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Flow-c Anesthesia Machine

Compact solution for a streamlined workflow

This document is intended to provide information to an international audience outside of the US.

GETINGE

A smoother workflow for busy ORs

Crowded workspaces. Packed schedules. Different patients. Complex techniques. These are the challenges you face every operation, every day.

That is why we've developed the Flow-c: a compact anesthesia machine where every detail has been designed to ease your daily work.

With innovation and smart design, Flow-c helps you to create an efficient working environment to ensure the highest standards of care.

Experience the Flow.

Designed with you
– to get work flowing

Every detail of the Flow-c has been thoughtfully designed in collaboration with clinicians to ease your daily work in the fast-paced OR.

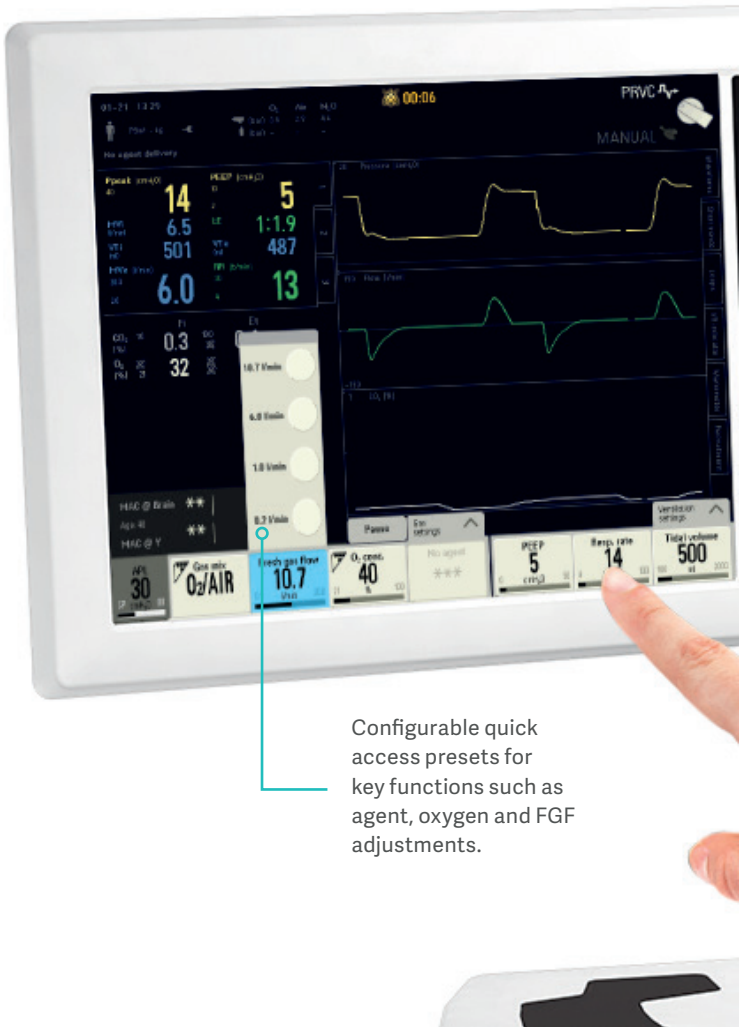
The rear of an anesthesia machine often becomes a tangled mess. But not with the Flow-c. Cables and hoses are routed inside panel arms and behind the back covers.

Easy to use
The intuitive touch screen gives you one point of control for all functions. The system's simplicity of operation saves time and contributes to safety in busy ORs. Tools are right where you want them, so you can work in an ergonomic and comfortable position.

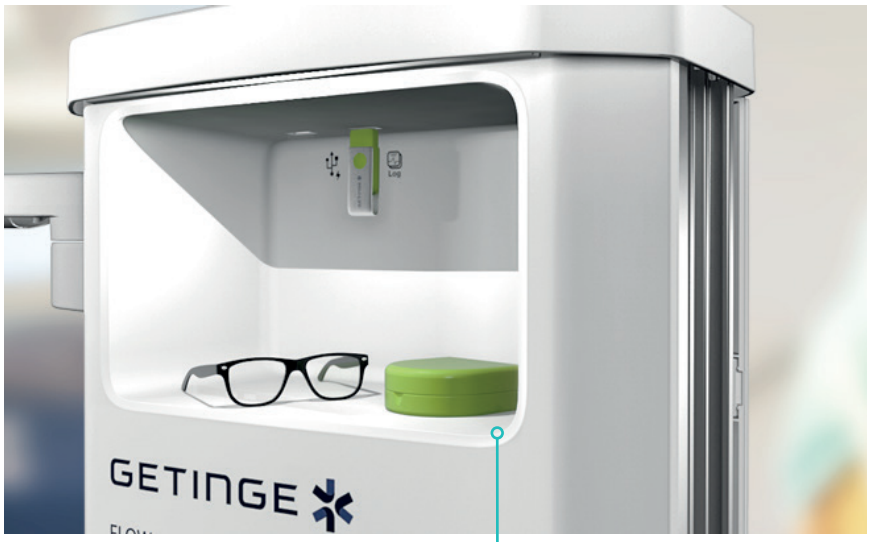
Flexible mounting
Mounting capabilities are one area where our focus on design innovation stands out. Despite its compact footprint, Flow-c packs in a greater rail length than other machines on the market. We were determined that its compact form should add flexibility, not limit it, and we have used every millimeter of space to the full. Rails are stepless, so you can personalize your Flow-c, adding monitors, tables and other accessories where it best suits you.

Cable management without clutter
The back of the Flow-c minimizes the clutter of hoses and cables. These are neatly routed and covered by specially designed panels, contributing to improved hygiene and safety.

Convenient details
Small features often have a big impact on the experience of using a machine every day. After listening carefully to users, we've introduced some details that will make a difference to your workflow. We know your hands are often full, so we've added practical hooks for convenient placement of tubes and more. You'll also find surprisingly generous table and drawer space, as well as USB ports for data transfer and charging.

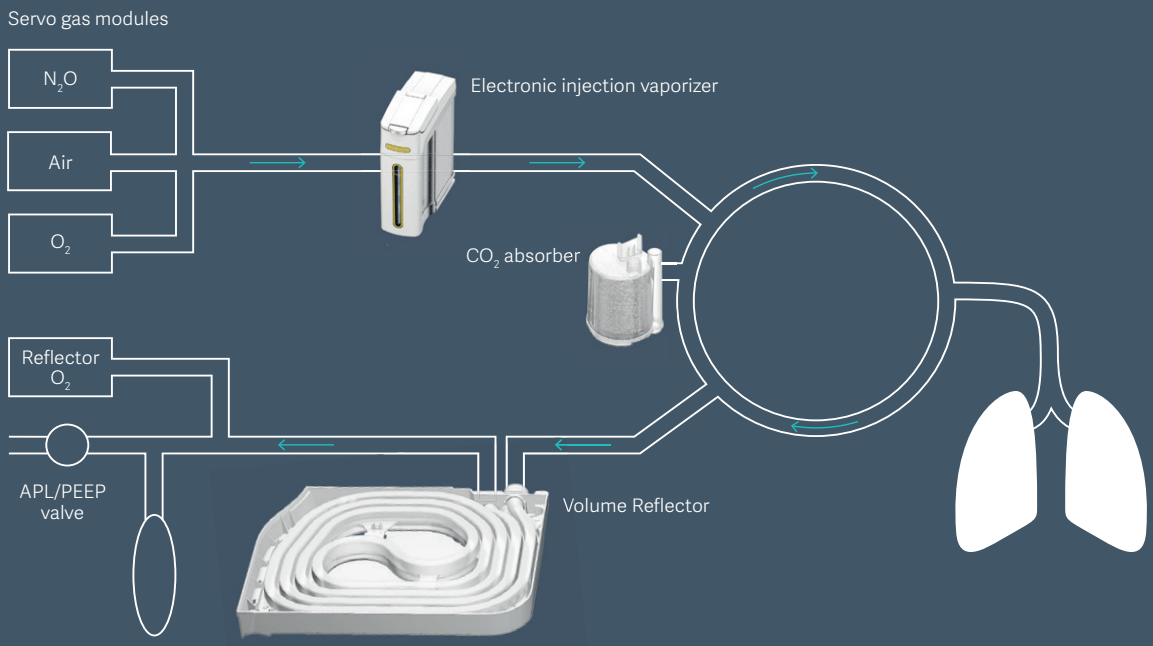


Configurable quick access presets for key functions such as agent, oxygen and FGF adjustments.



