APPENDIX 3

FRAMEWORK AGREEMENT SPECIFICATION
MAINTENANCE, REPAIR AND CALIBRATION OF MEDICAL EQUIPMENT

1. Introduction

1.1. The Framework Agreement is for the maintenance, repair and calibration of medical equipment and includes the following options:

1.1.1. Fully Comprehensive Cover;
1.1.2. Planned Preventative Maintenance Cover;
1.1.3. Parts and Labour Cover;
1.1.4. Labour Only Cover;
1.1.5. Best Effort Cover;
1.1.6. Special Component Cover; and
1.1.7. Collaborative (First Line) Cover.

1.2. The Framework Agreement is for the following Lots:

Lot Number	Lot Title
1	Beds, Furniture and Pressure Area Care
2	Patient Bathing, Handling and Transport
3	Temperature Control
4	Patient Assessment, Monitoring and Life Support
5	Microscopes
6	Dental Equipment Maintenance
7	Endoscopy
8	Ophthalmology
9	Lasers
10	Renal and Urodynamics
11	Tier 1 - Imaging Equipment
12	Tier 2 – Imaging Equipment
13	General Theatre, Orthopaedics and Physical Therapy
14	Decontamination
15	Laboratory, Pathology and Analysis Equipment
16	Radiotherapy Equipment and Treatment Systems
17	Robotic Surgical Systems

1.3. Full technical specifications of the services 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 services awarded to the Framework Agreement mean that the service no longer meets the minimum requirements outlined in the Specification, NHS Supply Chain reserves the right to exclude that service 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. Services 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 cover levels and all Lots

2.1. All electrical work must comply with **BS EN 62353:2014** (Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment) or **IEC60601-1** (Medical electrical equipment) or equivalent.

2.2. Maintenance of lifting equipment including any equipment used for lifting or lowering loads, including attachments used for anchoring, fixing or supporting the lift must ensure the Purchasing Authority can meet their obligations under the Lifting Operations and Lifting Equipment Regulations 1998 (LOLER) to protect their staff and patients. Where applicable, equipment must be load tested at the time of delivery of the service activity and the load testing performed must be in line with OEM specifications/guidelines.

2.3. Maintenance of all work equipment including any machinery, appliance, apparatus, tool or installation for use at work must ensure the Purchasing Authority can meet their obligations under the Provision and Use of Work Equipment Regulations 1998 (PUWER). Where applicable, all work equipment is to be maintained in an efficient state, in efficient order and in good repair; and that maintenance operations on work equipment can be carried out safely in line with OEM specifications/guidelines.

2.4. Where service modality specific legislation exists for "in-service use" of particular equipment (including the Non-Automatic Weighing Instruments Regulations 2000), the regulation requirements concerning repair, verification and requalification of the equipment must be complied with.

2.5. All maintenance work must ensure the Purchasing Authority can meet their obligations under the Health and Safety at Work Act and Electricity at Work Regulations to protect their staff and patients.

2.6. Electrical services 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).

2.7. For the purpose of this specification calibration is defined as the determination of the accuracy of an instrument, usually by measurement of its variation from a standard to ascertain necessary correction factors.

2.8. Where applicable, all maintenance, repair and calibration procedures carried out must conform to the original equipment manufacturer's (OEM) specifications.

2.9. Applicants must have access to the required tools and documentation of the OEM in order to be able to perform safe and effective maintenance, repair and calibration activities.

2.10. When required, all calibration and/or output checks must be performed in accordance with the original manufacturer's specifications and procedures with supporting paperwork provided to the Participating Authority to ensure full traceability of all work undertaken.

2.11. All tools and equipment requiring calibration and used for the maintenance of medical devices must be calibrated in accordance with manufacturer's guidelines and bear a label confirming the period of validity before recalibration is required. If it is not possible to attach a label, calibration certificates must be available to the Participating Authority upon request.

2.12. Where applicable, all corrective interventions must include appropriate calibration, functional and safety checks and electrical safety testing and following corrective interventions, the equipment must be left operating to the OEM specification.

2.13. Where the results of a calibration indicate the need for adjustment or repair, the pre adjustment/repair results must be highlighted to the Participating Authority to allow for an evaluation of the effect of the 'as found' condition on previous usage.

2.14. If required following an upgrade or an update: calibration, performance validation, performance verification or Quality Assurance must be carried out to ensure that the device is operating as detailed in the OEM specification (consulting the Participating Authority in relation to local settings for the equipment). The Participating Authority must be made aware of the authenticity of the upgrade or update and if it has or has not been provided by the OEM. If the requirement for equipment performance validation and devices being passed fit for purpose is the responsibility of the Participating Authority the performance must initially be validated by the service engineer (An example of equipment where this may be the case may include Radiotherapy Equipment).

2.15. Following all maintenance, repair and calibration work, a hard copy or electronic service record confirming all work undertaken must be provided free of charge to the Participating Authority within 2 working days of the service visit.

2.16. Applicants must provide free of charge access to all maintenance records/service reports throughout the term of the maintenance contract to NHS Supply Chain or the customer.

