APPENDIX 3

FRAMEWORK AGREEMENT SPECIFICATION
THERMOMETER DEVICES AND SUPPORT PRODUCTS 2021

1. Introduction

1.1. The Framework Agreement is for the supply of thermometer devices and support products for body temperature measurement including phase change thermometers, electronic thermometer devices with corded probe, associated covers and accessories, electronic thermometer devices with flexible probe tip and associated covers, electronic thermometer devices with rigid probe tip and associated covers, tympanic devices, associated covers and accessories, non-contact temporal artery devices and accessories.

1.2. The Framework Agreement is for the following Lots:

Lot Number	Lot Title
Lot 1	Phase Change Thermometers
Lot 2	Electronic Thermometer Devices with Corded Probe, Associated Covers and Accessories
Lot 3	Electronic Thermometer Devices with Flexible Probe Tip and Associated Covers
Lot 4	Electronic Thermometer Devices with Rigid Probe Tip and Associated Covers
Lot 5	Tympanic Thermometer Devices, Associated Covers and Accessories
Lot 6	Non Contact Temporal Artery Thermometer Devices and Accessories

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

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 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.

2.2. In accordance with the Control of Substances Hazardous to Health Regulations 2002 (as amended) safety data sheets for all product lines that fall under these Regulations must be provided by Applicants to NHS Supply Chain.

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. 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 Directive 2002/95/EC).

2.5. All product lines and packaging should be latex free where possible. If a product line or any packaging contains latex this must be clearly labelled on the product line or packaging (as applicable) to inform the user.

2.6. All product line(s) must be supplied with a minimum 2 years shelf life, not including the batteries included in the thermometer devices.

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

2.8. All instructions for use must be written in English or pictograms.

2.9. All product lines must measure in Celsius as a minimum.

2.10. All product lines must be suitable for clinical use in near-patient areas.

2.11. Temperature reading must be identifiable.

2.12. All product lines must audibly and/or visually alert the end user as to when the temperature has been taken.

2.13. When present, batteries must be housed in the product in a secure way to prevent them falling out when product is used as per manufacturer's instructions. This will ensure function of the product is not detrimentally affected.

2.14. All products lines must be mercury free.

3. Lot 1 – Phase Change Thermometers

3.1. This Lot includes devices which use samples of inert chemicals which melt at progressively higher temperatures. These chemicals are mounted as small dots in a matrix on a device which can be used to take an oral and/or axillary measurement to produce a temperature reading that is taken from the last dot to melt.

3.2. Standards and Legislation

STANDARD AND LEGISLATION
All products within this Lot must comply with the relevant standards (or equivalent) as listed below: **BS EN 12470-2:2000+A1 2009** Clinical Thermometers. Phase Change type (dot matrix) thermometers **ASTM E825 - 98(2016)** Standard specification for Phase Change Type disposable fever thermometer for intermittent determination of human temperature.

3.3. Must be designed to work in the mouth and/or axilla.

3.4. Instructions for use (IFU's) must state the length of time that the device is to be left in anatomical site when measuring temperature.

3.5. IFUs must indicate in English or pictograms, the anatomical sites for the temperature to be taken from.

4. Lot 2 – Electronic Thermometer Devices with Corded Probe, Associated Covers and Accessories

4.1. This Lot includes products which measure temperature either orally, axillary or rectally by use of a corded probe. These devices identify the temperature in a numerical reading. These devices require single use probe covers which assist with infection control and are also included within this Lot.

4.2. Standards and Legislation

STANDARD AND LEGISLATION
All products within this Lot must comply with the relevant standards (or equivalent) as listed below: **BS EN ISO 80601-2-56:2017+A1:2020 (or equivalent)** Medical electrical equipment. Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. **ASTM E1112 - 00(2018)** Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature **ASTM E1104 - 98(2016)** Standard Specification for Clinical Thermometer Probe Covers and Sheaths

4.3. All product lines must be able to be cleaned to prevent cross contamination.

4.4. If mode settings are present, the correct mode for the anatomical site to be measured can be identified.

4.5. Information on automatic mode settings must be contained within IFUs or made available to NHS Supply Chain or end user on request.

