Royal Cornwall Hospitals
NHS Trust

Medical Equipment Management Policy

V5.0

August 2025

Summary

This policy lays down the method and associated responsibilities by which the Trust manages its medical devices, which includes procurement, maintenance, decontamination, disposal and reporting of adverse incidents, to ensure that all risks associated with using medical devices are minimised and that statutory obligations are met.

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Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

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1. Introduction

1.1. The Trust recognises the risks created by the use of medical devices to patients, staff and others, and requires that safe working practices be maintained. The Trust aims to ensure that all staff that operate diagnostic or therapeutic medical devices can do so in a safe and effective manner, and that all medical devices are:

- Suitable for their intended use.
- Properly understood by the user.
- Maintained to an appropriate standard.
- Effectively controlled throughout their life cycle.

1.2. This policy is not exhaustive, and no information or lack thereof contained within should overrule good sense and judgement of an individual executing an action or responsibility concerning medical devices; when any such individual has concerns – particularly when safety related – then these should be raised as appropriate, as soon as safe and practicable to do so.

1.3. The policy should be read in conjunction with the Medical Devices Training Policy, Procurement Policy, Management of Contractors Policy, the Patient Safety Incident Response Policy and the Risk Assessment and Management Strategy and Policy.

1.4. Many aspects of the Trust's generic Health and Safety Policy are applicable to medical devices.

1.5. This version supersedes any previous version of this document.

2. Purpose of this Policy/Procedure

The purpose of this document is to outline a systematic approach to the management of all aspects of the lifecycle of medical equipment, and to ensure that all risks associated with the evaluation, acquisition, deployment, use, monitoring, record integrity, reprocessing, modification, maintenance, record generation and storage, decommissioning and disposal of medical equipment are minimised.

3. Scope

3.1. This policy is intended primarily for Royal Cornwall Hospital Trust staff who are responsible for the use and management of UKCA, CE or CE UKNI medical equipment, or its evaluation. This policy does not cover the management of ionising radiation-generating devices, or surgical instrumentation, and any practices and responsibilities pertaining to "medical devices" or "medical equipment" listed herein exclude such equipment.

3.2. With respect to evaluations, this policy may be used as a guide for the trial of other items that are not classified as medical equipment, such as single use or disposable medical devices or other clinical products, which are managed by the Clinical Products Procurement Group, as the principles of patient safety and methodological governance will still apply.

4. Definitions / Glossary

4.1. **Adverse Incident**: An event involving medical devices and/or equipment which produces, or has the potential to produce, unexpected or unwanted outcomes that affect the safety of patients, service users or other people. Examples may include where:

- A patient, client, user, carer or professional is injured as a result of a medical device or equipment failure or its misuse.
- A patient's or client's treatment is interrupted or compromised by a medical device or equipment failure.
- Misdiagnosis due to medical device or equipment failure leads to inappropriate treatment.
- A patient's or client's health deteriorates due to a medical device or equipment failure.

4.2. **User**: An employee, carer, patient or client who uses a medical device or item of equipment in a healthcare facility or at home (e.g. infusion pump, wheelchair, chair lift etc.)

4.3. **Clinical Technology (DCT)**: A specialist service, based in Medical Physics and Clinical Technology, that deals with the management, maintenance and assurance of all medical equipment for the Trust.

4.4. **Evaluation**: An Evaluation is the assessment undertaken to review how well an item performs against a defined specification. An evaluation will always involve a trial and may include a demonstration.

- A Trial is the process for formally testing through actual usage the effectiveness, safety, usability and suitability of an item. A trial item will normally be left in the Trust for a certain length of time for staff to use in a clinical environment under controlled conditions.
- A Demonstration involves the presentation of an item for staff to view, displayed by a representative of the company who will explain its functionality. The item is not used by staff on patients and the item is not left in the Trust.

4.5. **Medical Device:** The term "medical device" encompasses medical devices as legally defined in the Medical Devices Directive, other medical devices and assistive technologies. Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer, to be used on human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease; or,
- Diagnosis, monitoring, treatment of, or compensation for an injury or handicap; or,
- Investigation, replacement or modification of the anatomy or physiological process; or,
- Control of conception, and which does not achieve its intended action by pharmacological, immunological or metabolic means, but it may assist the human body in its function by such means**.**

4.6. **Medical Equipment**: The term “medical equipment” is used by the Trust to mean medical devices requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

4.7. **MHRA:** Medicines and Healthcare products Regulatory Agency – A Government agency and the Notified Body that is responsible for the regulation of medicines and medical devices and equipment used in healthcare organisations and the investigation of harmful incidents.

4.8. **PPM:** ‘Planned Preventative Maintenance’ – a regular ‘scheduled service’, a maintenance programme performed by Clinical Technology that involves the correction or prevention of faults by calibration and replacement of parts, in order to keep the medical device performing as intended by the manufacturer.

5. Ownership and Responsibilities

5.1. Executive Responsibility

The Chief Medical Officer shall be responsible for the safe management of medical devices and compliance with relevant regulation, exercised through the Medical Equipment Board. Working responsibility and Chairing of the Medical Equipment Board may be delegated to an authorised, consistent Deputy, though overall accountability is retained.

5.2. Role of the Medical Equipment Board

The Medical Equipment Board shall ensure adequate governance is in place around the control of medical devices, providing assurance to the Chief Medical Officer and Trust Management Group regarding the safe use of medical devices, and overseeing issues relating to their maintenance, procurement, risk and safety. The Terms of Reference for the Board is at Appendix 3.

5.3. **Role of the Medical Equipment Procurement Group**

The purpose of the Medical Equipment Procurement Group (MEPG), which reports to the Medical Equipment Board (MEB), is to oversee the evaluation of potential new medical equipment and to collectively approve all Pre-Acquisition Questionnaires[1] for medical equipment purchase. The Group will encourage the use of best practice methodology for the evaluation and recommendation of medical devices, making use of standardised proforma documentation to capture and report the outputs of its work. The Terms of Reference for the Group is at Appendix 4.

5.4. **Role of the Medical Device Safety Officer (MDSO)**

The MDSO shall ensure the Trust meets its obligations for the monitoring and associated actions of incidents related to medical devices as defined by the MHRA, as well as co-ordinating/ facilitating other device-related safety activities as laid down in national guidelines and this policy.

5.5. **Role of Care Groups**

Care Groups shall be responsible for the safe use of medical devices within their respective clinical areas and shall ensure that adequate local systems are in place to manage equipment in accordance with this policy, as well as with other applicable policies such as the Medical Devices Training Policy.

Day-to-day equipment management may be delegated to the appropriate nominated managers of wards/clinical areas, though the requirement for systematic oversight and assurance at Care Group level remains. Any references to the responsibilities of the “Care Group” in this policy may be exercised by such appropriate clinical area managers through documented systematic delegation. The Care Group must satisfy itself that such nominated personnel fully understand their responsibilities as laid down in this policy.

5.6. **Role of Clinical Technology**

DCT shall provide subject matter expertise and advice for all aspects of through-life support for medical equipment within the Trust (not including equipment involving ionising radiation or sterile surgical instruments). This could include provision of servicing and maintenance, or assurance of 3rd party provision of such services, as appropriate to the specific equipment, as well as other specialist services.

5.7. **Role of Equipment Users**

Any staff member involved in the use of medical equipment shall ensure:

- They are trained and competent in the use the equipment they are required to use.

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[1] Nominated individuals from stakeholder groups who contribute to the process of approving PAQs have a responsibility to review all PAQs within a 4 week period, to prevent delays to equipment orders being placed.

- They only use medical equipment if authorised to do so.
- They check the “Do Not Use After” label before use.
- All medical equipment is suitably decontaminated after each patient use in accordance with the trusts decontamination policy Decontamination Policy (cornwall.nhs.uk)
- All medical equipment is appropriately stored when not in use.
- They follow all relevant local procedures.
- They report any defects or faults with equipment immediately.
- They clearly label defective equipment and ensure they are taken out of action and affix an OPF 51(Fault and Contaminated Status) form to the device FaultAndDecontaminationForm.pdf (cornwall.nhs.uk)
- They endeavour to make equipment available for maintenance.
- They report all adverse events to their line manager immediately.
- Manufacturers’ guidelines and instructions are followed, as well as any additional technical instructions supplied by DCT, the Medical Device Training Officer, or the Care Group.
- They carry out pre-use checks and fault reporting as per section 6.6.2.

5.8. Role of Independent Contractors

The Trust requires that Contractors comply with all relevant policies; managers of the area where contractors are working shall ensure that they are aware of any relevant Trust policies and local applicable procedures.

6. Standards and Practice

6.1. Procurement

6.1.1. **Rationale.** It is incumbent upon the Care Group to ensure as far as reasonably practicable that medical equipment in its area is safe, efficacious, adequate in number and fit-for-purpose for its intended clinical application.

6.1.2. The Care Group shall ensure that it takes all reasonable steps to ensure sufficient availability of suitable medical equipment to meet clinical needs. This should include forward identification of requirements and evaluations for new equipment or equipment replacement due to age or condition, and full and proactive engagement with the annual Medical Capital Equipment (MCE) bidding and prioritisation process.

The Care Group shall ensure that any new types or models of equipment it wishes to purchase that are new to the Trust undergo thorough and objective evaluation under the approval and auspices of the MEPG via Cornwall Procurement Service.

6.1.3. Further guidance is available at Appendix 5. The link to the MCE Bid form along with guidance for completion of the form is at Appendix 7.

6.2. Acceptance Procedures for New Equipment

6.2.1. **Rationale** - Simple receipt inspections can save time and inconvenience when putting medical equipment into use by assuring that what has been delivered is correct and in good condition. The Trust also has a statutory obligation to consider appropriate checks and tests on new medical equipment in order to ensure the safety of both patients and equipment operators, and to ensure good governance around the life cycle of such equipment.

6.2.2. Care Groups shall ensure that all new medical equipment is physically accepted by DCT prior to its first clinical use within the Trust.

6.2.3. Much small medical equipment is delivered to DCT in the first instance, so any checks will be routinely conducted before the equipment is sent to the clinical areas. However, some equipment, particularly highly-specialised or bulky items, may come directly to the clinical area, so acceptance must be arranged through liaison with DCT. Following acceptance, any items will have asset labels appended to them.

6.2.4. DCT shall:

- Carry out basic receipt checks, to include so far as possible confirmation that the correct items have been received and that there are no visible signs of damage, when entering the equipment onto the asset register.

- Carry out any mandatory or recommended commissioning checks, testing, assembly or calibration as instructed by the manufacturer (where no arrangement has been made for this to be carried out by 3rd party).

- Assess the need for specialist configuration and/or performance verification, depending on the nature of the device and its area of use.

- Consider the need for and extent of any electrical safety testing (see section 6.3 below).

It should be noted that for simple devices bought frequently or in large volume, anything more than basic receipt actions may be inappropriate; such equipment types should be first agreed by Head of Clinical Technology. In such cases, a random sample testing regime at delivery will be implemented.

6.3. Electrical Safety Testing

6.3.1. **Rationale**. Electrical faults can lead to fire or risk to life from shock. The Health and Safety At Work Act 1974 and BS 7671 Requirements for Electrical Installations impose a statutory obligation to consider the need and scope of safety testing; there are no specific requirements or guidance for extent and frequency of any tests on medical equipment, and this should instead be assessed and proportionate to the risk, nature and usage of the equipment in question. Most incidents pertaining to electrical safety stem from the poor condition of cables, plugs and connectors.

