Penlon AnaVue 4000 Patient Monitor

PATIENT MONITORING SOLUTIONS

- Modular patient monitor for anaesthesia and critical care
- User-defined multi-parameter display
- Seamless monitoring with the EMS plug-in module
- Full transport functionality as a secondary display, remote from main monitor
- Programmable touchscreen configuration
- FDA and CE certified

Penlon

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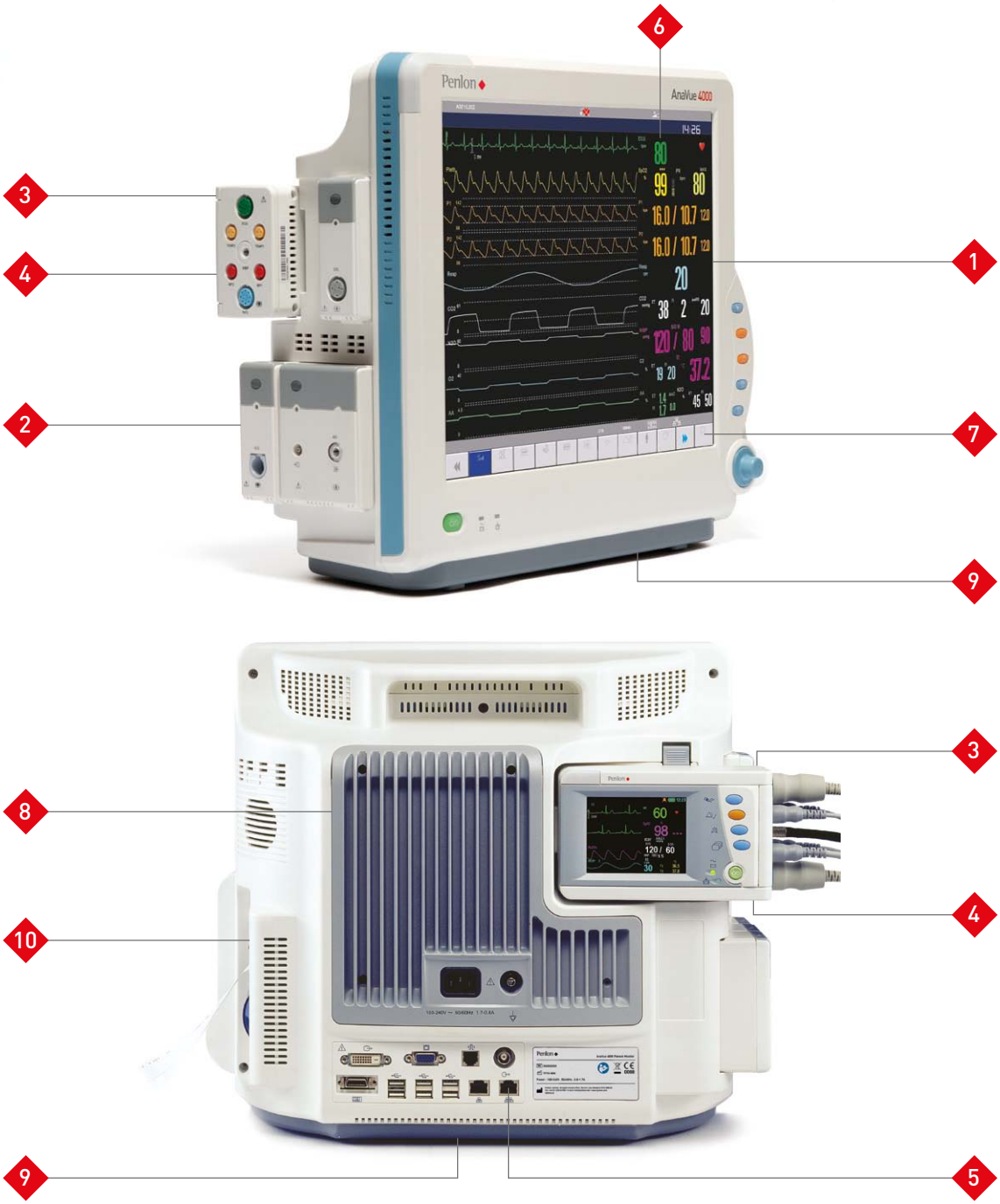
Penlon AnaVue 4000 Patient Monitor



Simple intuitive user interface enables clinical staff to concentrate on improved patient outcomes with accurate physiological data

1. 17" TFT LCD touchscreen colour display and slave screen capability
2. Parameters: ECG, RESP, NIBP, SpO_2, TEMP, IBP, CO_2, Anaesthetic Gas/O_2, C.O., ICG, CSM, EEG and BIS
3. Multi-parameter, dual-function EMS - Plug-in module/Transport monitor with 3.5" touchscreen
4. 8-hour trend data storage on EMS
5. Networkable as standard, with wireless LAN option
6. Unique display management function uses scalable screen elements to customize the display
7. User-definable smart-key controls
8. Quiet, fan-less cooling system
9. Rechargeable lithium battery
10. 2 GB SD memory card for enhanced data storage handling (upgradeable to 4 GB)

The Penlon AnaVue 4000 Patient Monitor is a sophisticated system that delivers continuous monitoring and data upload during patient transfers.

Modular design and extensive range of parameters provide flexibility for a wide variety of clinical situations, including the operating theatre and recovery.

Control and Visualisation
17" TFT colour touchscreen display with prompt knob, smart-key control and audio/visual indicators.

Calculations
Perform haemodynamic calculations and concentration calculations of commonly used drugs

Customisable Display
Unique display management function uses scalable screen elements to customize the display.

Networking Capabilities
RJ45 wired networking as standard, with IEEE 802.11g wireless option.

Patient Profiles
Suitable for adult, paediatric and neonatal patient profiles.

Anaesthetic Gas Monitoring
Mainstream or Sidestream, five anaesthetic agents, and measurement of CO_2, N_2O and O_2 (Sidestream only).

Alarms
Audible and visual alarms with colour coding separate for physiological and technical alarms.

Connectivity
Extensive range of connection ports including DVI, VGA, USB, analogue ouput and HIS (HL7 compatible).

Battery BackUp
Provides power to the machine for up to 1 hour, in the event of an AC mains power failure.

Cooling System
Quiet, fan-less cooling system provides unintrusive operation.

Mounting Options
Rolling stand, wall mount or anaesthesia workstation mounting options.

Thermal Recorder
Output patient information, measurement data, review data and up to three waveforms.

Maintenance and After-Sales Support
Comprehensive warranty provides peace of mind and after-sales support. Additional services and warranties can be purchased to meet your particular needs.

Standards Compliant
Fully compliant to ISO 80601-2-13, ISO 80601-2-30, ISO 80601-2-55, EN 12470-4 and IEC 60601-1.

EMS - Continuous Monitoring

Multifunctional plug-in module; can be detached and used for standalone monitoring during patient transfer and recovery.

1 **Multi-parameter Module**
The EMS functions as a multi-parameter plug-in module. Select up to six parameters (see table, opposite).

2 **Patient Transfer**
Easy to remove/refit. Functionality includes patient data storage during transfer (max. 8 hours trend data).

3 **At the Bedside**
Connect to another host monitor and upload patient data. EMS is compact and lightweight (0.6 kg), and gives up to 60 minutes operation (rechargeable lithium ion battery). Full standalone functionality with 3.5" touchscreen.

4 **Colour TFT LCD Display**
3.5" display with automatic screen rotation to portrait or landscape orientation.

1

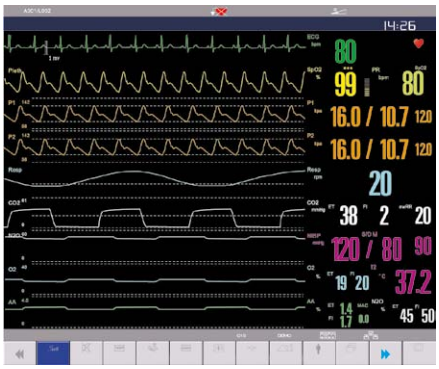
2

3

4

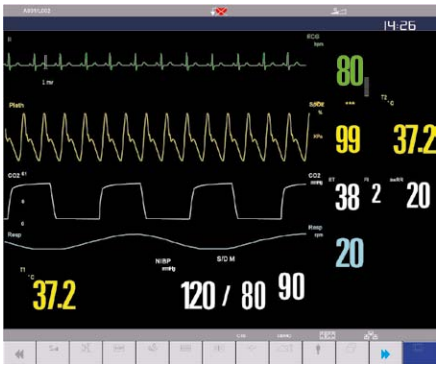
Anaesthesia Gas Analysis

Mainstream or Sidestream, five anaesthetic agents, and measurement of CO_2, N_2O and O_2 (Sidestream only) with fast response times



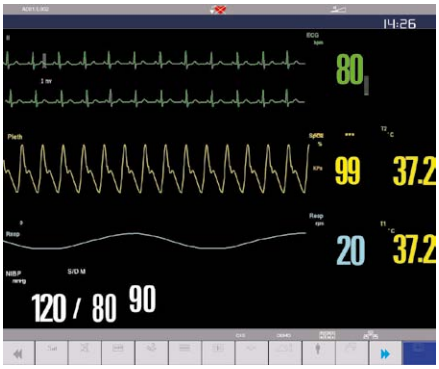
$EtCO_2$ Monitoring

Mainstream, Sidestream or Microstream $EtCO_2$ provide accurate measurement irrespective of patient profile and clinical status



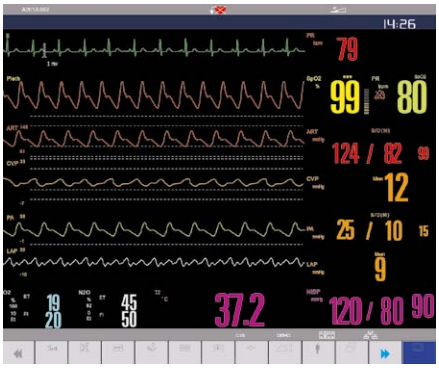
SpO_2 Monitoring

Standard SpO_2 module, plus optional Masimo MX™ or Nellcor SpO_2 modules available



IBP Monitoring

Multi-waveform display for up to four channels of invasive blood pressure measurement



The modular design of the AnaVue 4000 allows clinicians to configure the patient monitor to their clinical requirements, whether for anaesthesia or critical care applications.

