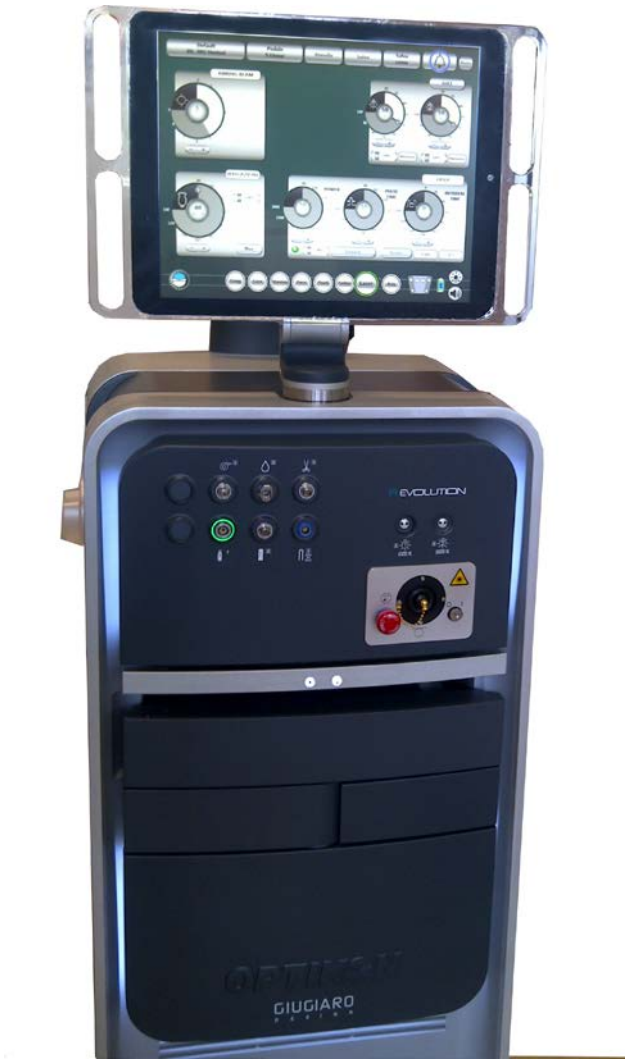

Endolaser Upgrade Module
for
R-Evolution CR

MANUAL FOR INSTALLATION AND USE

OPTIKON 2000 S.p.A.

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OPTIKON 2000 S.p.A. is an ISO 9001 and ISO 13485 certified company that produces surgical and diagnostic devices for ophthalmology.

All OPTIKON 2000 products are manufactured in compliance with the requirements of Directive 93/42/EEC on medical devices.

TABLE OF CONTENTS

1. FOREWORDS

This manual contains important information relevant to the safety and use of the endo-laser section of the R-evolution CR.
It must be read and stored together with the main user manual of the equipment (1X1012EN), of which it must be considered integral part.
For proper use of the Surgical System and for the safety of the User and the Patient, also read and observe the instructions for use supplied with the single accessories.
The Laser Module of the R-evolution CR is an ophthalmic laser for therapeutical use.
The chapter "Clinic Manual" within this manual give indications on the possible applications and the relevant risks.

1.1 DISCLAIMER

The user of this system must carefully read the specific warnings provided in this manual. It is the responsibility of the operator to guarantee the assigned personnel a thorough knowledge of the instrument's operation before use. In no case is OPTIKON 2000 S.p.A. liable for any burns or accidental or consequential damage caused to the buyer, operators or patients following the use of the product.

The use of the system is subject to professional medical evaluation. OPTIKON 2000 S.p.A. is not liable for any clinical problem resulting from an incorrect use of this apparatus and does not provide any medical recommendation.

OPTIKON 2000 S.p.A. declares to be responsible for the safety, reliability and performance only if:

- updates, calibrations and repairs are carried out by personnel which has been authorised by OPTIKON 2000 S.p.A.;
- the Users have read the present instructions and act according to the safety warnings and advices given in the manuals; guidelines for parameters settings given in the Clinical Manual must be evaluated and adapted to the specific conditions of actual patients;
- The operating theatre where the surgical system is installed and its electrical wiring conforms to IEC 601-1 and IEC 825-1 safety standards.
- The Surgical system is periodically verified and calibrated, as required by the present manual.

IMPORTANT NOTE:

Every effort has been made so that all the illustrations and information precisely represent the product and its operation as they were at the time this manual was printed. It is possible, however, that during the existence of this manual modifications have been made in order to continue to effectively satisfy the needs of the users. At times, such modifications are made without advance notice.

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2. LIMITED WARRANTY CONDITIONS

All the OPTIKON 2000 S.p.A. instruments and accessories sold and installed in the European Union are guaranteed against manufacturing and material defects for ONE YEAR from the invoicing date. The guarantee on the consumable material is limited to the first use of the apparatus.

For the warranty conditions outside the European Union, contact your authorised OPTIKON 2000 S.p.A. distributor.

All the parts covered by the warranty will be repaired or replaced free of charge.

The warranty includes the search for the defect's cause, repair of the failure and final inspection of the unit or components.

This warranty does not cover any problems which are the result of improper use, accidents, incorrect use and tampering or modifications made by persons who are not part of the authorised OPTIKON S.p.A. technical service.

OPTIKON 2000 S.p.A. reserves the right to verify, in case of failures, if the instrument and/or its accessories have been modified or tampered with in any way, or if they have been damaged by improper use.

OPTIKON 2000 S.p.A. also reserves the right to modify the instrument and/or its accessories in the event operating techniques require such modifications.

The warranty is not valid if the serial number of the instrument and/or accessories attributed by OPTIKON 2000 S.p.A. is missing, tampered with and/or unreadable.

The warranty does not include the expenses for returning the instrument and accessories: all charges for shipping , packaging, etc. shall be borne by the buyer.

In the event of an explicit request for work by OPTIKON technicians, all travelling and lodging expenses shall be charged to the customer.

OPTIKON 2000 S.p.A. is not liable for damages caused during transport. If this occurs, the customer must immediately notify the carrier that handled the delivery.

3. GENERAL INFORMATION

3.1 KEY TO SYMBOLS

We wish to furnish you with information on the safety aspects involved in working with this system. This section contains a summary of the most important information on safety-related topics.

Hazard symbols

The following safety information has been incorporated into the user manual. Please note this information and act with particular care in these cases.

WARNING	Indicates a hazard which can cause damage leading to **fatal** or **serious injuries**.
CAUTION	Indicates a hazard which can cause damage leading to **injuries in need of medical attention**.
INFORMATION	Indicates a hazard which can cause damage leading to **injuries with no need of medical attention**.

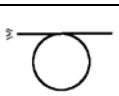
3.2 TABLE OF SYMBOLS

The table below shows some I.E.C. (International Electrotecnic Commission) approved symbols and their meanings. These symbols are often used on medical instruments to enable quick and simple communication of information and warnings. At times two or more symbols are combined together in order to obtain special meanings.

