CE 0051

R-Evolution
R-Evolution CR

COMBINED EYE SURGERY MEDICAL DEVICE

MANUAL FOR INSTALLATION AND USE

OPTIKON 2000 S.p.A.

Via del Casale di Settebagni 13 - 00138 Rome – Italy
Tel. +39 06 8888355 – Fax. +39 06 8888440
e-mail: sales@optikon.com
www.optikon.com

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. DISCLAIMER

The user of this Medical Device 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 Medical Device 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 Medical Device is used in compliance with the user instructions;
- the electrical system to which the Medical Device is connected proves to be in compliance with IEC safety regulations.

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 Medical Device. 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.**

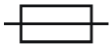
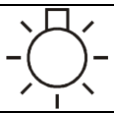
3.2 TABLE OF SYMBOLS

The table below shows some I.E.C. 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.

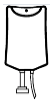
SYMBOLS PUBLISHED BY IEC

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

	SEE OPERATING INSTRUCTIONS
	NOMINAL FUSE RATING
	EXTERNAL COMPRESSED AIR INLET
	AIR INJECTION SOCKET
	LIGHT SOURCE SOCKET
	DIATHERMY SOCKET
	FOOTSWITCH SOCKET
	BATTERY CHECK

OTHER SYMBOLS ON THE EQUIPMENT

	SCISSORS SOCKET
	SILICONE OIL INJECTION SOCKET
	PHACO SOCKET
	VITRECTOMY SOCKET
	KNOB FOR UNLOCKING CASSETTE
	USB SOCKET
	IRRIGATING SOLUTION

	INCREASE LEVEL
	DECREASE LEVEL
	CONTROLLED IRRIGATION
	SPHYGMOMANOMETER ARM CUFF

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 Medical Device 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 R-Evolution Surgical Medical Device has been designed to be used in surgical theatres by qualified medical personnel (eye surgeon) for surgical procedures for treatment of the anterior segment of the eye. The equipment has been designed for the implementation of irrigation, irrigation/ aspiration, phacoemulsification of crystalline lens, anterior vitrectomy, bipolar diathermy coagulation techniques. The R-Evolution CR also features posterior vitrectomy, air and silicone oil tamponade, endo-ocular illumination. The Medical Device is intended for use in clinics, hospitals, and other institutions of human medicine.

3.4 INTENDED USE

The R-Evolution is intended for surgical treatments, such as extra-capsular extraction, phacoemulsification or glaucoma in the anterior segment of the human eye, the R-Evolution CR also for surgical treatment of retinal detachment and other pathologies of the vitreous body and the posterior segment of the human eye. Malfunctions during the use of the Medical Device 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 Medical Device in brain or heart surgery is excluded.

⚠ **WARNING** **Risk of injury to the patient!**

- The diathermy section of the R-Evolution must not

be used with patients with a pace maker or other cardiac stimulators without consulting a cardiologist in advance.

3.5 NOTES FOR THE OPERATOR

- Use the Medical Device 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 the user manual before starting up the Medical Device. Please note the instructions for use of the other equipment as well.
- Before using the device, all medical staff must have read and understood all instructions included in the present user manual.
- Keep the user manual in a place that is easily accessible at any time to the staff charged with operation of the Medical Device.
- The Medical Device may only be used by qualified medical employees who understand the possible risks associated with the use of this medical device and completed adequate training in the prevention and management of clinical complications, if any.
- The Medical Device 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 Medical Device.

- Adequate training is essential for proper installation and operation of the R-Evolution, 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 Medical Device 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 device.
- For transports over extended distances (e.g. dismantling, return for repair purposes, etc.), you need to package the device in its original package or special return shipment packages. For details, please contact your dealer or Optikon 2000 Service.

Set-up and installation

INFORMATION **Risk of damaging the Medical Device!**

- Make sure that the installation conditions and the use of the device meet surgical requirements:
  - Low vibration
  - Clean environment
  - Avoidance of extreme mechanical loads

INFORMATION **Risk of damaging the Medical Device!**

The maximal height level of the infusion pole is 290 cm.

- Do not install the R-EVOLUTION under a low ceiling.

INFORMATION **Risk of damaging the Medical Device!**

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

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

⚠ **WARNING** **Risk of fire or explosions!**

The Medical Device 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 Medical Device in damp rooms. Do not expose the device to water splashes, dripping water or sprayed water.

- To ensure safe operation, do not install the Medical Device 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.

Operation

⚠ **CAUTION** **Risk of injury to the patient or user!**

- Please comply with the maximal loads on the following components:
  - Maximal load on instrument tray 1 kg.
  - Maximal load of bottle and irrigation solution 1 kg.

⚠ **CAUTION** **Risk of injury to patient or user!**

Risk of tipping when crossing doorsteps.

- Push the device slowly and carefully by its handle over doorsteps of up to 3 cm. If the doorstep is higher than 3 cm, the equipment must be moved over the doorstep by two people.

INFORMATION **Risk of minor injury to the patient!**

A logo with rotating white dots at the lower right edge of the screen indicates that the system is working properly.

- If the dots around the logo cease to move, the software is in idle and you have to discontinue the use of the Medical Device.
- Before each use, carry out the installation, surgical

configuration and operating procedures described herein. If a malfunction occurs which cannot be corrected using the chapter "Remedying malfunctions", please label the device as non-functional and contact the Optikon 2000 service.

- Carefully follow the instructions when installing and using the unit in order to prevent harmful interference by with other devices. If the Medical Device 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.
- The sound emission capability of the equipment is tested at start-up.
  Verify that an acoustical signal is emitted during initialization.
- Malfunctions during the use of the Medical Device 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 device, but rather attach a sign to it stating that it is "out of order", and contact your local Optikon 2000 Service or local dealer.
- Do not pull on power cables or other connecting cables.
- Moving the equipment make sure that no hoses get pinched or pulled off.
- Never leave a Medical Device unattended while the light source is turned on in order to prevent retinal

damage on the eye of the patient from excessive irradiation times.

Maintenance

- This Medical Device 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.
- To prevent any impairment of the system safety as a result of aging, wear, etc., the institution operating the device must ensure, in accordance with the applicable national regulations, that the regular technical safety checks prescribed for this Medical Device 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 equipment and accessories for damage and legibility of the symbols/labels
  - Test of protective earthing impedance
  - Leakage current test
  - Functional test of all switches, buttons, outlets, and indicator lamps of the Medical Device.

Modifications

⚠ **WARNING** **Risk of injury to the patient's eye!**

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

- Do not change the shape of a vitrectomy handpiece or phaco tip used with the R-EVOLUTION (i.e. do not kink, cut or scratch).

⚠ **WARNING** **Risk of injury to the patient's eye!**

Changes due to the application of manual force to the height level of the infusion pole lead to an incorrect

height level of the bottle and patient injury.

- The height level of the infusion pole must not be modified or changed by the application of manual force.

- Modifications and repairs of this Medical Device or any system operated together with this device may only be performed by the Optikon 2000 Service or other suitably authorized persons.

Disposal

⚠ **CAUTION**

Pollution of the environment!

Inappropriate disposal may contaminate the environment!

- Do not dispose of the device 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 those sets that are approved and recommended by Optikon 2000.

⚠ **CAUTION** **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. Check the Instructions for Use of the accessories for compatibility with the R-EVOLUTION.

- The use of accessories and cables that are not enclosed in the scope of delivery of the Medical Device may lead to increased emission of electromagnetic interference or reduced immunity of the device to interference. Only use spare parts approved by Optikon 2000 for this device.
- 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.

Electrical system

INFORMATION **Risk of equipment malfunctions!**

- Use only USB pendrives that are free from viruses.
- Virus-free USB sticks must be used exclusively.

- The Medical Device 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 to a mains supply having the characteristics shown on the rear panel of the console. To guarantee safe operation, the equipment must be properly grounded.
- To avoid the risk of electrical shock, this device may only be connected to a properly grounded supply unit.
- 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 Medical Device is not in use.
- Before replacing fuses, switch off the Medical Device and let it cool down a few minutes.
- If required by the regulations and guidelines in the country of use, the Medical Device must be connected to an uninterruptible power supply.
- Do not place any fluid-filled containers on top of the equipment. Make sure than no cleaning agents can enter the device.
- 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 Medical Device must be properly grounded to ensure safe operation.
- Additional potential equalization: The Medical Device must be incorporated into protective earth connectors.

Diathermy application

WARNING

Risk of injury in patients with cardiac pacemakers!

There is a possible risk in patients with a cardiac pacemaker or stimulation electrodes because the diathermy generator may generate RF interference. The pacemaker may fail.

- If you have concerns in this regard, please contact a knowledgeable physician for advice.

WARNING

Risk of injury to the patient's eye!

- When the bipolar diathermy handpiece and a monitoring system are used at the same time, all electrodes of the monitoring system that are not protected by resistors or high frequency inductors must be placed as far away as possible from the diathermy electrodes.
- Risk of burns or fire; do not use diathermy near conductive materials such as metal bed parts, inner-spring mattresses, and the like. Replace the electrode cables as soon as there is any evidence of wear.
- Use original diathermy cables from Optikon 2000 only.

CAUTION

Risk of burns!

- The PATIENT should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.).
- Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry gauze
- The cable of the bipolar diathermy should not touch the patient or other cables.
- Temporarily unused diathermy handpieces should be stored in a location that is isolated from the PATIENT.
- Severe RF (radio frequency) burns can result if the diathermy output current is diverted to the operator by careless handling.

- Always use the lowest output diathermy power level which is compatible to the surgical application.
- failure of the diathermy generator could result in an unintended increase of output power.
- Evidence of low output level or faulty operation of the bipolar diathermy handpiece, even though the equipment has been set for normal use, may indicate a bad contact in the electrodes connections.
- Using the bipolar diathermy handpiece , do not use flammable anesthetics, nitrogen monoxide or oxygen, if sufficient ventilation by a suitable aspiration system is not guaranteed.
- Flammable materials such as disinfecting agents and cleaning agents should be evaporated before using the bipolar diathermy handpiece.
  There is a risk of pooling flammable solutions under the patient or in body depressions, such as under the neck or in the eye orbit. Any flammable fluid deposited in these areas should be dried before using diathermy. Some materials such as cotton wool or gauze, if soaked with oxygen, can catch fire because of the sparks caused by the equipment in its normal use.
- Interference with other medical equipment due to the use of the bipolar diathermy handpiece is possible.
- R-evolution diathermy generator is designed for bipolar coagulation applications only, therefore no neutral electrode must be used.

⚠ **CAUTION**

Risk of injuries!

- Mainly due to the rectifying effect of arcs between the electrodes and tissue , diathermy may cause neuromuscular stimulation, with risk of injuries due to muscular contraction.

Irrigation/Aspiration application

WARNING

Risk of injury to the patient's eye!

Positioning the irrigation solution too low may cause the pressure in the eye of the patient is too low.

- Make sure that the irrigation solution is always at or above eye level of the patient.

- Please comply with the indications described in the "Set-up of the irrigation/aspiration tubing" chapter of this manual. Non-compliance with the indications specified therein may lead to serious consequences.
- Correct set-up of irrigation and aspiration lines is critical to ensure proper operation of the R-EVOLUTION.
- Switching from peristaltic mode to Venturi mode may cause anterior chamber collapse if a low impedance phaco tip is used (i.e. large bore phaco tip) and if the vacuum is set at a high level. To ensure patient safety, always check that the vacuum setting is proper for the desired type of pump before restarting aspiration after switching pump types.
- Use only original Optikon 2000 tubing sets.
- Do not prime or fine-tune the handpiece while it is situated in the eye of the patient as this could result in patient injury.
- Before any intervention make sure that a sufficient amount of balanced salt solution is available. Monitor the amount of balanced salt solution during the entire intervention.
- During the operation, keep monitoring the level of balanced salt solution in the infusion bottle. If the amount of balanced salt solution is deemed insufficient for completing the operation, immediately notify the surgeon and replace the infusion bottle or infusion bag proceeding as follows:

IRRIGATION BY GRAVITY

- Interrupt the surgical procedure and remove the handpiece from the incision.
- Close the clamp on the infusion hose.
- Unhook the bottle from the infusion pole when the bottle is almost empty.
- Remove the spike of the infusion set from the bottle, being careful not to touch it with your hands or any other non-sterile materials.
- Insert the infusion set's spike in the cap of the new bottle and hook it to the I.V. pole.
- If the drip chamber becomes completely empty, squeeze it to fill it with balanced salt solution until it is approximately 50% full.
- Re-open the infusion clamp.
- If air bubbles are observed in the irrigation tubing, ask the surgeon to activate just irrigation until the bubbles have been expelled, before reinserting the handpiece in the patient's eye.

CONTROLLED INFUSION

- Interrupt the surgical procedure and remove the handpiece from the incision.
- Close the clamp on the infusion hose.
- Disconnect the air tube from the "CONTROLLED" outlet located on the medical device console.
- Unhook the near-empty infusion container from its support.
- Remove the spike of the infusion set from the infusion container, being careful not to touch the needle with your hands and not to allow it to come into contact with any non-sterile material.
- Puncture the spike of the infusion set into the cap of a fresh infusion container and suspend it on the support.
- Connect the air tube to the "CONTROLLED" outlet of the medical device console.
- Re-open the irrigation clamp.

- If air bubbles are observed in the irrigation tubings, ask the surgeon to activate just irrigation until the bubbles have been expelled, before reinserting the handpiece in the patient's eye.

Ultrasound application

WARNING **Risk of injury to patient or user!**

Prolonged exposure to or direct contact with the vibrating phaco tip while testing the phaco tip for vibrations may cause damage to healthy tissue.

- Never place your hand or finger on the phaco tip or the silicone sleeve of the phaco handpiece while testing the phaco handpiece.

CAUTION **Risk of injury to the patient's eye!**

Burn injury caused by excessive ultrasound energy!

- Vibration noise should increase with ultrasound power setting, a constant high noise at all power levels indicates equipment malfunction.

CAUTION **Risk of injury to the patient's eye!**

Moving the phaco tip/silicone sleeve in the incision may cause corneal damage in the patient.

- Do not twist against and do not apply pressure to the wound.

CAUTION **Risk of injury to the patient's eye!**

Corneal burn injury caused by excessive ultrasound energy.

