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

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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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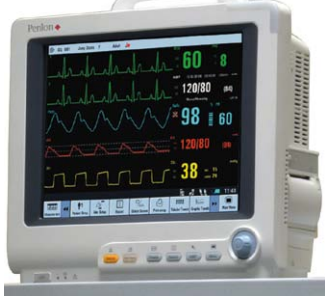
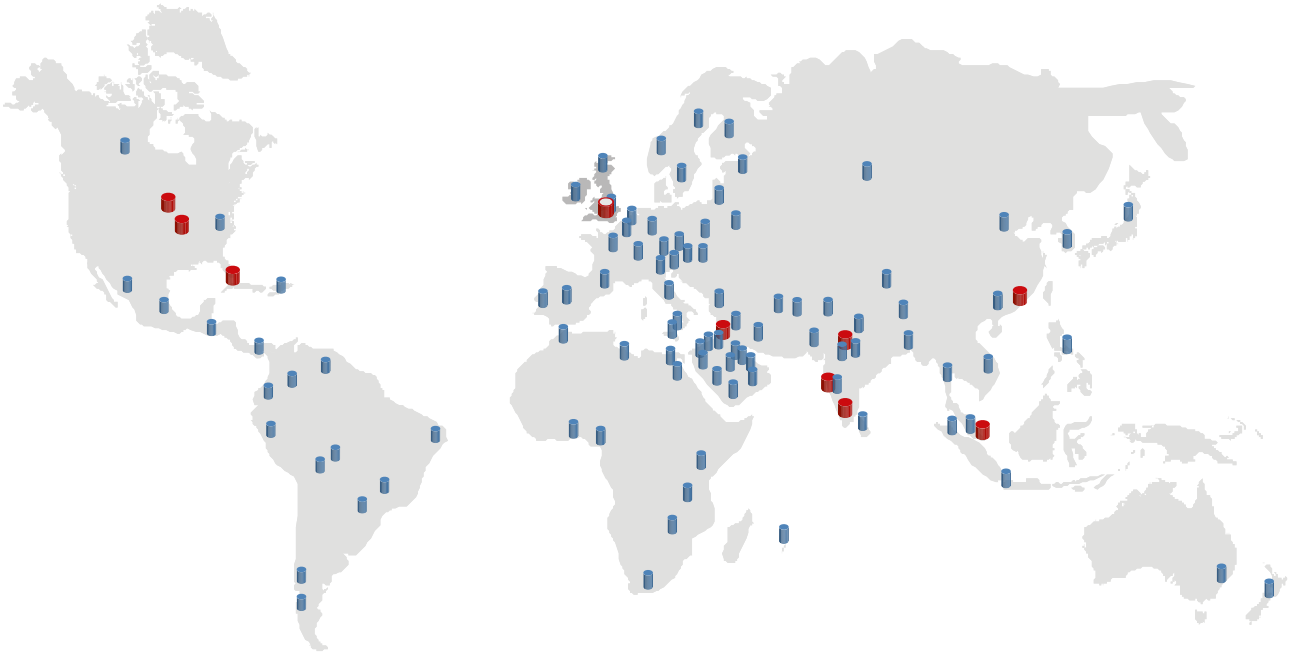