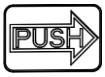
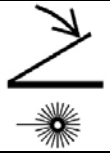
These are the symbols used on the R-Evolution label. Before using the unit, familiarize yourself with the symbols and definitions provided in the table.

SYMBOLS PUBLISHED BY IEC

SYMBOL	DESCRIPTION
	MANUFACTURER
	DATE OF MANUFACTURE
	ALTERNATING CURRENT
	RF EMISSION
	WARNING
	OFF (DISCONNECTED FROM MAINS)
	ON (CONNECTED TO MAINS)
	TYPE B APPLIED PART
	TYPE BF APPLIED PART
	SEPARATED WASTE COLLECTION FOR ELECTRICAL/ELECTRONIC EQUIPMENT
	EQUIPOTENTIALITY

	FOLLOW INSTRUCTIONS FOR USE
	SEE OPERATING INSTRUCTIONS
	NOMINAL FUSE RATING
	EXTERNAL COMPRESSED AIR INLET
	AIR INJECTION SOCKET
	LIGHT SOURCE SOCKET
	DIATHERMY SOCKET
	FOOTSWITCH SOCKET
	WARNING! LASER EMISSION
	LASER EMERGENCY STOP
	SOCKET FOR LASER FIBER OPTIC
	SOCKET FOR LASER STOP ON DOOR OPENING

OTHER SYMBOLS ON THE EQUIPMENT

	SCISSORS SOCKET
	SILICONE OIL INJECTION SOCKET
	PHACO SOCKET
	VITRECTOMY SOCKET
	KNOB FOR UNLOCKING CASSETTE
	LASER FOOTSWITCH SOCKET
	AUTOMATIC EYE PROTECTION FILTER SOCKET

3.3 TARGET GROUP

This user manual is intended for physicians, nurses and other medical and technical staff involved in the preparation, operation or maintenance of the device after appropriate training. It is the duty of the customer or institution operating the system to train and instruct all staff in the use of the system.

Additional service activities are not part of this user manual. These activities will be performed by staff specially trained for this purpose by Optikon 2000.

Range of applications

Purpose

The Endolaser upgrade module has been designed to be integrated in the R-Evolution CR surgical system for the use, in operating theaters, by qualified medical personnel (ophthalmic surgeon) to perform retinal photocoagulation surgical procedures. The system is intended for use in clinics, hospitals, and other institutions of human medicine.

3.4 INTENDED USE

The R-Evolution CR is intended for surgical treatments, such as extra-capsular extraction, phacoemulsification or glaucoma in the anterior segment of the human eye and for surgical treatment of retinal detachment and other pathologies of the vitreous body and the posterior segment of the human eye.

The Endolaser upgrade module extends its use to retinal photocoagulation and to endo cyclo photocoagulation of the retina (ECP). Malfunctions during the use of the system are indicated by a message on the display and alarm signals.

Any use other than the one stated above, is excluded as it may cause unforeseeable risks. In particular, the use of this system in brain or heart surgery is excluded.

WARNING

Risk of injury to the patient!

- Do not use the R-Evolution CR and the Endolaser Upgrade module for uses other than the ones for which they have been designed.

3.5 NOTES FOR THE OPERATOR

- Use the system only for the intended purpose as described.
- Comply with the legal regulations regarding market surveillance and obligatory reporting applicable in the respective country, as well as any further regulations and standards.

User qualification

- Please familiarize yourself thoroughly with the contents of this user manual and with the user manual of the R-evolution CR before starting up the system. Please note the instructions for use of the other equipment as well.
- Before using the system, all medical staff must have read and understood all instructions included in the present user manual and in the user manual of the surgical system.
- Keep the user manual in a place that is easily accessible at any time to the staff charged with operation of the system.
- The system may only be used by qualified medical personnel who understand the possible risks associated with the use of this medical system and completed adequate training in the prevention and management of clinical complications, if any.
- The system must be used exclusively by staff who received adequate training and instruction. It is the duty of the customer or institution operating the system to train and instruct all staff using the system and to the impede its use by non properly qualified personnel.

  Note: The use of the Endolaser module is protected by a key-switch. The key needed to operate the laser is supplied by the Optikon authorized personnel at the time of installation.

WARNING

Risk of injury to the patient and/or operators!

- Keep the Endolaser key in a safe place, never leave it inserted in the front panel switch when the laser is not to be used.

- Adequate training is essential for proper installation and operation of the R-Evolution CR training that is provided by Optikon 2000. Contact your local Optikon 2000 Service for details.

Transportation

CAUTION

Risk of injury to the patient's eye!

This system has been packaged to minimize the risk of damage in shipment.

- If you notice any shipping damage, notify the carrier and do not use the system.
- For transports over extended distances (e.g. dismantling, return for repair purposes, etc.), you need to package the system in its original package or special return shipment packages. For details, please contact your dealer or Optikon 2000 Service.

Set-up and installation

WARNING

Risk of injury to people and/or damage to the system!

- The installation of the Surgical System in the operating theatre must be performed by technical personnel trained and authorized by Optikon.
- Make sure that the installation conditions and the use of the system meet surgical requirements:

– Low vibration
- Clean environment
– Avoidance of extreme mechanical loads
- Operating theatre and its electrical wiring must conform to IEC 601-1 e IEC 825-1 safety standards.

INFORMATION

Risk of damaging the system!

Closed or obstructed ventilation openings may cause the system to overheat.

- Install the R-EVOLUTION CR system such that the ventilation openings are not closed or obstructed.

WARNING

Risk of fire or explosions!

The system is not design to work in hazardous areas.

- R-Evolution must not be used:
- in areas where there is a risk of explosion.
- if inflammable anesthetics or volatile solvents, such as alcohol, benzene or similar chemicals, are present at a distance of less than 25 cm.

- Do not use or store the system in damp rooms. Do not expose the system to water splashes, dripping water or sprayed water.
- To ensure safe operation, do not install the system in a location where it may be exposed to heating appliances or radiators, direct sunlight or any other source of heat with extremely high temperatures.

WARNING

Risk of injury to the user!

- The equipment is provided with a connection to a door switch to be wired to the entrance of the operating theater. This safety systems stops laser emission when the door is opened, thus avoiding damages to the sight of people entering the operating theatre without proper eye protection. Verify that this protection device is properly installed.

Operation

- Carefully follow the instructions when installing and using the unit in order to prevent harmful interference by with other devices. If the system causes harmful interference with the function of other devices (can be detected by turning the unit off and on again), the user is encouraged to try to remedy the interference by one or more of the following measures:
  - Reorient or relocate the other devices.
  - Increase the distance between the devices.

- Connect the unit to an outlet of a circuit different from the one to which the other devices are connected.
- Please contact your local dealer or the Optikon 2000 Service.

- Malfunctions during the use of the system are indicated by a message on the display and alarm signals Remedy the malfunction and confirm the message by pressing the corresponding key on the display. If the malfunction cannot be eliminated or the error keeps recurring, do not continue using the system, but rather attach a sign to the system stating that it is "out of order", and contact your local Optikon 2000 Service or local dealer.
- Never leave the system unattended when the laser is enabled.

