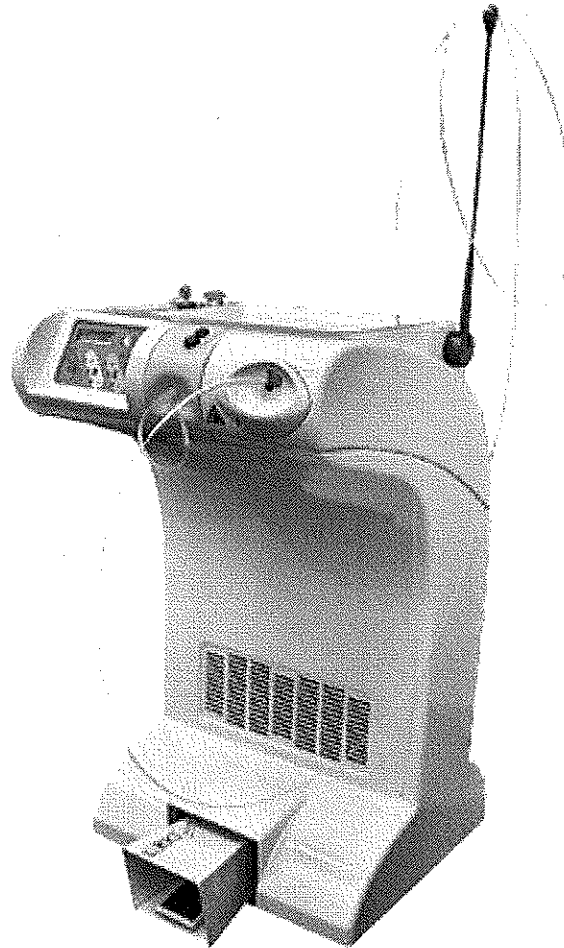




USER MANUAL

for the LOKKI Lis SURGICAL LASER



Tel: 781-935-0004
Fax: 781-935-7602
www.bryancorp.com

IMPORTANT
READ THIS MANUAL BEFORE USING YOUR LASER



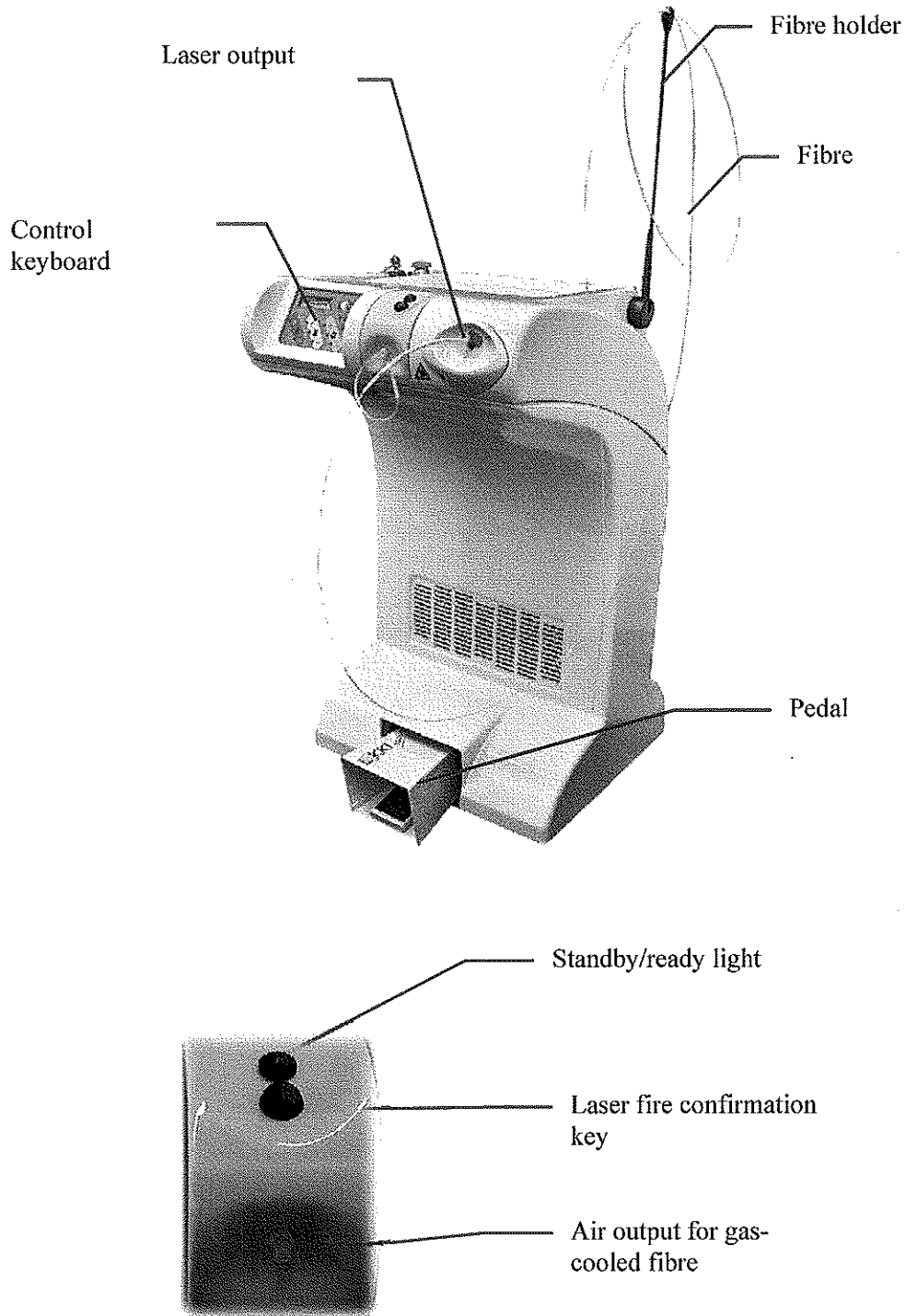
LOKKI 14, rue Frédéric Mistral 38 370 Les Roches de Condrieu (France)
Tel: (33) 04 74 31 61 00 Fax: (33) 04 74 31 61 37 E-mail: lokkisa@lokki.fr

CONTENTS

1	LOKKI Lis DESCRIPTION	4
2	INTRODUCTION	5
3	GENERAL DESCRIPTION	5
3.1	Operating principle	5
3.2	Description of the appliance	5
3.2.1	Control keyboard	5
3.2.2	Laser output	7
3.2.3	Control pedal	7
3.2.4	Fibre holder	7
3.2.5	Stopping/Starting	8
3.2.6	Electric power supply	9
3.2.7	Accessories	9
4	TECHNICAL SPECIFICATIONS	11
4.1	Appliance specifications	11
4.2	Safety systems	12
4.2.1	Switch key	12
4.2.2	Emergency stop	12
4.2.3	On lights	12
4.2.4	Door safety or external safety	12
4.2.5	Laser standby/ready	12
4.2.6	Safety labels	13
4.2.7	Pedal	14
4.2.8	Safety shutter	14
4.2.9	Electrical safety	14
4.2.10	Safety trips	14
4.2.11	Alarm system	15
4.2.12	Laser output safety	16
4.2.13	Eye safety	16
5	INSTALLATION, STARTING UP, USE	17
5.1	Room for use	17
5.2	Optical fibre installation	17
5.3	Starting up	17
5.4	Choosing the emission mode	18
5.5	Aiming beam	19
5.6	Stopping system	19
6	HANDLING PRECAUTIONS	20
6.1	Safety measures	20
6.2	Optical fibre	20
7	INFORMATION ON CLINICAL APPLICATIONS	21
7.1	Effect on tissue	21
7.2	Main indications	21
7.2.1	THORACIC SURGERY	21
7.2.2	GYNECOLOGY	21
7.2.3	PNEUMOLOGY	21