- Always use the lowest ultrasonic output power level which is compatible to the surgical application.
- Do not activate the phaco handpiece while the phaco tip is surrounded by air. The ultrasonic power should be applied to the phaco handpiece with the phaco tip immersed in a sterile test chamber filled with infusion fluid or in a beaker of sterile fluid at ambient temperature. Non-compliance with these instructions can lead to damage to the phaco tip and/or phaco handpiece.
- Please make sure that the phaco handpiece is properly connected to the irrigation/aspiration system of the R-evolution and it is used together with the system only.
- A loud buzz from the phaco handpiece at minimum

power setting may indicate a malfunction of the power regulation circuitry which may cause corneal burns or endothelial damage. Please contact your local dealer or the Optikon 2000 Service.

- Never press the phaco tip/silicone sleeve against the wound in order to prevent the phaco tip from over-heating.
- Undesirable increase of the output power may be indicative of a malfunction of the R-Evolutio. Please contact your local dealer or the Optikon 2000 Service.

Vitrectomy application

- Never activate the vitrectomy handpiece while the cutting tube is surrounded by air. The cutting tube should always be test run in a beaker of sterile solution. Testing in air will cause irreparable damage to the cutting tube.

Illumination

⚠ **WARNING** **Risk of injury to the patient's eye!**

- Adapt the irradiation intensity and the corresponding duration of exposure by selecting suitable irradiation settings.

⚠ **WARNING** **Risk of injury to the patient's eye!**

Retinal damage due to excessive power level.

- Although the fiber optic endo-ocular illumination system is designed for no or minimal emission of Infrared and Ultraviolet radiation, to avoid possible damage to the retina, always use the minimum power level which is compatible to the surgical application.

INFORMATION **Risk of minor injury to the user!**

Light output ports that are turned on are hot.

- Turn off the light and wait several minutes before you touch the light output ports!
- To reduce the risk of retinal damage, the edge of the fiber optic illumination probe should not be situated in the immediate vicinity of the retina.

Air-silicone oil tamponade

WARNING

Risk of injury due to excessive air pressure!

- An audible air leakage at power up may indicate Silicone section malfunction. Please, consult your local Optikon 2000 Service.

- To avoid possible eye infections, use only the original Optikon 2000 air infusion hose for air tamponade which is provided with an air sterilization filter.
- The use of non-standard air supply tubing kit may compromise the accuracy of intra-ocular air pressure and compromise sterility of air.
- During the injection of silicone oil, the intraocular pressure is not controlled by the R-Evolution CR such that the surgeon is in charge of controlling the intraocular pressure (IOP). It is important to check silicone flow at the preset injection pressure before inserting the cannula in the eye.
- Release the foot switch to discontinue the injection of silicone oil. In any case of emergency, you can take the silicone oil infusion tubing off the silicone supply unit.

OPTIKON 2000

Digital Sphygmomanometer (MOPP)

⚠ **CAUTION**

Do not apply the cuff to an arm with another medical equipment attached. The equipment may not function properly.

- Measurements may be distorted if the device is used close to televisions, microwave ovens, cellular telephones, X-ray or other devices with strong electrical field.

⚠ **WARNING**

Risk of injury!

With people who have a severe circulatory deficit in the arm, consult a specialist before using the device, to avoid medical problems.

- Do not apply the cuff on an arm receiving an intravenous drip or blood transfusion. It may cause injury or accidents.
- Do not apply the cuff on an arm with an unhealed wound.
- Do not apply the cuff on the arm on the side of a mastectomy.
- The device is not intended for neonatal use, neither for use on preeclamptic patients.

INFORMATION

Risk of device malfunction.

- Do not modify the device. It may cause accidents or damage to the device.
- Clean the arm cuff with a dry, soft cloth or a cloth dampened with water and neutral detergent. Never use alcohol, benzene, thinner or other harsh chemicals.
- Avoid tightly folding the cuff or storing the hose tightly twisted for long periods, as such treatment may shorten the life of the components.
- Verify that the cuff size is adequate for the arm of the patient.
- Place the arm cuff directly against the skin, as clothing may cause a faint pulse and result in a measurement error.
- Constriction of the upper arm, caused by the tightly rolling up a shirtsleeve, may prevent accurate readings.
- Proper functioning of the device has only be tested with Optikon arm cuffs. Always use original spare parts.

4. TECHNICAL SPECIFICATIONS

4.1 GENERAL SPECIFICATIONS

PARAMETER	SPECIFICATION
Manufacturer:	OPTIKON 2000 S.p.a. via del Casale di Settebagni, 13 00138 Rome - Italy
Model:	R-Evolution / R-Evolution CR
Regulatory compliance:	93/42/EEC Medical Devices Directive (MDD)
Technical standards:	EN60601-1; EN60601-1-2 ; EN60601-2-2 ; EN80601-2-58 ; EN60601-2-30
ENVIRONMENTAL SPECS	
Storage and transport:	temp range –10°C to +70°C, humidity 10-100% (non-condensing), atmospheric pressure 500-1060hPa
Operation:	temp range +10°C to +35°C, humidity 30-75%, atmospheric pressure 940-1060hPA (for max aspiration vacuum); 810-1060hPA (aspiration vac. up to 500mmHg)
ELECTRICAL SPECS	
Input voltage:	100-240 Vac.
Frequency:	50/60 Hz
Power consumption:	420 W
Line fuses:	100-240 Volt: T4AH 250V
COMPRESSED AIR SPECS (R-Evolution CR only)	
Input air pressure:	from 500 to 800 KPa (72 to 116 PSI)
Air consumption:	32 normal litre/minute
IRRIGATION	
Fluid delivery:	gravity fed - eye pressure determined by the height of irrigation source or Controlled
Valving element:	solenoid driven pinch valve
Control:	system footswitch
ASPIRATION	
Aspiration pump types:	R-Evolution: rotary vane and peristaltic R-Evolution CR: Venturi and peristaltic
Actuating medium:	(Venturi pump) pressurized air from external source pressure: 500÷800 KPa (72÷116 PSI)
Flow:	at least 30 normal litre/minute @ 600mmHg
Default vacuum level:	user programmable
Available vacuum range:	5 to 700 mmHg

OPTIKON 2000

PARAMETER	SPECIFICATION
Default flow rate:	user programmable
Available flow rate range:	1 to 90cc/min (peristaltic only)
Available aspiration rise time: ..	from 0.5s to 12s (25 levels)
Surgeon mode (linear aspiration):	linear aspiration (vacuum and/or flow rate) from minimum to maximum user programmable values, linearly controlled via system footswitch
Safety device:.....	vacuum sensor; monitors the vacuum in the aspiration line
Control:	system footswitch
POSTERIOR VITRECTOMY (R-Evolution CR only)	
Handpiece type:	pneumatically powered guillotine cutter (VIT), pneumatically powered microscissors (SCISS)
Cutting mode:.....	reciprocating motion
Default cut rate:	user programmable
Available cutting rate:.....	from 60 to 10.000 cuts per minute (VIT) from 120 to 20.000 cuts per minute (Twedge) from 60 to 310 cuts per minute (SCISS)
Single cut mode:	Available for Scissors only
Port size:	0.5mm
Actuating medium:.....	pressurized air from external source
Operating pressure:	2.3bar to 4.2bar
Surgeon mode (Linear cut):.....	linear cut rate from programmable start frequency to programmable end frequency, controlled via system footswitch
Control:	system footswitch
ANTERIOR VITRECTOMY	
Handpiece type:	pneumatically powered guillotine cutter
Cutting mode:.....	reciprocating motion
Default cut rate:	user programmable
Available cutting rate:.....	from 60 to 4.200 cuts/min (CR 60 to 10.000cuts/min)
Port size:	0.5mm approx.
Actuating medium:.....	pressurized air from external source (CR) or from internal oil less compressor (R-EVOLUTION)
Operating pressure:	2.3bar
Surgeon mode (Linear cut):.....	linear cut rate from 0 to preset controlled via system footswitch
Control:	system footswitch
DIATH (DIATHERMY)	
Type:	bipolar generator - generator stops when RF power is not needed

PARAMETER	SPECIFICATION
Operating frequency:	2 MHz
Nominal power:.....	9W (200 Ohm LOAD)
No load max. voltage:	100 V
Default bipolar power:	user programmable
Available bipolar power:	5 to 100% (percent)
Surgeon mode (linear power): ..	allows linear control of the DIATHERMY power via system footswitch depression
Handpiece type:	bipolar microforceps, slim stat pencil eraser, intraocular diathermy pencils
Diathermy cable:	two poles, 26 gauges, 75 ohm, 200V max, steam autoclavable. Use only original OPTIKON 2000 S.P.A. diathermy cable
Control:	system footswitch
ILLUMINATION (R-Evolution CR only)	
Source type:	Three independent LED lamps
Luminous flux:	400+400+400lm
Intensity adjustment:	20 levels + 4 protection and epiretinal membrane visualization enhancement cut-off filters
AIR INJECTION SECTION (R-Evolution CR only)	
Nominal pressure:	from 5 to 120 mmHg
Actual IOP:	Nominal pressure ± 3 mmHg
Safety devices:.....	Air activation sound
SILICONE INJECTION SECTION (R-Evolution CR only)	
Nominal pressure:	from 0,4 to 5 bar
Signals:	Silicone injection activation sound, Low pressure at air inlet
PHACOEMULSIFIER	
Handpiece type:	piezoelectric, four crystals and six crystals models
Frequency:	approx. 43KHz (39.5-44KHz)
Tip stroke:.....	from 0 to 100µm
Power:	panel or linear control of the U/S power from programmable start value to programmable end value via system footswitch depression.
U/S Mode:	Linear or Panel; Continuous, Autolimit, Short Pulse, HD Pulse, Single Burst, Multi-Burst, Continuous Burst, Programmable Emission Mode
U/S Timer:.....	from 0.00 minutes to 9.59 minutes – Equivalent Phaco Time display

OPTIKON 2000

PARAMETER	SPECIFICATION
SPHYGMOMANOMETER (MOPP) (R-Evolution CR only)	
Measurement method:.....	Oscillometric measurement
Device validation:	The Medical Device has been clinical investigated according to the requirements of ISO 81060-2:2013
Measurement range:	Systolic: 25-280mmHg Diastolic: 10-220mmHg Pulses: 20-230 Beats per Minute
Overpressure limit:.....	300mmHg
Standard Arm Cuff size:	27-35cm
EQUIPMENT CLASSIFICATION ACCORDING TO IEC 60601-1	
Type of protection against electric shock:	class I
Degree of protection against electric shock:	
Diathermy:	Type BF, floating both at high and low frequencies
U/S:	Type B
Vitrectomy:.....	Type BF
Illumination:	Type BF
Air:	Type BF
Silicone:.....	Type BF
Scissors:.....	Type BF
Sphygmomanometer arm cuff: ..	Type BF
Degree of protection against harmful ingress of water (unit) :	IPX0
Degree of protection against harmful ingress of water (footswitch):	IPX8
Degree of safety of application in the presence of a flammable anaesthetic mixture:.....	not suitable
DIMENSIONS	
Height:	165 cm
Width:	54 cm
Depth:	57 cm
Weight:.....	130 Kg

NOTE:
1) Weight and dimensions shown are approximate.
2) Specifications are subject to change without notice.

4.2 EMC TABLES

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

The **R-Evolution devices** are suitable for use in the specified electromagnetic environment. The purchaser or user of the **R-Evolution** 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 devices are** intended for use in the electromagnetic environment specified below. The customer or the user of the **R-Evolution** 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.

OPTIKON 2000

Recommended Separation Distance for non-LIFE SUPPORTING EQUIPMENT

The **R-Evolution devices are** intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **R-Evolution** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the **R-Evolution** 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:

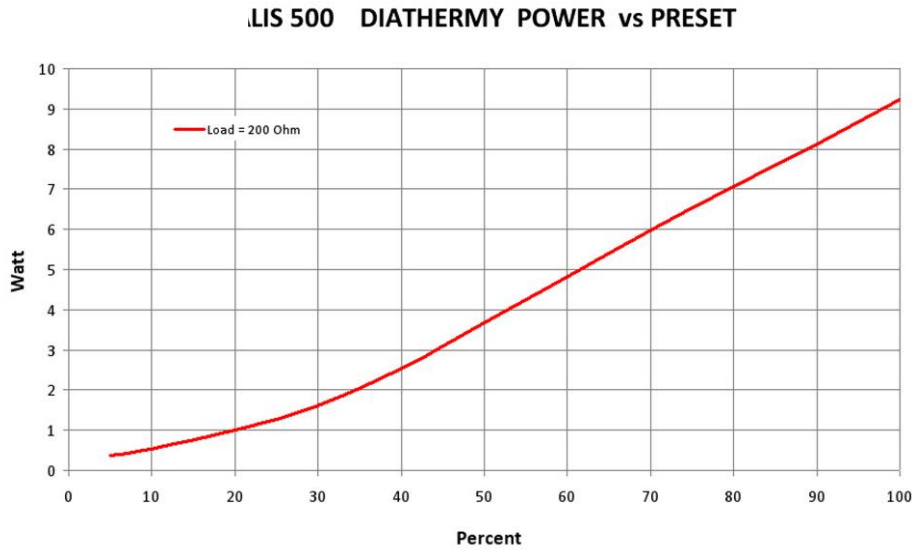
(1) at 80MHz and 800MHz, the separation distance for the higher frequency range applies

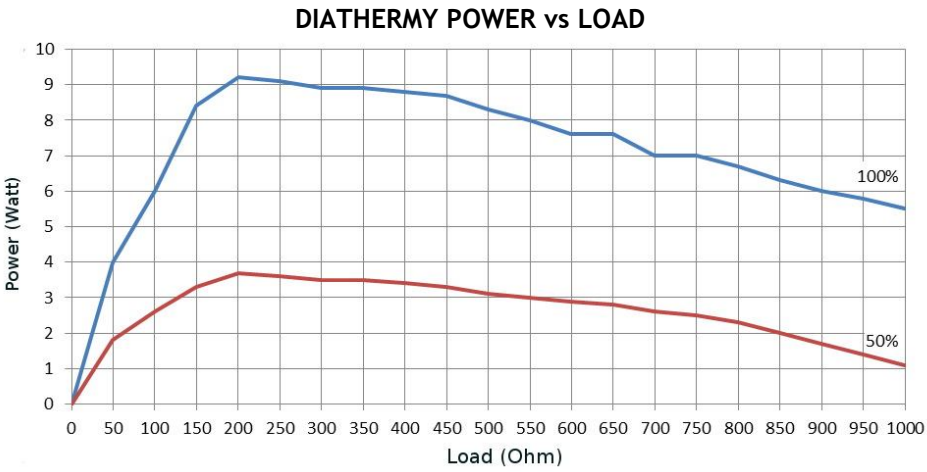
(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

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 DIATHERMY POWER CHARACTERISTICS





4.4 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.