The interface presents key information at a glance, and requires minimal training – so you can focus on the patient.

The Flow-c has a convenient shelf, giving easy access to the USB ports. The work-space is lit by a dimmable LED lamp.



Next-generation technology at the core

– for effective and gentle treatment

The Flow family was created by the engineers behind the world-class Servo ventilator platform. The innovative technology at the heart of your Flow-c ensures superior ventilation performance[1], and outstanding agent efficiency reducing the use of costly and harmful anesthetic agents.

The power to care

Ventilation performance is not only about modes. Most importantly, it's about ensuring the power and precision needed to ventilate all patient categories. Power when you need it, yet gentle on the lungs – that's a key strength of our next-generation Flow core technology.

Servo gas modules

The Servo gas modules enable ICU-quality ventilation. They deliver up to 200 l/min inspiratory flow and are capable of adjusting pressure and flow several times within every breath, according to each patient's needs.

Volume Reflector rebreathing system

Our patented Volume Reflector is a smart rebreathing system. In combination with Servo gas modules, it enables accurate tidal volumes down to 5 ml, providing better ventilation performance compared to bellows, turbine and piston-operated systems.[1]

The rigid Volume Reflector is never empty, ensuring uninterrupted ventilation, and compensates effectively for any leakage.[2] The Volume Reflector is oxygen driven, minimizing the risk of hypoxic mixtures. It has a small system volume for fast wash-in and wash-out and a rebreathing fraction of 98%.

Electronic injection vaporizers

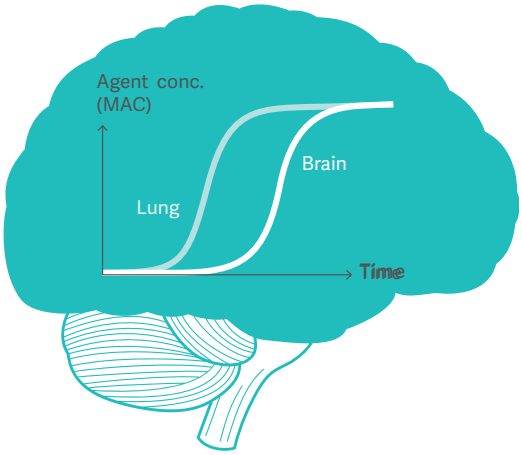
Electronic injection technology enables precise delivery of agents, primarily during the inspiratory phase, with minimal waste. The lightweight and maintenance-free vaporizers can be refilled and exchanged while the machine is running, and do not require annual calibration.

Low-flow anesthesia the safest[5] way

Active inspired O_2Guard protects your patients

O_2Guard is designed to prevent hypoxia.[4] This unique safety mechanism overrules the clinician´s settings and increases the flow of fresh gas and oxygen should the O_2 level drop below 21%. Conventional guards will only trigger an alarm. The O_2Guard is a standard feature on all Flow models. Learn more at www.getinge.com/o2guard

»O_2Guard is the only commercially active inspired hypoxic guard available.«[5]

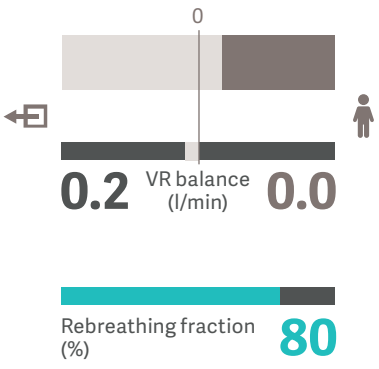


Agent concentration in target organ – MAC Brain guides you

Due to pharmacokinetics there is a time delay in agent concentrations between the lungs and the target organ, the brain. The unique MAC Brain tool visualizes the difference to support better dosing and planning of agent delivery.

Visual support when lowering the flows

The VRI (Volume Reflector Indicator) is a useful visual guide that enables you to optimize the rebreathing fraction and thus save anesthetic agent. The tool makes it simple to set the optimal Fresh Gas Flow (FGF) and volume ratio. Agent consumption can easily be monitored via the interface.



See the bigger picture

– ownership with less stress and easier flow

Minimizing your long-term costs

The purchase price is just one part of the total cost of owning an anesthesia machine over time, so we have designed the Flow-c to minimize cost of ownership. From an intuitive interface that optimizes workflows and minimizes staff training time, to innovations that significantly reduce consumption of anesthetic agents.

Getinge Care: protecting your investment

Optimizing uptime is an excellent way to boost productivity and reduce costs. A Getinge Care service plan ensures your equipment always performs to its full potential, allowing you to focus on saving lives.

Smart fleet management reduces risks

We make it easy to manage a large fleet of Flow machines. They all share the same user-friendly interface, and they have many components in common, such as the Volume Reflector and vaporizers. Getinge Online gives you fleet overview and can be accessed from any device.

We also offer an extensive range of readily available consumables. These are designed for the highest possible level of patient safety and outstanding ease of use.

Extensive training programs

Keeping skills updated improves patient outcomes, reduces risks and boosts productivity. We tailor training to meet your needs, which includes e-learning in addition to hands-on training courses.

Optimized equipment with Getinge Online

Getinge Online gives you access to real-time information about your Flow-c machines, e.g. agent consumption, running hours, next preventive maintenance. Through the portal a service technician can resolve most issues remotely, saving time and costs.

Connectivity between devices with MSync

MSync makes it easy to connect the Flow-c to patient monitor, HIS and patient data management system. Patient data is transferred via HL7 (MSync) in real time to support decision-making.

Flow-c at a glance

– everyday work that simply flows

15" tiltable and rotatable touch screen
Flexible and intuitive to use

USB ports and LED light
Data transfer and charging easily accessible. Three-step dimmable LED lights up the workspace

Open platform
Customize to match your needs

Flexible workspaces
Practical for your everyday needs

Electronic vaporizer
Precise and cost-efficient

Smart cable and hose management
Less clutter, easier cleaning and improved mobility

Central 4-wheel brake and cable pushers
Enhances device mobility

215 cm multipurpose rails
Extensive mounting options

Flow-c Anesthesia Machine

Technical specifications

Gas volumes, flows and leakages associated with the breathing system are stated in the technical specifications and adhere to BTPS reference conditions. (Body temperature, ambient pressure, Saturated).

All gas concentration readings are normally referenced to dry gas conditions, ambient room temperature and atmospheric pressure (ATPD).