7.2.4	ENT	21
7.3	Advice for clinical use	22
7.3.1	Chosen setting	22
7.3.2	Laser firing duration	22
7.3.3	Moving the fibre	22
7.3.4	Cleaning the fibre	22
7.3.5	Recommendations	22
7.4	Reminders on laser physics	23
7.4.1	Theoretical table of energy density according to the distance between the fibre and the tissue	23
7.4.2	Theoretical table of spot diameter according to the distance between the fibre and the tissue	23
7.4.3	Theoretical graphical representation to scale (x20) of the surface of the area treated with fibres of 320 μm , 600 μm and 800 μm	24
7.4.4	Comparison of theoretical energy density ratios between fibres according to distance	24
8	MAINTENANCE	25
8.1	Annual inspection of your appliance	25
8.2	Your everyday maintenance	25
8.3	Sterilisation and Disinfection	25
8.3.1	The appliance	25
8.4	Changing the optical fibre	25
8.5	Putting in or changing the cooling liquid	26
9	TROUBLESHOOTING	27
9.1	Definition of the most common problems	28
10	CALIBRATION	30
11	STORAGE AND TRANSPORT CONDITIONS	31
11.1	Packaging:	31
11.2	Storage and transport:	31
12	CONDITIONS OF USE	32
13	CONTACT DETAILS	33
14	APPENDICES	34
14.1	Installing an optical fibre	35
14.2	Single-use fibres	36
14.3	DEEE/WEEE directive	37

1 LOKKI LIS DESCRIPTION



2 INTRODUCTION

LOKKI *Lis* is an Nd:YAP laser designed for endoscopic surgery, with applications in various areas: thoracic surgery, pneumology, ENT and gynaecology.

IMPORTANT: *This appliance must ONLY be used by surgeons who have received special training and have familiarised themselves with this manual.*

LOKKI will not be held liable for any use of the appliance or part of the appliance other than that set out in this manual.

3 GENERAL DESCRIPTION

3.1 Operating principle

The LOKKI *Lis* laser is an Nd:YAP pulsed laser.

This appliance works with a technology which uses the Nd:YAP crystal (Yttrium-Aluminium-Perovskite doped with Neodymium), emitting a wavelength of 1 340 nm, making it possible to obtain specific effects on tissues.

The laser beam is emitted in the form of short pulses (200 μ s), at a rate which can be varied according to the desired action mode.

It is transmitted by thin, flexible optical fibre, which is carried to the area to be treated using an endoscope channel.

The 1 340 nm wavelength is absorbed to a high degree by the tissues, and in particular by the water they contain. The luminous energy of the laser beam is thus converted into thermal energy, in a concentration high enough to induce coagulation and/or vaporisation.

IMPORTANT: *The optical fibres are specific to our laser and its wavelength. Using other fibres may destroy your appliance and these fibres: Major risk of hazardous exposure to laser radiation.*

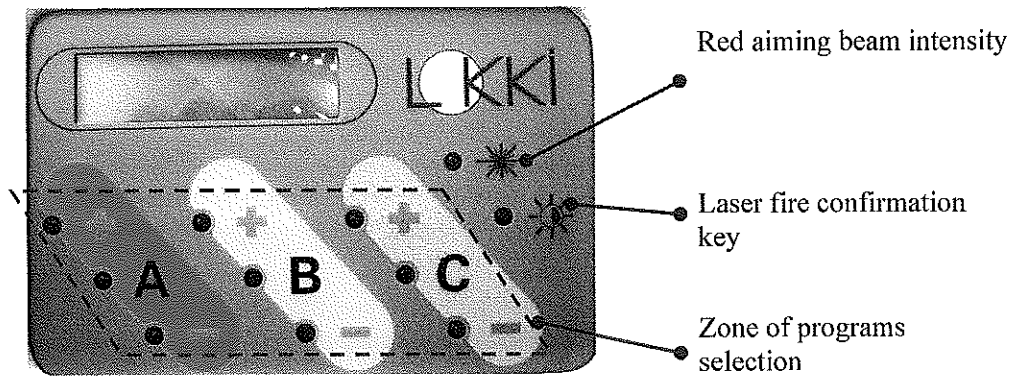
3.2 Description of the appliance

LOKKI *Lis* is a compact appliance which is very easy to use.

3.2.1 Control keyboard

A simple, clear keyboard (next page) lets you choose and measure the desired action mode. It is controlled by a microprocessor and shows the laser emission parameters using a liquid crystal display and lights near the selection keys.

There are 9 preset parameters for ease of use. The keyboard is divided into three programme selection zones which correspond to different treatment types.



Zone	Keys	Example of functions performed
Red zone (A)		Coagulation – vaporisation - cutting
Yellow zone (B)		Vaporisation - coagulation
Green zone (C)		Hard tissue ablation – localised effect

For each zone, three power settings are possible:

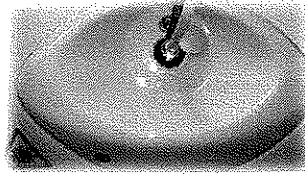
Setting zone	Keys	Level
Top key (+)	or or	maximum power
Central key (=)	or or	medium power
Bottom key (-)	or or	minimum power

Control keys:

Laser fire confirmation key	or	Stop or start status represented by the corresponding light
Intensity setting key for the red aiming beam		4 power levels by pushing the key repeatedly, represented by the corresponding light

3.2.2 Laser output

The fibres are connected at this opening, which is protected by a cover.

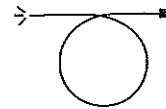


Yellow symbol



Standard symbol
Laser radiation warning

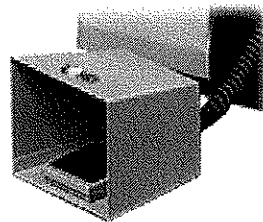
Symbol at laser output



Laser beam output area
“Optical instrument” standard symbol

3.2.3 Control pedal

The control pedal may be taken out of its housing and positioned to better suit the user’s working position.

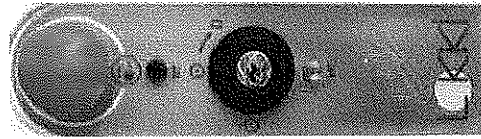


3.2.4 Fibre holder

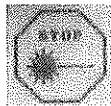
This holds the fibre during use and stops it from falling to the ground.

3.2.5 Stopping/Starting

The switch key is located at the top of the appliance, along with the appliance's emergency stop button.



3.2.5.1 Definition of the symbols in this area



Standard symbol located under the emergency stop button showing the "Laser emergency stop" function

Permanent key position: laser on if started.

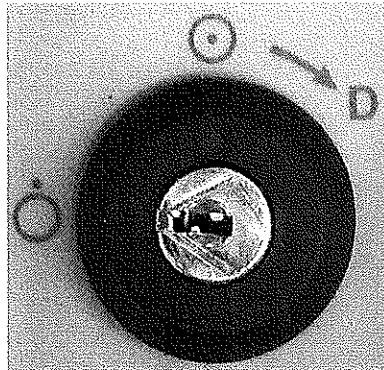


"Standby/Ready" standard symbol

Permanent key position: laser stopped



"Power off" standard symbol



Temporary position for turning the laser on

Green light



Shows there is mains voltage in the appliance

Yellow light

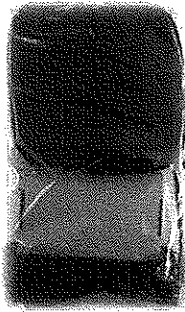


Shows the appliance is turned on

3.2.6 Electric power supply

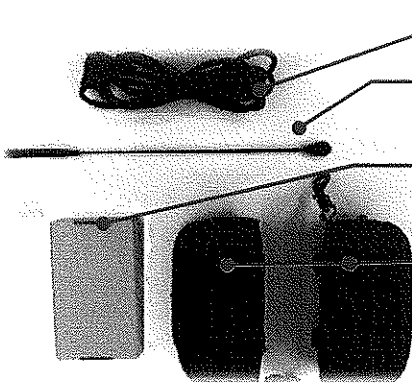
The laser is plugged into a mains socket with the specifications set out in [§ 4.1](#). A fastening system is provided at the back of the appliance to roll up the mains lead supplied.

