ATTACHMENT 4B

FRAMEWORK AGREEMENT SPECIFICATION
PULSE OXIMETRY, CAPNOGRAPHY AND RELATED PATIENT MONITORING TECHNOLOGIES

1. Introduction

1.1. The Framework Agreement is for the supply of pulse oximetry, capnography and related patient monitoring technologies, and their associated consumables and accessories. The Framework Agreement is for products for monitoring the following five key base modalities:

1.1.1. Saturated Pulse Oximetry (SpO_2).
1.1.2. End-tidal Carbon Dioxide ($ETCO_2$).
1.1.3. Near Infra-red Spectroscopy (NIRS).
1.1.4. Transcutaneous Carbon Dioxide Partial Pressure (PCO_2).
1.1.5. Depth of Anaesthesia.

1.2. Related and/or complimentary information such as: Carbon Monoxide (CO), Respiratory Rate (RR), Pulse Rate (PR), Temperature (Temp), Non-Invasive Blood Pressure monitoring (NiBP), Fractional Concentration of Inspired CO_2 ($FiCO_2$) and MetHb may also be displayed on some multi output devices alongside the base modality.

1.3. The Framework Agreement is for the following Lots:

Lot Number	Lot Title
1	Monitors and Devices
2	Consumables
3	Pulse Oximetry Monitors with Oxygen Delivery

1.4. Full technical specifications of the product lines awarded to the Framework Agreement (each a "**Technical Specification**" and together the "**Technical Specifications**") must be made available to NHS Supply Chain on request during the term of the Framework Agreement.

1.4.1. Applicants must notify NHS Supply Chain immediately about any proposed changes to the Technical Specifications throughout the term of the Framework Agreement.
1.4.2. If changes to the Technical Specification of any product line awarded to the Framework Agreement mean that the product line no longer meets the minimum requirements outlined in the Specification, NHS Supply Chain reserves the right to exclude that product line from the Framework Agreement.
1.4.3. NHS Supply Chain reserves the right to request evidence of compliance with the Specification throughout the term of the Framework Agreement.

1.5. This Framework Agreement Specification makes reference to a number of standards and legislation. The list of standards and legislation is not intended to be exhaustive and any relevant standards and legislation which applies to the Framework Agreement (even if not stated) must be complied with by Applicants (together with those listed in this Framework Agreement Specification the "**Standards and Legislation**").

1.6. Product lines must comply with the Standards and Legislation (as amended, extended or re-enacted from time to time).

1.7. Evidence of compliance to the Standards and Legislation must be provided by Applicants awarded to the Framework Agreement ("**Suppliers**") to NHS Supply Chain on request during the term of the Framework Agreement; in the event that sufficient evidence is not provided by Suppliers NHS Supply Chain reserves the right to suspend product lines until such evidence is provided by Suppliers.

2. Criteria applicable across all product lines

2.1. Standards and Legislation

STANDARD AND LEGISLATION
Where products are classed as Medical Devices as per the definition under Medical Devices Regulation 2017/745 the following will apply: **Medical Devices Directive 93/42/EEC (as amended)** All products must have their CE or UKCA marking evident on the product and/or packaging. **Or** **Medical Devices Regulation 2017/745 (as amended)** All products must have their CE marking evident on the product and/or packaging. **BS EN ISO 20417:2021 (previously BS EN 1041:2008 +A1:2013.)** Medical devices. Information to be supplied by the manufacturer **BS EN ISO 15223-1:2016 or BS EN ISO 15223-1:2021** Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Where applicable products must also meet the below requirements **BS EN ISO 80601-2-61:2019** Medical electrical equipment. Particular requirements for basic safety and essential performance of pulse oximeter equipment **BS EN 60601-1-2:2015**

Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests.

BS EN ISO 80601-2-55:2018
Medical Electrical Equipment. Particular requirements for the basic safety and essential performance of respiratory gas monitors.

BS EN ISO 5356-1:2015
Anaesthetic and Respiratory Equipment. Conical connectors. Cones & Sockets.

BS EN 80601-2-30:2010+A1:2015
Medical electrical equipment. Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

BS EN 62366-1:2015+A1:2020
Medical devices. Application of usability engineering to medical devices

2.2. On request applicants must provide NHS Supply Chain with Safety Data Sheets (SDS) for all products that fall under REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) 2007 –more specifically, an SDS must be provided if a substance or a mixture supplied is classified as hazardous under the CLP Regulation (EC) No 1272/2008.

