Penlon Prima 320 Advance Anaesthetic Machine

ANAESTHESIA SOLUTIONS

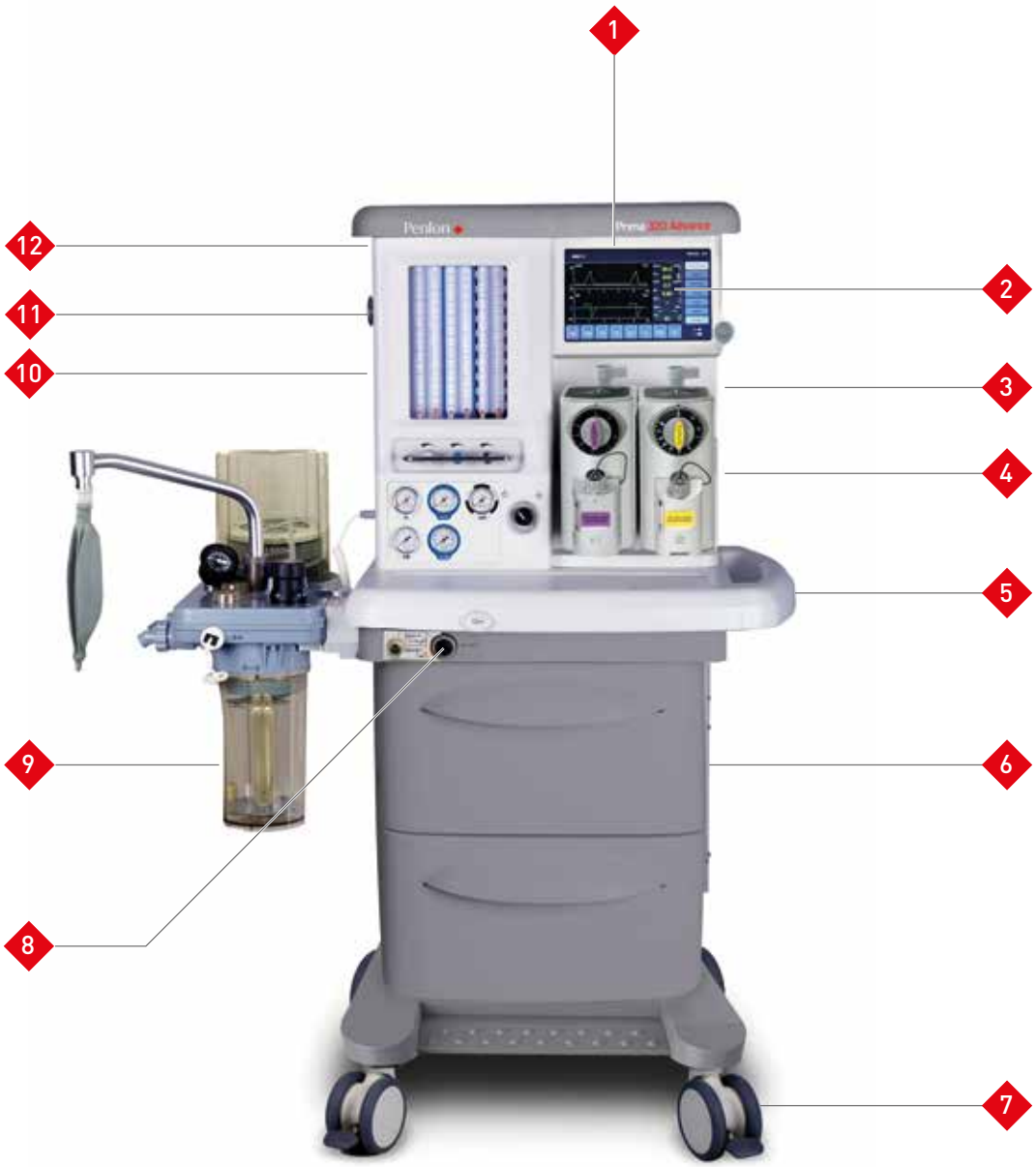
- 10.4" TFT colour touchscreen
- Eight ventilation modes
- Optional Anaesthetic Gas, CO_2 and SpO_2 monitoring
- Integrated CO_2 absorber and bellows unit with ventilator interface
- Selectatec compatible back bar
- Switchable front facing common gas outlet

NOW WITH OPTIONAL MAINSTREAM

Anaesthetic Gas Monitoring

Penlon

Penlon Prima 320 Advance Anaesthetic Machine



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

1. 10.4" TFT colour touchscreen
2. Eight ventilation modes
3. Optional Anaesthetic Gas, N_2O, CO_2 and SpO_2 monitoring
4. Selectatec® compatible backbar (two stations)
5. LED illuminated work spaces
6. Large capacity drawer units
7. Optional central brake
8. Switchable front facing common gas outlet for open and closed circuit operation
9. Integrated CO_2 absorber and bellows unit with ventilator interface
10. GCX™ compatible aluminium uprights for additional accessory mounting
11. Optional auxiliary O_2 outlet
12. Three electrical outlets

The Penlon Prima 320 Advance is a high specification anaesthetic machine providing the ideal solution for today's busy operating room

Clinician-focused choices and benefits, including intuitive 10.4" TFT touchscreen with eight ventilation modes and optional Anaesthetic Gas, CO_2 and SpO_2 gas monitoring

Ventilator Control and Visualisation
10.4" TFT colour touchscreen ventilator display with navigator wheel and audio/visual indicators.

