ATTACHMENT 4B
Framework Agreement Specification
Patient Assessment Devices

1. Introduction

1.1. The Framework Agreement is for the supply of Patient Assessment Devices including Blood Pressure Monitoring, Otoscopes, Pupil Size and Reaction Measuring Devices and Ophthalmoscopes, Stethoscopes, Patient Weighing Scales and Measuring Devices, Proctoscopes, Rectoscopes, Anoscopes and Sigmoidoscopes, Dermatoscopes and Hyfrecators, Personal Health Monitors, Movement Disorder Assessment Devices, Assessment Lights, Ear Irrigation Devices, General Patient Assessment Products, Consumables and related accessories.

1.2. The Framework Agreement is for the following Lots:

Lot Number	Lot Title
1	Blood Pressure Monitoring
2	Otoscopes, Retinoscopes, Ophthalmoscopes and Pupil Size and Reaction Measuring Devices
3	Stethoscopes
4	Patient Weighing Scales and Measuring Devices
5	Proctoscopes, Rectoscopes, Anoscopes and Sigmoidoscopes
6	Dermatoscopes and Hyfrecators
7	Personal Health Monitors
8	Movement Disorder Assessment Devices
9	Assessment Lights
10	Ear Irrigation Devices
11	General Patient Assessment Products

1.3. 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.

1.3.1. Applicants must notify NHS Supply Chain immediately about any proposed changes to the Technical Specifications throughout the term of the Framework Agreement.

1.3.2. 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.

1.3.3. NHS Supply Chain reserves the right to request evidence of compliance with the Specification throughout the term of the Framework Agreement.

1.4. 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**").

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

1.6. 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 where applicable

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 Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)** 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 or UKCA 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 15223-1:2021** Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. **BS EN 60601-1-2:2015+A1:2021** Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests. **EN 60601-1:2006 + Cor. :2010 + A1:2013** Medical electrical equipment - Part 1: General requirements for basic safety and essential performance **BS EN 60601-1-2:2015+A1:2021**

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

BS EN 60601-1-11:2015+A1:2021
Medical electrical equipment – general

BS EN 60601-1-2:2021
Medical electrical equipment – Electromagnetic disturbances

EN 62304:2006 + A1:2015
Medical Device Software

BS EN 62366-1:2015+A1:2020
Medical Devices – Usability

Where products are sterile, they must comply with either applicable standard below or equivalent international standard to designate device as sterile.

BS EN 556-1-2001
Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices.

BS EN556-2-2015
Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for aseptically processed medical devices.

Where a product is sterilised an applicable validated sterilisation and routine control process must be applied, for example:

BS EN ISO 14937:2009
Sterilization of health care Sterilization of health care products.

BS EN ISO 11137 series
Sterilization of health care products. Radiation

BS EN ISO 17665-1:2006
Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for 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) or UK Medical Devices Regulations 2002

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 manufacturer's 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 latex this must be labelled on the product line or packaging (as applicable) to inform the user.

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

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

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

2.11. 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.

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

2.13. Instructions for storage and disposal of the 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.

2.14. Information on 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.

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

2.16. 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.

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

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

2.19. Where a product is reusable, the product must be able to be cleaned to prevent cross contamination.

2.20. 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.

2.21. Where applicable, products must be supplied sterile and individually wrapped.

2.22. Individual packaging must be of durable construction preventing the product from being pushed through or tampered with and must not tear or rip apart during transportation and storage, to avoid damage to the product and / or breaches of product sterility and to reduce risk of plastic packaging being a foreign body when device being used.

2.23. Where applicable, the product packaging must include a non-adherent tab which allows the product packaging to be opened at one end maintaining sterility.

2.24. Where applicable, the word single use and / or symbol must be depicted on the individual product packaging to inform the user of the product's single use status in line with labelling (ISO 15223).

2.25. Where applicable for products that are sterile, the transparent side of the individual packaging must allow visualisation of the contents.

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

2.27. 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.

2.28. All product line(s) must be supplied with a minimum 12-month shelf life on receipt of delivery.

2.29. All product lines must include a free of charge warranty for a minimum of 12 months (including repair, parts, labour and servicing) from the date of acceptance by the customer.

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

2.31. 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.

2.32. 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.

2.33. 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.

2.34. 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.

2.35. Where applicable, any digital connectivity, software, associated apps and modems must meet the requirements of the customer alongside provision of required training and ongoing support. Customers may use the NHS Digital Technology Assessment Criteria for health and social care (DTAC) for assessment of the devices and it is recommended that suppliers familiarise themselves with these criteria to meet clinical safety, data protection, technical security, interoperability and usability and accessibility standards.

2.36. Devices must be tested and assessed to account for differences pertaining to population characteristics to reduce biases against medical device users of different genders, ethnicities, or other socio-demographic groups, for example accuracy of device on different characteristic faces and testing of devices that use infrared on different skin tones.

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

2.38. Reusable device's must be able to be cleaned to prevent cross contamination and must have available cleaning / decontamination instructions contained within IFUs.

2.39. Where applicable must state process for safe destruction within IFU.

2.40. Where tubing is present it must be crush resistant under the intended use and while within product packaging.

2.41. Must be stated if mains or battery powered.

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

2.43. Where the device is battery powered it must be stated within IFU's and / or on individual product packaging if batteries are supplied with device.