2.17. Applicants must make historical service records and reports available for a minimum of 3 years.

2.18. Electronic copies of service history records, service visit reports and service repair reports must be returned free of charge and on request to the Participating Authority at the end of the contract period. Hard copies must be made available on request to the Participating Authority and to NHS Supply Chain and be provided free of charge.

2.19. In the event that Applicants access a device remotely to carry out a diagnostic investigation, a fault correction or an update/upgrade a full record of activity and outcome must be made by the Applicants and this must be made available free of charge to the Participating Authority upon request.

2.20. All service visit and service repair reports must document:

- 2.20.1. Equipment description / equipment name / equipment serial number;
- 2.20.2. Site and location of equipment;
- 2.20.3. Date of visit;
- 2.20.4. Details of travel and labour;
- 2.20.5. Engineer name;
- 2.20.6. Engineer signature (in the event of an electronic report it is accepted that an engineer signature may not be possible);
- 2.20.7. Participating Authority representative name;
- 2.20.8. Participating Authority representative signature confirming service completion and acceptance of work;

2.20.9. Contract type (Local supplier name for the contract);
2.20.10. Description of works;
2.20.11. Details of parts exchanged or replaced including part serial number/Identification number to allow traceability;
2.20.12. The source of parts (e.g. OEM/Non-OEM/OEM Reclaimed/OEM Refurbished). In the event that OEM parts are always used by the Applicant it is not required that the report includes source of parts;
2.20.13. Detail of work carried out to include faults, breakages, breakdowns, visit number, call out / planned preventative maintenance (PPM) number and possible cause of fault;
2.20.14. If required as a result of the maintenance or repair activity and if performed by the service engineer, details of any Quality Assurance or Performance Verification or Performance Validations activity including result/outcome;
2.20.15. Details of remedial action taken including corrected settings and where applicable any verification with legal requirements performed;
2.20.16. Details of any changes made to the device (e.g. system settings);
2.20.17. Details of any upgrades or updates made and the need for any re training of end users as a result of the upgrade or update; and
2.20.18. Where applicable and in relation to radiation safety, state whether any work on the equipment has significantly affected patient radiation dose as required by HSE guidance PM77 3rd Edition and IRR17 legislation.
2.20.19. Where applicable all Applicants must meet the DSP Toolkit Standards as set out by NHS Digital for more information please see https://www.dsptoolkit.nhs.uk/Help/overview.

2.21. Subject to a due diligence check of the system being completed by the OEM prior to any update being supplied and installed (such consent to be agreed by the parties in writing prior to the due diligence taking place), any **safety critical software updates** (which are defined as updates that ensure that the device will perform as intended by the OEM and not compromise the clinical condition or the life of patients, or the safety and health of users or, where applicable, other persons) must be provided free of charge by the OEM as part of the service contract (refer to 2.22 in the event that the OEM is not the nominated service provider) and the Participating Authority must be informed if additional user training is required once installed.

2.22. Where the system is not being maintained by the OEM or their authorised agent, the OEM must make the Participating Authority and, if possible/applicable, the nominated Applicant aware of the need to install safety critical/performance/reliability updates that are required. Where Applicable, subject to a due diligence check of the system being completed by the OEM prior to any update being supplied and installed (such consent to be agreed by the parties in writing prior to the due diligence taking place), it will be the responsibility of the OEM to install these updates and to agree how and when

this will be done with the Participating Authority and to confirm that the installation is complete.

2.23. Any performance or reliability related software updates (which are defined as updates that ensure that the device will perform as intended by the original equipment manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons) must be provided free of charge as part of the service contract and the Applicant must inform the Participating Authority if additional user training is required once installed.

2.24. The Supplier shall cooperate fully with NHS Supply Chain or, as the case may be, any replacement supplier during any re-procurement and handover period or novation of the Framework Agreement or any Contract prior to and following the expiry or earlier termination of this Framework Agreement. This cooperation shall extend to providing access to all information relevant to the operation of this Framework Agreement and signing any documents, as reasonably required by NHS Supply Chain to achieve a fair and transparent re-procurement and/or an effective transition without disruption to routine operational requirements.

2.25. After any work has been carried out all work areas and medical equipment must be left clean, tidy and to the Participating Authority's satisfaction and in a condition no worse than before the work was started.

2.26. A manned, English speaking non-premium rate customer service telephone helpline must, as a minimum, be available to a customer under a specific maintenance contract from Monday to Friday between 9am and 5pm or 8am to 4pm (Core Hours) excluding bank holidays. This service must reach a person who is able to support a customer with general queries that may include:

- 2.26.1. Response times;
- 2.26.2. Confirming cover levels;
- 2.26.3. Arranging emergency call out visits;
- 2.26.4. Requesting service reports;
- 2.26.5. Checking progress on any incident; and
- 2.26.6. Logging a customer complaint.

2.27. A manned, English speaking non-premium rate service and or technical support telephone helpline must, as a minimum, be available to a customer under a specific maintenance contract from Monday to Friday between 9am and 5pm or 8am to 4pm (Core Hours) excluding bank holidays. This service must reach a person with product/service knowledge and who is able to support a customer with technical queries that may include:

- 2.27.1. Equipment faults including reporting a new fault and following up on previously reported faults;
- 2.27.2. First line maintenance queries;
- 2.27.3. End user operational queries;

2.27.4. Providing clarity and explanations for technical terminology;
2.27.5. Technical queries;
2.27.6. Booking a service visit;
2.27.7. Arranging emergency call out visits; and
2.27.8. Part number and costing detail for parts.