EMS Parameter Options

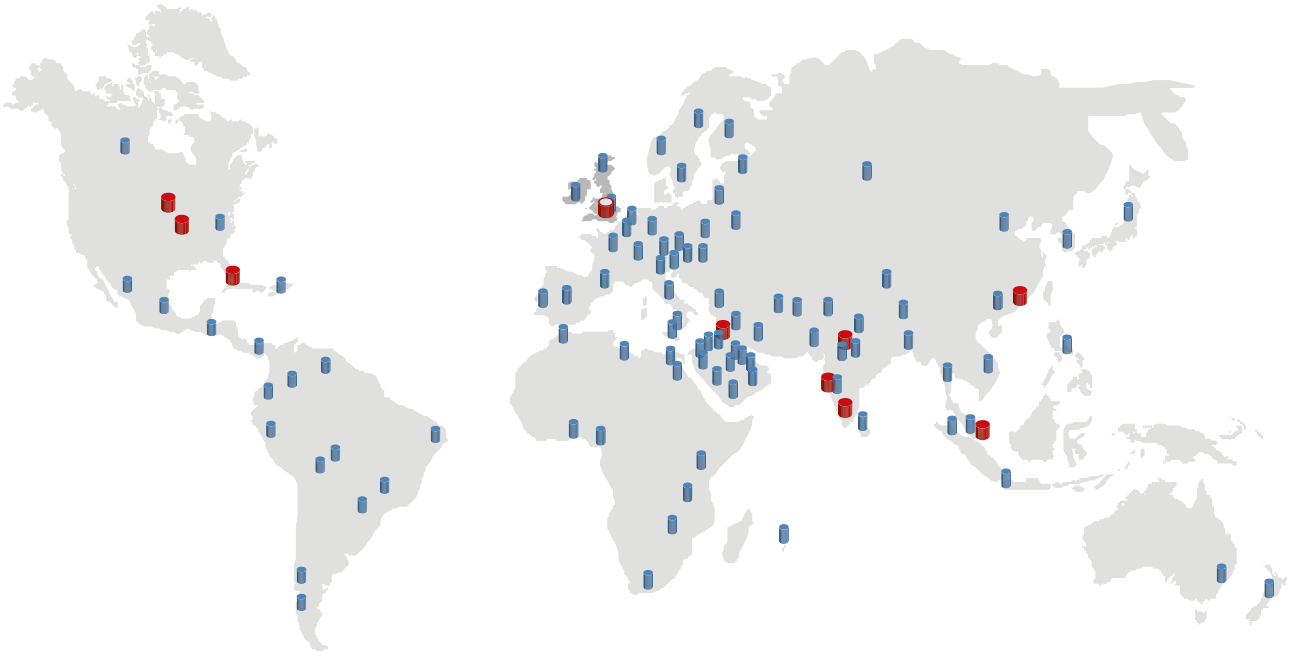
Configuration	RESP	2-TEMP	NIBP	2-IBP	3/5 ECG	12 ECG	SpO_2	Touch screen
EMS Module #1	✓	✓	✓	✓	✓		Standard	✓
EMS Module #2	✓	✓	✓	✓		✓	Standard	✓
EMS Module #3	✓	✓	✓		✓		Standard	✓
EMS Module #4	✓	✓	✓			✓	Standard	✓
EMS Module #5	✓	✓	✓	✓	✓		Nellcor	✓
EMS Module #6	✓	✓	✓	✓		✓	Nellcor	✓
EMS Module #7	✓	✓	✓		✓		Nellcor	✓
EMS Module #8	✓	✓	✓			✓	Nellcor	✓
EMS Module #9	✓	✓	✓	✓	✓		Masimo	✓
EMS Module #10	✓	✓	✓	✓		✓	Masimo	✓
EMS Module #11	✓	✓	✓		✓		Masimo	✓
EMS Module #12	✓	✓	✓			✓	Masimo	✓

About Penlon

Penlon was founded in 1943 by personnel from the Department of Anaesthesia at Oxford University. One of the first products was the Macintosh Laryngoscope, then a revolutionary design, and still the most widely used today, invented by the late Sir Robert Macintosh, Professor of Anaesthetics.

Today Penlon continues to design, engineer and build high quality anaesthesia products at its UK operations headquarters. The company is proud to have over 70 years' dedicated experience, many awards for product design, and an impressive four Queen's Awards for Enterprise, one for 'Innovation' and three for 'International Trade'.

Penlon devices feature intuitive user interfaces that require minimal operator training, putting clinicians in control, enabling them to focus on what is most important – patient safety and wellbeing.



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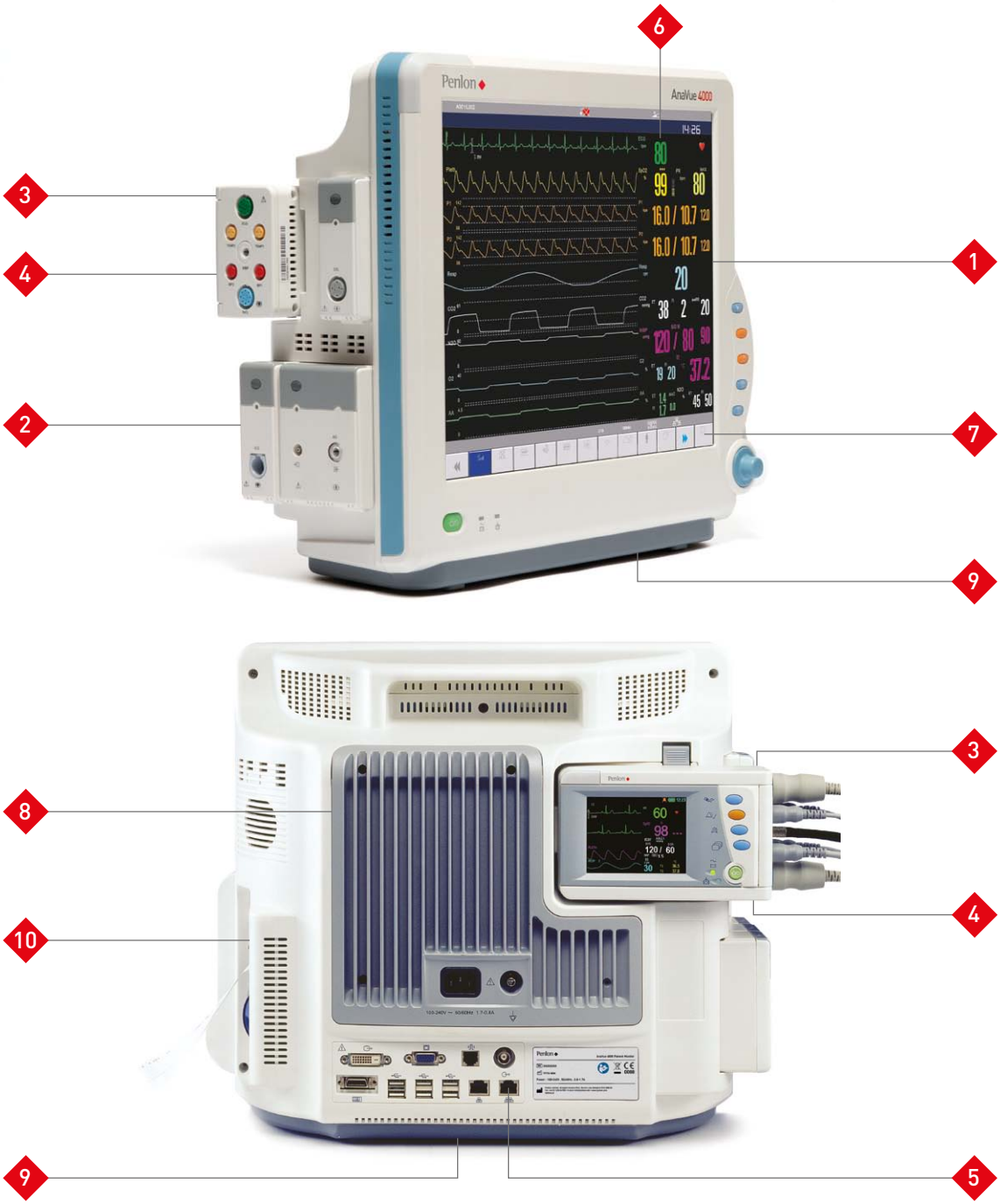
Penlon AnaVue 4000 Patient Monitor Technical Specification

PATIENT MONITORING SOLUTIONS

Penlon



Simple intuitive user interface enables clinical staff to concentrate on improved patient outcomes with accurate physiological data, and to respond immediately to any change in condition.

1. 17" TFT LCD touchscreen colour display and slave screen capability
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Physical Specifications

Dimensions	
Size (H × W × D)	389 × 434 × 206 mm
Weight	<11 kg
Display	
Type	Colour TFT LCD
Size	17" / 431.8 mm
Resolution	1280 × 1024 pixels
Anti-Glare Screen	Fitted
External Display Option	
Type	Medical-grade TFT display
Size	15 inch, 17 inch, or larger
Resolution	1024 × 768 pixels
EMC	MPR II, CISPR 11B
Third-Party Certificate	UL, C-UL, TUV, CE, FCC
Recorder	
Type	Thermal dot array
Horizontal Resolution	16 dots/mm (at 25 mm/s paper speed)
Vertical Resolution	8 dots/mm
Paper Width	50 mm
Paper Length	15 m
Recording Speed	12.5, 25, 50 mm/s
Waveforms	3 tracks, maximum
Recording Process	Real-time recording, periodic recording, alarm recording
Battery	
Type	Rechargeable lithium ion battery
Model	LB-08
Size	105 × 78 × 20 mm
Weight	<360 g
Quantity	1 or 2
Rated Voltage	11.1 VDC
Capability	4000 mAh
Operating Time	≥60 minutes. A single, new and fully charged battery at 25°C ambient temperature, with a SpO_2 sensor and NIBP connected, using AUTO mode, at 15 minute intervals
Charge Time	6 hours to achieve 100% (standby)
Delay Before Turn Off	5 to 15 minutes after the low battery alarm first occurs
Battery Capability Indicator	Fitted
Mainframe LEDs	
Physiological Alarm Indicating	1 lamp (Yellow/Red)
Technical Alarm Indicating	1 lamp (Blue/yellow)
Power Indicating	1 lamp (Green/Orange) AC mains power: Lights green when turning the monitor on and off. Battery power: Lights orange only when turning on the monitor.
Battery Charging Indicating	1 lamp (Orange)
Audio Alarm System	
Speaker	Audible alarm; QRS tone Controls pitch tone and multi-level volume. Alarm tones meet the requirement of IEC 60601-1-8.
Alarm Loudness Pressure	45 to 85 dB. Tested at 1 metre from the speaker
Input Device	
Function Buttons	Six buttons: record, freeze, pausing alarm, acknowledging alarm, NIBP measurement, power switch
Touch Buttons	Thirteen: Facilitate the operation of shortcut menus
Control Knob	Fitted
Mouse Input	Supported
Touchscreen	Optional
Connectors	
Power	Single AC power inlet
Wired Network	Single RJ45 interfaces
Wireless Network	Supports IEEE 802.11g
USB	Six sockets, Type: Standard USB 1.1
Video Output	Single standard DVI-D connector (supports dual-screen display), Single standard VGA connector
Auxiliary Output	Single standard BNC connector: nurse call or analog signal output
Equipotential Grounding Point	One
Defibrillation Synchronization	One RJ11 connector