6.3.2. **Care Groups shall ensure:**

- Daily equipment checks by users include a visual check of plugs, electrical cables and their connections, as well as the power socket (any lack of integrity of the latter to be reported to Estates).

- Users are aware that where power cables are detachable, only the lead appropriate to that equipment is used and that these are never substituted for inappropriate leads from non-medical equipment (e.g. kettles).

6.3.3. **DCT shall:**

- Conduct a full Electrical Safety Test (EST) during every PPM for medical equipment.

- For receipt checks of mains-powered equipment, conduct a thorough visual inspection of power leads, plugs and connections.

- Assess the need/benefit for full electrical safety testing during acceptance testing based on risks associated with that equipment. Note: where significant testing and verification is being conducted and EST would impose no significant added burden, then this should always be conducted even if such testing would otherwise have been deemed unnecessary.

6.3.4. Estates shall ensure that routine Portable Appliance Testing (PAT) is not conducted on any item of medical equipment.

6.3.5. Where detachable mains leads are issued by DCT (e.g. as replacements), an EST will be conducted with nominal 5-year validity as a backstop: once the lead is in use with an item of equipment then it will be tested as part of the system during its PPM cycle.

6.4. Asset Register

6.4.1. **Rationale**. In order to facilitate effective equipment management and control, all medical equipment will be identified with a unique number and recorded on the Trust's asset management database.

6.4.2. DCT shall maintain the ‘eQuip’ system as the single authoritative inventory for Trust medical devices, as well as the single repository for recording all maintenance activity, be that conducted by Clinical Technology or by an external service provider.

6.4.3. Care Groups shall notify DCT if devices are to be withdrawn from use so that the asset register can be updated and remain accurate, as well as advice sought on the appropriate manner of disposal. It should be noted that for large equipment, DCT does not offer a removal or storage service and it is incumbent upon the disposing area to arrange as required, though DCT may co-operate on this should it be decided that the items can be disposed of via auction.

6.5. Device Instructions

6.5.1. **Rationale** - All users must have access to manufacturers’ or locally produced instructions both for reference purposes and to ensure that the device is operated properly and safely at all times.

6.5.2. Care Groups shall ensure that all equipment operators have access to instructions appropriate for the equipment/task/environment. These instructions should be kept up-to-date with assistance from the Medical Devices Training Officer as appropriate.

6.5.3. Where instructions are produced locally for patients or their carers, the issuing unit must follow MHRA Managing Medical Devices guidelines as well as follow standard Trust publication procedures.

Where any shortcomings are perceived in instructions, the MDSO should report this to the MHRA as an adverse incident.

6.6. Care of Equipment by Users

6.6.1. **Rationale**.- Some basic steps by equipment users will help ensure that devices are used safely and effectively, and that the availability of equipment is maximised for clinical use.

6.6.2. Care Groups shall ensure that:

- Users must follow the manufacturer’s guidelines on the care and user maintenance of equipment and devices.
- Regular basic checks are performed by users prior to use. These should consist of, as a minimum, checking for any obvious signs of damage, cleanliness and faults affecting performance or safety, paying particular attention to the integrity of power cables.
- Maintenance labels are checked to ensure servicing is not overdue.
- Faults are reported as per the guidelines issued by the relevant maintenance provider. A clear description of any fault is required to aid in diagnosis and a prompt turn-around of equipment.

- Equipment is stored in a safe and secure location when not in use. Storage facilities should take into account any special requirements for infection control, temperature, humidity, etc. and that any equipment that has rechargeable batteries is kept on charge.

- Adequate local systems are in place to ensure these processes, and audits are conducted for verification.

6.7. Servicing and Maintenance

6.7.1. **Rationale** - Timely routine servicing and fault rectification is essential if equipment is to operate effectively and within required parameters of use, to ensure the safety of staff and patients, and to optimise the operating lifespan of the device.

6.7.2. The large numbers of medical devices in use across the Trust have a variety of different 'support solutions', but are primarily categorised by:

- Maintenance provided through a manufacturer or other contracted 3rd party provider.

- Maintenance provided in-house by DCT.

- Combination of both.

6.7.3. DCT shall:

- Offer timely PPM support for equipment when an in-house support solution has been identified, agreed and resourced during the procurement process, or where it agrees that it has been historically undertaken and such support remains viable.

- When resources to conduct PPMs are strained, undertake risk-based prioritisation to include factors such as the risk category of the equipment, risk levels associated with clinical areas, the urgency of clinical need, length of time beyond the servicing becoming due, and the availability of alternative devices.

- Highlight to clinical areas particular risks or concerns regarding equipment

- Endeavour to highlight to Wards/Departments when certain categories/items of medical equipment will soon require servicing. Nonetheless, it remains the responsibility of Care Groups to ensure that their devices remain in date for servicing and that any out-of-date devices are not used unless a risk assessment has been made as per paragraph 6.7.4.

- Assist Care Groups in seeking remedial action from 3rd party maintenance providers when it has become apparent that such service provision has not been undertaken or is not to the standard required.

- Endeavour to turn round equipment as quickly as possible or provide swap-out or loan equipment where possible.

- Inform Care Groups if in-house support ceases to remain viable and offer advice in such cases on establishing a support contract or seeking to replace with new equipment.

- Manage the in-situ testing and maintenance of certain bed-head equipment such as wall suction and flow meters through the mobile technical service offered by the Medical Equipment Library, and certain other items as agreed with clinical areas. This will also include swap-out-on-request of certain small devices such as gas regulators.

- Manage the maintenance of all medical equipment centrally controlled by the Medical Equipment Library.

- Report on particular areas of risk and concern to the MEB.

6.7.4. Care Groups shall:

- Ensure any pre-use functional and visual checks must be carried out by all users prior to using any medical device, as per section 6.6.2.

- Ensure that medical equipment is made available for Planned Maintenance at the appropriate time.

- Raise any specific concerns regarding 3rd party contracted support with DCT, who will liaise with Procurement and suppliers as appropriate.

- Facilitate access to equipment requiring servicing for DCT or 3rd party contractors as soon as practicable; where equipment is inaccessible (e.g. linked to a patient) for a protracted period then action such as swapping out such equipment should be considered.

- Where equipment is significantly beyond service date, risk assess the on-going use of equipment against clinical urgency of need and – if equipment is to remain in use – record such decisions via local risk management procedures.

- Where a manufacturer or other contracted service provider caries out maintenance of medical equipment on site, forward a record of the visit and work done in a timely manner to DCT for logging on the asset management system (this would normally be a copy of the company service report).

- Ensure that an adequate support solution is always in place for all clinical equipment held; advice may be sought from DCT in case of uncertainty.

6.7.5. The Medical Equipment Board shall:

- Review particular risks, limitations or concerns regarding equipment compliance, and consider accepting/mitigating/escalating or other solutions as appropriate.

6.8. Assurance Reports

6.8.1. **Rationale** - Pivotal to understanding the issues of equipment management, both corporately at Trust committees and at Divisional level to inform management of clinical areas, is the provision of structured Service and Maintenance Assurance (SMA) reports. In RCHT this is enabled by:

- The designation of DCT as the sole provider of equipment maintenance assurance, regardless of support solution.
- A single, authoritative central inventory of equipment (asset database) and associated servicing schedules.
- A system for generating standardised reports for defined Key Performance Indicators.

6.8.2. As described in section 6.7 items of medical equipment maintained under a service contract, even if not directly owned by the Trust, are still regarded as Trust medical devices and are not treated any differently in terms of assurance. This category of items forms an integral part of the monthly reports, and this should be reviewed carefully as it is the Trust, rather than the maintenance provider, that retains ultimate responsibility for the safe use of all such devices used for patient care.

6.8.3. DCT shall:

- Produce SMA reports on a monthly basis using data generated from the central inventory of equipment (asset register). These will be provided to the Care Group triumvirates.
- Respond to requests for additional data, should a Ward or Care Group need further details on any particular aspect of the report. Requests should be made to DCT and will normally be responded to within 5 working days.
- Present Trust-level summary SMA reports to the Medical Equipment Board.
- Produce different bespoke reports on an ad hoc basis – for example to aid inventory or replacement planning. Managers who feel this may be appropriate to their area should in the first instance discuss their specific requirements and the feasibility of assistance with DCT.

6.8.4. Care Groups shall:

- Share with DCT, at the earliest opportunity, direct dialogue with or maintenance correspondence/reports from a 3rd party maintenance provider.

- Monitor SMA reports via internal governance processes to identify possible areas of concern. The Care Group General Manager is accountable and responsible for ensuring that equipment is adequately maintained.

- Respond, including making entries on the risk register (where applicable) and undertaking remedial actions, with on-going monitoring via internal governance processes. DCT may be able to provide additional information or advice on possible steps towards resolution.

- Make such information available to the Medical Equipment Board (MEB) and respond to requests for further information/assurance from the MEB.

6.8.5. The Medical Equipment Board (MEB) shall:

- Review and approve KPIs for equipment maintenance compliance.

- Review and approve standard assurance report templates for reporting performance against KPIs. These will be constructed to provide an overarching snapshot for consideration at Trust-level groups, as well as a more tailored report pertinent to Care Group managers and be broken down in terms of maintenance conducted both in-house and by external providers.

- Review as required Care Group responses to SMA reports, which could include review of risk register entries and review of progression of action plans. Matters identified as requiring escalation in order to effect a resolution will be taken to Trust Management Group (TMG).

- Monitor the overall status of service and maintenance compliance within the organisation, including performance of internal maintenance carried out by DCT and by 3rd party suppliers.

6.9. Decontamination

6.9.1. It is essential that all necessary measures are taken to ensure that medical equipment is robustly decontaminated after use in order to prevent the spread of contamination to other patients, staff or other devices.

6.9.2. Users of medical devices are responsible for the decontamination of the equipment in accordance with the Trust Decontamination Policy. Any equipment that has been decontaminated must be labelled as such.

6.9.3. Care Groups shall ensure that no medical device is sent to DCT, e.g. for maintenance or repair (or to any other location, such as a manufacturer after a loan period) unless it has been properly cleaned and decontaminated prior to return and labelled as such. Furthermore, no

equipment that may have been potentially exposed to Covid-19, either directly from a suspected Covid patient or indirectly from use in a clinical area with confirmed Covid cases, should be sent to DCT without prior arrangement so that additional measures may be considered before maintenance is conducted. Note that where DCT is required to maintain equipment in situ, then such equipment also requires prior decontamination and certification. Equipment maintenance will not proceed if this is found not to be the case, or contamination is discovered.

6.9.4. DCT shall report via Datix any equipment received that has not been decontaminated to a satisfactory standard.

6.10. Single Use Devices

Medical devices that are designated for 'single use' by the manufacturer and labelled as such must not be reprocessed or reused under any circumstances. This will include those devices that have been opened in error although not used.

6.11. Equipment Loaned to Patients (End Users)

6.11.1. **Rationale** - It is essential that any user receives appropriate guidance in the use and maintenance of equipment loaned to them by the RCHT.

6.11.2. Care Groups responsible for issuing equipment to patients shall ensure:

- They are given an appropriate level of training and demonstration
- They are given documentation and written guidance to include:
  - The name of the device.
  - Operating instructions (see 6.5).
  - Acceptable and appropriate use of the equipment.
  - Action to be taken by them in the event of a failure or fault.
  - Instructions on routine testing, cleaning and maintenance.
  - What to do when any servicing becomes due.
  - Emergency contact details.