2.44. Where battery powered device, it must be stated type of batteries to be used and how to correctly insert batteries within IFU's.

2.45. Must have a means of displaying remaining battery power for example, on device / machine.

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

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

2.48. Must have ON/OFF switch allowing for immediate use in emergency situations.

2.49. Must have decontamination and cleaning instructions included in IFU's.

2.50. Must be robust enough to resist breakage when used as directed by the manufacturer.

3. Lot 1 – Blood Pressure Monitoring

3.1. This Lot is for Blood Pressure Monitoring machines and related accessories including;

- 3.1.1. Sphygmomanometer Digital (Oscillometric) Monitors
- 3.1.2. Sphygmomanometer Aneroid (Auscultatory) Monitors
- 3.1.3. Sphygmomanometer and Stethoscope Set
- 3.1.4. Sphygmomanometer 24-hour Ambulatory Monitors
- 3.1.5. Brachial Index Monitors.
- 3.1.6. Related Accessories

3.2. Standards and Legislation

STANDARD AND LEGISLATION
Aneroid Devices must comply with; **BS EN ISO 81060-1:2012** Non-invasive sphygmomanometers. Requirements and test methods for non-automated measurement type.

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 1060-3:1997+A2:2009
Non-invasive sphygmomanometers. Supplementary requirements for electro-mechanical blood pressure measuring systems.

BS EN 1060-4:2004
Non-invasive sphygmomanometers. Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers.

Where applicable products must conform to.

US Association for the Advancement of Medical Instrumentation (ANSI/ AAMI SP10/ BS ISO 81060-2:2009).

3.3. All products within this lot must meet the following:

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

3.3.2. Must be stated within IFU's and / or on product packaging the intended patient population, for example, age, weight, and body part.

3.3.3. Where the device is intended for self-use, it must come with a precaution for the need to consult a physician for interpretation of blood pressure reading.

3.4. **Sphygmomanometer Digital (Oscillometric) Monitors** - An electrically powered device designed to noninvasively measure blood pressure using a self-contained software program that regulates automatic arm-cuff inflation and measurement cycles.

3.4.1. Must meet all previous points of 3.3 and the following:

3.4.1.1. All monitors must provide a minimum of systolic and diastolic readings.

3.4.1.2. Accuracy of readings must be within +/- 5 Millimetres of mercury (mmHg) and / or 0.7 Kilopascals (kPa).

3.4.1.3. Must be stated with IFU's where the device has the capability to store data and must be stated length of time data is stored for.

3.4.1.4. Where present if device has a neonatal mode must be stated in IFU's, and the device must identify correct cuff is connected.

3.5. **Sphygmomanometer Aneroid (Auscultatory) Monitors-** A device designed to measure blood pressure consisting of an inflatable cuff that fits around a limb (arm or thigh), an inflation bulb for controlling the air pressure within the cuff, an aneroid sphygmomanometer, and tubing. The aneroid sphygmomanometer consists of a bellows, which expands as the pressure in the cuff increases, and a mechanical amplifier that transmits this expansion through a lever to an indicator needle which rotates around a circular, calibrated scale. The sphygmomanometer may be mounted to a wall, placed on a table, or handheld (portable).

3.5.1. Must meet all the previous points of 3.3 and the following:

3.5.1.1. Scale numbers on the sphygmomanometer must be durable and legible.

3.5.1.2. Must have and inflation bulb which is used to inflate pressure in cuff and valve which can be opened to release pressure within cuff in a controlled manner.

3.5.1.3. Cuff pressure must be shown in either Millimetres of mercury (mmHg) and / or Kilopascals (kPa).

3.6. **Sphygmomanometer and Stethoscope Set –** An aneroid sphygmomanometer and a stethoscope in a kit.

3.6.1. Must meet all previous points 3.3, stethoscopes in the kit must meet all points in 5.4 and the following:

3.6.1.1. Must contain as a minimum both aneroid sphygmomanometer and a stethoscope.

3.6.1.2. Scale numbers on sphygmomanometer must be durable and legible.

3.6.1.3. Must have an inflation bulb which is used to inflate pressure in cuff and valve which can be opened to release pressure within cuff in a controlled manner.

3.6.1.4. Cuff pressure must be shown in either Millimetres of mercury (mmHg) and / or Kilopascals (kPa).

3.7. **Sphygmomanometer 24-hour Ambulatory Monitors -** Also known as Ambulatory Blood Pressure Monitoring (ABPM) is when your blood pressure is measured as you move around, living your normal daily life. It is measured for up to 24 hours. A small digital blood pressure monitor is attached and connected to a cuff around the upper arm.

3.7.1. Must meet all previous points 3.3 and the following:

3.7.1.1. Must have the ability to record at least two measurements per hour during times set by clinician.

3.7.1.2. Must have ability to store data captured over the 24-hour period.

3.7.1.3. Product must be designed to be portable (compact and light weight).

3.8. **Brachial Index Monitors -** An automated, battery-powered, portable electronic device designed to calculate the brachial pressure index (BPI), used in the diagnosis of peripheral vascular disease (PVD). It typically consists of a control/analysis/display unit with cuffs placed around an arm and one or both ankles or toes; it uses integrated transducers to measure cuff pressure oscillations which represent the fluctuations of pressure in the underlying blood vessels. The device is typically operated by a healthcare professional.

3.8.1. Must meet all previous points 3.3 and the following:

3.8.1.1. 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.