3.2.7 Accessories



● Accessory packet

Accessory packet contents



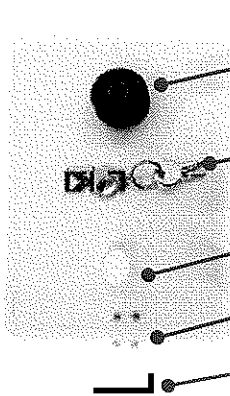
● Power cord

● Fibre holder

● Accessory box

● 2 x pairs of protective goggles. . See [§3.2.7.1](#)

Accessory box contents



● Endoscope filter. See [§3.2.7.2](#)

● 2 x switch keys

● Air filter

● 2 x fuses

● Allen keys

3.2.7.1 Pair of goggles

The pair of protective goggles must be worn during treatment for safety reasons. These goggles are specific to the specifications of this laser and meet the NF EN 207 standard. See eye safety §4.2.13

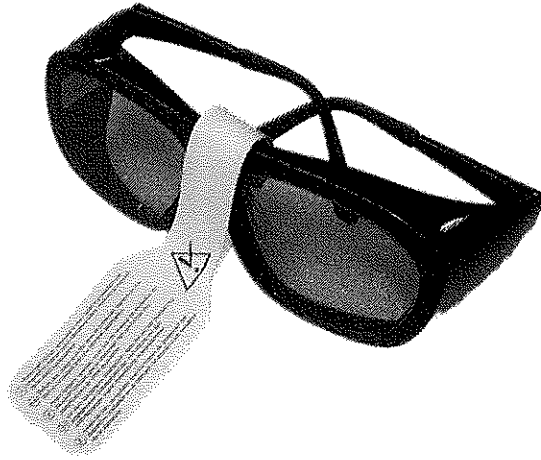


Photo shown for information purposes only

3.2.7.1 Filter endoscope

For direct vision endoscopy, the surgeon must either wear special protective goggles (required optical density 4 at a wavelength of 1 340 nm), or place the eye filter, delivered with the machine, onto the endoscope. See Accessories §3.2.7.



4 TECHNICAL SPECIFICATIONS

4.1 Appliance specifications

- Treatment laser : Nd:YAP (Class 4)
- Wavelength : 1 340 nm
- Max average power : 20 Watts (+20% / - 10%)
- Peak power : 4 kW
- Pulse duration : 200 μ s (+50 μ s)
- Repetition rate : 5, 10 and 30 Hz
- Aiming laser : red laser diode (655 nm)
- Aiming laser power : 3 mW
- Beam transmission (specific to Medisurge s.a.s):
 - Sheathed non-gas-cooled optical fibres of 320 μ m
 - Sheathed gas-cooled or non-gas-cooled optical fibres of 600 μ m
 - Sheathed gas-cooled or non-gas-cooled optical fibres of 800 μ m
- Beam divergence : Digital Aperture = 0.22 or approximately 12.7° (semi-angle at fibre outlet)
- Nominal ocular hazard distance (NOHD): 5.80 m
- Eye protection: Required optical density 4 minimum at 1340 nm in compliance with NF EN207 standard
- Selection of 9 programmes by microprocessor-controlled keyboard:
 - Three preset action modes:
 - Red zone (A): 30 Hz (vaporisation, soft tissue coagulation)
 - Yellow zone (B): 10 Hz (surface vaporisation)
 - Green zone (C): 5 Hz (hard tissue ablation, localised effect)
 - Three power levels for each mode (+, medium, -)
- Controlled by double switch moving pedal
- Mains power supply
 - 115V- 12.5A single phase with earth
 - 2 x Time delay fuses: 12.5AT size: 5x20
- Classification: class 1, Type BF
- Operating mode: intermittent
- Independent liquid cooling in closed circuit (contains: 2.8 litres)
- Ordinary device, not protected against water logging
- Mobile device, on 4 swivelling castors
- Size:
 - width : 460 mm
 - depth : 535 mm
 - height : 800 mm
- Weight: 57 kg

IMPORTANT:

Appliance not suitable for use in the presence of:

- *any flammable anaesthetic mixture*
- *oxidising gases*
- *oxygen-saturated cotton wool-type materials which may ignite at high temperatures*

4.2 Safety systems

IMPORTANT: *In order to ensure that this class 4 appliance is used in the safest possible conditions, it is important to know and understand the various safety measures and requirements intended for this purpose.*

PLEASE NOTE: *Using the controls and adjusting the settings or performing procedures in any way other than specified here may cause hazardous exposure to laser radiation.*

4.2.1 Switch key

IMPORTANT: *LOKKI Lis may only be used by surgeons who have received special training and familiarised themselves with the appliance.*

Therefore, a key system (2 keys are provided with the appliance) ensures that it can only be started up by the person in charge following a cycle of 2 separate stages, providing a cooling off period to prevent accidental start-up. This system starts and stops the appliance.


PLEASE NOTE: *When the laser is not in use, the key (at the "STOP" position) must be removed to avoid it being used by any unqualified or unauthorised person.*


4.2.2 Emergency stop

An "Emergency stop" button, located at the top of the appliance, means it can be stopped immediately in hazardous or uncontrolled situations. This button must always be accessible to any person in the vicinity of the laser.

IMPORTANT: *Do not place the laser in an area where access to the switch key and emergency stop button is blocked.*

4.2.3 On lights



A green light  located next to the key at the top of the appliance shows that the appliance is connected to mains power.

An orange light  located next to the key at the top of the appliance lights up when the laser has started and can be used after its initialisation phase.

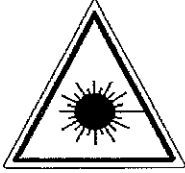
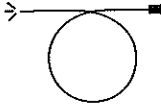

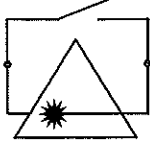

4.2.4 Door safety or external safety

A remote locking connector, when connected to a shut-off switch for the door of the room, only authorises laser emission if the door is closed. However, so that the appliance can be used, it is delivered with a plug which temporarily neutralises this safety measure.

4.2.5 Laser standby/ready

At start-up, the standby/ready light  located at the front of the appliance is green. To authorise laser emission, press the green button. The corresponding light flashes for 2 seconds then turns orange, meaning the laser is ready to fire. The button of the keyboard  can be also used to authorise laser emission.

4.2.6 Safety labels

 <p>on the front panel, near the laser output</p>	 <p>This symbol means the laser beam exits at the end of the fibre On the laser output</p>
<div data-bbox="420 531 660 856" style="border: 1px solid black; padding: 5px;"> <p>LOKKT s.a. 14 rue Frédéric Mistral 38 370 Les Roches de Condrieu FRANCE Tel.: (33) 4 74 31 61 00 MEDICAL LASER</p> <p>Power requirement 115 V - 50 Hz - single-phase Absorbed power: 1360 VA Class I, Type BF Self contained cooling liquid Serial number: Date of manufacturing:</p> <p>THIS EQUIPMENT IS NOT PROTECTED AGAINST INFLAMMABLE ANESTHETICS EFFECTS</p> </div> 	<p>On the back panel</p> <p>Serial number of your appliance</p>
	<p>On the back panel: indicates the external safety device</p>
<div data-bbox="272 1241 797 1423" style="border: 1px solid black; padding: 5px;"> <p>115 V / 50 Hz</p> <p>Fuses:</p> <p>2x12.5 A. TIME DELAYED</p>  </div>	<p>On the back panel, near the mains connector</p>
<div data-bbox="355 1514 727 1675" style="border: 2px solid black; border-radius: 15px; padding: 10px;"> <p>DANGER</p> <p>VISIBLE AND INVISIBLE LASER RADIATION IN THE EVENT OF OPENING DANGEROUS EXPOSURE OF THE EYE OR OF SKIN WITH THE DIRECT OR SCATTERED RADIATION</p> </div> <p>on the back panel</p>	<div data-bbox="873 1472 1312 1696" style="border: 2px solid black; border-radius: 15px; padding: 10px;"> <p>VISIBLE AND INVISIBLE LASER RADIATION IN THE EVENT OF OPENING DANGEROUS EXPOSURE OF THE EYE OR OF SKIN WITH THE DIRECT OR SCATTERED RADIATION LASER INSTRUMENT OF CLASS 4</p> <p>LASER OF TREATMENT Type : Nd:YAP Wavelength: 1340 nm Pulse duration : 200 µs +/- 50µs Repetition rate: 5 to 30 Hz Maximum power: 20 W +20%/-10%</p> <p>AIMING BEAM Diode Laser 655 nm - 3 mW</p> </div> <p>on the back panel</p>

4.2.7 Pedal

For reasons of safety during laser emission, the control pedal has two switches. One of the switches deactivates a safety device in the optical unit and the other switch controls the electronics for managing laser firing.

