ENGINEERING INTERNATIONAL GROUP s.r.l.

MORPHEUS M

Anaesthesia Unit

Code: OM3.S5

Rev.10- 01/02/2022

GENERAL DESCRIPTION

	The MORPHEUS M anaesthesia unit is completed with:e ▪ mechanic gas mixing system, ▪ electronic lung ventilator with 12” TFT color display, ▪ valves group: open, semi-closed, closed, heated, with soda lime absorber, ▪ SIARETEX rapid connection device, Selectatec compatible for 2 vaporizers, ▪ gas supply group, ▪ gas analysis system (optional function).
Intended use	The MORPHEUS M is an anaesthesia unit and it can be used on adult, children and newborn patients. The MORPHEUS M is suitable for administration of Oxygen - Air - Nitrous Oxide - Halothane - Enflurane - Isoflurane - Sevoflurane - Desflurane mixtures.

NORMS

CE 0476	The device complies with the essential requirements and it is realized according to the references of the Annex II of 93/42/EEC Medical Devices Directive.
Class and type according to EN 60601-1	Class I Type B
National classification of medical devices	Z1203010101
Class according to 93/42 EEC Directive	Class IIb, Rule 9, Type: Active according to MDD 93/42 EEC Annex IX
Electromagnetic compatibility (EMC)	Conform to the requirements of the EN 60601-1-2 and following updating’s

Norms	EN 60601-1 :2006/A1 :2013; EN 60601-1-2 :2015; EN 60601-2-13:2006/A1:2007; EC 60601-1-6:2010/AMD1:2013; EN 60601-1-8:2007 / A11:2017; EN 62304:2006/ AC: 2008; EN ISO 14971:2012; EN ISO 4135:2001; DIR. 2011/65/CE; D.Lgs 49/2014.
File number reference	2164258
Unique Device Identification **(UDI) number**	0 80 3373726 0 1 0 4
Basic-UDI-DI	

ENVIRONMENTAL CONDITIONS

Operating	▪ Relative humidity: 10 al 90% non-condensing ▪ Temperature: from +10 to +40°C
Storage	▪ Relative humidity: < 90% ▪ Temperature: from -25 to +70°C

STRUCTURE

Structure	Light aluminium alloy and plastic moulds
Wheels	Pivoting antistatic wheels, diameter 100 mm (2 with brakes)
Drawer	No. 3 full extension drawers
Cylinder support	No. 2 vertical cylinders supports, on the back side (for cylinders up to 10 litres capacity) and round rubber pads
Support for 2 vaporizers	On horizontal guide (SIARETEX rapid connection device, Selectatec compatible for 2 vaporizers)
Auxiliary power supply outlets	No. 1 SCHUKO 220 Vac outlet (max. 6 A)
Work shelf lighting	12Vdc by led
Dimensions (W x D x H)	71 x 77 x 138 (L x P x H) cm (without monitor).
Weight	72 kg (without accessories)

TECHNICAL DATA

Electric power supply	100 ÷ 240Vac / 45 ÷ 60Hz
Maximum power	120 Watt
Back-up battery	12Vdc - 3 Ah Pb battery which guarantees an autonomy of around 120 minutes
Charging time	Around 10 hours

ELECTRONIC GAS MIXING SYSTEM

It has the function to regulate the capacity and the concentration of gas mixture (Air, O_2, N_2O) as well as to deliver it to the anaesthetic gas vaporizer.

It allows to select the mixture to be delivered (Air - O_2, or N_2O - O_2) and the O_2 enrichment for delivered mixture in case of emergency.

The anaesthesia module includes a device which guarantees a minimum concentration of 25% oxygen in all conditions (MIX-LIFE device).

The three pressure gauges on the front panel allow the continuous control of medical gas feeding pressure coming from the gas pipelines system.