3.9. Accessories for use with products in this Lot must be compatible with blood pressure monitoring devices, they include but are not limited to:

3.9.1. Stands,
3.9.2. Mounting Accessories,
3.9.3. Bulbs,
3.9.4. Inflation Bags,
3.9.5. Inflation Bulbs,
3.9.6. Bladders,
3.9.7. Bulbs,
3.9.8. Valves,
3.9.9. Connectors,
3.9.10. Power Supplies and Adaptors,
3.9.11. Pouches,
3.9.12. Patient Belts,
3.9.13. Cables,
3.9.14. Trolley Stands,
3.9.15. Carry Cases,
3.9.16. Printers,
3.9.17. Tubing,
3.9.18. Software.

3.10. Please note Blood Pressure Cuffs are not within the specification of this tender as there is a separate NHS Supply Chain Framework Agreement for this area.

4. Lot 2 – Ophthalmoscopes, Retinoscopes, Otoscopes and Pupil Size Measuring Devices

4.1. This Lot includes;

4.1.1. Ophthalmoscopes
4.1.2. Retinoscopes
4.1.3. Otoscopes
4.1.4. Pupil Size and Reaction Measuring Devices

4.1.5. Otoscope and Ophthalmoscope sets.

4.1.6. Ophthalmoscopes and Otoscope Accessories

4.2. **Standards / Directives / Legislative requirements**

STANDARD AND LEGISLATION
Ophthalmoscopes must comply with; **BS EN ISO 10943:2023** Ophthalmic instruments. Indirect ophthalmoscopes **Direct Ophthalmoscopes must comply with;** **BS EN ISO 10942:2022** Ophthalmic instruments. Direct ophthalmoscopes

4.3. **Ophthalmoscopes** - An electrically powered, ophthalmic instrument designed to be positioned close to the patient's eye to examine the interior of the eye and related structures [e.g., fundus (retina), cornea, aqueous, lens, and vitreous] by producing an image. It consists of a main unit (commonly referred to as the head) with a built-in light source directed through the pupil to illuminate the interior of the eyeball, a mirror with a single hole for viewing, and a dial containing lenses of different powers.

4.3.1. Must be stated on individual product packaging and / or within IFU's ophthalmoscope type for example if LED or standard.

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

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

4.3.4. Where 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.

4.4. **Retinoscopes -** An ophthalmic device that is used to measure the refractive errors of the eye through the projection of a beam of light into the eye, and the observation of the movement of the illuminated area on the retinal surface and of the refraction of the emergent rays.

4.4.1. Must be stated on individual product packaging and / or within IFU's when battery powered, or mains powered.

4.4.2. Where battery powered must include instructions about battery care / maintenance.

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

4.5. **Otoscopes** – An electrically-powered device designed for examination of the outer ear canal and tympanic membrane (eardrum) by direct viewing through the ear opening. It consists of a main unit (commonly referred to as the head) with a built-in light source intended to illuminate the interior of the ear canal with a detachable cone-shaped tube (speculum) inserted in the ear canal; it may facilitate the application of air pressure for pneumatic otoscopy.

4.5.1. Must be stated on individual product packaging and / or within IFU's otoscope type for example if LED, fibre optic or non-fibre optic.

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

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

4.5.4. Where 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.

4.6. **Pupil Size and Reaction Measurement Device -** An automated device which is a portable, handheld device that provides a reliable and objective measurement of pupillary size, symmetry, and reactivity through measurement of the pupillary light reflex.

4.6.1. Must display pupil reactivity numerically to identify changes in pupils' size and reactivity.

4.6.2. Must have ability to record and store data to be reviewed by clinicians.

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

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

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

4.6.6. Must have a means of displaying remaining battery power for example, on device / machine.

4.6.7. Where 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.

4.7. **Otoscope and Ophthalmoscope sets.**

4.7.1. Must contain handle and attachments for both Otoscope and Ophthalmoscopes within the set.

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

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

4.7.4. Where 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.

4.8. **Ophthalmoscopes and Otoscope Accessories -** Support products within this Lot must be compatible with proposed devices including but not limited to:

4.8.1. Replacement Bulbs/Lamps (LED, halogen / xenon illumination),

4.8.2. Otoscope specula disposable

4.8.3. Otoscope specula reusable

4.8.4. Specula Dispensers,
4.8.5. Wall Mounts,
4.8.6. Chargers/ Adaptors,
4.8.7. Cases and Cables,
4.8.8. Pouches,
4.8.9. Lenses,

5. Lot 3 – Stethoscopes

5.1. This lot includes:

5.1.1. Single use stethoscopes
5.1.2. Multi patient use Stethoscopes
5.1.3. Electronic Stethoscopes
5.1.4. Pinard Foetal Stethoscopes
5.1.5. Accessories for Stethoscopes

5.2. **Stethoscopes -** A device designed for listening to sounds from the heart, lungs, and/or gastrointestinal tract and in combination with a sphygmomanometer when measuring blood pressure. It typically comprises a membrane at the listening head connected by a split "Y" tube to the headgear with ear olives that are placed into the user's ears. Can be single use or reusable device.

5.3. **Single Patient Use Stethoscope –** A stethoscope designed for single patient use within environments such as infection diseases or other high risk of infection environments. Must not be reusable.