- This system is a sophisticated high-technology product. To ensure optimal performance and safe working order, we recommend, as part of regular scheduled maintenance, having it checked yearly by Service personnel authorized by Optikon 2000.

WARNING

Risk of injury to the patient!

- The power emission of the laser system is subject changes due to ageing of components. Correct calibration of the laser must be verified yearly by qualified technicians, authorized by Optikon.

- To prevent any impairment of the system safety as a result of aging, wear, etc., the institution operating the system must ensure, in accordance with the applicable national regulations, that the regular technical safety checks prescribed for this system are performed on schedule and to the stipulated extent. The technical safety checks must be performed by the manufacturer or qualified persons only. The scope of the technical safety checks should at least comprise the following items:
  - Availability of the user manual
  - Visual inspection of the system and accessories for damage and legibility of the symbols/labels.
  - Test of protective earthing impedance
  - Leakage current test
  - Function test of all switches, buttons, outlets, and indicator lamps of the system.

Modifications

WARNING

Risk of injury to the patient's eye!

Modified products might break during application and cause malfunction of the system.

- Do not change the shape of accessories (i.e. do not kink, cut, or scratch).
- Modifications and repairs of this system or any systems operated together with this system may only be performed by the Optikon 2000 Service or other suitably authorized personnel.

Disposal

CAUTION

Pollution of the environment!

Inappropriate disposal may contaminate the environment!

- Do not dispose of the systems along with normal domestic waste.

  Separate disposal according to the local laws/regulations governing the disposal of electrical and electronic equipment is required.
- Infected parts may contaminate user or the environment. Dispose waste collection fluids according to the local laws/regulations governing the disposal of organic materials.

Approved accessories

WARNING

Risk of injury to the patient's eye!

- Use only original accessories and consumables made by Optikon 2000 that are designed for use with the R-EVOLUTION CR systems. Check the Instructions for Use of the accessories for compatibility with the R-EVOLUTION CR.

- The use of accessories and cables that are not enclosed in the scope of delivery of the system may lead to increased emission of electromagnetic interference or reduced immunity of the system to interference. Only use spare parts approved by Optikon 2000 for this system.
- Additional equipment connected to medical electrical devices must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). In addition, all configurations must meet the requirements for medical electrical systems (see IEC 60601-1-1 or Clause 16 of the 3rd edition of IEC 60601-1). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible for the compliance of the system with the requirements for medical electrical systems. Please note that that local laws take priority over the above mentioned requirements. If in doubt, consult your local Optikon 2000 service or the local representative.

INFORMATION

- The system is set for use with a line voltage of 100 – 240 V (± 10 %), 50-60Hz . Please check that the local line voltage corresponds to this voltage.
- Always replace the fuse with one of the same type.
- To reduce the risk of electric shock, do not remove the protective cover. Have an authorized service technician replace the fuses.
- Connect the R-EVOLUTION CR to a mains supply having the characteristics shown on the rear panel of the console. To guarantee safe operation and to avoid electric shock, the surgery system must be properly grounded.
- Before connecting the unit to the power supply, or disconnecting it, make sure that the main switch is off.
- The main switch be kept turned off when the surgery system is not in use.
- Before replacing fuses, switch off the system and let it cool down a few minutes.
- If required by the regulations and guidelines in the country of use, the system must be connected to an uninterruptible power supply.
- Do not place any fluid-filled containers on top of the system. Make sure than no cleaning agents can enter the system.
- Never attempt to connect any electrical connectors by force (plugs, sockets). If a connector does not fit into a socket, check whether it's intended for another one. If a connector is damaged, please contact your local Optikon 2000 Service.
- Do not use power strips.
- The systems must be properly grounded to ensure safe operation.
- Additional potential equalization: The system incorporates protective earth connector.

LASER endo coagulation

WARNING

Risk of injury!

- The use of the laser system is reserved exclusively to the ophthalmic surgeon. Use is protected by a key. Do not leave this key plugged in the R-Evolution if the laser must not be used.

  Safeguard the key properly to avoid the use of the laser by non-authorized personnel.

WARNING

Risk od injury!

- To minimize the risk of unwanted laser emissions, activate the laser (select "ready") only when the Surgeon is ready to use it, select stand-by at the end of the treatment.

WARNING

Risk of injury to the Operator's eye!

- The laser beam reflected by the retina of the patient may injury operator's eyes. Confirm that the safety filter is properly installed on the microscope or wear protective goggles before enabling laser emission.

- Usare esclusivamente fibre ottiche originali di Optikon 2000.

WARNING

Risk of injury to the eyes of operating theater personnel!

- Operating theater personnel may be hit by direct or indirect laser radiation, i.e. because of a damaged fiber optic.
- Al people assisting to laser treatment or within the nominal ocular hazard distance must be informed of this risk.
- All people in the operating theatre where the laser treatment is performed must wear appropriate safety protection googles.
- If protection googles are damaged or the lens appears discolored, do not use them and replace with new googles.
  More details are given below.

WARNING

Risk of injury to the patient's eye!

- Adjust the power of laser emission and pulses length properly. Always start with low power and short pulses settings, then increase gradually until the desired effect is achieved.

- Evident signs of low laser power output, even though the equipment is set for normal use, may indicate a defective fiber optic.
- Observe quality (shape and brightness) of the aiming beam before shooting the laser pulses. A round shape and a brightness similar to previous treatments indicate that the laser optical path is in good working order. If the shape of the aiming beam is irregular and/or brightness is not normal, do not use the laser.

WARNING

Risk of injury to operating theatre personnel!

- To avoid possible reflections, no object should be on the optical path of the laser.
- During functional checks, all personnel in the laser treatment operating theatre must wear protective googles suitable for protection against 532nm laser emission. Never direct the laser beam toward people.

Specifications for safety googles for protection of operating theatre personnel (available from Optikon):

Laser type	Blocked wavelength	Optical density	DIN- / EN- identification
Green	532nm	OD 6	D > 315-532nm L4 IR> 315-532nm L6

Automatic and manual safety filters for protection of the eyes of the operator are available for all microscope major brands. Inquire with your local Optikon representative for more details.

WARNING

- In case of malfunction, a red push-button on the front panel of the R-evolution allows emergency stop of the laser system. For more information, see chapter "5.2 System Components".