Signal Output

Auxiliary Output Interface	
Standards Compliance	EN 60601-1: short circuit protection and leakage current
Output Impedance	Rated 50 Ω
ECG Analog Signals Output	
Bandwidth (–3 dB ref. to 10 Hz)	Diagnosis mode: 0.05 to 120 Hz Monitor mode: 0.5 to 40 Hz Surgery mode: 1 to 25 Hz
Signal Range	-5 to +5 V
Signal Delay	25 ms (in diagnosis mode, filter off)
Sensitivity	1V/mV ±5%
Pace Rejection/ Strengthener	None
IBP Analog Signals Output	
Bandwidth (-3 dB ref. 0 to 1 Hz)	0 to 12.5 Hz
Signal Delay	55 ms (filter off)
Sensitivity	1V/100 mmHg ±5%
Nurse Call Output	
Drive Mode	Relay
Electric Specification	Connect to an isolated power supply: ≤60W, ≤2A, ≤36VDC, ≤25VAC
Isolated Voltage	1500 VAC
Signal Type	N.C., N.O.
Alarm Delay Time	<3 s
Defibrillator Synchronization Signal Output	
Output Impedance	50 Ω ±10%
Delay	≤35 ms (from R wave crest to pulse raise)
Amplitude	High level : 3.5 V to 5 V; Maximal output current: 1 mA
	Low level: < 0.5 V; Maximal input current: 5 mA
Pulse Width	100 ms ±10%
Rise and Drop Time	< 1 ms
Digital Video Output (DVI-D Connector)	
Video Signal	Single Link TMDS
DDC Signal	12C compatible

Data Storage	
Trend Data	Long trend: 168 hours, minimum resolution is 1 minute (store when power goes off)
	High resolution trend: 2 hours, minimum resolution is 5 seconds
Parameter Alarm Event	500 groups of parameter alarm events and associated parameter waveform at the alarm trigger point
ARR Event	500 groups of ARR event and the associated waveform
NIBP Measurement Result	1000 groups
Holographic Waveform	Storage time is dependent on the stored waveforms and quantity

ECG Specifications

ECG	
Standards	EN 60601-2-27 / IEC 60601-2-27, ANSI/AAMI EC 13 , IEC 60601-2-25
Lead Type	3 lead: I, II, III 5 lead: I, II, III, aVR, aVL, aVF, Vx 12 lead: I, II, III, aVR, aVL, aVF, V1-V6
Lead Standard	AHA, IEC
Gain	2.5 mm/mV (×0.25); 5 mm/mV (×0.5); 10 mm/mV (×1); 20 mm/mV (×2); 40 mm/mV (×4); Auto
CMRR	Diagnostic mode ≥ 90 dB Monitor mode ≥ 105 dB Surgery mode ≥ 105 dB
Bandwidth (-3dB)	Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Surgery mode: 1 to 25 Hz
AC Filter (50/60 Hz Line Frequency)	Diagnostic mode: 50/60Hz; AC filter shuts off automatically
	Monitor and Surgery mode: 50/60Hz; AC filter turns on automatically
	Decreasing depth for AC filter: -20 dB
Input Impedance	≥ 5.0 MΩ
ECG Signal Range	±10.0 mV
Electrode Offset Potential	±500 mV
Patient Leakage Current	< 10 μA
System Noise	≤ 30 μVpp (RTI)

Standardizing Signal	1 mV ± 5%
Baseline Recovery	Monitor mode: ⩽ 3 s; Surgery mode: ⩽ 1 s
Indication of Electrode Separation	Every electrode (exclusive of RL)
Sweep Speed	6.25, 12.5, 25, 50 mm/s
Protection	Breakdown voltage: 4000 VAC 50/60 Hz
Baseline Recovery	<5 s after defibrillation (Monitor or Surgery mode)
Electrode Recovery Time After Defibrillation	ECG waveform will recover to the baseline in 10 seconds
Pacer Pulse Mark	With pacer pulse detector: complies with IEC 60601-2-27; 50.102.12. For the pacer pulse (in compliance with following conditions) the pacer mark will be signed on the screen (⩾ 2 mm): • Pacing pulse amplitudes: ±2 to ±700 mV • Pacing pulse widths: 0.1 to 2 ms • Rise time: 10 to 100 µs
HR	
Measurement Range	Adult: 10 to 300 bpm Paediatric/Neonatal: 10 to 350 bpm
Resolution	1 bpm
Accuracy	±1% or ±1 bpm, whichever is greater
Detecting Sensitivity (II lead)	Adult: ⩾ 0.2 mVpp
Response of HR to QRS Amplitude: 1 mVp-p; width: 10 ms	Adult: without response Paediatric and Neonatal: with response
Alarm Range	0 to 350 bpm, high/low limit can be adjusted continuously
ST Segment	
Measurement Channels	Calculating I, II, V lead etc., at the same time Default : II lead
Measurement Range	-2.0 to +2.0 mV
Accuracy	-0.8 to +0.8 mV: ±0.02 mV or ±10%, whichever is greater; Over ±0.8 mV: unspecified
Resolution	0.01 mV
Alarm Range	-2.0 to +2.0 mV, high/low limit can be adjusted continuously

Arrhythmia Analysis	
Type	ASYSTOLE, VENT FIB/TACH, PAC, RUN PVCs, COUPLET, BIGEMINY, TRIGEMINY, R ON T, TACHY, BRADY, MISSED BEAT, ST Elevation, ST Depression, PNP, PNC, NOISE, V-TACH, VPB, Frequent PVCs, VENT BRADY, EXTREME TACHY, EXTREME BRADY, NON-SUSTAIN VT, VENT RHYTHM, PAUSE, IRREGULAR HR, MULTI PACS
ECG/ST/Arrhythmia Supplemental Information as Required by AAMI EC13	
Electrosurgery Protection (Electrocautery Unit Protection)	Cut mode: 300 W Coag mode: 100 W HR change: ⩽10% Resuming time: ⩽10 s Complies with ANSI/AAMI EC 13:2002, 4.2.9.14
Input Circuit Current	< 0.1 µA
Tall T-Wave Rejection Capability	Minimum recommended : 1.2 mV T-Wave amplitude; Complies with ANSI / AAMI EC 13:2002, 4.1.2.1 c
Heart Rate Averaging	⩽ 50 bpm, once every two beats; 50 to 120 bpm, once every four beats; > 120 bpm, once every six beats
HR Meter Accuracy and Response to Irregular Rhythm	Ventricular bigeminy: 80 bpm Slow alternating ventricular bigeminy: 60 bpm Rapid alternating ventricular bigeminy: 120 bpm Bidirectional systoles: 90 bpm
Response Time of HR Meter to Change in HR	HR change from 80 to 120 bpm: less than 10 s HR change from 80 to 40 bpm: less than 10 s Complies with ANSI / AAMI EC13-2002: 4.1.2.1 f
Time to Alarm for Tachycardia	Vent Tachycardia 1 mVp-p, 206 bpm: Gain 0.5, Range 6.5 to 8.4 s, Average 7.2 s Gain 1.0, Range 6.1 to 6.9 s, Average 6.5 s Gain 2.0, Range 5.9 to 6.7s, Average 6.3 s
	Vent Tachycardia 2 mVp-p, 195 bpm: Gain 0.5, Range 5.4 to 6.2s, Average 5.8 s Gain 1.0, Range 5.7 to 6.5s, Average 6.1 s Gain 2.0, Range 5.3 to 6.1s, Average 5.7 s

Recovery Time Of Electrode Polarization After Defibrillation	ECG waveform will recover to the baseline within 10 seconds in Monitor and Surgery mode
Indicator for ECG Working Abnormally	Each amplificatory channel has ECG abnormal operation indication. Complies with EC13 2002, 4.2.9.1.
Pacemaker Pulse Rejection Performance	Rejection of pacemaker pulses with amplitudes from ±2 mV to ±700 mV and widths from 0.1 to 2.0 ms (Method A)

RESP Specification

RESP	
Measurement Method	Thoracic impedance
Lead	Selected from: I (RA-LA) or II (RA-LL); Default: II
Excitation Frequency	Sine wave: 64.8 kHz
Excitation Current	≤ 0.3 mA
Measuring Impedance Range	0.2 to 3 Ω
Baseline Impedance Range	500 to 2000 Ω (using a defibrillator-proof cable with a resistance of 1 kΩ)
Gain	×0.25, ×1, ×2, ×4
Bandwidth	0.25 to 2.0 Hz (-3 dB)
Sweep Speed	6.25, 12.5, 25 mm/s
RR	
Measurement Range	0 to 150 rpm
Resolution	1 rpm
Accuracy	±2 rpm or ±2% , whichever is the greater
Alarm Range	0 to 150 rpm, high/low limit can be adjusted continuously
Delay Of Apnea Alarm	10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60 seconds

NIBP Specification

NIBP	
Standard	IEC 80601-2-30
Measurement Type	Automatic oscillometry
Measurement Mode	Manual , Auto, STAT

Intervals For Auto Measurement Time	1, 2, 2.5, 3, 4, 5, 10, 15, 30, 60, 90 minutes; 2, 4, 8, 12 hours	
STAT Mode Cycle Time	5 minutes, at 5 seconds interval	
Measurement Types	Sys, Dia, Map	
Measurement Range (mmHg)	Sys	Adult: 30 to 270 mmHg
		Paediatric: 30 to 235 mmHg
		Neonatal: 30 to 135 mmHg
	Dia	Adult: 10 to 220 mmHg
		Paediatric: 10 to 220 mmHg
		Neonatal: 10 to 100 mmHg
	Map	Adult: 20 to 235 mmHg
		Paediatric: 20 to 225 mmHg
		Neonatal: 20 to 125 mmHg
Cuff Pressure Range	0 to 300 mmHg	
Resolution	1 mmHg	
Pressure Accuracy	Static:	±3 mmHg
	Clinic:	Average error: ±5 mmHg, standard deviation: ≤8 mmHg
PR Range	40 to 240 bpm	
Cuff Auto Deflation	The cuff will deflate automatically when: 1. Power is off 2. Measurement time is greater than 120 seconds (90 seconds for neonate) 3. Cuff pressure is greater than the overpressure protection value set by the software and hardware	
Measurement Time	Typical: 20 to 45 seconds (depending on HR and moving interference).	
	Maximal: 120 seconds (adult/ paediatric), 90 seconds (neonate)	
Initial Inflation Pressure	Adult default: 170 mmHg Paediatric default: 130 mmHg Neonatal default: 100 mmHg	
Software Overpressure Protection	Adult: 297 ±3 mmHg Paediatric: 252 ±3 mmHg Neonatal: 147 ±3 mmHg	