Documentation is kept by the department loaning the item and is to consist of:

- Date of loan and expected length of loan.
- Confirmation of instructions given to patient/carer regarding usage, maintenance and professional support available in case of equipment failure (signed by patient to confirm).

- Asset number.
- When routine servicing requirements are due and how they will be met.
- Procedure for recall of equipment at end of use or for regular maintenance of long-term loan item.

6.11.3. A record document, MD11 is available at Appendix 4 and also on the DCT intranet site.

6.12. Equipment Library

RCHT has a centralised Medical Equipment Library for certain key items of medical equipment. To ensure that this service remains effective and that there is optimum availability of equipment for all areas when needed, any ward utilising such equipment must co-operate fully with MEL staff in returning those items when no longer in use.

6.13. Equipment Evaluations

6.13.1. **Rationale** - It is vital that all equipment new to the Trust is first thoroughly evaluated, and that there is a standardised process as well as centralised oversight, regardless of procurement route. Such measures protect both the user and the patient, reduce unnecessary delays, and minimise the risk of potential litigation to the Trust from allegations of unfairness.

6.13.2. Care Groups wishing to evaluate new equipment shall:

- Obtain MEPG approval for the evaluation prior to the event.
- Follow the process for the evaluation of medical equipment at Appendix 6.
- Ensure no receipt of equipment from commercial representatives outside of this process.
- Ensure that all requirements for the receipt of medical equipment as laid down in this policy are also applied to equipment on trial, including facilitating DCT's acceptance testing and asseting, and ensuring adequate instructions and training of personnel.
- Ensure adequate consultation concerning requirements for decontamination, infection control, IT/networking, e-Care, Estates and information governance.
- Ensure that the risks associated with the trial have been properly assessed and documented.
- Inform DCT when the equipment has been removed from the Trust.

6.13.3. The MEPG shall:

- Consider requests for evaluations.

- Consider requests for expedited ‘trial-lite’ evaluations.
- Ensure a suitable Clinical Lead has been appointed.
- Oversee the process for the evaluation of medical equipment at Appendix 6.
- Assure the adequacy and objectivity of data collected during the trial, reviewing this prior to any purchase being agreed.
- Take appropriate action when aware of equipment that has arrived in the Trust through irregular routes or without following this policy.
- Consider new and renewed Pre-Acquisition Questionnaires for approval[2]

6.13.4. DCT shall:

- Record the receipt of all trial equipment in a partitioned category on eQuip.
- Apply a tracking label to the equipment.
- Carry out acceptance checks as appropriate to the item[3].

6.13.5. Invitations to suppliers are arranged by Cornwall Procurement Service, and clinical staff must not arrange this themselves. It is important that representatives from DCT, Health and Safety, Infection Control, CITS (if applicable) and Estates (if applicable) are included in the trials process. Where possible, running joint trials with CPFT should be considered.

6.13.6. The MHRA document Managing Medical Devices Jan 21 section 3.3 contains factors that should be taken into consideration when determining evaluation criteria; the MEPG may require additional factors to be considered. The link to the Medical Device Evaluation Trial Outcome form and completion guidance notes are contained at Appendix 8.

6.13.7. Where equipment is being sought for a device is so specialised it is known that no other alternative exists, it may be possible for an expedited evaluation or “trial-lite” to be authorised by the MEPG. In such cases, a thorough justification should be provided with the request.

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2 Collective final approval is given by the MEPG, though certain members contribute to this process by giving individual approval as representatives from their specialist areas; such members should review all PAQs within a 4-week period to prevent delays to equipment orders being placed.

3 In most cases a basic visual inspection will be sufficient, dependent upon there being a Master Indemnity Agreement with the supplier. The need for additional testing such as (Medical Grade) EST or performance verification will be assessed on an individual basis, dependent on the nature, complexity and risk of the device, and the extent of manufacturer involvement.

6.13.8. Under normal circumstances and where reasonably practicable, trials should be completed within 12 months of the original request. The MEPG may deem the trial request to have lapsed if an excessive time period has passed with no progress or action if there is no demonstrable reason for the delay.

6.14. Incident Reporting

6.14.1. **Rationale**. Reporting incidents is an essential way by which a “learning organisation” is able to identify risks and prevent future re-occurrence by putting appropriate measures or changes in practices in place. The Trust promotes an “open culture” of reporting, and incidents must never be ‘overlooked’.

6.14.2. For all incidents and ‘near misses’ involving medical equipment, Care Groups shall have local systems in place to ensure:

- All such events are recorded via the Datix incident reporting system, categorised appropriately, and all necessary technical details entered (specifically including the device ID number).
- The device and any associated consumables are labelled and appropriately quarantined.
- Staff are aware to contact the MDSO and appropriate technical point-of-contact within DCT, as appropriate.
- Events are independently investigated if appropriate, or that staff cooperate fully with the MDSO if the latter is involved.

6.14.3. It is essential that care is taken to categorise incidents correctly, as failure to do so could seriously affect the efficacy of any subsequent investigation. It is particularly important to note that just because medical equipment is involved in an incident does not imply that it should be categorised as medical equipment incident. For example, a device switched off in error during use is probably not an equipment failure, but rather a failure of training or process.

6.14.4. 6.14.3. The MDSO shall review all reported incidents involving medical devices and inform the MHRA if appropriate, keeping a central record of such reports.

6.14.5. The MDSO shall present a summary and exception report on medical device incidents to the Medical Equipment Board.

6.15. Medical Device Development and Modifications

6.15.1. Care Groups shall ensure that no medical device is used for any purpose other than that for which it was designed, unless as part of properly approved and coordinated clinical trials or research.

6.15.2. Substantial modification of any medical device must be avoided. Where such a need is perceived advice must be sought from DCT prior to any action.

6.16. Potential Hazards from Mobile Communications

Radio waves emitted from Mobile Communications Equipment may affect electronic medical equipment especially when in close proximity. Clinical areas may require appropriate risk assessments to be completed if mobile phones and radio devices are to be permitted in those areas. Further guidance may be found at the website: https://www.gov.uk/government/publications/electromagnetic-interference-sources/electromagnetic-interference-sources

6.17. Medical Device Safety Instruction

6.17.1. The MHRA occasionally issues Safety Action Bulletins relevant to medical devices. Equipment manufacturers also sometimes issue Field Safety Notices when potential safety concerns are discovered and require mitigating actions. The Clinical Effectiveness Team co-ordinate such notices for the Trust, while the MDSO will co-ordinate implementation and action by DCT.

6.17.2. The MDSO shall maintain a tracking database recording all applicable safety notices and consequential actions, including 'live' statuses and completion/closure/replacement dates.

6.18. Swap-out Equipment

6.18.1. DCT holds a variety of medical equipment for the purpose of loaning to clinical users in order to release medical equipment for maintenance, known as 'swap-out' equipment. This process is vital in ensuring the Trust's devices are compliant with servicing requirements, and to allow an area to continue clinical procedures with minimal disruption when equipment becomes faulty. This equipment is not 'spare' and under normal circumstances cannot be loaned out for use simply because of increased demand; such action adversely affects maintenance planning with consequences to other clinical areas and puts the Trust at risk of statutory non-compliance.

6.18.2. Where the circumstances are deemed exceptional enough to warrant consideration of the use of swap-out equipment, a request shall be made by email to the Head of Clinical Technology from the appropriate Head of Service or member of the Care Group triumvirate, stating why the equipment is needed and for how long, and this will be considered. Note that a lack of planning for adequate equipment needs is not sufficient justification, and open-ended requests will not be acceptable. Routes other than described cannot be considered as it could jeopardise DCT Quality certification.

7. Dissemination and Implementation

7.1. This policy will be published on the Trust Document Library following endorsement of the Medical Equipment Board and authorisation by the Chief Medical Officer.

7.2. The training aspects relating to the implementation of this policy are contained within the main body of this document.

8. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	1) Monitoring of medical device planned maintenance. 2) Medical Device training. 3) Risk management.
Lead	Chair of Medical Equipment Board.
Tool	1) Review of maintenance assurance reports derived from the Trust central asset management system ('eQuip'). 2) Review of assurance reports regarding medical device training across the organisation. 3) Review of corporate risks relating to medical devices and equipment risks escalated by divisions.
Frequency	At each Medical Equipment Board meeting.
Reporting arrangements	DCT will provide monthly assurance reports and where appropriate analyses and recommendations to both the Medical Equipment Board and the Divisional Associate Directors.
Acting on recommendations and Lead(s)	The Medical Equipment Board will lead on Device recommendations, executed through DCT and relevant Divisional managers, in conjunction as required with the Medical Equipment Procurement Group. The Chair of the Medical Equipment Board will provide exception reports to the Trust Management Group.
Change in practice and lessons to be shared	Medical Equipment Board. Medical Device Links. Ward/Departmental managers. Medical device training (thought Medical Device Training Officer). Learning and Development.

9. Updating and Review

This policy will normally be reviewed no less than every three years unless an earlier review is required.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

10.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Medical Equipment Management Policy V5.0
This document replaces (exact title of previous version):	Medical Equipment Management Policy V4.0
Date Issued/Approved:	30 July 2025
Date Valid From:	August 2025
Date Valid To:	August 2028
Directorate / Department responsible (author/owner):	Head of Clinical Technology
Contact details:	01872 253549
Brief summary of contents:	Outlines all aspects of managing medical equipment, including evaluation processes.
Suggested Keywords:	Devices, Instruments, Machines, Maintenance, Repair
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Medical Equipment Board. Care Group Governance.
General Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming approval by specialty and care group management meetings:	Kevin Wright
Links to key external standards:	CQC Regulation 15

Information Category	Detailed Information
Related Documents:	• Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. • Care Quality Commission (Registration) Regulations 2009. • Medical Device Regulations. • MHRA Managing Medical Devices Jan 2021.
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Medial Physics

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
17 Feb 2003	1.1	Original.	Not known.
15 June 2007	1.4	Changes to training and maintenance sections.	R Cranage
01 July 2008	1.5	Minor Corrections.	R Cranage
23 January 2009	1.6a	Changes to reflect S4BH C4b and NHSLA requirements.	R Cranage/ SA Rundle
02 June 2009	1.6b	Clarification of maintenance risk process and incident reporting.	R Cranage / SA Rundle
22 July 2009	1.6.2	Minor corrections and change to title of exec lead.	R Cranage / SA Rundle
February 2011	1.7	Minor Revisions and corrections.	P Conroy
09 May 2011	1.8	Policy reformatted to conform to Trust template.	Andrew Rogers Corporate Records
10 May 2011	1.9	Revision to wording to maintenance paragraph.	P Conroy
11 Jan 2012	1.9.1	Revision of wording reflecting NHSLA comments to para 6.3.	P Conroy

Date	Version Number	Summary of Changes	Changes Made by
20 May 2012	1.9.2	Insertion of Para in 6.6 for Contractor documentation.	P Conroy
29 May 2014	2.0	Revision with updates.	P Conroy
13 November 2017	3.0	Interim policy revision, pending full review.	MGJ Bird
04 April 2018	3.1	Update to reflect service and maintenance assurance report and ToR's of Medical Equipment Board.	T Foy pp. MGJ Bird
04 November 2021	4.0	Complete re-write and incorporation of the previous Trial and Evaluation of Medical Equipment Policy.	MGJ Bird, Head of Clinical Technology
March 2023	4.1	Introduction of 'Trial-lite' and control of general utilisation of 'swap-out' equipment, plus minor enhancements to appendices.	MGJ Bird, Head of Clinical Technology
March 2025	5.0	Full review - Revision with updates.	EC Mealing, Head of Clinical Technology

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Medical Equipment Management Policy V5.0
Directorate and service area:	Medical Physics
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Trevelyan Foy, Director of Medical Physics and Clinical Technology
Contact details:	01872 252495

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Outlines all aspects of managing medical equipment, including evaluation processes.
2. Policy Objectives	To ensure that medical equipment is used safely, competently and effectively for the best care of patients and to comply with the relevant external legislation and guidance.
3. Policy Intended Outcomes	Safe use of Medical Equipment and effective governance around equipment evaluation.
4. How will you measure each outcome?	Refer to section 8 of policy.
5. Who is intended to benefit from the policy?	All staff and patients.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Medical Equipment Board.
6c. What was the outcome of the consultation?	Approved.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	No aspect of this policy has been identified as impacting upon this equality strand.
Sex (male or female)	No	No aspect of this policy has been identified as impacting upon this equality strand.
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	No aspect of this policy has been identified as impacting upon this equality strand.
Race	No	No aspect of this policy has been identified as impacting upon this equality strand.
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	No aspect of this policy has been identified as impacting upon this equality strand.
Religion or belief	No	No aspect of this policy has been identified as impacting upon this equality strand.