4. 4.TECHNICAL SPECIFICATIONS

4.1 GENERAL SPECIFICATIONS

PARAMETER	SPECIFICATION
Manufacturer:	OPTIKON 2000 S.p.A. via del Casale di Settebagni, 13 00138 Roma - Italia
Model:	Upgrade LASER Module for R-Evolution
Regulatory compliance:	93/42/EEC Medical Devices Directive (MDD)
60601-1 Classification:	(laser) type BF applied part
ENVIRONMENTAL SPECS	
Storage:	temperature range from +5°C to +60°C, humidity max. 90%
Atmospheric pressure:	700 – 1200 mbar
Operation:	temperature range from +15°C to +28°C, humidity max. 85%
Atmospheric pressure:	700 – 1200 mbar
ELECTRICAL SPECS	
Power consumption:.....	420 W
LASER SPECS	
Laser type:	Diode pumped and frequency doubled Nd:YVO
Wave length:	532nm
LASER class:	IV
Laser Power:	Adjustable from 50mw to 2000mW
Pulses length:	Adjustable from 10ms to 2s
Pulses interval:.....	Adjustable from 0 to 1s
Accuracy of Internal Treatment Power Measuring:	±5/%
Cooling system:	Thermo-electric
Nominal **O**cular **H**azard **D**istance:	10m
Aiming beam wavelength:	625-645nm
Aiming beam LASER class:	II
Aiming beam power:	Adjustable from 0 to 1mW
Expected life:	6 years (2500 treatments per year)

NOTA:

1) See R-evolution CR user manual REF 1X1012EN for weight and dimensions.
2) Specifications are subject to change without notice.

4.2 EMC TABLES

The R-Evolution CR is intended for use in the electromagnetic environment specified below. The customer or the user of the R-Evolution CR should assure that it is used in such an environment.

The **R-Evolution CR** is suitable for use in the specified electromagnetic environment. The purchaser or user of the **R-Evolution CR** should assure that it is used in an electromagnetic environment as described below:		
Emissions test	**Compliance**	**Electromagnetic Environment**
RF emissions CISPR 11	Group 1	This **R-Evolution CR** uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	This **R-Evolution CR** is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY
The R-Evolution CR is intended for use in the electromagnetic environment specified below. The customer or the user of the R-Evolution CR should assure that it is used in such an environment.

The **R-Evolution CR** is suitable for use in the specified electromagnetic environment. The purchaser or user of the **R-Evolution CR** should assure that it is used in an electromagnetic environment as described below:			
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**	**Electromagnetic Environment**
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	IEC 60601-1-2 Test level	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 > 3 m	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_n for 0.5 cycles 40 % U_n for 5 cycles 70 % U_n for 25 cycles 0 % U_n for 5 s	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **R-Evolution CR** requires continued operation during power mains interruptions, it is recommended that the **R-Evolution CR** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	IEC 60601-1-2 Test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

non-LIFE SUPPORTING EQUIPMENT

The **R-Evolution CR** is intended for use in the electromagnetic environment specified below. The customer or the user of the **R-Evolution CR** should assure that it is used in such an environment			
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**	**Electromagnetic Environment**
			Portable and mobile RF communications equipment should be used no closer to any part of the **R-Evolution CR,** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance**
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \times \sqrt{P}$ 80 MHz to 800MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5GHz
Conducted RF EN 61000-4-6	3 V 150 kHz to 80 MHz	3 V	$d = 1.2 \times \sqrt{P}$
			Where *P* is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths for fixed RF transmitter, as determined by an electromagnetic site survey, should be less then the compliance level in each frequency range Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE:
U_T is the a.c. mains voltage prior to application of the test level
Note 1:At 80 MHz and 800 MHz, the higher frequency range applies.
Note2:These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF

transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the R-Evolution is used exceeds the applicable RF compliance level above, the R-Evolution should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the R-Evolution unit.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Recommended Separation Distance for non-LIFE SUPPORTING EQUIPMENT

R-Evolution CR is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of R-Evolution CR can help preventing electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and R-Evolution CR as recommended below, according to the maximum output power of the communications equipment.

The **R-Evolution CR** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **R-Evolution CR** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the **R-Evolution CR** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150KHz to 80MHz $d = 1.2 \times \sqrt{P}$	**80MHz to 800MHz** $d = 1.2 \times \sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at the maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated 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 80MHz and 800MHz, the separation distance for the higher frequency range applies

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

For transmitters rates at maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

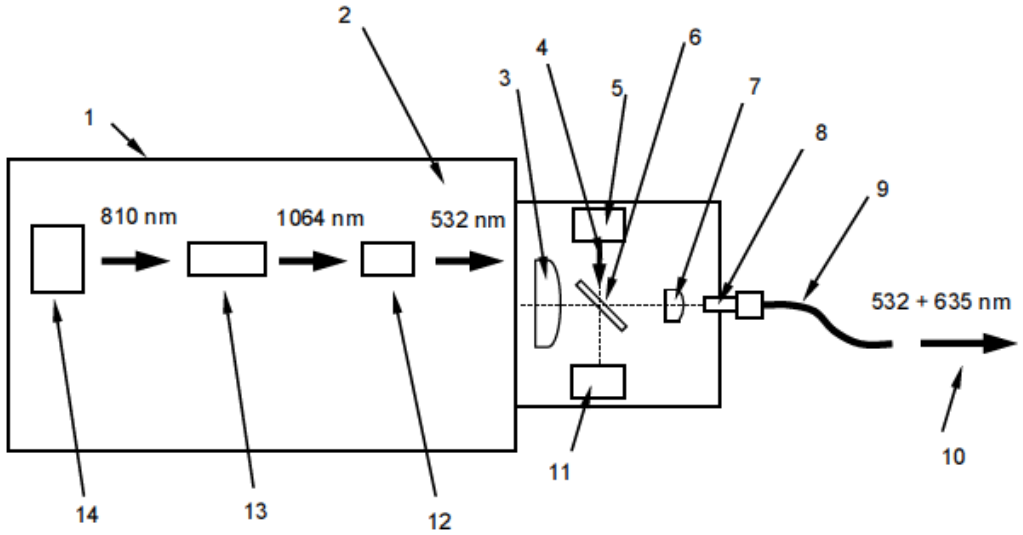
NOTE:
Note 1-At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2-These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

4.3 WIRING DIAGRAMS

On request, OPTIKON 2000 S.p.A. provides wiring diagrams, component lists, descriptions, calibration instructions or other information that may help the operator's trained technical personnel during repair of the repairable elements of the apparatus.

4.4 OPTICAL BEAM PATH



(1) Green Power Laser Generator 532 nm	(8) SMA Connector
(2) Green Beam Path 532 nm	(9) Fiber of Delivery Device
(3) Collimating Lens	(10)) Output Beam 532 + 635 nm
(4) Red Aiming Beam Path 635 nm	(11) Green Power Laser Measuring Diode 532 nm
(5) Red Aiming Beam Laser 635 nm	(12) Frequency Doubling Crystal (KTP)
(6) Beam Splitter	(13) Laser Crystal (Nd:YVO)
(7) Coupling Lens	(14) Laser Diode

5. INSTALLATION AND USE

Before first start-up

CAUTION	**Risk of injury to the patient's eye!** Optikon 2000 Service or an expert authorized by Optikon 2000 will install the system. Please make sure that the following requirements continue to be met for further operation: • The connecting parts must be seated properly. Screw connections are tightened. • All cables and plugs are in perfect condition, i.e. show no signs of wear, kinks or other damage. • The voltage set on the instrument corresponds to the rated line voltage on the site of installation. • The power plug may be connected only to a socket provided with a faultless protective earth conductor. • The device is connected to the power cord supplied for this purpose.