PLEASE NOTE: *This control pedal has a safety cover to prevent it being accidentally depressed by anyone other than the user. However, it must be kept away from any area where patients or other people are in circulation.*

4.2.8 Safety shutter

The safety shutter, located in the optical cavity, is an active safety device and closes in the event of a problem with the functioning of the keyboard or pedal.

4.2.9 Electrical safety

LOKKI *Lis* contains an isolation transformer which limits leakage current with a value below 500 μ A.

The external casing of the laser and optical fibres is made of insulating material, but for greater safety, all the metal components are earthed.

4.2.10 Safety trips

The appliance stops automatically when the level of cooling liquid is too low or the temperature of the laser emitter becomes too high.

4.2.11 Alarm system

The standards for this laser require it to be fitted with an alarm informing the user of the machine's different statuses. This sound is produced by an electroacoustic transducer with internal electronics, emitting at an unalterable 2300 Hz \pm 300Hz.

Adjusting settings: The alarm system for this laser cannot be adjusted or deactivated.

Checking the alarm system: When starting up the laser, during the regulation system initialisation phase, a sound emitted at regular intervals confirms that this laser's alarm system is working.

IMPORTANT: *You must not use your laser if the alarm system check does not emit any sound.*

Whatever the alarm condition set out below, no failure detected can incur any additional risk to the patient or practitioner compared to normal operation of this laser.

Alarm system activation conditions:

Alarm conditions	People concerned	Type of sound emitted	Type of Signal	Burst frequency	Machine status	Information	Alarm condition stopping condition
Audible sign of laser radiation emission	All people in the vicinity of the laser.	Variable burst frequency emission	Information signal No generation delay	5 Hz	Working	Laser firing in programme C	When laser shooting stops
				10 Hz	Working	Laser firing in	When laser shooting stops
				30 Hz	Working	Laser firing in programme A	When laser shooting stops
Technical alarm	Practitioner	Continuous emission	Alarm signal No locking No generation delay	N/A	Technical defect / Laser emission blocked	Thermal defect in the optical unit	After cooling
						Thermal defect in the high voltage power supply	After cooling
						Failure of the high voltage power supply	After after-sales department intervention
						Auxiliary power supply defect	After after-sales department intervention

4.2.12 Laser output safety

When the fibre is disconnected, gravity causes the safety shutter to fall down in front of the laser output, preventing laser emission when the fibre is disconnected.

4.2.13 Eye safety


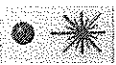
The 1340 nm beam is invisible and carries high levels of power. Protective goggles must be worn by anyone looking at the laser action area. The appliance is delivered with 2 pairs of goggles specific to the Nd:YAP beam (1340 nm), with required optical density 4 in compliance with the NF EN 207 standard. (Compulsory data written on the goggles). Additional goggles may be ordered from LOKKI.



Photo shown for information purposes only

- For direct vision endoscopy, the surgeon must either wear special protective goggles (required optical density 4 at a wavelength of 1340 nm), or place the eye filter, delivered with the machine, onto the endoscope.
- For endoscopy through a video system (without direct viewing), goggles are not required.

IMPORTANT: Before removing the optical fibre from the endoscope, it is important to put

the appliance in standby (green push button  or key ).

The nominal eye safety distance is 5.80 m from the distal extremity of the optical fibre. The red aiming beam (see §4.1) overlaid onto the 1340 nm laser beam is hazardous to the eye.

IMPORTANT: Never point the laser beam towards anyone, in particular the patient's eyes.

5 INSTALLATION, STARTING UP, USE

5.1 Room for use

PLEASE NOTE: Check that the mains voltage for the room where the laser is to be installed complies with the specifications shown on the appliance's data sheet (see §4.1). This appliance needs energy during firing and must be directly plugged into a wall socket, and must not pass through any extension leads or multi-socket adaptors (surge protectors).

5.2 Optical fibre installation

IMPORTANT: When installing a fibre, handle with great care as it is very fragile. The optical fibre is specific to our laser and its wavelength. Using different fibres from those sold by Medisurge s.a.s may destroy your appliance and the fibre: Major risk of hazardous exposure to laser radiation.



See Appendix: Installing an optical fibre.

5.3 Starting up

Due to transport restrictions, your appliance will come with no cooling liquid inside.

IMPORTANT: Do not intervene or start the laser before it has reached room temperature (Transport or storage at a very different temperature from use temperature: problem of thermal shock and condensation which may cause the appliance to break down)


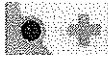


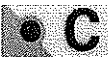



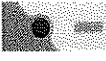
Put the cooling liquid in place (see § 8.5) before starting up for the 1st time




- Take the laser to the location where it will be used
- Plug the laser into a power supply compatible with the appliance (see §4.1); the green light at the top of the appliance should light up
- If necessary, take the pedal out of its housing to place it in a convenient position for the user
- Insert the key into its housing
- Turn the key by an initial quarter turn (permanent position) , then by a second quarter turn (temporary position) , then release the key, which returns to its permanent position (see § 3.2.5.1)
- The orange light indicates that the laser is on
- The keyboard lights come on
- You may hear a slight hum (pump, fans)
- The display says LASER READY
- The appliance is on in position "C -", now choose your emission mode if different.

PLEASE NOTE: Do not depress the pedal while starting up.

5.4 Choosing the emission mode

From the nine preset parameters (one of nine keys) below, choose the desired action mode:

Zone	A 30 Hz	Zone	C 5 Hz	Zone	B 10 Hz
	20 W 666 mJ		3,3 W 660 mJ		7 W 700 mJ
	15 W 500 mJ		2,5 W 500 mJ		5,5 W 550 mJ
	10 W 333 mJ		1,7 W 340 mJ		4 W 400 mJ

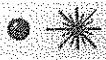

ZONE	Keys	Example of functions performed
Red zone (A)		Coagulation – vaporisation - cutting
Yellow zone (B)		Vaporisation - coagulation
Green zone (C)		Hard tissue ablation – localised effect

For each zone, there are three power settings:

- Top key (+) = maximum power
- Central key = medium power
- Lower key (-) = minimum power

At start-up, the default setting is C – (minimum power & frequency). The light located at the front of the appliance is green.


The laser emission parameters appear on the alphanumeric screen for a second after one of the control keys is selected.



- To confirm laser emission, press the  or  key. The corresponding light flashes for 2 seconds then turns orange, meaning that the laser is ready to fire.
- Place the end of the fibre into contact with or a few millimetres from the tissue to be treated.
- Press the pedal to trigger laser emission. Note the effect produced, then let go of the pedal to stop the action.

5.5 Aiming beam

LOKKI Lis' wavelength of 1340 nm is invisible and an aiming laser has been overlaid onto the Nd:YAP beam. This aiming laser projects a low power red beam at the optical fibre output point. (Specifications in §4.1).