About Penlon

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

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

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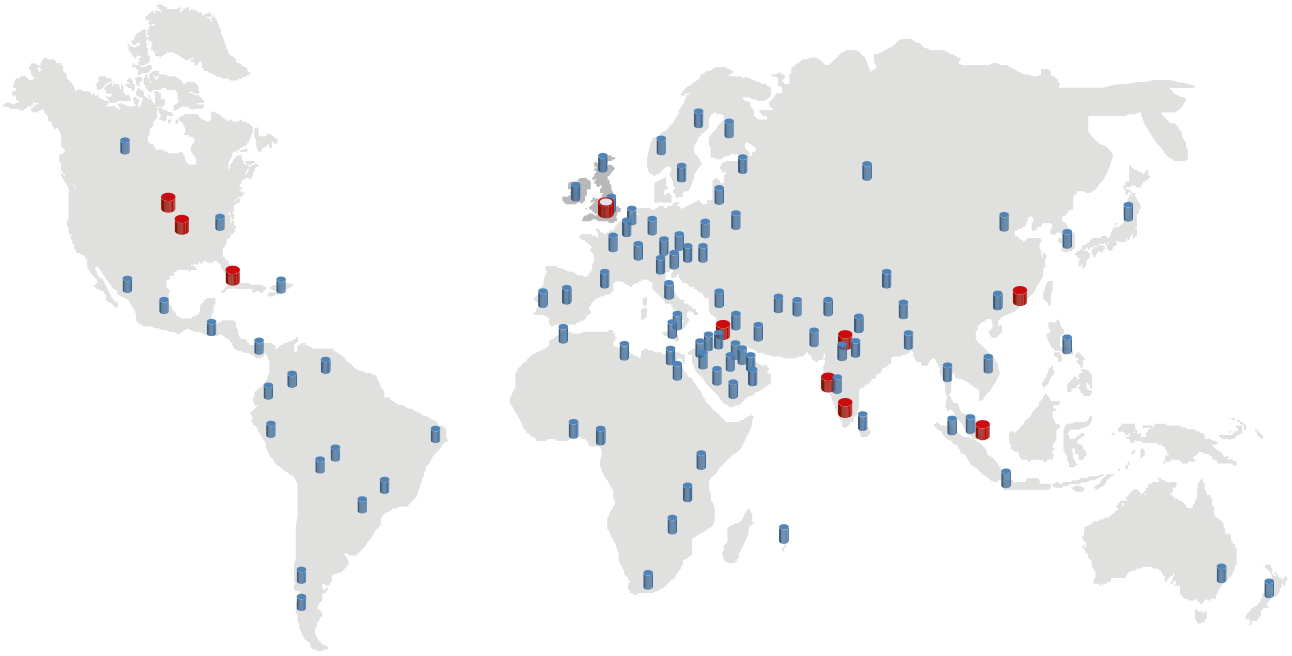

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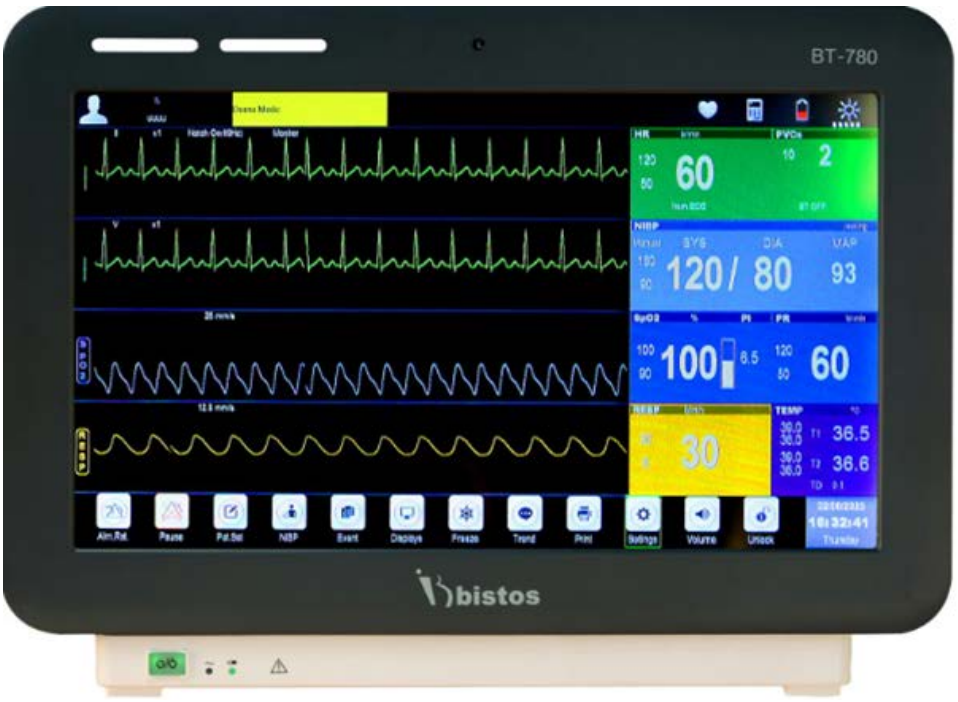
BT-780 PATIENT MONITOR