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 Medical Device. 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 nominal voltage of the equipment corresponds to the rated line voltage at 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.

Before each use

⚠ **CAUTION**

Injury to the patient's eye!

- Make sure that all specified "Requirements for operation" are fulfilled.
- Reattach covers or caps that were removed before. Close any existing openings with the relevant caps.
- Take note of any and all symbols and signs attached to the equipment.
- The ventilation openings must not be closed or covered.
- Check whether the R-EVOLUTION offers enough room for maneuvering to avoid damage to the cables and ensure unrestricted movement of the device, and to have an easy access to reach power switch to disconnect electrical supply.

- Connect equipotential connector on the rear of the device to equipotential connector of Operating Room by equipotential cable. It is necessary to have a second ground reference in case of malfunction of main plug earth.
- The power supply plug is used as a method for simultaneous electrical insulation of all poles from the mains. Do not position the device in a such way that it would be difficult to disconnect the power supply plug from the mains.
- Check the user settings of the selected user profile to avoid unexpected behavior of the Medical Device.

After each use

- At the end of the surgery session, disconnect all surgical instruments from the console. Lower the electrical mayo tray to its minimum level and store it in its receptacle in the console.
- Use the main power switch to switch off the equipment.
- The main power switch must always be off when the Medical Device is not in use. And cable plug must be removed from the main supply.
- (CR only) Disconnect the compressed air supply hose from the operating theatre wall socket.

Liability and warranty

Warranty and liability depend on the applicable contractual stipulations.

INFORMATION

Loss of warranty

No modifications to the Medical Device may be made. The manufacturer shall not be liable for damage caused by unauthorized persons tampering with the device. Furthermore, this will forfeit any rights to claim under warranty.

5.1 DESCRIPTION OF THE APPARATUS

The R-EVOLUTION CR provides the surgical modules / functions described below:

Irrigation system

The R-EVOLUTION features both gravity irrigation and controlled irrigation.

Gravity irrigation

When irrigation is gravity fed, the flow rate of the liquid and the irrigation pressure are determined by the height level at which the infusion source is placed. The R-EVOLUTION control an automatic motorized infusion pole that can be sued to adapt the height level of the irrigation medium.

⚠ **CAUTION** **Injury to the patient's eye!**

Use the higher hook to suspend balanced salt solution bottle for anterior segment surgery.
Use the lower hook for posterior segment surgery.
Use the lower hook when performing Controlled irrigation

Controlled irrigation

If the "Controlled irrigation" function is used, the irrigation pressure for the infusion is automatically set by the R-EVOLUTION. This system for controlling the irrigation pressure provides a number of advantages as compared to simple gravity-fed irrigation, such as dynamic control of the intraocular pressure with automatic compensation of fluctuations due to the aspiration flow, this both in cataract and in retinal surgery. In order to take advantage of the "controlled irrigation" function, a controlled irrigation bag or a controlled irrigation administration set must be used. These devices are available through Optikon. A valve is used for sterile control of the On/Off status of irrigation by means of the foot switch or by means of a soft key in the graphical user interface.
Always use the lower IVP hook when performing Controlled irrigation.

Aspiration system

The R-EVOLUTION features an aspiration function by action of their two-pump system. Depending on surgical needs or preference, the surgeon can select either a flow pump (peristaltic) or a vacuum pump (Venturi or rotary vane).

The purpose of the cassette receptacle is to secure the I/A cassette.
Fluids and particulate materials are aspirated at the distal end of the tip and subsequently deposited in the collection tank of the disposable tubing set.

A safety vacuum sensor monitors the vacuum level in the aspiration tubing and adapts the pump action according to need. This vacuum reading is performed with a "closed system": a sterile membrane in the I/A cassette completely separates the vacuum sensor from the sterile fluids.
The pumps in the R-EVOLUTION are controlled by a microprocessor. The vacuum level can either be preset on the touchscreen or controlled by the surgeon via the foot switch (linear mode).

Vitrectomy

The vitrectomy handpiece connects to the vitrectomy socket . Essentially, it consists of two parts:

- **CUTTER TIP** (blade) and
- **BODY** (containing the drive mechanism actuated by compressed air)

The vitrectomy handpiece uses the single acting actuator principle: air pressure effects the out-stroke of the blade (cutting port closes). Once the pressure is no longer applied, the in-stroke is achieved by a built-in spring.

The tip contains the cutting element which consists of an outer (fixed) and an inner reciprocating tube acting in longitudinal direction, which are matched to each other.

Used for aspiration, the inner tube has a front end blade with a sharpen outer edge. At the front end, the outer tube has a lateral opening for cutting and aspiration.

The tissues are cut and simultaneously aspirated by the longitudinal reciprocating action of the inner tube, generated by pneumatic pulses generated by the device.

The extremely close distance between the inner and outer tubes creates a slight constant tension that provides a self-sharpening effect. It is evident that such precision combines with the guillotine design to afford ideal cutting properties. The cutting speed (from 60 to 10.000 cuts/min if a standard cutter is used or 120-20.000 cuts/min using Twedge cutter) and vacuum level (from 5 to 700 mmHg) can be adjusted using the switching elements on the touchscreen.

Bipolar Diathermy

Bipolar diathermy uses radio frequency (RF) currents to produce heat in body tissues and thus cause coagulation. The energy of a RF oscillator (inside the equipment) is conducted to a pair of electrodes (diathermy forceps or diathermy pen) that are touched against the biological tissues to be treated. The application of bipolar high frequency (RF) power contributes to the reduction of undesired neuromuscular stimulation.

R-Evolution generates adjustable output power on the diathermy socket (1) in the range from 0.1 to approx. 9 Watt @ 200 Ω.

Illumination

The R-Evolution CR features three high-intensity LED lamps (fiber optic illuminators) and, on two out of the three, it features filters to protect retina from the blue components of the light and for optimal viewing conditions during retinal surgery procedures.

Each of the three independent illumination systems is powered by a LED lamp focused on the head of the fiber optic. LED lamps emit, virtually, only in the visible, therefore, no IR or UV filter is necessary and maximum patient safety is assured.

An electronic system allows the light level to be adjusted on 20 levels without affecting the color of the light. There are 3 different yellow filters (435nm, 475nm and 515nm)

to emphasize the presence of membranes when colorants are used and to protect the retina of the patient from unnecessary exposure to blue radiations and thus enables longer treatment times.

A green filter improves contrast, even with no colorants, as it darkens the red eye structures making white membranes and other ocular tissues more visible.

Air tamponade

The air tamponade system utilizes a sophisticated technology for automatic control of the ocular pressure. This allows the surgeon to introduce sterile air at a preset value (in mmHg), while the system automatically balances variations due to possible losses from the surgical incisions.

The air delivery module of the R-Evolution CR is designed to supply sterile air at adjustable low pressure settings over the entire range of 5-120 mmHg.
A disposable encapsulated membrane filter is fitted to the air supply tubing connected to the air socket on the front panel, such that virtually all types of particles are removed, when the air passes through this filter.
Switching between BSS irrigation to air tamponade and back to BSS is achieved by an automatic system, controlled by touch screen or footswitch. No need to act on any manual stopcock.

Silicone oil tamponade

The silicone oil injection device is a compact, self-contained unit. It comprises a syringe, pre-filled with silicone oil, coupled via high pressure tubing to the front panel of the Medical Device.

The syringe is activated by compressed air that is controlled in linear fashion by the footswitch.

Phacoemulsification

The piezoelectrical phaco handpiece made by Optikon 2000 can be connected to the phaco socket. The phaco handpiece contains a piezo transducer that vibrates at a frequency of approx. 43 KHz and end strokes of approx. 100 µm. The piezo transducer of the phaco handpiece comprises three distinct components:

- The **PIEZOELECTRIC CERAMIC ELEMENT** converts the electrical energy supplied by the control console directly into mechanical vibratory motions of approx. 43,000 cycles per second (43 kHz).
- The **BODY** amplifies and mechanically transmits the motion of the piezoelectric ceramic element to the phaco tip.
- The **PHACO TIP** vibrates longitudinally and thus facilitates fragmentation of the tissue in a circumscribed area about the contact surface of the phaco tip to the cataract. The maximal re-use cycles of the phaco tips are described in the Instructions for Use enclosed with these units.

The internal energy loss processes of the piezo ceramic element cause the piezo transducer to heat up while it vibrates at high frequency such that the fluid aspirated from the eye is also used to dissipate the heat.

The R-EVOLUTION features the patented **Minimal Stress circuit** that facilitates measurement of the phaco tip motion (stroke) in real-time. This information is used by the microprocessor to stabilize the stroke of the phaco tip.

The main advantages of this system are as follows:

- U/S power preset indicates the effective phaco tip stroke and corresponds to microns of phaco tip movement.
- Different phaco handpieces are equalized and compensated with respect to the typical loss of efficiency due to aging effects.
- The tip vibration is no longer affected by differences in cataract hardness or temperature fluctuations in the handpiece.
- The requisite average energy and peak energy are lower compared to standard phacoemulsification.
- Reduction of bouncing of cataract fragments.
- Phaco handpieces can be tested by the equipment to verify their efficiency, avoiding operation of the device below the acceptable limits.

Ultrasonic power can be delivered in Continuous or Pulsed mode

- In Continuous mode, the phaco energy is supplied to the handpiece continuously and without interruption if the footswitch is depressed beyond mechanical feedback point 2 (area C, see "System footswitch" description).

- In Pulse mode, the power is emitted in the form of pulses in preset intervals, if the footswitch is situated in area C, after having passed position 2. The surgeon can select between the following settings in pulse mode:

- **Pulsed** power is made available in linear or panel control mode. It generates periodic pulses of ultrasound power. The user may select from a range of 1-100 pulses/sec. At each repetition frequency, the user can set the length of the active cycle (duty cycle) choosing among three available levels (named as "Standard", "Cold", "Ice Cold" and corresponding approximately to an on time of 50%, 25% and 10% respectively), thus limiting the ultrasonic energy delivered to the minimum needed level.

- **HD pulse** automatically adjusts pulses duty cycle according to the occlusion state of the surgical tip, this allows fast removal of the cataract fragments engaged by the tip and avoids unnecessary emission of energy when the tip itself is free from occlusions.

- **Single Burst** delivers single bursts of ultrasound power with a duration of 120 ms. The surgeon must return the foot switch to area C, pause for approx. ½ sec and then press it back into area C to obtain another single burst.

- **Multi Burst** generates ultrasound pulses with a duration of 80 ms, with additional bursts being generated (approx. 1 burst per second) when the foot switch has passed tactile position 2 and reaches area C. As the foot switch is depressed further the limit stop, the frequency of bursts increases up to a maximal rate of 4 bursts per second.

- **Cont Burst** yields a pulse duration of 80 ms. Once the foot switch has passed tactile position 2 and reaches area C, the pulse are generated consecutively at an increasing rate. At maximal depression of the foot switch, the bursts blend together and the units

delivers continuous ultrasound power.

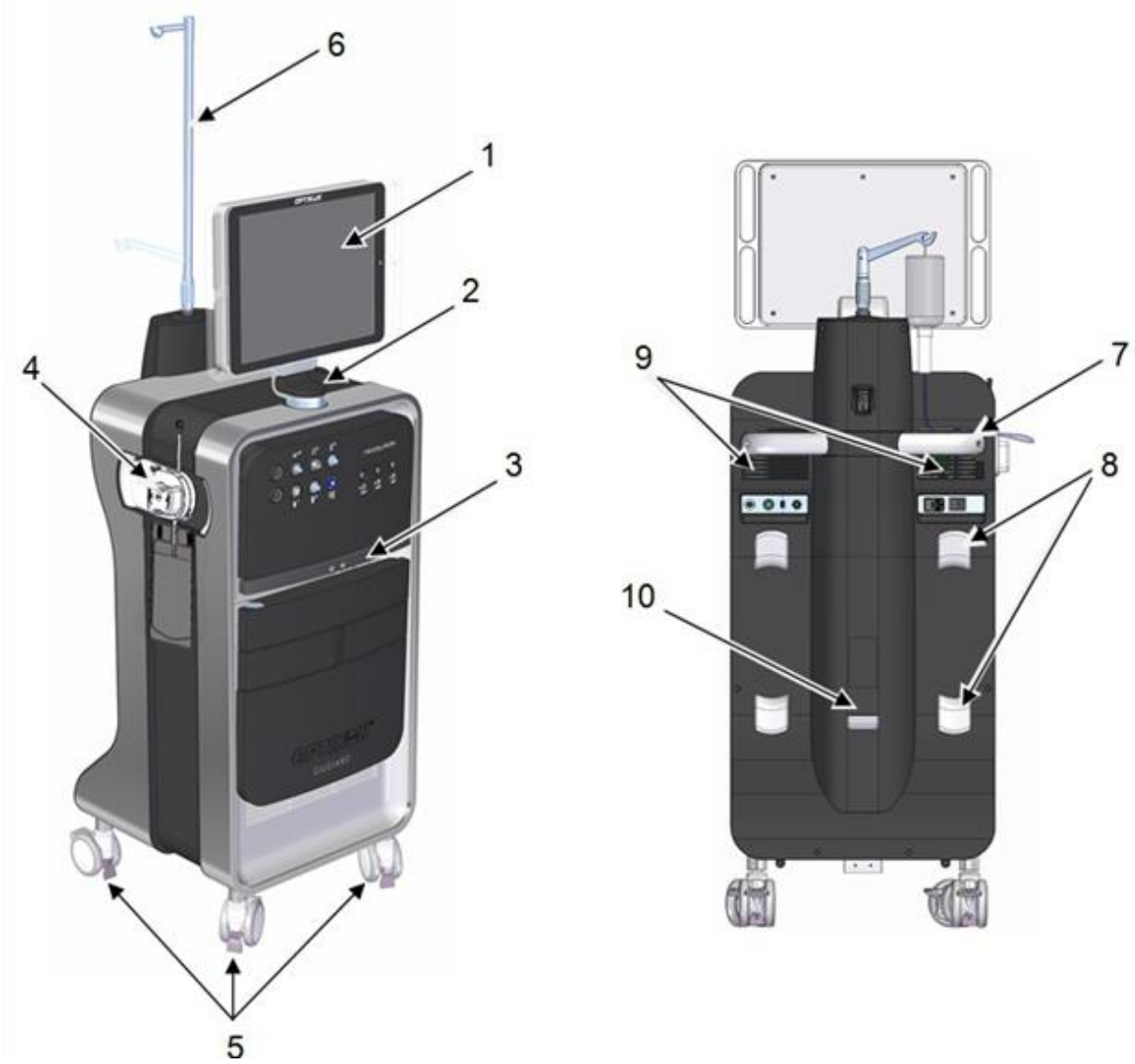
- Programmable Emission Mode R-EVOLUTION features a new sophisticated Programmable Emission Mode (PEM). PEM. allows the surgeon to design his own ultrasound emission pattern, the one which fits his surgical techniques or cataract hardness best. This function leads to a substantial reduction of the ultrasound energy needed for cataract removal.

