

OS4 Ophthalmic Surgery System MD 1105.08

General Information

Intended use: The OS4 surgery system is depending on the configuration intended to be used in surgical procedures in the anterior and posterior eye segment.

The full-feature surgery system “anterior/posterior with endolaser” includes the following functions:

- irrigation and aspiration (I/A function)
- ultrasound phaco (PHACO function)
- bipolar diathermy for coagulation of bleeding and coaptation of conjunctiva during eye surgery (DIA function)
- bipolar diathermic capsulotomy (CAPS function)
- bipolar diathermic deep sclerotomy ab interno (HFDS GLAU function)
- operation of a vitrectomy instrument (VIT function)
- injection and extraction of viscoelastic substances (INJECTION and EXTRACTION function)
- retinal photocoagulation with endolaser (LASER function)
- intra-ocular illumination (LUM function)
- Maintaining intra-ocular pressure by air (AIR function) and active infusion (GFI function, gas-forced infusion)
- Fluid-/Air-exchange

Notified Body: DQS Medizinprodukte GmbH, 60433 Frankfurt am Main, Germany

Manufacturer: Oertli Instrumente AG, 9442 Berneck, Switzerland

Certification: CE0297

GMDN-Code: 45072

Technical Data

Classifications

Protection class : 1

CE Classification: Class IIb according Rule 9.2, 11.2

Application parts: non-earthed, Type BF (IEC 60601-1)

Noise level: < 70 dB (A)

DESCRIPTION OF MODEL

Dimensions and weights

Dimensions:	Device: 490 x 520 x 1540 mm (W/D/H, infusion pole retracted) Tray: 800 x 350 mm
Weight:	Device: 75 kg (weight with tray VC860300) Pedal: 6 kg Tray: 7 kg

Electrical data

Mains voltages:	115 / 230 VAC
Mains frequency:	50 Hz / 60 Hz
Power consumption:	600 VA
Fuses	3x T 6.3 AH, 250 V, high breaking capacity
Operating mode:	Continuous
Service life:	10 years from the date of manufacture

Power data in the individual functions

PHACO:	26 – 28.8 kHz, 28 kHz nominal 40 W ± 8 W (100% / 1100 Ω) $V_{RMS} = 210V$ (40W / 1100 Ohm)
Vacuum:	5 mmHg – 650 mmHg Accuracy: ± 20% or 30 mmHg (greater value) Adjustable increment: 5 mmHg
Peristaltic flow:	0 ml/min – 60 ml/min Adjustable increment: - 0 – 10 ml/min : 0.1 ml/min - 10 – 60 ml/min: 1 ml/min Accuracy: ± 20%
Reflux peristaltic:	15 ml/min, accuracy: ± 20% 150 mmHg, accuracy: ± 20%
Reflux venturi:	100 mmHg Accuracy: ± 20%
VIT:	- 60 – 10'000 cuts/min with CF cutter, accuracy: ± 20% - 30 – 5'000 cuts/min with SPS vitrectomy cutter, accuracy: ± 20% Max. output pressure: 3.5 bar
DIA:	500 kHz ± 100 kHz 0 – 8 W nominal (50 Ohm) DIA (100%): 95 V max. output voltage (idling voltage)

DESCRIPTION OF MODEL

CAPS:	500 kHz \pm 100 kHz, specific output values Regular: 7.8 W \pm 1.5 W (50 Ohm), 340 V max. output voltage (idling voltage) High: 9.2 W \pm 1.8 W (50 Ohm), 365 V max. output voltage (idling voltage)
HFDS:	500 kHz \pm 100 kHz, specific output values HFDS: 7.3 W \pm 1.4 W (50 Ohm), 320 V max. output voltage (idling voltage)
AIR/GFI:	0 mmHg - 120 mmHg \pm 10%, min. 5mmHg Increment: 1 mmHg
Visco injection:	0.05 – 5.0 bar Accuracy: 0.5 – 5 bar \pm 0.2 bar
Visco extraction:	0.01 – 1.0 bar, Accuracy: - 0.2 – 0.8 bar \pm 0.1 bar - 0.8 – 1 bar \pm 20%
Light:	LED: 17 lm \pm 25% (23G) LEDplus: 19 lm \pm 25% (23G)
Laser:	Working beam: - Laser class 4, max. 1.5 W cw - 532 nm, max. pulse length: 5 sec Increments: - Laser power: 10 mW - Pulse duration: 10 ms - Pulse interval: 10 ms Aiming beam: - Laser class 3R, max. 5 mW cw - 635 nm

Transport and storage conditions

Temperatur:	-20°C - +55°C
Air pressure:	500 hPa - 1060 hPa
Relative air humidity:	10 - 90% non-condensing

Operating conditions

Temperature:	+14°C - +28°C
Air pressure	700hPa - 1060hPa
Relative humidity	30% - 75% non-condensing

DESCRIPTION OF MODEL

Revision: 25.08.2022 page 4

Supply pressure

Supply pressure: Pressurised air: 5 to 9 bar, 55 NI/min
Connection: NIST EN ISO 5359 connection

Device Accessories

VE860010	Dual-linear, wireless pedal for OS 4
VE860001	Instrument table for OS 4
VX100911	Compressed air hose, 5m, NIST-AIR connection on one end
VK340833	UPF user protection filter, passive, for Zeiss/HS Moeller microscope
VK340846	UPF user protection filter, passive, for Leica microscope
VK340990	UPF user protection filter, passive, for Topcon microscope
VK860001	Laser safety goggles, filter impact OD6+, blocked wavelength 532 nm
F18. P1E01. 1001MED	The user manual VV016040 for OS4 surgery system contains a detailed list of consumables and instruments that can be used with the device.

TECHNICAL DATASHEET

Article Number	VC860200	VC860300
Description	OS 4 surgical platform, anterior/posterior	OS 4 surgical platform, anterior/posterior with endo laser
Phaco	✓	✓
I/A	✓	✓
DIA/CAPS/HFDS GLAU	✓	✓
Anterior vitrectomy	✓	✓
Posterior vitrectomy	✓	✓
Injection/Extraction	✓	✓
Endo Phaco	✓	✓
Laser		✓
Gas forced infusion (GFI)	✓	✓
Fluid/gas exchange	✓	✓
Intraocular illumination		
Light LED	✓	✓
Light LED	✓	✓



Fig. 1: Frontview



Fig. 2: Frontview, with instrument table expanded



Fig. 3: Backview

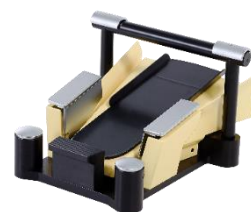


Fig. 4: Duallinear pedal