2.28. Any product line used as part of the service provided that contains phthalates must be indicated on the packaging in accordance with Directive 2007/47/EC (amending Directives 90/385/EEC and 93/42/EEC).

2.29. All product lines used as part of the service provided (and their packaging) should be latex free where possible. Any products or packaging containing latex must be clearly labelled as such to inform the user.

2.30. Any mandatory replacement spare parts or consumables replaced as part of the service provided must be in accordance with the OEM schedules and product specifications.

2.31. The Applicant must have access to OEM spare parts or spare parts to the same technical specification (including physical dimensions, material strength, mechanical properties and compatibility) that enable the device to operate safely and within the manufacturers specifications and do not adversely affect the equipment's performance longevity or outstanding manufacturer's warranty.

2.32. The Applicant must complete a risk assessment when a decision is made to use previously used OEM spare parts, OEM refurbished, OEM reclaimed or new non-OEM spare parts and this risk assessment must be made available to the Participating Authority. In the event that the OEM refurbished, or OEM reclaimed parts have been provided by the OEM, proof of testing/validation by the OEM will be accepted as an alternative to a risk assessment.

2.33. If the applicant uses new non OEM spare parts, previously used OEM spare parts, OEM refurbished spare parts or OEM reclaimed spare parts to deliver the service, prior agreement must be obtained from the Participating Authority and the use of such spare parts must be documented in the service record for the equipment.

2.34. Previously used, reclaimed or refurbished OEM spare parts must not be used to repair a device unless the previous history of the part is known. The Applicant must be able to provide full traceability for the OEM reclaimed or refurbished spare parts.

2.35. Non-OEM refurbished spare parts, Non-OEM reclaimed spare parts and counterfeit spare parts must not be used by the Applicant.

2.36. The Applicant must be able to identify all critical parts (which the Medicines and Healthcare products Regulatory Agency – MHRA - define as components that might reasonably be expected to cause failure of a piece of equipment in such a way that affects its safety or effectiveness and consequently results in death or injury to a user/patient should it stop working) and information including manufacturers/suppliers name, spare part name, serial number and product code to allow individual components to be traced back to the supplier if necessary.

2.37. All replacement batteries must have the same technical specification (including, where applicable, active memory and current limiting/capacity indicating features) to provide the same power and lifecycle as those provided with the original device as detailed in the original manufacturers' specification.

2.38. When replacing batteries, the Applicant must follow the OEM's specification and the latest instructions from the OEM to ensure that the correct battery specification is being used during the lifetime of the equipment.

2.39. The Applicant must ensure that when maintenance and/or repair of equipment is carried out, that it does not remove any identification marks associated with the original device including conformity marks such as a CE mark/UKCA mark and where required by regulation, the data plate including type approval and verification status.

2.40. If the Applicant assigns a new serial number to a medical device, the original manufacturer's serial number and new serial number must be included in all subsequent documentation.

2.41. An engineer must not leave the site of a Participating Authority until the equipment under repair or maintenance is calibrated, tested (electrical tests where applicable to include all alarms, alert and safety systems and rechargeable or replaceable batteries being fully functional and calibrated to original equipment manufacturer's specifications), confirmed to be in full working order and the service report/visit report is completed with all required details. If this requirement cannot be satisfied at the time of the visit the engineer must leave the equipment in a safe manner and inform the Participating Authority before leaving.

2.42. In the event that a safety risk or an error in operation which renders the equipment unsafe or no longer complying with applicable regulation is identified and cannot be corrected when performing maintenance, repair or calibration activities, the service engineer must recommend to the Participating Authority that the device be removed from operation. The service engineer must document in the service report/visit report of the Participating Authority chooses to ignore the recommendation.

2.43. A minimum of 3 months warranty must be provided on all spare parts and repairs effective from the date of installation or repair, with the warranties being transferrable to the Participating Authority.

2.44. Applicants must have a system for managing and responding to alerts and field safety corrective action notices when issued by the manufacturer or the Medicines and Healthcare products Regulatory Agency (MHRA) and by NHS England. The Applicants will be responsible for carrying out any alert actions.

2.45. Where an Applicant is maintaining a device that employs the use of Ionising Radiation, the service engineer must work in accordance with either the Applicant's local rules or with the Participating Authority's local rules as required by the IRR17 (Ionising Radiation Regulations 2017) legislation. If the engineer works to the Applicant's local rules, formal arrangements must be in place to hand over the radiation controlled area between employers, and the work must be supervised by the Applicant's Radiation Protection Supervisor (RPS) appointed under IRR17 to ensure that the work is carried out in accordance with the local rules (this does not mean that the RPS has to be on site during the service).

2.46. Where an Applicant is installing a device or component that employs the use of Ionising Radiation, and where there may be radiation protection implications arising from that installation, the Applicant is responsible for conducting a Critical Examination of the installation as required by IRR17 and must consult with a Radiation Protection Adviser (RPA). The RPA may be appointed either by the Applicant or by the Participating Authority. For new installations, the preferred arrangements for the Critical Examination and RPA appointment should be agreed by the Applicant and the Participating Authority at the time of equipment purchase.

