisable to replace the spray water in the reservoir at the beginning of each working day.

Clean and disinfect the reservoir before refilling it with fresh water.

Waterline maintenance:

In order to protect patients from contamination through the loss of spray water quality used for cooling and irrigation of the treatment site, spray water quality standards need to be met.

Recommendations for dental unit water quality have been published by the American Dental Association (ADA) not to exceed 200 cfu/ml and the Center for Disease Control (CDC) not to exceed 500 cfu/ml. European Union Drinking Water Standards specify a maximum of 100 cfu/ml. Refer to your national regulatory authorities for recommendations specific to your local area.

It is imperative that the source water meets these requirements. But only using quality source water will not eliminate bacterial contamination in treatment water if biofilms that form in the water system are not controlled. Most strategies to improve the quality of dental water employ the use of chemical treatment. A number of products to remove or inactivate dental unit waterlines biofilm are available in the market.

Fotona recommends the use of A-dec ICX water treatment tablets with sufficient capacity to treat 0.7 l of water. Read and consider the instructions and precautionary statements provided by the manufacturer of the tablets. Every time the water reservoir has to be refilled and at the start of every day, proceed as follows:

- empty the remaining water from the reservoir
- flush the reservoir thoroughly with clean water
- drop the tablet into the empty reservoir (to prevent contamination, avoid touching the tablet)
- fill the reservoir with water and attach to the laser system
- wait 60 seconds for the tablet to fully dissolve.

Contact your local Fotona representative in case you want to use other products.

Test or monitor water bacterial counts before the first use and then weekly (or at other appropriate intervals based on established results). If your water quality goal is not met, treat the waterline system by a single use of higher concentration chemicals (e.g. Sterilex Ultra, *The Sterilex Corp.)* . Only follow the initial startup instructions for Sterilex Ultra and then continue daily use of the above prescribed agents.

Fotona recommends flushing the dental unit waterlines for 20-30 seconds after each patient.

NOTE

It is recommended to use demineralized water with the water spray system to ensure the maximal life-span of the system.

Air/Water Spray Air Bleeding System

An air bleeding system is fitted inside the Fidelis II laser system console to avoid air bubbles entering. The air bleeding device is located on the inner left hand side of the console and is accessible by opening the front panel on the Fidelis II console.

To ensure proper function of the air/water spray, it is strongly recommended to check the air bleeding device for any air at regular intervals, e.g. at the start of each working day when checking the water spray level.

When necessary, bleed the system by pressing the relief button on top of the air bleeding device to remove the collected air from the system. Press the relief button until all air is removed from the air bleeding device reservoir; indicated by water starting to drip from the relief button.

4.6 R14 fiber tip replacement mode

Before proceeding to replace the fiber tip this mode has to be activated. By activating this mode water and dirt contamination in the inner space of the handpiece is reduced.

- Press the AIR or WATER key to enter the spray setting mode.
- Press the MENU key.
- Press the SET key.
  The air flow is activated and the fiber tip can be replaced.
- Press the SET key again when the fiber tip has been replaced.
- The air flow is stopped and the spray setting mode is reactivated

4.7 Intra-Operative Instructions

System READY and STANDBY Modes

The system mode is controlled by the STANDBY and READY keys.
If the system is in STANDBY mode, pressing the READY key will start the calibration of the selected laser parameters.

NOTE

If the Nd:YAG laser source is selected, it is necessary to pick up the Nd:YAG handpiece from its holder before pressing the READY key.

The message "USE Nd:YAG TOOL" appears on the display, if the handpiece is not picked up before pressing the READY key.

Pick up the handpiece or press the STBY key. In both cases the system reverts to STANDBY mode.

If the Er:YAG laser source is selected, the Nd:YAG handpiece should be replaced in its holder on the system console before pressing the READY key.

Immediately after pressing the READY key, a red led light in the upper right corner of the READY key is lit and the message "WAIT" appears on the system display.

The system performs a calibration of the laser with the selected parameters. The safety shutter is closed during the calibration of the laser.

After the calibration is completed, the safety shutter opens, the aiming beam emerges from the handpiece, and the message "EMISSION" appears on the system display.

The footswitch is enabled. By pressing the footswitch, the treatment laser beam with the selected parameters is delivered from the handpiece.

While the footswitch is pressed, an audio signal indicates that the laser is delivering laser energy from the handpiece.

NOTE

If the footswitch is pressed during the calibration process, the advisory message "USERS INTERVENTION RELEASE FOOTSWITCH" appears on the screen.

After releasing the footswitch, the system reverts to STANDBY mode.

To complete the calibration, press the READY key again.

If the system is in READY mode, pressing the STANDBY key reverts the system to the STANDBY mode.

The safety shutter closes.

The system automatically reverts to STANDBY mode, when the treatment parameters are changed (by pressing the MODE, ENERGY/POWER, FREQUENCY, SOURCE or TIME keys) in READY mode.

NOTE

The laser system automatically reverts to STANDBY mode after 3 minutes without any action in READY mode.

CAUTION !