Protected Characteristic	(Yes or No)	Rationale
Marriage and civil partnership	No	No aspect of this policy has been identified as impacting upon this equality strand.
Pregnancy and maternity	No	No aspect of this policy has been identified as impacting upon this equality strand.
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	No aspect of this policy has been identified as impacting upon this equality strand.

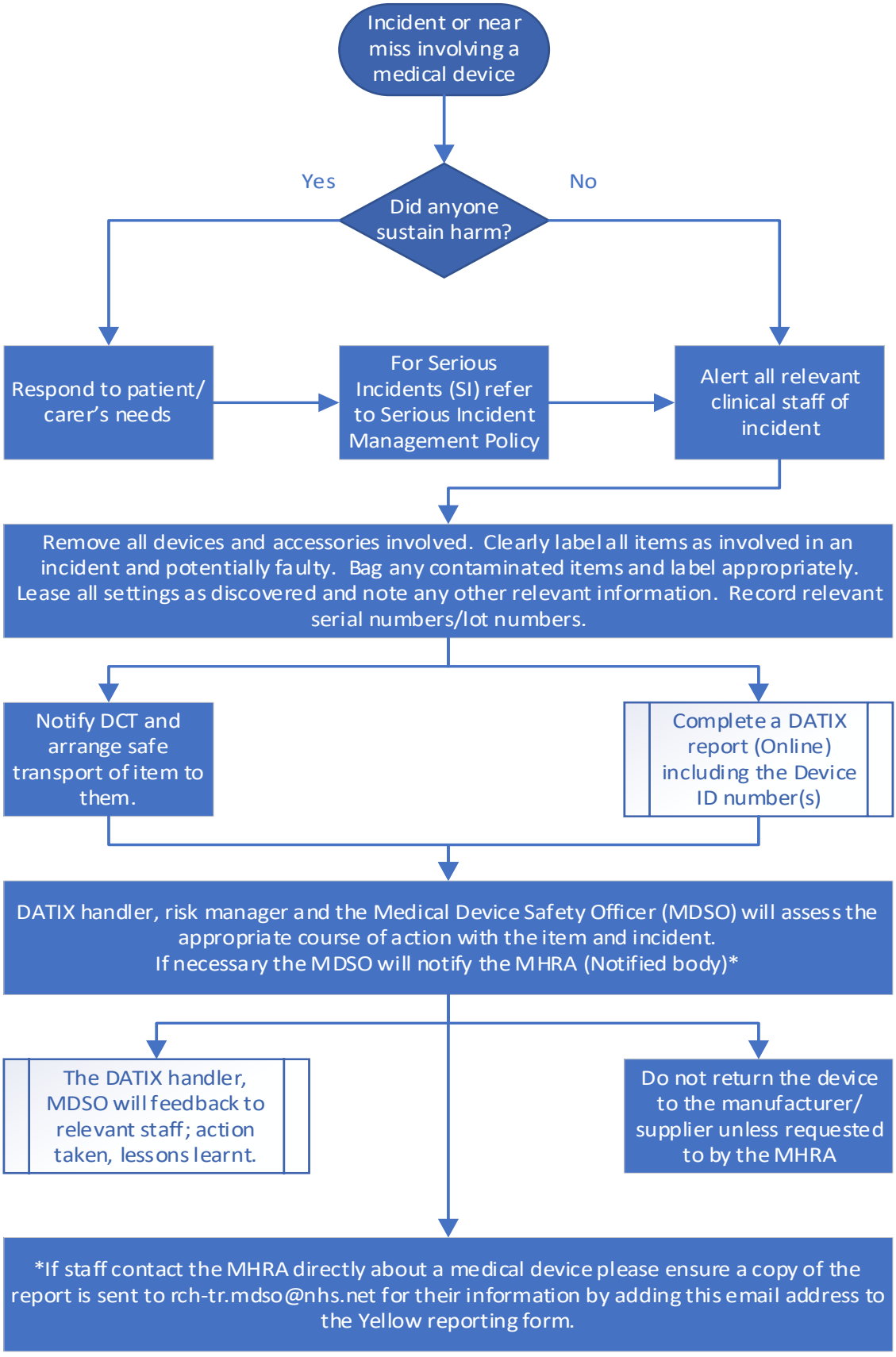
A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Trevelyan Foy, Director of Medical Physics and Clinical Technology

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Procedure Following an Adverse Incident with a Medical Device



Appendix 4. Record Sheet for Issuing Medical Device for use outside RCHT

Please refer to the procedure notes for further details.

1) Training Requirements

Staff member and end user should ensure all items on this list are covered.

1. Pre-checks	Before use, ensure the device is safe to use and perform any maintenance check requires.
2. General use	Be aware of the capabilities of the device and its clinical use, and how to check it during use.
3. Faults/alarms	Know about any common faults and errors with use and the actions to take in the event of any alarms.
4. Cleaning	Appropriate cleaning process between use.
5. Contacts	General contact numbers for routine enquiries and emergency contact numbers in case of faults or alarms which cannot be resolved.
6. Return	Method of returning the device after use, or for routine service.
7. Consumables	Information of how to obtain additional accessories for the device.

2) Confirmation of Training and Identification of Device

Item Issued: (Manufacturer and serial/ID number	
Destination of item: (e.g patients home/district/hospice)	
Agreed date of review/return	
Last Service Date (Please note if service is required within the loan period):	
We, the undersigned, agree that training and information about the medical device to be issued has been given and understood.	
Staff member performing training	
Patient (OR PERSONS TAKING RESPONSIBILITY FOR ITEM) CONFIRMATION	
I understand that this medical device is for named patients use only. I have been given clear explanation (and written instructions) of its use. I will take reasonable care of it and report any faults to:……..	
Staff member performing training	
PLEASE PRINT AND SIGN YOUR NAME:	Date:

Name of person receiving the device (Please note if district nurse/hospice)		
Patient NHS Number (and Address)		

3) Storage Form

i) Keep original form in patients notes as evidence of training given (copy may be given to patient).

ii) Record loan of any ward/RCHT device in separate folder and confirm its return.

iii) Equipment Library device: Contact on EXT: 3049 where the Medical Equipment Library (MEL) will record the loan and confirm return of the device to RCHT.

4) Return of Loan Equipment

This Item is On Loan From the Royal Cornwall Hospital. Please return it promptly.

On return of item, patient may ask a member of staff to confirm receipt on this form.		
Item returned to (Location)	Received by (staff to PRINT name)	Date of return

Record Sheet for Issuing Medical Device for use outside RCHT (continued):

Appendix 5. Medical Equipment Board – Terms of Reference

TERMS OF REFERENCE

Medical Equipment Board (MEB)

CONSTITUTION

The Medical Equipment Board shall provide assurance to the Trust Board:

- Regarding the safety, suitability, servicing, availability and safe use of all medical devices in use across the Trust.
- That the Medical Equipment funding and procurement is prioritised in line with the priorities of the Trust.

The Board holds delegated responsibility and authority from the Finance Committee to make expenditure of the Medical Capital Equipment Allocation of the Capital Programme.

CONDUCT OF BUSINESS

The Board will meet monthly to carry out its responsibilities. The Chair of the Board may call for additional meetings should the need arise.

The Board will be supported by the Board Secretary who will agree the agenda with the Chair and produce all necessary papers, attend meetings to take minutes, keep a record of matters arising and issues to be carried forward and generally provide support to the Chair and members of the Board.

MEMBERSHIP AND QUORUM

The Board will comprise of:

- Chief Medical Officer or Nominee (Chair).
- Board Secretary.
- Capital Accountant/Financial Manager.
- Head of Procurement or Nominee/Procurement Capital Equipment Lead.
- Director of Medical Physics and Clinical Technology.
- Head of Clinical Technology.
- Clinical Engineering Lead/Medical Devices Safety Officer.
- Head of Governance or nominee.
- Nursing Representative(s).
- CFT representative.
- Deputy Financial Controller.
- Sterile Services Representative.
- Health and Safety Lead or Deputy.

- Medical Devices EPR Team Lead.
- Quality Support and Logistics Team Leader.
- Capital Programme Manager .

The Chair may request ad hoc attendance by an appropriate clinical or other subject matter expert.

The Chair (or nominee) plus three members present shall constitute a quorum.

Any member who cannot attend should where possible send a suitable nominee or submit an update report.

DUTIES

Medical equipment provision and replacement:

- Collect bids on an annual basis for equipment provision in future year(s).
- With support from the Clinical Directors, review and prioritise bids.
- Agree and forward recommended future medical equipment funding requirements to the Capital Delivery Group in time for consideration and approval of a future capital plan.
- Receive recommendations from the Medical Equipment Procurement Group regarding:
    i) Preferred manufacturer/model (including clinical rationale/need, training impact, ability to support equipment).
    ii) Costs and timescales via the procurement routes available (e.g. capital purchase, lease, loan via purchase of consumables).
    iii) Revenue costs associated with maintenance and support (either external contract or in-house by Clinical Technology) .
- Subsequently monitor and commit expenditure within the allocated budget according to risk and Trust priorities, highlighting any requirements for further funding should the need arise.
- Identify, for successful bids:
    i) A preferred procurement method (e.g. capital, lease) and associated funding
    ii) A preferred equipment service and maintenance route (“support strategy”), ensuring such arrangements are adequate, safe and resourced.
- Consider urgent equipment requests via this process on an ad hoc basis.

Medical equipment safety:

- Receive reports on:
    - The maintenance of all medical equipment in use across the Trust, including those under contracted maintenance arrangements.
    - Medical equipment training.
    - Medical equipment incidents and device safety alerts.
    - Medical equipment decontamination and infection control issues.
- Review Trust-level medical equipment policies.

- Review corporate-level risks on the risk register, providing oversight of such risks.
- Underwrite or escalate issues arising from the above responsibilities as necessary.

ACCOUNTABILITY AND REPORTING ARRANGEMENTS

The Chair of the Board will provide a summary assurance report to the Finance and Performance Committee.