4.6. Device must be robust enough to withstand clinical use in varying settings when used in accordance with manufacturer's instructions.

4.7. Device and covers must be designed to fit into appropriate anatomical site without causing harm to the patient.

4.8. Cover must not detrimentally affect the devices ability to take the temperature.

4.9. Disposable covers must be single use and be stated on individual product packaging.

4.10. Disposable covers must have a means of removing the disposable probe cover to prevent cross contamination to the user, for example with a release button.

4.11. Disposable covers must not come off the device during temperature reading when applied as per manufacturer's instructions.

4.12. Covers must be designed to be dispensed individually when applied as per manufacturer's instructions.

4.13. Additional Lines for Electronic Thermometer Devices with Corded Probe include:

- 4.13.1. Wall Bracket.
- 4.13.2. Desk mount.
- 4.13.3. Cradle.
- 4.13.4. Holder.
- 4.13.5. Security Tether.
- 4.13.6. Thermal Carry Case.
- 4.13.7. Disposable Probe Cover Container.
- 4.13.8. Calibrator.
- 4.13.9. Charger.

5. Lot 3 - Electronic Thermometer Devices with Flexible Probe Tip and Associated Covers

5.1. This Lot includes products which measure temperature either orally, axillary or rectally by use of a flexible probe tip. These devices identify the temperature in a numerical reading and can also be referred to as digital thermometers. These devices can be used with single use probe covers which assist with infection control and are also included within this Lot.

5.2. Standards and Legislation

STANDARD AND LEGISLATION
All products within this Lot must comply with the relevant standards (or equivalent) as listed below: **BS EN ISO 80601-2-56:2017+A1:2020 (or equivalent)** Medical electrical equipment. Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

ASTM E1112 - 00(2018)
Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature

ASTM E1104 - 98(2016)
Standard Specification for Clinical Thermometer Probe Covers and Sheaths

5.3. All product lines must be able to be cleaned to prevent cross contamination.

5.4. If mode settings are present, the correct mode for the anatomical site to be measured can be identified.

5.5. Information on automatic mode settings must be contained within IFUs or made available to NHS Supply Chain or end user on request.

5.6. Device must be robust enough to withstand clinical use in varying settings when used in accordance with manufacturer's instructions.

5.7. Device and covers must be designed to fit into appropriate anatomical site without causing harm to the patient.

5.8. Cover must not detrimentally affect the devices ability to take the temperature.

5.9. Disposable covers must be single use and be stated on individual product packaging.

5.10. Disposable covers must have a means of removing the disposable probe cover to prevent cross contamination to the user, for example with a tab.

5.11. Disposable covers must not come off the device during temperature reading when applied as per manufacturer's instructions.

5.12. Covers must be designed to be dispensed individually when applied as per manufacturer's instructions.

6. Lot 4 - Electronic Thermometer Devices with Rigid Probe Tip and Associated Covers

6.1. This Lot includes products which measure temperature either orally, axillary or rectally by use of a rigid probe tip. These devices identify the temperature in a numerical reading and can also be referred to as digital thermometers. These devices can be used with single use probe covers which assist with infection control and are also included within this Lot.

6.2. Standards and Legislation

STANDARD AND LEGISLATION
All products within this Lot must comply with the relevant standards (or equivalent) as listed below: **BS EN ISO 80601-2-56:2017+A1:2020 (or equivalent)** Medical electrical equipment. Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. **ASTM E1112 - 00(2018)** Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature **ASTM E1104 - 98(2016)** Standard Specification for Clinical Thermometer Probe Covers and Sheaths

6.3. All product lines must be able to be cleaned to prevent cross contamination.

6.4. If mode settings are present, the correct mode for the anatomical site to be measured can be identified.

6.5. Information on automatic mode settings must be contained within IFUs or made available to NHS Supply Chain or end user on request.