The system must be kept in STANDBY mode at all time, except during actual treatment.
Keeping the system in STANDBY mode prevents accidental laser exposure if the footswitch is inadvertently pressed.

Setting the Aiming Beam Power Level

To observe the visibility of the aiming beam laser, the aiming beam level should be set in READY mode, when the safety shutter is opened.

To adjust the aiming beam intensity, hold a non-reflective surface, such as a wooden tongue depressor, in front of the laser beam delivery unit (fiber-optic delivery unit or handpiece). The aiming beam should appear on the flat surface as a red spot.

Press the MENU key on the control panel and by pressing the "+" or "-" keys adjust the intensity (visibility) of the aiming beam.

WARNING !

While adjusting the aiming beam intensity in READY mode, do not press the footswitch.

In READY mode the treatment beam emerges from the fiber-optic delivery unit or handpiece when pressing the footswitch.

WARNING !

Do not use the fiber-optic delivery unit or handpiece if the red aiming beam is not visible, this may indicate that the fiber-optic delivery unit or handpiece is damaged.

Using the system under these circumstances could result in accidental laser exposure to operating room personnel and/or the patient or may cause fire in the operating room.

Starting the Treatment

- Press the READY key to enter READY mode, if the system is in STANDBY mode.
- Aim the aiming beam at the target tissue.
- Press the footswitch to activate the treatment beam with the selected parameters.

While the footswitch is pressed, an audio signal indicates that the treatment beam is emerging from the fiber beam delivery unit or handpiece.

NOTE

The footswitch can be pressed in 2 stages. By pressing the footswitch down to the first stage, in READY mode, only the air/water spray is activated without treatment laser emission. The treatment laser is activated when pressing the footswitch down completely to the second stage.

The 2 stages in pressing down the footswitch allow the operator to check the spray action and settings before treatment laser energy is delivered to the target tissue.

The operator should check spray action and settings whenever intending to deliver treatment laser energy to the target tissue.

During the Treatment

Note: applicable for laser systems with Nd:YAG laser source

Always revert the system to the STANDBY state and place the Nd:YAG handpiece in its holder on the system console if surgery is interrupted for any reason (e.g. to change the fiber-optic delivery unit or handpiece).

After the Treatment

After the treatment, the following steps should be performed:

- If the system is in READY mode, press the STANDBY key to enter STANDBY mode.
- Turn the key in the keylock switch to the OFF position.
- If desired, switch off the main switch at the rear of the device.
- If desired, disconnect the fiber-optic delivery unit or handpiece.
- Clean the system console and keyboard as instructed in the "Cleaning the Laser Console External Surface" section.
- If desired, remove the footswitch plug from its port at the rear of the device.
- If desired, unplug the power cord of the device from mains electrical supply outlet.

4.8 Moving the System

Before moving the system:

- Switch off the main power switch (located at the rear of the device).
- Lock the articulated arm and remove the fiber-optic delivery unit from its port on the device.
- Disconnect the power plug from the mains electrical supply outlet.
- Disconnect the footswitch from its port on the device.
- If the doorswitch interlock is used, detach its connector from its port at the rear of the device.

4.9 Advisory messages

The laser system displays several advisory messages during normal laser operation and functioning, besides also displaying advisory messages in the event of any irregularities during operation.
The table below lists the different advisory messages displayed by the system, including a description and clarification where thought necessary.
For further information, in the event an advisory message or the circumstances surrounding the advisory message may not be fully understood, we strongly recommend contacting your local Fotona distributor.

Advisory message	Description / Explanation
Fotona Lasers Fidelis Plus II	Appears when the system has completed the start-up procedure, after switching on the main switch at the rear of the device. The key in the keylock switch is in the OFF position.
Test Program CRC 0 .....OK Test Program CRC 1 .....OK	Indicates that the system is performing a Power On selftest of the built-in microprocessor and performing a program integrity check. If an error is detected the system will try to automatically restart and repeat the Power On selftest.
TURN KEY OFF	Appears when the system was switched off with the main switch, and the keylock switch remained in ON position while switching the device on again. Turn the key in the keylock switch to the OFF position and switch the device on again.
Running Self test Please wait	Indicates that the system is about to perform the Power-On Self Test of the system integrated circuitry, during the start-up procedure.
Running Self test	Indicates that the system is performing the Power-On Self Test of the system integrated circuitry, during the start-up procedure. Each dot represents a checkpoint during the self-test. If the system does not complete the self test successfully, it will display a “SYSTEM ERROR XX” message and will shut down. *Contact the technical service.*
Running Self test .....OK	Indicates that the system has successfully completed the Power-On Self Test of the system integrated circuitry, during the start-up procedure.
USERS INTERVENTION INTERLOCK CLOSE DOOR	Indicates that the doorswitch interlock plug is not (properly) inserted in the doorswitch interlock port on the system, OR if the doorswitch interlock connection was installed on the laser operating room door, that the door has been opened. *Insert the doorswitch interlock plug into the doorswitch interlock port at the rear of the system, OR close the door.*