Assistant Venipuncture Inflation Mode	Inflation pressure (should be close to diastolic pressure): Adult : 20 to 120 mmHg (normally 80 mmHg); Paediatric: 20 to 80 mmHg (normally 60 mmHg); Neonatal: 20 to 50 mmHg (normally 40 mmHg).		
	Time after which cuff will deflate automatically: Adult /paediatric: 180 seconds Neonatal: 90 seconds		
Alarm Range	Sys/Dia/Map: 0 to 300 mmHg; high/low limit can be adjusted continuously		
SunTech NIBP (option)			
Measurement Method	Oscillometric: Diastolic values correspond to Phase 5 Korotkoff sounds.		
Measurement Range	Adult:	SYS	40 to 260 mmHg
		DIA	20 to 200 mmHg
		MAP	26 to 220 mmHg
	Child:	SYS	40 to 160 mmHg
		DIA	20 to 120 mmHg
		MAP	26 to 133 mmHg
	Neonate:	SYS	40 to 130 mmHg
		DIA	20 to 100 mmHg
		MAP	26 to 110 mmHg
Pressure Measurement Accuracy	± 3 mmHg (± 0.4 kPa) or 2% of readings above 200 mmHg		
	Ambient temperature range: 50 to 104°F (10 to 40°C)		
	Humidity range: 15 to 90%		
Pressure Transducer Accuracy	±3 mmHg, between 0 and 300 mmHg		
	Operating conditions: 0 to 60°C		
Unit	mmHg, kPa		
Pulse Rate Range	30 to 220 bpm		
Pulse Rate accuracy	2% or 3 bpm, whichever is greater		
Inflation Time for Cuff	<75 s		
Measurement Protection Time	Adult:	<180 s	
	Child:	<180 s	
	Neonate:	<90 s	

Initial Inflation Pressure	Adult:	120 to 280 mmHg default 160 mmHg
	Child:	80 to 170 mmHg default 120 mmHg
	Neonate:	60 to 140 mmHg default 90 mmHg
Startup Initialization Period	7 s	
Intervals for AUTO Measurement Time	1, 2, 3, 4, 5, 10, 15, 30, 60, 90 minutes 2, 4, 8, 12 hours	
Overpressure Protection	Hardware and software double protection	
	Adult:	<300 mmHg
	Child:	<300 mmHg
	Neonatal:	<150 mmHg
Alarm Indication	Audio and visual alarms	
Measurement Mode	Adult:	Manual, Auto and STAT
	Child:	Manual, Auto and STAT
	Neonatal:	Manual, Auto

Standard SpO_2 Specification

SpO_2	
Measurement Range	0 to 100%
Measurement Method	Digital SpO_2 technique
Resolution	1%
Accuracy	70 to 100%: ±2% 0 to 69%: unspecified
Average Time	Normal: 8 s, slow: 16 s, fast: 4 s
Anti-Interference Ability	Anti-interference of movement and electrocautery unit
Resisting Low Perfusion Ability	PR amplitude ≥0.1% with value of SpO_2 displayed
PR Modulation Tone (Pitch Tone)	Fitted
Auto Light Adjustment	Multilevel light adjustment, with high power fit ability
Alarm Range	0 to 100%, high/low limit can be adjusted continuously

Sensor	The LED for the pulse oximeter sensor produces red light (approximately 660 nm in wavelength) and infrared light (approximately 905 nm). Emitted light energy is ⩽ 15 mW. This information is particularly useful for clinicians (e.g. in optical dynamic therapy).
PR	
Measurement Range	25 to 255 bpm
Resolution	1 bpm
Accuracy	±1% or ±1 bpm, whichever is the greater
Average Time	8 s
PR Alarm Range	0 to 300 bpm; high/low limit can be adjusted continuously
PI	
Measurement Range	0.05 to 20%

Nellcor SpO_2 Specification

SpO_2	
Measurement Range	0 to 100%
Resolution	1%
Accuracy	70 to 100%: ±2% (adult/paediatric) 70 to 100%: ±3% (neonate) 0 to 69%, unspecified
Average Time	8 s, 16 s
PR	
Measurement Range	20 to 300 bpm
Accuracy	20 to 250 bpm: ±3 bpm 251 to 300 bpm: unspecified
Resolution	1 bpm

Masimo SpO_2 Specification

SpO_2	
Measurement Range	0 to 100%
Resolution	1%
Accuracy	70 to 100% ±2% adult/pediatric, non-motion conditions 70 to 100% ±3% neonate, non-motion conditions 70 to 100% ±3% motion conditions 0 to 69% unspecified
Average Time	2 to 4, 4 to 6, 8, 10, 12, 14, 16 seconds
PR	
Measurement Range	25 to 240 bpm
Accuracy	±3 bpm non-motion conditions ±5 bpm motion conditions
Resolution	1 bpm
SpCO	
Measurement Range	0 to 100%
Accuracy	0 to 40% ±3% non-motion conditions >40% unspecified
SpMet	
Measurement Range	0 to 100%
Accuracy	0 to 15% ±1% non-motion conditions >15% unspecified
PI	
Measurement Range	0.05 to 20%
SpHb	
Measurement Range	0 to 25 g/dl
Accuracy	8 to 17 g/dl ±1% non-motion conditions 8 g/dl or 17 g/dl unspecified
SpOC	
Measurement Range	0 to 35 ml/dl

Temp Specification

Temp	
Standard	EN 12470-4
Measurement Type	Thermal resistance
Measurement Range	0 to 50°C (32 to 122°F)
Accuracy	±0.1°C or ±1°F (exclusive of probe)

Resolution	0.1°C or 1°F
Unit	°C or °F
Data Update Period	Every 1 to 2 seconds
Minimum Accurate Measuring Time	Surface: <100 seconds; Coelom: <80 seconds
Self Check	Approximately every 5 to 10 minutes
Temp Sensor Resistance	2252 Ω (25°C)
Alarm Range	0.0 to 50.0°C; (high/low limit can be adjusted continuously)

IBP Specification

IBP		
Standard	EN 60601-2-34 / IEC 60601-2-34	
Measurement Type	Directly invasive pressure measurement	
Sensitivity of Transducer	5 µV/V/ mmHg, ±2%	
Impedance of Transducer	300 to 3000 Ω	
Static Pressure Measurement Range	–50 to +350 mmHg	
Static Pressure Measurement Accuracy	Excluding the transducer: ±1 mmHg or ±2% of the reading, whichever is the greater	
	Including the transducer: ±4 mmHg or ±4% of the reading, whichever is the greater	
Dynamic Pressure Measurement Range	-50 to +350 mmHg	
Dynamic Pressure Measurement Accuracy	±4 mmHg or ±4% of the reading, whichever is the greater	
Resolution	1 mmHg	
Unit	mmHg, kPa, cmH_2O	
Frequency Response	0 to 20 Hz	
Type of Measurement	ART, PA, CVP, RAP, LAP, ICP, P1/P2	
Alarm Range	ART	0 to 350 mmHg
	PA	-10 to +120 mmHg
	CVP/RAP/ LAP/ICP	-10 to +40 mmHg
	P1/P2	-50 to +350 mmHg

Zero Pressure Calibration	When the IBP sensor is connected or during IBP measurement: connect to standard atmosphere and perform a zero calibration every 4 hours.
Pressure Range Zero Calibration	±200 mmHg
Accuracy of Pressure Zero Calibration	±1 mmHg

CO_2 Specification

CO_2	
Measurement Mode	Sidestream, mainstream, microstream
Measurement Type	Infrared spectrum
Alarm Range	0 to 150 mmHg; high/low limit can be adjusted continuously
Sidestream CO_2 Module (Standard)	
Measurement Range	0.0 to 13.1% (0 to 99.6 mmHg)
Resolution	0.1% or 1 mmHg
Units	%, mmHg, kPa
Accuracy	0% to 4.9%: ±0.3 % (±2.0 mmHg) 5.0% to 13.1%: <±10 % of the reading
Measurement Range of awRR	3 to 150 rpm
Warm-Up Time	Reaches 97% of full specification within 45 seconds, and full specification within 10 minutes
Rise Time	Approximately 100 ms when using a 1.5m sampling tube and adult water trap, with a 120 ml/min flow rate
CO_2 Response Time	<4 seconds when using a 1.5 m sampling tube and adult dehydration flask, with a 120 ml/min flow rate
Sample Flow Rate	User adjustable, 50 ml/min, 100 ml/ min, 150 ml/min, 200 ml/min, 250 ml/min
Calibration	Offset calibration, auto/manual; gain calibration
Mainstream CO_2 Module (CAPNOSTAT5)	
Warm-Up Time	Capnogram displayed in less than 15 seconds, at an ambient temperature of 25°C, full specification within 2 minutes
Measurement Range	0% to 19.7% (0 to 150 mmHg)

Resolution	0.1% or 1 mmHg
Stability	Short term drift: ±0.8 mmHg over four hours Long term drift: Accuracy specification is maintained over a 120 hour period
Rise Time	<60 ms
Units	%, mmHg, kPa
Accuracy	0 to 40 mmHg, ±2 mmHg 41 to 70 mmHg, ±5% of reading 71 to 100 mmHg, ±8% of reading 101 to 150 mmHg, ±10% of reading Temperature: 35°C
awRR Measurement Range	0 to 150 rpm
awRR Measurement Accuracy	±1 rpm
Microstream CO_2 Module (LoFlo)	
Warm-Up Time	Capnogram displayed in less than 20 seconds, at an ambient temperature of 25°C (Full specification within 2 minutes)
Measurement Range	0% to 19.7 %(0 to 150 mmHg)
Resolution	0.1% or 1 mmHg
Stability	Short term drift: ±0.8 mmHg over four hours Long term drift: Accuracy specification will be maintained over a 120 hour period
Units	%, mmHg, kPa
Accuracy (760 mmHg at 25°C)	0 to 40 mmHg: ±2 mmHg 41 to 70 mmHg: ±5% of reading 71 to 100 mmHg: ±8% of reading 101 to 150 mmHg: ±10% of reading (when RR <80 rpm, all the range is ±12% of reading) Gas temperature: 25°C
Total System Response Time	<3 s
awRR Measurement Range	2 to 150 rpm
awRR Measurement Accuracy	±1 rpm
Sample Flow Rate	50 ml/min ± 10 ml/min