Measuring Ocular Perfusion Pressure

A digital blood pressure monitor allows R-EVOLUTION CR to periodically measure patient diastolic and systolic pressure and, also using intraocular pressure, it calculates the Mean Ocular Perfusion Pressure (MOPP). The equipment shows the MOPP on the touch screen monitor and draws in the irrigation preset dial colored areas. A green area indicates irrigation pressures for which the MOPP is greater than 35mmHg (safe area, according to medical literature).
A yellow and a red area indicate, respectively, irrigation pressures very close or above the said safety limit.
If the irrigation pressure is kept in the red (MOPP below 35mmHg) for more than 30 seconds, an information message alerts the surgeon suggesting to lower the irrigation pressure.
This system strongly reduces the probability of retinal iatrogenic damages caused by irrigation pressure too high for the specific patient.

5.2 DEVICE COMPONENTS

5.2.1 Overall view



1 19" Touchscreen
The touchscreen allows the Operator to set parameters and to read their actual value. The touch screen can be covered by a dedicated drape for sterile operation.

2 Touchscreen hinge
The touchscreen can be swiveled to the left or right or somewhat up and down to improve the visibility.

3 Instruments tray
The foldable instrument tray allows the Surgeon or nurse to place and prepare the required surgical set and accessories. The tray is

attached to an articulated arm and it can be moved up/down electrically. For sterile use, a single use sterile drape is available. The instrument tray can be kept inside the housing if it is not used.

4 I/A Cassette and cassette receptacle

5 Steerable casters with locking tabs
The Medical Device is equipped with four steerable casters which allow easy positioning in the OR. The locking tabs prevent the device from moving or rolling away.

At least two locking tabs must be pressed down to position the Medical Device.

- Press locking tab down to block the caster.
- Press locking tab up to release the caster.

6 Infusion pole with bottle holders
The computer controlled electric pole allows moving to the memorized height the balanced salt solution container during procedures involving gravity irrigation. The higher hook is only used for anterior segment surgery performed with gravity feed irrigation. The lower hook is for posterior segment surgery and also to suspend the proprietary pressurized irrigation bag during any surgical procedure involving “controlled irrigation”.

7 Handgrip
It is used to move and relocate the Medical Device within the O.R.

8 Cable holder(s)
The two couples of cable holders are used to reel up the power cable, footswitch cable and gas hose.

9 Ventilation grids
These grids allow removing hot air from the device. Do not occlude the grids to avoid overheating.

10 Footswitch flange
It is used to hang the footswitch for storing, when not in use.

5.2.2 Front panel connectors and control elements

1 US (Phaco) socket with pilot lamp
The connector of the phaco handpiece connects to this socket.

2 Vitrectomy socket with pilot lamp
The connector of the vitrectomy handpiece connects to this socket.

3 Diathermy socket with pilot lamp
The connector of the bipolar diathermy handpiece connects to this socket.

4 Air tamponade socket with pilot lamp
The connector of the air hose with filter connects to this socket.

5 Silicone oil injection socket with pilot lamp
The connector of the silicone oil tamponade system connects to this socket.

6 Scissors socket with pilot lamp
The connector of the pneumatic scissors connects to this socket.

Each 1-6 ring-like pilot lamp illuminates when the relevant function is selected.

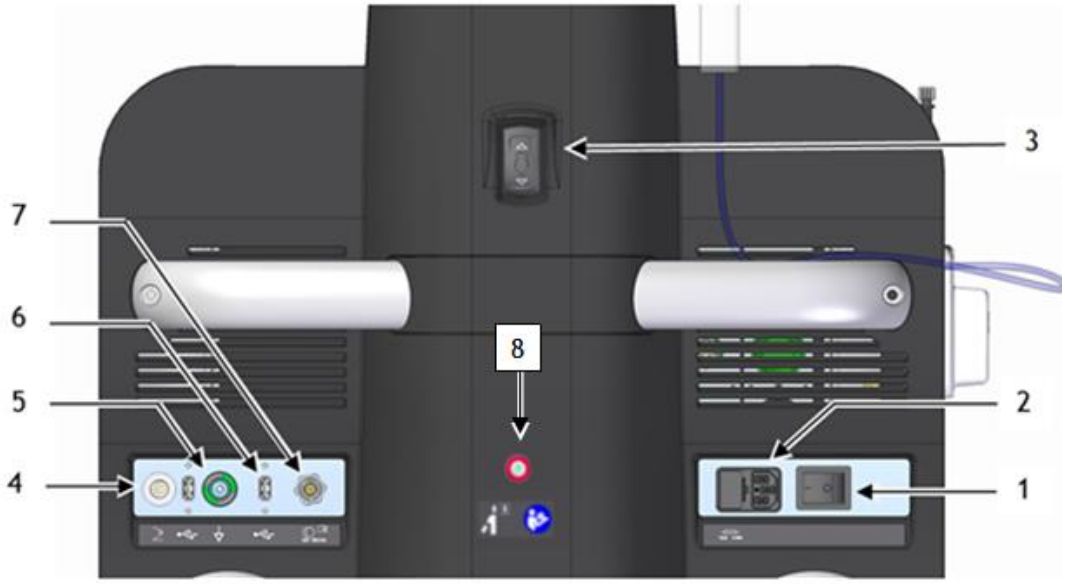
7-8 LED Light source sockets, with filters
The connector of the fiber optics connects to this socket.

9 LED Light source sockets, without filters
The connector of the fiber optics connects to this socket.

10 Mayo tray height adjustment push-buttons
These arrow keys are used to adjust the level of the motorized tray for surgical instruments.

11 Power-ON push button, with pilot lamp
To turn the equipment on, switch to ON the power switch “1” on the rear panel, push and hold pushed, until its pilot lamp goes on, this push button.

5.2.3 Rear panel connectors and control elements



1 Power switch
The power switch is used to turn the device on/off.

2 Fuse carrier and power plug
Only connect the Medical Device to an outlet which is provided with a properly connected protective ground conductor.

3 **IVP** Rocker switch
This is used to control the infusion pole without using the touchscreen.

4 Footswitch connector
Footswitch connector is connected to this socket when used in wired mode or for recharging internal batteries.

5 System ground connector
This connector can be used to connect the R-EVOLUTION CR to the grounding of the device.

6 USB connectors
An USB memory device can be connected to these sockets for software upgrades or import/export of user programs.

7 Air inlet plug
External compressed air inlet for Venturi pump, vitrectomy handpiece, and silicone oil injection.
The air pressure must be in the range from 500 to 800kPa. The available flow must be at least 32Nl/min.

8 Sphygmomanometer connection
The air hose of the sphygmomanometer arm cuff connects to this socket

5.2.4 **Footswitch**

The foot switch for surgical equipment allows the surgeon to activate the selected function on his device. The functions "On/Off" are activated by means of the side buttons, whereas the linear functions are activated by means of the foot pedal.

The foot switch has the following functions:

- Nine commands of the "on/Off" type consistent with the setting of the device to which it is connected.
- Simultaneous linear control over two functions depending on how far the foot pedal is depressed or swiveled to the side. For example: U/S power and degree of aspiration or vitrectomy cutting rate and degree of aspiration.

The foot switch may work wireless or it may connect to the foot switch socket on the rear panel of the equipment.

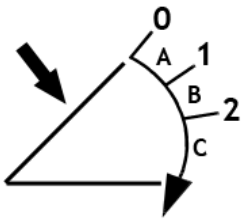
⚠ **CAUTION** **Risk of infection!**

The foot switch cannot be autoclaved.

- For information about cleaning and/or disinfection of the foot switch, please refer to the "Maintenance and care" chapter in this manual.

The foot switch comprises the following components:

1 Main paddle
The paddle can be moved in horizontal and vertical directions to trigger certain functions.



The vertical direction of the foot pedal is subdivided into three areas with two tactile positions. Certain functions are assigned to each area and can be triggered by pressing the foot pedal (see image on left).

Resting position
Area A is situated between the resting position and the first tactile C position.

Tactile position 1
Area B is situated between the first tactile position and the second tactile position.

Tactile position 2

Area C is situated between the second tactile position and the limit stop.

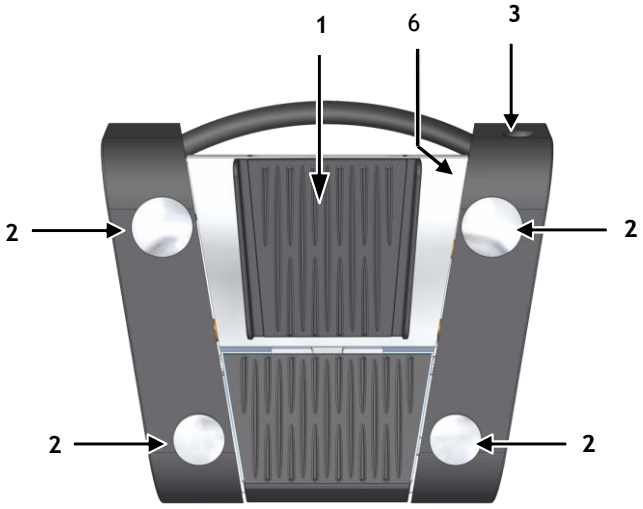
2 Side buttons

3 Socket for connection cable
To connect the foot switch to the connector block of the R-EVOLUTION for wired operation. Also used for battery charger.

4 Carrier bracket
For storage and carrying the foot switch in the main unit.

5 Rating label

6 Battery check pilot lamp
The wireless footswitch is energized by rechargeable batteries, the Battery Check pilot lamp flashes alternating between green and red while recharging and became green, fixed when the charging has been completed. The lamp is off when the pedal is not connected to the battery charger or to the console.



The footswitch battery recharges automatically whenever the footswitch is wired to the console. It can also be recharged using the dedicated battery charger supplied with the device. A full charge allows using the footswitch for more than a surgery session.
The battery level can be verified on the console during use (battery icon on the lower right corner of the monitor). If the battery level becomes low, an alarm message is generated.
Fully recharge the battery before first use or following a long period of inactivity.
The battery must be replaced by Technical Service personnel only.

OPTIKON 2000

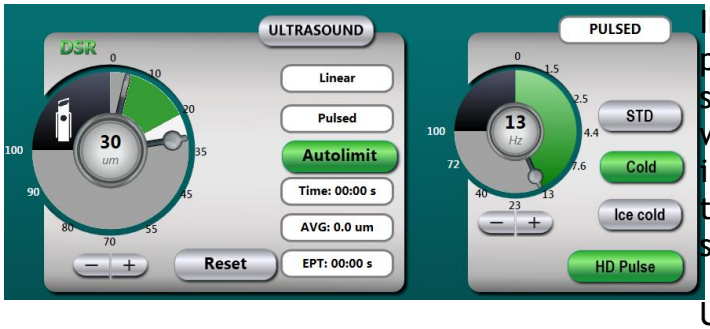
The multi-function footswitch is programmed through the R-EVOLUTION touch-screen monitor. Refer to “5.6.8 Footswitch programming“ for further details.

5.3 TOUCHSCREEN AND USER INTERFACE

The R-Evolution 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, maximum pre-set limit for U/S power (30µm) is shown both at the centre of the dial wheel and by the larger radial finger indicator. The thinner finger indicates the power programmed at ultrasound start (5 µm).

Ultrasounds are emitted in Pulsed mode (13Hz), with a low duty cycle (Cold)

Actual U/S power (20 µm) is indicated by the green filled area from 5 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.

OPTIKON 2000

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.

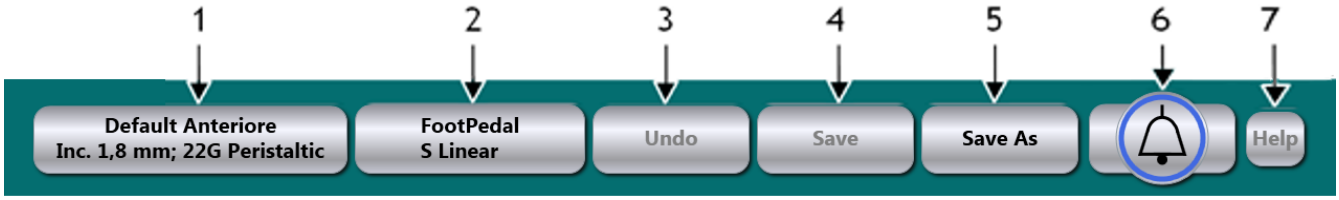
A new child window will open, allowing control of all additional parameters.

"DSR Settings" in this example refers to the initial and final values for ultrasound power emission when in linear mode.

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.

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 software is in idle and you have to discontinue the use of the Medical Device.
  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 colour of the higher priority active alarm.

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

Press “OK” 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 INSTALLATION PROCEDURE

5.4.1 Installation of the equipment

The unit has been packed such as to minimize the risk of damage during shipping.

- Open the package and examine the components for damage. When cutting the packing material, be careful not to damage the contents.