Advisory message	Description / Explanation
USERS INTERVENTION ATTACH FOOTSWITCH	Indicates that the footswitch is not connected. *Connect the footswitch to the device.*
SYSTEM OVERHEATED PLEASE WAIT	Indicates that the system cooling liquid has overheated, possibly due to a too high ambient temperature. *Stop the treatment. Do not switch off the system. Wait at least 10 minutes for the system to cool down and/or until the message disappears. Resume normal operation.*
DOOR OPEN …. …. INTERLOCK	Appears when during normal operation, the laser operating room door has been opened. (Only when the remote doorswitch interlock connector has been installed.) *Close the laser operating room door and press the READY key to resume normal operation.*
USER INTERVENTION RELEASE FOOTSWITCH	Indicates that the footswitch has been pressed too quickly after pressing the READY key. The system requires some time after pressing the READY key to calibrate the laser treatment settings. *Release the footswitch.*
CAN NOT CALIBRATE	Indicates that the selected energy settings cannot be achieved during calibration. *Normal laser operation is possible at lower energy settings. Notify the technical service.*
ENERGY LOW	Indicates that the selected energy settings cannot be achieved during operation. *Normal laser operation is possible at lower energy settings. Notify the technical service.*
USE ND:YAG TOOL	Indicates that the Nd:YAG laser handpiece is still in its resting position in the handpiece holder in READY mode, after pressing the footswitch. *Pick up the Nd:YAG handpiece and continue normal operation.*
RELEASE ND:YAG TOOL	Indicates that the Nd:YAG handpiece has not been placed in its resting position in the handpiece holder, while the Er:YAG laser has been selected for use. *Place the Nd:YAG handpiece in its resting position in the handpiece holder.*
USERS INTERVENTION ATTACH FIBER	Indicates that the Nd:YAG fiber-optic beam delivery unit is not attached to the fiber-optic port on the laser system. *Attach the Nd:YAG fiber-optic beam delivery unit to the system.*
SYSTEM ERROR	Indicates that an error has been detected. The device will be automatically disabled. *Notify the technical service immediately.*

Advisory message	Description / Explanation
EMERGENCY STOP	Indicates that the Emergency-Off Push Button was activated. *Follow the "Restarting the System" procedure described in this operation manual.*

MAINTENANCE

5.1 General

The Fotona laser systems have been designed to provide years of trouble-free operation.
The built-in computer processor performs self-diagnostics and initiates corrective actions when necessary, as well as automatic calibrations to ensure a properly functioning system.
If a non-correctable error is detected, the laser system will disable and a message will be displayed on the screen.

Er:YAG Laser (applicable for laser systems with Er:YAG laser source)

A dirty window, lens or damaged fiber tip on the handpiece are the most common cause of reduced transmission of the Er:YAG laser beam.

In this case, it is advisable to clean the window, lens or to replace the fiber tip.

If the handpiece lenses or misalignment of the articulated arm cause the failure, they should be replaced or aligned by technical service.

Nd:YAG Laser (applicable for laser systems with Nd:YAG laser source)

A decrease in system performance in most cases indicates that the exposed distal end of the fiber-optic delivery fiber must be stripped and scribed (cut), or replaced.

If no visible aiming beam emerges from the fiber, it is advisable to replace the fiber-optic delivery unit assembly.

Replacement fibers can be purchased from the local Fotona distributor.

5.2 Troubleshooting Guide

All laser systems are rigorously, environmentally and mechanically tested.

In the unlikely event that the laser system fails to operate properly most errors are detected and displayed by the system itself.

If the system displays a message, which advises you to call technical service, do not attempt to repair the device yourself or to open the console.

Because of high voltages in the device, any unqualified repair attempt may be life threatening.

Before switching on the system, always verify:

- that the mains electrical power supply is on.
- that the main switch is in the OFF position and all electrical connections are correct and intact.
- that the doorswitch interlock plug is inserted in the doorswitch interlock port, if the doorswitch interlock is used in conjunction with a remote switch. Close the interlock protected door.
- that the beam delivery system is properly connected.
- that the footswitch is properly connected.

CAUTION !

Do not use the device, if the control panel display does not show anything, after switching on the main switch at the rear of the device and after turning the key in the keylock switch to the ON position
Switch the system off and notify the technical service.

NOTE

If an error is detected and the device does not display a message, switch the system off.
Wait for 1 minute and then switch the system on again.
In case the error repeats, notify the technical service.

Errors with advisory messages (such as “Attach footswitch”, “Attach doorswitch”, etc.) can be remedied by the user.

All other errors detected by the system and displayed as "SYSTEM ERROR XX", need the intervention of the technical service. In such cases, please notify your Fotona representative and/or notify the technical service.

5.3 Operator Maintenance

Cleaning the Laser Console External Surface

After each treatment session, wipe the external surface of the laser console and the control panel with a cloth dampened with a non-caustic cleaning solution, such as soap and water, isopropyl alcohol, or a “hospital-grade” disinfectant, in order to maintain cleanliness and hygiene.

Dry the console with a clean cloth.

Do not spray or pour cleaning agents on the laser system console.