AG Specification

Mainstream AG Module (IRMA AX+)		
Measurement Type	Infrared spectrum	
Measurement Mode	Mainstream	
Measured Parameters	CO_2, N_2O, Agent (ISO, ENF, SEV, HAL, DES)	
Resolution	1%	
Calibration	Zeroing recommended when airway adapter is changed. Span calibration not required for the IR bench.	
Warm-Up Time	Concentrations measured and automatic agent identification within 10 seconds (Full accuracy within 20 seconds)	
Rise Time (Flow Rate: 10 L/Min)	CO_2 : ⩽ 90 ms N_2O : ⩽ 300 ms ISO, ENF, SEV, HAL, DES : ⩽300 ms	
Total System Response Time	<1 s	
Primary Agent Threshold	0.15%. NOTE: When an agent is identified, concentrations will also be reported at below 0.15%, as long as apnea is not detected. When the concentration has passed the threshold, the concentration will be reported at below 0.3%.	
Secondary Agent Threshold	0.2% +10% of total agent concentration	
Agent Identification Time	< 20 s (typically < 10 s)	
Measurement Range	CO_2:	0 to 15%, accuracy ± (0.3%ABS + 4%REL)
	N_2O:	0 to 100%, accuracy ± (2%ABS + 5%REL)
	ISO, ENF, HAL:	0 to 8%, accuracy ± (0.2%ABS + 10%REL)
	SEV:	0 to 10%, accuracy ± (0.2%ABS + 10%REL)
	DES:	0 to 22%, accuracy ± (0.2%ABS + 10%REL)
awRR Measurement Range	0 to 150 rpm	

awRR Measurement Accuracy	±1 rpm	
Alarm Range	SEV, ISO, ENF, HAL, DES	0% to 30% High/low limit can be adjusted continuously
	CO_2	0% to 10% High/low limit can be adjusted continuously
	N_2O	0% to 100% High/low limit can be adjusted continuously
Sidestream AG module (ISA OR+)		
Measurement Mode	Sidestream	
Sampling Flow Rate	50 ± 10 ml/min	
Measurement Parameters	CO_2, N_2O, O_2, Agent (ISO, ENF, SEV, HAL, DES)	
Compensation	Automatic compensation for pressure and temperature, and broadening effects on CO_2	
Calibration	Span calibration is not required for the IR bench. An automatic zero reference calibration is performed at startup and then every 24 hours.	
Warm-Up Time	<20 s (Concentrations reported, automatic agent identification enabled, and full accuracy)	
Typical Rise Time at 50 ml/Minute Sample Flow	CO_2	≤ 250 ms
	N_2O	≤ 350 ms
	O_2	≤ 450 ms
	ISO, ENF, SEV, HAL, DES	≤ 350 ms
Total System Response Time	<3 s (with 2 m sampling line)	
Primary Agent Threshold	0.15% When an agent is identified, concentrations will also be reported at values below 0.15%	
Secondary Agent Threshold	0.2% +10% of total agent concentration	
Agent Identification Time	<20 s (typically <10 s)	
Measurement Range	CO_2:	0 to 15%, accuracy ± (0.3 kPa + 4% of reading)
	N_2O:	0 to 100%, accuracy ± (2 kPa + 5% of reading)
	HAL, ENF, ISO:	0 to 8%, accuracy ± (0.2 kPa + 10% of reading)
	SEV:	0 to 10%, accuracy ± (0.2 kPa + 10% of reading)
	DES:	0 to 22%, accuracy ± (0.2 kPa + 10% of reading)
	O_2:	0 to 100%, accuracy ± (2 kPa + 2% of reading)
awRR Measurement Range	0 rpm to 150 rpm	
awRR Measurement Accuracy	±1 rpm	

ICG Specification

ICG		
Measurement Type	Measurement of thoracic electrical bioimpedance	
Measurement Range	HR:	40 to 250 bpm
	SV:	5 to 250 mL
	SI:	5 to 125 mL/m^2
	C.O.:	1.4 to 15 L/min
	TFC:	15 to 143/kΩ
Accuracy	HR:	±2 bpm
	SV:	Unspecified
	C.O.:	Unspecified
Alarm Range	C.I.:	0.0 to 15.0 L/min/m^2, high/low limit can be adjusted continuously
	TFC:	10 to 150/kΩ, high/low limit can be adjusted continuously

C.O. Specification

C.O.	
Measurement Type	Thermal dilution method
Wave Type	Thermal dilution curve
Measured	C.O., TB, TI, C.I.

Range	C.O.:	0.1 to 20 L/min
	TB:	23.0 to 43.0°C
	TI:	-1.0 to 27.0°C
Resolution	C.O.:	0.1 L/min
	TB:	0.1°C
	TI:	0.1°C
Precision	C.O.:	2% SD
	TB/TI:	±0.1°C
TB Alarm Range	23 to 43°C, high/low limit can be adjusted continuously	

CSM Specification

CSM	
EEG Sensitivity	±400 µV
Noise	< 2 µVp-p, < 0.4 µV RMS, 1 to 250 Hz
CMRR	>100 dB
Input Impedance	>50 Mohm
CSI and Update	0 to 100. Filter 6 to 42 Hz, 1 second update
EMG	0 to 100 logarithmic. Filter 75 to 85 Hz, 1 second update
BS%	0 to 100%. Filter 2 to 42 Hz, 1 second update
Wireless Range	Up to 10 metres
Display Size	32 × 17 mm
Alarms	High / Low with user selectable limit
Artefact Rejection	Automatic
Sensor Impedance Range	0 to 10 kOhm / measurement current 0.01 µA
Battery	9V Alkaline or rechargeable NiMH (6AM6/IEC:6LR61/ANSI:1604A)
Supply Current	30 mA (typical)
Maximum Battery Lifetime - Alkaline	30 h (stand alone) 18 h (transmitting wireless)
Maximum Battery Lifetime - Rechargeable	10.5 hours
Charging Time	4 hours (CSMX04 only)
Weight	130 g with battery
Dimensions	114 × 60 × 31 mm
Classification	Internal power supply / Class II, type BF, continuous use

Sensors	Danmeter Neuro Sensors™
Cable Length	195 cm (77 inches) with 35 cm (14 inches) split
Mounting Options	Velcro strip (42 x 25 mm)
Memory	Data recording: 18 hours

BIS Specification

BIS	
Measurement Index	EEG measurement specifications Sensor detection display Alarm range and error setting
Wave Shape	Electroencephalograph waveform (EEG)
Parameter Measurement Range	a) BIS measurement range is 0 to 100; b) EMG measurement range is 30 to 55 dB (bar chart) with intensity between 30 dB and 80 dB (tendency chart); c) SQI measurement range is 0 to 100%; d) SR measurement range is 0 to 100%; e) SEF measurement range is 0.5 to 30 Hz; f) TP measurement range is 40 to 100 dB g) BC measurement range is 0 to 30 (only limited to the combined use of an external sensor with a BIS module)
EEG Measurement Specification	a) Input impedance > 5 MΩ; b) Noise(RTI) <2 uv (0.25 to 50 Hz) c) Input signal range ± 1 mV d) EEG bandwidth between 0.25 and 110 Hz
Sensor Detection Display	The monitor screen displays sensor graphs with numbers indicating the impedance value of electrodes. Detection results are shown in two colours: • Green indicates passing • Red indicates Noise, high impedance, or lead shedding
Alarm Range and Error Setting	BIS: 0 to 100, with the upper and lower limits continuously adjustable; Alarm error: ±1

EMS Specification

Size and Weight	
Size	160 × 99 ×71 mm
Weight	<0.6 kg
Display	
Screen	3.5 inch, TFT LCD, 320×240 pixels
Waveform	Up to 12 tracks
Battery	
Type	Rechargeable lithium ion battery
Model	LB-02
Size	62.5 × 40.5 × 11.5 mm
Weight	<50 g
Quantity	1
Rated Voltage	3.7 VDC
Capability	1800 mAh
Operating Time	≥60 minutes: New / fully charged battery at 25°C ambient temperature, with SpO_2 sensor connected (ECG, Temp, IBP , NIBP not connected) in AUTO mode for 15 minute interval.
Charging Time	Standby state: ≤ 6 hours
Delay Before Turn Off	5 to 10 minutes after the low battery alarm first occurs
Battery Capability Indicator	Fitted
Buttons	
Buttons	Five buttons: NIBP start/stop, acknowledging alarm, pausing alarm, change screen, and power switch
Indicators	
Physiological Alarm Indicator	Yellow/Red light
Technical Alarm Indicator	Blue light
Power Indicating Lamp	Green/Orange light
Battery Charging Indicator	Orange light
Audio Indicator	
Speaker	Gives audible alarm and QRS tone. Alarm tones meet the requirement of IEC 60601-1-8.
Alarm Pressure	45 to 85 dB, tested at 1 metre from the speaker
Connector	
Connection to Host Monitor	Single cable connector

Environmental Specification

Environmental		
Operating Temperature	General:	5 to 40°C
	IRMA AX+ sensor:	10 to 40°C
	ISA OR+/AX+ sensor:	5 to 50°C
Operating Humidity	15 to 85% (non-condensing)	
Operating Atmospheric Pressure	700 to 1060 hPa	
Transportation and Storage Temperature	-20 to +55°C	
Transportation and Storage Humidity	10 to 93% (non-condensing)	
Transportation and Storage Atmospheric Pressure	500 to 1060 hPa	

Power Specification

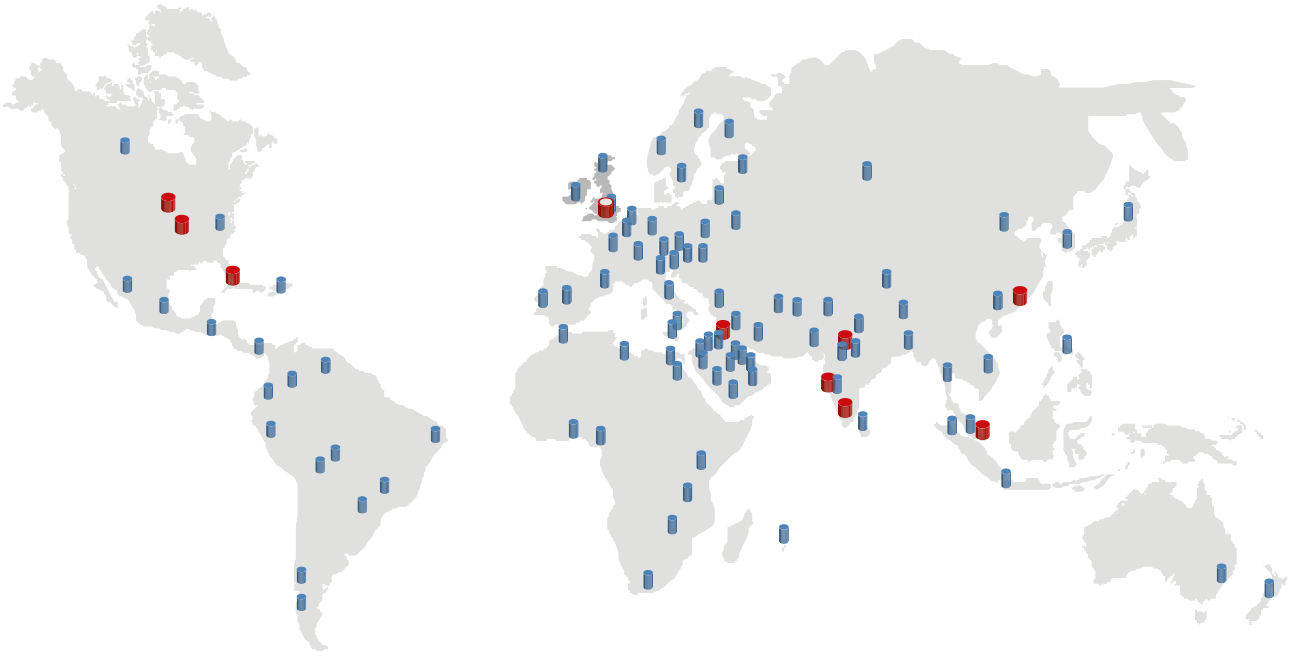
Power	
Input Voltage	100 to 240 VAC
Frequency	50/60 Hz
Earth Leakage Current	<0.3 mA
Input Current	1.7 to 0.8 A
Standards Requirement	According to IEC 60601-1 and IEC 60601-1-2
Fuse	T 2.5A/250V, 2-Φ 5 × 20 mm, integrated in the power module

About Penlon

Penlon was founded in 1943 by personnel from the Department of Anaesthesia at Oxford University. One of the first products was the Macintosh Laryngoscope, then a revolutionary design, and still the most widely used today, invented by the late Sir Robert Macintosh, Professor of Anaesthetics.