Enhanced Patient Safety
Accurate mechanical anti-hypoxic device and automatic drive gas switching function.

Waveforms and Respiratory Loops
Choice of up to 10 waveform and respiratory loop displays.

Dual Flow Sensors
Inspiratory and expiratory volume measured and displayed on the screen.

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

Gas Monitoring
Optional Mainstream Anaesthetic Gas and Sidestream CO_2 and SpO_2 monitoring.

Alarms
Audible and visual alarms with colour coding to highlight importance.

Electrical Power
Three electrical power outlets to meet your requirements.

Battery BackUp
Provides power to the machine for up to 2 hours, in the event of an AC mains power failure.

Gas Supply Options
Two cylinder yokes (O_2 and N_2O) and three central pipeline connections (O_2, N_2O and Air). O_2/Air ventilator drive gas options.

Auxiliary Common Gas Outlet (ACGO)
Control switch and front outlet for connecting an open breathing circuit.

Active AGSS
Disposes of waste gas and prevents possible health hazards to operating room staff.

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 80601-2-55 and IEC 60601-1.

1 Ventilation Modes
Eight ventilation modes are available (VCV, PCV, PRVC, SPONT/PSV, SIMV-V, SIMV-P, SIMV-PRVC, and Manual) with PEEP available in all modes except Manual.

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 Penlon Patient Monitors
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.

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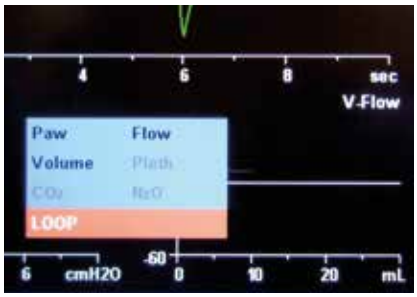
Ventilation Modes

Eight ventilation modes are available as standard (VCV, PCV, PRVC, SPONT/PSV, SIMV-V, SIMV-P, SIMV-PRVC, and Manual) with PEEP available in all ventilation modes except Manual.

Waveform Display

Two user-selectable waveform displays with a choice of Airway Pressure, Flow Rate, Tidal Volume, P–V Loop, V–F Loop, CO_2 or Pleth.



Monitoring

All measured parameters are grouped on-screen in an easily accessible display window, including Anaesthetic Gas, N_2O, CO_2 and SpO_2.

Trends Data

Trend review of parameter values within a specific time period up to 24 hours. User selectable parameter and time scale options.

The Penlon Prima 320 Advance anaesthetic machine provides advanced ventilation modes, accurate control and monitoring capabilities in a cost-effective workstation.

Alarms

User adjustable high and low alarm limits for all measured parameters and 100 event alarm log.

Features and Benefits

Features	Benefits
Cascade flow tubes	Accurate gas delivery, particularly at low flow rates
Multi-mode ventilator	Suitable for multiple patient types and clinical cases
Optional Anaesthetic Gas, N_2O, CO_2 and SpO_2 monitoring	Comprehensive gas monitoring for enhanced economy and patient safety
Integrated heater and water trap on the CO_2 absorber	Reduces the risk of condensation
Absorber CO_2 bypass	Can change absorbent while ventilating a patient
Eight ventilation modes	Comprehensive choice provides optimum patient care
Selectatec back bar	Can be used with any compatible vaporizer
Mechanical anti-hypoxic device and automatic drive gas switching	Enhanced patient safety
Maintenance and after-sales support	Customer peace of mind
Air or O_2 drive gas	Ensures continuous use of ventilator
Territory-specific power outlets	Power external devices
AGS (anaesthetic gas scavenging) system	Alleviates contamination in theatre
Patient cable management arm	Reduces cable clutter
Oxygen therapy outlet	For recovery and added safety
Optional side mounted suction controller kit	Keeps airways clear

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.