The condition for measured inlet gas pressures and flows is STPD (Standard Temperature and Pressure Dry); 20 °C, standard pressure at 101.3 kPa and 0 % relative humidity (dry).

Weight and dimensions

Base system weight (out of the box weight)	120 kg (249 lbs)
System nominal weight *	134 kg (295 lbs)

* Equipped with control panel, patient cassette, one full vaporizer, one CO_2 absorber.

System max weight including maximum load	270 kg (595 lbs)
Dimensions of base plate	697 × 863 mm (27.4" × 34.0")
Drawers	1
Vertical rail	4
Wheels	Four wheels (diameter 125 mm/4.9")
Working surface/writing table	380 mm × 480 mm (15.0" × 18.9")
Reading lamp	Adjustable LED light integrated into the shelf tower.

Display

Type	LED touch screen, complete with 11 membrane switches and one rotary knob
Size	432 mm × 295 mm (17.0" × 11.6")
Placement	Attached to display arm
Viewing area	15"
Waveforms	Up to 6 waveforms, user configurable
Trends	• Graphic display, 1 to 24 hour resolution • Numeric display, 1 to 60 minute resolution

Essential performance (term defined in IEC 60601-1)

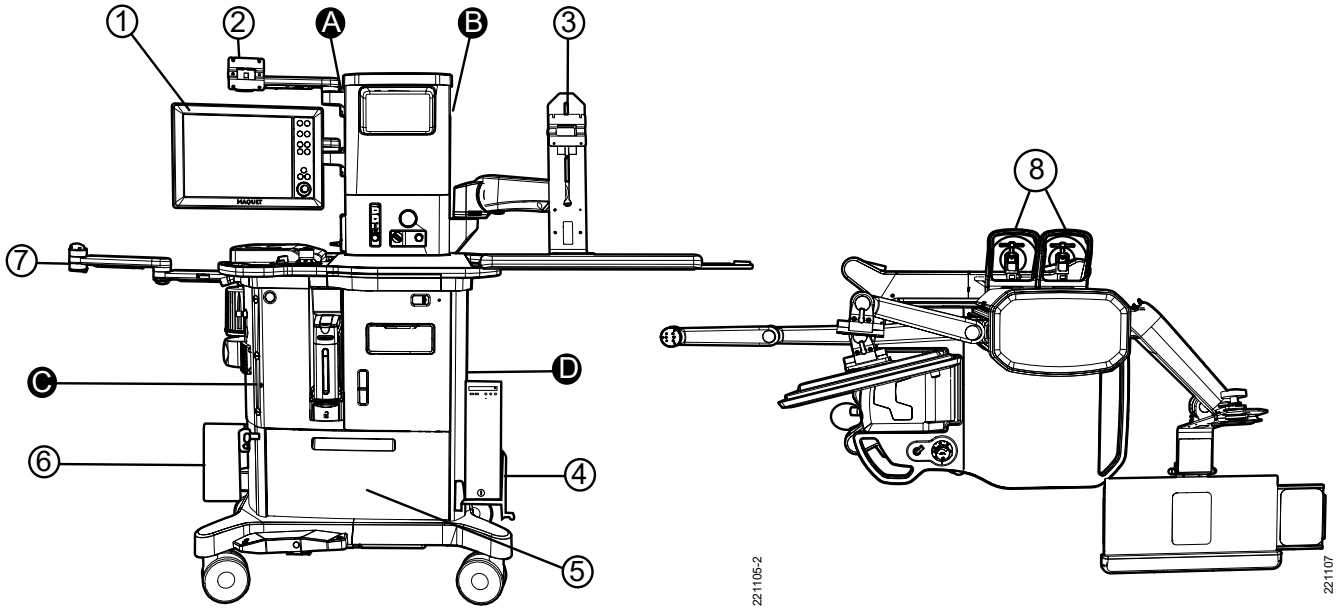
- Oxygen flow under all conditions except the failure of the oxygen supply or generation of a clinical and/or technical alarm.
- Delivery of a non-hypoxic gas mixture to the patient or generation of a clinical and/or technical alarm.
- Non-delivery of excessive concentrations of a volatile anesthetic agent or generation of a clinical alarm.
- Airway pressure monitoring and associated clinical alarms (Ppeak, PEEP).
- Gas measurement accuracy (for Isoflurane, Desflurane, Sevoflurane, CO_2, N_2O, O_2) and generation of gas measurement associated clinical alarms or generation of a technical alarm.
- Delivery of ventilation at the patient connection port within the alarm limits set by the operator or generation of a clinical or technical alarm.

Environment

Environment	Operating conditions	Non-operating conditions
Ambient temperature	+15 °C to +35 °C (+60 °F to +95 °F) (Desflurane: +15 °C to +30 °C, +60 °F to +85 °F)	-25 °C to +60 °C (-15 °F to +140 °F)
CO_2 absorber	15 °C to 35 °C (60 °F to 95 °F)	0 °C to 35 °C (32 °F to 95 °F)
Storage at higher temperatures can result in reduced efficiency and service life due to moisture loss. When correctly stored, canisters will maintain absorption capacity for a period of two years.		
Battery	+15 °C to +35 °C (+60 °F to +95 °F)	+5 °C to +40 °C (+40 °F to +104 °F)
When the system is disconnected from a mains power supply, a fully charged battery can be stored in the anesthesia system for up to six weeks at temperatures between +5 °C and +40 °C (+40 °F and +105 °F). At temperatures between +50 °C and +60 °C (+125 °F and +140 °F) storage time is one week. If these limits are exceeded, battery performance can no longer be guaranteed.		
Relative humidity (non-condensing)	15% to 95%	<95%
Atmospheric pressure	700 hPa–1060 hPa	470 hPa–1060 hPa

Maximum weight, number, and position of accessories

- Accessories must be installed according to any installation and safety guidelines given in the accessories installation instruction. Additional local, regional, and/or national guidelines related to occupational safety may apply.
- The following illustrations show a typical configuration. The setup given in the table has been verified by the manufacturer. The manufacturer assumes no responsibility for other configurations.
- The functionality of the system is extended by installing accessory carriers with appropriate accessories using the vertical rails.



Ref.no	Accessory carrier	Accessory	Rail	Max. load
1	Control panel arm	Control panel	A, B	
2	• GCX arm with VESA interface • Monitor arm slide-in plate • Monitor arm 2 pin	Patient monitor	A, B	12.5 kg (27.5 lbs)
3	Height adjustable arm VESA Remark: Installed in lowest rail position. Requires Extra mains power outlet option.	PDMS system	B	13.6 kg (30.0 lbs)
4	• CPU mounting small * • CPU mounting large ** * CPU width/max.height/ max. depth: 76-114/356/356 mm (3.0-4.9/14.0/14.0") ** CPU width/max.height/ max. depth: 114-178/457/457 mm (4.9-7.0/18.0/18.0")	• CPU • CPU	• D • D	• 11.3 kg (24.9 lbs) • 18.2 kg (40.1 lbs)
5	N/A Remark: Incl. vaporizer, etc.	Drawer with load	N/A	10 kg (22.0 lbs)
6	• Horizontal short rail DIN • Horizontal short rail Duoflex	Suction container	C, D	3 kg (6.6 lbs)
7	Equipment arm	• Downward pole short • Upward pole short • Quad hook for cable management • Parameter box	C	7.5 kg (16.5 lbs)
8	• Backup gas rack O_2 Pin index • Backup gas rack Air Pin index • Backup gas rack N_2O Pin index	Backup gas cylinders	N/A	7 kg (15.4 lbs)/cylinder