CAUTION	**Risk of injury to the patient's eye!** • Make sure that all specified "Requirements for operation" are fulfilled. • Be sure that all symbols and marking on the system have been understood. • The ventilation openings must not be closed or covered. • Check whether the R-EVOLUTION CR offers enough room for maneuvering to avoid damage to the cables and ensure unrestricted movement of the system, and to have an easy access to reach power switch to disconnect electrical supply. • If necessary, connect equipotential connector on the rear of the device to equipotential connector of Operating Room by equipotential cable. This gives a second ground reference in case of malfunction of main plug earth.. • Check the user settings of the selected user profile to avoid unexpected behavior of the system.

After each use

- Set the laser to stand-by at the end of the treatment.

- Use the main power switch to switch off the system.
- The main power switch must always be off when the system is not in use. And cable plug must be removed from the main supply.

5.1 DESCRIPTION OF THE APPARATUS

The LASER upgrade module includes a solid state LASER having a wavelength of 532nm and a power of 2000mW, which is ideal for photo coagulation of the retina.

Optikon makes available laser fibers of various shape and gauges, optimized for 20, 23 and 25G vitro-retinal surgical techniques.

The device allows adjustment of laser emission in terms of power, pulses length and interval between pulses.

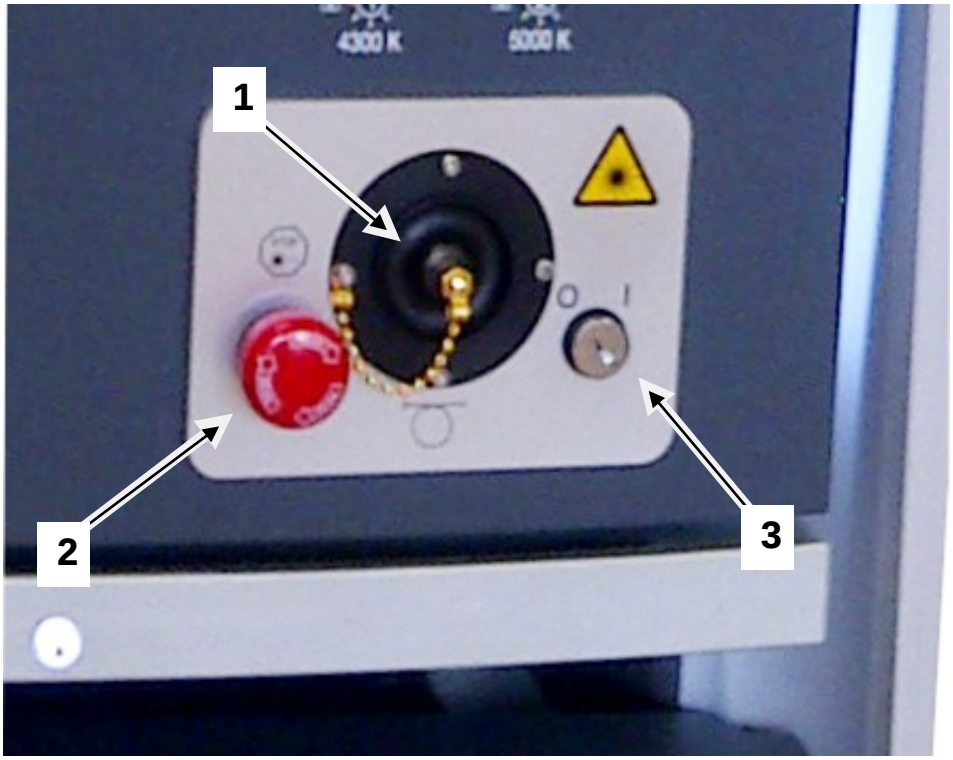
Two counters display number of emitted pulses and laser energy delivered.

A low power adjustable intensity aiming beam allows to precisely aim to the area to be treated.

User Protection Filters are available, both active (automatically inserted in the visual path just before laser emission) and passive (manually inserted).

5.2 SYSTEM COMPONENTS

5.2.1 **Front panel**



1 Fiber optic connector

The probe for endo-ocular coagulation plugs into this connector.

To avoid ingress of dust in the laser cavity, always close the connector with the cap when fiber is not connected

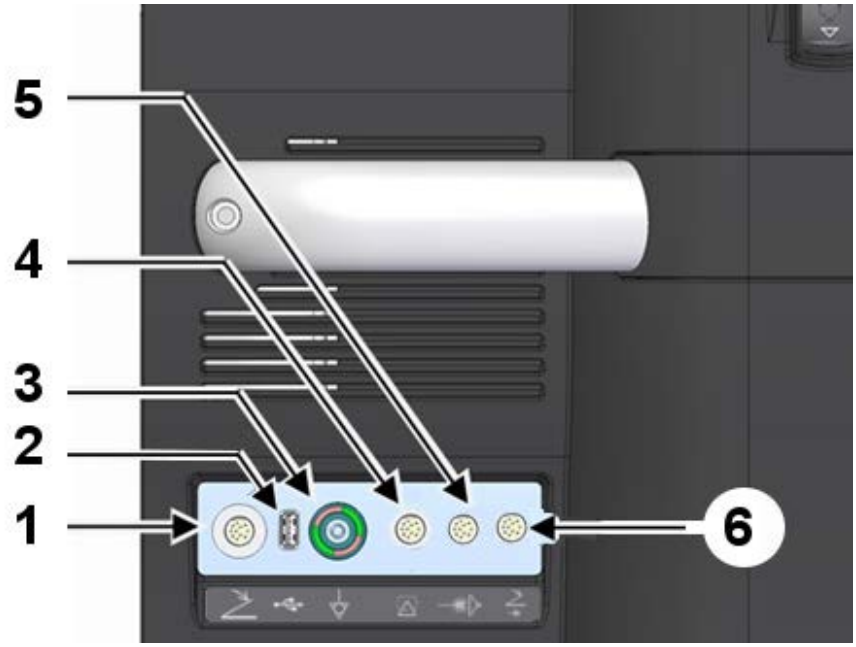
2 Emergency stop button

In case of emergency, push this button to stop laser emission instantaneously. Rotate the button a few degrees clockwise to release it and to allow re-activation of laser emission.

3 Power on key

The use of the laser system is intended for authorized medical personnel only. The laser power on switch is activated by a key. Do not leave the key connected to the equipment when the laser is not to be used.

5.2.2 **Rear panel connectors and controls**



1 System footswitch connector
The System footswitch controls activation of all R-evolution CR functions but laser emission. The System footswitch can be used either wired to this connector or in wireless mode.

2 USB connector
An USB memory device can be connected to this socket for software upgrades or to import/export user programs.