Today Penlon continues to design, engineer and build high quality anaesthesia products at its UK operations headquarters. The company is proud to have over 70 years' dedicated experience, many awards for product design, and an impressive four Queen's Awards for Enterprise, one for 'Innovation' and three for 'International Trade'.

Penlon devices feature intuitive user interfaces that require minimal operator training, putting clinicians in control, enabling them to focus on what is most important – patient safety and wellbeing.



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Penlon Prima 465 Anaesthesia System

ANAESTHESIA SOLUTIONS

- Electronic gas mixer with digital flowmeters
- 12.1" TFT colour touchscreen
- Optional anaesthetic gas monitoring
- Integrated heated absorber module
- Selectatec® compatible backbar
- Designed and built in the UK

Penlon

Penlon Prima 465 Anaesthesia System

All the features and options you need to configure a system to your exact specification

1. 12.1" TFT touchscreen display with electronic gas mixer and digital flowmeters
2. Up to eight ventilation modes
3. Versatile top shelf with secure GCX™ mounting system for patient monitors
4. Penlon SP M5 patient monitor
5. Territory-specific electrical outlet options
6. Selectatec® compatible backbar (two station)
7. Up to three cylinders
8. Illuminated work space with pull-out writing surface
9. GCX™ compatible aluminium uprights for additional accessory mounting
10. Large capacity drawer units
11. Integrated CO_2 absorber and bellows unit with ventilator interface
12. Backlit dual Common Gas Outlet (CGO)

The Penlon Prima 465 is the latest high-end anaesthesia system from Penlon providing the ideal solution for today's busy operating room

Clinician-focused choices and benefits, including intuitive 12.1" TFT touchscreen with electronic gas mixer, digital flowmeters and optional anaesthetic gas monitoring

Platform

The Prima 465 Anaesthesia System has evolved from a strong core specification, and is suitable for adult, paediatric and neonatal patient profiles.

- Fully compliant to ISO 80601-2-13 Standard and to the Restrictions of Hazardous Substances (RoHS) Directive.

Flow control and visualisation

The Prima 465's user friendly 12.1" touchscreen display provides:

- Electronic gas mixer with selectable gas combinations (O_2, O_2 + AIR or O_2 + N_2O), adjustable O_2 concentration and control of fresh gas flow rate
- Intuitive interface provides overall parameter settings, measurements and graphic trend data
- Optional Sidestream or Mainstream anaesthetic gas monitoring
- Optional Sidestream CO_2 monitoring
- Optional Masimo SpO_2 monitoring

For enhanced patient safety all models utilise an electronic anti-hypoxic device and a backup O_2 gas delivery system.

Options and accessories

Wide choice of territory-specific electrical power outlets, and a forward facing socket. Penlon also supplies an AGS system (anaesthetic gas scavenging), a patient cable management arm, an oxygen therapy flowmeter, and a side mounted suction controller kit.

Patient monitoring

12.1" TFT LCD touchscreen colour display; standard parameters: 3/5 lead ECG, RESP, NIBP, SpO_2, PR, 2-TEMP, and 2-IBP; three module slots for additional parameters: 12 lead ECG, SunTech NIBP, Sidestream/Microstream/Mainstream $EtCO_2$, Sidestream/Mainstream Anaesthetic Gas/O_2, Nellcor SpO_2, 2-IBP, 2-TEMP and Cardiac Output.

System components

A reliable platform, combining advanced features and value for money. The Prima 465 is easy to use and maintain, with proven performance.

1 **Intuitive user interface**
An easy to use 12.1" TFT touchscreen display with electronic gas mixer, and digital flowmeters. Up to eight ventilation modes are available including VCV, PCV, PSV, PRVC, SIMV-VCV, SIMV-PCV and SIMV-PRVC, with PEEP available in all ventilation modes. Anaesthetic gas monitoring, Sidestream CO_2, and Masimo SpO_2 monitoring are also available.

2 **CO_2 Absorber**
A high performance absorber with a ventilator interface as standard that provides ventilator mode switching, triggered by the bag/ventilator control. The unit has a built-in heating system, and the main components are autoclavable.

3 **Anaesthesia Vaporizers**
The award winning Sigma Delta and the new Sigma EVA desflurane vaporizers offer multiple agent and filler system options to suit all clinical requirements.

4 **SP M5 Patient Monitor**
A lightweight and compact patient monitor with a 12.1" colour TFT touchscreen display, extensive parameter options, rechargeable battery and optional wireless networking.

Maintenance and after-sales support

Penlon is committed to a successful, long term relationship with all our customers. Comprehensive warranty provides user peace of mind and after-sales support.

Additional services and warranties can be purchased to meet your particular needs.

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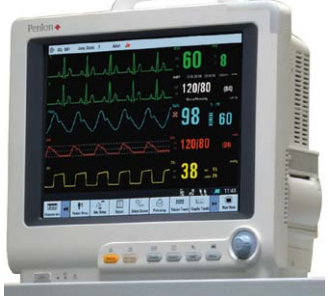

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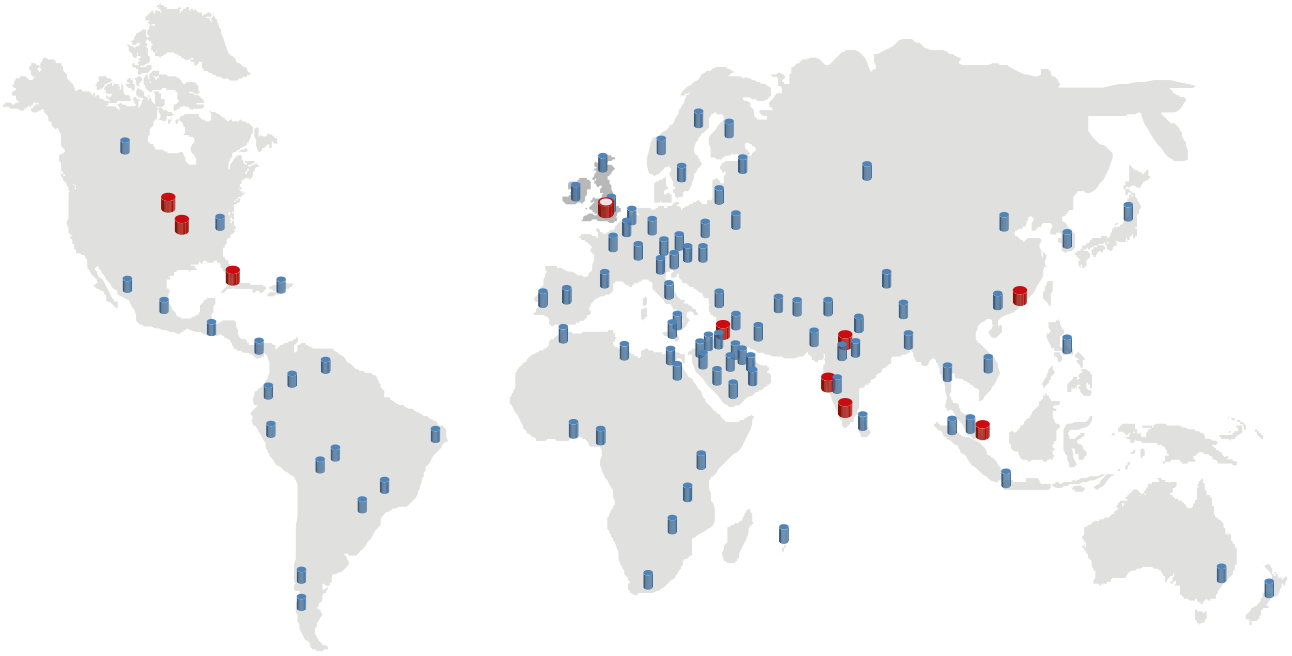

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Penlon Prima 465 Anaesthesia System

Technical Specification

ANAESTHESIA SOLUTIONS

Penlon

All the features and options you need to configure a system to your exact specification

1. 12.1" TFT touchscreen display with electronic gas mixer and digital flowmeters
2. Eight ventilation modes
3. Versatile top shelf with secure GCX™ mounting system for patient monitors
4. Territory-specific electrical outlet options
5. Selectatec® compatible backbar (two station)
6. Up to three cylinders
7. Illuminated work space with pull-out writing surface
8. GCX™ compatible aluminium uprights for additional accessory mounting
9. Large capacity drawer units
10. Integrated CO_2 absorber and bellows unit with ventilator interface
11. Backlit Auxiliary Common Gas Outlet (ACGO)
12. Oxygen therapy flowmeter

Physical Specifications

Dimensions	
Size (H × W × D)	1310 × 790 × 700 mm
Weight	125 kg
Top Shelf	
Size (W × D)	710 × 350 mm
Loading	30 kg - evenly distributed
Work Surface	
Height	860 mm
Size (W × D)	580 × 250 mm
Loading	30 kg - evenly distributed
Illumination	LED
Writing Tablet (Optional)	
Size (W × D)	300 × 220 mm
Loading	10 kg - evenly distributed
Rail	
Top Rail	Top shelf with GCX™ mounting system for patient monitors
Side Rail	GCX™ compatible aluminium uprights for accessory mounting
Medical Rail	200 mm on the machine side
Drawers	
Size (H × W × D)	120 × 545 × 350 mm
Number of Drawers	3
Loading	10 kg - evenly distributed
Castors	
Diameter	125 mm
Brakes	Individually braked
Display	
Type	Colour TFT touchscreen
Size	12.1" / 307 mm
Resolution	800 × 600 pixels
Construction	
Material	Frame: Aluminium and plastic Base: Aluminium

Ventilator Specifications

Ventilator Specification	
Type	Fully integrated, electronically controlled and pneumatically driven
Modes	• Volume Control Ventilation (VCV) • Pressure Control Ventilation (PCV) • Pressure Regulated Volume Control (PRVC (PCV-VG)) • Synchronised Intermittent Mandatory Ventilation - Volume Control Ventilation (SIMV-VCV) • Synchronised Intermittent Mandatory Ventilation - Pressure Control Ventilation (SIMV-PCV) • Synchronised Intermittent Mandatory Ventilation - Pressure Regulated Volume Control (SIMV-PRVC) • SPONT/Pressure Support Ventilation (PSV) with apnea backup (VCV or PCV) • Manual
Bellows	Universal (adult and paediatric) ascending bellows
Drive Gas	Type: O_2/Air – Automatic changeover
	Inlet pressure: 290 to 600 kPa
	Max flow: ≤ 120 L/min
Compensation	Compliance, Fresh Gas, Barometric
Flow Sensors	Inspiratory and expiratory (reusable)
Data Interface	1 × Serial port (for service only), 1 × RS232, 1 × VGA
Ventilator Settings	
Tidal Volume	Range: 10 to 1600 mL (0 to 1600ml measured in PCV) Increments: 10 to 100 mL (5 mL); 100 to 1600 mL (10 mL)
Inspiratory Tidal Volume (VTI)	Range: 0 to 2500 mL Resolution: 1 mL. Error of ±20 mL or actual value ±15%, whichever is greater
Expiratory Tidal Volume (VTE)	Range: 0 to 2500 mL Resolution: 1 mL. Error of ±20 mL or actual value ±15%, whichever is greater
Minute Ventilation (MV)	Range: 0 to 60 L / min Resolution: 0.1 L / min. Error of ±1 L/min or actual value ±15%, whichever is greater
Spontaneous Minute Ventilation (MVspn)	Range: 0 to 60 L / min Resolution: 0.1 L / min. Error of ±1 L/min or actual value ±15%, whichever is greater