5.3.1. Must be provided with safe disposal instructions once device has been used as per manufactures instructions.
5.3.2. Must be on individual product packaging that device is single patient use and is not to be reused.
5.3.3. Must be stated on individual product packaging and / or within IFU's if single head or double head.

5.4. **Multi Patient Use Stethoscopes –** A stethoscope which is designed for one clinician to use on multiple patients, must be decontaminated between uses. This is a reusable device.

5.4.1. Long term practice or hospital use stethoscopes are required for a variety of uses and including cardiology, adults, neonates, and paediatrics; stethoscopes can also be electronic and in variations of:

5.4.1.1. single sided chest piece, single tube,
5.4.1.2. dual sided chest piece, single tube,
5.4.1.3. dual sided chest piece, twin tube,
5.4.1.4. dual sided chest piece, with dual binaural for teaching.
5.4.1.5. Must be able to be cleaned to prevent cross contamination and must have available cleaning / decontamination instructions contained within IFU's.

5.5. **Electronic Stethoscopes** – Also known as Digital Stethoscopes are an external electronic listening device designed to detect and amplify extremely weak body sounds that may be difficult to perceive when using a mechanical stethoscope. This device may differentiate between sound tones and accentuate one (e.g., blood flow through a defective heart valve) over another. It is typically designed to be connected to a computing device, which may operate interpretive software sometimes provided with the stethoscope, for recording and/or display.

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

5.5.2. Battery life must be stated within IFU's and / or on individual product packaging.

5.5.3. Must be stated within IFU's and / or on individual product packaging where has wireless connection to app for recording data.

5.5.4. Must be stated within IFU's and / or on individual product packaging if device has ability to switch between bell and diaphragm modes.

5.6. **Pinard Foetal Stethoscopes -** A mechanical listening device that is used for listening to foetal heart sounds. It is typically designed as a hollow tube (trumpet-shaped) to transmit the foetal heart sound through the inner channel by air conduction and is pressed against the outside of the mother's abdomen and the user will place their head and ear to the listening end of the device.

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

5.7. **Accessories for use with Stethoscopes -** must be compatible with proposed devices including but not limited to:

5.7.1. Stethoscope Covers,
5.7.2. Replacement Ear Tips,
5.7.3. Diaphragms and Rims,
5.7.4. Chest Pieces,
5.7.5. Tubing,
5.7.6. Binaurals,
5.7.7. Identification Tags,
5.7.8. Bell Sleeves,
5.7.9. Software to allow sound sharing.
5.7.10. Replacement rechargeable batteries
5.7.11. Replacement cables

6. Lot 4 – Patient Weighing Scales and Measuring Devices

6.1. This Lot is for Weighing Scales and Patient Measuring Devices including medical weighing scales, swab/organ/diaper weighing scales, body composition analysers, height measures, measuring station, tape measures and measuring device accessories.

6.2. Standards / Directives / Legislative requirements

STANDARD AND LEGISLATION

Medical weighing scales must comply with;

2014/31/EU Directive
NAWI (Non-automatic weighing instruments)

BS EN 45501:2015
Metrological aspects of non-automatic weighing instruments

Wireless Connectivity solutions must meet the below directives;

2014/53/EU
Radio Equipment Directive

EN 300328 V2.2.2
Wideband transmission systems - Data transmission equipment operating in the 2,4 GHz band

6.3.All products within this lot must meet the following:

6.3.1. Where product is reusable, it must be able to be cleaned to prevent cross contamination and must have available cleaning / decontamination instructions contained within IFU's.

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

6.3.3. Must be robust enough to resist breakage when used as directed by manufacturer.

6.3.4. Where applicable must state process for safe destruction within IFU.

6.4.Medical weighing scales, body composition analysers and medical swab/organ/diaper weighing scales must be validated to Council directive 90/384/EEC on non-automatic weighing instruments.

6.4.1. Medical Weighing Scales for measuring patient weight, includes:

6.4.1.1. Portable Scales, adult / baby,
6.4.1.2. Wheelchair Scales,
6.4.1.3. Column Scales,
6.4.1.4. Bed Scales,
6.4.1.5. Transfer board within built scale,
6.4.1.6. Floor Mechanical Scales,
6.4.1.7. Floor Digital Scales,
6.4.1.8. Chair Scales,
6.4.1.9. Hoist Scales,
6.4.1.10. Handrail Scales,
6.4.1.11. Platform Scales,
6.4.1.12. Measuring Stations,
6.4.1.13. Where relevant, above devices with Bi-directional EPR integration (data flows in two directions, incoming and outgoing)

6.4.1.14. All medical weighing scales must provide readings as a minimum in kilograms (Kg).

6.5. **Medical Swab/organ/nappy weighing scales** – Medical weighing scales designed to be used to weigh medical swabs, organs and or nappies to provide accurate fluid loss.

6.5.1. Must state on individual product packaging and/or within IFU's where product has a tare function.

6.5.2. Product must be waterproof.

6.5.3. Must be stated on individual product packaging and / or within IFU's when product is supplied with or without scoop.

6.5.4. All medical weighing scales must provide readings as a minimum in kilograms (Kg).

6.6. **Body Composition Analyser -** An electronic device designed to estimate body composition (i.e., percent body fat, lean, bone, and/or hydration). It may be in the form of a unit with electrodes applied to the surface of the patient's body, or a scale(s) placed on the floor and upon which the patient stands to measure total body weight. Both types perform by passing a low electrical current through the body; personal characteristics may be manually entered.