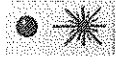


IMPORTANT: *Never point the laser beam towards anyone, in particular the patient's eyes.*

The  key is used to set brightness (3 levels) or remove the aiming beam, which has a default setting of maximum brightness.

You can bring up the aiming beam on its own if laser firing has not been confirmed and the pedal is depressed, by pressing the  key of the keyboard or .

IMPORTANT: *If you cannot see the aiming beam spot at the distal extremity of the distribution system, despite having confirmed it with the corresponding key, this can be a sign that the optical fibre has deteriorated or is not working correctly.*

5.6 Stopping system

- At the end of the treatment session, press the  or  key to deactivate laser emission. The corresponding light goes out.
- When you have finished using the laser, stop the appliance by turning the key to the "STOP" position  (see § 3.2.5.1) and remove the key to prevent use of the laser by unauthorised persons.

6 HANDLING PRECAUTIONS

6.1 Safety measures

The 1 340 nm laser beam is invisible and carries high levels of power, so safety measures must be observed:

- The practitioner and anyone looking at the laser action area must wear special protection (required optical density 4 at a wavelength of 1340 nm).
- Two pairs of goggles are provided with the appliance, in compliance with the NF EN 207 standard. Additional goggles may be ordered from LOKKI.
- For direct vision endoscopy, the surgeon must either wear special protective goggles (required optical density 4 at a wavelength of 1 340 nm), or place the eye filter, delivered with the machine, onto the endoscope.
- For endoscopy through a video system (without direct viewing), goggles are not required.
- The laser must not be used in the presence of explosive or highly flammable substances such as certain anaesthetics or endogenous gases.
- Adhesive solvents and flammable solutions used for cleaning and disinfection must be removed by evaporation before using the appliance.
- Avoid pointing the laser beam towards highly reflective surfaces.

IMPORTANT: *Never point the laser beam towards any sensitive areas other than the area to be treated, particularly the patients' eyes.*

6.2 Optical fibre

The optical fibre is very fine and fragile, and must be handled with great care.

IMPORTANT: *This fibre is specific to our laser and its wavelength. Using different fibres from those sold by Medisurge s.a.s may destroy your appliance and the fibre: Major risk of hazardous exposure to laser radiation.*

- During everyday use, pay special attention to the curvature of the fibre (maximum radius of curvature of 100 mm), mainly near the laser output and fibre holder.
- Do not place any heavy objects onto the optical fibres and do not step on the fibres (or on the white Teflon protective sheaths).

PLEASE NOTE: *Failure to follow the instructions stated above can lead to deterioration of the fibre, for which LOKKI will not be held liable.*

7 INFORMATION ON CLINICAL APPLICATIONS

7.1 Effect on tissue

The effects on tissue depend:

- on the tissue (laser-tissue interaction specification of the wavelength)
- on the setting (repetition frequency and pulse energy)
- on the distance between the end of the fibre and the tissue (in contact or a few millimetres away)
- on how long the laser beam is applied for...

The main effects obtained are incision, vaporisation, coagulation of tissue....

7.2 Main indications

7.2.1 THORACIC SURGERY

Non-gas-cooled fibre

- Resection of pulmonary parenchyma metastasis
- Reduction of pulmonary fissures

7.2.2 GYNECOLOGY

Endoscope + non-gas-cooled fibre

- Destruction of peritoneal endometriosis implants
- Total and subtotal hysterectomy
- Adhesiolysis
- Endometriosis
- Myomectomies

7.2.3 PNEUMOLOGY

Endoscope + gas-cooled (coagulation and vaporisation)

Endoscope + non-gas-cooled (cutting)

- Tracheobronchial tumours
- Tracheal stenosis

7.2.4 ENT

Endoscope + non-gas-cooled fibre

- Coagulation and conisation

IMPORTANT: *Certain surgical procedures may lead to complications (for example, risk of air embolism when using the air-cooled optical fibre). Prior training in the surgical procedure is therefore necessary.*

7.3 Advice for clinical use

This appliance must only be used by surgeons who have received special training and familiarised themselves with this user manual and with the appliance.

IMPORTANT: *Before using this laser on your patients, you must understand how the laser works. During laser treatment, be aware of the effects note, sensations, noise...*

To avoid necrosis of fragile tissue, several rules must be followed:

7.3.1 Chosen setting

The power used must be the minimum power needed for a treatment. However, if the power is too low, the treatment risks being ineffective and the user will tend to keep repeating it (necrosis possible). It is preferable to set a higher power and fire very short bursts while moving the fibre, in order to avoid it heating up.

7.3.2 Laser firing duration

We recommend keeping laser action time to a strict minimum, even if this means firing again in the same place if necessary. **Work in short bursts** while trying to control the impact of each pulse when moving the fibre.

If the foot is held on the pedal for approximately 2 min, a safety trip cuts off the laser emission. To continue treatment after firing has been automatically stopped, let go of the pedal then depress it again. We recommend leaving it to stand for a time to allow the tissue to cool down.

7.3.3 Moving the fibre

Always take care to prevent energy from accumulating: **move the fibre or brush it** constantly. Never let it remain static.

7.3.4 Cleaning the fibre

Check for residues and damage at the distal extremity during treatment. Blood, tissue residue or damage risk causing overheating or alteration of the extremity of the fibre. This has a direct impact on laser radiation power density and therapeutic effect on tissue, and constitutes a considerable hazard for the patient.

During treatment, the fibre may be cleaned with hydrogen peroxide or a sterile pad dipped in sterile water.

PLEASE NOTE: *Do not activate the laser during cleaning, and allow the distal extremity of the fibre to cool down first.*

7.3.5 Recommendations

PLEASE NOTE: *Using the controls and adjusting the settings or performing procedures in any way other than specified here may cause hazardous exposure to laser radiation.*

7.4 Reminders on laser physics

Joule (J): amount of energy delivered according to the following formula:

$$1 \text{ Watt} = 1\text{J} \times 1\text{Hz} \text{ (1 cycle per second)}$$

Fluence or energy density (J/cm^2): amount of energy per surface unit

The laser beam at the fibre output diverges by 12.7° approximately. Further away from the extremity of the fibre, the energy diminishes very quickly in proportion to the distance squared.

Energy is greatest on contact; the area treated is the same size as the fibre. When working a few millimetres away from the tissue, the area of impact of the beam is greater (see table below) and the energy diminishes.

7.4.1 *Theoretical table of energy density according to the distance between the fibre and the tissue*

Fibre size	Energy density or Fluence (J/cm^2)			F_{600} / F_{320}	F_{800} / F_{320}	F_{800} / F_{600}
	320 μm	600 μm	800 μm	DE_2 / DE_1	DE_3 / DE_1	DE_3 / DE_2
Fibre upon contact	DE_1	DE_2	DE_3	3.52	6.25	1.78
Fibre 2 mm away	$DE_1 / 15$	$DE_2 / 6$	$DE_3 / 5$	1.51	1.94	1.28
Fibre 4 mm away	$DE_1 / 44$	$DE_2 / 16$	$DE_3 / 11$	1.28	1.50	1.17