Respiratory Rate (ftotal)	Range: 0 to 100 bpm Resolution: 1 bpm. Error of ±2 bpm or actual value ±10%, whichever is greater
Spontaneous Breathing Frequency (fspn)	Range: 0 to 100 bpm Resolution: 1 bpm. Error of ±2 bpm or actual value ±10%, whichever is greater
Peak Airway Pressure (Ppeak)	Range: 0 to 100 cmH_2O Resolution: 1 cmH_2O. Error of ±(2% + 4% of full scale actual reading)
Mean Airway Pressure (Pmean)	Range: 0 to 100 cmH_2O Resolution: 1 cmH_2O. Error of ±(2% + 4% of full scale actual reading)
Inspiratory Plateau Pressure (Pplat)	Range: 0 to 100 cmH_2O Resolution: 1 cmH_2O. Error of ±(2% + 4% of full scale actual reading)
Minimum Airway Pressure (Pmin)	Range: -20 to 100 cmH_2O Resolution: 1 cmH_2O. Error of ±(2% + 4% of full scale actual reading)
Compliance (Cdyn)	Range: 0 to 300 mL/cmH_2O Resolution: 1 mL/cmH_2O. Error of ±20% or ± 5 mL/cmH_2O, whichever is greater
Airway Resistance (Rst)	Range: 0 to 600 cmH_2O / (L / S) Resolution: 1 cmH_2O / (L / S). Error of ±20% or ±5 cmH_2O, whichever is greater
Fresh Gas Flow of O_2	Range: 0.2 to 15 L/m Resolution: 0 to 1 L/m: 0.01 L/m 1 to 15 L/m: 0.1 L/m
Fresh Gas Flow of N_2O	Range: 0 to 12 L/m Resolution: 0 to 1 L/m: 0.01 L/m 1 to 12 L/m: 0.1 L/m
Fresh Gas Flow Rate of AIR	Range: 0 to 15 L/m Resolution: 0 to 1 L/m: 0.01 L/m 1 to 15 L/m: 0.1 L/m
FiO_2	Range: 15 to 100% Resolution: 1%. Error is ±(2.5% +2.5% of full scale actual reading)
$EtCO_2$ (Optional)	Range: 0 to 100 mmHg Resolution: 1 mmHg. Error is ±(0.43% of the volume percentage +8% of the gas concentration) - equivalent to the optional units used to monitor kPa and mmHg.
Inhalation of Carbon Dioxide (Optional)	Range: 0 to 100 mmHg Resolution: 1 mmHg. Error is ±(0.43% of the volume percentage +8% of the gas concentration) - equivalent to the optional units used to monitor kPa and mmHg.
MAC Values (Optional)	Range: 0 to 10 Resolution: 0.01

Respiratory Rate	Range: 1 to 100 bpm Increments: 1 bpm
Inspiratory Rate	Range: 0.1 to 10.0 seconds Increments: 0.1 seconds
Respiratory Ratio (I:E)	Range: 30:1 to 1:150 Resolution: 0.1. Error of ±20%
Inspiratory Pause	Range: 0 to 60% Increments: 5%
PEEP	Range: 0 to 100 cmH_2O Resolution: 1 cmH_2O. Error of ±(2% + 4% of full scale actual reading)
Pressure Support	Range: 0 to 70 cmH_2O Increments: 1 cmH_2O
Pressure Control	Range: 5 to 70 cmH_2O Increments: 1 cmH_2O
Flow Trigger	Range: 1 to 20 L/min Increments: 0.1 L/min
Pressure Trigger	Range: 1 to 20 cmH_2O Increments: 1 cmH_2O
PSV Insp Termination Level	4 Range: 5 to 80% Increments: 5% hours
Ventilator Monitoring	
Standard Parameters	PEEP, Pmean, Pplat, Pmin, Ppeak, VTi, Vte, Fspn, MV, MVspn, Rst, Cdyn, I:E, FiO_2
Optional Parameters	Multi-Gas: MAC, Fi N_2O, EtN_2O, Fi CO_2, $EtCO_2$, Fi AA, EtAA SpO_2: SpO_2, Pulse, PI
Standard Waveforms	Flow, Volume, PAW, P-V (Loop), V-F (loop), P-F (loop)
Optional Waveforms	Multi-Gas: AA, CO_2, N_2O SpO_2: Pleth, PI
Anaesthetic Gas Monitoring	
Type	Dräger Sidestream
Sampling Rate	200 ± 20 mL/min
Automated Cyclical Zeroing and Duration	Zeroing: Once per day (first zeroing 35 minutes after power on, then once every 24 hours) Duration: ≤20 s
O_2 (Paramagnetic) if fitted	Range: 0 to 100 Vol.% Accuracy: ±(2.5 Vol.% +2.5 % rel.) Rise time (t10 ... 90): <500 ms
CO_2	Range: 0 to 13.6 Vol.% Accuracy: ±(0.43 Vol.% +8 % rel.) Rise time (t10 ... 90): <300 ms
N_2O	Range: 0 to 100 Vol.% Accuracy: ±(2 Vol.% + 8% rel.) Rise time (t10 ... 90): <300 ms

Anaesthetic Gases (Range)	Halothane: 0 to 8.5 Vol.% Isoflurane: 0 to 8.5 Vol.% Enflurane: 0 to 10 Vol.% Sevoflurane: 0 to 10 Vol.% Desflurane: 0 to 20 Vol.% Accuracy: ±(0.20 Vol.% +15 % rel.) Rise time (t10 ... 90): <450 ms
Operational Characteristics	
Voltage Input Range	12.0 V to 32.0 V -5 % +10 %
Power Consumption	Steady state ≤6 W (depending on variant) Warm up ≤18 W (depending on variant)
Data Sample Rate	20 ms (depending on setting)
Data Transfer Rate	19,200 kB/s (configurable)

Alarms

Settings	
Tidal Volume	High: 10 to 2000 ml, OFF Low: OFF, 10 to 1600 ml
Minute Ventilation	High: 1 to 99 l Low: 0 to 98 l
Respiratory Rate	High: 1 to 100 bpm Low: 0 to 99 bpm
Airway Pressure	High: 10 to 99 cmH_2O Low: 1 to 98 cmH_2O
Apnea Alarm	Range: 10 to 60 seconds Increments: 1 second
FiO_2 (Optional)	High: 19 to 100%, OFF Low: 18 to 99%
$EtCO_2$ (Optional)	High: 0.1 to 13.3% Low: 0 to 13.3%
$FiCO_2$ (Optional)	High: 0.1 to 13.3%
Inhalation Anaesthetic Gas (Optional) - Upper Limit	Sevoflurane: 0.1 to 9.9%, OFF Isoflurane: 0.1 to 7.9%, OFF Halothane: 0.1 to 7.9%, OFF Enflurane: 0.1 to 7.9%, OFF Desflurane: 0.1 to 19.9%, OFF
Inhalation Anaesthetic Gas (Optional) - Lower Limit	Sevoflurane: 0 to 9.8% Isoflurane: 0 to 7.8% Halothane: 0 to 7.8% Enflurane: 0 to 7.8% Desflurane: 0.1 to 19.8%
End Tidal Anaesthetic Gas (Optional) - Upper Limit	Sevoflurane: 0.1 to 9.9%, OFF Isoflurane: 0.1 to 7.9%, OFF Halothane: 0.1 to 7.9%, OFF Enflurane: 0.1 to 7.9%, OFF Desflurane: 0.1 to 19.9%, OFF
End Tidal Anaesthetic Gas (Optional) - Lower Limit	Sevoflurane: 0 to 9.8% Isoflurane: 0 to 7.8% Halothane: 0 to 7.8% Enflurane: 0 to 7.8% Desflurane: 0.1 to 19.8%
Pulse (Optional)	Upper limit: 31 to 250 bpm Lower limit: 30 to 249 bpm
SpO_2 (Optional)	Upper limit: 50 to 99%, OFF Lower limit: 49 to 99%
PI (Optional)	Upper limit: 0.1 to 20% Lower limit: 0 to 19.9%

Anaesthetic Agent Delivery

Vaporizer Mounting	
Vaporizers	Sigma Delta and Sigma EVA (Sev, Iso, Hal, and Des)
Number of Positions	Two
Type	Selectatec® compatible backbar

Sigma Delta Vaporizer

Dimensions	
Cagemount	219 × 133 × 158 mm (H x W X D)
Selectatec compatible	242 × 120 × 190 mm (H x W X D)
Dräger compatible	242 × 100 × 190 mm (H x W X D)
Physical Specification	
Weight	4.8 kgs
Volume	Min: 35 ml Max: 250 ml
Anaesthetic Agents	Sevoflurane, Isoflurane, Halothane
Filling Systems	Key fill, Quik-Fil or Pour fill
Concentration Control Dial Scale	0 to 2% vol, increments of 0.2% ≥2%+, increments of 0.5%
Environmental	
Operating Temperature	Sev: 15 to 40°C (58 to 104°F) Iso: 15 to 35°C (58 to 95°F) Hal: 15 to 35°C (58 to 95°F)
Operating Temperature	-5 to 40°C (23 to 104°F)
Transport Temperature	-5 to 40°C (23 to 104°F)
Atmospheric Pressure	11.5 to 110 kPa

Flow range	
Operating flow	0.2 to 15 L/min
Pressure Range	
Operating Pressure Range	0 to 5 kPa (0 to 0.7 psi)
Maximum Manifold Pressure	38 kPa (5.5 psi)
Maximum Test Pressure	38 kPa (5.5 psi)

Electrical Specification

Power	
Input Voltage	100 to 240 V
Input Frequency	50/60 Hz
Overload Protection	10A thermal circuit breaker
Power Cable	3 m permanently attached lead
Power Outlets	4 (3 × rear, 1 × front) 2A max. per outlet
Fuses	T2AH 250 V ceramic (5 × 20 mm) high breaking capacity (on live and neutral on each outlet)
Electromagnetic Compatibility	Meets the requirements of EN 60601-1-2
Battery Back Up	
Type	Ni-MH
Back Up Power	90 minutes, approximate
Charge Time	4 hours
Battery	GRPH-18670 8400P 12 V