6.6.1. Body composition analysers must, as a minimum, have the ability to measure:

6.6.1.1. Weight,

6.6.1.2. Fat-Free Mass,

6.6.1.3. Fat Mass,

6.6.1.4. Body Water

6.7. **Height Measures -** A device designed to measure the height of a patient. It can be, e.g., a wall-mounted graduated scale or a freestanding vertical graduated rod with an adjustable cross-piece that is placed on the top of the patient's head. It may provide analogue or digital readings.

6.7.1. Height measures within this Lot includes:

6.7.1.1. Mats/Boards,

6.7.1.2. Measuring Rods. (Including floor-standing, wall mounted, portable).

6.7.1.3. All medical height measures must provide readings as a minimum in Centimetres (cm).

6.8. **Weight and Height Measuring Station –** A medical device which measures and weighs in a single step, contains a display which shows height and weight.

6.8.1. With digital or ultrasound height measure

6.9. **Measuring Tape** - A flexible device intended to be used in a clinical setting to establish an accurate measurement of length greater than a standard ruler (e.g., the girth of a patient's waist or thigh, or the length of a leg).

6.9.1. Must be stated on individual product packaging and/or within IFU's if reusable or single use.

6.9.2. Measuring tape must provide readings in Centimetres (cm) as minimum.

6.9.3. Material type must be stated on individual product packaging and or within IFU's.

6.10. **Measuring device accessories are products which can be used with compatible scales, items include but are not limited to:**

6.10.1. Carry Cases,
6.10.2. Attachable Printers and Consumables,
6.10.3. Adaptors,
6.10.4. Trollies,
6.10.5. Positioners and supports,
6.10.6. Ramps,
6.10.7. Stands,
6.10.8. EPR (Electronic Patient record), integration software,
6.10.9. Network connectivity module.

7. Lot 5 - Proctoscopes, Rectoscopes, Anoscopes and Sigmoidoscopes

7.1. This Lot is for devices to be used for examining the large intestine, anal cavity, rectum or colon, including Proctoscopes, Rectoscope, Anoscopes, Sigmoidoscopes.

7.2. **Proctoscopes** - An endoscope with a rigid inserted portion intended for the visual examination and treatment of the rectum and anus. It is inserted into the body through the anus during proctoscopy. Anatomical images are transmitted to the user by the device by direct or magnified viewing. Can be single use or reusable device.

7.2.1. Proctoscopy is a common medical procedure in which an instrument called a proctoscope or a rectoscope is used to examine for example the anal cavity, rectum, or sigmoid colon.

7.3. **Rectoscopes** - An endoscope with a rigid inserted portion intended for the visual examination and treatment of the rectum and anus. It is inserted into the body through the anus during rectoscopy. Anatomical images are transmitted to the user by the device typically through relayed lens optics. It is commonly used to examine the structures of the rectum for irregularities. This can be single use or reusable device.

7.4. **Anoscopes** - An endoscope with a rigid inserted portion intended for the visual examination and treatment of the anus and rectum. It is inserted into the body through the anus during anoscopy. The anatomical images are illuminated by a light source and can be viewed by the user through relayed lens optics or direct vision. This device is commonly used to examine/diagnose patients suffering pain in the rectum/anus, haemorrhoids, or anal fissures. Can be single use or reusable device.

7.4.1. Anoscopy is an examination in order to evaluate problems of the anal canal.
7.4.2. Anoscopy is used to diagnose for example haemorrhoids, anal fissures, and some cancers.

7.5. **Sigmoidoscopes** - An endoscope intended for the visual examination and treatment of the sigmoid colon (the distal S-shaped part of the large intestine leading to the rectum). It is inserted through the anus during sigmoidoscopy or proctosigmoidoscopy. Anatomical images are transmitted to the user by the device through relayed lens optics or a fibreoptic bundle. This device is commonly used to examine the structures and lining of the sigmoid colon and for indications of altered bowel habit, colonic cancer, or polyps. Can be flexible fibreoptic, flexible video or rigid scope and are reusable devices.

7.5.1. Sigmoidoscopy is the minimally invasive medical examination of the large intestine from the rectum through the nearest part of the colon, the sigmoid colon.

7.5.2. All products within this lot that are sterile must be indicated as such on the packaging.

7.5.3. All products within this lot that are single use must be marked as such.

7.5.3.1. Accessories within this Lot include but are not limited to:

7.5.3.1.1. Filters,

7.5.3.1.2. Bellows,

7.5.3.1.3. Disposable Light Stems,

7.5.3.1.4. Luer Locks,

7.5.3.1.5. Light Sources,

7.5.3.1.6. Autoclavable / Non-Autoclavable Adapters for Light Sources,

7.5.3.1.7. Haemorrhoid banders.

7.5.3.1.8. Pre-paid annual calibration cost

8. Lot 6 – Dermatoscopes and Hyfrecators

8.1. This Lot is for Dermatoscopes, Hyfrecators and related accessories.

8.2. **Dermatoscopes** - An electrically powered, hand-held instrument intended to be used for the microscopic examination of the external skin layers. The device has a built-in light source and magnification system that provides the user with the visualization of the structures of the epidermis and epidermal-dermal junction. This device is commonly used for the examination of skin structures and to assess abnormal colour and pattern changes of pigmented skin lesions (e.g., spongy birth marks, malignant melanoma).