15.6" Multi-Parameter Patient Monitor

ECG, Resp., SpO_2, NIBP, Temperature

Optional CO_2, IBP, Multi-gas, C.O., Masimo SpO_2

Touch screen

Central station / Ultra slim design / Over 5 hours battery use

Dual Screen Central monitoring station

Technical Specification

Model			BT-780
Category			**Patient Monitor**
Display			15.6" Color Touch LCD
ECG	Lead Type		3/5 lead
	Gain Selection		x0.125, x0.25, x0.5, x1, x2, x4, auto
	Sweep Speed (mm/s)		12.5, 25, 50
	Bandwidth : Diagnostic Mode		0.05-100 Hz
	Monitoring Mode		0.5-40 Hz
	Surgery Mode		1-25 Hz
	Strong Mode		5-20 Hz
	Heart Rate Range (bpm)		Adult : 15-300
			Pediat / Neonate : 15-350
Resplration	Method		Trans-thoracic Impedance
	Measurement Range		0-120 rpm
	Sweep Speed (mm/s)		6.25, 12.5, 25
SpO_2	Measurement Range		0-100 %
	Accuracy (70-100%)	Adult / Pediatric	±2 %
		Neonate	±3 %
	Accuracy (0-69%)		Unspecfied
	Perfusion Index		0.05-20 %
	Pulse Rate Range (bpm)		25-250
NIBP**	Method		Automatic Oscillometric
	Operation Mode		Manual / Auto / STAT
	Parameter		Systolic, Diastolic, Mean
	Systolic Range (mmHg)	Adult	30-280
		Pediatric	30-230
		Neonate	30-145
	Diastolic Range (mmHg)	Adult	10-220
		Pediatric	10-165
		Neonate	10-105
	Mean Range (mmHg)	Adult	10-240
		Pediatric	10-175
		Neonate	10-115
Temperature	Range		0-50 ˚C (41 to 122 ˚F)
	Parameter		T1, T2, and TD
IBP*	Channel		2 Channel / 4 Channel
	Range (mmHg)		-50 to 400
Printer*	Type		Themal dot array
	Print Speed (mm/s)		12.5, 25, 50
	Paper size (mm)		50
CO_2*	Method		Masimo ISA / Bistos
	Range		Masimo IRMA / Bistos
Multi-gas/O_2*			Masimo ISA
SpO_2-Masimo*			Masimo SpO_2
CO_2*	Method		Thermodilution
	Range		0.2-20 L/min
Battery	Type (capacity)		Li-ion (4400 mAh)
	Run Time		5 hour
	Charging Time		4 hour
PC Software Interface			RJ45, USB, Nursing call
Warranty			2 year

bistos

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Specifications : BT-780 15.6" Multi-parameter Patient Monitor

