SPACELABS HEALTHCARE

Data Sheet

Multigas Module 1.00
92518

The 92518 Multigas Module monitors gas concentrations and alerts clinical personnel when the concentration of anesthetic agents, oxygen, carbon dioxide, or nitrous oxide falls outside of defined limits. The anesthetic agent being administered is automatically identified.

Features

	Note: *Module use is restricted to one patient at a time.*
Measurement of respiration rate, carbon dioxide, oxygen, nitrous oxide, and anesthetic agents	Up to two agents may be simultaneously detected; inspired and expired values for halothane (HAL), isoflurane (ISO), enflurane (ENF), sevoflurane (SEV), desflurane (DES); inspired and expired values for N_2O and O_2; inspired CO_2 (I CO_2) and end tidal CO_2 ($EtCO_2$)
Automatic features	Identification of agents; pressure and temperature compensation
Suspend mode	Allows module to remain warmed up between cases while sampling is turned OFF
MAC/AGEMAC values	Automatic MAC value calculation and AGEMAC adjustment based on patient age and body temperature
Paramagnetic oxygen sensor	Oxygen concentration is measured using a paramagnetic oxygen sensor

Product Specifications

Physical dimensions	
Height	11.3 cm (4.7 in)
Depth	17.84 cm (17.43 in)
Width	5.6 cm (2.33 in)
Weight	1.026 kg (2.26 lb)
Carbon dioxide	
Range	0 to 113 mmHg (0 to 15 kPa), 0 to 15%
Resolution	1 mmHg (0.1 kPa), 0.1%
Measurement rise time	<250 ms typically
Accuracy	±(0.2 vol% + 2% of reading)
Values	I CO_2, $EtCO_2$, and instantaneous CO_2
Gas gross effect	<0.2% (O_2, N_2O, anesthetic agents)
	Note: • *mmHg values for CO_2 are based on an ambient barometric pressure of 760 mmHg* • *Helium typically decreases CO_2 readings by <0.6 vol%*
Oxygen	FiO_2 and $ETCO_2$ are displayed after one breath and have a continuously updated breath average. ET will typically decrease below nominal value (ET_{nom}) when respiration rate (RR) exceeds the RR threshold (RR_{th}) according to the following formulas: • CO_2: $ET=ET_{nom} \times 70/RR$ for RR_{th} >70 • N_2O, O_2, DES, ENF, ISO, SEV: $ET=ET_{nom} \times 50/RR$ for RR_{th} >50 • HAL: $ET=ET_{nom} \times 35/RR$ for RR_{th} >35 Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.

Range	0 to 100%
Accuracy	±(1 vol% + 2% of reading)
Measurement rise time	<450 ms typically
Values	Inspired oxygen (FiO_2), expired oxygen (FeO_2), and instantaneous O_2
Gas gross effect	<2 vol% N_2O, <1 vol% anesthetic agents
Nitrous oxide	
Range	0 to 100%
Resolution	5%
Accuracy	±(2 vol% + 2% of reading)
Measurement rise time	<350 ms typically
Values	Inspired nitrous oxide (I N_2O), expired nitrous oxide (E N_2O), and instantaneous N_2O
Gas gross effect	<2 vol% anesthetic agents
Anesthetic agent	
Ranges	• HAL, ENF, ISO: 0 to 5% • SEV: 0 to 8% • DES: 0 to 20%
Resolution	0.1%
Accuracy	±(0.15 vol% + 5% of reading)
Measurement rise time	<350 ms typically
Values	Inspired agents (I HAL, I ENF, I ISO, I SEV, I DES) and expired agents (E HAL, E ENF, E ISO, E SEV, E DES), and instantaneous agents
Gas gross effects	<0.15 vol% N_2O
Agent identification	
Identification threshold	0.15 vol% typical
Identification time	<20 s (for pure agents)
Identification threshold for two agents	0.2 vol% + 10% of total concentration
MAC	
Range	0 to 9.9
Resolution	0.1
Accuracy	Depends on accuracy of expired N_2O and expired anesthetic agent readings

AGEMAC	Determined by the age and body temperature of the patient; if more than one temperature value is available, the higher value is used
Range	0 to 9.9
Resolution	0.1
Accuracy	Depends on accuracy of expired N_2O and expired anesthetic agent readings
	Note: *Measured values are shown as ATPD (ambient temperature and pressure, dry gas).*
Respiratory rate	Measurement based on CO_2 waveform; breath detection is based on a 1% change in CO_2 level. Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.
Range	1 to 95
Resolution	±1 BPM
Apnea time out	
Range	20 to 45 s
Resolution	5 s
Accuracy	±1 s
Warm up	<20 s for concentration reporting, automatic agent identification, and full accuracy specification
Sample line flow rate	50 ± 10 ml/min
Compensation	Automatic for atmospheric pressure, CO_2-O_2, and CO_2-N_2O collision broadening effect
CO_2 waveform scales	Selectable at 0 to 120 mmHg, 0 to 100 mmHg, 0 to 80 mmHg, 0 to 60 mmHg, 0 to 40 mmHg (0 to 15 kPa, 0 to 12.5 kPa, 0 to 10 kPa, 0 to 7.5 kPa, 0 to 5 kPa), 0 to 15%, 0 to 12.5%, 0 to 10%, 0 to 7.5%, 0 to 5%
O_2 and N_2O waveform scales	Selectable at 0 to 100%, 0 to 80%, 0 to 60%, 0 to 40%, 0 to 20%
Anesthetic agent waveform scales	
HAL, ISO, ENF	0 to 5%, 0 to 4%, 0 to 3%, 0 to 2%, 0 to 1%
SEV	0 to 8%, 0 to 6%, 0 to 4%, 0 to 2%, 0 to 1%
DES	0 to 20%, 0 to 15%, 0 to 10%, 0 to 5%, 0 to 2.5%
Waveform speed	Selectable at 25, 12.5, 6.25, 3.12, 1.56 mm/s
Parameter units	%, mmHg (kPa) for CO_2; % for O_2, N_2O, and agents; BPM for respiration rate
Alarms	User-selectable; respiration rate, inspired and expired N_2O, inspired and expired agents, $EtCO_2$, FiO_2, and FeO_2 (high and low values monitored), I CO_2 (high values monitored), and apnea time out; all alarms default to OFF
Gas calibration	Calibration from external gas mixture
Occlusion	Automatically detects and attempts to clear sample line occlusions
Agent mix detected	Status message shows when a mixture of more than two agents is detected.
Suspend sampling	In Suspend mode, sensors continue to operate but pumps stop and waveform and numeric zones are cleared, allowing sensors to remain warmed up.