2.47. If loan equipment is provided by the Applicant, it must be of an equivalent or higher standard to the equipment it is replacing. The Applicant will be responsible for ensuring the loan equipment meets the requirements of the Participating Authority and performing any non-fault repairs (this excludes accidental damage caused by the Participating Authority) for the duration of the loan period.

2.48. All service engineers must have passed a Disclosure and Barring Service (DBS) check; documentation must be available for inspection by the Participating Authority on request during the term of this Framework Agreement and this must be in line with Data Protection Regulations.

2.49. All service engineers must carry photographic identification that can be validated by the Participating Authority.

2.50. The Applicant must employ and have available to respond, at least one fully trained, competent engineer for the Lots that the Applicant is awarded to, and who is at all times:

2.50.1. employed by the Supplier on a PAYE basis and is always defined as an employee under section 230 of the Employment Rights Act 1996; and

2.50.2. able to carry out the duties required by the Participating Authority and as a minimum meet the requirements set out in this Specification with the requisite skills, competency, capability and experience to ensure that it complies with its obligations under this Contract. This will include the Supplier providing a sufficient number of trained and competent staff to provide the required services during staff holidays or absence.

2.51. Service engineers must be trained and competent in the safe use of the tools and equipment used when carrying out maintenance, repair and calibration activities within the Lots that the applicant is awarded to.

2.52. All engineers carrying out routine planned maintenance and/or unplanned repair work must be trained and hold valid certification to confirm that they can meet the service requirements of the OEM (or have attended an equivalent training course) and are competent to maintain the equipment in accordance with OEM specifications and any legal requirements relating to the particular equipment. NHS Supply Chain reserves the right to request copies of training certificates during the term of this Framework Agreement and also evidence of qualification to carry out tasks to which legal requirements pertain.

2.53. The applicant is required to take full responsibility for the provision of training for their service engineers, which must include on-going refresher training to ensure that engineers remain competent to carry out maintenance, repair and calibration activities within the Lots that the applicant is awarded to.

2.54. The applicant accepts that by conforming to this Specification they confirm that all training is current and records for their service engineers are in place and up to date and will be provided on request to the Participating Authority and/or NHS Supply Chain during the term of this Framework Agreement; if copies are required they must be provided in electronic format and free of charge.

2.55. Once in place, the detail and content of a maintenance contract must not be changed unless by mutual agreement of all parties. (This would be in relation to a mix of equipment/variations where no penalties are to be charged for an update of the asset portfolio for that specific contract and this will include decommissions being removed and ex warranty equipment being added to the contract. Any notice period and changes must be notified to the Participating Authority.)

2.56. All maintenance contract quotations must be supported by a detailed cover level document as detailed in the Framework Agreement.

2.57. In the event that the applicant fails to carry out the required number of PPM visits as detailed in the PPM schedule, the Participating Authority must be able to claim partial credits equivalent to the value of the missed PPM visit(s) from the applicant. This will be on the proviso that the contract start date confirmed by the Participating Authority is in line with either the expiry of a current maintenance contract or the expiry of a warranty period, therefore giving the supplier suitable notice to be able to equally spread and book in the recommended number of PPM visits as per the OEM PPM schedule or as per the maintenance contract agreement should this number differ.

2.58. In the event that a supplier has been unable to book in PPM visits or obtain access to carry out confirmed PPM visits due to the Participating Authority failing to confirm an appointment slot or failing to provide access to the equipment during an agreed PPM time slot, the applicant must be able to evidence this in order to mitigate a potential claim for compensation by the Participating Authority.

2.59. Applicants must provide customer references on request to the Participating Authority and/or NHS Supply Chain during the term of this Framework Agreement.

2.60. Where applicable and if required by the Participating Authority, applicants must be responsible for the collection and delivery (and associated costs) of medical equipment from the clinical environment or agreed despatch area and the return of the equipment to the clinical environment or agreed receipts area once the maintenance, repair or calibration activity has been completed.

2.61. Where the applicant is providing a service for endoscopes or decontamination equipment, the applicant will be required to observe and work within the British Society of Gastroenterology Guidance for Decontamination of Equipment for Gastrointestinal Endoscopy 2014. (Appendix 5b to the Invitation to Tender – BSG Guidelines) Specifically:

- 2.61.1. Applicant must have competent personnel to carry out decontamination tasks on equipment used in clinical environments.
- 2.61.2. Applicants must ensure that they have suitable processes and methods for decontamination and that they use the appropriate agents/chemicals that do not cause material damage to the equipment when used.
- 2.61.3. Applicants must ensure that repaired equipment is returned and re-installed free of contamination risk.
- 2.61.4. In the event that non-OEM spare parts and repair methods are used by the applicant, the applicant must be able to provide detailed

and risk assessed advice on the validated decontamination methods used and decontamination material compatibility.

2.61.5. Additionally, all work carried out by the service engineer must support the Participating Authority in any activity undertaken to meet the recommendations of CFPP 01-06 for the management and decontamination of flexible endoscopes (CFPP 01-06 Choice Framework for Local Policy and Procedures on the management and decontamination of flexible endoscopes).