Cleaning the Cooling Air Filter

An air filter, to filter incoming cooling air, is located behind the laser front panel. The air filter cartridge can be easily removed by pushing down the handle, which is accessible from the bottom part of the front panel.

After removal, clean the air filter or replace it. New air filters are available from the local Fotona distributor.

Reassemble the air filter cartridge in reverse order.

A dirty and blocked air filter may reduce the cooling capacity of the system, which may lead to overheating of the laser.

The air filter should be cleaned at least twice a year.

Electrical power supply

Electrical power must be supplied from a 230VAC ±10%, single phase, 50/60Hz, 16A outlet with a grounding.
The system comes with a power cord that cannot be detached from the device.
An adequate plug and electrical power supply outlet must be provided and all electrical requirements must be fulfilled prior to installing the system onsite.

The system has been designed to provide allowable leakage currents for Class I, Type B devices in accordance with the requirements of EN 60601-1 (IEC 60601-1) and UL 544; an additional isolation transformer is not required.

For safety reasons, periodical testing of the onsite electrical power supply utilities on a yearly basis, including measurements of leakage currents, is recommended. It is advisable to have the testing done by a qualified and certified technical service.

Water Utilities

The Fotona Fidelis lasers incorporate an internal self-contained cooling system.
No water utilities for cooling purposes are required for system operation.

Evacuation (Suction) Utilities

The customer must provide an efficient evacuation utility to be used for suction of the remains of ablated and vaporized tissue.

The filters in this evacuation utility must be checked and replaced regularly by the customer according to its manufacturer's instructions.

5.4 Regular Maintenance

Replacing the Deionizing Cartridge

The laser system is cooled by a closed loop water-to-air heat exchanger.

A deionizing cartridge has been incorporated in the cooling system, to keep the cooling liquid clean and deionized.

The deionizing cartridge should be replaced once a year. It is advisable to replace the deionized cooling liquid at the same time.

NOTE
The deionizing cartridge and the cooling liquid should be replaced only by qualified service personnel, authorized by Fotona.

NOTE

The air filter should only be replaced by qualified service personnel, authorized by Fotona.

Regular Inspection of Laser Safety Related Features

❖ **Energy meters calibration**

The laser system incorporates two energy meters per laser source; they should be checked for calibration on a yearly basis.

NOTE

The energy meters should only be calibrated by qualified service personnel, authorized by Fotona.

❖ **Leakage currents and grounding impedance of the laser system measurements**

This procedure should be performed on a yearly basis. The earth leakage current and patient leakage current, as well as the grounding impedance of the laser system should be measured during the procedure.

NOTE

Leakage currents and grounding impedance should only be measured , according to the instructions in the system's Service Manual, by qualified service personnel, authorized by Fotona.

SPECIFICATIONS

6.1 LASER:

Fidelis II Er:YAG laser

Laser wavelength:	2940 nm
Output energy per pulse:	80 to 1500 mJ in 10 mJ steps
Pulse repetition rate:	2 to 50 Hz
Max. average power:	20 W
Pulse width:	Variable in 5 steps: SSP Mode: 50 microseconds VSP Mode: 100 microseconds SP/MAX Mode: 300 microseconds LP Mode: 600 microseconds VLP Mode: 1000 microseconds
Laser system classification: (according to EN 60825-1/2001 or IEC 825-1 or US CDRH CFR 21 1040.10)	Class IV
Classification according to MDD/93/42/EEC, Annex IX 9/12.7.93:	Class IIb, Rule 9

Fidelis II Nd:YAG laser

Laser wavelength:	1064 nm
Output power:	0.25 to 15 W in 0.25W steps
Pulse repetition rate:	10 to 100 Hz in 5 Hz increments
Pulse width:	VSP Mode: 100 microseconds SP Mode: 180 microseconds LP Mode: 320 microseconds
Laser system classification: (according to EN 60825-1/2001 or EC 825-1 or US CDRH CFR 21 1040.10)	Class IV
Classification according to MDD93/42/EEC, Annex IX 9/12.7.93:	Class IIb, Rule 9

6.2 GENERAL:

Power requirements:	- rated voltage: 230 V - long term input power: 3.0 kVA - long term current rating: 13 A - momentary input power: 3.9 kVA - momentary current rating: 17 A - frequency: 50/60 Hz
Electrical connection:	non-detachable power supply cord
Class of equipment:	Class I equipment
Type of equipment:	Type B equipment
Protect. earth impedance	< 200 mΩ
Leakage currents:	- earth leakage currents < 500 µA - patient leakage currents < 100 µA
Circuit breaker:	16A
Target indicating device:	- aiming beam - semiconductor diode laser at a wavelength of 650 nm - Power 1 mW max. - adjustable in 7 steps from 0 to max. - Laser Classification: Class I
Safety goggles:	To operate the device, according to EN 207/1998 and EN 60825-1/2001 safety goggles with the following safety levels are prescribed: - 2940 nm I,R L5 (for Europe) OD 5 (elsewhere) - 1064 nm I,R L7 (for Europe) OD 7 (elsewhere)
Mechanical:	
Construction:	mobile equipment
Degree of protection:	IPX0 (IEC 529)
Cooling:	internal water-to-air
Dimensions:	55 x 33 x 82 cm (Length x Width x Height)
Weight:	Console 88 kg without articulated arm Shipping weight 145 kg