Accessory	Equipment weight	Max load
Additional writing table	4.5 kg (9.9 lbs)	5 kg (11.0 lbs)
GCX arm with VESA interface Monitor arm slide-in plate Monitor arm 2 pin	2 kg (4.4 lbs)	12.5 kg (27.5 lbs)
Equipment arm	3 kg (6.6 lbs)	7.5 kg (16.5 lbs)
CPU mounting	2.5 kg (5.5 lbs)	18.2 kg (40.1 lbs)
Height adjustable arm VESA	10 kg (22.0 lbs)	13.6 kg (30.0 lbs)

Standards – safety and functionality

Safety	IEC 60601-1:2005 + A1:2012 IEC 60601-1-2:2014 IEC 60601-1-8:2006 + A1:2012 ISO 80601-2-13:2011 + A1:2015 IEC 62304:2006 + Cor1:2008 + A1:2015 ISO 5360:2016
Electromagnetic compatibility	IEC 60601-1-2:2014 Refer to **Electromagnetic Compatibility, Flow-c Anesthesia System**
Respiratory gas monitoring	ISO 80601-2-55:2011
Anesthetic gas delivery	ISO 80601-2-13:2011 + A1:2015
Usability	IEC 62366-1:2015
Cleaning	IEC 60601-1:2005 + A1:2012 ISO 80601-2-13:2011 + A1:2015
Classification according to IEC 60601-1:	
Class I equipment	According to the type of protection against electrical shock
Type B equipment	According to the degree of protection against electrical shock
Continuous operation	According to the mode of operation
Classification according to EU Medical Directive 93/42/EEC:	
The anesthesia system is classified as IIb	
Classification according to IEC 60529:	
Ingress Protection	IP21 Valid when the patient cassette is in place and the patient cassette lid is closed. Make sure any fluid has been wiped from the connections in the vaporizer slots before connecting a vaporizer.

IP number	First digit – Solids	Second digit – Liquids
IP21	Protected against solid foreign objects of 12.5 mm diameter and greater.	Protected against vertically falling water drops.

Power supply

Mains power

Mains power	100–240 V, AC 50–60 Hz (without auxiliary power outlets) 100–120 V, 220–240 V, AC 50–60 Hz (with auxiliary power outlets)
Power consumption	300 VA (auxiliary power outlets not included) 1500 VA (maximum auxiliary configuration)

Battery

Type	Sealed acid-lead rechargeable
Capacity	18 Ah
Operating time	Approx. 90 minutes
Charging time	Approx. 6 hours

Auxiliary power outlets

All auxiliary power outlets are connected to an isolation transformer.
Voltage depends on mains power supply.

Voltage	Type of electrical outlet	Max load total	Max load from each outlet
220–240 V	4 × IEC	• 5 A	• 5 A
	• 4 × CEE 7/3 (EU)	• 5 A	• 2 A
	• 4 × BS 1363 (UK)	• 5 A	• 2 A
100–120 V	• 4 × IEC	• 10 A	• 10 A
	• 4 × CEE 7/3 (EU)	• 10 A	• 4 A
	• 4 × BS 1363 (UK)	• 10 A	• 4 A
	• 4 × NEMA 5-15R (US)	• 10 A	• 4 A

Gas supply

All gases and anesthetic agents must conform to the European and American Pharmacopeia.

Required minimum concentration of oxygen supplied to the system is 99.5 vol. % of O_2.

When using Oxygen 93, the required O_2 concentration is 90.0–96.0 vol.%.

Central gas

Supply pressure: • O_2 • Air • N_2O	 • 250–600 kPa (2.5–6.0 bar, 36–87 psi) * • 250–600 kPa (2.5–6.0 bar, 36–87 psi) ** • 250–600 kPa (2.5–6.0 bar, 36–87 psi)	
Hospital central gas supply must be able to deliver a flow of at least 60 l/min at a supply pressure of 280 kPa (2.8 bar, 41 psi)		
Connection standards	AGA DISS NIST French standard British standard	
Maximum levels	Air • H_2O <7 g/m³ • Oil <0.5 mg/m³ • Chlorine must not be detectable	O_2 • H_2O <20 mg/m³
If the compressed air is generated by a liquid ring compressor there is a potential risk of chlorine in the supplied air.		
Maximum inlet gas temperature	<35 °C (<95 °F)	
External vacuum source pressure	-0.9 to -0.6 bar (-90 to -60 kPa)	

Backup gas

Cylinder connection standards	• Pin index safety system (PISS) • DIN
DIN connections	6, 9, 12, 13
Backup gas rack, excluding valves Size Weight	 655 mm × 140 mm (25.8" × 5.5") (H × Ø) Max 7 kg per cylinder, including gas.
Cylinder configuration	Max. two cylinders and only one of each • O_2 • Air • N_2O
Cylinder pressure • O_2 • Air • N_2O	 Max. 20,000 kPa (200 bar, 2900 psi) Max. 20,000 kPa (200 bar, 2900 psi) Max. 8,000 kPa (80 bar, 1160 psi)
Pressure measurement	Electronically measured cylinder pressure.
Cylinder safety valve opening pressure • O_2 • Air • N_2O	 650 kPa (6.5 bar, 94 psi) 650 kPa (6.5 bar, 94 psi) 650 kPa (6.5 bar, 94 psi)

* The auxiliary O_2 device will not meet specified performance if the supply pressure is less than 300 kPa (3 bar, 44 psi).

** The Venturi vacuum ejector pump will not meet specified performance if the supply pressure is less than 300 kPa (3 bar, 44 psi).

Suction unit

Type	High vacuum/high flow rate
Vacuum ejector pump – Venturi	
Compressed air consumption (Suction unit)	50–90 Nl/min* at a supply pressure equivalent to patient suction supply pressure (Air).
Max free flow (suction flow)	28 Nl/min
Max. vacuum (suction)**	-0.9 to -0.6 bar (-90 to -60 kPa), at a supply pressure equivalent to patient suction supply pressure (Air).
External vacuum source – Medical vacuum system	
External vacuum source pressure	-0.9 to -0.6 bar (-90 to -60 kPa)

* Normal liter (Nl) – volume of gas given ambient conditions, for example current atmospheric pressure.
** Max. vacuum varies as a function of atmospheric pressure and supply pressure. Highest performance is obtained at sea level when the supply pressure is approx. 4 bar. Performance decreases with increased altitude.