3 Equipotential connector
Equipotential point of R-evolution (Reference earth point).

4 Door safety switch connector
The R-EVOLUTION CR must be connected to a safety switch activated by the operating theatre access door, in a such way that laser emission is instantaneously arrested when the door is open.

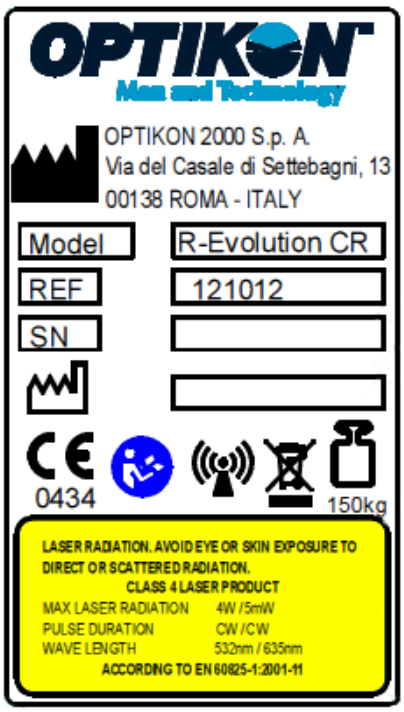
5 Operator automatic eye protection filter connector
The automatic safety operator eyes protection filter connects to this socket. The protection filter will insert automatically when the laser footswitch is depressed and before laser emission.
If a manual filter is used instead, the operator must verify that the filter is properly mounted on the microscope and confirm it before enabling Laser emission.

6 Laser footswitch connector
The Laser is controlled by a dedicated pedal, which is connected to this socket.

5.2.3 **Laser footswitch**

The laser is controlled by a dedicated footswitch, which is protected against accidental activation by a metal shield.
The footswitch must be connected to socket (6) before the laser is powered on by key switch.

5.2.4 **Symbols and labels**



Main label
(on the rear panel of the R-evolution CR)

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front panel labeling

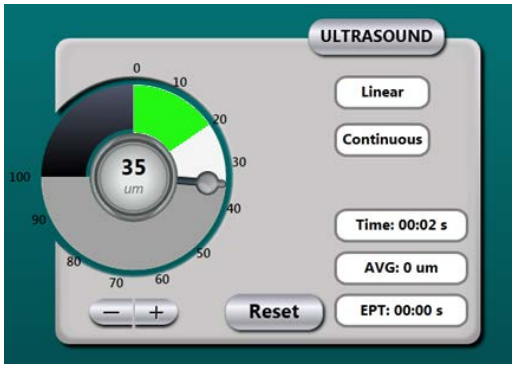
Connectors labeling
(rear panel)

5.3 5.3 TOUCHSCREEN AND USER INTERFACE

The R-Evolution CR is equipped with an interactive touch-screen and LCD (Liquid Crystal Display). The user interface consists of a graphic software, running under the Windows platform, simulating the various keys and displays.

The user can select the equipment function and adjust the relevant parameters by touching the screen in the appropriate areas. Actual and preset values for each parameter are displayed. If a sterile drape is placed on the monitor the equipment can be operated by a sterile scrub nurse.

In order to make the interface screen as much readable as possible, the R-Evolution user interface has been designed so that function keys, preset and actual parameters values are always visible on the screen, while setup keys for less frequently used settings are hidden during equipment operation. Parameters are logically grouped in parameter windows.



In the example on the left, pre-set limit for U/S power (35µm) is shown both at the centre of the dial wheel and by the radial finger indicator.

Actual U/S power (20 µm) is indicated by the green filled area from 0 to 20.

To adjust the parameter value, the user touches the area of the dial wheel close to the desired new pre-set limit.

A fine adjustment can be achieved by touching the - and + keys immediately under the dial wheel.

To set the status or value of less frequently changed parameters, such us Linear/Panel control or Emission mode, the user touches the “Ultrasound” button at the top of the window.

A new child window will open, allowing control of all additional parameters.

Touch a key to change the desired parameter and then “OK” to close the child window.

Some settings, e.g. P.E.M. and Pulsed, may require the system to present to the user additional dial wheels, push buttons or other controls.

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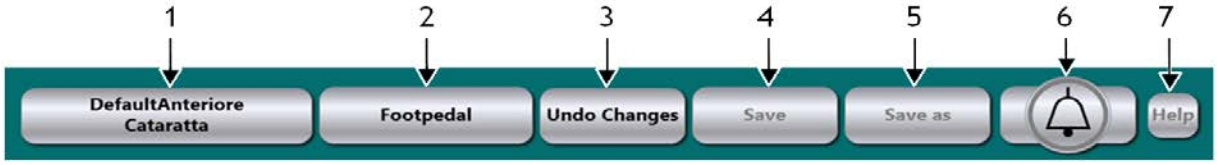
A bar at the top of the touch screen contains a series of buttons and indicators:



1. Active User Program Button/indicator.
   To access the available program list, depress this button.

2. Footswitch Program Button/indicator.
   Footswitch can be configured to operate according to Surgeon preferences. To access the available footswitch program list, depress this button.

3. Undo Changes Button/indicator.
   Allows undoing any change done by the user to the currently active program.

4. Save Button/indicator.
   Allows updating current User Program with all changes done by the User (current configuration). Default Programs cannot be modified and updated.

5. Save as Button/indicator.
   Allows saving the current configuration as a new User Program.

6. Alarm Button/indicator.
   Pushing this button, the list of currently active alarms appears on the screen.

7. Help Button.
   Pushing this button a context sensitive help appears on the screen.

A status bar, at the very bottom of the screen, indicates the actual status of the equipment by expanding the relevant indicator for the active surgical function (in the example above, Sculpt).

Touch the button indicator of any other surgical function to switch the equipment to the desired operating mode.

An Optikon logo, circled by white flashing dots indicates that the system software is operating normally.

INFORMATION

Risk of minor injury to the patient!

- If the dots around the logo cease to move, the system is in idle and you have to discontinue the use of the

system.
The user should periodically look at the logo to check for the system status.

Equipment error messages are categorized on three level of severity:

-  Warnings have higher priority. Errors of this level are numbered 1xx and indicated by a red symbol. An error of this priority requires to interrupt the use of the equipment.
-  Cautions have a lower priority. Errors of this level are numbered 2xx and indicated by a yellow symbol. An error of this priority impedes the use of a specific function only.
-  Information have the lowest priority. Errors of this level are numbered 3xx and indicated by a blue symbol. An error of this priority requires user attention to perform a specific action.

Refer to the "System alarm messages" chapter in this manual for a detailed description of all error messages, their causes and possible corrective actions.

Equipment warnings and error messages pop-up on the screen. Once the user has acknowledged the warning/error message, the pop-up disappears, the error is memorized into the warnings/errors messages board.

As a reminder of the still active alarm condition, the Alarm symbol (the bell at the top right of the screen) will appears circled in the color of the higher priority active alarm..

Touching the alarm symbol, causes the system to display a list of all the active alarms.