The Board will report by exception to Trust Management Group.

REVIEW ARRANGEMENTS

The Board Terms of Reference and performance to be reviewed annually (April).

SUB COMMITTEE ARRANGEMENTS

Medical Equipment Procurement Group (MEPG).

Appendix 6. Medical Equipment Procurement Group – Terms of Reference.

TERMS OF REFERENCE

MEDICAL EQUIPMENT PROCUREMENT GROUP

CONSTITUTION

- The Group is established under the authority of the Medical Equipment Board (MEB) of Royal Cornwall Hospitals NHS Trust to undertake the duties set out within these terms of reference.
- The Group will report to the Medical Equipment Board.

CONDUCT OF BUSINESS

The Group will meet monthly to carry out its responsibilities. The Chair of the Group may call for additional meetings should the need arise.

The Group will be supported by a secretary, who will agree the agenda with the Chair and produce all necessary papers, attend meetings to take minutes, keep a record of matters arising and issues to be carried forward and generally provide support to the Chair and members of the Group.

MEMBERSHIP AND QUORATE REQUIREMENTS

The Group will comprise of:

- Chief Medical Officer or Nominee (Clinical Lead / Chair).
- Quality Support and Logistics Team Leader (DCT).
- Capital Programme Manager.
- Head of Clinical Technology.
- Group Secretary.
- Procurement Service Equipment Lead.
- Co-opted Procurement and MPCT Representative(s).
- Divisional Representatives.
- Infection Prevention and Control Service Lead.
- Moving and Handling Advisor RCHT and Moving and Handling Advisor CFT.
- Tissue Viability Service Lead.
- Sterile Services Representative.
- Governance Team Representative.
- CFT Representative.
- Medical Devices EPR Team Lead.

The Chair may request ad hoc attendance by appropriate clinical or other subject matter experts.

The Chair (or nominee) plus three members present shall constitute a quorum.

All members must attend 80% of scheduled meeting within 12 months.

Any member who cannot attend should where possible send a suitable nominee or submit an update report.

DUTIES

The purpose of this Group is to support the Medical Equipment Board (MEB) in assessing medical equipment bids and business cases for new medical equipment for use within the Trust in order to present to the MEB:

- Recommendations regarding preferred device(s) to be procured, co-ordinating and overseeing associated trials and/or evaluations.
- Costed through-life service and maintenance support options.
- Costed supply-route options (e.g. capital, lease etc.).

The key objective of the Group will be to oversee evaluation of potential new medical equipment, taking into account the following factors:

- Fitness for purpose.
- Clinical and cost effectiveness.
- Relevant national guidance e.g. NICE.
- Best practice examples, e.g. from other health organisations.
- Results of trials and evaluations.
- Training.
- Risk assessment.
- Supply arrangements.
- Scope for standardisation across the Trust.
- Through-life support solutions.
- Infection control and decontamination.

The Group will encourage the use of best practice methodology for the evaluation and recommendation of medical devices, making use of standardised proforma documentation to capture and report the outputs of the group's work.

ACCOUNTABILITY AND REPORTING ARRANGEMENTS

The Group is directly accountable to the Medical Equipment Board, and the Chair of the Group shall provide a report to each sitting of the MEB.

REVIEW ARRANGEMENTS

The Group Terms of Reference and performance will be reviewed annually by both the Medical Equipment Procurement Group and the MEB.

SUB COMMITTEE ARRANGEMENTS

None

Appendix 7. Guidance for Procurement of Medical Equipment

Advice must be sought from the Procurement Department and DCT about the procurement of medical devices. For more information see the RCHT Procurement Policy. Advice regarding the Medical Capital Equipment programme and bids for funds may be sought from the Medical Physics Business Manager.

Prior to ordering any new medical device the following factors should considered.

- Clinical requirements.
- Maintenance strategy, costs and implications.
- Additional costs, such as consumables and IT licences.
- Safety.
- Compatibility with other devices.
- Patient needs.
- Whole life cost.
- Training requirements.
- Standardisation / preferred devices.
- Evaluation requirements.
- Decontamination procedures.

Where possible, standardisation of common types of equipment is desirable in order to lessen operator confusion, facilitate ease of training and equipment availability and to take advantage the economies which can be made from bulk purchasing.

Those responsible for the purchase of devices must be aware of the technical and revenue implications of their choice of equipment, to assist in keeping maintenance and revenue costs to a minimum. It cannot be assumed that DCT will be resourced or technically able to service or maintain all new equipment, nor can it offer a breakdown service during periods of warranty, so early engagement on this issue is essential. Any equipment that represents new capability will generally require an initial support contract and/or enhanced warranty to be in place.

The Trust’s procurement practice is to purchase standard equipment from the Trust’s recommended list (updated by the Procurement Department) or those that have been approved by the Medical Equipment Procurement Group. Prior to any procurement of equipment not on the recommended list, advice must be sought from DCT and the Procurement Department, and approval sought from the MEPG following an evaluation.

Purchasers of new equipment must ensure that an assessment has been performed on the use of the device in their area before purchase. This assessment must cover arrangements for the maintenance and decontamination of the device and identifying a training route for users.

When deciding on equipment numbers to be purchased, it is essential that spare capacity is factored in to cope with equipment failure and downtime for maintenance, which could be days or weeks if the items need to be sent off or a company field representative needs to visit the hospital. Having a sufficient stock of spare equipment will help reduce potential future clinical cancellations. Depending on the device, swap-out items managed by DCT may be an appropriate approach – DCT can advise on this.

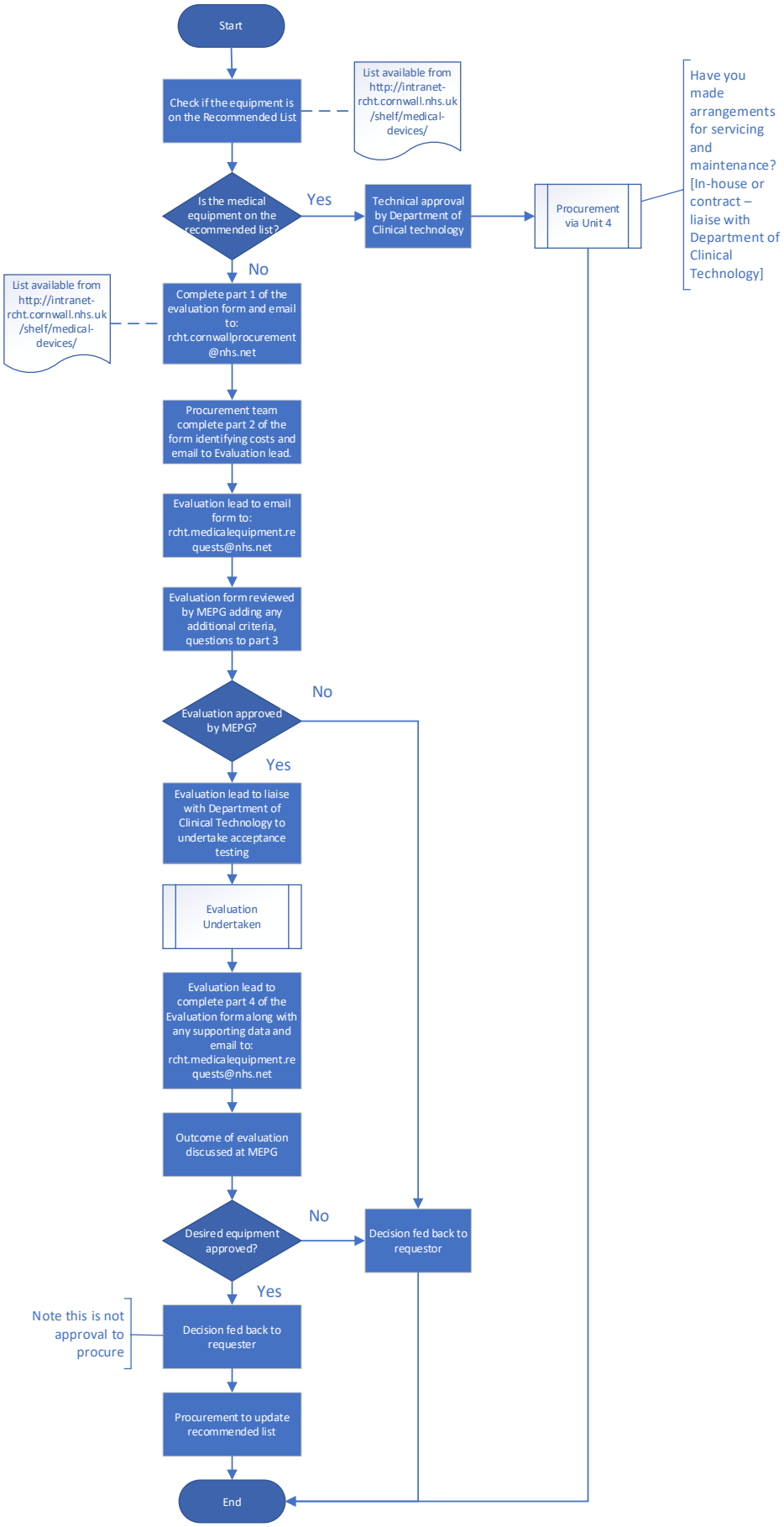
Purchases from Charitable Funds must also be made via the Procurement Department (see the Trust 'Guidelines on the use and application of Charitable Funds'). Note that individual departments are responsible for on-going revenue costs and charitable funds will not support on-going maintenance.

Loan Equipment or consumables must not be accepted by the Trust without authorisation from the Procurement Service and DCT; failure to do so is likely to render the Trust insurance and liability policy invalid, exposing both users and organisation to risk.

Where invasive reusable devices are purchased, it is the responsibility of the Manufacturer or his Agent to supply validated decontamination instructions. These must be obtained during the evaluation and procurement process.

It should be noted that all new purchases of equipment require either a newly-approved or extant Pre-Acquisition Questionnaire (PAQ).