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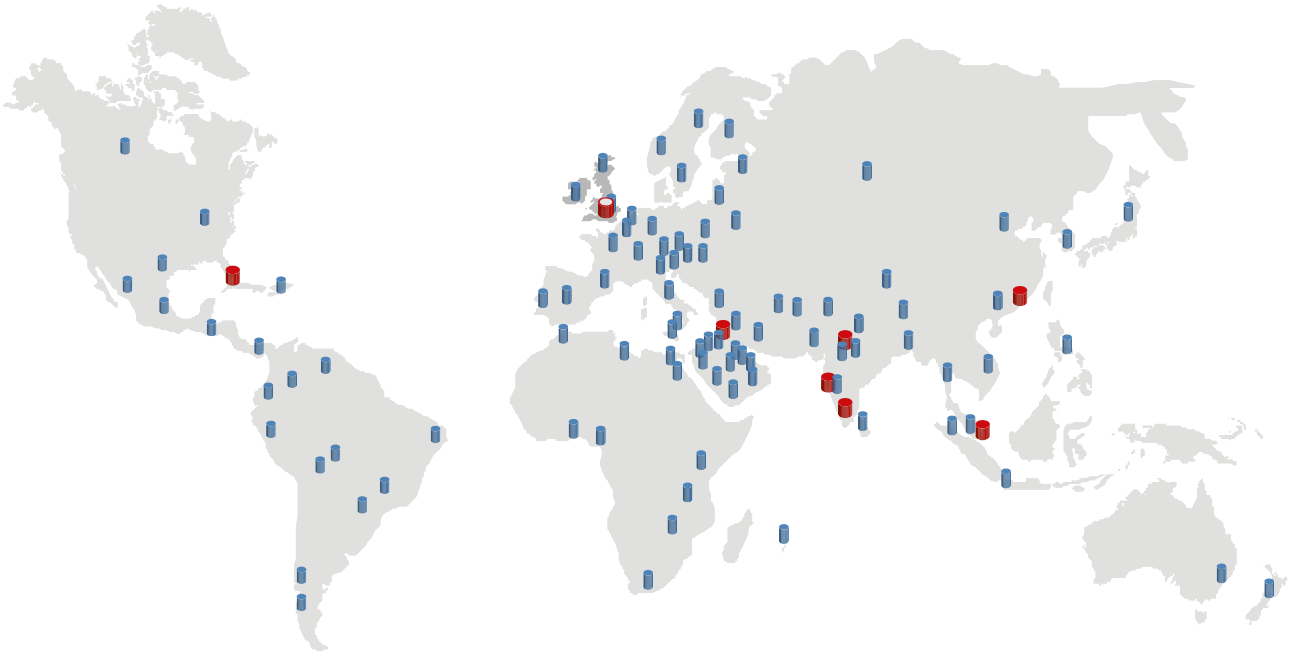
Penlon devices feature intuitive user interfaces that require minimal operator training, putting clinicians in control, enabling them to focus on what is most important – patient safety and wellbeing.



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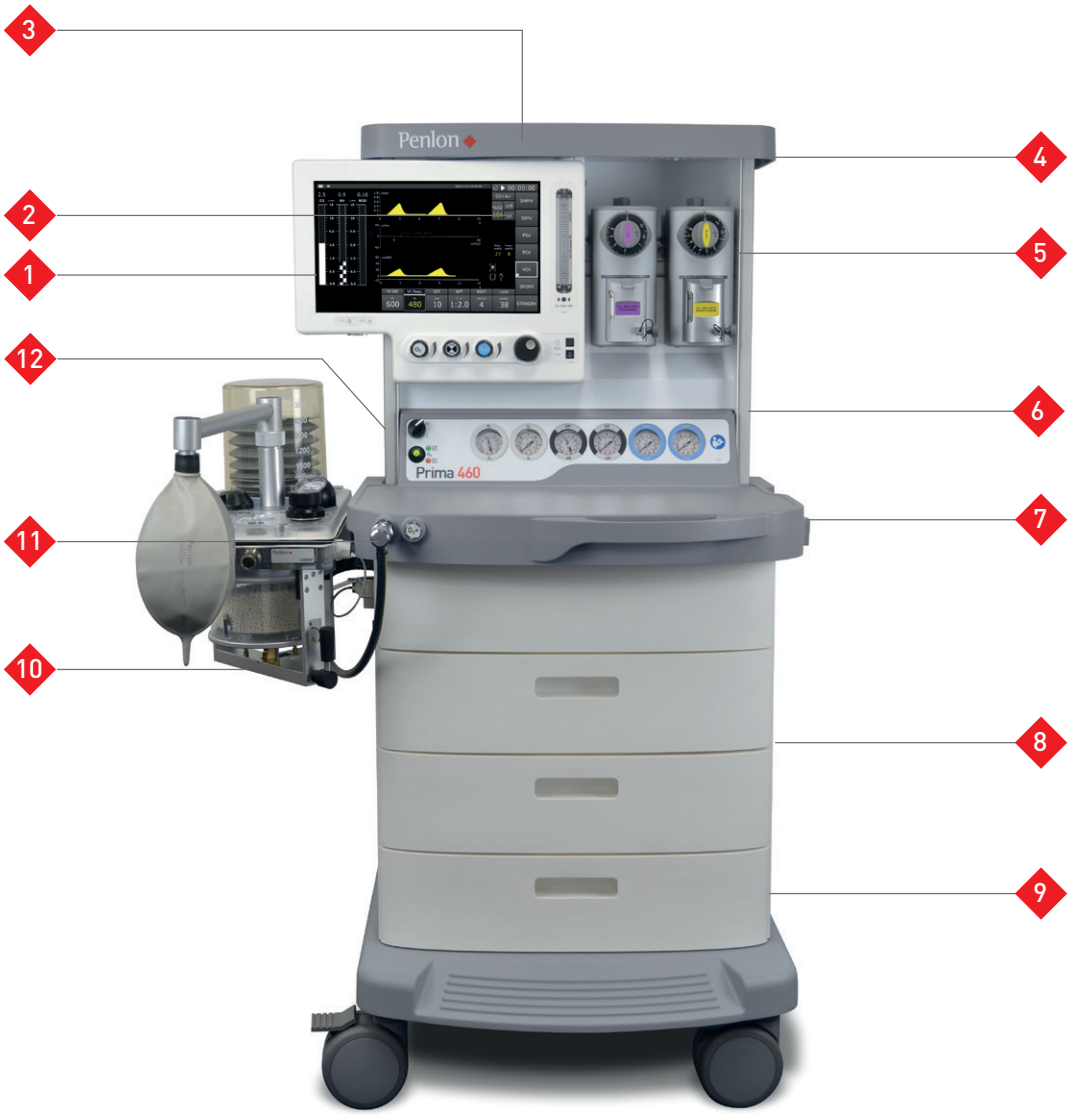
Penlon Prima 460 Anaesthetic Machine