Environmental conditions:

Operation:	- ambient temperature range +10 °C to +25 °C; must be above dew point - relative humidity range of 30% to 75% - non condensing - atmospheric pressure range of 700 hPa to 1060 hPa
Storage and transport:	- ambient temperature range -40 °C to +70 °C (without cooling water) - relative humidity range of 10% to 100% (incl. condensation) - atmospheric pressure range of 500 hPa to 1060 hPa

External connections:

- Potential equalization terminal
- Doorswitch connector (NC contact)
- Footswitch connector (NC & ON contact)

Footswitch cable length:	3 m
Power cord length:	2 m

Compatible beam deliveries:

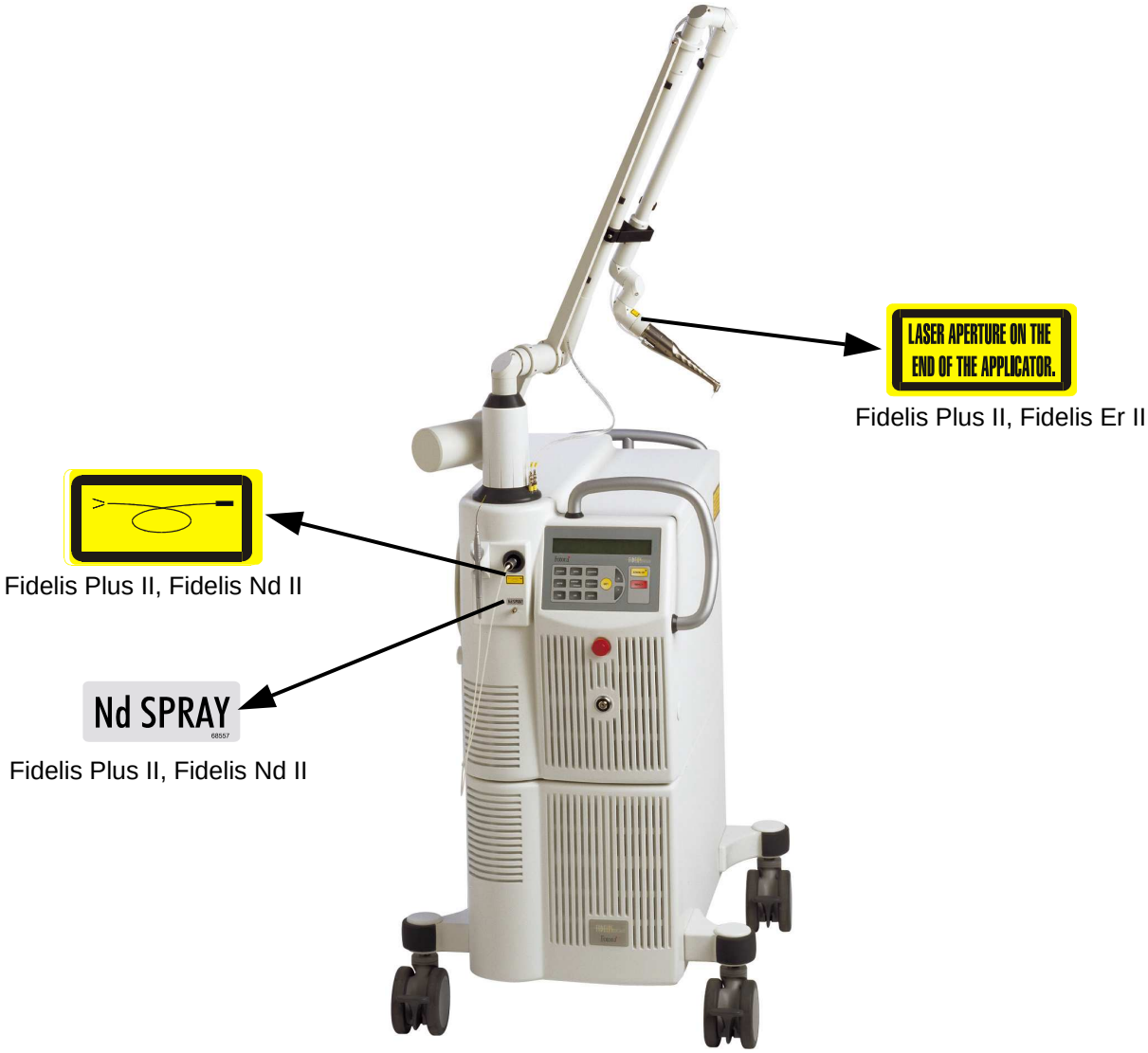
For Er:YAG laser: *(Fidelis Er II and Fidelis Plus II)*	7-mirror articulated arm permanently attached to the system
For Nd:YAG laser: *(Fidelis Nd II and Fidelis Plus II)*	Fiber-optic delivery units with fiber core sizes: - 200 µm - 300 µm