Pneumatic Specification

Auxiliary Common Gas Outlet (ACGO)	
Connector	22 mm male taper with coaxial 15 mm female taper connections
Gas Supply	
Pipeline Supply Pressure	280 to 600 kPa (40.6 to 87.0 psig)
Territory Specific Pipeline Connections	UK/Europe: NIST USA: DISS Australia: SIS
Connections	3 × Pipeline, with inlet filter Up to 3 × Pin-indexed cylinder, with inlet filter
Regulator Diaphragm Bursting Pressure	2800 kPa (406 psig)
Pipeline Flow Rate	Air/O_2: 40 to 100 L/min N_2O: ≤ 15 L/min
Cylinder Supply Pressure	19,985 kPa (2900 psig)
Fresh Gas Safety Valve	90 cmH_2O
Reduced pressure from regulator (at 5 L/min) - UK	310 kPa + 15 kPa / -35 kPa (45 psig + 2 psig / -5 psig)
Reduced pressure from regulator (at 5 L/min) - US/ Canada/Japan	380 kPa + 15 kPa / -35 kPa (55 psig + 2 psig / -5 psig)
Reduced pressure from secondary regulators (at 5 L/min) - O_2 and N_2O	152 to 241 kPa (22 to 35 psig)
Reduced pressure from secondary regulators (at 5 L/min) - Air	207 to 283 kPa (30 to 41 psig)
Auxiliary Gas Outlets	
Connections	2 × O_2, self-sealing 2 × Air, self-sealing
Supply Pressure	Pipeline: Supply pressure Cylinder: Reduced pressure from the cylinder supply secondary regulator
Flow Rate	60 L/min (maximum) per gas
Auxiliary Oxygen Flowmeter	
Range	0 to 10 L/min
O_2 Control	
O_2 Flush Range	25 to 75 L/min when button is fully depressed
Gas Mixer	
Type	Electronic
Anti-Hypoxic Fresh Gas Mixture	
Type	Electronic
Minimum O_2 concentration	25% +5%/-4% (of total O_2 and N_2O flow) minimum 21% O_2

Environmental

Operating Conditions	
Temperature	+10 to 40°C (50 to 104°F)
Atmospheric Pressure	70 to 106 kPa
Altitude	2438 m (8000 feet) maximum
Humidity	10 to 95% R.H. non-condensing
Transport and Storage Conditions	
Temperature	-5 to 40°C (23 to 104°F)
Atmospheric Pressure	50 to 106 kPa
Humidity	10 to 85% R.H. non-condensing
Electromagnetic Compatibility	
Immunity	Meets the requirements of EN 60601-1-2
Emissions	CISPR 11 group 1 class A
Approvals	EN 60601-1-2, 80601-2-13
European Notified Body	CE 0088

Breathing System/Absorber

CO_2 Absorber	
Absorbent Volume	1.5 L
Absorbent Type	Loose fill
Heater	Yes, integrated
APL Valve	
Range	Yes, Min. to 70 cmH_2O integrated
Bag/Vent Switch	
Type	Toggled bi-stable switch
Breathing System	
Valves	Visible inspiratory and expiratory check valves
Pressure Gauge	
Range	-2 to 10 kPa (-20 to 100 cmH_2O)
Cleaning and Disinfection	
O_2 Sensor (Cleaning)	Wipe with mild detergent, dry with a lint-free cloth
All parts of the breathing circuit except the O_2 sensor (Disinfecting)	Wash with mild detergent, soak for 30 minutes in 30 to 41°C detergent (pH 7.0 to 10.5)
All parts of the breathing circuit except the O_2 sensor, airway pressure gauge and relief valve assembly (Sterilisation)	Autoclave at a maximum temperature of 121°C for a minimum of 15 minutes and a maximum of 30 minutes.

Anaesthetic Gas Scavenging System (AGSS)

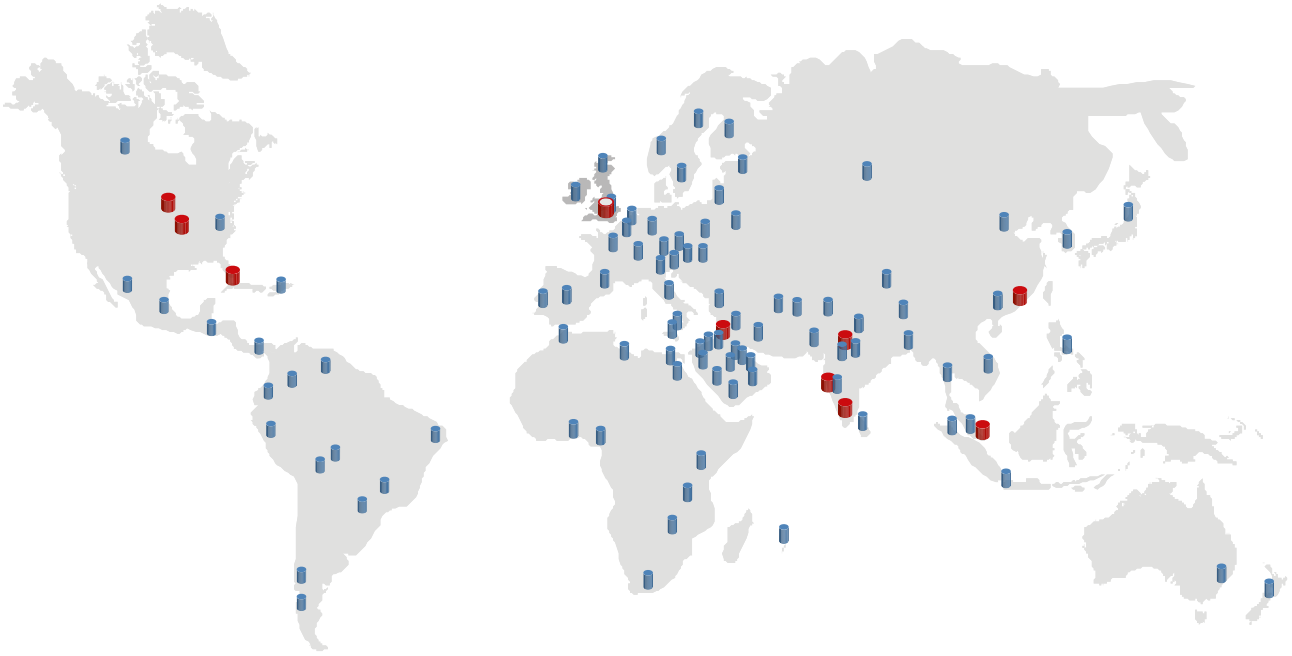
Physical	
Type	Active
Type of Disposal System	For use with a high flow rate disposal system
Dimensions	420 × 77 × 99 mm (H × W × D)
Mounting	Side of the system
Safety Indicator	If the flow rate falls below 60 L/min, the float will fall below the bottom of the window

About Penlon

Penlon was founded in 1943 by personnel from the Department of Anaesthesia at Oxford University. One of the first products was the Macintosh Laryngoscope, then a revolutionary design, and still the most widely used today, invented by the late Sir Robert Macintosh, Professor of Anaesthetics.

Today Penlon continues to design, engineer and build high quality anaesthesia products at its UK operations headquarters. The company is proud to have over 70 years' dedicated experience, many awards for product design, and an impressive four Queen's Awards for Enterprise, one for 'Innovation' and three for 'International Trade'.

Penlon devices feature intuitive user interfaces that require minimal operator training, putting clinicians in control, enabling them to focus on what is most important – patient safety and wellbeing.



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EC Certificate Full Quality Assurance System: Certificate GB20/965349

The management system of

Penlon Limited

Abingdon Science Park, Barton Lane, Abingdon, Oxfordshire, OX14 3NB, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 01 December 2020 until 13 October 2023
and remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 03 January 2017
and first certified by SGS Belgium NV since 28 February 2020

Certification is based on reports numbered GB/PC 240635

Authorised by

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Penlon Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 6

Detailed scope

Non-sterile anaesthesia and anaesthetic equipment, insufflation equipment, patient monitoring, oxygen therapy systems and medical hose assemblies.
Oxygen therapy flowmeters & bubble humidifiers;
AVS Ventilator, AVS MRI Ventilator & Nuffield 200 Ventilator;
Anaesthesia workstations with integrated ventilator - Prima 300 range:
Prima 320 / Prima 330e / Prima 320 Advance / Prima 325/Prima 465
Anaesthesia workstation Prima 400 series:
Prima 440, Prima 445, Prima 450, Prima 451 MRI, Prima 460, Prima 465;
A200 SP Absorber & A200SP MRI Absorber for use as part of a closed breathing system for anaesthesia;
Sigma EVA Vaporizer, Sigma Delta Vaporizer & Sigma Delta MRI Vaporizer for the provision of accurate concentrations of the anaesthetic drugs into the fresh gas supply;
Penlon Oxygen Therapy Range to provide controlled flow of humidified Oxygen to be administered to a patient:
AnaVue 4000 Patient Monitor
ESO 2 Emergency Ventilator restricted for the treatment of COVID-19 (SARS-CoV-2)
Vivid Vue Patient Monitors range models: Vivid Vue 8, Vivid Vue 10 and Vivid Vue 12

Appendix Page to note following devices:
Class IIa devices
- **Oxygen Therapy Flowmeters & Bubble Humidifiers**
- **Medical Hose assemblies**

Class IIb devices
- **AVS Anaesthesia Ventilator and Accessories**
- **AVS MRI Anaesthesia Ventilator and Accessories**
- **Nuffield 200 Ventilator and accessories**
- **Prima 320 Anaesthetic Machine and Accessories**
- **Prima 320 Advance Anaesthetic Machine and Accessories**
- **Prima 325 Anaesthetic Machine and Accessories**
- **Prima 330e Anaesthetic Machine and Accessories**
- **Prima 450 Anaesthetic Machine and Accessories**
- **Prima 460 Anaesthetic Machine and Accessories**
- **Prima 465 Anaesthesia Machine and Accessories**
- **Prima 440 Anaesthetic Machine and Accessories**

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Penlon Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 6

Detailed scope

• Prima 445 Anaesthetic Machine and Accessories
• Prima 451 MRI Anaesthetic Machine and Accessories
• A200SP Absorber and Accessories
• A200SP MRI Absorber and Accessories
• Sigma Delta Vaporizers and Accessories
• Sigma Delta MRI Vaporizers and Accessories
• Sigma EVA Vaporizer
• AnaVue 4000 Patient Monitor and Accessories
•ESO 2 Emergency Ventilator restricted for the treatment of COVID-19 (SARS-CoV-2)
•Vivid Vue Patient Monitors range models: Vivid Vue 8, Vivid Vue 10 and Vivid Vue 12 and Accessories

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

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Certificate GB20/965272

The management system of

Penlon Limited

Abingdon Science Park, Barton Lane, Abingdon,
Oxfordshire, OX14 3NB, UK

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, Manufacture, Inspection, Service & commissioning of Anaesthesia and Anaesthetic Equipment and accessories; suction, airway management and insufflation equipment and accessories, and patient monitoring equipment and accessories.

This certificate is valid from 10 February 2020 until 13 October 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 13 October 2021
Issue 1. Certified since 19 December 2016

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