3. Cover Level Specifications

3.1. For the purpose of this specification the terms "Maintenance Service" is the combination of all technical, administrative, and managerial actions during the life cycle of an item intended to retain it in, or restore it to, a state in which it can perform the required function. The following cover levels are included in this Framework Agreement.

3.2. **Fully Comprehensive Cover** must provide a complete and routine maintenance programme including planned preventative maintenance (as detailed in 3.3) and repair in accordance with the OEM's specification. Typically, the expectation would be that special components (e.g.: glassware, magnets, coils, detectors, probes, or transducers) are included as standard but this aspect of the contract can be agreed on a case by case basis with the Participating Authority. In addition to the requirements listed in Section 2 of this Specification this level of cover must, as a minimum, also include the following:

3.2.1. A technical response to a fault within 2 working hours, Monday to Friday, 9am to 5pm or 8am to 4pm (Core Hours). Technical response can be classed as either an engineer to site or technical support over the telephone provided by a qualified and competent member of your organisation or remote diagnostics to determine the cause of the fault.

3.2.2. For non-critical equipment where non availability of equipment will not prevent the Participating Authority from delivering a service or a patient treatment, the physical presence of a qualified and competent engineer (if required /if need is identified by initial remote diagnostics/technical support provided to determine the cause of the fault) is required within 12 working hours (Core hours) of the need of on-site presence being established (fault is defined as when the device is in a condition where the intended performance or safety requirements are not met or where the physical integrity of the device has been breached).

3.2.3. For critical equipment where non availability of equipment will prevent the Participating Authority from delivering a service or a patient treatment, the physical presence of a qualified and competent (if required /if need is identified by initial remote diagnostics/technical support provided to determine the cause of the fault) is required within 4 working hours (Core hours) of the need of on-site presence being established (fault is defined as when the device is in a condition where

the intended performance or safety requirements are not met or where the physical integrity of the device has been breached).

3.2.4. No limit on the number of non-fault (excludes accidental damage)/corrective repairs within the contract period.

3.2.5. All spare parts and consumables specified by the OEM's Planned Preventative Maintenance (PPM) schedule.

3.2.6. All repair parts specified by the OEM's specification.

3.2.7. As required electrical and mechanical safety checks included in the PPM schedule.

3.2.8. All preventative interventions must include appropriate calibration, functional and safety checks as required before the equipment is returned to the user.

3.2.9. Any PPM which is undertaken at the same time as the corrective maintenance must be recorded in the service record/visit report.

3.2.10. Unless otherwise agreed, be supported by a PPM schedule for the contract term that is issued to the Participating Authority within 10 working days of receipt of the Purchase Order which must detail the number of PPM visits and proposed dates for the PPM visits. (It is accepted that dates for PPM visits can subsequently change and should be agreed between by both parties and that dates may change due to equipment being available to the applicant as agreed with the Participating Authority).

3.2.11. Have equally spaced PPM visits through the contract term.

3.2.12. Where Lifting Operations and Lifting Equipment Regulations (LOLER) are relevant, PPM visits are to be in line with this requirement.

3.2.13. Ensure that PPM visits are scheduled to minimise impact upon patient care and service delivery (within the defined response times for the maintenance contract).

3.2.14. Allowance for the replacement of batteries as part of the PPM plan if required, if batteries are chargeable this must be stated on the cover level document.

3.2.15. All breakdown and maintenance labour costs including charges for call-outs and repairs.

3.2.16. All travel and accommodation charges.

3.2.17. For Lots 11 and 12, an Uptime Guarantee percentage value equal to or above 98% which must be documented in the cover level document (as detailed in Schedule 7) attached to the quotation, (Uptime Guarantee is defined as the time during which a piece of equipment is operating or can be operated during service coverage hours defined in the cover level document). The Uptime Guarantee will exclude scheduled works which include any pre-planned and agreed downtime which has been scheduled with the Participating Authority in order to perform service contract works such as routine PPM visits, required safety alert notified works, any required software/hardware upgrades.

3.2.18. For all other lots, an Uptime Guarantee percentage value equal to or above 96% which must be documented in the cover level document (as detailed in Schedule 7) attached to the quotation, (Uptime Guarantee is defined as the time during which a piece of equipment is operating or can be operated during service coverage hours defined in the cover level document). The Uptime Guarantee will exclude scheduled works which include any pre-planned and agreed downtime which has been scheduled with the Participating Authority in order to perform service contract works such as routine PPM visits, required safety alert notified works, any required software/hardware upgrades.

3.2.19. A requirement that in the event that accidental damaged renders the device beyond repair, the Applicant must notify the Participating Authority.

3.3. **Planned Preventative Maintenance Cover** (PPM) Cover provides a proactive routine maintenance programme in line with the OEM's recommendations. PPM cover contracts are entered into to minimise a devices risk of failure to ensure its continued and proper operation in addition to the requirements listed in Section 2 of this Specification this level of cover must, as a minimum, also include the following:

3.3.1. The provision and replacement of all non-durable life limited components /parts (including filters, O ring seals) and consumables specified in the original equipment manufacturers PPM schedule.

