The Royal Wolverhampton NHS
NHS Trust

Policy Number: HS11
Title of Policy: Management of Medical Devices Policy

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Management of Medical Devices Policy

1.0 Policy Statement

- The Trust has a general duty under the Health and Safety at Work Act to safeguard health, safety and welfare of patients and staff when using medical equipment. These general duties are further extended under the Management of Health and Safety at Work Regulations and the Provision and Use of Work Equipment Regulations.
- There is also a requirement for the Trust to have in place good management procedures for medical devices as identified through the Medicines and Healthcare Products Regulatory Agency (MHRA) Medical Device Regulations (2002:2019), Institute of Physics and Engineering in Medicine (IPEM) Report 95 – Risk Management and its Application to Medical Device Management, Care Quality Commission (CQC) Fundamental Standards 12 Safe care and treatment and 15 Premises and equipment.

2.0 Definitions

- **Medical Devices** (Article 1, 2.a of MDD 93/42 EEC) **-** Refers to an instrument, apparatus, appliance material or other article, whether used alone or in combination, together with any software or app necessary for its application, which is intended by the manufacturer to be used for the purposes of:
  - Diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or physical impairment;
  - Investigation, replacement or modification of the anatomy or of a physiological process;
  - Control of conception.
- **Single Use Medical Device -** A device that is intended to be used on an individual patient during a single procedure and then discarded. It must not be used on another patient.
- **f2 -** Refers to the Medical Devices Performance Management System and Trust Asset Register, which is used for recording and managing all technical interventions carried out during the whole lifecycle of medical devices used within the Trust.
- **Apps, software and databases** (Med dev 2.1 /6) **-** All must first achieve the criteria in Article 1, 2.a of MDD 93/42 EEC directive. The following examples of medical device software can be applied.
  - An app that calculates medicine dose for you to inject.
  - Risk scoring a medical condition or disease on a calculation or data that informs a clinician to make a decision or diagnosis.
  - Software that directly drives a medical device as a standalone piece of software or is embedded within another system.
- **Medical device consumable -** Is an accessory to a medical device which can be detached or removed and may be subject to being disposed of after:
  - single use,
  - single patient use.

- a recommended number of uses or cycles,
- misuse,
- damage or failure due to normal wear and tear.

- **UKCA Mark** (MDR 2002:2019) – All medical device manufacturers must comply by July 2023 with requirement for valid UKCA mark on the medical device (formerly CE mark). Evidence must be provided by a manufacturer's letter of conformance.
- Unless specifically stated as part of a maintenance contract and, or consumable deal, responsibility for replacement of medical device consumables will be with Wards, Departments or Divisions. Replacement of consumables does not form part of the maintenance of the device.
- Examples of consumables are as follows:
  - Blood pressure cuff,
  - SpO2 sensor and lead,
  - Batteries that the user has access to as part of the devices design and does not require any specific tools, and
  - ECG leads.
- **TRUST-** RWT Acute and Community services.
- **MPCE -** The Trust's Medical Physics and Clinical Engineering Department.
- **Medical Devices Helpdesk –** Trust NET based medical device issue reporting portal. The Helpdesk portal allows for the reporting of medical devices issues 24/7. Calls logged through the Helpdesk are transmitted to all Clinical Engineering workshop sections, responded to by the appropriate section and assigned to a clinical technologist(s) for action. Clinical Engineering responses to Helpdesk calls are monitored, measured and reported on through a set of defined Key Performance Indicators (KPI).
- **SafeHands/Teletracking/Equipment Tracker -** This real-time locating system uses radio-frequency and infra-red signals to track the location and movement of asset tagged medical devices.
- **Personal Identifiable Data (PID) -** Is information that can be used on its own or with other information to identify, contact or locate a single person, or to identify an individual in context.
- **Medical laboratory equipment -** Equipment used in laboratory where tests are done on clinical specimens in order to obtain information about the health of a patient as pertaining to the diagnosis, treatment and prevention of disease.
- **OEM -** Original Equipment Manufacturer.
- **Off-label -** Modifying existing devices or using them for purposes not intended by the manufacturer.
- **CIS –** Clinical Information Systems is the specialist MPCE clinical computing/software team responsible for maintaining clinical applications/servers and associated interfaced medical devices.

Some examples of medical devices covered under this policy are in the table.