Press again the alarm symbol (bell) to close the alarm list and to resume normal operation.

All errors are automatically logged in the system memory and they are accessible in Service mode to Optikon Service Technicians.

For further details on the use of the Graphical User Interface, please refer to the description of the use of the individual equipment functions.

5.4 OPERATION

WARNING

Risk of injury!

- Laser emits potentially dangerous radiations which may cause burns and damages to sight. Before using laser, read carefully advices in the chapter 3.5 Notes to operator.

Switch on the laser module by rotating the power on key, located on the front panel, clockwise.
Connect preferred fiber optic to the fiber optic connector on the front panel.
In the “Posterior segment” surgical frame, press the “Laser” touch button in the lower line of the screen.
The page below will appear:

Move the slider button close to the power adjustment dial to the “on” position.

If a manual eye protection filter is in use, a pop-up will request to confirm that this filter is properly installed on the microscope. Verify that the filter is installed and confirm.

Adjust the aiming beam, laser emission power and on/off pulses time as required. Always start from low power-short pulse on time adjustments and then increase these values gradually until the desired surgical effect is achieved. Suggested starting settings for power and pulse time are found in the chapter “Clinical manual” for most of the common applications.

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Direct the fiber against a white surface and verify the brightness and shape of the aiming beam spot: a good quality of the aiming beam indicates that the overall laser optical path and the fiber optic are functioning properly.

If the aiming beam spot appears irregular or dim, replace the endo-fiber. If this action does not solve the problem, the laser cannot be used.

Defective fiber optic

Functional fiber optic 

Before enabling laser emission, verify that all personnel in the operating theatre wears eye protective glasses.

Touch the “Enable” button located near the ON/OFF switch, the Laser module starts preheating.

Press footswitch to activate laser emission.
Press “Enable” again to disable laser at the end of the surgical treatment.

The laser disables emission automatically if not used for more than four minutes.

6. System alarm messages

WARNING

Error messages on the touchscreen

Error messages with a red warning sign (L100 series) indicate a serious system error that cannot be remedied by the user.

- In case of Warning error messages, please contact the Optikon 2000 service team.
- Please note the explanations for each error message on the next pages.

CAUTION

Error messages on the touchscreen

Error messages with a yellow warning sign (L200 series) indicate a moderate system error that can be remedied by the user or our service.

- Please note the explanations for each error message on the next pages.

INFORMATION

Error messages on the touchscreen

Error messages with a blue warning sign (L300) indicate a minor system error or instruction that can be remedied by the user.

- Please note the explanations for each error message on the next pages.

All error messages are accompanied by an acoustic signal built with a group of tones which is specific of each error series.

The table below explains error codes relevant to the laser module only, refer to the equipment user manual REF 1X1012IT for other error codes.

L100 error series

Id	Message	Probable cause	Corrective measure
L100	Unrecoverable malfunction: laser stopped	An error has encountered which does not allow safe use of the laser module.	Contact Optikon 2000 service dept.
L166	Laser footswitch malfunction.	Footswitch is defective	Switch off the laser module by rotating the key on the front panel and replace footswitch

L168	Active user protection filter malfunction	The eye filter does not operate correctly	Replace the automatic eye protection filter

L200 error series

Id	Message	Probable cause	Corrective measure
L250	Laser over temperature. Please, wait until it has cooled down.	The laser has been in use for long time at high power and overheated	Wait for the laser to cool down
L212	Output power too low	Could be a transient error	Press OK and try again. If error persist, Contact Optikon 2000 service dept.
L267	Verify and confirm that the eye protection filter is inserted.	No automatic eye protection filter has been detected, confirmation that a manual filter is in use is required to proceed	Verify that the manual eye safety filter is properly installed on the optical path of the microscope and then press OK
L270	Active eye protection filter not in place. Please, place it correctly and confirm.	The automatic eye protection filter is installed but not properly positioned on the microscope.	Verify correct positioning of the filter
L271	Emergency stop	Emergency stop button has been depressed	If the button has been depressed by mistake, rotate it approximately 30 degrees clockwise to release the button and to return the laser in standby mode.

L300 error series

Id	Message	Probable cause	Corrective measure
L392	Laser Fiber not connected	Laser cannot be used because the fiber optic is not connected	Verify that the fiber optic is properly connected and that its ring-nut is completely screwed into the front panel connector
L360	Room door open	The safety system has forced the laser into the standby mode because the operating theatre access door has been opened	Wait until door is closed before re-enabling the laser
L365	No laser footswitch detected	Laser footswitch is not connected to the system	Switch off the laser module by rotating the key on the front panel and connect the footswitch.
L394	Active eye protection filter not ready, please wait.	The automatic eye protection filter has just been installed and it is being tested	Wait for filter test completion

7. Care and maintenance

7.1 EQUIPMENT MAINTENANCE

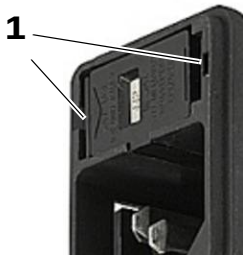
Changing fuses

The fuses for the control unit are located in the power inlet at the back of the unit. To change the fuses, proceed as follows:

CAUTION

Risk of injury to the user!
Hot fuses can cause skin burns.

- Before changing the fuses turn off the device and allow it too cool down for a few minutes



- Turn off the system using the power switch.
- Pull the power chord.
- Press lock levers (1) and remove the fuse holder.
- Remove the defective fuses and install new fuses.

INFORMATION

Risk of damaging the system!
Incorrect fuses may damage the system.

- Use fuses with the correct ratings only! Fuses rating depend on the line voltage setting of the system; please refer to the rear panel label for details.

- Re-install the fuse holder. Lock levers (1) must audibly snap in.
- Plug the power cord back in.
- Turn the unit on at the power switch.

7.2 MAINTENANCE OF THE SURGERY SYSTEM

CAUTION

Risk of injury to the patient's eye!

Malfunction of the system may injure the patient!

- Have your Optikon authorized service partner perform a safety check on the equipment in accordance with IEC 62353 and a verification of laser power calibration in the following cases:

- during the installation of the system,
- at regular intervals (every 12 months),
- during maintenance work,
- after repairs, upgrades, calibration, and soft- and firmware updates.

INFORMATION

Risk of damaging the system!

- To keep the system safe, check the unit conformity with electric current leakage limits according to standard EN 60601-1 at least once a year. Contact the technical division of your facility or your authorized distributor or the Optikon 2000 Service.
- Store the R-EVOLUTION CR surgery system in a clean dry location.
- Remove I/A tubing after each use.
- To prevent any impairment of the system safety as a result of aging, wear, etc., the user must ensure, in accordance with the applicable national regulations, that the regular technical safety checks defined for this system are performed on schedule and to the stipulated extent. The technical safety checks may be performed by the manufacturer or qualified persons only. The scope of the technical safety checks should at least comprise the following items:

- Availability of the user manual
- Visual inspection of the system and accessories for damage and legibility of the labels
- Test of protective earthing
- Leakage current test
- Function test of all switches, buttons, sockets and indicator lamps on the system.