F_{320} Fibre fluence 320 μm

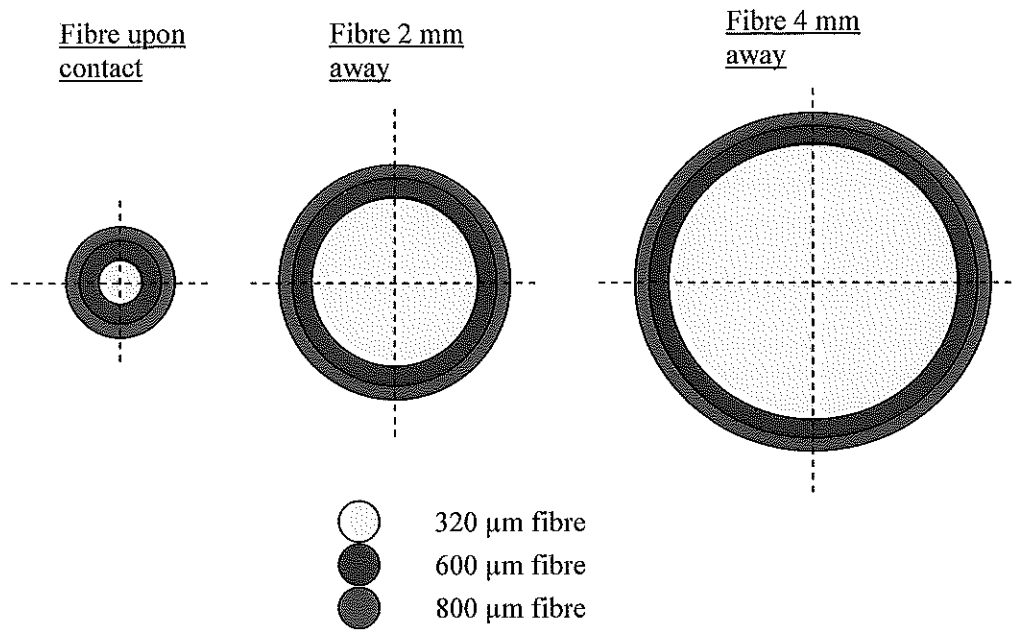
F_{600} Fibre fluence 600 μm

F_{800} Fibre fluence 800 μm

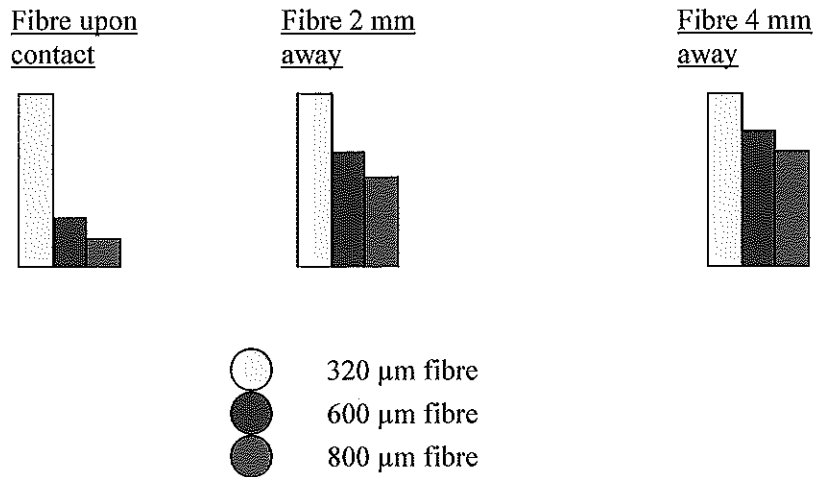
7.4.2 *Theoretical table of spot diameter according to the distance between the fibre and the tissue*

Fibre size	Spot diameter (mm)			Spot diameter ratio		
	320 μm	600 μm	800 μm	d_2 / d_1	d_3 / d_1	d_3 / d_2
Fibre upon contact	d_1	d_2	d_3	1.88	2.50	1.33
Fibre 2 mm away	$3.8 \times d_1$	$2.5 \times d_2$	$2.1 \times d_3$	1.23	1.39	1.13
Fibre 4 mm away	$6.6 \times d_1$	$4.0 \times d_2$	$3.3 \times d_3$	1.13	1.23	1.08

7.4.3 *Theoretical graphical representation to scale (x20) of the surface of the area treated with fibres of 320 µm, 600 µm and 800 µm*



7.4.4 *Comparison of theoretical energy density ratios between fibres according to distance*



Note: energy being equal, fluence is therefore greater with the 320 µm fibre than with the 800 µm fibre, i.e. $DE_1 > DE_3$.

8 MAINTENANCE

8.1 Annual inspection of your appliance

IMPORTANT: *The CE standardisation system for this appliance requires testing of its laser specifications and therefore testing of the laser emission parameters (safety devices, output power).*

An *annual inspection* is therefore required to ensure that the appliance is working properly. For instance, it includes:

- replacements:
 - of the control pedal if necessary
 - of the cooling liquid
 - of the resin filter if saturated
- of various checks:
 - of the cooling circuit
 - of the lens, with cleaning if necessary
 - of the appliance electronics
 - of laser emission measurement

This inspection must be carried out by a LOKKI trained and approved technician.

8.2 Your everyday maintenance

For patient safety and to ensure that your appliance works correctly, the operations which you can perform yourself are detailed below.

IMPORTANT: *To avoid any biological cross-contamination, you must sterilise or disinfect (following the explanations below) all the accessories and parts which will come into contact with the patient before using the appliance (including taking receipt of your new appliance).*

8.3 Sterilisation and Disinfection

The following parts of the appliance may come into contact with the patient. They must be sterilised or disinfected.

8.3.1 *The appliance*

The keyboard and appliance must be wiped with a disinfectant wipe or a pad soaked with alcohol after each patient.

IMPORTANT: *Do not use disinfectant spray directly on the laser as the product may seep into the appliance, via the lens for example, and cause a malfunction or deterioration of the laser effect which may be irreversible.*

8.4 Changing the optical fibre

PLEASE NOTE: *Before any operation, check that the appliance is switched off: The appliance must be unplugged from its mains power supply.*

Disconnecting a fibre may cause hazardous exposure to laser radiation.

8.4.1.1 Installing the new fibre:

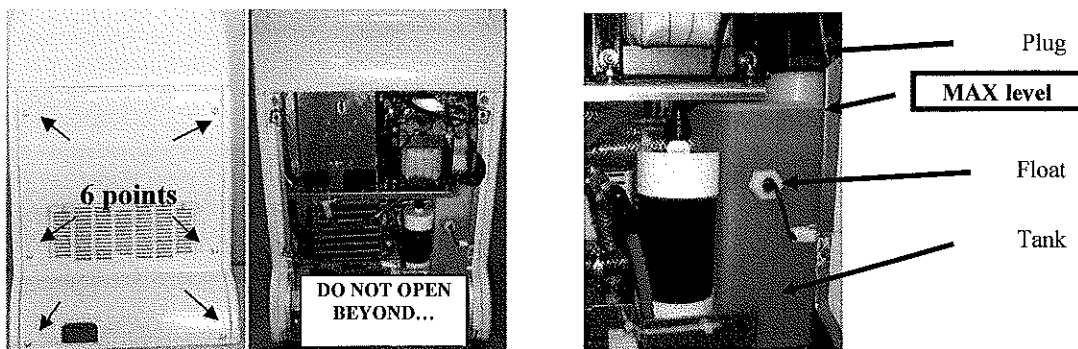
See Appendix: § 14.1: Installing an optical fibre.

8.5 Putting in or changing the cooling liquid

IMPORTANT: *The appliance must be unplugged from its mains power supply: Before any operation, check that the appliance is switched off. Do not plug it in again before the back panel has been put back in place.*

Do not intervene or start the laser before it has reached ambient temperature.

(Transport or storage at a very different temperature from use temperature: problem of thermal shock and condensation which may cause the appliance to break down.)