Oxygen rotameter	▪ Scale: 0.1 - 15 L/min. ▪ Resolution: 0.1 L/min up to 1 L/min and 1 L/min up to 15 L/min ▪ Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worse case.
Nitrous oxide rotameter	▪ Scale: 0.2 - 12 L/min. ▪ Resolution: 0.1 L/min up to 1 L/min and 0.5 L/min up to 12 L/min ▪ Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worse case.
Air rotameter	▪ Scale: 0.1 - 15 L/min. ▪ Resolution: 0.1 L/min up to 1 L/min and 1 L/min up to 15 L/min ▪ Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worse case.
Low flows oxygen rotameter	▪ Scale 0.1 - 1 L/min. ▪ Resolution: 0.05 L/min ▪ Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worse case.
Low flow nitrous oxide rotameter	▪ Scale: 0.1 - 1 L/min. ▪ Resolution: 0.05 L/min ▪ Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worse case.
Medical gas supply	OXYGEN ▪ Pressure included between 280 kPa and 600 kPa (2,8 – 6 bar) ▪ Minimum flow required 90 L / min
	NITROUS OXIDE ▪ Pressure included between 280 kPa and 600 kPa (2,8 – 6 bar) ▪ Max. required flow 15 L/min.
	MEDICAL COMPRESSED AIR ▪ Pressure included between 280 kPa and 600 kPa (2,8 – 6 bar) ▪ Max. required flow 90 L/min.

Gauges	No. 3 on front panel (O_2 - N_2O - AIR), scale 0 - 6 bar
Alarms	Lack or low oxygen pressure with consequent cut-off of nitrous oxide delivery
Safety devices	▪ AGAINST THE ADMINISTRATION OF HYPOXIC MIXTURES MIX-LIFE: it always guarantees a minimum concentration of 25 % oxygen on mixtures which includes nitrous oxide. ▪ IN CASE OF LACK OR LOW OXYGEN PRESSURE CUT-OFF: audible alarm with immediate cut-off of nitrous oxide delivery. ▪ AGAINST OVERPRESSURE IN FLOWMETER BOX: Safety valve calibrated at 0.8 bar for the protection of the glass rotameters. ▪ IN CASE OF LACK OR COMPRESSED AIR LOW PRESSURE: All the devices (gas feeding) supplied by compressed air are automatically supplied by oxygen. ▪ AGAINST THE SIMULTANEOUS DELIVERY OF AIR AND N2O: Selection by membrane key on the flowmeter front panel.
Control for activation of exit of fresh gas for manual ventilations	▪ Setting of MANUAL modalities on ventilator (MAN) with automatic deviation of fresh gas to the manual system of anaesthesia unit valves group, or to a TO-AND-FRO circuit with visual indicator. ▪ Automatic deactivation of manual ventilation systems directly by ventilator control.
O_2 emergency by-pass	By apposite membrane key on the front shelf, max flow 35 L/min.
IN gas sockets on gas supply group	▪ No. 3 sockets for distribution system (O2 - N2O - AIR) ▪ No. 2 sockets for cylinder (O2 - N2O)
OUT gas sockets on gas supply group	▪ No. 1 sockets for O2 ▪ No. 1 sockets O2 - AIR for active scavenger feeding ▪ No. 1 fresh gas connector for external use for ex. TO AND FRO (selectable by apposite membrane key on the front shelf - AUX).
Other	▪ Socket for recycle of exhaust monitor gas ▪ Connection for anaesthetic gas scavenging (optional device: active type, or passive type)

BREATHING SYSTEM

- Compact system with automatic connections, easy dismountable and autoclavable.
- It allows the ventilation in modality: real open circuit, semi-closed circuit, closed circuit at low flows.
- The system also allows the spontaneous and manual ventilation in case of anaesthesia unit breakdown or machine off.
- Top special CO2 absorber canister of 1,5 Kg with rapid connection: this allows canister replacement also during interventions (the canister is autoclavable and reusable).
- The recycling system is a selective type, hence the soda lime and fresh gas consumption are reduced to the minimum.
- The heated valves group reduces the condensation and heats the fresh gas.
- The transition from one ventilation modality to another is completely controlled by the ventilator without any user's action on valves group.