3.3.2. All life limited components/parts must be provided and be available to the engineer in order to be able to carry out the PPM activity.

3.3.3. Any PPM which is undertaken at the same time as the corrective maintenance must be recorded in the service report/visit report or recorded separately if this is the standard process followed by the Applicant.

3.3.4. Ensure that PPM visits are scheduled to minimise impact upon patient care and service delivery (within the defined response times for the maintenance contract)

3.3.5. Be supported by a PPM schedule for the contract term that is issued to the Participating Authority within 10 working days of receipt of the Purchase Order (unless otherwise agreed) and detailing the number of PPM visits and proposed dates for the PPM visits.

3.3.6. PPM visits must be equally spaced through the contract term.

3.3.7. Where Lifting Operations and Lifting Equipment Regulations (LOLER) are relevant, PPM visits are to be in line with this requirement.

3.3.8. PPM visits must be completed within 10 working days of the date stated on the PPM schedule, variation to the date must be agreed by the Participating Authority. (It is accepted that dates for PPM visits can subsequently change and should be agreed between by both parties).

3.3.9. All preventative interventions must include appropriate calibration, functional and safety checks as required before the equipment is returned to the user.

3.3.10. All travel and labour charges relating to the PPM activity.
3.3.11. All electrical and mechanical safety checks.

3.4. **Parts and Labour Cover** must provide for scheduled/unscheduled repairs or the replacement of failed components with cover to be provided as a minimum Monday to Friday, 9am to 5pm or 8am to 4pm (core hours), excluding holidays and bank holidays. In addition to the requirements listed in Section 2 of this Specification this level of cover must, as a minimum, also include Parts, labour charges and travel costs.

3.5. **Labour Only Cover** – such as Labour Only, Repair Only, Calibration Only, Testing Only. Labour Only Cover can include scheduled/unscheduled repairs, the replacement of failed components, equipment calibration (with traceability to UK Primary standards), commissioning or testing. Cover to be provided as a minimum Monday to Friday, 9am to 5pm or 8am to 4pm (core hours), excluding holidays and bank holidays. In addition to the requirements listed in Section 2 of this Specification this level of cover must, as a minimum, also include labour charges and travel costs.

3.6. **Special Component Cover** must offer a flexible solution to customers who are looking to control costs and to spread risk across their equipment base and must be restricted to equipment type (e.g. Ultrasound) particularly where high value components including glassware, magnets, coils, detectors, probes, batteries or transducers are involved. In addition to the requirements listed in Section 2 of this Specification this level of cover must make provision for multiple items (of the same type) to be covered under one protective maintenance plan and, as a minimum, the plan must include the following:

3.6.1. A link to a maintenance contract ordered via this Framework Agreement or can be a standalone package.
3.6.2. If a standalone package, provide cover provided as a minimum Monday to Friday, 9am to 5pm or 8am to 4pm (core hours), excluding holidays and bank holidays.
3.6.3. Confirmation of the total number of high value components covered.
3.6.4. Confirmation of the main equipment serial number(s) that the high value components are linked to.
3.6.5. Confirmation of the parameters of the risk share and the mechanism for how the Participating Authority will be charged or reimbursed if the agreed risk share is fully utilised, exceeded or underutilised.
3.6.6. Confirmation of the costs for the purchase of the further special components in the event that the Participating Authority fully utilises the agreed number of special components covered by the contract.
3.6.7. Delivery of new/replacement components.
3.6.8. Removal and disposal of replaced components.
3.6.9. Installation of replacement components.

3.7. **Best Effort Cover** can be offered as a modification to another cover level when there is a valid reason why full cover in relation to the maintenance package quoted cannot be provided. Best Effort Cover must make provision for the ability for the maintenance contract to be terminated either by the Applicant or the Participating Authority without penalty should the contract be deemed to be no longer viable by either party. The modification can include one of the following in the quotation for the cost of the service to be provided (alternatives can be provided by the Applicant but must be supported with reasons why a Best Effort Approach is being taken):

3.7.1. Support of equipment that is beyond the manufacturers recommended equipment lifespan.

3.7.2. Alternative response times for engineer support, e.g. due to geographical limitations.

3.7.3. Parts availability for equipment that is beyond the manufacturers recommended equipment lifespan and supported by an end of life notice.

3.8. **Collaborative (First Line Cover)** must combine the in-house maintenance / engineering / EBME / Biomedical teams of the Participating Authority with the expertise and knowledge of the Applicant. This cover allows the Applicant to provide training to the in-house teams that enables them to carry out an initial assessment of a fault or failure and to identify if supplier intervention or a corrective action is required. This cover can be offered as a modification to an existing cover level or can be offered as a standalone cover level.

3.8.1. The contract must specify the number of personnel that the initial training is being provided for. These personnel will be identified by the Participating Authority and will be deemed suitable to receive the training.

3.8.2. The contract must detail an agreed training plan and must be supported by a competency assessment at the end of the training activity.

3.8.3. The contract must detail the type and duration of the training that is to be provided as part of the contract.

3.8.4. The charges for the initial training provided and any travel or accommodation costs associated with the training to be provided and any tools and specialist training materials must be detailed in full and be shown separately from the on-going service provision costs.