Anesthetic Gas Scavenging System (AGSS)

Type	Passive system (including a flow indicator) integrated into the system
Scavenging flow	Minimum 25 l/min (STPD), or 10 l/min (STPD) over the set minute volume, whichever is greater.
Outlet connections	• 30 mm ISO taper • DISS EVAC • 12.7 mm/½" in hose Barb • 25 mm/1" Barb • AGA EVAC • WAGD-to-Vacuum connector • 22 mm out. diam. connector and 22 mm int. diam. connection tube

Fresh gas flow

Gas mix	Air/O_2 O_2/N_2O O_2	Electronic Servo controlled Electronic Servo controlled Electronic Servo controlled
Fresh gas flow range	• MAN = 0.1–20 l/min • AUTO = 0.1–20 l/min (FGF delivery depending on set MV) • AFGO = 1.0–20 l/min	
Fresh gas O_2/Air Flow (numerical/bargraph)	Selectable	
Fresh gas O_2/N_2O Flow (numerical/bargraph)	Selectable	
O_2 concentration accuracy in the fresh gas:		
• Air/O_2 (21%–100%) • O_2/N_2O (28%–100%)	• Fresh gas flow 0.3–20 l/min: ±5% • Fresh gas flow 0.3–20 l/min: ±5%	• Fresh gas flow <0.3 l/min: ±20%* • Fresh gas flow <0.3 l/min: ±20% **
Setting resolution, O_2	1%	
Setting resolution, Flow	0.1 l/min	
O_2 Flush	• Approximately 56 l/min • 2 cmH_2O expiratory resistance when APL is set to SP	
Auxiliary O_2		
Auxiliary O_2 flow range	0–15 l/min***	

* Specification valid in typical clinical range for minimal flow anesthesia: Respiratory Rate 5–35 breaths/min, Tidal Volume 100–700 ml, Minute Volume <10 l/min, Pressure 5–40 cmH_2O, Set O_2 50–100%.
** Specification valid in typical clinical range for minimal flow anesthesia: Respiratory Rate 5–35 breaths/min, Tidal Volume 100–700 ml, Minute Volume <10 l/min, Pressure 5–40 cmH_2O, Set O_2 50–100%.
*** The apparent gas flow will increase if the ambient pressure decreases.

Breathing system

Type	Circle system with volume reflector
System volume (incl. absorber, without patient tubings and manual breathing bag)	Approx. 2.8 l
The patient circuit configurations are intended to provide the following range of inspired tidal volumes	• Adult: 22 mm tubing, Tidal Volumes 100–2000 ml. • Infant: 15 mm tubing, Tidal Volumes 25–350 ml. • Infant: 10–12 mm tubing, Tidal Volumes 5–100 ml * * VC: 20–100 ml, PC: 5–100 ml
Drive gas	O_2
CO_2 absorber, volume	• Approx. 700 ml (reusable and disposable version 1) • Approx. 800 ml (disposable version 2)
CO_2 absorber, absorbent material	Sofnolime™
Patient tube connections	22/15 mm ISO cone
Type of material (breathing circuit system)	• PPSU (Polyphenylsulphone) • SBC (Styrene-butadiene copolymer) • PP (Polypropylene)
System compliance (volume of gas lost due to internal compliance – manual mode only)	Approx. 3 ml/cmH_2O , i.e. 90 ml at a pressure of 30 cmH_2O
Inspiratory/expiratory flow resistance of the system (the figures here apply to the breathing tubes recommended by the manufacturer)	• 10 mm breathing circuits (including Y-piece): – <2.8 cmH_2O at a flow of 2.5 l/min – <5.5 cmH_2O at a flow of 15 l/min • 15 mm breathing circuits (including Y-piece): – <1.3 cmH_2O at a flow of 2.5 l/min – <2.1 cmH_2O at a flow of 15 l/min – <4.4 cmH_2O at a flow of 30 l/min • 22 mm breathing circuits (including Y-piece): – <1.1 cmH_2O at a flow of 2.5 l/min – <2.0 cmH_2O at a flow of 15 l/min – <3.7 cmH_2O at a flow of 30 l/min – <6.0 cmH_2O at a flow of 60 l/min

Manual ventilation

Electronic APL valve	Spontaneous breathing (SP) and adjustable pressure up to 80 cmH_2O

AFGO – Additional Fresh Gas Outlet (option)

Type	• 22 mm coaxial/15 mm conical outlet connections • Pneumatic powered SW controlled (from control panel)

Emergency backup ventilation

Emergency APL valve	SP–80 cmH_2O , SP = 2 cmH_2O
O_2 emergency flow	0–10 l/min

Breathing circuits and accessories

Note that the table applies to the breathing circuits recommended by the manufacturer.

Compliance	• 10 mm breathing circuits: <0.4 ml/cmH_2O • 15 mm breathing circuits: <0.7 ml/cmH_2O • 22 mm breathing circuits: <1.8 ml/cmH_2O
Internal volume	• 10 mm breathing circuits: 0.4 l • 15 mm breathing circuits: 0.7 l • 22 mm breathing circuits: 1.8 l
Flow resistance in each limb including Y-piece	• 10 mm breathing circuits: – At 2.5 l/min: <3.0 cmH_2O/(l/s) – At 15 l/min: <6.0 cmH_2O/(l/s) – At 30 l/min: <10 cmH_2O/(l/s) (30 l/min not applicable for intended patient tidal volume range) • 15 mm breathing circuits: – At 2.5 l/min: <1.5 cmH_2O/(l/s) – At 15 l/min: <1.5 cmH_2O/(l/s) – At 30 l/min: <2 cmH_2O/(l/s) • 22 mm breathing circuits: – At 2.5 l/min: <0.5 cmH_2O/(l/s) – At 15 l/min: <0.7 cmH_2O/(l/s) – At 30 l/min: <1.0 cmH_2O/(l/s)
Flow resistance for angled adapter	• At 2.5 l/min: <0.2 cmH_2O/(l/s) • At 15 l/min: <0.6 cmH_2O/(l/s) • At 30 l/min: <1.0 cmH_2O/(l/s)
• Flow resistance for 22 mm joint adapter	• At 2.5 l/min: <0.2 cmH_2O/(l/s) • At 15 l/min: <0.2 cmH_2O/(l/s) • At 30 l/min: <0.2 cmH_2O/(l/s)

Ventilator

Type	Pneumatic powered Servo controlled
Patient range	Neonatal to Adult
Ventilation modes	• Manual/Bag • Additional Fresh Gas Outlet (AFGO, option) • Volume Control (VC) • Pressure Control (PC, option) • Pressure Support (PS, option) • Pressure Regulated Volume Control (PRVC, option) • Synchronized Intermittent Mandatory Ventilation (SIMV, option) • Low VT ventilation (option) • High performance ventilation (option)
Tidal volume range (volume controlled modes)	20–350 ml, ±10% or 10 ml, whichever is greater * 50–1600 ml, ±10% or 10 ml, whichever is greater 50–2000 ml, ±10% or 10 ml, whichever is greater ** Note that the Flow-c delivers tidal volumes down to 5 ml when using Pressure Control
Tidal volume setting range	Infant range: • 20–350 ml, resolution 1 ml * • 50–350 ml, resolution 1 ml Adult range: • 100–1600 ml, resolution 10 ml • 100–2000 ml, resolution 10 ml **
Minute volume setting range	Infant range: 0.3–20 l/min Adult range: 0.5–60 l/min
Inspiratory pressure (pressure controlled modes)	• 0–80 cmH_2O ±15% or ±2 cmH_2O, whichever is greater • 0–120 cmH_2O ±15% or ±2 cmH_2O, whichever is greater **
Inspiratory pressure setting range	Infant range: • 0–80 cmH_2O, resolution 1 cmH_2O Adult range: • 0–80 cmH_2O, resolution 1 cmH_2O • 0–120 cmH_2O, resolution 1 cmH_2O **
Compressible volume compensation	Yes
Inspiratory flow	200 l/min (3.3 l/s)
Breathing frequency	4–100 ±1 breaths/minute
I:E (VC, PC)	1:8.3–4:1
PEEP	0–50 cmH_2O
Trigger	Flow/Pressure
Inspiratory pause (VC)	0 to 30% or 0–1.5 s

* Option Low VT ventilation is required.
** Option High performance ventilation is required.