Compatible handpieces:

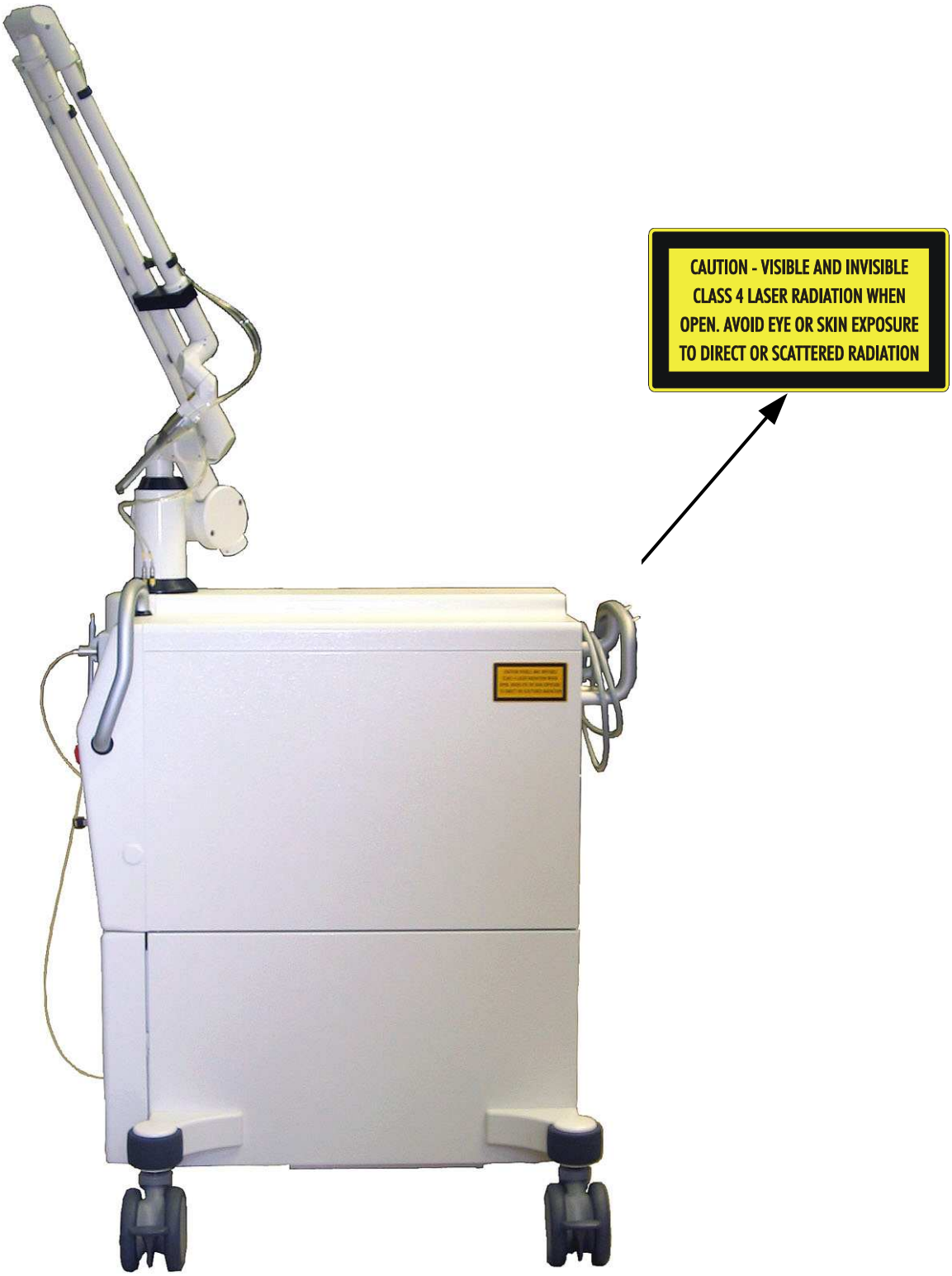
For Er:YAG laser :	R02-F, R04-F, R05-F, R06-F, R07, R08, R09-2, R09-3, R09-2G, R11, R14-A, R14B
For Nd:YAG laser :	R21, R22, R24