1. Laser unplugged! Remove the back panel using the Allen key (6 fixing points) found in the accessory packet
see § 3.2.7.2
2. Unscrew the plug from the tank to your right and fill it up to the mark above (top of the tank). Take care not to overfill.
3. Close the tank
4. Replace the back panel. Start the appliance. Let the appliance run for 10 to 15 minutes to remove air bubbles from the cooling circuit
5. Repeat steps 1 to 4 to check and top up the liquid level

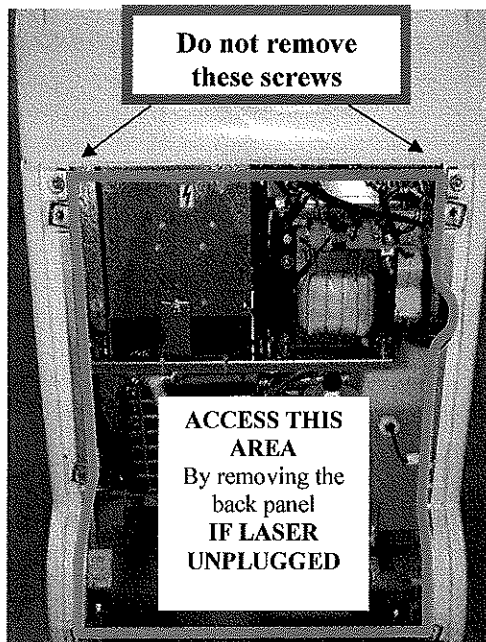
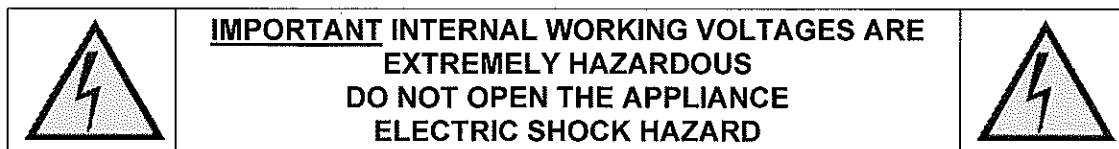
IMPORTANT: *You may only remove the back panel of the appliance. Do not switch the appliance on with the back panel removed or disassemble the appliance.*

9 TROUBLESHOOTING

LOKKI *Lis* is built to rigorous standards, however, should a fault arise with your appliance, please check the following points before calling your approved retailer or the LOKKI after-sales department (see contact details §9.1).

Handling or modifying the appliance in any other way, or attempting to open it, will automatically void the warranty.

Do not disassemble or open the appliance, even partially, for any reason. The appliance is designed to use very high voltage levels internally (>500 V), which are fatal. Only an authorised LOKKI laser technician is authorised to work on the appliance. Do not switch the appliance on again after removing the back panel.






Back of the laser after removing the back panel

9.1 Definition of the most common problems

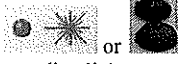
Due to transport restrictions, your appliance will come with no cooling liquid inside.

IMPORTANT: CHECK THAT THE COOLING LIQUID IS IN YOUR LASER BEFORE STARTING UP FOR THE FIRST TIME. See §8.5

Problem	Conditions	Possible causes	Notes
The laser will not start	Green light off  BT	<ul style="list-style-type: none"> Check that there is a power supply (following information in §4.1) to the mains socket Check the power cord and its connection to the laser and the mains socket Check the fuses in the mains connector: <ul style="list-style-type: none"> Unplug the appliance from the mains socket Unplug the power cord from the laser Remove the fuse holder from the mains connector Replace the 2 fuses¹ (see features in §4.1) Close the connector and plug the appliance back in <p>If this does not solve your problem, contact your after-sales department §13</p>	<p>This appliance needs energy for firing and must be plugged directly into a wall socket, and not pass through any extension leads or multi-socket adaptors (surge protectors)</p> <p>Only use LOKKI parts</p>
The laser will not start	Green light on  BT Orange light off  HT	<ul style="list-style-type: none"> Using the key starts the appliance, then it stops straightaway <ul style="list-style-type: none"> Open the back panel of the laser and check the level of cooling liquid in the right-hand tank: the level must be at least 2 cm above the float² Using the key has no effect: <ul style="list-style-type: none"> Open the back panel of the laser and check the level of cooling liquid in the right-hand tank: the level must be at least 2 cm above the float² Check the emergency stop button is not engaged. A door safety device at the back of the appliance (near the mains socket connector) must be in place. Check your wiring if you are using this safety device. <p>If this does not solve your problem, contact your after-sales department §13</p>	<p>Only use LOKKI cooling liquid</p>
The laser emits a continuous "beep" sound and the central light shines red	The laser stops during laser treatment	<ul style="list-style-type: none"> Generally due to overheating of the laser part: <ul style="list-style-type: none"> Leave the appliance on to keep it cool until the continuous beep stops (approximately 5-6 minutes) <p>If the continuous sound does not stop, contact your after-sales department §13</p>	<p>Check that nothing in the environment around the appliance is blocking the air flow needed for cooling.</p> <p>Check that the appliance is being used in accordance with the conditions for use set out in § 12</p>
	Outside of a treatment phase	<p>Contact your after-sales department §13</p>	

¹ 2 parts are supplied in your accessory packet.



² Plastic part fixed to the tank with a black wire leading out.

Problem	Conditions	Possible causes	Notes
The laser will not fire	When the pedal is depressed	<ul style="list-style-type: none"> Check that firing confirmation  have actually been confirmed: Corresponding light on. If the appliance emits a continuous sound and will not fire, see above. 	
The laser fires	But power or effectiveness is considerably reduced	<ul style="list-style-type: none"> Check your fibres: <ul style="list-style-type: none"> Clean the fibre § 7.3.4 Check your fibre sheaths, which must not have any folds or kinks, for example Test with another fibre Check and note the intensity of the aiming beam (without confirming firing) Effectiveness varies according to how hard you press the pedal: contact your after-sales department §13 <p>If this does not solve your problem, contact your after-sales department §13</p>	The compulsory annual inspection §8.1 can reduce this risk
The laser works but there is no power or effectiveness	You hear the laser fire and a variable intermittent sound at the frequency of the selected programme	<ul style="list-style-type: none"> Check your fibres: <ul style="list-style-type: none"> Check your fibre sheaths, which must not have any folds or kinks, for example Test with another fibre Check that the aiming beam is there (without confirming firing) To detect the appearance of the beam according to how hard you press the pedal: contact your after-sales department §13 <p>If this does not solve your problem, contact your after-sales department §13</p>	The compulsory annual inspection §8.1 can reduce this risk
	You cannot hear any laser fire or variable intermittent sound according to the selected programme	<ul style="list-style-type: none"> Laser fire and an intermittent sound occur according to how hard you press the pedal: contact your after-sales department §13 <p>If this does not solve your problem, contact your after-sales department §13</p>	The compulsory annual inspection §8.1 can reduce this risk
Others		Contact your after-sales department, who will be able to help you analyse your situation and advise you on how to proceed §13	

IMPORTANT: You must stop using your laser and contact your after-sales department §13 for an expert to assess your laser in the following cases:

- If you note any changes to the specifications or functioning of your laser during use
- If you note external deterioration (drop, impact, damage to the premises...)

Under no circumstances must you handle the appliance yourself.

	<p>IMPORTANT INTERNAL WORKING VOLTAGES ARE EXTREMELY HAZARDOUS DO NOT OPEN THE APPLIANCE ELECTRIC SHOCK HAZARD</p>	
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10 CALIBRATION

The emission specifications of the LOKKI *Lis* laser are set at the factory, during the final appliance test. Given the care taken to protect the optical components, these specifications are particularly secure.

In order to ensure that you are able to provide treatment for a long time to come, the standardisation system requires these features to be tested annually by a LOKKI trained technician, with a previously calibrated test wattmeter. This check is part of the annual inspection.

During the entire time the laser is in use, the user must contact the LOKKI after-sales department in the event of a noticeable drop in the effectiveness of their appliance (see contact details in chapter § 13).

11 STORAGE AND TRANSPORT CONDITIONS

11.1 Packaging:

The laser is transported in special LOKKI packaging designed to comply with the physical restrictions involved in transporting this type of technology and to ensure that the appliance's output specifications are maintained to the fullest possible extent. The means of transport arranged also comply with these restrictions.

Any failure to comply may cause the appliance and its specifications to deteriorate, preventing it from being used.