6.6. Device must be robust enough to withstand clinical use in varying settings when used in accordance with manufacturer's instructions.

6.7. Device and covers must be designed to fit into appropriate anatomical site without causing harm to the patient.

6.8. Cover must not detrimentally affect the devices ability to take the temperature.

6.9. Disposable covers must be single use and be stated on individual product packaging.

6.10. Disposable covers must have a means of removing the disposable probe cover to prevent cross contamination to the user, for example with a tab.

6.11. Disposable covers must not come off the device during temperature reading when applied as per manufacturer's instructions.

6.12. Covers must be designed to be dispensed individually when applied as per manufacturer's instructions.

7. Lot 5 – Tympanic Thermometer Devices, Associated Covers and Accessories

7.1. This Lot includes products which measure temperature within the ear cavity by taking a reading from the tympanic membrane. These devices identify the

temperature in a numerical reading, and require probe covers to assist with infection control which are also included in this Lot.

7.2. Standards and Legislation

STANDARD AND LEGISLATION
All products within this Lot must comply with the relevant standards (or equivalent) as listed below: **BS EN ISO 80601-2-56:2017+A1:2020 (or equivalent)** Medical electrical equipment. Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. **ASTM E1104 - 98(2016)** Standard Specification for Clinical Thermometer Probe Covers and Sheaths

7.3. All product lines must be able to be cleaned to prevent cross contamination.

7.4. If mode settings are present, the correct mode for the anatomical site to be measured can be identified.

7.5. Information on automatic mode settings must be contained within IFUs or made available to NHS Supply Chain or end user on request.

7.6. Device must be robust enough to withstand clinical use in varying settings when used in accordance with manufacturer's instructions.

7.7. Device and covers must be designed to fit into appropriate anatomical site without causing harm to the patient.

7.8. Cover must not detrimentally affect the devices ability to take the temperature.

7.9. Disposable covers must be single use and be stated on individual product packaging.

7.10. Disposable covers must have a means of removing the disposable probe cover to prevent cross contamination to the user, for example with a release button.

7.11. Disposable covers must not come off the device during temperature reading when applied as per manufacturer's instructions.

7.12. Covers must be designed to be dispensed individually when applied as per manufacturer's instructions.

7.13. Additional Lines for Tympanic Thermometer Devices include:

7.13.1. Wall Bracket.
7.13.2. Desk mount.
7.13.3. Cradle.
7.13.4. Holder.
7.13.5. Security Tether.
7.13.6. Thermal Carry Case.
7.13.7. Disposable Probe Cover Container.
7.13.8. Calibrator.
7.13.9. Charger.

8. Lot 6 – Non-Contact Temporal Artery Thermometers and Accessories

8.1. This Lot includes devices which are used to generate a temperature reading from the forehead. These devices read the heat emitted from the skin above the temporal artery and show as a numeric reading. No contact is required, the device is held away from the patient and is therefore often referred to as 'non-contact'.

8.2. Standards and Legislation

STANDARD AND LEGISLATION
All products within this Lot must comply with the relevant standards (or equivalent) as listed below: **BS EN ISO 80601-2-56:2017+A1:2020 (or equivalent)** Medical electrical equipment. Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. **ASTM E1965 - 98(2016)** Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

8.3. All product lines must be able to be cleaned to prevent cross contamination.

8.4. Additional Lines for Non Contact Temporal Artery Thermometers include:
8.4.1. Wall Bracket
8.4.2. Desk mount
8.4.3. Cradle
8.4.4. Holder
8.4.5. Security Tether
8.4.6. Thermal Carry Case
8.4.7. Disposable Probe Cover Container
8.4.8. Calibrator
8.4.9. Charger