LABELLING

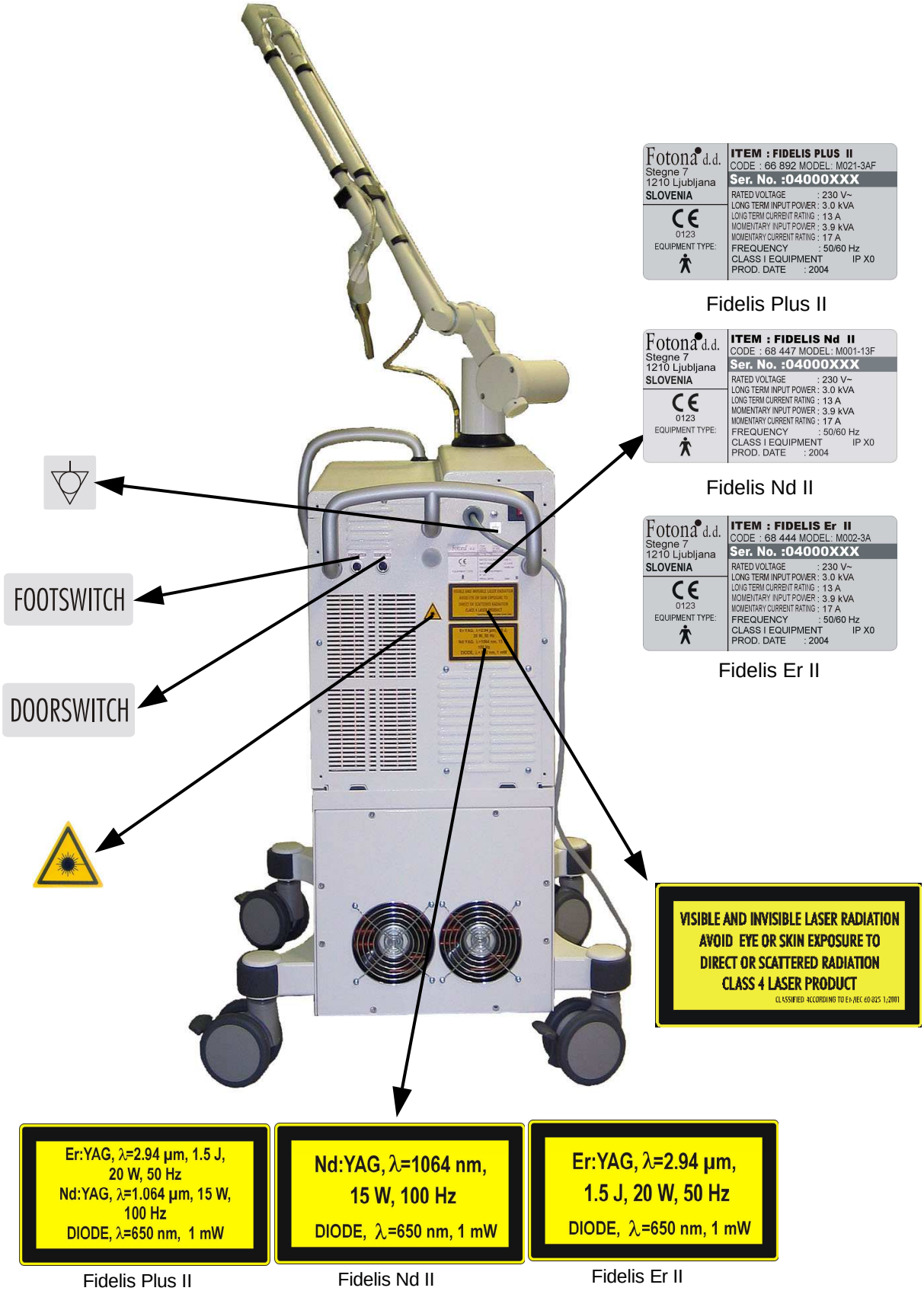
According to EN 60825-1 and EN 60601-2-22 safety standards, the Fotona laser systems have warning labels on specific locations to indicate conditions under which the operator could be subjected to laser radiation.
For the label locations, refer to the figures below.



Fidelis Plus II front view



Fidelis II side view



Fidelis II rear view

STORAGE AND SHIPMENT

The laser system has been designed for long-term storage in a normal office environment.

Protect the system from adverse conditions such as extreme temperature and condensing moisture.

In no case should the laser system be exposed to temperatures below 0°C. Cooling system damage, as well as moisture induced damage to the electronics of the system could ensue under such circumstances.

If long-term storage is anticipated, enclosing a package with fresh silica-gel desiccant will protect the console from condensed water.

WARRANTY

The laser system is warranted to be free from defects in components and workmanship for 12 months from the date of installation at the original purchaser onsite.

The warranty expires if personnel, not authorized by Fotona, take part in any attempted repairs to the system. The warranty does not apply in the event of misuse, negligence or accidental damage.

Note that certain limitations apply to Fotona's warranty. The handpieces are warranted for 60 days. The optical parts (such as lenses, sapphire windows, fiber tips), which are in contact with the operator or patient while operating the handpiece, are not under warranty.

9.1 Warranty Shipments, Returns and Adjustments

Any warranty claim must be made promptly and must be received by Fotona within the applicable warranty period.

In the event that the device must be returned for repair and/or adjustment, authorization from Fotona must be obtained. Instructions on how and where the device should be shipped will be provided by Fotona. Any system or component, returned for examination and/or repair under warranty, should be shipped insured and prepaid via the means of transportation specified by Fotona. Shipping charges for all systems or components, replaced or repaired under warranty, shall be the sole responsibility of the purchaser.

In all cases Fotona has sole responsibility for determining the cause and nature of the failure, and Fotona's determination with regard thereto will be final.