Functional Characteristics	
Display	
Type	Color TFT touch screen LCD
Size and resolution	15.6", 800 x 600 pixels
LED	
Alarm indicator	Yellow & red
Adaptor power indicator	1 green
Battery status indicator	1 green
Audio	
Speaker	Alarm sound (45 ~ 85dB), key pressing sound
	QRS sound, PR sound
	Alarm sound meets the IEC60601-1-8
Data Storage	
Trend	168hours, resolution : 1min
Alarm event	200 physiological and 100 technical alarm events
NiBp measurement result	1,000 groups
Function	
Multi-language	English,Turkish,Spanish, French, Polish, German, Italian, Hungarian
Trend	Graphic/tabular
Alarm	
Mode	Visual, audible, information, parameter flashing
Alarm delay	Off, 1s, 2s, 3s, 4s, 5s, 6s, 7s, 8s
Pause duration	1, 2, 3, 4, 5, 10, 15min or permanent
System	Low battery
Interface	
Auxiliary	Nurse call
RJ45 (LAN)	CMS
USB	S/W upgrade
ECG	
Standard compliance	IEC60601-2-27
Lead type	5Lead : I, II, III, aVR, aVL, aVF, V
	Upgradable to 12-lead
Wave gain	Auto, x0.25, x0.5, x1, x2, x4mm/mV
Wave sweep speed	12.5, 25, 50mm/s
Band width	Diagnostic mode : 0.05 ~ 100Hz
	Monitoring mode : 0.5 ~ 40Hz
	Surgery mode : 1 ~ 25Hz
CMRR	> 100dB
Notch	50/60Hz (can be set on or off)
Differential input	> 5MΩ
Electrode polarization voltage range	±400mV
Baseline recovery time	< 5s after defibrillation (monitor and surgery mode)
Calibration signal	1mV (peak-peak), accuracy ±3%
Lead-off detection current	Measuring electrode : < 0.1μA
	Drive electrode : < 1μA
HR measuring range	Adult : 15 ~ 300bpm
	Pediatric/Neonate : 15 ~ 350bpm
HR measuring resolution	1bpm
HR measurement accuracy	±1bpm or ±1%, whichever is greater
HR accuracy & response to irregular rhythm	Ventricular bigeminy : 80±1bpm
	Slow alternating ventricular bigeminy : 60±1bpm
	Rapid alternating ventricular bigeminy : 120±1bpm
	Bidirectional systoles : 90±2bpm
HR time to alarm for tachycardia	0.5/1/2mV, 206bpm ventricular tarchycardia : < 10s
	1/2/4mV, 195bpm ventricular tarchycardia : < 5s

HR alarm upper limit (bpm)	Adult : 16 ~ 300, 1bpm step
	Pediatric/Neonate : 16 ~ 350, 1bpm step
HR alarm lower limit (bpm)	Adult : 15 ~ 299, 1bpm step
	Pediatric/Neonate : 15 ~ 349, 1bpm step
Pacing pulse identification	Detection range : ±2mV ~ ±700mV
	Pulse width : 0.2ms ~ 2.0ms
Pacing pulse average HR	15s data
Pacing pulse interval of HR Refreshing	Every second
Pacing pulse HR change response time	≤ 10sec
Pacing pulse tall T-wave suppression	2mV
Alarm	Communication, configuration, selfcheck error
	Lead off
	HR high/low, PVCS high
	Asystole, VF/VTA, R on T, Tachycardia/bradicardia, PVC frequent/couplet/singlr/bigeminy/trigeminy, Miss Beat
	Pacemaker not capture/work
	Signal weak, ST-I, II, II high/low
Respiration	
Measurement method	Trans-Thoracic impedance
Operation modes	Auto
Measuring lead	Lead RA-LA, RA-LL, LA-RL, LL-RL
Wave gain	X0.5, x1, x2
Respiratory impedance range	0.2 ~ 3 Ω
Base line impedance	500 ~ 2,000Ω
Sensitivity	1,2,3,4,5
Wave sweep speed	6.25mm/s, 12.5mm/s, 25mm/s
Measurement accuracy	±2rpm
Measurement range	0 ~ 120rpm
Bandwidth	0.3 to 2 Hz(-3dB)
Alarm	RR high/low
	Apnea
	Respiration artifact
Temperature	
Standard compliance	ISO80601-2-56
Measurement method	Thermistor
Measuring range	0℃ ~ 50.0℃ (32°F ~ 122.0°F)
Resolution	0.1℃
Measurement accuracy	±0.1℃ or ±0.2°F (without probe)
Number of channel	2
T1/T2 alarm upper limit	0.1℃ ~ 50.0℃, 0.1℃/°F step
T1/T2 alarm lower limit	0℃ ~ 49.9℃, 0.1℃/°F step
Temperature difference alarm upper limit	0℃ ~ 50.0℃, 0.1℃/°F step
Alarm	T1, T2 Sensor off
	T1/T2 high/low, TD high
NiBp	
Standard compliance	IEC80601-2-30
Measurement method	Automatic oscillometric method
Operating mode	Manual, automatic, continuous(STAT)
Useful life	100,000times
Measurement interval in automatic mode	1/2/3/4/5/10/15/30/60/90/120/180/240/480min
Typical measurement time	20~40s
Normal mode measuring range (mmHg)	Systolic : Adult(30~280), Pediatric(30~230), Neonate(30~145)
	Mean : Adult(10~240), Pediatric(10~175), Neonate(10~115)
	Diastolic : Adult(10~220), Pediatric(10~165), Neonate(10~105)
Measurement accuracy	Maximum average error: ±5mmHg
	Maximum standard deviation: 8mmHg
Resolution	1mmHg