The REF 111012 (CR 121012) R-Evolution is made up by the following parts:

REF	DESCRIPTION
	Console
3M1854	Dust Cover
1X1012U0	Instructions for use.
	IEC60601 Safety check Test Report (attached to the IFU)
565035	2 4AHT fuses
554138	Mains power supply cable
3M2093	IV Pole extension rod
374578	Compressed air supply hose (CR only)

The wireless footswitch REF 112104:

REF	DESCRIPTION
	Multifunction footswitch
3M0678	Footswitch-Console connection cable
3N0800	Battery charger

⚠ **CAUTION**

Risk of injury caused by transport damage

- If the package or contents are damaged, please notify the carrier (post office, railway or shipping agent) and the Optikon 2000 Service without delay.
- Check that the contents correspond to those indicated on the enclosed shipping documents. Notify the Optikon 2000 Service of any discrepancies without delay.

To install the Medical Device, proceed as described below:

Adequate training is essential for proper installation

and operation of the R-EVOLUTION and its accessories. Training on the installation and use is provided by Optikon 2000 for both systems. Contact your local Optikon 2000 Service for details.

It is the responsibility of the user to clean and sterilize the handpieces, tips, I/A tubing and any other reusable microsurgical accessories.

- Open the package of the medical device and its accessories.
- Take R-EVOLUTION out of its transport package.
- Comply with the corresponding Instructions for Use when unpacking sterile and re-sterilizable microsurgical accessories.
- Check if the pressure of the pressure supply is consistent with the value indicated on the rear panel (from 500 to 800 kPa - 72.5 to 116 psi).
- Take the compressed air supply hose and connect the gas input port "GAS INLET" to the wall compressed air supply line.

INFORMATION

Risk of crushing - mind your fingers!

There is a risk of crushing your fingers when you fold up the instrument tray in its compartment.

- Move down the tray to its lower position, then push it in its receptacle placing the fingers under the tray.

- Connect the foot switch cable to the socket labeled "FOOTSWITCH CONTROL".
- Connect the alternating current power cable to the AC power inlet.
- Connect the other end of the AC power cable to a grounded wall socket.

Relocating the device

The Medical Device is provided with a handle that can be used to safely and easily transport the device to a different installation location. Please use the handle for the purpose indicated. Four locking tabs on the base allow you to conveniently select the installation conditions.

- None of the locking tabs has been pressed:
  The Medical Device can be positioned easily and without effort and in all orientations in the OR and at the operating table.
- All locking tabs have been pressed:
  The Medical Device is fixed in place preventing it from rolling away. After the device has been positioned as desired at the operating table, you should press the locking tabs down.

Installation of the Medical Device in the O.R.

To install the Medical Device in the OR, please proceed as follows:

- Release all locking tabs.
- Hold the equipment by the handle and then push it gently to the desired location.
- The Medical Device must be positioned on level

ground.

- Press at least two locking tabs of casters and make sure that the Medical Device cannot roll away on its own accord.

Preparing the Medical Device for sterile operation

CAUTION

Risk of infection!

The patient or user may be infected if accessories loose sterility.

- For sterile use of the touchscreen, use the sterile drape.
- If you use the REMOTE CONTROL and the instrument tray, please use the corresponding drape.
- The Medical Device may be operated by suitably instructed staff only.

Sterile single-use drapes can be used to cover the device in sterile condition. The following drapes are available for the R-EVOLUTION surgical equipment:

- SCREEN DRAPE R-EVOLUTION
- REMOTE CONTROL COVER
- TRAY COVER R-EVOLUTION

Please comply with the Instructions for Use of each drape when placing the drapes.

Powering the device up

Before switching the device on, verify that:

- The compressed air line has been connected.
- The power cable has been connected.
- The foot control panel has been connected (unless it will be used in wireless mode).

⚠ **WARNING** **Risk of injury to the patient's eye!**

- Audible hissing of air at power-up may indicate a malfunction of the silicone section.

  Please contact your local dealer or the Optikon 2000 Service.

⚠ **CAUTION** **Functional test**

- The software checks the validity of the calibration at power-up. If there is any discrepancy, the safe default calibration is stored and you are prompted to calibrate the Medical Device (5 sounds).

  Please contact your local dealer or the Optikon 2000 Service.

To power the Medical Device up, proceed as follows:

- Press the power switch on the rear panel.
- The infusion pole drives a few centimeters up and down.
- The Medical Device performs a self-test, during which a start screen showing the Optikon logo is visible on the display.
- Once the Medical Device is powered up, the configuration menu is displayed on the screen.
- At first start-up, the Medical Device displays the standard user profiles, "Factory Default", and the operating interface in English. During subsequent log-ins, it shows also the new users, if any, and the interface in the language chosen.

5.4.2 Installation of the Easysys I/A cassette

For proper cassette installation, proceed as follows:

- Connect the male plug of the administration set into the corresponding connector on the short line at the top of the I/A cassette.
- Insert the I/A cassette into the side panel by lining up the reference line on the I/A cassette and the corresponding dot on the side panel.
- Rotate the I/A cassette clockwise until it snaps into place.

⚠ **CAUTION** **Injury to the patient's eye!**

Use the higher hook to suspend balanced salt solution bottle for anterior segment surgery.
Use the lower hook for posterior segment surgery.

⚠ **CAUTION** **Risk of infection!**

Exchanging the infusion bottle, pathogens may enter into and contaminate the balanced salt solution.

- Never touch the drip chamber spike when attaching, exchanging or removing the infusion bottle.
- Puncture the drip chamber spike into the infusion bottle or the infusion bag for controlled irrigation.
- Connect the end of the irrigation and aspiration tubings to the corresponding connectors of the respective handpiece.

⚠ **CAUTION** **Risk of injury to the patient!**

- Before you use the phaco handpiece, always subject the irrigation/ aspiration tubing to a priming procedure. During the priming procedure, the irrigation/aspiration hose set is checked for proper installation and operation and the hose is filled with liquid. This prevents possible malfunction and injury to the patient.

To remove the I/A cassette, proceed as follows:

To take out the I/A cassette at the end of the surgery press the “PUSH” button

Wait for the peristaltic pump to be fully retracted.

- Rotate the I/A cassette counterclockwise until its reference line and the corresponding dot on the side panel are lined up.
- Remove the I/A cassette

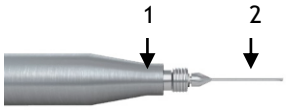
5.4.3 Installation of phaco accessories

WARNING **Risk of injury to the patient's eye!**

Priming while the phaco tip is used in a patient may cause serious damages to the eye structures.

- Never perform a priming procedure while the Medical Device is in use on a patient.

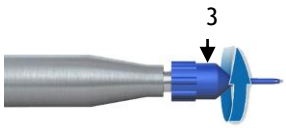
Connecting the phaco tip to the phaco handpiece



- Screw the appropriate phaco tip (2) into the end of the phaco handpiece (1) making sure that the threads engage properly. Tighten the tip with your fingers only.

- Carefully place the opening of the wrench (on the flange side) over the phaco tip (2) without damaging the tip such that the phaco tip wrench engages the slits on the base of the tip.
- Carefully **tighten** the phaco tip with the phaco tip wrench clockwise.
- Then remove the phaco tip wrench.

Connecting the silicone sleeve to the phaco tip



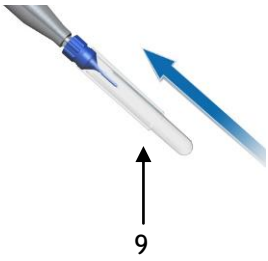
- Carefully slide the threaded silicone sleeve (3) over the phaco tip until the threads engage.
- Slowly tighten the silicone sleeve on the phaco handpiece until the end of the silicone sleeve leaves just as much of the phaco tip exposed as desired by the Surgeon.
- The phaco handpiece (1) is now ready to receive the irrigation/aspiration hoses from the I/A cassette system.

Connecting the irrigation/aspiration hoses

- In order to connect the aspiration hose of the irrigation/aspiration hose set, slide the end connector into the corresponding connector on the phaco handpiece and tighten it by pushing while slightly rotating.

- In order to connect the irrigation hose of the irrigation/aspiration hose set, slide the end connector of the male Luer lock into the corresponding female connector on the phaco handpiece and tighten it by pushing while slightly rotating.

Priming procedure



- Fill the test chamber (9) with balanced salt solution and slide it onto the silicone sleeve.

- Place the test chamber at the eye level of the patient.

- Connect the I/A cassette to the Medical Device, if this has not already been done, and connect it to the infusion bottle.

- Plug the electrical power plug of the phaco handpiece into the U/S socket (1) on the front of the unit.

- Press the <Prime> key on the lower left corner of the screen.

- After completion of the priming procedure, the following display is shown "U/S Ready"

5.5 USER PROGRAMS

Configuration of users programs

All default parameters of the R-EVOLUTION can be adapted to suit the individual needs of the user. The parameters thus set are saved for later re-use in programs and assigned to the users.

The R-EVOLUTION can store up to 30 different users and up to 40 programs per user.

⚠ **CAUTION**

Risk of injury to the patient!

- Changes made to software settings during the application may lead to patient injury.

Creating users and programs

Creating a new user or new program

- Prior to creating a new user or new program, set the desired operating parameters in the cataract (Anterior Segment) or retina (Posterior Segment) mode.
- The "Undo" key is displayed when a parameter has been modified. If you press the <Undo> key, the previous settings are restored.
- Press the <Save as>
- A virtual keypad showing the current user name is displayed.
- If the new program belongs to the current user, enter the name of the new program and then press the <Save> key . For a new program to be saved, the name of the new programs must include at least three characters and one letter.
- In order to create a new user, press the <New user>. The cursor is then moved to the "User" field, in which a name can be entered for the new user.
- Confirm the new user name by pressing the <Save> key and then move the cursor to the "Program" field.

Save the program to an existing user

- Press the <Select user> key. The existing users are then displayed in the pop-up window called "Select user".
- Select one of these users and press the <OK> key.
- This closes the pop-up window and the cursor moves into the "Program" field, in which the name of the new program can be entered.

Changing programs

- Adapt the various operating parameters in the cataract or retina mode.
- The "Undo Changes" key is activated to indicate that a program has been modified. If you press the < Undo Changes > key, the previous settings are restored.
- To permanently save the modifications made in the same program, press the <Save> key

  Modifications cannot be saved to the DEFAULT programs. In order to save modifications into a new program, you need to create a new program (Save as).

Deleting a program

- Select program the program you wish to delete.
- The key with the name of the active program is green-active. Press the <Delete> key, to delete the active program (after confirmation).
- Subsequently, the previous program of the same user, if any, is loaded.

If all programs of the active user have been deleted, the user is removed, and the system loads the DEFAULT program. DEFAULT programs cannot be deleted.

5.6 OPERATION

5.6.1 Irrigation / Aspiration

Installation of the irrigation and aspiration hoses and I/A cassette

- For information about the installation of the irrigation and aspiration hoses and exchangeable I/A cassette, please refer to the relevant chapter.

Connection of hoses and handpiece

- Select the I/A cannula needed and carefully insert it into the coaxial I/A handpiece .
- Rotate the silicone sleeve onto the cap of the I/A cannula .

The silicone cap should be pressed gently onto the cap until the silicone sleeve has passed the aspiration connector on the I/A cannula .

- Connect the irrigation/aspiration hoses of the installed irrigation/ aspiration lines by sliding the end connectors into the corresponding irrigation and aspiration connectors on the handpiece line.

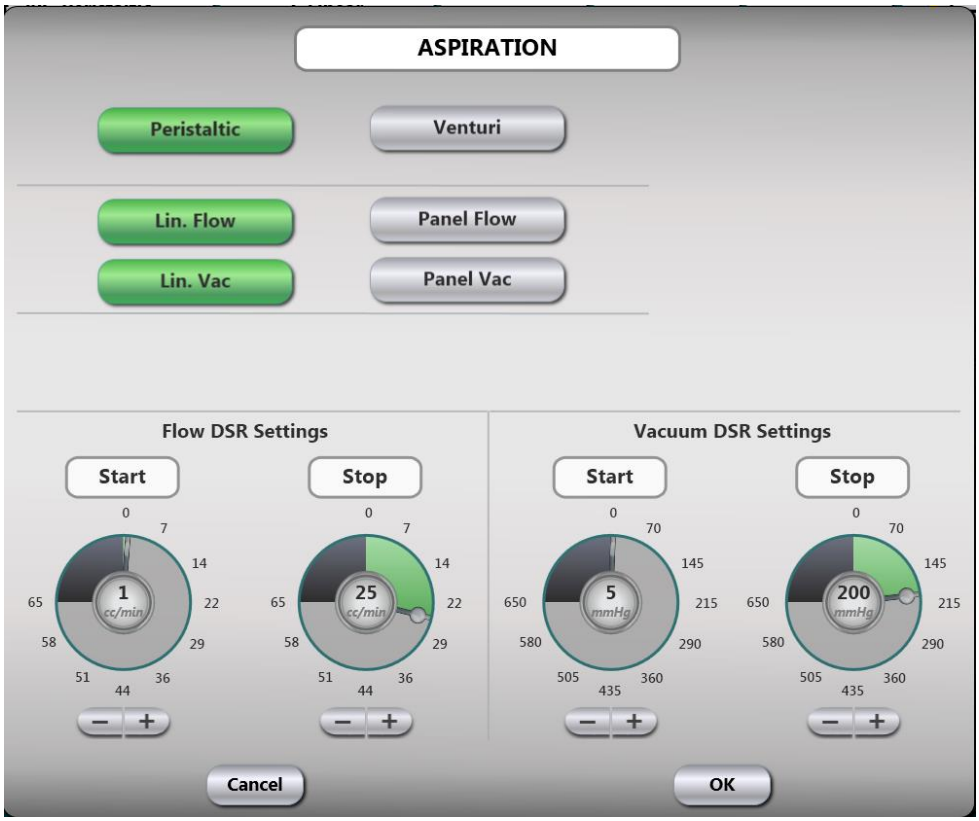
For information on the installation and application of bimanual handpieces, please refer to the Instructions for Use of the respective handpiece.

Select function

- Touch the <Cortex> button .

Aspiration settings

- The R-EVOLUTION is equipped with an I/A cassette such that both a peristaltic pump and a Venturi or rotary vane pump are available simultaneously. In order to switch between the two aspiration modes, press the <Peristaltic> or the <Venturi>/<Rotary vane> button in the "Aspiration" frame.