ANAESTHESIA SOLUTIONS

- 15.4" high-definition touchscreen display
- Virtual flowmeter
- Seven ventilation modes with PEEP
- Suitable for adult, paediatric and neonates
- HIS connectivity

Penlon

Penlon Prima 460 Anaesthetic Machine



The features and options you need

1. 15.4" high-definition touchscreen display with intuitive user interface and virtual flow display
2. Seven ventilation modes with PEEP in all modes
3. Versatile top shelf with secure GCX™ mounting system for patient monitors
4. Electrical outlet options
5. Selectatec® compatible backbar (two station)
6. Up to three cylinders
7. Illuminated work space
8. GCX™ compatible aluminium uprights for additional accessory mounting
9. Standardised large capacity drawer units
10. Integrated CO_2 absorber and bellows unit with heater fitted as standard
11. Optional backlit Auxiliary Common Gas Outlet
12. Optional oxygen therapy flowmeter

The Penlon Prima 460 is the latest update to the Penlon anaesthetic machine range, providing the ideal solution for today's busy operating room

Clinician-focused choices and benefits, including intuitive 15.4" high-definition touchscreen with virtual flow display and user-selectable waveform and respiratory loop displays

Flow Control and Visualisation
15.4" high-definition touchscreen display provides virtual flow display, O_2 concentration and gas mixture.

Enhanced Patient Safety
Accurate mechanical anti-hypoxic device, total flow display and backup O_2 gas delivery system.

Waveforms and Respiratory Loops
Airway Pressure plus two user-selectable waveform or respiratory loop displays.

Dual Flow Sensors
Inspiratory and expiratory volume measured and displayed on the screen.

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

Monitoring
Oxygen, pressure and flow monitoring with flexible GCX™ mounting for gas and patient monitors.

Alarms
Audible and visual alarms with colour coding to highlight alarm levels.

Electrical Power
Wide choice of territory-specific electrical power outlets.

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

Gas Supply Options
Up to three cylinder yokes and three central pipeline connections for O_2, N_2O and Medical Air.

Optional Auxiliary Common Gas Outlet (ACGO)
Illuminated switch and front outlet provide visual indication of open breathing circuit.

Active AGSS
Disposes of waste gas and prevents possible health hazards to operating room staff.

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 and the Restrictions of Hazardous Substances (RoHS) Directive.

1 Ventilation Modes
Seven ventilation modes are available (VCV, PCV, PSV, SPONT, SIMV, SMMV and Manual) with PEEP available in all modes except Manual.

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 heater and all 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 Penlon Patient Monitors
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.

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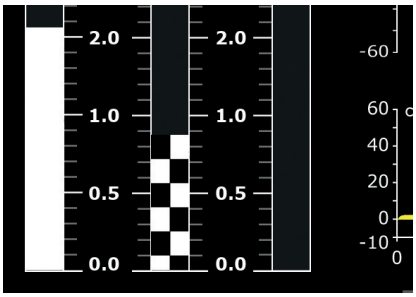
Ventilation Modes

Seven ventilation modes are available as standard (VCV, PCV, PSV, SPONT, SIMV, SMMV and Manual) with PEEP available in all ventilation modes except Manual.