3.8.5. Once a Collaborative Cover Contract has been established between the Participating Authority and the Applicant, it is expected that any subsequent refresher training be provided by the applicant to the Participating Authority as detailed in the initial agreement/maintenance contract, Free of Charge. Costs for refresher training over and above the initial agreement/maintenance contract (e.g. additional personnel) must be stated if this type of contract is renewed by the Participating Authority.

3.8.6. The contract must make provision for the Applicants engineer to provide the appropriate level of support to correct a fault in the event that the in-house team are unable to correct an identified fault.

4. Lot 1 – Beds, Furniture and Pressure Area Care

4.1. The maintenance, repair and/or calibration of beds, furniture and pressure area equipment, including:

4.1.1. Beds;
4.1.2. Cots;
4.1.3. Dynamic mattresses and cushions;
4.1.4. Chairs and furniture; and
4.1.5. Treatment couches.

5. Lot 2 – Patient Bathing, Handling and Transport

5.1. The maintenance, repair and/or calibration of equipment for patient bathing, handling and transport, including:

5.1.1. Patient bathing such as lifts, baths, showers, cubicles and associated equipment;
5.1.2. Patient hoists and scales;
5.1.3. Patient transfer chairs, stretchers, wheelchairs and stand aids; and
5.1.4. Patient trolleys, powered trolleys and mortuary trolleys.

6. Lot 3 – Temperature Control

6.1. The maintenance, repair and/or calibration of equipment for temperature control including:

6.1.1. Blood tracking equipment;
6.1.2. Body chambers;
6.1.3. Chillers, fridges and freezers for use in laboratory, blood bank, mortuary, pharmacy and for medical equipment;
6.1.4. Cryogenic systems;
6.1.5. Ice machines;
6.1.6. Medical product and sample carriers;
6.1.7. Patient temperature control and associated equipment;
6.1.8. Plasma freezers and thawers;
6.1.9. Platelet agitators and incubators;
6.1.10. Temperature loggers, monitoring and mapping; and
6.1.11. Ultra-low temperature freezers.

7. Lot 4 – Patient Assessment, Monitoring and Life-Support

7.1. The maintenance, repair and/or calibration of equipment for patient assessment, monitoring and life-support, including:

7.1.0. Anaesthesia equipment;
7.1.1. Cardiac electrophysiology equipment;
7.1.2. Cardiac lung function equipment;
7.1.3. Cardiac transducers;
7.1.4. Defibrillation devices;
7.1.5. Heart and lung perfusion equipment;
7.1.6. Intra-aortic balloon pumps;
7.1.7. Jaundice meters;
7.1.8. Mobile or static pumps including infusion, syringe, volumetric, patient controlled pain relief and associated equipment such as syringe drivers;
7.1.9. Neonatal incubators/warmers;
7.1.10. Non specified trauma/life support equipment;
7.1.11. Oxygen concentrators, regulators and therapy systems;
7.1.12. Patient assessment and testing equipment;
7.1.13. Patient monitoring and recording equipment;
7.1.14. Phototherapy units;
7.1.15. Spirometers;
7.1.16. Temporary pacing units;
7.1.17. Ventilators and continuous positive airway pressure (CPAP) devices including associated equipment such as Humidifiers; and
7.1.18. Wound treatment equipment.

8. Lot 5 – Microscopes

8.1. The maintenance, repair and/or calibration of microscopes and associated equipment, including:
8.1.1. Microscopes including inverted, upright, laboratory, ophthalmic, pathology, surgical, outpatient and dental;
8.1.2. Microscopy camera and imaging systems; and
8.1.3. Slide scanners.

9. Lot 6 – Dental Equipment

9.1. The maintenance, repair and/or calibration of equipment for general dental Equipment, including:
9.1.1. Dental chairs;
9.1.2. Dental compressors; and
9.1.3. Dentistry equipment and tools.

10. Lot 7 – Endoscopy

10.1. The maintenance, repair and/or calibration of equipment for Endoscopy, including:
10.1.1. Electro-medical equipment;
10.1.2. Flexible endoscopes;
10.1.3. Rigid endoscopes; and

10.1.4. Endoscopes used with ultrasound.

11. Lot 8 – Ophthalmology

11.1. The maintenance, repair and/or calibration of equipment for ophthalmology, including:

11.1.1. Aberrometry equipment;
11.1.2. Computerised sight charts;
11.1.3. Corneal equipment, pachymetry equipment and cross linking equipment;
11.1.4. Lens meters;
11.1.5. Ophthalmic diagnostic testing equipment such as biometry equipment; ultrasound equipment, phoropter equipment and auto-refractors;
11.1.6. Ophthalmic imaging equipment such as slit lamps;
11.1.7. Perimeter equipment and field analyser equipment;
11.1.8. Phacoemulsification and vitrectomy equipment;
11.1.9. Pupilometer equipment such as pupillary distance (PD) meters; and
11.1.10. Specular microscopy equipment.