Initial inflation pressure (mmHg)	Adult : 160(default) Pressure setting range:140mmHg, 160mmHg, 180mmHg
	Pediatric : 140(default) Pressure setting range:140mmHg, 160mmHg
	Neonate : 100(default) Pressure setting range:100mmHg, 120mmHg
Overpressure protection point (software)	Adult: 300mmHg
	Pediatric: 240mmHg
	Neonate: 150mmHg
Overpressure protection point (hardware)	Adult: 320~330mmHg
	Pediatric: 265~275mmHg
	Neonate: 160~165mmHg
Static Pressure accuracy	±3mmHg
Supply voltage	10V~14VDC
Maximum power consumption	3.6W
Quiescent current	50mA
Maximum current during measurement	180mA
Maximum current during inflation	300mA
Alarm	Communication, selfcheck, CFG error
	System error, measurement timeout
	Cuff loose, no, leak, type error
	Air pressure error
	Over range, signal weak/unstable/saturated
	Over pressure
	Module reset failed
	Systolic, mean, diastolic high/low
SpO2	
Standard compliance	ISO80601-2-61
Display range	0% ~ 100%
SpO2 display resolution	1%
SpO2 accuracy	Adult/Pediatric : 70 ~ 100% ±2%
	Neonate : 70 ~ 100% ±3%
	0 ~ 69% : Unspecified
Wave sweep speed	12.5mm/s, 25mm/s
Wave mode	Scan, fill
Pulse volume	0, 1, 2, 3, 4, 5, 6, 7, 8, 9 level
SpO2 alarm preset limits	Upper Alarm Limit : 1% ~ 100%
	Lower Alarm Limit : 0% ~ 99%
SpO2 alarm preset accuracy	±1%
SpO2 alerting signal generates delay	Off,1s,2s,3s,4s,5s,6s,7s,8s
SpO2 value refresh period	1s/time
Average period	Low Sensitivity : 7 ~ 8s
	Intermediate Sensitivity : 4 ~ 6s
	Advanced Sensitivity : 2 ~ 3s
Perfusion index	0.05 ~ 20%
PR Measurement Range	25 ~ 250bpm
PR Resolution	±1bpm
PR Measurement accuracy	±2% or ±2bpm, whichever is greater
Alarm	Communication stop/error
	No sensor/ sensor off
	Search timeout
	Search pulse(weak)
	SpO2, RR high/low
IBP (Option)	
Standards compliant	IEC60601-2-34
Channel	2-ch, 4-ch
Pressure measurement range	-50 ~ 400 mmHg