Appendix 8. Evaluation Process



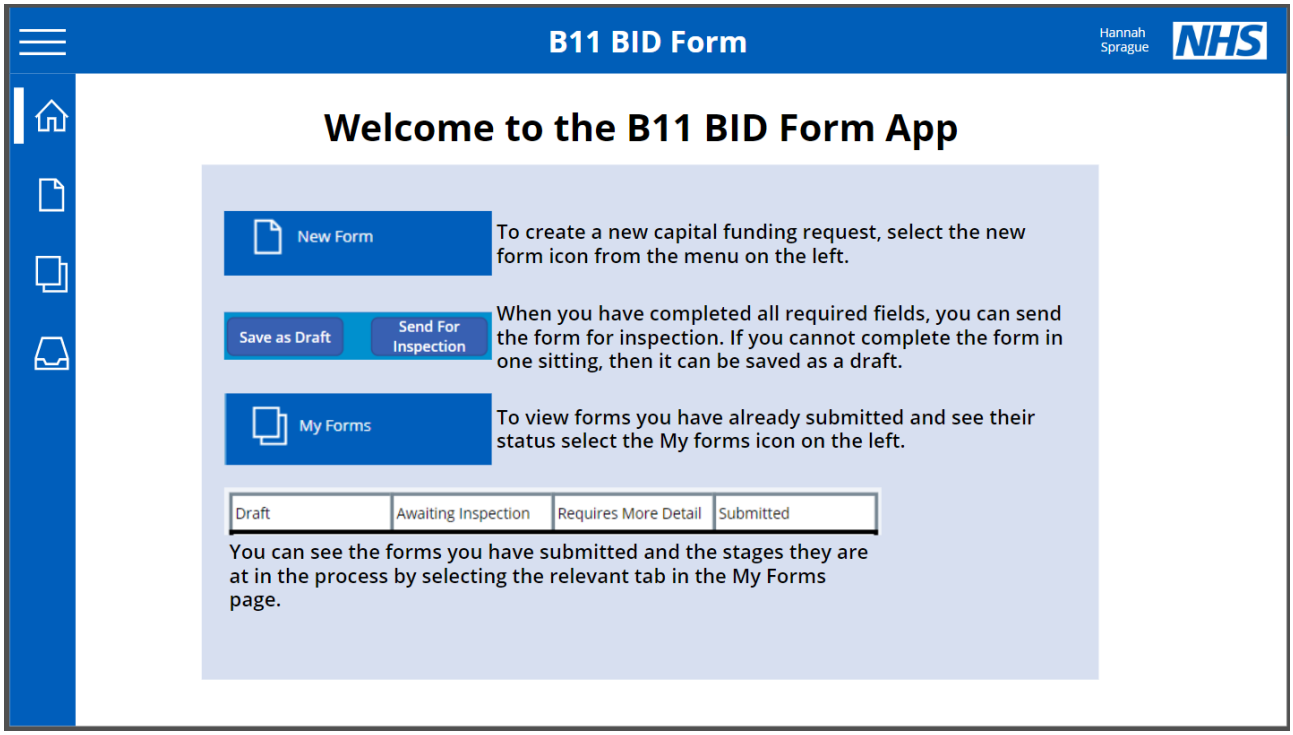
Appendix 9. Capital Bid Form for the Medical Equipment Board (MEB) and Guidance Notes for Completion

Each year, in order to establish a budget requirement for capital medical equipment purchases, bids are requested from Care Groups to ascertain a rough value of the equipment required across the Trust. Completion of the bid is a crucial component of this process, as it provides the MEB with the information required to prioritise an equipment request.

The bid submissions are all managed through a dedicated App which can be located on the Clinical Shelf of the Intranet under 'Medical Devices'. A link to the App is also below:

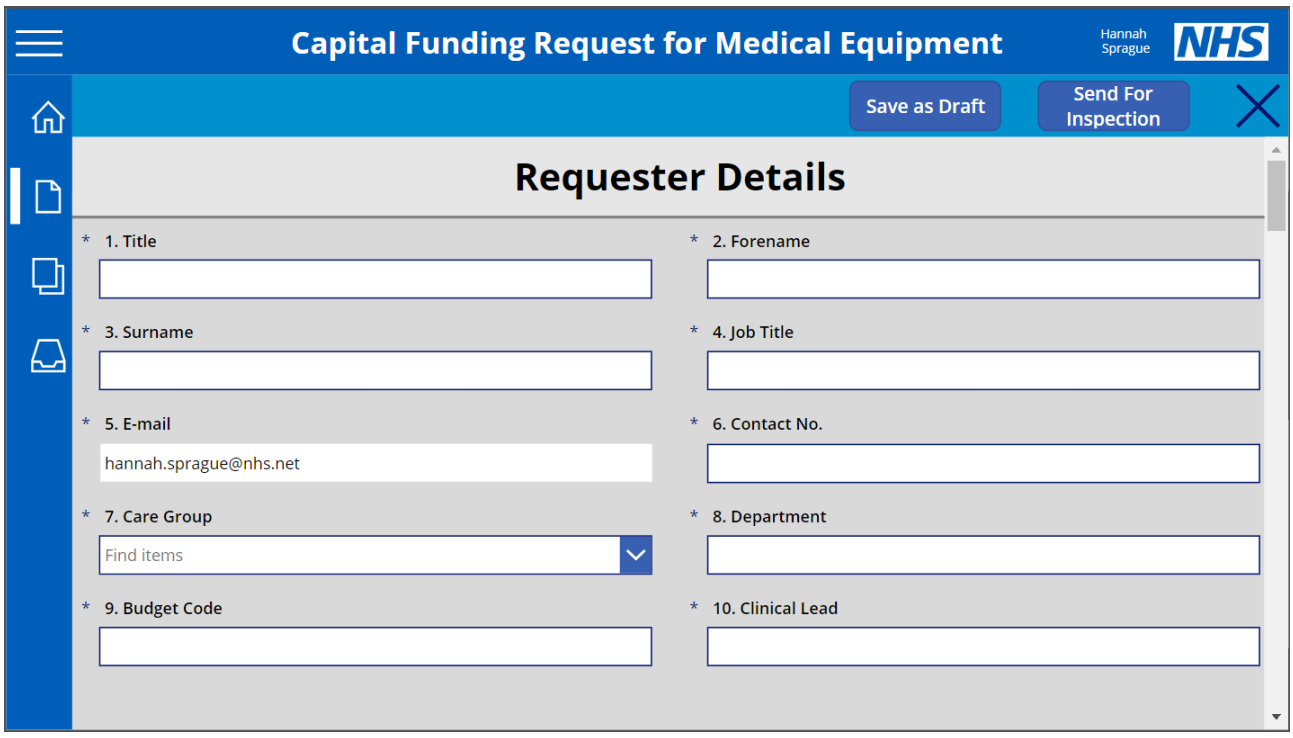
B11 BID Form - Power Apps

On the 'home' screen basic instructions can be found.

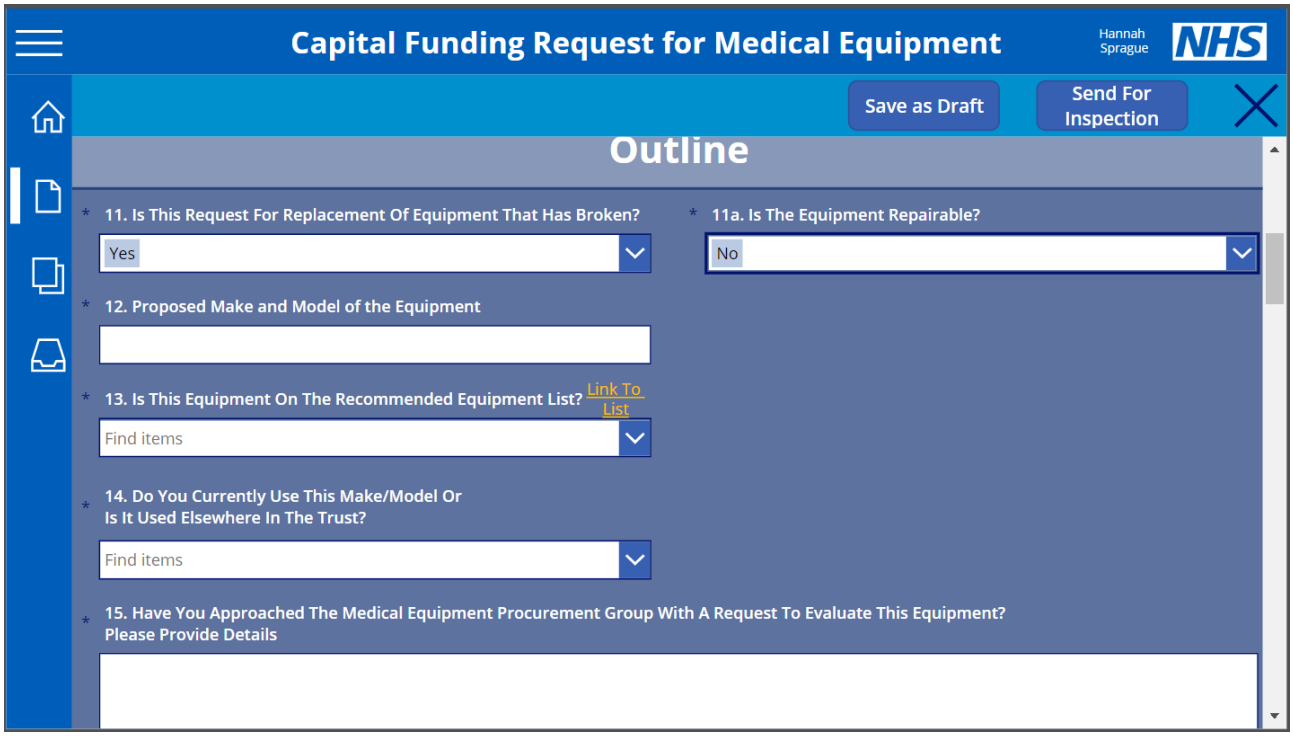


Bids must be completed in full – **all fields are mandatory** (submission will not be possible until all fields are completed) and as much detail as possible should be provided.

The first section of the form provides contact details for further information if required and contains essential information that will speed up the process of purchasing, should the bid be approved for funding.

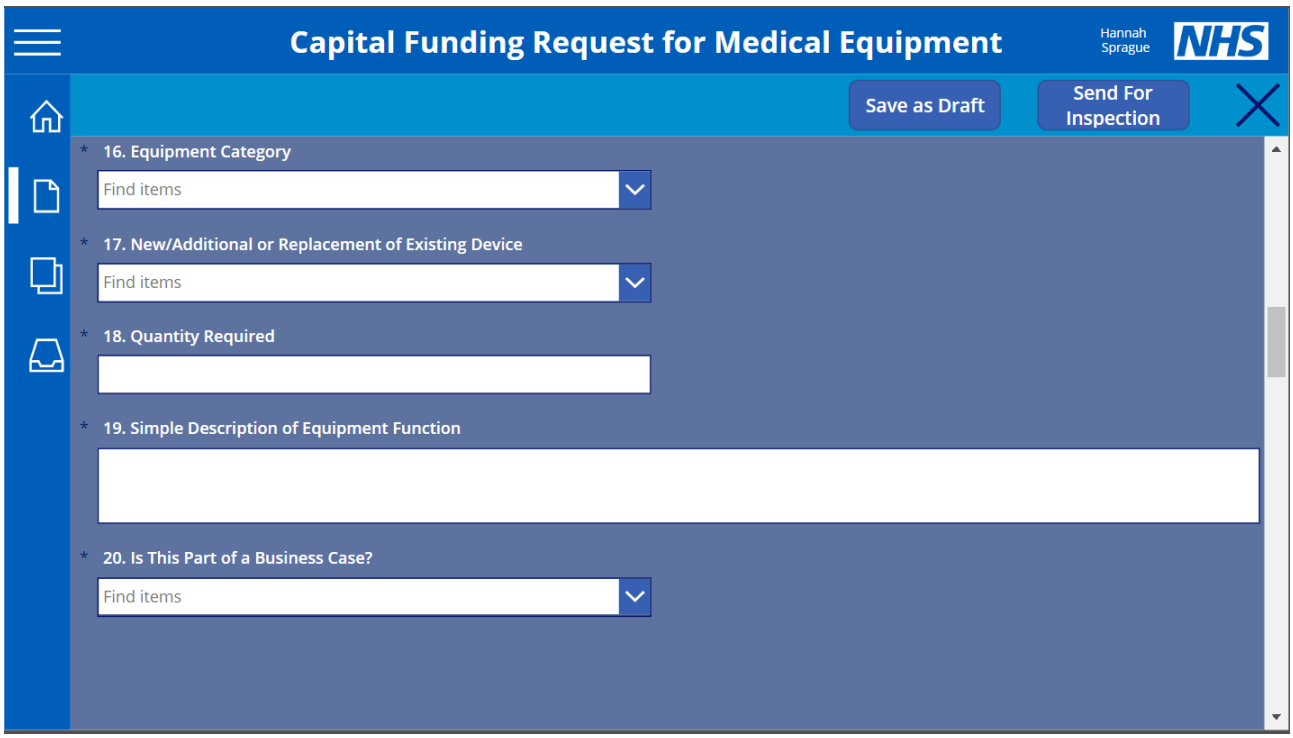


Items that are broken beyond economic repair and require urgent replacement are flagged – historically referred to as ‘Blue Smoke’ bids:

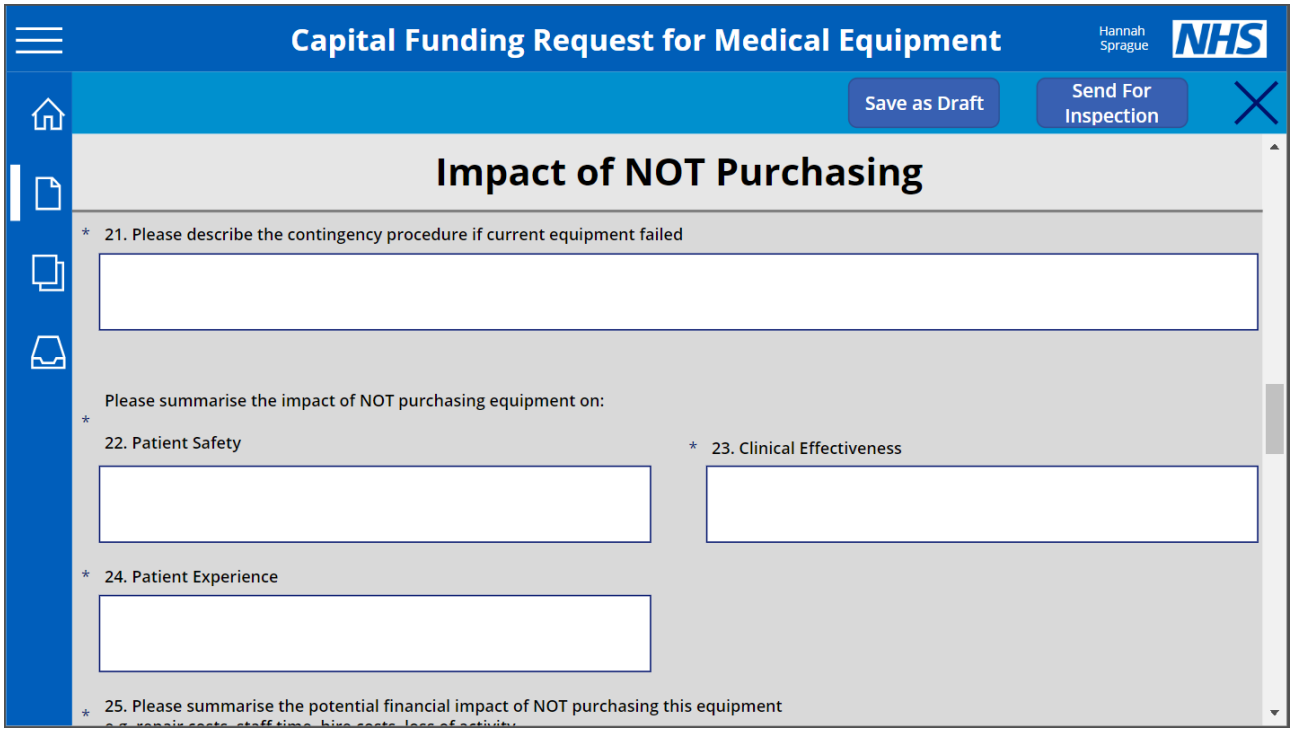


Identifying the make and model of equipment and whether it is an approved Trust standard item informs whether a product evaluation may be required before purchasing. These trials are overseen by the Medical Equipment Procurement Group, which reports to the MEB. Purchases **cannot** be placed for new equipment to the Trust that has not been trialled and approved.

The description of function of the equipment should be completed in simple terms, explaining what the equipment does and **avoiding the use of acronyms or specialist vocabulary**.

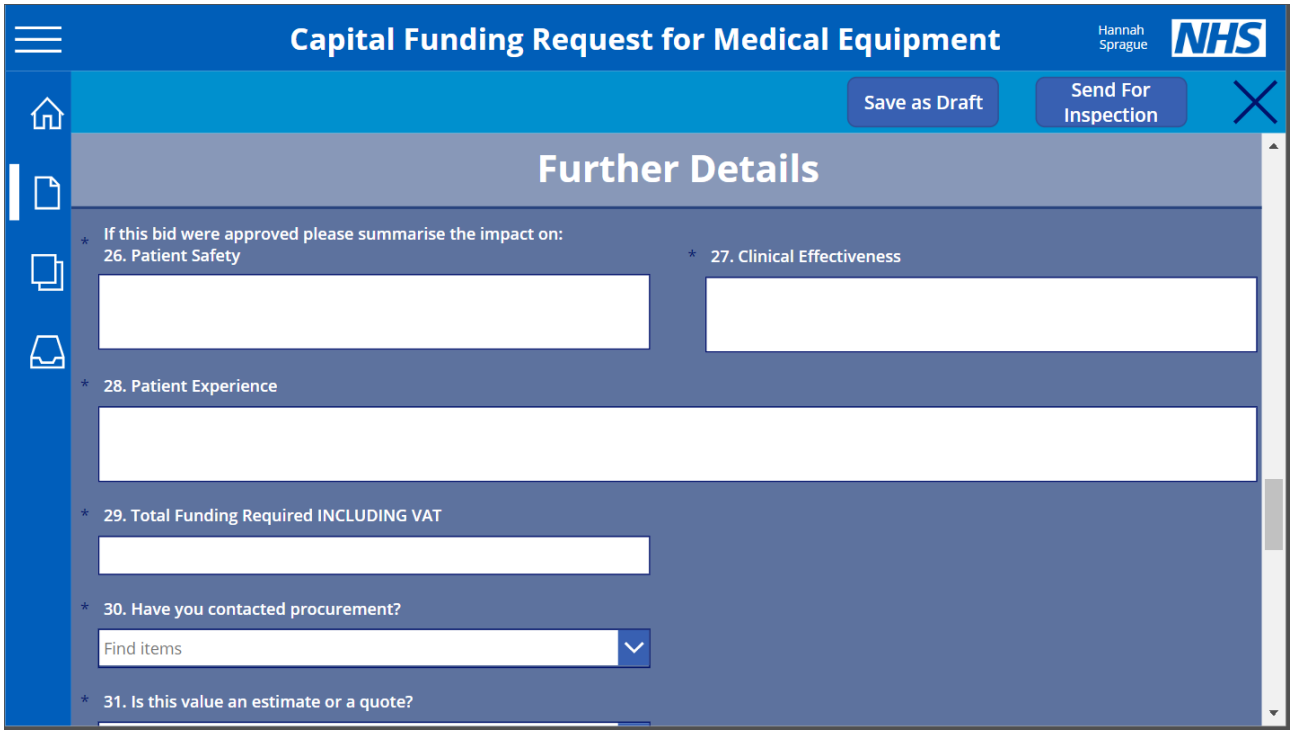


The forms request an explanation of the contingency procedures in place in the event of this equipment failing. This section **should not** describe the **impact** of the equipment failure on the service (e.g. inability to perform a certain procedure) – it should detail **what steps would be taken in response to this** (e.g. referral of patients to other hospitals for that procedure).

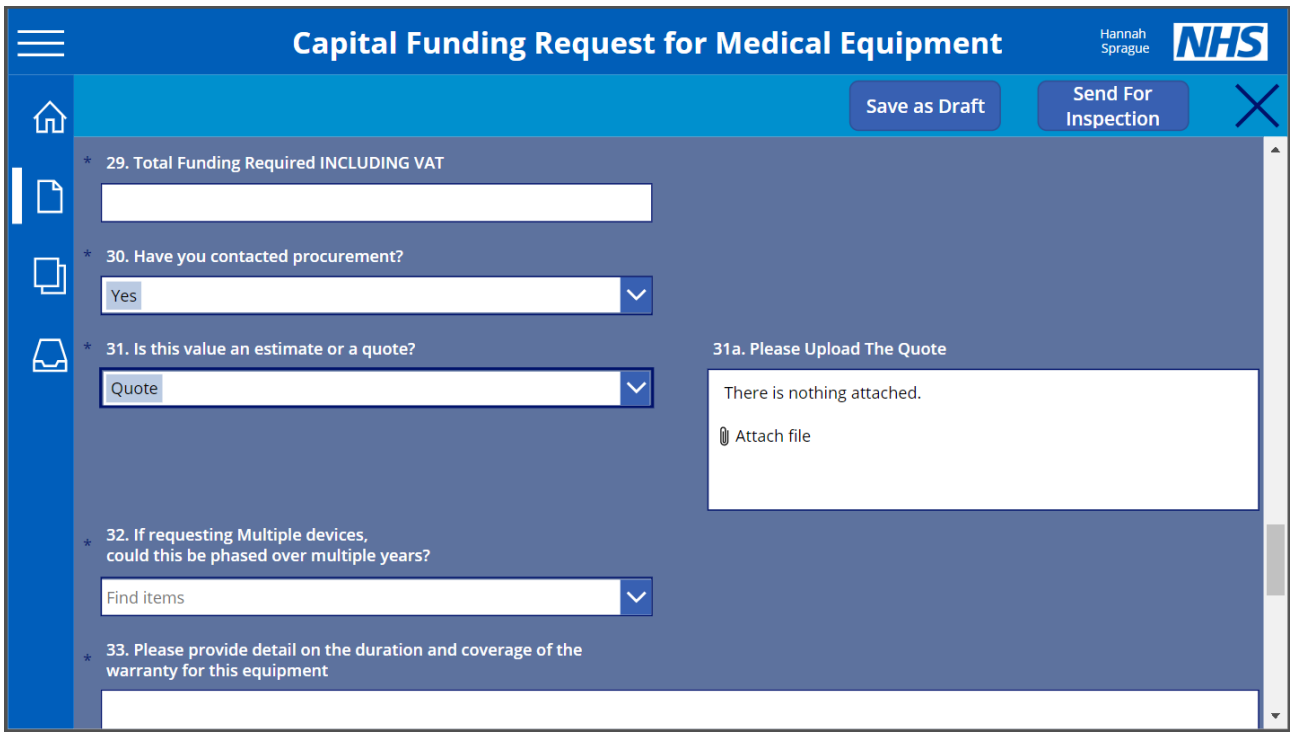


The following questions are asking for an explanation on how patient safety, clinical effectiveness and patient experience are affected by **remaining in the current situation**. In other words, if you have some old equipment, how **is** this affecting patient safety? This section focuses on the **present situation**.