The foregoing warranty is exclusive and in lieu of all other warranties, whether written or oral or implied and shall be purchaser's sole remedy and Fotona's sole liability under contract or warranty or otherwise for the product. Fotona disclaims any implied warranty or merchantability or fitness for a particular purpose.

In no event can Fotona be held liable for any incidental or consequential damages arising from or in connection with the use or performance of the goods delivered hereunder.

The primary purpose of this provision is to limit Fotona's potential liability arising from this sale.

9.2 Decontamination of Returned Equipment

Equipment sent back to Fotona or authorized service facilities for repair, must be properly decontaminated in order to comply with transportation laws.

The decontamination must be performed with a chemical germicide approved for use as a "Hospital Disinfectant".

A Decontamination Certificate (provided in this Manual) must be enclosed with the shipment.

If equipment is received without a Decontamination Certificate, Fotona will assume that the equipment is contaminated and will charge the customer with the cleaning costs.

ENERGY METERS CALIBRATION PROCEDURE

NOTE

Only qualified service personnel, authorized by Fotona, should perform the calibration procedure.

NOTE

A calibrated energy/power meter with measurement accuracy of at least ± 7 % at wavelengths 2940 nm and 1064 nm should be used to perform the calibration procedure.

The purpose of the calibration procedure is to check whether the output energy corresponds to the energy set by the operator and displayed on the control panel screen within an accuracy range of ± 20 percent.

The laser system uses two energy meters per laser. The feedback energy meter is used to control the output energy with a digital on-line feedback loop. The monitor energy meter reading must match the reading of the feedback energy meter. This forms a double safety structure.
If the readings of these two energy meters differ for more then a prescribed value, the system will disable the laser, close the safety shutters, block the entire system and display an energy meters mismatch message.

The laser system uses laser beam delivery systems, which have certain losses in transmitted laser beams.
To assure the system displays the treatment energy accurately, these losses are compensated by the system itself.

10.1 Energy Meter Calibration Procedure for the Er:YAG Laser

(Note: Applicable for laser systems with an Er:YAG laser source.)

NOTE

Carefully inspect the attached handpiece for damage before the calibration procedure.

The exit window or fiber tip and the proximal input lens must be clean.

It is advisable to use a new exit window or fiber tip for the calibration procedure.

The Er:YAG laser energy meter calibration procedure is as follows:

- Switch on the system.
- Select the Er:YAG laser source and the corresponding handpiece.
- Enter the laser parameters menu and set laser parameters to the values most frequently used.
- Disable the spray function by setting WATER and AIR to 0.

- Press the READY key. After the safety shutter opens, aim the red aiming beam at the center of the external energy meter at a distance of approximately 15 cm.
- Press the footswitch and compare the measured energy displayed by the external energy meter.

  The energy meter is calibrated correctly, if the readings correspond to the set energy within a ± 20 % range. The system energy meter or the laser beam delivery system transmission factor has to be recalibrated, if the values differ for more than ± 20 %.system.

  Refer to the Service Manual for this service procedure.
- Repeat the measurements at different laser settings.

10.2 Energy Meter Calibration Procedure for the Nd:YAG Laser

(Note: Applicable for laser systems with an Nd:YAG laser source.)

NOTE

Before starting the energy meter calibration procedure, check if the red aiming beam exiting the handpiece is a regular round shape.

If it is not, the fiber-optic delivery unit may be damaged at the proximal or distal end or the fiber coupling optics may be misaligned.

To check the alignment of the fiber coupling optics, please refer to the Service Manual.

If the fiber coupling optics is aligned and distal end of the fiber is properly scribed, but the emerging aiming beam is still not of a regular round shape, then replace the complete fiber-optic delivery unit.

Proceed with the calibration procedure described below if the shape of the aiming beam is regular.

The Nd:YAG laser energy meter calibration procedure is as follows:

- Switch on the system.
- Select the Nd:YAG laser source and the corresponding fiber-optic delivery type.
- Enter the laser parameters menu and set laser parameters to the values most frequently used.
- Disable the spray function by setting WATER and AIR to 0.
- Press the READY key. After the safety shutter opens, aim the red aiming beam at the center of the external power meter at a distance of approximately 15 cm.
- Press the footswitch and compare the measured energy displayed by the external energy meter.

  The system energy meter is calibrated correctly, if the readings correspond to the set energy within a ± 20 % range. The system energy meter or the beam delivery system transmission factor has to be recalibrated, if the values differ for more than ± 20 %.

  Refer to the Service Manual for this service procedure.
- Repeat the measurements at different laser settings.

DECONTAMINATION CERTIFICATE

The undersigned certifies that the Fotona device being returned herein by

_____	_____
Individual/Institution	City, State, Country

has been cleaned and is free from biohazards, including - but not limited to - human or animal blood, tissue or fluids or components thereof.

The undersigned also agrees to reimburse Fotona for any costs incurred in cleaning the enclosed equipment, in the event said item(s) are received by Fotona in a contaminated condition.

_____	_____
Model	Model
_____	_____
Serial No.	Serial No
_____	_____
Typed/Printed Name	Position/Title

_____
Signature and Date