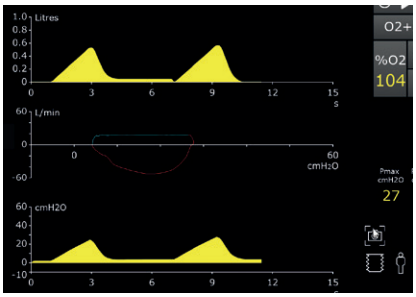
Fresh Gas Control

Fresh gas flow is controlled using a proven conventional control system and mechanical anti-hypoxic device. Gas mixture is displayed using a colour-coded virtual flow display on the touchscreen.



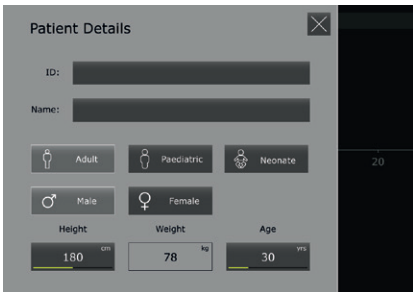
Waveform Display

Airway Pressure plus two user-selectable waveform or respiratory loop displays with a choice of Flow Rate, Tidal Volume, P–V Loop, V–F Loop or P–F Loop.



Patient Details

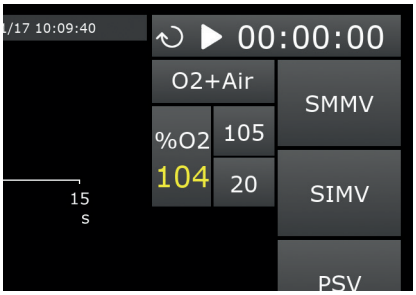
Patient details can be entered via the on-screen keyboard. Automatic average weight calculations are adjusted when height and weight are changed. Compatible with HL7 hospital information system (HIS).



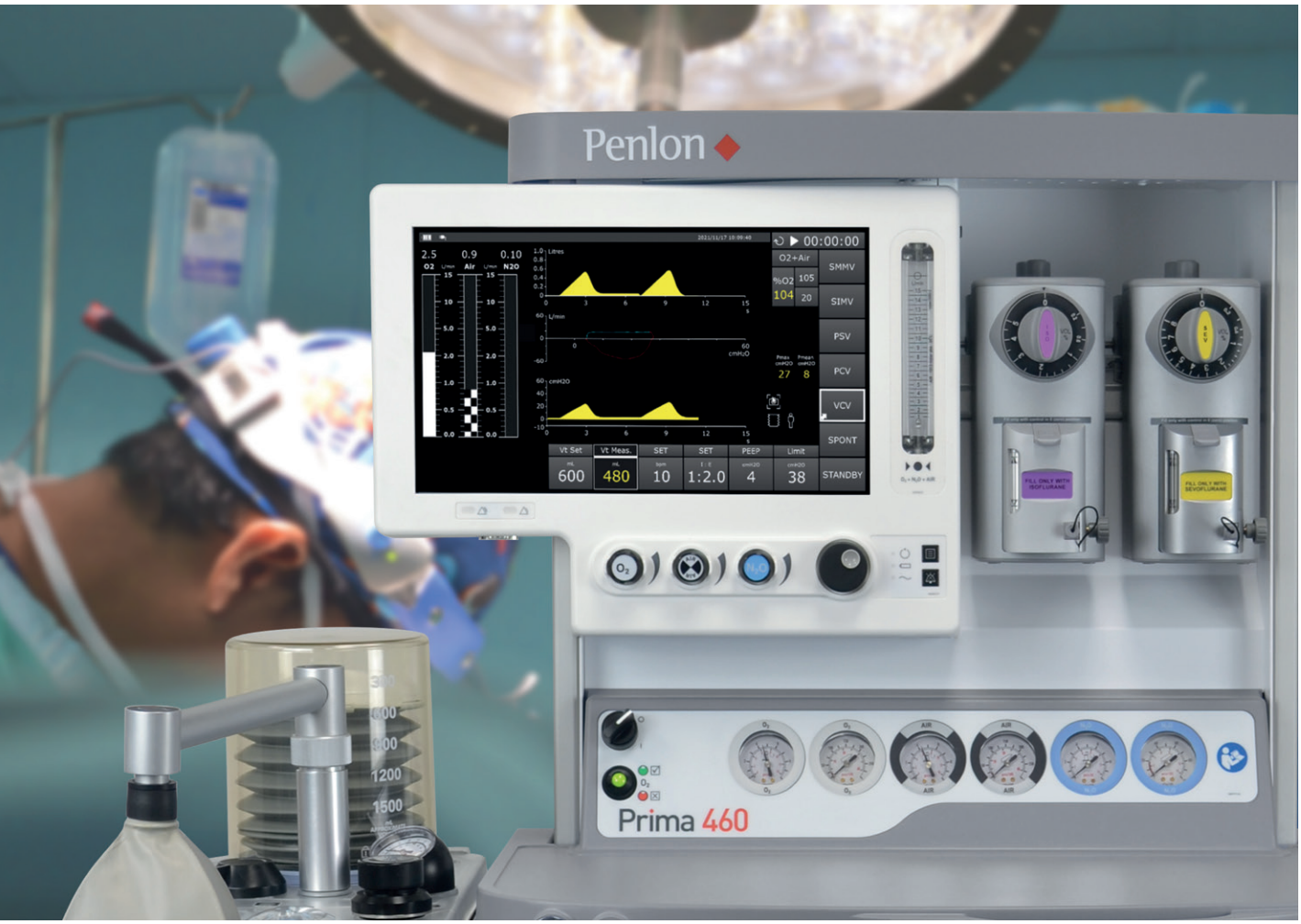
The Penlon Prima 460 anaesthetic machine provides PEEP in all ventilation modes, accurate control, and a virtual flow display in a familiar and easy-to-use workstation.