12. Lot 9 – Lasers

12.1. The maintenance, repair and/or calibration of laser equipment, including:

12.1.1. Dermatological lasers;
12.1.2. Ophthalmic lasers; and
12.1.3. Surgical lasers.

13. Lot 10 – Renal and Urodynamics

13.1. The maintenance, repair and/or calibration of Renal and Urodynamics equipment, including:

13.1.1. Haemodialysis equipment;
13.1.2. Haemofiltration equipment;
13.1.3. Peritoneal dialysis equipment; and
13.1.4. Urodynamics equipment and treatment systems.

14. Lot 11 – Tier 1 - Imaging Equipment

14.1. The maintenance, repair and/or calibration of tier 1 imaging equipment including:

14.1.1. Computed tomography (CT) scanners;
14.1.2. Fluoroscopy and angiography equipment;
14.1.3. Hybrid imaging systems;
14.1.4. Imaging surgical systems such as surgical navigation systems and focussed ultrasound equipment;
14.1.5. Magnetic resonance imaging (MRI) scanners; and

14.1.6. Nuclear medicine imaging systems such as gamma camera systems and positron emission tomography (PET).

15. Lot 12 – Tier 2 - Imaging Equipment

15.1. The maintenance, repair and/or calibration of imaging equipment including:

15.1.1. Bladder scanners;
15.1.2. Bone densitometry equipment;
15.1.3. Clinical imaging specimen cabinets;
15.1.4. Computerised and digital radiography readers (CR and DR);
15.1.5. Contrast injectors;
15.1.6. Dental imaging equipment such as X-Ray and ultrasound;
15.1.7. Lithotripsy equipment;
15.1.8. Mammography (digital and analogue) equipment;
15.1.9. Medical photography, printing and associated equipment;
15.1.10. Mobile image intensifiers (MII);
15.1.11. Mobile X-Ray systems;
15.1.12. Patient positioning and quality assurance systems;
15.1.13. Static X-Ray Systems; and
15.1.14. Ultrasound equipment including physiotherapy.

16. Lot 13 – General Theatre, Orthopaedics and Physical Therapy

16.1. The maintenance, repair and/or calibration of equipment for general theatre, orthopaedics and physical therapy, including:

16.1.1. Anatomical simulation and training equipment;
16.1.2. Arthroscopy equipment;
16.1.3. Insufflators;
16.1.4. Mobile or fixed theatre lights, pendants, booms, beams and control panels;
16.1.5. Non-surgical treatment including light therapy;
16.1.6. Operating tables and transfer systems;
16.1.7. Orthopaedic power tools;
16.1.8. Physical treatment such as rehabilitation and physiotherapy;
16.1.9. Rotablation equipment;
16.1.10. Smoke evacuators;
16.1.11. Suction units; and
16.1.12. Surgery systems such as electrosurgical, cryosurgical and hydrosurgical.

17. Lot 14 – Decontamination

17.1. The maintenance, repair and/or calibration of equipment for decontamination, including:

17.1.1. Automated endoscope reprocessors;
17.1.2. Bed pan washers;

17.1.3. Drying cabinets including endoscope storage;
17.1.4. Health technical memorandum (HTM) testing equipment;
17.1.5. Laboratory water systems;
17.1.6. Macerators;
17.1.7. Sterilisers including fogging devices, steam and hydrogen peroxide;
17.1.8. Trolley washers;
17.1.9. Ultrasonic cleaners;
17.1.10. Ultraviolet (UV) systems;
17.1.11. Washer disinfectors including chambers; and
17.1.12. Water treatment and purification systems including reverse osmosis.

18.Lot 15 – Laboratory, Pathology and Analysis Equipment

18.1. The maintenance, repair and/or calibration of laboratory, pathology and analysis equipment, including:
18.1.1. Amplification equipment;
18.1.2. Analysers and meters;
18.1.3. Automated systems;
18.1.4. Blending equipment;
18.1.5. Cabinets, chambers and hoods such as ultraviolet, smoke, fume, anaerobic, laminar flow, glove and humidity/temperature controlled;
18.1.6. Chromatography, spectroscopy and spectrometry equipment;
18.1.7. Coagulation equipment;
18.1.8. Digital morphology equipment;
18.1.9. Drying equipment;
18.1.10. Gel and liquid analysis including culture systems;
18.1.11. Heating equipment;
18.1.12. Histology, histopathology, cytology and microbiology equipment;
18.1.13. Liquid handling and measurement equipment;
18.1.14. Mixing equipment;
18.1.15. Mortuary tables;
18.1.16. Point of care marker and analysis equipment;
18.1.17. Pumping equipment;
18.1.18. Sample/tissue preparation and processing and associated equipment;
18.1.19. Screening and immunoassay systems, analysers and processors;
18.1.20. Separation equipment;
18.1.21. Shaking equipment;
18.1.22. Slicing equipment;
18.1.23. Storage and safety equipment; and
18.1.24. Weighing and measuring equipment.

19.Lot 16 – Radiotherapy Equipment and Treatment Systems

19.1. The maintenance, repair and/or calibration of laboratory, pathology and analysis equipment, including:

19.1.1. Radiotherapy treatment and planning systems such as Linear Accelerators (LINAC); and

19.1.2. Brachytherapy seeds and associated systems.

20. Lot 17 – Robotic Surgical Systems

20.1. The maintenance, repair and/or calibration of robotics systems, including:

20.1.1. Robotic systems including surgical systems.