MAINTENANCE OF ACCESSORIES

CAUTION

Risk of injury to patient or user!

Wet surfaces may cause electrical shock as RF currents may find a path through wet surfaces.

- Make sure that the diathermy handpiece is completely dry before using it.
- Avoid dropping or mishandling handpieces and accessories. It is critical to handle these components with utmost care and inspect them thoroughly for any damage or wear after each use.
- Periodically inspect the fluid lines, fittings, external O-rings and handpieces for any damage or wear.
- Reassemble all parts before storing.
- Place tip protective caps over handpieces (where provided) before wrapping and storing.

7.3 CARE OF THE DEVICE

Cleaning

The medical staff is responsible for keeping the medical device and further equipment in optimal operating condition. The simple steps described below constitute a practical guideline for defining a suitable care and maintenance program.

INFORMATION

Damages to the device

- Clean the front panel with a soft cloth dampened with distilled water.
  If necessary, use neutral detergent only.
- It is not permissible to use media that damage the surgery system.
- For cleaning please refer to the indications given in the relevant instructions for use.

Sterilization

WARNING

Injury to patient or user!

- The console, foot switch and I.V. pole cannot be sterilized.
- For reprocessing accessories, please refer to the indications given in the relevant instructions for use.

Disinfection

INFORMATION

Surface damages to the device.

- Use a disinfectant based on aldehyde and/or alcohol. The addition of quaternary compounds is acceptable. To prevent damaging surfaces, disinfecting components other than those listed below must not be used.

The maximum concentrations are:

- For alcohol (tested with 2 propanol): 60%
- For aldehyde (tested with glutaraldehyde): 2%
- For quaternary compounds (tested with DDAC): 0.2%

8. Laser Clinical Manual

8.1 FOREWORDS

Most Ophthalmologists today are very familiar with the use of a variety of laser wavelengths and laser products from different manufacturers, nonetheless it is extremely important that every new laser is approached as though it were completely different to the one that the user previously gained their experience on – it.

As a result of this, all settings given in this clinical manual are meant only as guidelines and it remains, as always, the responsibility of the operating Ophthalmologist to ensure that they establish the optimal settings for each and every case that they treat.

With a new laser, one must be prepared to forget previously learned settings and work gradually upwards until one has established optimal settings and thresholds relative to the new laser.

This clinical manual provides a summary of guidelines for the most common applications.

Please note that although these applications have all received FDA and other approvals, their inclusion does not guarantee that the application has received approval in your country.

Additionally, we recommend that the reader refers to textbooks and literature for a more comprehensive description of contemporary surgical laser techniques.

A bibliography is included at the back of this manual, but we especially recommend:

Kampik, A. (1992): Laser Yearbook of Ophthalmology, Zuelpich, published by Biermann

8.2 LASER INTENDED USE

The intended treatments for the R-evolution CR laser are:

Photocoagulation: By radiating the tissue with the laser the temperature of the tissue can be increased. This is due to absorption of radiation in the tissue and the transformation of laser energy into thermal energy. Depending on the intensity of the laser radiation, the tissue shrinks, becomes coagulated, burned, or vaporized. Based on these effects the eye is healed.

8.3 CONTRAINDICATIONS

This device may only be used for medical purposes. For use in dermatology, urology, otolaryngology, dentistry and internal medicine no clinical evaluations were performed. Thus the use of our unit for these applications is prohibited by law.

8.4 SIDE EFFECTS

Allergies to green laser light may occur due to laser treatment. This is the only known side effect. In case of allergy to green laser light the indication should be carefully considered by the user.

8.5 PRINCIPLES OF OPERATION

The cw frequency doubled Nd:YVO laser system of the R-evolution CR performs coagulation treatments at 532 nm.
The physiological mechanism of photocoagulation is based on a thermally induced denaturation of macro-molecular proteins. The transformation of light energy into heat results mainly from the absorption of the chromophores xantophyll, melanine and haemoglobin. Depending on the intensity of the irradiation, the tissue can be caused to shrink, coagulate, carbonise or even evaporate. Certain beneficial therapeutic effects are based on healing processes and scar formation.
CW frequency doubled Nd:YVO, at 532 nm, generates exactly the same laser light such as the cw frequency doubled Nd:YAG laser and requires also exactly the same energy. Compared to argon the cw frequency doubled Nd:YVO requires about the same energy as argon to achieve photocoagulation because it's green light is better absorbed by haemoglobin and less by xantophyll and there is a resultant reduction in scattering. The clinical results are about the same as with argon photocoagulation - if not better. The harmful side lines (like blue) as they get produced by the argon laser are not present with the frequency doubled Nd:YVO laser. By putting less energy into the eye, it reduces the post-operative complications. As it is a solid state, rather than gas tube, laser it also offers clear economic advantages over conventional argon systems and is much easier to maintain.
Whereas cw diode lasers at 810 nm has a much deeper penetration, cw frequency doubled Nd:YVO at 532 nm has a similar depth of penetration to argon and is therefore suitable for all retinal procedures currently performed by argon lasers. The lower scattering and lesser absorption by xantophyll makes it safer to use in the area of the macula.
In general one can summarize that the laser treatment should be started with rather low power and short pulse length and those parameters are increased step by step according to the desired and achieved effect.

8.6 APPLICATIONS

The cw frequency doubled Nd:YVO can, as has been previously mentioned, be used as an alternative to argon in all of its traditional applications. As these are already very well established and documented, it is not our intention here to go through of all the indications, contraindications and procedures. However, should the reader be interested, we especially recommend the following book:

Bloom, Steven M./Bruckner, Alexander J. (1997): Laser Surgery of the Posterior Segment (2nd ed. Up), Philadelphia, Lippincott-Raven.

8.7 ENDOPHOTOCOAGULATION

Used mainly in conjunction with argon, as an auxiliary procedure in vitro retinal surgery, may be performed equally well with the cw frequency doubled Nd:YVO.
Two endo fibers, straight or curved, are available for this procedure. Both consist of 0.2mm flat-ended silica fibers (numerical aperture 0.22) encased in a steel housing, with an outer aperture of approximately 0.9mm.

Endophotocoagulation of Chorio-Retina
The straight probe is used for endophotocoagulation of the chorio retina, particularly for scatter treatment of diabetic retinopathy, with recommended starting values as per the following table:

Power (mW)	Exposure duration (ms)	Energy (J)
300	200	0.06

If there is no or insufficient effect, the exposure duration or power should be increased.

Endocyclophotocoagulation

The curved probe is used for endocyclophotocoagulation in cases of a concomitant glaucoma, using the same recommended starting values as in the previous table for endophotocoagulation. The probe should be directed against the ciliary body, if there is no whitening of the ciliary body, increase the exposure duration.
In both procedures the dosage depends very strongly on the distance of the probe from the retina or ciliary body - the intensity of the impact may be varied simply be varying the distance.

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