Graphical User Interface

Clear, easy to use graphical user interface (GUI) with high-definition display of settings, and new stopwatch function.



Features and Benefits



Features	Benefits
Rotameters combined with a virtual flowmeter	Accurate gas delivery with measured flows
Multi-mode ventilator with seven ventilation modes	Suitable for multiple patient types and clinical cases
Integrated heater and water trap on the CO_2 absorber	Reduces condensation risk and improves patient comfort
Absorber CO_2 bypass	Can change absorbent while ventilating a patient
Selectatec back bar	Can be used with any compatible vaporizer
Mechanical anti-hypoxic device and total flow display	Enhanced patient safety
Maintenance and after-sales support	Customer peace of mind
Integrated on-screen stopwatch function	Provides accurate timekeeping during procedures
HL7 connectivity	Provides Hospital Information Systems (HIS) capability
Territory-specific power outlets	Power external devices
AGS (anaesthetic gas scavenging) system	Alleviates contamination in theatre
Improved cable and hose management	Reduces clutter and trip hazards
Oxygen therapy flowmeter	For recovery and added safety
Side mounted suction controller kit	Keeps airways clear

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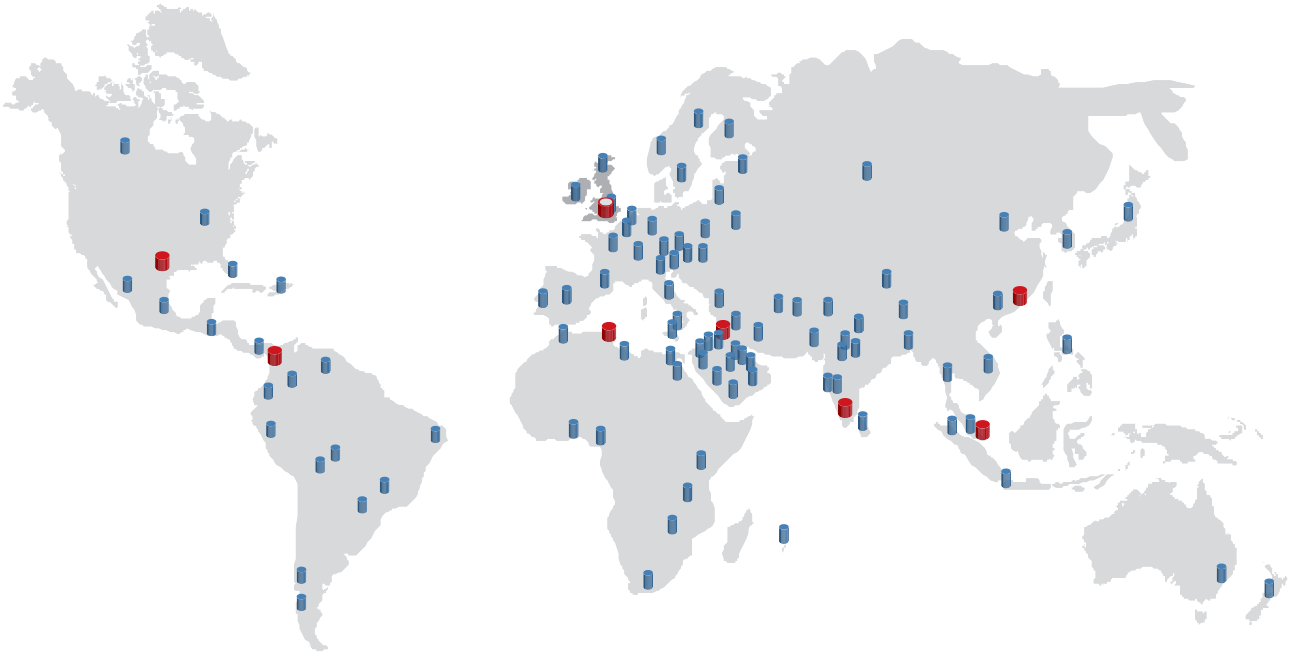