Respiratory monitoring

Administered breaths	1–100 ±1 breaths/minute
Loops	Flow–Volume Volume–Pressure
Lung characteristics	Airway resistance (Rdyn) Compliance (Cdyn) Elastance (Edyn)
Inspiratory Minute Volume	0.3–60 l/min
Accuracy Insp. Minute Volume	±15% or ±15 ml multiplied by the breathing frequency, whichever is greater
Expiratory Minute Volume	0.3–60 l/min
Accuracy Exp. Minute Volume	±15% or ±10 ml multiplied by the breathing frequency, whichever is greater
Inspiratory Tidal Volume	5–2000 ml
Accuracy Insp. Tidal Volume	±4 ml (5–20 ml range) * ±15% or 15 ml, whichever is greater (20–2000 ml range) * Accuracy valid for O_2/Air gas mix, O_2 concentration at 60%, RR at 30 and I:E ≥1:2
Expiratory Tidal Volume	5–2000 ml
Accuracy Exp. Tidal Volume	+7/-4 ml (5–20 ml range) * ±15% or 10 ml, whichever is greater (20–2000 ml range) * Accuracy valid for O_2/Air gas mix, O_2 concentration at 60%, RR at 30 and I:E ≥1:2
Mean Airway Pressure	0–100 cmH_2O
Peak Airway Pressure	0–140 cmH_2O
End Expiratory Airway Pressure	-40–100 cmH_2O
Airway Pressure	-30–140 cmH_2O
Airway pressure accuracy (applicable to all pressure measurements)	±5% or ±2 cmH_2O, whichever is greater

Alarms

Expiratory Minute Volume: High	0.5–60 l/min
Expiratory Minute Volume: Low	0.01–40 l/min
Excessive leakage	The difference between the maximum and minimum pressures during inspiration is too low
Airway pressure: High	10–120 cmH_2O
Continuous APL pressure (manual mode only)	Activated when the measured airway pressure exceeds predefined values for more than 15 seconds. Predefined values depend on current APL setting.
High continuous pressure (automatic mode only)	Airway pressure is constant above set PEEP level +15 cmH_2O more than 15 seconds
Negative airway pressure	Measured airway pressure is below -10 cmH_2O for more than one second
Regulated Pressure Limited (PRVC mode only)	Permissible pressure limits pre-set tidal volume
PEEP: High	0–55 cmH_2O
PEEP: Low	0–47 cmH_2O
Respiratory Rate: High	1–140 B/min and OFF
Respiratory rate: Low	1–140 B/min and OFF
Apnea	5–45 s and OFF
Long apnea (manual mode only)	Infant: No breath detection for up to 60 s Adult: No breath detection for up to 120 s
Check breathing circuit	Activated when inspiratory and expiratory pressures fail to meet preset requirements because of blocked or disconnected tubing
Limited battery capacity	Less than 18 minutes left of battery operation
No battery capacity	Less than 3 minutes left of battery operation
Water trap missing/Replace water trap	The gas analyzer has detected that a water trap replacement is needed
Gas alarms	
FiO_2: High	23–99% and OFF
FiO_2: Low	18–99%
EtO_2: High	13–99% and OFF
EtO_2: Low	10–99% and OFF
$FiCO_2$: High	0.1–10%
$EtCO_2$: High	0.1–10%
$EtCO_2$: Low	0.1–9.9% and OFF
FiAA: High	• 0.1–5.0% and OFF (ISO) • 0.1–8.0% and OFF (SEV) • 0.1–18% and OFF (DES)
FiAA: Low	• 0.1–5.0% and OFF (ISO) • 0.1–8.0% and OFF (SEV) • 0.1–18% and OFF (DES)
EtAA: High	• 0.1–5.0% and OFF (ISO) • 0.1–8.0% and OFF (SEV) • 0.1–18% and OFF (DES)
EtAA: Low	• 0.1–4.0% and OFF (ISO) • 0.1–6.0% and OFF (SEV) • 0.1–12% and OFF (DES)
Agent mixture: MAC >3	The MAC_{40} of the secondary agent is ≥0.6 and the total MAC_{40} value is ≥3

Alarms (continued)

Agent mixture	The second agent is MAC ≥0.6 and the total MAC value is <3
High continuous MAC	Measured MAC exceeds time limit: • MAC >2.2; from starting a new case, until 15 minutes after the first vaporizer activation. • MAC >1.8 otherwise
FiN_2O: High	Inspiratory N_2O gas supply >80%
Occlusion in sampling line	Detected occlusion reported from Y-piece gas analyzer

Vaporizer

Active vaporizers slots	1	
Agents	Isoflurane, Sevoflurane and Desflurane	
Type	Electronic Injector	
Weight (full)	Approx. 3.2 kg (7.1 lbs)	
Dimensions	70 × 215 × 178 mm (2.8" × 8.5" × 7.0")	
Agent capacity	300 ml	
Residual capacity	30 ml (triggering the low level alarm)	
Setting range	Isoflurane Sevoflurane Desflurane	0, 0.3–5%, OFF 0, 0.3–8%, OFF 0, 1.0–18%, OFF
Accuracy	±15% of set value or ±5% of maximum possible user setting (whichever is greater)	
Filling system	Isoflurane Sevoflurane Desflurane	• Maquet filling adapter • Quik Fil®, Maquet filling adapter and SAFE-T-SEAL filling adapter attached to anesthetic agent bottle • SAFE-FIL™
Emptying system	Maquet drain adapter for SAFE-T-SEAL vaporizer	
Vaporizer filling speed	Approx. 4 ml/s	
Tank liquid level	Optical and electronic	

Gas analyzer

Measuring technology	O_2 Agents, CO_2, N_2O	Paramagnetic sensor IR sensor
Warm-up time	ISO standard accuracy Full accuracy	Within 60 s Within 10 minutes
Sampling flow and tolerance	225 ml/min ±10% (Return to circuit), BTPS condition	
Sampling line	Length: 2.0 m 2.5 m 3.5 m 4.5 m	Inner diameter: 1.3 mm 1.5 mm 1.5 mm 1.5 mm

Measured parameters

Resp. rate	2–100 breaths/minute	
Respiration rate measurement accuracy	<60 breaths/minute >60 breaths/minute	±1 breath/minute Unspecified
Inspiratory and End-Tidal O_2 Concentration	Yes	
Inspiratory and End-Tidal CO_2 Concentration	Yes	
Inspiratory and End-Tidal N_2O Concentration	Yes	
MAC Y (age dependent)	Yes	
MAC Brain (age dependent)	Yes	
Inspiratory and End-Tidal Agent Concentration	Yes	

Gas measurement accuracy	Gas conc.	Accuracy [%ABS]	Interference	[%ABS]
O_2	0–25% 25–80% 80–100%	±1 ±2 ±3	N_2O CO_2 Any agent	0.2 0.2 1.0
N_2O	0–20% 0–40% 40–80%	±2 ±3 ±5	CO_2 O_2 Any agent	0.1 0.1 0.1
CO_2	0–1% 1–5% 5–7% 7–10% >10%	±0.3 ±0.2 ±0.3 ±0.5 Unspecified	N_2O O_2 Any agent	0.1 0.1 0.3
Isoflurane	0–1% 1–5% >5%	±0.15 ±0.2 Unspecified	CO_2 N_2O O_2 2nd agent	0 0.1 0.1 0.2
Sevoflurane	0–1% 1–5% 5–8% >8%	±0.15 ±0.2 ±0.4 Unspecified	CO_2 N_2O O_2 2nd agent	0 0.1 0.1 0.2
Desflurane	0–1% 1–5% 5–10% 10–15% 15–18% >18%	±0.15 ±0.2 ±0.4 ±0.6 ±1.0 Unspecified	CO_2 N_2O O_2 2nd agent	0 0.1 0.1 0.2
Drift of measurement accuracy	The accuracy includes stability and effects of device drift during operation between calibrations.			