Pressure measurement accuracy	±3 mmHg or±2%, whichever is greater
Pressure resolution	1 mmHg
PR measurement range	35 ~ 250 bpm
PR measurement accuracy	±3bpm
PR resolution	1bpm
Transducer sensitivity	5μV/V/mmHg
Transducer resistance range	300-3,000Ω
Supply voltage	+12VDC
Maximum power consumption	≤5W
Scan speed	12.5mm/s, 25mm/s
Alarm	IBP1, 2 communication stop/error
	IBP1, 2 sensor off
	Art-sys, PA-sys, P1-sys, P2-sys high
	Art-dia, PA-dia, P1-dia, P2-dia high
	Art-mean, PA-mean, CVP-mean, LAP-mean, RAP-mean, ICP-mean, P1-mean, P2-mean high
EtCO2 Mainstream & Sidestream (Option)	
Measurement parameters	EtCO2、FiCO2、AwRR
Measuring range	0-15%
Accuracy	±0.2%+2% of the reading
Resolution	EtCO2/FiCO2 : 1mmHg, AwRR : 1rpm
Rise time	200ms, typical at 50ml/min flow rate
Total response time	within 3 seconds(within 2m Nomoline sampling)
AWRR range	0-150bpm
AWRR Accuracy	±1 breath
Apnea delay	20s, 25s, 30s, 35s, 40s, 45s, 50s, 55s, 60s
Warm-up time	Full accuracy within 10 seconds
Sampling flow rate	50ml/min(+/-10ml/min)
Operating mode	Standby, measure
O2 compensation	Low, mid, high
N2O compensation	On, off
Alarm limit	EtCO2 lower limit : 0~149mmHg
	EtCO2/FiCO2 upper limit : 1~150mmHg
	AWRR lower limit : 0~119rpm
	AWRR upper limit : 1~120rpm
Alarm	Communication stop/error
	CO2 sensor off/error
	O2 sensor error/replace
	adaptor/sampling line no/check
	Parameter accuracy error
	O2, Air calibration error
	S/W, H/W error
	Motor accuracy error
	CO2 factory calibration error
	Adaptor, sampling line replace
	O2 port error
	CO2, O2, N2O out of accuracy
	CO2 temp., pressure out of accuracy
	CO2 zero required
	CO2 zeroing/sleeping
	CO2 module calibrating/calibration error
	EtCO2, FiCO2, AWRR high/low
	Apnea
C.O. (Cardiac Output : Option)	
Method	Thermodilution
Measurement range	C.O. : 0.2 ~ 20 L/min
	BT : 23 ~ 45℃±0.5 ℃
	IT : 0 ~ 20℃±0.5 ℃

Resolution factor	C.O. : 0.1L/min
	BT, IT : 0.1℃
Accuracy	C.O. : ±10%
	TB, TI : ±0.5℃
Scope of alarm limit	BT high limit : (Low limit +0.1) ~ 43℃
	BT low limit : 23.0 ~ (high limit -0.1) ℃
	Step size : 0.1℃
Alarm	BT sensor off
	BT high/low
	C.O. high
Printer (Option)	
Type	Thermal dot array
Print speed	12.5, 25, 50mm/s
Paper size	50mm(W) x 2m
Power	
Power cord	Input : AC 100 ~ 240V (50/60Hz)
	Input Current: 1.6-0.6A
Consumption	13.5W
Rechargeable battery	11.1V Li-ion 4,400mA
	Operating Time : 5hrs
	Charging Time : 4hrs
Standard Configurations	
ECG cables and lead wire	1ea(5lead)
ECG electrode for adult	1pack(25pcs)
SpO2 adult reusable sensor	1ea
SpO2 extension cable	1ea
NiBp adult cuff	1ea
NiBp extension tube	1ea
Temperature sensor	1ea
Earthing cable	1ea
Power cord	1ea
Power cord Bracket	1ea
Fuse	2ea
Operation manual	1ea
Options (Function)	
IBP	Sensor cable & package
EtCO2 Mainstream (Bistos)	Airway adaptor & module
EtCO2 Sidestream (Bistos)	Sampling tube
EtCO2 IRMA Mainstream (Masimo)	Airway adaptor & module
EtCO2 ISA Sidestream (Masimo)	Sampling tube
C.O.	Sensor cable
Printer	Printer & paper
Cart	
Options (Accessory)	
ECG cables and lead wire	5/3 lead
ECG electrode	adult/neonate
SpO2 reusable sensor	adult/pediatric/neonate
SpO2 disposable sensor	adult/pediatric/neonate
Skin & rectal temperature sensor	adult/pediatric/neonate
NiBp cuff	adult(27~35cm)/pediatric(14~21.5cm)/neonate(4*9cm)
Physical Characteristics	
Dimension	
Main unit	320(W) x 65(D) x 250(H)mm
Packing	400(W) x 350(D) x 290(H)mm
Weight	
Main unit	
Packing	
Environmental Conditions	