2.3. If a product line contains phthalates this must be indicated on the packaging of that product line in accordance with Directive 2007/47/EC (amending Directives 90/385/EEC and 93/42/EEC).

2.4. If a product contains DEHP this must be stated on the individual product packaging or instructions for use (IFU) and/or made available to NHS Supply Chain or end user on request.

2.5. Electrical product lines must comply with the requirements of the Directive on waste electrical and electronic equipment (WEEE Directive 2012/19/EU) and the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2 Directive 2011/65/EU).

2.6. Where present, batteries must be housed within the product in a secure way to prevent them falling out where product is being used as per manufacturers instructions. This is to ensure functionality of the product is not detrimentally affected by improperly housed batteries.

2.7. All product lines and packaging should be latex free where possible. If a product line or any packaging contains or does not contain latex this must be labelled on the product line or packaging (as applicable) to inform the user.

2.8. During the term of the Framework Agreement Applicants must make NHS Supply Chain aware of any awarded product line that is classed by the MHRA as a Medicinal Product.

2.9. All product line(s) must be supplied with a minimum 1 year's shelf life.

2.10. All product lines must be delivered free of charge to a location as directed by either NHS Supply Chain or the customer.

2.11. IFUs must be written in English or pictograms and included on the individual product packaging and/or within the unit of issue (UOI) and/or made available to NHS Supply Chain or end user on request.

2.12. Any cautions / warnings / contraindications to use must be provided in IFU.

2.13. Must state details strictly necessary to identify the device for the user on the individual product packaging.

2.14. Lot number and expiry date must be stated on the individual product packaging.

2.15. All products must have their CE or UKCA marking evident on the product and/or packaging.

2.16. For ordering purposes an identifier for example reference / manufacturing product code (MPC) must be stated on the individual product packaging and/or unit of issue packaging.

2.17. Product must be robust enough to resist breakage when used as directed by manufacturer.

2.18. Instructions for storage and disposal of device must be contained on the individual product packaging and/or IFU and/or made available to NHS Supply Chain or end user on request

2.19. If MRI compatible it must be stated on the individual product packaging and/or unit of issue packaging.

2.20. Where the product contains tubing, the packaging must be designed to minimise the risk of kinking of tubing while in storage.

2.21. The product constituent's raw material/s must be made available to NHS Supply Chain or end user on request to support with customer recycling requirements.

2.22. Information on country of origin must be made available to NHS Supply Chain or end user on request.

2.23. Information on weight of product must be made available to NHS Supply Chain or end user on request to provide trust with weight waste information.

2.24. External product packaging must be made of recyclable material.

2.25. Where packaging can be recycled this must be displayed on the packaging.

2.26. Where a product is reusable, product must be able to be cleaned to prevent cross contamination. Must have available cleaning / decontamination instructions which must be stated on the individual product packaging or IFU and/or made available to NHS Supply Chain or end user on request.

2.27. Training and implementation must be provided on request and in accordance with trust requirements through mutual agreement. This could be for example, providing ongoing support including pre-implementation education, supplier support and implementation guidance, bespoke clinical training, eLearning and post-implementation support.

2.28. Training and education around the maintenance, testing and calibration of the devices must be provided on request and in accordance with trust requirements through mutual agreement.

2.29. Where the product is to be used only in a specific part of the body, instructions/guidance must be provided with the individual product in English and on the product where possible, including diagrams if feasible.

2.30. Where tubing is present it must be crush resistant under the intended use.

2.31. Where head straps and ear loops are present they must have a firm fit but be able to be detached in an emergency.

3. Lot 1 – Monitors and Devices

3.1. This Lot is for pre-configured monitors & devices that measure at least one of the base modalities detailed in paragraph 3.2 (where multi modalities are required this is specified in the Product Line Description - Appendix 8). For clarity, this is a complimentary Framework to Patient Monitoring Equipment, Related Accessories and Services Framework Agreement, which covers bespoke and configurable monitors and devices.

3.2. The base modalities are as follows:

3.2.1. Saturated pulse oximetry (SpO_2); measurement which measures the ratio of oxygenated to deoxygenated haemoglobin via a wristband, watch, tape/wrap, finger probe or sensor placed at a specific part of the body, e.g. Finger, ear, etc. Can be single use or reusable.

3.2.2. Endtidal CO_2 ($ETCO_2$); a measurement (also known as capnography) which measures carbon dioxide concentration in the breath via an airway adaptor and/or sample line.