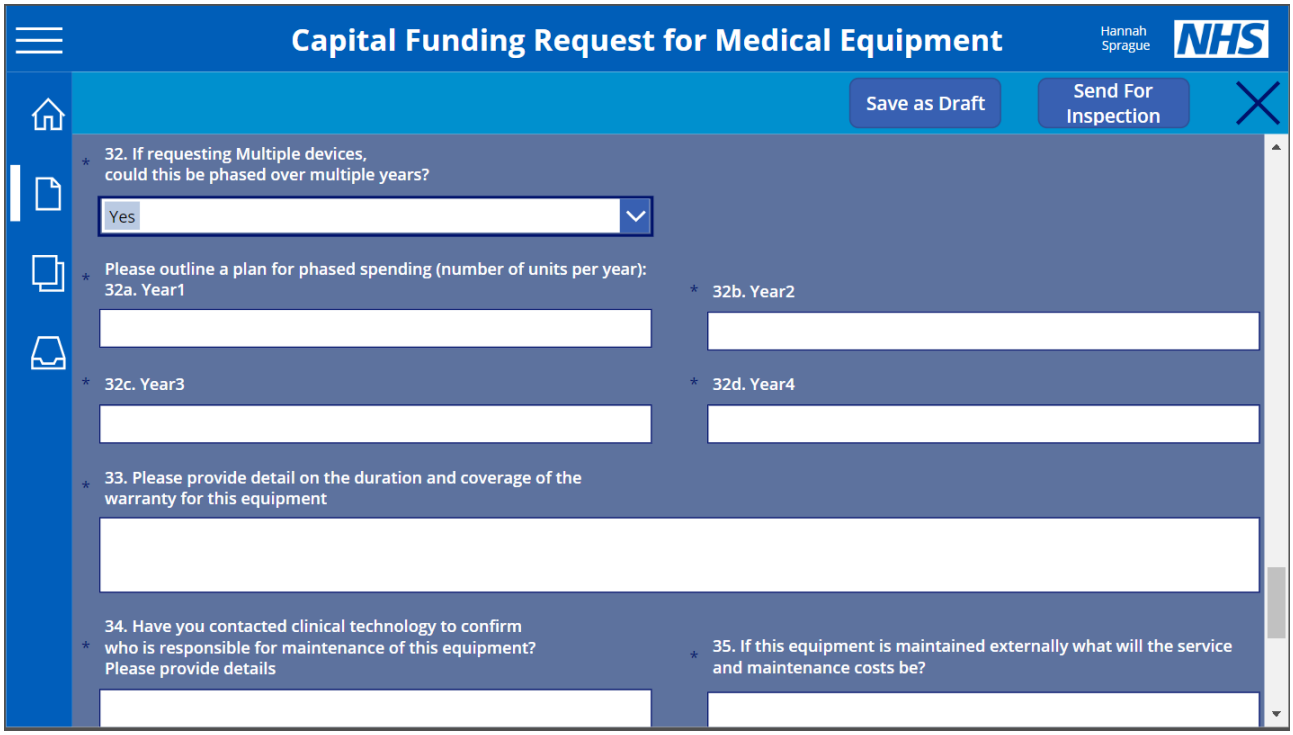
To further understand the rationale for the bid, the form then requires an explanation on the **positive impact that this purchase would have** on patient safety, clinical effectiveness and patient experience.



Requestors are highly encouraged to involve the procurement department before submitting a bid to the Medical Equipment Board. Procurement can provide assistance with obtaining quotations, inform on any procurement rules or regulations that may apply and they can also advise on whether trials may be needed. In order to determine how much funding is required, the form then asks for the cost of the equipment. Estimates can be given, but may be inaccurate, and so obtaining quotations via procurement is encouraged. Where a quotation has been obtained, this must be uploaded in the designated file upload section of the bid form.

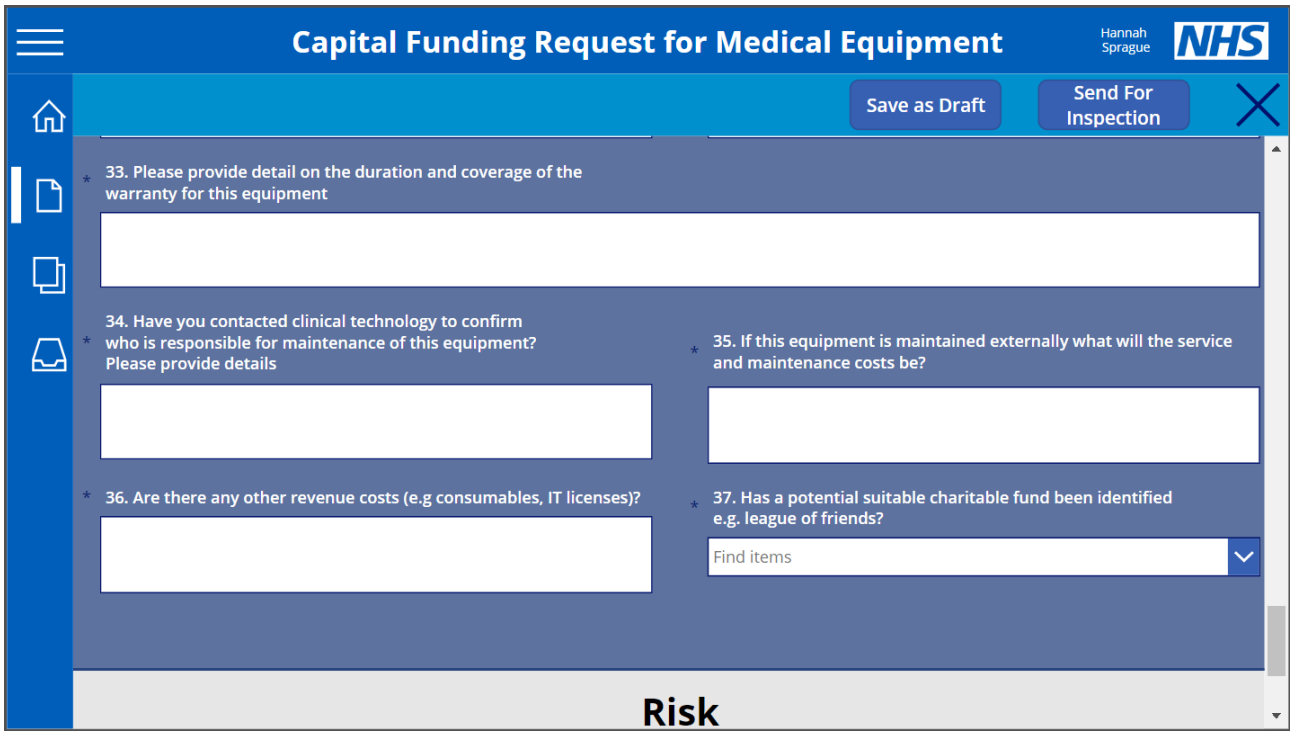


If requesting more than one device, consider whether you need all the devices at once. If there is potential to spread the cost over multiple years, then this ultimately means we can fund a greater number of bids each year. Enter the number of devices that could be purchased in each year. For example – if eight units are required, you could phase this into two per year for four years.



Clinical Technology may not be able to provide maintenance support for all devices – it is important that this is checked before you place your bid. If the equipment cannot be maintained in house, then you will need to find out the costs of a maintenance contract which will need to be paid by your Care Group. There may be savings in taking a maintenance contract out at point-of-sale, and so the availability of revenue funds to cover

this **is important to discuss this with your Care Group Finance Manager**. Similarly, other costs which **cannot** come from capital funding include consumables – if these are required you will need to be prepared to purchase them via revenue, and so calculation of these costs are required before asking for the equipment.



Finally, the form will ask for a risk register entry. Although not essential to support every bid with a risk register entry, risk assessment and clear scoring of the impact this has on patients will increase the chance of bids being approved for capital funds. It also provides a means for Care Group oversight and a means of escalation when bids are not funded.

Appendix 10. Medical Device Trial Outcome Form and Guidance Notes for Completion

http://doclibrary-rcht-intranet.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/Websites/Intranet/AZServices/M/MedicalPhysicsAndClinicalTechnology/MedicalEquipmentEvaluationForm.docx

The evaluation specification should be specific to the type of equipment being evaluated and be clear and measurable.

The evaluation specification should be divided into two categories – ESSENTIAL and DESIRABLE, and be of a generic nature, i.e. the specifications should not be written around those of a particular (favoured) piece of equipment, since the specification must be able to withstand scrutiny by independent sources. The MEPG may request additional criteria are added to the original evaluation specification at the stage of trial approval, as they will consider the wider picture, including future proofing and IT integration.

When evaluating equipment there are three main components to take into consideration for the specification criteria:

- Clinical – effective, safe and easy-to-use.
- Technical – ability to maintain (either internally or externally) and the associated cost of this; availability of spare parts, specialist support and technical training.
- Financial – overall cost (refer to whole life cost below).

The **Clinical** component should be undertaken by the staff group who would use the equipment, should acquisition take place.

The **Technical** component will relate to the maintenance, performance, manufacturer's support and compliance to relevant standards. This may also include proof of concept in connecting to IT systems and the e-Care system. The maintenance burden is increasingly a factor when procuring equipment (e.g. requires comprehensive servicing every 3 years rather than annually). New equipment should also be assessed from an electrical safety perspective (e.g. is the power lead detachable, which could give rise to the use of an incorrect lead), as well as other aspects of safe use. Clinical Technology and CITS should be involved in the technical evaluation of equipment via MEPG.

For the **Financial** component, assistance may be required from Finance and Procurement.

The **whole-life cost** of the equipment will need to be established. Whole-life costs include:

- Purchase price of equipment.
- Depreciation costs over the life of the equipment.
- Approx. cost of consumables over the expected life of the equipment.
- Warranty period of equipment.
- Cost/frequency of maintenance.

- Cost of licensing for software and upgrades.
- Cost of middle ware to support e-Care integration.
- Ongoing costs of user/technical training.
- Cost of staff time, e.g., training, additional work.
- Standardisation and compatibility with existing equipment.

Note: *The lowest purchase price of the product does not necessarily equate to the lowest whole-life cost.*

Scores awarded by individuals MUST be justified with supporting comments – including positive scores. Without justification of scoring, manufacturers can challenge the results of the evaluation, and so for full transparency, each score **must** be explained. When the scoring is collated for the final trials form, the comments do not need to be included on this document, but the information should be stored securely and submitted as a supporting document.

Scoring should follow this format:

Score	Outcome
0	Does not meet requirement
1	Partially meets requirement
2	Meets requirement
3	Exceeds requirements

Following evaluation there will either be a preferred product, or the trial will have found that the product is not suitable. Either outcome must be explained fully in the “rationale” section on the trials form.

The MEPG prior to trial will have advised if there are any additional considerations and these should be explicitly addressed in the “feedback on questions raised by MEPG” section.

For the preferred product, various funding options should be considered (finance and procurement can assist with this). The cost of purchase, lease and consumables deal should be clearly documented to allow evaluation of the best way to purchase the equipment.

Procurement Options (Preferred equipment only)

Funding source	Unit cost (Exc VAT)	Number of units	Cost p.a. (Exc VAT)	Term	Comments	Preferred Choice (✓)
Capital or Revenue						
Lease						
Consumables funded rental						

Finally, evaluation outcomes must be approved by the triumvirate of the care group carrying out the evaluation. The MEPG will not approve any new products to the Trust without full care group approval which has been documented clearly (as below):

Triumvirate confirmation of outcomes

Signed **Clinical lead**		**Job Title**		**Date**	
Name (Print)		**Care Group**		**Extension Number**	
Signed on behalf of Care Group		**Job Title**		**Date**	
Name (Print)		**Care Group**			