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

8.2.2. Must be stated within IFU's and/ or on individual product packaging if Dermatoscopes can be used with batteries or be mains powered.

8.3. **Hyfrecators** - A low-power high-frequency AC (alternating current) medical electro-surgical device, which regulates an electrical current used to heat a probe or forceps for example to burn or sear body tissue. These are not intended for cutting tissue.

8.3.1. The output amount of power must be adjustable depending on clinical requirement.

8.3.2. Must have ability to connect different tips for example electrodes, forceps.

8.3.3. Accessories within this Lot include but not limited to:

8.3.3.1. Body Imaging Unit,
8.3.3.2. Wireless Data Transmitter,
8.3.3.3. Handles,
8.3.3.4. Heads,
8.3.3.5. Contact Plates with and without Scale,
8.3.3.6. Leads,
8.3.3.7. Oils,
8.3.3.8. Camera Adaptors with/ without Camera,
8.3.3.9. Connection Kits,
8.3.3.10. Cords,
8.3.3.11. Photo Accessory Sets,
8.3.3.12. Chargers,
8.3.3.13. Batteries,
8.3.3.14. Belt Clips,
8.3.3.15. Smartphone/ Tablet Compatible Accessories,
8.3.3.16. Sterile Biopsy Punch,
8.3.3.17. Sterile Curette,
8.3.3.18. Biopsy Blade.
8.3.3.19. Dessication / Coagulation needles
8.3.3.20. Electrode Balls
8.3.3.21. Foot control pencils
8.3.3.22. Bipolar forceps
8.3.3.23. Pre-paid annual calibration cost

9.Lot 7 – Personal Health Monitors

9.1. This Lot is for medical grade monitoring devices to be used for personal assessment of health. Including:

9.1.1. Step Counters/ Pedometers,
9.1.2. Activity Wristbands,
9.1.3. Falls Detection Device,
9.1.4. Calorie Monitors,
9.1.5. Personal Sleep Trackers,
9.1.6. Handheld Personal Electrocardiographs,
9.1.7. BMI Calculators,
9.1.8. Portable Personal Pulse Stress Monitors.

9.2. All products within this lot must meet all of the following:

9.2.1. Must have a means of displaying remaining battery power for example, on device and / or via software.
9.2.2. Must include instructions about battery care / maintenance if required.
9.2.3. Where battery operated, batteries must be provided with the device.

9.2.4. Where device is rechargeable it must charge automatically when connected to an external power source and have identifiable marker to show when charging for example light.

9.2.5. Size must be stated on the individual product packaging or unit of issue packaging, for example adult or paediatric and / or a marking in lb./ kg (other equivalent measure) indicating the maximum patient weight for which it is intended to be used.

9.2.6. Suppliers must have available instructions for safe use in English or pictograms, which must be made available to NHS Supply Chain on request.

9.2.7. Must be stated within IFU's and / or on individual product packaging if the device requires connecting to a wireless app to store data.

9.2.8. 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.

9.2.9. Must be stated within IFU's and / or on product packaging intended patient population for example, age, weight, and body part.

9.3. **Step Counters/ Pedometers** – A medical grade device worn on the body that measure steps and/or distance travelled.

9.3.1. Must include step counter, batteries and an instruction manual written in English.

9.3.2. Must be stated within IFU's and / or on individual product packaging if device counts steps and / or distance.

9.4. **Activity Wristbands** - A medical grade wrist-worn device that can detect a combination of for example, walking steps, running distance, heart rate, sleep patterns.

9.4.1. Must include step counter, calories burned, active minutes, hours slept and ability to set goals.

9.4.2. Must include batteries and an instruction manual written in English.

9.5. **Falls Detection Device –** A medical grade device that is worn and can for example, detect falls, have a location tracker, monitors heart rate and have two-way voice communication.

9.5.1. Must include falls detection**.**

9.5.2. Must have means of alerting for help/assitance.

9.5.3. Must have ability to track location.

9.5.4. Must have ability to connect to mobile app.

9.5.5. Must have ability to identify low battery.

9.6. **Calorie Monitors** – A medical grade device designed to Automatically count calories and see daily progress.

9.6.1. Must include calorie counter and burned fat counter.

9.6.2. Must include batteries and an instruction manual written in English.

9.7. **Personal Sleep Trackers** – A medical grade device which captures an array of data that may include heart rate, heart rate variability, respiration, snoring, time awake, time sleeping, sleep interruptions, and body temperature. Some may also monitor room temperature, humidity, noise level, and light.

9.7.1. Must include sleep hours and sleep efficiency trackers.

9.7.2. Must include batteries and instruction manual written in English.

9.8. **Handheld Body Mass Index (BMI) Calculators** - Portable device capable of calculating the BMI of a patient:

9.8.1. Must have an automatic switch off.

9.8.2. Must include batteries and an instruction manual written in English.

9.8.3. Must be a handheld device.

9.9. **Personal Electrocardiographs** - monitors heart when doing normal activities. It helps to detect abnormal heart rates and rhythms (arrhythmias).

9.9.1. Must be cordless.

9.9.2. Must have on screen display.

9.9.3. Must have minimum storage for 200 readings.

9.9.4. Must be provided with an instruction manual written in English.

9.10. **Personal Pulse Stress Monitors** – A wearable device that monitors physiological stress indicators for example heart rate.