- The respiration rate limit for accurately measured end-tidal values is <60 breaths/minute for I:E = 1:1, <40 breaths/minute for I:E = 1:2 and <30 breaths/minute for I:E = 1:3.
- The accuracy of the gas measurements may be affected if the Ethanol concentration is higher than 0.1%, the Methane concentration is higher than 1% or the Acetone concentration is higher than 1%.
- The partial pressure and the percentage volume of CO_2, N_2O, O_2 and anesthetic agent depend on the amount of water vapor in the breathing gas. A partial H_2O pressure of 11 cmH_2O is automatically compensated for by the analyzer. Higher H2O partial pressures will further dilute the gas sample; at 30 cmH_2O the general error of all measured gases is -2%.

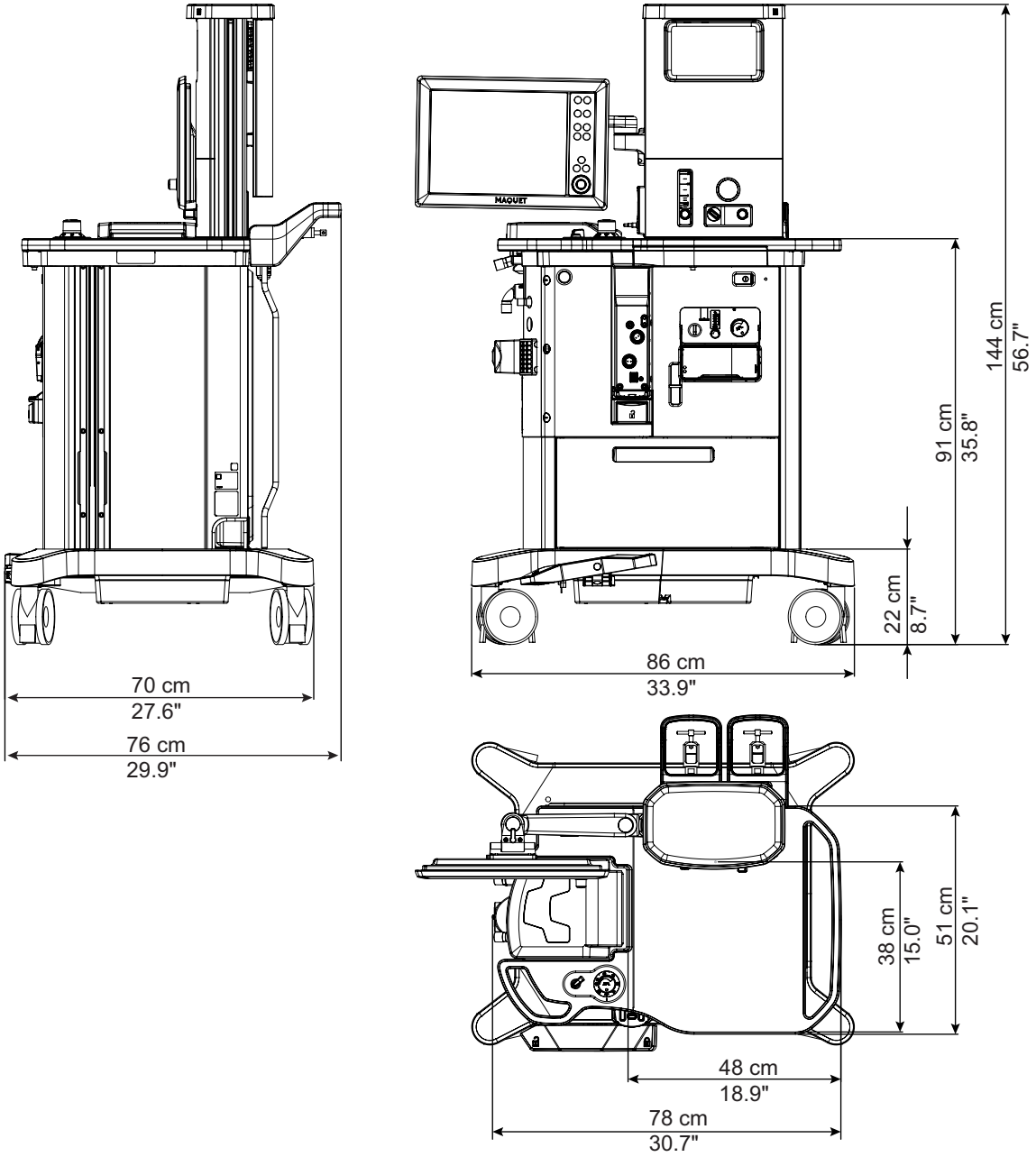
External communication

	Quantity	Type	Description
Serial ports	2	RS232	FCI (Flow Communication Interface) protocol
USB	2	USB 1.1	• One port for communication • One port for power supply
Video out	1	VGA	Interface for slave monitor
Ethernet	1	RJ45	Network connection for use with Remote service

Ordering information

Flow-c Anesthesia Machine and accessories:
See separate information in "System flowchart, Flow-c", Order no MX-7880.

Dimensional drawings



Next-generation Flow core technology

Reduces the need for an ICU ventilator in the OR:

- Servo gas modules deliver up to 200 l/min inspiratory flow and adjusts pressure and flow several times within every breath.
- Innovative Volume Reflector rebreather ensures accurate and precise gas delivery.
- Small system volume (2.7 l) allows fast wash-in and wash-out, saving time and agent consumption.

Electronic injection vaporizer

- Fast and precise delivery of anesthetic agents.
- Lightweight and possible to fill during use. Holds 300 ml.
- No heating time for Desflurane.

Low-flow anesthesia

- Fresh Gas Flow (FGF) limit: 0.1 l/min
- VRI (Volume Reflector Indicator) displays the FGF and minute volume ratio to optimize the rebreathing fraction.

Active hypoxic guard

- O_2Guard actively intervenes when there is risk of hypoxia, providing added safety at low flows.

Pause function

- Temporarily stops gas flows and ventilation, giving you time to focus on the patient.

Space-saving design

- Compact and lightweight (86 x 68 cm, 115 kg).
- Easy to move and adapt to different situations.

Battery backup

- 90 minutes for added safety in case of power failure.

Easy cleaning and service

- Just seven parts need to be dismantled for cleaning, saving costs and supporting infection control.
- Preventive maintenance is optimized to reduce complexity with few and easy accessibility parts that are only changed every two years.

Low cost of ownership

- Modern, easily upgradable platform.
- Maintenance free components, the oxygen and flow sensors are non-consumptive.
- Lower anesthesic agent consumption.
- Reduced training requirements.

Smart clips, hooks and arms

For convenient placement of suction device, manual breathing bag and other accessories.

Large drawer

With slots for spare vaporizers and an optional lockable compartment.

EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

acc. to Directive 93/42/EEC on Medical Devices

Name and Address of the Manufacturer:	Maquet Critical Care AB Röntgenvägen 2 SE-171 54 Solna, Sweden

On our sole responsibility, we hereby declare that the product(s)

Product Description:	Anesthesia System
Product Identification:	Flow-c Anesthesia System, System version 4.9
Product-No.:	See Annex I of this document
Classification (acc. to Annex IX of MDD)**:**	Class IIb

comply with the relevant provisions of the following Directive(s):

Directive 93/42/EEC on Medical Devices

Notified Body:	TÜV SÜD Product Service GmbH ID No. 0123 Zertifizierstelle, Ridlerstraβe 65 80339 München, Germany
Conformity Assessment Procedure:	acc. to Annex II excluding (4) of Directive 93/42/EEC

Directive 2011/65/EU on the restriction of the use of certain substances in electrical and electronic equipment

This declaration is valid until the next change of the product or until the expiration date of the Certificate (No. G1 072017 0014, **dated 2020-01-22**, valid to **2024-05-26**) issued by the notified body. Any modification of the medical device not authorized by us will invalidate this declaration.

For the signature of the Manager for Product Compliance on behalf of Maquet Critical Care AB see left corner of page.

ANNEX I
TO THE EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Product(s) Covered:

Trade Name	Article No.
Base unit	
Flow-c Anesthesia System	6887700
Additional ventilation modes	
PRVC	6688202
PS with backup	6688200
SIMV (VC) and SIMV (PC)	6688197
Pressure Control	6888006
Low VT ventilation	6887892
High performance ventilation	6887889
Additional options	
HLM/CBP	6887895
Insp hold/Exp hold	6887896
Predicted body weight (PBW)	6887893
Agent usage	6887888
Optional module, Additional Fresh Gas Outlet (AFGO)	6681887
AFGO adapter kit, onsite upgrade	6887999
AFGO adapter kit	6887704
O2 Only	6890455
Oxygen 93	6890925

Maquet Critical Care AB
Röntgenvägen 2
171 54 Solna, Sweden

Phone: +4610-335 73 00
Email: Regulatory.Affairs@maquet.com
www.getinge.com

Mm-0340, ver 19

ANNEX I
TO THE EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

AGC (Automated Gas Control)	**6881990**
Recruitment Maneuvers	**6886518**

Absorber

CO2 Absorber Disposable	6677845
CO2 Absorber disposable 12 pcs	6887738
CO2 Absorber Reusable	6692582
Dust Filter for CO2 Absorber Reusable	6880430

Vaporizer

Vaporizer Sevoflurane, QUIK FIL	6682285
Vaporizer Desflurane, Saf-T-Fil	6682287
Vaporizer Isoflurane, Maquet filling	6682280
Vaporizer Sevoflurane, Maquet filling (Abbott, Baxter)	6682282
Vaporizer Sevoflurane Maquet filling	6886601
Vaporizer Sevoflurane QUIK FIL	6886611
Vaporizer Isoflurane Maquet filling	6886621
Vaporizer Desflurane SAF-FIL	6886631
Vaporizer Sevoflurane SAFE-T-SEAL	6887135
Vaporizer Sevoflurane SAFE-T-SEAL	6887523
MAQUET filling adapter tube for isoflurane bottle	6682290
MAQUET filling adapter tube for sevoflurane bottle (Abbott, Baxter)	6682292
Cover for Vaporizer Slot	6880158

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ANNEX I
TO THE EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Vaporizer Holder	6880155

O2 flowmeter / suction equipment

External suction vacuum	6887709
Venturi for Suction	6887710
Hydrofobic Bacterial Filter (5 pcs)	6887498

Backup gas supply

Backup gas rack O2, Pin index	6887416
Backup gas rack Air, Pin index	6887417
Backup gas rack N_2O, Pin index	6887418
Connector DIN 6	6886811
Connector DIN 9	6886812
Connector DIN 12	6886813
Connector DIN 13	6886814

EVAC outlet Connections

EVAC Restrictor	6880156
22 mm out. Diam. Connector	6692740
30 mm out. Diam. ISO taper connection	6673980
12.7 mm/½" in house Barb connector	6679627
25 mm/1" in house Barb connector	6679630
AGA EVAC connector	6679645
WAGD-to-Vacuum connector	6692742

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ANNEX I
TO THE EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Connection tube 22 int. diam, (disposable), 50 m	6189646
DISS EVAC connector	6679647

Gas analyzer parts

Water trap Dryline A, 10 pcs	6522747
Water trap Dryline 1, 10 pcs	6889352

Extra breathing system parts

Patient cassette complete, extra	6680325
Volume reflector, extra	6887614

Reusable parts

Tube joint/adapter 22 mm	6425581

Hardware mounting kits

Flexible Man bag arm	6887717
Tubing hook small	6887713
Tubing hook large	6887712
Suction tip holder	6887714
Hook and y-piece holder	6880548
Cable holder	6693747
Lockable compartment for drawer	6887718
Additional table	6676962
Hook and hook holder	9368952

ANNEX I
TO THE EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Clamp, 1 slot	9358193
Horisontal short rail DIN	6887115
Horisontal short rail Duoflex	6887834
Clamp, for Duoflex rail, 10 x30 mm	6038819
Clamp, for DIN rails, 10 x 25 mm	6038801
Monitor arm 2 pin (Philips)	6887066
Panel interface Height adjustable	6886960
Long divider for big drawer	6886664
Channel cover kit, 10 pcs	6887960
Gas bottle support Flow-c/e	6890148
Top Mount	**6892715**
Horizontal channel slide in plate	**6892716**
Horizontal channel mount VESA 75	**6892717**

For upgrade of installed Flow-c

Upgrade via freight, Flow-c	6888360
Upgrade via E-delivery, Flow-c	6888359

Cleaning adapter

Cleaning adapter kit	6681910

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 072017 0013 Rev. 01

Holder of Certificate: **MAQUET CRITICAL CARE AB**
Röntgenvägen 2
171 54 Solna
SWEDEN

Facility(ies):
MAQUET CRITICAL CARE AB
Röntgenvägen 2, 171 54 Solna, SWEDEN

See Scope of Certificate

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design, development and manufacturing of Anaesthesia, Monitoring, Ventilator Systems and Perfusion Systems**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 072017 0013 Rev. 01

Report No.: 713193727

Valid from: 2020-12-30

Valid until: 2023-12-29

Date, 2020-12-28

Christoph Dicks
Head of Certification/Notified Body

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ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 072017 0014 Rev. 01

Manufacturer:

MAQUET CRITICAL CARE AB
Röntgenvägen 2
171 54 Solna
SWEDEN

Facility(ies):

MAQUET CRITICAL CARE AB
Röntgenvägen 2, 171 54 Solna, SWEDEN

Product Category(ies): **Anaesthesia, Monitoring, Ventilator and Perfusion Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713161324

Valid from: 2020-01-22
Valid until: 2024-05-26

Date, 2020-01-22

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 072017 0015 Rev. 00

Manufacturer:

MAQUET CRITICAL CARE AB
Röntgenvägen 2
171 54 Solna
SWEDEN

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.: 713170827

Preceding certificate No.: This certificate is issued for the first time

Valid from: 2020-02-17
Valid until: 2025-02-16

Date of initial issuance / Rev.00: 2020-02-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-02-17

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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 072017 0015 Rev. 00

Device(s):	Risk classification	CND Code	Intended Purpose
INSTRUMENTS FOR ANESTHESIA AND PULMONARY VENTILATION SUPPORT	IIb	Z120301	Intended for respiratory support, administration of anesthetic and treatment of neonatal, pediatric and adult patients.

The validity of this certificate depends on conditions and/or is limited to the following: ./.

Revision History including Changes:

Revision / Issue Date / Report
Rev. 00 / 2020-02-17 / 713170827

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