⚠ **CAUTION** **Risk of injury to the patient's eye!**

- Switching between peristaltic pump and Venturi or rotary vane pump during the surgery without changing the settings may lead to injury to the patient.

INFORMATION: the flow rate and the vacuum limit can be set independently for the peristaltic pump, whereas only the vacuum can be set in case of the Venturi and rotary vane pump. Using the Venturi or rotary vane pumps, the actual flow rate increases with the vacuum setting and size of the aspiration cannula.

⚠ **WARNING** **Injury to the patient's eye!**

Changing the height level of the infusion pole by manually forcing it can lead to a wrong indication of the bottle height level and to injury to the patient!

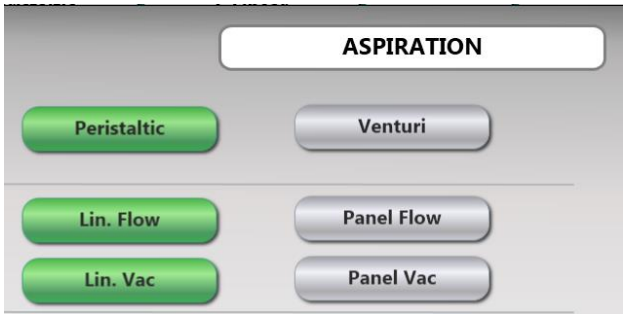
- Do not force the infusion pole modifying its height.

⚠ **CAUTION** **Injury to the patient's eye!**

Anterior chamber instability may be caused if the height level of the infusion pole or the vacuum settings are incorrect!

- Start with low safe settings for the vacuum and increase them in increments to determine the correct settings for vacuum and height level of the infusion pole while making sure that the anterior chamber is stable.

The set values of flow (peristaltic pump only) and vacuum level can be adjusted using the "+ -" buttons or the slider.

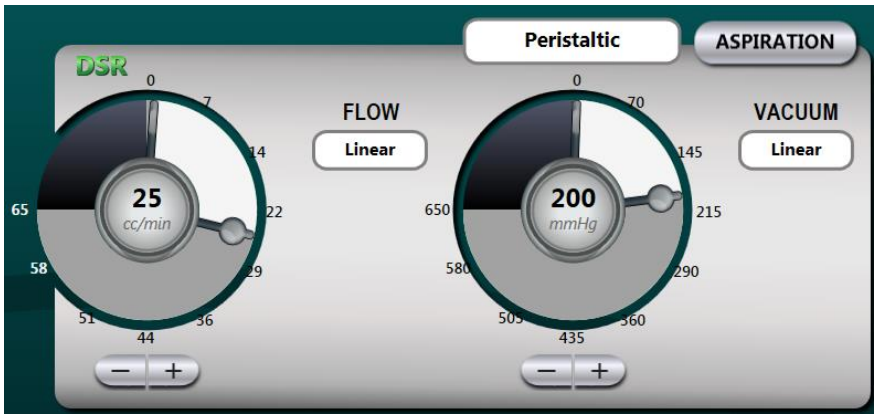


Vacuum and flow rate can be controlled both in "fixed" and in "linear" control mode.
In order to switch to "linear" mode, press the <Lin.Flow> and/or <Lin.Vac> buttons, and in order to switch to "fixed" mode, press the <Panel Flow> and/or <Panel Vac> buttons

When a function is controlled in "fixed" mode, it reaches automatically the User preset value as it is activated by the footswitch.

When in "linear" mode, the Surgeon, by footswitch depression or rotation, can linearly control the function value from a start value to a final "stop" value previously set in "DSR Settings" (Dynamic Setting Regulation).

Values set in "DRS Settings" are shown in the working screen by two finger indexes delimitating the linear regulation range.



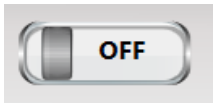
Irrigation settings

- In Anterior segment surgery, if gravity fed irrigation is used, hang the irrigating solution bottle to the higher hook on the IV pole. In retinal surgery and for controlled irrigation use the lower hook on the IV pole.

INFORMATION if the higher hook is used to suspend irrigating solution bottle, add 50cm to the bottle height indication shown in the irrigation frame.

- Set the infusion pole height level to match the vacuum settings and I/A tip that is connected, in order to maintain proper fluid balance.
- Activate irrigation by pressing the foot switch beyond its standby position.

Continuous irrigation (irrigation flows even after the foot switch is released) can be activated by the slider switch on the touchscreen or by pressing the corresponding side button on the foot switch, depending on the programming of the foot switch.



- In order to discontinue continuous irrigation, press the <Off> button on the touchscreen or press the foot switch button again.

WARNING **Injury to the patient's eye!**

The patient may be injured if the waste container of the I/A cassette is full.

- Make sure not to exceed the capacity of the

I/A cassette or waste container.

⚠ **WARNING** **Injury to the patient's eye!**

The intraocular pressure is reduced if the quantity of balanced salt solution is insufficient.

- Keep an eye on the level of balanced salt solution in the infusion bottle during the surgery. If the level required for the surgery is no longer provided, alert the physician and replace the infusion bottle or infusion pouch.

5.6.2 **Phacoemulsification**

Display of the message, "Connect handpiece", on the screen indicates that the phaco handpiece is not connected or not being recognized.

Priming

The "Please prime ..." message indicates that a priming procedure is required. Press the <Priming> button to activate the priming process; the irrigation/aspiration lines are checked for correct connection and correct function and filled completely with balanced salt solution. The priming of irrigation/aspiration can be by-passed under certain conditions, i.e. when the phaco handpiece or phaco tip need to be replaced after successfully running the priming procedure. To bypass the priming of irrigation/aspiration, press the system foot switch beyond

region C: a pop-up window opens to inquire if you really wish to bypass the priming procedure.

Fine tuning

A simple, preliminary test called Tuning (fine tuning) is needed each time a phaco handpiece is connected or each time the phaco tip is changed. The purpose of fine tuning is to match the response of the phaco handpiece to the existing unit. At the end of the priming procedure or if the priming procedure is bypassed, the unit automatically runs a fine tuning. If the fine tuning is not successful, the message, "Please check tip", is displayed for four seconds and the user needs to repeat the priming procedure.

INFORMATION

Damage to the phaco tip!

- Do not activate the phaco handpiece while the phaco tip is surrounded by air. The ultrasound power should be supplied to the phaco handpiece when the phaco tip is immersed in a test chamber filled with infusion fluid or a beaker filled with a sterile liquid at room temperature. Non- compliance with these instructions can lead to damage to the phaco tip and/or phaco handpiece.

⚠ **WARNING**

Injury to the patient's eye!

Although the R-EVOLUTION is equipped with a sophisticated power control circuitry to limit the ultrasound power that is supplied to the eye, care is still necessary to prevent damage to the endothelium of the eye (corneal injury).

- Always use the lowest ultrasound power level that is sufficient for cataract removal.
- The incision should not be too tight around the sleeve and allow for some leakage of balanced salt solution.
- Do not stress the incision by torsions while trying to reach fragments of nucleus in the eye.
- If the phaco tip is situated fully in the nucleus, the

aspiration flow stops and the tip is no longer correctly cooled down. Do not activate ultrasound power for extensive periods of time or at high levels if the phaco tip is occluded.

In ultrasounds mode, besides irrigation aspiration parameters, which are adjusted as described in the previous section, the Surgeon can set ultrasounds power level and emission mode.

Ultrasounds can be emitted in “Continuous” mode, Pulsed mode (where three preset levels of duty cycle, named as “STD”, “Cold” and “Ice Cold” respectively are available), Single Burst, Multiple Burst, Continuous Burst or PEM (user Programmable Emission Mode).

If peristaltic aspiration is chosen, “Autolimit” mode (maximum stroke limited to 50µm during tip occlusion) can be activated to limit possibility of corneal damages.

“HD Pulse” mode, also available with peristaltic aspiration only, automatically adjusts pulses duty cycle according to the occlusion status of the phaco tip, thus minimizing the time needed for phacoemulsification of the cataract, while maintaining ultrasounds emitted power to the lowest level possible.

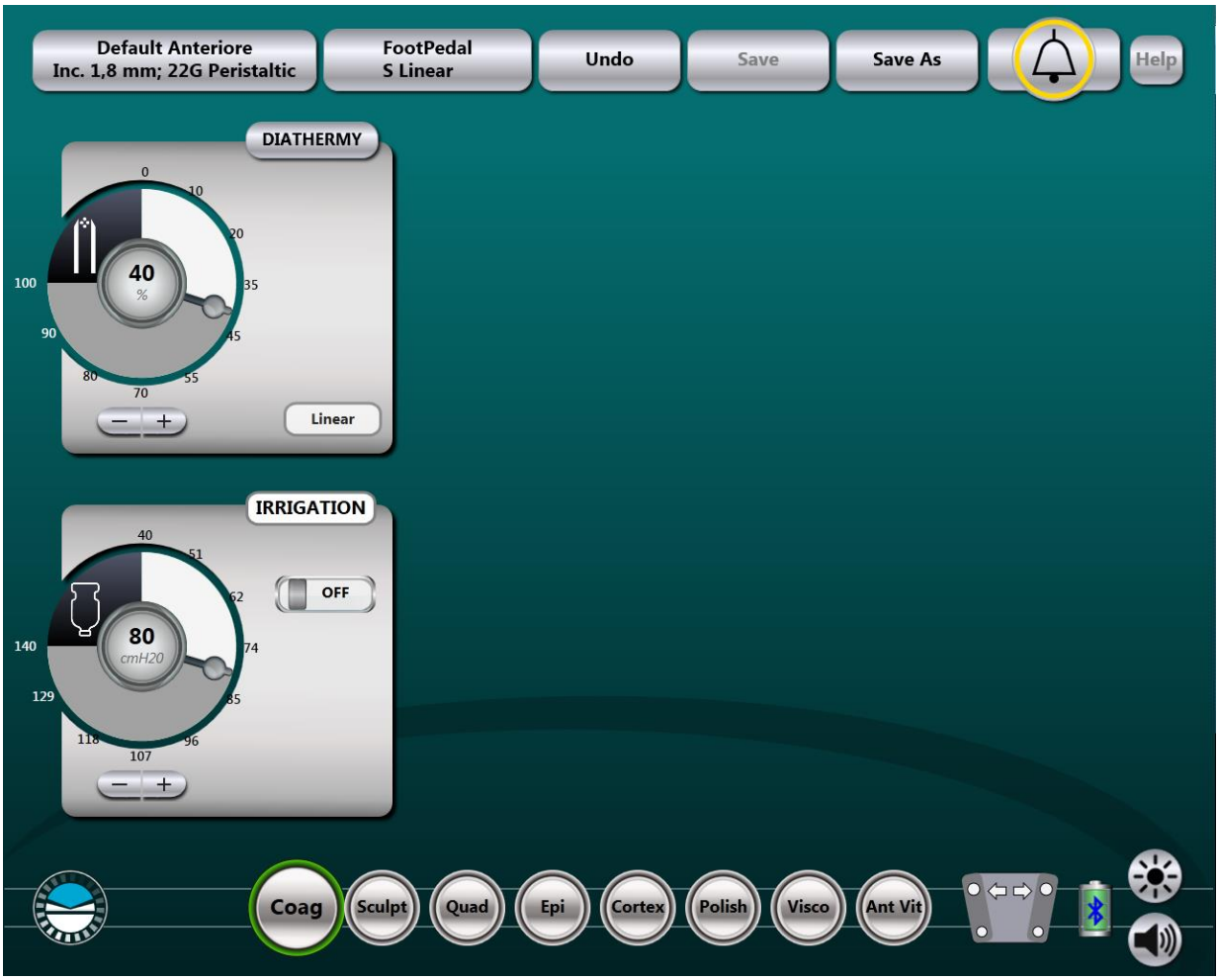
If “Linear” control mode is chosen, Ultrasound emission can be linearly controlled by system footswitch depression or rotation from a “Start” power to a final “Stop” power (DSR mode). Note that “Start” power can be set either smaller or greater than “Stop” power

Basic settings for retina modes

5.6.3 Bipolar endodiathermy for retinal surgery

Connecting accessories

- Plug the desired endodiathermy handpiece, such as, e.g., diathermy pin, into the bipolar diathermy cable.
- Plug the connector of the bipolar diathermy cable into the diathermy socket of the device.



Diathermy settings

- Adjust the preset power level in the "Diathermy" frame using the + - buttons or the slider. If you are uncertain about the power to use, it is always

advisable to begin with a low setting eventually increasing it gradually to obtain the desired surgical effect.

Bipolar diathermy can be carried out both in "fixed" power control mode or "linear" power control mode. In the latter case, the delivered power is linearly controlled from 5% to the preset limit by pressing the foot switch.

- To switch between "linear" and "fixed" mode, press the <linear> and <fixed> buttons.

Adjusting a parameter does not change the default parameters. To recall the previous parameters press “Undo”, to permanently save the new settings in the memory of the device refer to “Creating an User Program”.

5.6.4 Vitrectomy

WARNING **Injury to the patient’s eye!**

Non-sterile air might enter into the patient's eye if the vitrectomy handpiece is connected incorrectly.

- The vitrectomy handpiece should always be tested for proper function using a beaker with a sterile solution, before placing the handpiece in the patient's eye.

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Three vitrectomy sub-modes are available: “Core1”, “Core2” and “Shaving”.
These are independent memory areas where the Surgeon can save irrigation, aspiration and cutting parameters optimized for the various phases of the retinal surgery.
User can switch between phases either by touch screen or by system footswitch.
A “Link” button in the irrigation frame allow linking irrigation pressure in all phases of the vitrectomy.
If the “Link” button is not active, the irrigation pressure can be independently set for the various phases.
The “Max” button in the irrigation frame, sets irrigating pressure to a value which is higher than blood arteriosus pressure, to allow an immediate, momentary stop of retinal hemorrhages.

⚠ **WARNING** **Injury to the patient’s eye!**

Maintaining the irrigating pressure at a value which is greater than arteriosus pressure may cause permanent damages to the retinal tissue.

- The “Max” button must be activated for the shortest possible time. An alarm is automatically triggered if irrigating pressure is kept over 70mmHg for more than one minute.