9.10.1. Must be portable.

9.10.2. Must include batteries.

9.10.3. Must be provided with an instruction manual written in English.

10. Lot 8 – Movement Disorder Assessment Devices

10.1. This Lot is for all Movement Disorder Assessment Devices:

10.1.1. Wearable Movement Disorder Device

10.1.2. Handheld Movement Disorder Device

10.2. **Wearable Movement Disorder Device –** An MHRA registered medical wearable device that can continuously monitor a combination of for example bradykinesia, dyskinesia, tremor, immobility. The device makes data available to a clinician for review for example through an app and / or database. This is a reusable device.

10.2.1. Where device is rechargeable it must charge automatically when connected to an external power source and have identifiable marker to show when charging for example light.

10.2.2. Suppliers must have available instructions for safe use in English or pictograms, which must be made available to NHS Supply Chain on request.

10.2.3. Must be stated within IFU's and / or on individual product packaging if the device requires connecting to a wireless app to store data.

10.2.4. 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.

10.2.5. Must be stated within IFU's and / or on product packaging intended patient population for example, age, weight, and body part.

10.3. **Handheld Movement Disorder Device –** A medical grade device designed to be held by the patient, the inbuilt sensor assesses the fine motor control of the fingers. This is a reusable device.

10.3.1. Device must have ability to store data for example via connection to tablet through wireless connection.

10.3.2. Device must have inbuilt sensors with motion detection.

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

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

10.3.5. Where device is rechargeable it must charge automatically when connected to an external power source and have identifiable marker to show when charging for example light.

11. Lot 9 – Assessment Lights

11.1. This Lot is for lighting suitable for clinical examinations including:

11.1.1. Headlights,

11.1.2. Examination Lighting,

11.1.3. Magnifying Lamp,

11.1.4. Binocular Loupe,

11.1.5. Bulbs and Accessories

11.2. **Headlights** – A device which is a portable source of light that is worn by the clinician on their heads.

11.2.1. LED headlight with permanent and/or blinking light function.

11.3. **Examination Lights** - device intended to provide light to illuminate a site of patient examination and/or treatment. It typically consists of one or more light bulb(s) and, depending upon the design, reflectors or mirrors which focus and reflect the light. The device can be fixed to a ceiling, wall, or supported on a mobile mount.

11.3.1. LED lamps with / without reflector,

11.3.2. Halogen lamps with / without cool light reflector,

11.3.3. LED must have minimum bulb life stated within IFU's and / or on individual product packaging.

11.3.4. Halogen must have minimum bulb life stated within IFU's and / or on individual product packaging.

11.4. **Magnifying Lamps** – A device which combines quality lighting with high-focus magnification for ultimate visibility.

11.4.1. Must have a lens that has as a minimum 1.75 x magnification.

11.5. **Binocular Loupe** – An optical device used for viewing details of objects with some magnification, used in a close distance from the eye.

11.5.1. Must have a lens that has a minimum 2 x magnification.

11.5.2. Portable and able to attach to head.

11.6. **Support Products in this Lot include but are not limited to:**

11.6.1. Replacement bulbs (halogen, LED),
11.6.2. Table / Celling / Rail / Wall mount or mobile stands,
11.6.3. Lenses,
11.6.4. Disposable sheaths,
11.6.5. Portable power supply,
11.6.6. Carry case,
11.6.7. Headband.

12. Lot 10 - Ear Irrigation Products

12.1. This Lot if for all Ear Irrigation Devices and accessories for use with Ear Irrigation, Products include but are not limited to:

12.1.1. Electronic Ear Irrigation Devices,
12.1.2. Electronic Ear Irrigation Starter Kits,
12.1.3. Ear Micro Suction Pumps,
12.1.4. Ear Irrigator Accessories,

12.2. **Electronic Ear Irrigation Device** – An electronic device designed to pump water into the ear canal to flush cerumen (ear wax) out of the ear canal during the procedure.

12.2.1. Must have ability to pump water into ear canal with a variable pressure control.

12.3. **Ear Irrigation Stater Kit** - A collection of items intended to be used to flush cerumen (ear wax) out of the ear canal during an ear/nose/throat (ENT) procedure. It consists of electronic ear irrigation device and accessory items (e.g., carry case, a cup to collect used irrigation solution). This is a reusable device.
12.3.1. Must meet all 2.2.

12.4. **Ear Micro Suction Pumps** – A suction powered device used to remove cerumen (ear wax) from the ear canal.

12.4.1. Must have ability for clinician to set pressure on suction device.

12.5. **Ear Irrigator Accessories** include but are not limited to:
12.5.1. Disposable Ear Jet Tips,
12.5.2. Cleaning Tablets,
12.5.3. Ear Tanks,
12.5.4. Ear Curettes,
12.5.5. Valves and Washers,
12.5.6. Capes.

13. Lot 11 – General Patient Assessment Products

13.1. This Lot is for assessment products used in various general patient assessments. Products include:

13.1.1. Fob Watches,
13.1.2. Tuning Forks,
13.1.3. Diabetic Neuropathy Device
13.1.4. Nasal Clips,
13.1.5. Reflex Hammer,
13.1.6. Torch Examination Pen (Disposable /Reusable)
13.1.7. Tongue Depressors,
13.1.8. Sensory Block Assessment Device

13.2. **Fob Watches** - A small watch device which attaches to clinicians' uniform, which for example can be used for timings of observations.

