

Technical Specifications: R-Evolution® CR with Integrated Laser Module

GENERAL INFORMATION

Manufacturer	OPTIKON 2000 S.p.A. Via del Casale di Settebagni, 13 - 00138 Rome - Italy
Model	R-Evolution® CR with integrated LASER module
Ref	R-Evolution® CR: 121012 LASER module: 128910
Regulatory compliance	93/42/EEC Medical Device Directive (MDD)
Technical standards	EN60601-1 EN60601-1-2 EN60601-2-2 EN80601-2-58 EN60601-2-30 EN60601-2-22 EN60825-1 ISO15752

ENVIRONMENTAL SPECIFICATIONS

Storage and transport	Temperature range +5°C - +60°C, humidity 10% - 100% (non-condensing), atmospheric pressure 700 -1060 hPa
Operating	Temperature range +15°C - +28°C, humidity 30% -75%, atmospheric pressure 940 -1060 hPa (for max aspiration vacuum); 810-1060 hPa (aspiration vacuum up to 500 mmHg)

ELECTRICAL SPECIFICATIONS

Input voltage	100-240 VAC
Frequency	50/60 Hz
Power supply	420 W
Fuses	100-240 Volt: T4AH 250V

COMPRESSED AIR SPECIFICATIONS

Air inlet pressure	500 - 800 kPa (72 - 116 PSI; 5 - 8 bar)
Air consumption	32 Normal litre/min

IRRIGATION

Fluid delivery	Microprocessor-controlled active infusion or gravity fed (ocular pressure determined by the height of irrigation source)
Valves	Pinch valve
Control	Footpedal

ASPIRATION

Aspiration pump types	Peristaltic and Venturi
Actuating medium	Peristaltic pump: rollers Venturi pump: air from an external source at 500-800 kPa (72-116 PSI; 5-8 bar)
Default vacuum level	User programmable
Available vacuum range	5 - 700 mmHg
Default flow rate	User programmable
Available flow rate range	1 – 90 cc/min (peristaltic only)
Vacuum rise time	Peristaltic: adjustable on 25 levels (0.5s-12s) Venturi: adjustable on 2 levels (fast/slow)
Aspiration mode	Peristaltic: fixed or linear flow rate combined with fixed or linear vacuum Venturi: fixed or linear vacuum
System feedback	Vacuum sensor, measuring the vacuum in the aspiration line
Control	Footpedal

ANTERIOR VITRECTOMY

Handpiece type	Pneumatically powered guillotine cutter
Default cutting rate	User programmable
Available cutting rate	60 - 10,000 cuts/min 120 - 20,000 cuts/min with Twedge™ technology
Pneumatic drive	Pressurized air from an external source
Cutting mode	Fixed or linear
Control	Footpedal

POSTERIOR VITRECTOMY

Handpiece type	Pneumatically powered guillotine cutter (VIT), pneumatically powered microscissors (SCISS)
Default cutting rate	User programmable
Available cutting rate	120 - 20,000 cuts/min with Twedge™ technology 60 - 310 cuts/min (SCISS)
Single cutting mode	Available for scissors only
Pneumatic drive	Pressurized air from an external source
Cutting mode	Fixed or linear
Control	Footpedal

DIATHERMY

Type	Bipolar generator - the generator stops when the RF power supply is not needed
Operating frequency	2 MHz
Nominal power	9 W (200 Ohm LOAD)
No load max. voltage	100 V
Default power	User programmable
Available range	5% - 100%
Handpiece type	Bipolar forceps, diathermy brush, endodiathermy probes
Diathermy cable	Bipolar, 75 Ohm, 200V max, steam autoclavable
Control	Linear control of the DIATHERMY power via footpedal

ILLUMINATION

Source type	Three independent LED lamps
Luminous flux	400 lm each LED lamp
Intensity adjustment	20 levels
Light filters	4 selectable color filters free of harmful UV and IR emissions

FLUID/AIR EXCHANGE

Available pressure	5 - 120 mmHg
Tolerance	Set pressure \pm 3 mmHg
System feedback	Digital sound indicating air ON

SILICONE OIL INJECTION

Available pressure	0.4 - 5 bar
System feedback	Digital sound indicating silicone oil injection

PHACOEMULSIFICATION

Handpiece type	Piezoelectric available with four or six crystals
Frequency	Approx. 40 kHz
Tip stroke	5 μ m steps up to 100 μ m
Power control	Fixed or linear control of U/S power via footpedal
U/S mode	Continuous, pulsed (with preset duty cycle), single-multiple-continuous burst
Occlusion mode	Autolimit, HD pulse
Timer U/S	0:00 - 9:59 min - Equivalent Phaco Time (EPT)

SPHYGMOMANOMETER (ANGEL™ TECHNOLOGY)

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 - 280 mmHg; Diastolic: 10 - 220 mmHg; Pulses: 20 - 230 beats per minute
Overpressure limit	300 mmHg
Standard arm cuff size	27 - 35 cm

LASER

LASER type	Diode pumped and frequency doubled Nd:YVO
Wavelength	532 nm
LASER class	IV
LASER power	Adjustable from 50 mW to 2,000 mW
Pulse length	Adjustable from 10ms to 2s
Pulse interval	Adjustable from 0 to 1s
Power accuracy (internal measurement)	\pm 5%
Cooling system	Thermoelectric (TEC)
Nominal ocular hazard distance	10 m
Aiming beam wavelength	625-645 nm
Aiming beam LASER class	II
Aiming beam power	Adjustable from 0 to 1 mW

EQUIPMENT CLASSIFICATION ACCORDING TO EN 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
Laser probe	Type BF
Degree of protection against water (system unit)	IPX0
Degree of protection against water (footpedal)	IPX8
Degree of safety in the presence of a flammable anaesthetics	Not suitable

W x D x H:
54 x 57 x 165 cm

Weight:
130 Kg


NOTE:

- 1) The weight and dimensions shown are approximate.
- 2) Specifications are subject to change without notice.