To set vitreous cutter parameters, hit the “Vitrectomy” button. The following adjustments are possible:
Stand by position (footswitch not depressed) of the cutting port can be set on “Open port” or “Closed port”.
Cutter duty cycle can be set on “Low”, “Medium” or High”. This affects, for a given vacuum level and cutting frequency, the Material (vitreous) Removal Capability: the higher is the duty cycle, the higher the removal capability.
The cutting frequency can be controlled either in “Panel” mode or in “Linear” mode. If “Linear” control mode is chosen, cutting frequency can be linearly controlled by system footswitch depression or rotation from a “Start” power to a final “Stop” power (DSR mode). Note that “Start” frequency can be set either smaller or greater than “Stop” frequency.

5.6.5 **Scissors**

⚠ **WARNING** **Injury to the patient’s eye!**

Non-sterile air might enter into the patient's eye if the scissors are connected incorrectly.

- The scissors should always be tested for proper function using a beaker with a sterile solution, before placing the scissors in the patient's eye.

INFORMATION **Damage to the scissors!**

Testing in air will cause irreparable damage to the scissors.

- The scissors should always be test run in a beaker of sterile solution. Aspiration is disabled during the use of the scissors.
- Activate the <open> button to use mode with an open tip. In order to return to the mode with a closed tip, press <closed>.
- The cutting rate can be adjusted using the + - buttons or sliders. The scissors can be operated in "linear" mode and in "fixed" mode. In "linear" mode, the cutting rate is linearly controlled by pressing the foot switch.
- If you intend to work in "Single cut" mode, activate the <Single cut> button. In order to return to multiple cut mode, press the <Multiple cut> button. In single cut mode, the motion of the scissors blade is linearly controlled by pressing the foot switch.

5.6.6 Illumination

The R-Evolution is equipped with a LED light-illumination system featuring three independent light sources. Lamp 1 and lamp 2 are equipped with blue light suppression filters and with a green filter.

- Connect the light guide fiber for endoillumination to the desired light guide fiber socket on the front panel of the device.

WARNING **Injury to the patient's eye!**

- Although the fiber optic endo-ocular illumination system does not emit infrared and ultraviolet radiations, always use the minimal power level sufficient for the surgical application to avoid possible damage to the retina.

WARNING **Injury to the patient's eye!**

- To reduce the risk of retinal damage, the edge of the fiber optic illumination probe should not be situated

in the immediate vicinity of the retina.

INFORMATION **Longer surgery time**

If the light guide socket is turned on and the fiber is not connected, the R-EVOLUTION automatically lowers the light emission, for better Surgeon comfort.

- Select the light source that you want to adjust and use the <on/off> key to turn it on or off.
- Adjust the light level of the selected lamp using the + - buttons or the slider.

A set of four filters allows to emphasize the presence of membranes.

Yellow filters also protects the eye of the patient from unnecessary exposure to blue radiation and thus enables longer treatment times

5.6.7 Tamponade

⚠ **WARNING** **Injury to the patient's eye!**

- In order to prevent any possibility of infecting the patient's eye, the original injection tube from Optikon 2000, equipped with an air sterilization filter should be used for air tamponade exclusively.

⚠ **CAUTION** **Injury to the patient!**

- The automatic intraocular pressure monitoring is calibrated for exclusive use of accessories manufactured or distributed by Optikon 2000 (membrane filters, tubing, scleral guide).

⚠ **WARNING** **Injury to the patient's eye!**

- The silicone stop valve is checked during power-up. Make sure that there is no hissing sound during power-up of the Medical Device.

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⚠ **CAUTION** **Injury to the patient's eye!**

- During the injection of silicone oil, the intraocular pressure (IOP) is not controlled by the R-Evolution CR such that the surgeon is in charge of controlling the IOP. It is important to check the silicone oil flow at set injection pressure before inserting the cannula into the eye.

⚠ **CAUTION** **Injury to the patient's eye!**

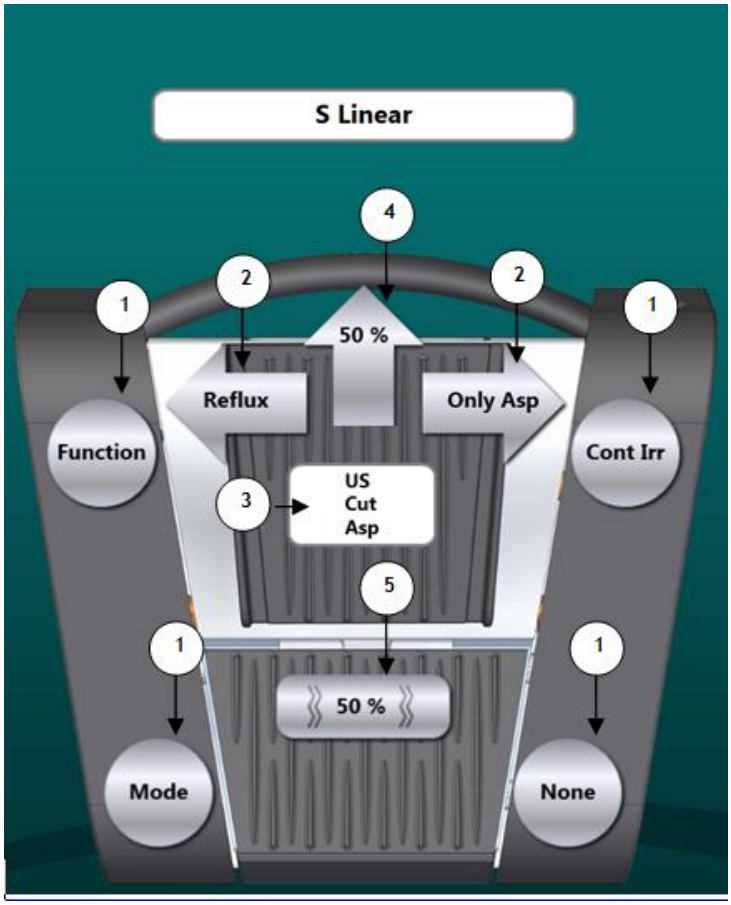
- Release the foot switch to discontinue the injection of silicone oil. In any case of emergency close the injection stop cock or take the silicone oil injection tubing off the silicone supply unit.

INFORMATION **Loss of silicone oil**

- In order to prevent silicone oil from leaking into the aspiration line of the I/A cassette, the silicone oil collection tank should be kept in a vertical position and be replaced as soon as it is completely filled with silicone oil.

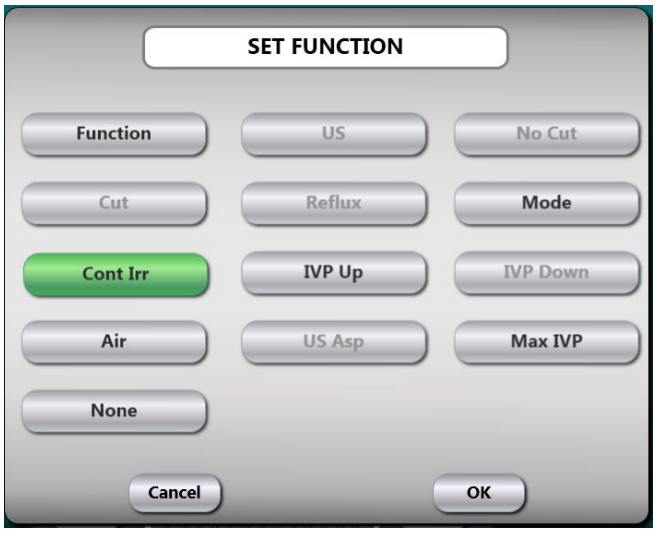
- In order to speed up the removal of high density oil, the enclosed Y connector can be used to connect two removal sets and use them simultaneously.
- For further details, please refer to the accompanying documents of the silicone oil removal set.

5.6.8 **Footswitch programming**



Push “System settings” button to access to the graphic footswitch programming interface.
This interface allows customization of the footswitch behavior:

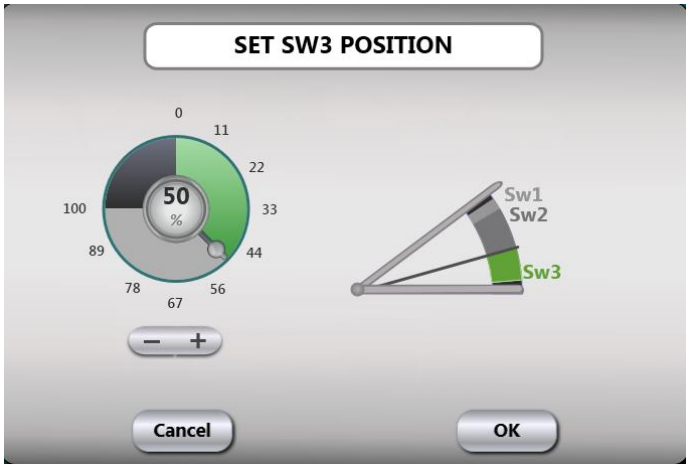
a. Touching any of the four round side buttons (1) or any of the side pointing arrows (2) on screen causes a pop-up window to show. This window allows chosing which function to link to the individual button or side movement of the main paddle.



Note that not all functions can be associated to all buttons or movements. Disabled functions are grayed.

b. The label (3) indicates which function is linked to the vertical movement of the main paddle (in the example, U/S, vit cut and Aspiration).

c. Touching the up pointing arrow (4), a pop-up window will appear allowing adjustment of the position of SW3 (U/S start point), thus allowing the user to custom share the vertical travel of the paddle between linear aspiration and linear adjustment of U/S power.



d. Touching the button (5), a pop-up window will allow adjustment of the tactile feedback (vibration strenght) of SW3 (U/S start).

Once a footswitch configuration has been programmed and saved, it can be recalled and saved within User programs. It is possible to use the same configuration through all the User program or to assign different footswitches to each stage of the program, i.e. “Single linear” in “Sculpt” and “Dual Linear” in “Quad”.

5.6.9 **Mean Ocular Perfusion Pressure (CR only)**

It is well known from medical literature that an elevated intra-ocular pressure impairs proper blood circulation in the retinal vessels and that, if this condition is maintained for an extended period of time, permanent retinal damages may occur.

The fact that some retinal surgeries, while properly executed from the technical point of view, did not cause the anticipated functional improvements, is often attributed to iatrogenic damage caused by the fact that an excessive irrigation pressure (and, consequently, IOP) has been set during the intervention.

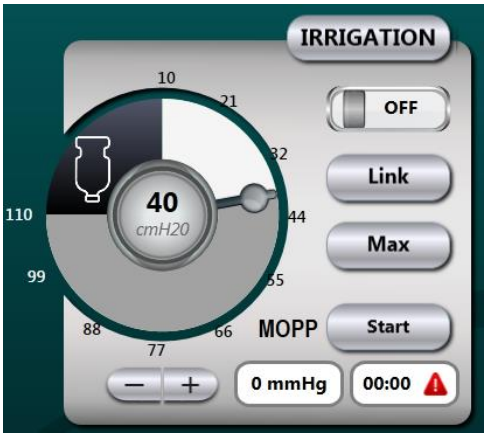
The limit to which the IOP can be set while keeping a proper retinal perfusion is a function of the diastolic and systolic pressure of the specific patient. The lower are these values, the lower the IOP must be kept.

The Mean Ocular Perfusion Pressure is a function of the difference between the mean arterial pressure (computed from diastolic and systolic pressure) and the Intra Ocular Pressure.

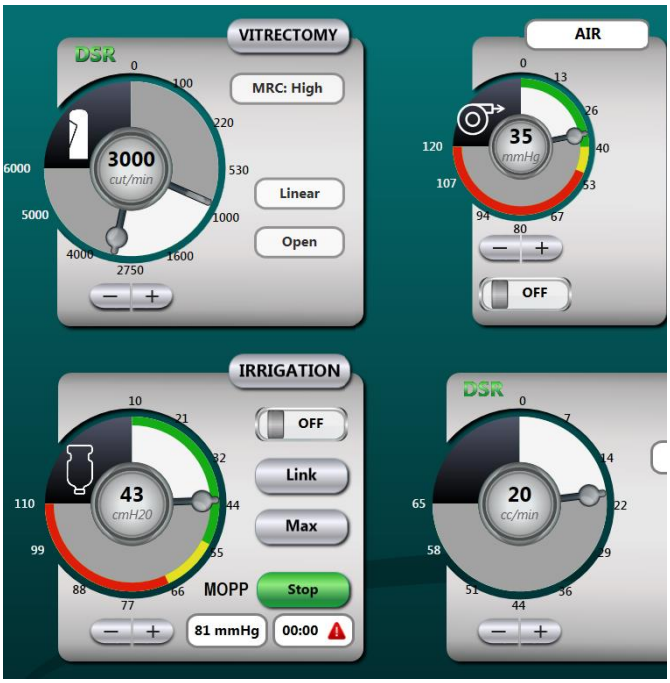
A MOPP equal or greater than 35mmHg, if considered to assure a proper perfusion of retinal vessels. If it is lowered below this value, the blood circulation in the retina gradually decreases, coming to a complete stop.

The digital blood pressure monitor allows R-EVOLUTION CR to periodically monitor the patient diastolic and systolic pressure and, on the basis of the set irrigation pressure, the IOP and the MOPP.