13.2.1. Must include a battery with a minimum of 12 month's life.
13.2.2. Must have mechanism to prevent the battery from engaging until the Fob watch is used for the first time.
13.2.3. Must have a locking bar pin to attach to clothing with a safety latch or clasp.

13.3. **Tuning Forks** - A hand-held, mechanical test instrument designed as an acoustic resonator used to test the hearing acuity of a patient, to diagnose hearing disorders, and to test for vibratory sense.

13.3.1. Must be calibrated for hearing tests and devices for testing vibration perception.

13.4. **Diabetic Neuropathy Device –** A small handheld medical device which is used to assess for loss of sensation in patients with diabetes. This is a reusable device.

13.4.1. Must have decontamination instructions within IFU's and / or on individual product packaging.
13.4.2. Must have ability to switch vibration on and off.

13.5. **Nasal Clips** - A cushioned, adjustable plastic clip designed to fit the nose snugly and comfortably, while applying pressure to the area just below the bridge of the nose in order to halt the flow of blood during a nosebleed (Epistaxis).

13.5.1. Must be single patient.
13.5.2. Must be designed for use with nose pads for gentle controlled epistaxis.

13.6. **Reflex Hammers** - A hand-held manual instrument designed to be used by an examining physician to gently tap near a patient's joints to test reflexes (e.g., patellar, ankle reflexes). Can be single use or reusable.

13.7. **Reusable Tourniquets** - Elasticated band which are used in the blood sampling procedure to restrict blood flow.

13.7.1. Product must be robust enough to resist breakage when tourniquet effect is being applied as directed by supplier.
13.7.2. Product design must minimise risk of harm to skin when tourniquet is applied as directed by manufacturer.

13.7.3. Must have quick release mechanism.

13.7.4. Instructions on how many times the product can be used and when to dispose of them must be included in instructions for use and must be provided to NHS Supply Chain and/or end user on request.

13.8. **Examination Pen Torches** – A small pen sized torch which can be used for example to assess pupil size, examine the oral cavity, these can be disposable or reusable devices.

13.8.1. Must be provided complete with battery.

13.9. **Tongue Depressors** - A hand-held device intended to be used to displace the tongue to facilitate examination of the surrounding organs/tissues. It is typically a double-ended flat device with rounded working ends made of wood or plastic materials; it may be aromatic/flavoured to make it less intrusive.

13.9.1. Must be smooth and free from splinters.

13.9.2. Must be made from wood or plastic, if made from plastic this must be latex free.

13.10. **Compliance with UK Government Timber Procurement Policy (only applicable to Tongue Depressors made from wood)**

13.10.1. Evidence of compliance to the UK Government Timber Procurement Policy 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.

13.10.2. The UK Government's Timber Procurement Policy requires that all timber and wood-derived products for supply or use in the performance of this Framework Agreement must be independently verifiable and come from:

13.10.2.1. a legal source; and

13.10.2.2. a sustainable source, which can include a FLEGT (Forest Law Enforcement, Governance and Trade) licensed or equivalent source.

13.10.3. Acceptable evidence can be:

13.10.3.1. Category A evidence is third party, independent certification of the timber and timber products by any of the forest certification schemes that meet the policy requirements such as Forest Stewardship Council (FSC) and Programme for Endorsement of Forest Certification (PEFC).

13.10.3.2. Category B evidence is alternative credible documentary evidence that provides assurance that the source is legal and sustainable.

13.10.4. Forest Law Enforcement, Governance and Trade (FLEGT) Voluntary Partnership Agreement (VPA).

13.10.5. See link with details of how to prove legality and sustainability: https://www.gov.uk/guidance/timber-procurement-policy-tpp-prove-legality-and-sustainablity.

13.10.6. UK Timber and Timber Products (Placing on the Market) Regulations (UKTR) and UK FLEGT Regulations or EU equivalent - EU Timber Regulations (EUTR)

13.10.7. This due diligence legislation prohibits placing timber on the UK or EU market that is illegally harvested.

13.10.8. To achieve this, it sets out procedures which those trading timbers within the UK or EU must put in place to minimise the risk of illegal timber being sold.

13.10.9. The regulation covers trade in timber products on the UK or EU market and applies to both imported and domestically produced timber. It covers most timber products commonly traded in the UK or EU except for recycled products.

13.10.10. The regulation applies to two types of organisations within the UK or EU timber supply chain. The bulk of the requirements apply to whoever first places the timber product on the UK or EU market. This organisation is referred to as the operator. In addition to requirements for operators, there are also requirements for traceability for all the other participants in the supply chain prior to sale to the final consumer. These organisations are all referred to as traders.

13.10.11. Guidance on complying with both UKTR and EUTR can be found at the following links: https://www.gov.uk/guidance/regulations-timber-and-flegt-licences.

13.10.12. https://ec.europa.eu/environment/forests/timber_regulation.htm

13.11. **Sensory Block Assessment Device –** A small handheld stick which has a detachable handle and a metal top, stored in the fridge and used to assess sensory block. This is a reusable device.

13.11.1. Must have decontamination instructions within IFU's and /or on individual product packaging.

13.11.2. Must have ability to detach handle for decontamination, handle must be secure during use as per IFU's.