3.2.3. Near infra-red spectroscopy (NIRS); measures the ratio of oxygenated to deoxygenated haemoglobin at a specific part of the body, typically used for brain oxygen measuring (called cerebral) but could also be at any other point in the body (called somatic) using a sensor. This modality is sometimes also referred to as regional (r)SO_2.

3.2.4. Transcutaneous CO_2 Partial Pressure ($tcPCO_2$), Gas monitoring, using conventional electrochemical techniques, provides non-invasive, accurate, and real-time monitoring of $PaCO_2$ and PaO_2.

3.2.5. Depth of Anaesthesia, A way to detect and process the signals recorded from an unconscious patient (in a state of anaesthesia), showing the degree of consciousness. It is based upon the bispectral index (BIS) analysis of the electroencephalogram waveform and other features of this, enabling detection of, e.g., levels of sedation, loss of consciousness, and recall. It is used during anaesthesia administration and in trauma.

3.3. Products within this Lot may include;

3.3.1. Finger based devices – An electrically powered device with an integrated sensor within a finger probe designed to display and continuously or intermittently measure and record results;

3.3.2. Hand-held devices - A device that displays and records results and is intended to be held in the hand during use. Sensors are connected to the unit via a cable/connector, and/or sample lines/airway adaptors connecting directly to the unit;

3.3.3. Wrist worn devices - A device that displays and records results and is intended to be worn on the patients wrist during use. Sensors are connected to the unit via a cable/connector, wireless/remote monitoring and/or sample lines/airway adaptors connecting directly to the unit;

3.3.4. Arm worn devices - A device that displays and records results and is intended to be worn on the patients arm during use. Sensors are connected to the unit via a cable/connector, wireless/remote monitoring and/or sample lines/airway adaptors connecting directly to the unit; and

3.3.5. Bedside/table-top monitors - A device that sits on a desk/table. This product maybe stand-alone or networked into hospital system. Sensors and/or sample lines/airway adaptors are connected to the unit via a cable/connector or wirelessly.

3.4. Devices measuring SpO_2 must have an accurate output, whereby the root mean-square (RMS) difference is less than or equal to 4% SpO_2 over the arterial saturation (SaO_2) range of 70% to 100%.

3.5. The pulse oximeter device accuracy must have the relevant supporting evidence from an appropriate clinical study/data where SpO_2 measurements have been compared with SaO_2 measurements. This must include testing to prove that the

pulse oximeter is accurate during motion, low perfusion and on use with dark skin pigmentation. This evidence must be provided on request at any time during the lifetime of the Framework Agreement.

3.6. Where devices measure pulse rate, the accuracy must be defined by the RMS difference between paired pulse rate data recorded with the pulse oximeter and a reference method – this can be an electronic pulse simulator, echo cardiogram (ECG) heart rate, palpated pulse, thoracic auscultation or a second pulse oximeter.

3.7. Pulse oximeter devices must show a numerical reading showing the SpO_2 measurement as a percentage. Capnometers must have a digital output showing the $EtCO_2$ output in kPa (kilopascals). Capnographs must show a waveform.

3.8. For screens that have the potential to be read at different angles, the device must have a marker to identify the correct reading position or there must be instructions which clearly indicate the correct reading position.

3.9. Devices can be battery operated and/or mains electric.

3.9.1. Where battery operated, batteries must be provided with the device.

3.9.2. Where mains operated, a standard UK power cable and three pin plug must be provided unless a specialist power supply/plug is required and this must be notified to us. UK voltage requirements are 240 Volts A/C (Alternating Current).

3.10. Any consumables supplied as part of a device purchase must meet the relevant Lot 2 – Consumables specification criteria as detailed below in section 4.

4. Lot 2 – Consumables

4.1. This Lot is for the various consumables required for pulse oximetry, capnography, near infra-red spectroscopy (NIRS) and/or transcutaneous CO_2 Partial Pressure, Depth of Anaesthesia devices.

4.2. Products within this Lot include:

4.2.1. Sensors.

4.2.2. Tapes/wraps.

4.2.3. Sample lines.

4.2.4. Airway adaptors.

4.2.5. Cables and connectors.

4.2.6. Water traps.

4.2.7. Capnography Masks.

4.2.8. Associate accessories.

4.3. Sensors - Electrically powered device designed to continuously or intermittently measure and record multiple physiological parameters. For adults, infant, paediatric, neonatal and/or a combination. Can be single patient use or reusable.