- Connect the arm cuff of the blood pressure monitor to the dedicated connector located on the rear panel of the R_EVOLUTION CR.
  The Irrigation frame will appear as in the following image:

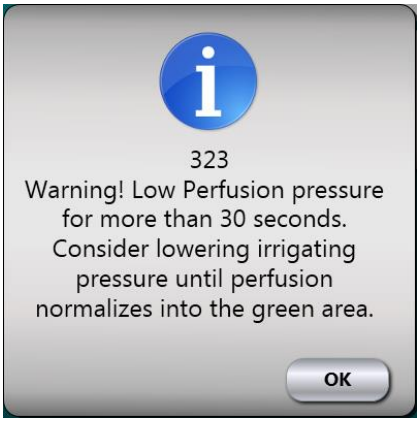


- Install the I/A cassette and position the sphygmomanometer cuff on the patient arm, then press “Start”.
  The blood pressure monitor will automatically measure the patient arterial pressure and the R_EVOLUTION CR will compute his MOPP.
  The equipment screen will appear as in the following image:

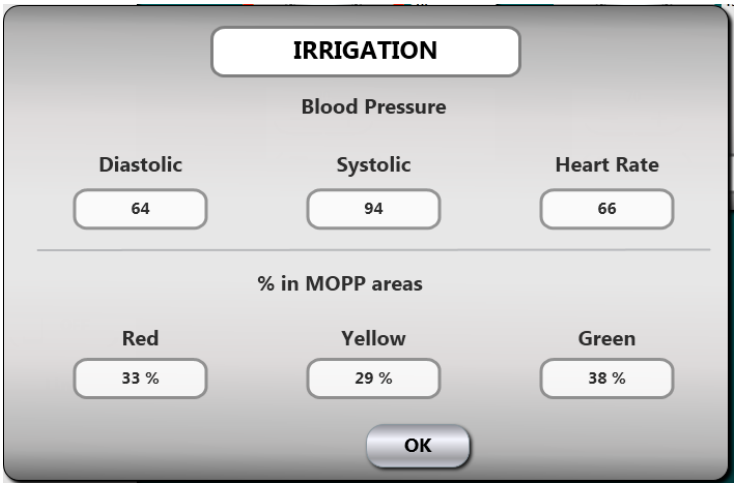


Around the dials to set BSS bottle height (or Controlled irrigating pressure) and air tamponade pressure, colored sectors will appear: settings of bottle height or infusion pressure in the green area cause a MOPP (about 10mmHg) greater than 35mmHg, thus allowing a proper blood circulation in the retinal vessels. Settings in the red sector cause a MOPP equal or smaller than 35mmHg, if they are mantained for a long period of time, a iatrogenic damage may occur.
The MOPP calculated from the last arterial pressure measure and from the current irrigating pressure is shown in the lower portion of the irrigation frame. The time passed in the red area is shown nearby, close to a red alert sign.

- An information message, suggesting to lower irrigation pressure as soon as possible, will appear if the said pressure has been in the red area for more than 30 seconds.



- Whenever needed, touch the “Irrigation” button to display a pop-up window showing the diastolic and systolic values acquired last and, in percentage, the time spent in the green, yellow and red colored areas respectively.



- Arterial pressure is measured periodically during the surgery. Ay the end of the surgical case, before removing the sphygmomanometer cuff from the patient arm, touch “Stop” in the “Irrigation” frame.
- All MOPP counters are automatically reset when the I/A cassette is replaced (new patient).

6. System alarm messages

⚠ **WARNING** **Error messages on the touchscreen**

Error messages with a red warning sign indicate a serious 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 indicate a moderate 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 indicate a minor error or an instruction that can be remedied/followed by the user.

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

100 Error messages

Id	Message	Probable cause	Corrective measure
100	"Air pressure error"	visual message + sound Error in air tamponade or Controlled irrigation system (output pressure much higher or lower than preset)	Please contact the Optikon 2000 service team.
101	"Pressure level error"	visual message + sound Incorrect pressure at output of proportional valve	Please contact the Optikon 2000 service team.
102	"Vacuum level error"	Vacuum exceeds preset value in Venturi mode	Please contact the Optikon 2000 service

			team
103	“Diathermy power mismatch”	Error in diathermy system (output power much higher or smaller than preset)	Please contact the Optikon 2000 service
104	“U/S enable failure”	Error in ultrasound system (power output not turned on despite prompting due to error in activation gate or wire contacting problem)	Please contact the Optikon 2000 service

200 Error messages

Id	Message	Probable cause	Corrective measure
200	"Air enable failure"	Error in air tamponade and Controlled irrigation systems (safety switch Off secondary transistor, is checked at start-up)	Please contact the Optikon 2000 service team.
201	"Watchdog failure"	Error in monitoring circuit (checked at start-up)	Please contact the Optikon 2000 service team.
202	"Serial communication fault"	Communication error between graphical user interface and control board	Please contact the Optikon 2000 service team.
203	"Diathermy enable / Diathermy reading mismatch"	Error in diathermy system (power output turned on due to error in activation gate)	Please contact the Optikon 2000 service team.
205	"Diathermy enable failure"	Error in diathermy system (power output not turned on despite prompting due to error in activation gate or wire contacting problem)	Please contact the Optikon 2000 service team.

Id	Message	Probable cause	Corrective measure
206	"Power supply / reference voltage mismatch"	Incorrect voltage reference at A/D transducer or incorrect +5V power value (checked at start-up)	Please contact the Optikon 2000 service team.
207	"US enable / US reading mismatch"	Error in ultrasound system (power output turned on due to error in activation gate)	Please contact the Optikon 2000 service team.
209	"Vacuum offset error"	Priming error: vacuum sensor offset excessive	a) Priming procedure was restarted after Err 210. Open the infusion clamp on the infusion set, briefly open continuous irrigation, and restart priming procedure. b) Vacuum sensor needs calibration Please contact the Optikon 2000 service team for calibration of the unit.
210	"No irrigation"	Priming error: Vacuum does not decrease after the pinch valve is opened.	Open the infusion clamp on the infusion set, briefly open continuous irrigation, and restart priming procedure.
211	"Too high infusion pressure"	The infusion pole is situated at too high a level	Lower the infusion pole as far as possible
212	"IVPole failure"	Error on the infusion pole	Please contact the Optikon 2000 service team.

Id	Message	Probable cause	Corrective measure
213 216 217	“Light 1 overheating” “Light 2 overheating” “Light 3 overheating”	The LED endoillumination system 1, 2 or 3 has reached an excessive temperature.	Verify that the rear panel ventilation grids are free from obstructions. Switch off the overheated LED and use one of the other two sources. If the problem persists, contact the Optikon 2000 service team.
214	“Battery discharged”	The battery of the wireless footswitch is discharged	Immediately wire the footswitch to the console to continue.
215	“Footpedal communication fault”	Pedal is switched off or batteries are completely dry.	Press paddle or connect by cable.

300 Error messages

Id	Message	Probable cause	Corrective measure
300	"Install I/A cassette"	The I/A cassette is not connected	Connect I/A cassette
301	"I/A cassette full, aspiration halted"	The waste collection container of the I/A cassette is full	Replace I/A cassette

Id	Message	Probable cause	Corrective measure
302	"Low input pressure	Pressure of the external air supply is too low or zero	a) Device is not connected to compressed air supply or stopcock is closed. Connect the device to compressed air source or open the stopcock. b) Pressure of the compressed air supply of the device is less than 450 kPa (65 psi). Check the pressure of the compressed air circuit.
303	"Major leakage"	Priming error: Peristaltic pump cannot establish a vacuum of 100 mmHg within 30 sec.	a) Test chamber is not installed on the sleeve. Make sure that the test chamber is properly installed on the sleeve. b) Irrigation/aspiration tubing is not connected to handpiece. Connect the irrigation/aspiration tubing from the cassette to the phaco handpiece. c) The I/A cassette is defective. Replace I/A cassette d) The pump system needs calibration. Please, contact the Optikon 2000 service team.

Id	Message	Probable cause	Corrective measure
304	"Aspiration line occluded"	Priming error: Vacuum level when priming the tubing exceeds 300 mmHg	a) Handpiece and tip may not have been properly cleaned before sterilization. Replace tip and/or handpiece. b) The I/A cassette is defective. Replace I/A cassette
305	"Minor leakage"	Priming error: Peristaltic pump cannot establish a vacuum of 300 mmHg	a) Irrigation/aspiration connectors are not fully engaged in the handpiece connectors. Connect the connectors properly. b) The sleeve or the test chamber is not correctly assembled. Verify that the test chamber is fully engaged on the sleeve and that the sleeve is properly positioned on the handpiece.
306	"Check tip"	Priming error: Phaco handpiece cannot be adjusted	a) Phaco tip is loose. Screw the phaco tip properly into the handpiece using the phaco tip wrench. b) Phaco tip is damaged. Inspect the phaco tip and replace according to need. c) Phaco handpiece is damaged. Replace phaco handpiece

Id	Message	Probable cause	Corrective measure
307	"Weak handpiece"	Phaco handpiece cannot deliver more than 50 micrometers.	a) Check if the phaco tip is loose and, if this is the case, tighten it properly using the phaco tip wrench. b) It is common that the piezoceramic element deteriorates with use and number of sterilization cycles. Please submit the handpiece to the Optikon service team.
308	Install Controlled irrigation	Controlled irrigation air line is not connected to the equipment output	Connect Controlled irrigation system correctly or use gravity feed irrigation instead.
310	"Low Stroke"	Ultrasound handpiece cannot deliver set stroke	a) Check if the phaco tip is loose and, if this is the case, tighten it properly using the phaco tip wrench. b) It is common that the piezoceramic element deteriorates with use and number of sterilization cycles. Please return the handpiece to the Optikon service team.
311	“Plug U/S handpiece”	The U/S handpiece is not connected to the console	Plug the U/S handpiece into the appropriate connector on the console. If the problem persist, replace the

Id	Message	Probable cause	Corrective measure
			handpiece.
312	“Please, prime”	Phaco handpiece is connected but not primed.	See “5.4.3 Installation of phaco accessories”
313	“Please, prime”	Vitrectomy handpiece is connected but not primed.	Follow on-screen instructions to prime and test the vitrectomy cutter.
314	“Please, prime”	I/A cassette is connected but not primed.	Follow on-screen instructions to prime and test the I/A cassette.
315	“Battery low”	The wireless footswitch battery is low.	Recharge the battery as soon as possible or wire the footswitch to the console.
316	“Battery temperature fail”	Wireless footswitch battery is overheating during recharge	The battery should be replaced, contact Optikon service dept.
317	“Battery fail”	Wireless footswitch battery is defective.	The battery should be replaced, contact Optikon service dept.
318	“For aspiration select peristaltic”	In “Fluids” mode, while injecting silicone oil Venturi pump cannot be used.	Select peristaltic pump to aspirate while injecting silicone oil
323	“Warning! Low perfusion pressure for more than 30 seconds. Cosider lowering irrigating pressure until perfusion normalizes into the green area”	Irrigating pressure has been set in the “red area” for more than 30 consecutive seconds.	Lower the irrigating pressure in the “green area” as soon as possible.

400 Other messages

Id	Message	Probable cause	Corrective measure
400	"Skip I/A Priming?"	One of the foot switch switches is being pressed.	a) if footswitch has been pressed involuntarily, remove your foot and press "NO" on the screen b) Defective foot switch. Replace foot switch
401	“Stop priming?”	Footswitch has been pressed during priming procedure.	If the footswitch has been pressed involuntarily, press “no”.

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 Medical Device using the power switch.

- Pull the power chord.
- Press lock lever (1) and remove the fuse holder.
- Remove the defective fuses and install new fuses.

INFORMATION **Risk of damaging the Medical Device!**

Incorrect fuses may damage the device.

- Use fuses with the correct ratings only! Please refer to the rear panel label for details.

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

Maintenance of the Medical Device

⚠ **CAUTION** **Risk of injury to the patient's eye!**

Malfunction of the Medical Device may injure the patient!

- Have your authorized service partner perform a safety check on the equipment in accordance with IEC 62353 that includes the following items:

- during the installation of the Medical Device,
- in regular intervals (every 12 months),
- during maintenance work,
- after repairs, upgrades, calibration, and soft- and firmware updates

INFORMATION **Risk of damaging the Medical Device!**

- To keep the Medical Device 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 in a clean dry location.
- Remove I/A tubing after each use.
- To prevent any impairment of the Medical Device 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 device 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 Medical Device 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 Medical Device

7.2 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.

⚠ **CAUTION** **Risk of infection!**

- 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 device.
- 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, like phaco tips, please refer to the indications given in the relevant instructions for use.

Disinfection

INFORMATION **Surface damage on 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. ACCESSORIES

This chapters lists accessories, spare parts and consumables designed by Optikon for the R-Evolution.
For detailed information, inquire with your local Optikon dealer or visit the www.optikon.com website.

⚠ **CAUTION** **Risk of injury to patient's eye!**

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

General use accessories

REF	Description
112104	Multifunction footswitch(pedal+ battery charger + connection cable)
122007	Remote Control
111008	Eclipse HD - Video Overlay system

Posterior segment surgical accessories (CR only)

Posterior Vitrectomy
"Optivit" 20, 23, 25G Vitrectomy cutters
"Twedge" Vitrectomy cutters (dual cut) 23, 25, 27G
Endoillumination
"Standard" 20, 23, 25, 27G Endoillumination probes
"Wide angle" 20, 23, 25G Endoillumination probes
"Chandelier" 20, 23, 25, 27G Endoilluminator
Irrigation / Aspiration
"Minimal IOP" Controlled irrigation kit
Drip chamber for Controlled irrigation
"Easysys" I/A cassette
20G Infusion cannula
Fluids removal cannulas, 20, 23, 25G
Valved trocars 23, 25, 27G
Non valved trocars 23, 25G
Active and passive "Charles" aspiration handpieces
Fluids exchange
Automatic stopcock air injection tube, with filter
Injection/removal kit for silicone oil

Diathermy
Endodiathermy handpieces 20, 23, 25G
Diathermy forceps
Pencil Esodiathermy handpiece
Diathermy cable
Phacoemulsification
“Slim 4” phacoemulsification handpiece (anterior and posterior segment)
“Six” phacoemulsification handpiece (anterior and posterior segment)
“Low friction” Pars Plana phacoemulsification tip

Anterior segment surgical accessories

Phacoemulsification
“Slim 4” phacoemulsification handpiece (anterior and posterior segment)
“Six” phacoemulsification handpiece (anterior and posterior segment)
1,8 to 3,2mm incision phacoemulsification tips
1,8 to 2,9mm incision “flared” phacoemulsification tips
“Sleeveless” 1mm incision phacoemulsification tips
Silicone sleeves for 1,8 to 3,2mm incision phacoemulsification techniques
Irrigation / Aspiration
I/A handpiece for quick insertion tips
Straight I/A tips, with silicone sleeve for incisions from 1,8 to 3,2mm
Angled I/A tips, with silicone sleeve for incisions from 1,8 to 3,2mm
I/A tips with metal sleeve
Diathermy
Pencil Esodiathermy handpiece
Diathermy forceps
Diathermy cable
Anterior Vitrectomy
20G Vitrectomy cutter, with irrigation sleeve
20, 23, 25G Vitrectomy cutters, without coaxial irrigation

R-Evolution procedure packs
Optikon 2000 supplies custom tailored procedure packs for both vitrectomy and phacoemulsification.
Procedure packs contains a selection of the accessories listed above.
For detailed information, inquire with your local Optikon dealer.