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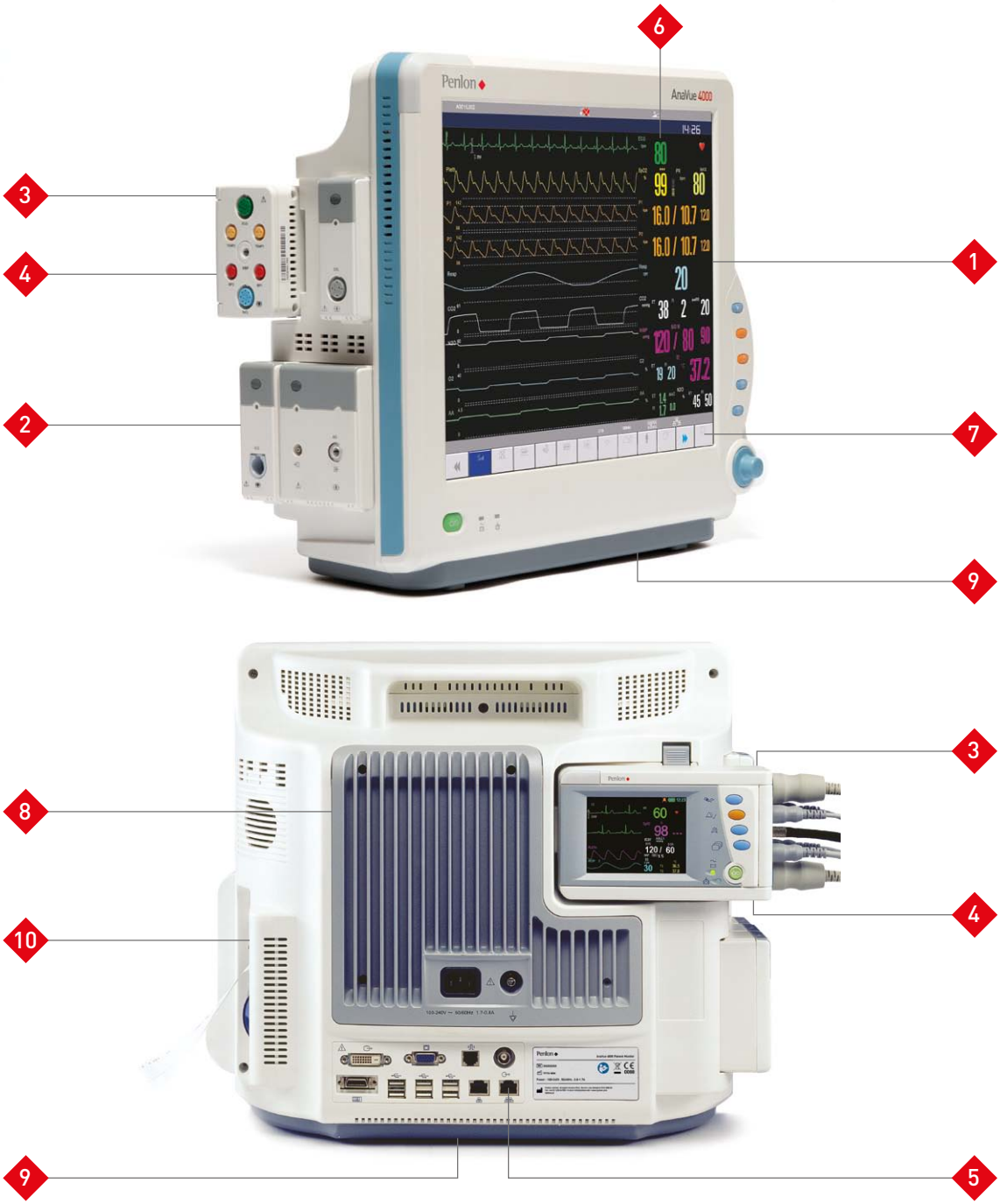
Penlon AnaVue 4000 Patient Monitor

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

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.

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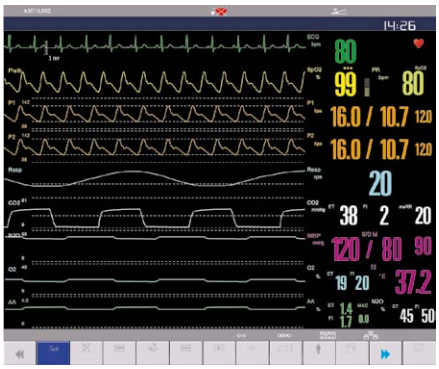
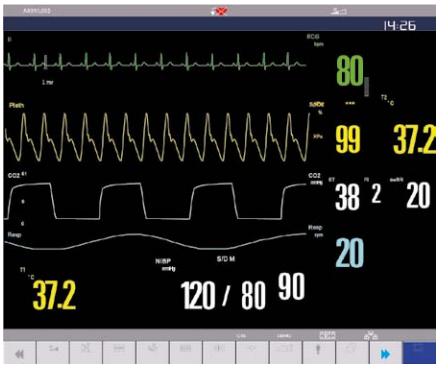
Anaesthesia Gas Analysis