IMPORTANT: *In the following cases, the appliance must not be used or started up, and you must contact your retailer as soon as possible:*

- *It comes without its packaging.*
- *It comes with non-LOKKI packaging (written on).*
- *It comes with the packaging damaged, unstrapped or open.*
- *If the appliance has deteriorated.*

11.2 Storage and transport:

The laser uses an internal liquid cooling circuit which consists mainly of water. Therefore there is a high risk of freezing if it is stored or transported at temperatures lower than 0°C, and therefore a risk of the cooling circuit and part of the lens being destroyed.

To prevent this, the appliance must be emptied before transport or storage.

If the appliance contains no cooling liquid:

- Temperature range: -10 to + 60 °C
- Relative humidity range: 10 to 100 %
- Atmospheric pressure range: 500 hPa to 1060 hPa

12 CONDITIONS OF USE

The laser uses an internal liquid cooling circuit and an air-to-liquid exchanger.

Therefore the appliance must be placed in a ventilated area to ensure air flow between the back and front of the laser.

IMPORTANT: *Therefore the appliance must not be installed in confined spaces (under a work surface). Certain conditions can set off the appliance's thermal safety trip.*

- Temperature range: +10 to +40 °C
- Relative humidity range: 10 to 90 %
- Atmospheric pressure range: 700 hPa to 1060 hPa

IMPORTANT: *When the temperature between storage or transport is very different from the use temperature (transport in the winter, etc.), take care to leave the appliance at use temperature for approximately 30 min at least without starting it up in order to prevent internal condensation or other phenomena which may cause breakdowns or malfunctions.*

13 CONTACT DETAILS

Manufactured by:

LOKKI SA

14 rue Frédéric Mistral
38 370 Les Roches de Condrieu
FRANCE

Tel: 04 74 31 61 00
Fax: 04 74 31 61 37
E-mail: lokkisa@lokki.fr
Website: www.lokki.fr

Your regional contact:

Your After-sales Department contact:

IMPORTANT: *Do not return any part or appliance without first contacting the after-sales department, who will open a file and provide you with a return number for your part or appliance. This number must be noted on all attached documents and the packaging in which you return the item. Without this number, the part will not be processed. Have the serial number for your appliance (on the back panel) ready before calling.*

*No part or appliance
will be taken back by the After-sales Department
without a return number*

Your SAV LOKKI contact:

LOKKI SA

For the attention of the After-sales
Department

14 rue Frédéric Mistral
38 370 Les Roches de Condrieu

Tel: 04 74 31 61 00
Fax: 04 74 31 61 37
E-mail : lokkisav@lokki.fr

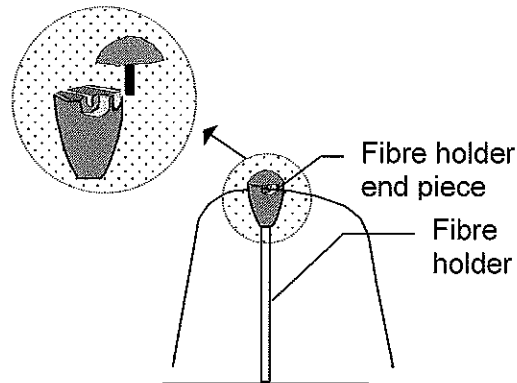
14 APPENDICES

14.1 Installing an optical fibre

IMPORTANT: *When installing a fibre, handle it with great care as it is very fragile.*

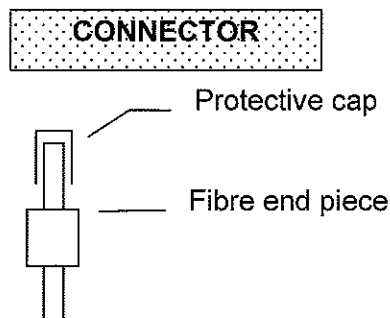
As the fibre is sterile, take care to use sterile handling methods during installation.

- The laser must be stopped
- Unfold the fibre holder
- Remove the fibre from its sterile packaging, keeping one hand close to the connector (part protected by a cap)
- Unscrew the fibre holder end piece
- Put the fibre into the fibre holder (see diagram below). Then screw the fibre holder end piece back



- Remove the protective cap from the fibre

PLEASE NOTE: *The fibre is no longer protected, so it must be handled with great care, avoiding contact with the entry face of the connector.*



- Release the safety shutter in order to access the laser output
- Connect the fibre to the laser. Screw down without forcing it to prevent stress on the fragile optical system.
- For the gas-cooled fibre: connect the air outlet of the fibre to the air outlet located at the front of the appliance.

PLEASE NOTE: *Failure to follow the instructions above may cause the fibre or the connection system to deteriorate, for which LOKKI will not be held liable.*

14.2 Single-use fibres

The fibres are **single-use fibres**. They must therefore be changed after each use.

The fibres are **sterile in hermetically sealed individual packaging**.

These fibres are sterilised with EO (Ethylene Oxide) and have a use-by date displayed on the individual packaging and its container.

IMPORTANT:

Discard after the use-by date or in the event of any packaging deterioration which could compromise the sterility of the end piece

Manufacturing date

Ref. FNPM 800
Disposable Laser Fibre with Open Surgery Handpiece
Fibre Laser Usage Unique avec Pièce à Main pour chirurgie ouverte
Fibre 800µm *conical* - HP L: 120 mm - Dia: 3 mm L:3.00 m

STERILE
STERILE
If individual pouch is not opened or damaged
si emballage individuel non ouvert et non endommagé

WARNING: FOR SINGLE USE ONLY
ATTENTION: A USAGE UNIQUE

Use-by date

LOT

Lot-Nr.
N° de Lot: A-6- 933

Lot number

Manufacturing Date.
Date de fabrication: 04.12.2006

Expiration Date.
À utiliser avant le: 04.12.2010

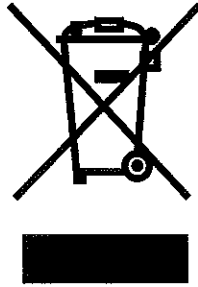
MediSurge s r l s
12003 Marseille
France
Phone +33 495 14 00 6

STERILE EO


CE 0459

IMPORTANT: THESE FIBRES ARE SINGLE-USE


14.3 DEEE/WEEE directive



Directive DEEE (Déchets des équipements électroniques et électroniques)


Le logo DEEE  signale des programmes de recyclage et des procédures destinés aux produits électroniques des pays de l'Union européenne. Nous vous recommandons de recycler vos produits. Pour toute question sur le recyclage, contactez votre revendeur local.

WEEE directive (Waste from Electrical and Electronic Equipment)

The WEEE logo  signifies specific recycling programs and procedures for electronic products in countries of the European Union. We encourage the recycling of our products. If you have further questions about recycling, contact your local sales office.

Comment éliminer ce produit (déchets d'équipements électriques et électroniques)

(Applicable dans les pays de l'Union Européenne et aux autres pays européens disposant de systèmes de collecte sélective)


Ce symbole  sur le produit ou sa documentation indique qu'il ne doit pas être éliminé en fin de vie avec les autres déchets ménagers. L'élimination incontrôlée des déchets pouvant porter préjudice à l'environnement ou à la santé humaine, veuillez le séparer des autres types de déchets et le recycler de façon responsable. Vous favoriserez ainsi la réutilisation durable de ressources matérielles.

Les particuliers sont invités à contacter le distributeur leur ayant vendu le produit ou à se renseigner auprès de leur mairie pour savoir où et comment ils peuvent se débarrasser de ce produit afin qu'il soit recyclé en respectant l'environnement.

Les entreprises sont invitées à contacter leurs fournisseurs et à consulter les conditions de leur contrat de vente. Ce produit ne doit pas être éliminé avec les autres déchets commerciaux.

Correct Disposal of this product (Waste Electrical & Electronic Equipment)

(Applicable in the European Union and other European countries with separate collection systems)

This marking  shown on the product or its literature, indicates that it should not be disposed of with other household waste at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of waste and recycle it responsibly to promote the sustainable reuse of material resources.

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take this item for environmentally safe recycling.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.