LUNG VENTILATOR FUNCTIONAL FEATURES

User's interface	12" TFT high resolution colour display with membrane keyboard and encoder
Control modality	Electronic by microprocessor
Dead space compensation system	Automatic
Automatic compensation of atmospheric pressure	Automatic compensation of atmospheric pressure on measured pressure: present (max. 5000 mt)
Flow generation	Electronic system
Gas feeding	▪ Medical compressed Air or Oxygen supply with pressure included between 280 kPa and 600 kPa (2,8 – 6 bar) ▪ OPTIONAL. Turbine driven: independent from the gas supply system (in this case it's necessary a pneumatic Oxygen supply only).
Self-Test	**Primary test:** at anaesthesia unit's start-up, a control test of Turbine presence, Medical Gas Supply presence, INSP and EXP flow sensors operation, pressure sensor, patient circuit losses, back-up battery state, oxygen cell, integrity of audible alarm is automatically performed. This test takes around 15 seconds. **Tests on demand**: the anaesthesia unit has a tests on demand which is activated by the user in the ventilator menu. This subtest permits to verify the dead space and losses or to perform the oxygen cell calibration.
Ventilation modalities	▪ APCV ▪ APCV-TV ▪ PSV ▪ APNEA BACK-UP ▪ SIMV (Volumetric +PS; SPONT) ▪ VC/VAC ▪ VC/VAC BABY (integrated NEONATAL ventilation mode) ▪ MANUAL
Breathing rate	From 4 to 120 bpm (step 1 bpm)
Inspiratory time	From 0.2 to 5 sec.
Inspiratory pause	From 0 to 60% of inspiratory time
SIMV rate	From 1 to 119 bpm
Tidal volume	From 5 to 1500 ml (< 50ml: step 1ml / 50-100ml: step 5ml / >100ml step 10ml)
Minute volume	From 1 to 30 liters
I:E Ratio	1:1, 1:1.5, 1:2, 1:3, 2:1, 3:1
Airways pressure limit (PLIM)	From 6 to 60 cmH_2O
Support pressure (PS)	From 5 to 60 cmH_2O
PEEP	OFF, 3 to 30 cmH_2O (step 1 cmH_2O)
Pressure trigger (I)	From -1 to -9 cmH_2O under the PEEP level
Flow trigger (I)	From OFF, 1 to 15 L/min (step 1 L/min)

Inspiratory Flow (FLOW)	Selectable ramp from 10 to 80 L/min (step 10 L/min)

USER INTERFACE

Displayed graphics	▪ CURVES: Pressure - Flow - Volume ▪ LOOPs: Volume / Pressure and Flow / Volume ▪ Measurement RANGE: automatic
Events	Memory storage up to 100 machine events including the alarms.
Trends	▪ Storage capacity (72 h) of all measured parameters ▪ Foreseen Trends: PAW; PEEP; VTe; ExpMV; Rate
Measured parameters	▪ PAW; PEEP; Rate; I:E; FiO2; Vte; ExpMV ▪ MAP; Pplateau; Tpause; Ti; Te; Fi; Fe; Cs; Ri;
Flow sensor	Internal to the valves group, by magnetic perturbance, reusable.
Oximeter	Minimum resolution 1% - Automatic calibration procedure
Bronchomanometer	-20 to 80 cmH_2O
Safety	▪ Electronic and mechanical limit of airways pressure ▪ Self-diagnosis system

ALARMS

Alarm types	▪ Low / High Airways Pressure, Low / High Breathing Rate, Low / High O2 Concentration, Low / High Tidal Volume, Electric Power Supply ▪ Apnoea, Low Battery, Low Gas Supply, Disconnected Patient Circuit, Can-Bus Failure

GAS ANALYSIS (OPTIONAL)

Gas analysis	Integrated software for analysis of CO_2, O_2, N_2O, AG automatic identification, MAC.
Mainstream device	▪ IRMA AX+ (CO2, N2O, primary and secondary agents, HAL, ISO, ENF, SEV, DES). ▪ IRMA CO2 (CO2)
Sidestream device	▪ ISA AX+ (CO2, N2O, Agents) ▪ ISA CO2 (CO2) ▪ ISA OR+ (CO2, N2O, Agents, O2)
Technical characteristics	Consult the relevant technical data sheets for mainstream and sidestream modules.

ACCESSORIES	
Standard accessories	▪ User's Manual ▪ O2 supply hose ▪ N2O supply hose ▪ Air supply hose ▪ O2 cylinder supply hose ▪ N2O cylinder supply hose ▪ Top Special CO2 absorber canister (no. 1 / canister with metal cover) ▪ O2 cell ▪ Patient circuit - Manual ventilation KIT ▪ Adult Mapleson C adult patient circuit ▪ Electric power supply cable
Optional accessories	▪ See current export price list

SIARE applies the UNI EN ISO 13485:2016 Quality System and the 93/42/EEC.

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