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



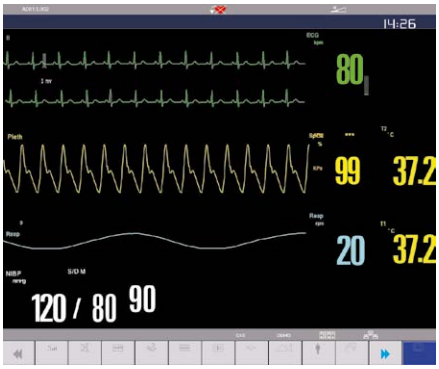
$EtCO_2$ Monitoring

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



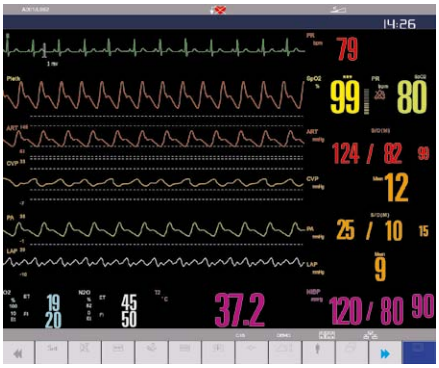
SpO_2 Monitoring

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	✓

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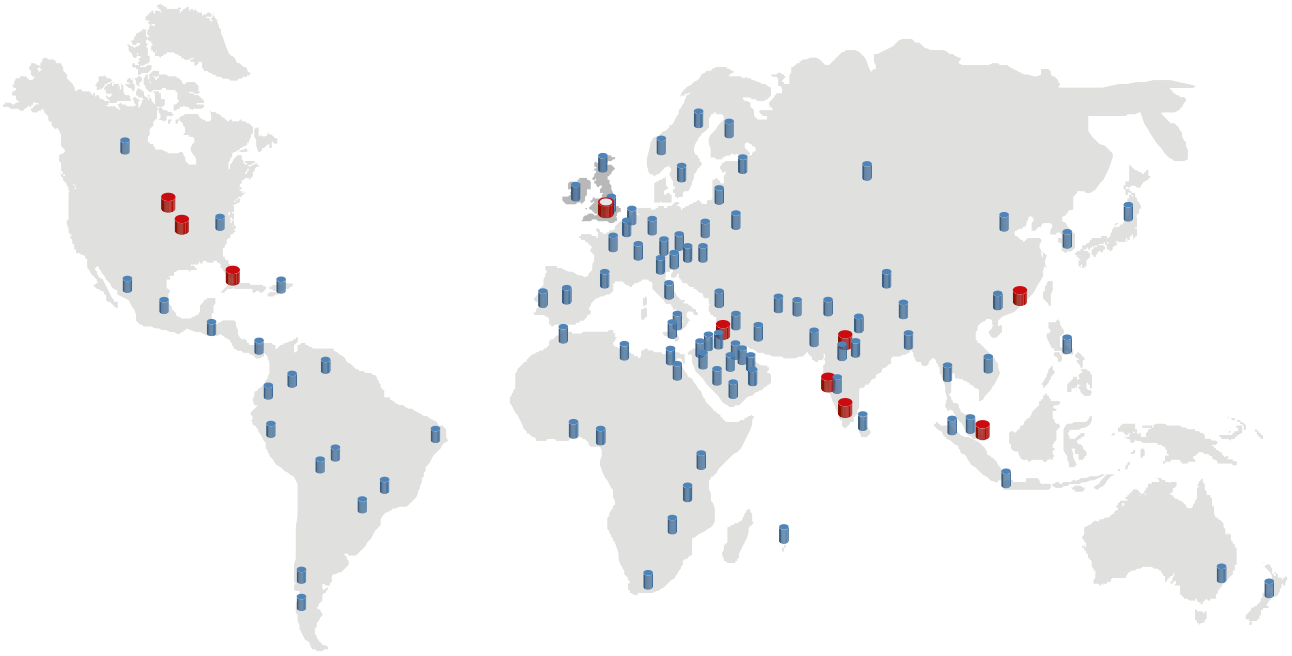

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EC Certificate Full Quality Assurance System: Certificate GB20/965349

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**

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, Service & commissioning of Anaesthesia and Anaesthetic Equipment, suction equipment, airway management and insufflation equipment and patient monitoring equipment.

This certificate is valid from 10 September 2021 until 13 October 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 2. Certified since 19 December 2016

Authorised by

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