Module parameter count	When computing parameter capacity, this module counts as two to four parameters.
Total system response time	<4 s (with 2 m NomoLine sampling line)

Monitor Compatibility

Monitors supported	• Qube® (91390) • Xprezzon® (91393)

Classifications

MDD	Class IIb
EN 60601-1	Class I Type BF defibrillator proof; device is not affected by patient defibrillation. Rated for continuous operation
CISPR 11	Group 1, Class A Suitable for use in all locations other than those allocated in residential environments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes

Electrical Specifications

N/A (Module using host power only)

For monitor electrical specifications, refer to *Xprezzon, Qube, and Qube Mini Operations Manual* (P/N 070-2112-xx)

Certifications

ASTM 1456, 1462, 1463; ISO 11196 (in lieu of ASTM 1452); CSA Z168-6, Z9918.

Environmental Requirements

Storage and transport	
Temperature	-40 to 70 °C (-40 to 158 °F)
Relative humidity	up to 95% (non-condensing) relative humidity (RH)
Altitude	-500 to 12,192 m (-1640 to 40,000 ft)
Operating	
Temperature	10 to 78 °C (50 to 172 °F)
Relative humidity	up to 95% (non-condensing) relative humidity (RH)
Altitude	-500 to 3,000 m (-1640 to 9843 ft)
Water ingress	Meets EN 60529 IPX1 only when installed in 91393 Xprezzon and 91390 Qube patient monitors.

Documentation

This product ships with a complete set of comprehensive documentation. Documentation is also available at https://www.spacelabshealthcare.com/manuals.

A full list of available supplies and accessories is available at https://www.spacelabshealthcare.com/supplies.

Regulatory Approvals

CE 0123	CE marked in accordance with the Medical Device Directive 93/42/EEC.
	Does not contain hazardous substances — China

Multigas Module complies with the following standards:

Identifier	Applicable standard editions or document number/revision and description
IEC 60601-1	IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1	EN 60601-1:2006+A1:2013+A2:2021 Medical electrical equipment – Part 1: General requirements for safety and essential performance
IEC 60601-1-2	IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and tests
EN 60601-1-2	EN 60601-1-2:2015+A1:2021 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances
AS CISPR 11	AS CISPR 11:2017 Australian EMC Standard: Industrial, scientific and medical equipment
EN 60601-1-8	EN 60601-1-8:2007/A2:2021 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
CAN/CSA C22.2 No. 60601-1	CAN/CSA C22.2 No. 60601-1:14/A2:22 Medical electrical equipment, Part 1: General requirements for safety and essential performance
EN ISO 80601-2-55	EN ISO 80601-2-55:2018 Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN/ISO 14971	EN/ISO 14971:2019 Medical devices – Risk management – Part 1: Application of risk analysis
IEC 62366-1	IEC 62366-1:2015+AMD1:2020 Medical devices – Application of usability engineering to medical devices
EN 62366-1	EN 62366-1:2015+A1:2020 Medical devices – Application of usability engineering to medical devices
EN 60601-1-6	EN 60601-1-6:2010/A2:2021 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62304	IEC 62304:2006+AMD1:2015 Medical device software - Software life cycle process
EN 62304	EN 62304:2006+A1:2015 Medical device software – Software life cycle process
ISO IEC 12207	ISO IEC 12207:2004 Information technology - Software life cycle process
EN 60601-1-4	EN 60601-1-4:1996, A1:1999 Medical electrical equipment, Part 1: Programmable medical systems
ISO 15223-1	ISO 15223-1:2021 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 20417	EN ISO 20417:2021 Medical devices – Information to be supplied by the manufacturer with medical devices

We are continuously improving our products. Specifications are subject to change without notice. Product images are provided for general reference. This product may not be available for sale in all countries.

Please refer to https://www.spacelabshealthcare.com/trademarks for a full listing of Spacelabs Healthcare trademarks. Other brands and product names used herein are trademarks of their respective owners.

SPACELABS HEALTHCARE

35301 SE Center Street, Snoqualmie, WA 98065 | T: +1 425 396 3300 | F: +1 425 396 3301
www.spacelabshealthcare.com