4.4. Tape/Wraps - Electrically powered sensor designed to continually monitor, these can be made of adhesive fabric or silicone material for example. Can be single patient use or reusable.

4.4.1. Device must be designed to fit into appropriate anatomical site without causing harm to the patient, when used as per IFU's.

4.5. Sample lines for adults, infant, paediatric, neonatal and/or a combination - A non-sterile device intended to enhance the capture of exhaled end-tidal carbon dioxide ($EtCO_2$) for evaluation of a patient's ventilatory, circulatory, or metabolic status, typically during the administration of anaesthesia. It is an adhesive, dome-like adaptor with connecting ports designed to function as an interface between an in-situ airway device (e.g. oropharyngeal airway, face mask, nasal oxygen cannula) and respiratory sampling tubing connected to a carbon dioxide monitor (capnograph). This is a single-use device.

4.6. Airway adaptors - A non-sterile device typically used during capnography and the administration of anaesthesia for adults, infant, paediatric, neonatal and/or a combination.

4.7. Cables & connectors - The signals are obtained through connected cables/leads/probes. It is designed to operate as part of a patient monitoring system enhancing the function of this system (the parent device). The module automatically plugs into the parent device when the user places it into a standardized slot in the parent device which then operates as a mainframe computer displaying the various parameters/information measured and provided by this module.

4.8. Water Traps - Designed to protect the machine/modules from humidity, secretions or contamination. Can be single use or reusable.

4.9. Capnography Masks - A non-sterile, flexible, form-shaped device designed to be placed over the nose and mouth to deliver oxygen (O_2) to a patient's airway, and to sample exhaled respiratory gases for monitoring the patient's ventilatory status. It includes exhaled air sampling tubing for connection to a carbon dioxide monitor (capnograph), or physiology-monitoring sedation/anaesthesia system, for the measurement of end-tidal carbon dioxide ($EtCO_2$) in expiratory gases; it is typically used during anaesthesia/sedation or bedside monitoring. This is a single-use device.

4.10. Associated Accessories - Includes equipment which is required for pulse oximetry, capnography, NIRS and/or transcutaneous CO_2 partial pressure, depth of anaesthesia devices for example.

4.11. Please note Blood Pressure Cuffs, Tubing, and Associated Products are not within the scope of this framework agreement as there is a separate NHS Supply Chain framework for this area.

5. Lot 3 – Pulse Oximetry Monitors with Oxygen Delivery

5.1. This Lot is for the monitors and devices which continuously monitor the Saturation of peripheral oxygen (SpO_2) and deliver automated titrated oxygen as required. The device is a closed-loop system designed to automatically adjust oxygen flow according to the patients' oxygenation.

5.2. Must have ability for clinician to set predefined value range for SpO_2.

5.3. Must safely connect to oxygen supply.

5.4. Must automatically adjust level of oxygen being delivered to main target range SpO_2.

5.5. Device must have audio and visual alarm that alerts the clinician once predefined parameters of SpO_2 have been exceeded.

5.6. Technical parameters such as reaction time to SpO_2, flow accuracy, flow range, and availability of the alarm must be contained within the IFU's.

5.7. Must have visual display screen which provides oxygen flow rate and SpO_2 reading.

5.8. Recommendations for the maintenance, safety testing and calibration of devices must be provided.

5.9. Device must audibly and/or visually alert the end user when it requires end user intervention, for example when devices malfunction, change in patient's SpO_2, low battery.

5.10. Must include instructions about battery care / maintenance if required.

5.11. Must be able to be cleaned to prevent cross contamination and must have available cleaning / decontamination instructions contained within IFU's.

5.12. Must be designed to suit the environment to be used in, e.g. bedside or ambulatory, be able to be relocated and transported by one able bodied person.

5.13. Where applicable, must have the ability to capture and export data as required.

5.14. Must be stated within IFU's or made available to NHS supply chain on request compatibility including with third party consumables or universal adaptors / connectors.

5.15. Pulse Oximetry Monitors with Oxygen Delivery Accessories.

5.15.1. Additional products may be included within this lot provided that they are an accessory to, and can be used in conjunction with, the function and operation of the pulse oximetry monitor with oxygen delivery. Examples of additional products that fall within the scope of this lot shall include but are not limited to:

5.15..1.1. Replacement charging cable

5.15..1.2. Replacement batteries