Operating temperature	10 ~ 40°C (50 ~ 104°F)
Operating humidity	5 ~ 85% non-condensing
Storage temperature	–20 ~ 60°C (–4 ~ 140°F)
Storage humidity	0 ~ 95% non-condensing
Warranty	
2years	
Certificates	
KFDA, CE	

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 25 June 2020 until 13 October 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. 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

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 **f** +32 (0)3 545-48-49 www.sgs.com

Penlon Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 3

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 Monitors
SP M5 and SPM8 Patient Monitors

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
• Prima 445 Anaesthetic Machine and Accessories
• Prima 451 MRI Anaesthetic Machine and Accessories

Penlon Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 3

Detailed scope

- A200SP Absorber and Accessories
- A200SP MRI Absorber and Accessories
- Sigma Delta Vaporizers and Accessories
- Sigma Delta MRI Vaporizers and Accessories
- Sigma EVA Vaporizer
- Penlon Patient Monitor range models: SP M5 and SP M8
- AnaVue 4000 Patient Monitor

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
ESO 2 Emergency Ventilator restricted for the treatment of COVID-19 (SARS-CoV-2)

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.

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

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 **f** +32 (0)3 545-48-49 www.sgs.com

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**

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.

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

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

EC CERTIFICATE
Full Quality Assurance System

Certificate No.: 243269-2017-CE-KOR-NA-PS Rev. 4.0 Project No.: PRJC-533956-2015-MSL-KOR Valid Until: 01 September 2023

This is to certify that the quality system of:

Bistos Co., Ltd.

7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

For design, production and final product inspection/testing of:

Monitoring devices of vital physiological parameters and Utilising non-ionizing radiation

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf

Place and date:
Høvik, 26 April 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Check Validity

Eugenie Winger Husebye
Technical Reviewer

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate EU1308401, Rev2.0 (NB 0470) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	01 September 2017
1.0	EU Rep change	13 April 2018
2.0	Re-certification for Fetal monitor and Neonatal Phototherapy unit (BT-300, BT-350, FM-20, Biocare FM-1, BT-400) Scope extension for pulse oximeter and patient monitor (BT-710, BT-720, BT-740, BT-770) The accessories (Feotal Doppler system probe and Cardiotocograph transducers) are removed (AY-DOP-300, AY-DOP-350, AY-UC-300, AY-UC-350)	01 September 2018
3.0	Editorial change	13 February 2020
4.0	**Scope extension to new model (BT-780)**	**26 April 2021**

Products covered by this Certificate:

Product Description	Product Name	Class
Fetal monitor	▪ BT-200 ▪ BT-350 ▪ FM-20 ▪ Biocare FM-1	IIa
Neonatal Phototherapy unit	▪ BT-400	IIa
Pulse Oximeter	▪ BT-710	IIb
Patient Monitor	▪ BT-720 ▪ BT-740 ▪ BT-770 ▪ **BT-780**	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Bistos Co., Ltd.	7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

EU Representative

OBELIS S.A, Bd. General Wahis, 53, 1030 Brussels, Belgium

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

Management System Certificate

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
243275-2017-AQ-KOR-NA-PS Rev. 2.0	**PRJC-533956-2015-MSL-KOR**	**12 August 2004**	**09 SEPTEMBER 2021**

This is to certify that the management system of:

Bistos Co., Ltd.

7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Design, manufacturing, Sales, Distribution, and servicing of Ultrasound Doppler system, Fetal monitor, Phototherapy, Patient Monitor, Pulse Oximeter, Incubator, Head-worn light, Infant Warmer and Electric Breast Pump.

Place and Date:
Høvik, 12 September 2018

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info