Function	Examples
Diagnosis or treatment of disease	Analysers, vascular dopplers, basic surgical instruments, x-ray machines, infusion pumps, syringe pumps, audiometers, defibrillators and flowmeters.
Monitoring of patients	ECG, pulse oximeter, blood pressure monitors, tympanic thermometers, bed monitors and CO meters.
Community based healthcare	Alcometers, domiciliary oxygen therapy systems, nebulisers, glucose tests, pressure care equipment, speech therapy devices, TENS, electric beds, couches and Telehealth.

3.0 Accountabilities

- **Chief Medical Officer -** To take overall responsibility for medical device management.
- **Health and Safety Steering Group and Patient Safety Improvement Group –** Tier 2 Groups working collaboratively with Tier 3 Medical Devices Group.
- **Medical Devices Group -** To take responsibility for the maintenance of this policy. Responsible for the oversight of medical devices within all locations.
- **Medical Devices Safety Officer (MDSO) -** The key roles are to promote the safe use of medical devices across the organisation and provide expert advice. As well as improving the quality of reporting, the MDSO will be the essential link between the identification and implementation of local and national medical devices safety initiatives and the daily operations to improve the safety of medical devices.
- **MPCE -** To take responsibility for delivery of medical device management and maintenance of an asset register (f2), provision of advice and support relating to medical devices.
- **Senior Sisters/Senior Charge Nurses/Department Managers/Matrons/Consultants -** Will take ownership and be responsible for the medical devices used in their areas. This includes responsibility for ensuring the following.
  - ➢ The safe and secure storage of medical devices.
  - ➢ Responsible for locally managed third-party external maintenance contracts and all associated documentation.
  - ➢ Staff check devices and items found requiring service and, or repair are brought to the attention of MPCE staff through the Medical Device Helpdesk.
  - ➢ That a sufficient stock of consumables is available for the provision of the continued safe and effective use of medical devices.
  - ➢ Staff awareness of the Equipment Tracker functionality within SafeHands, including application and benefits of real-time location of tagged medical devices.
  - ➢ Staff, awareness of policy and protocol adherence within their area of responsibility.
  - ➢ Identifying a link person for coordination of medical devices issues.

- That all staff (permanent, Bank and agency staff) who use equipment are trained. Training undertaken is recorded on the MPCE medical device training database by the Medical Device Trainers or specialist team in line with Protocol 4.

- **Division, Directorate and Departments (Trust Depts/Wards) -** To have responsibility for having an up-to-date inventory of all their medical devices within the area under their control and to work closely with MPCE in keeping their lists up to date. This is in order to demonstrate compliance with CQC Fundamental Standards 12 and 15.
  - Divisions, Directorates and Departments must have in place a procedure whereby all medical devices are functionally checked in accordance with the manufacturers' user guides prior to use on a patient, and that they are decontaminated in line with Trust's infection prevention protocols at regular intervals and in line with manufacturers' recommendations.
  - Divisions, Directorates and Departments must ensure the safe and secure storage of their medical devices.
  - Externally third party managed (non MPCE) medical device contracts: the budget holder on behalf of the organisation through a third party (OEM or other), must comply and produce documented evidence of maintenance records to meet with CQC Fundamental Standards 12 & 15 as part of the Health & Social care Act of 2014.
- **Procurement Managers/Buyers -** To lead in all procurement matters associated with medical devices and act as first point of contact when Division, Directorate and Departments require the purchase of medical devices.
  - Procurement Managers/Buyers and MPCE staff will work closely in relation to procurement, trials and tenders of medical devices ensuring compliance of this policy, OP109 conflicts of interest policy and all relevant legislation.
- **Finance Department -** Responsible for all asset lifetime costing of medical devices. MPCE and Procurement will work closely with them for new devices purchased and for devices being condemned/replaced.
- **Trust Equipment Group -** Responsible for all capital, approval, validation and business cases in relation to medical devices within the Trust. This will include new devices and those identified through equipment replacement programmes.
- **Medical Gases Management Group -** Responsible for having a policy in place to ensure the safety of all patients and staff involved in the supply, transportation, consumption, handling or maintenance of medical gases and their pipeline supply systems (MGPS) within the premises of the Trust.
- **Capital Project Management -** Medical devices as part of a capital project or refit must be declared, and adhere to and comply with HS11 protocols. Project Managers must liaise with Clinical Engineering Managers from the outset to ensure the correct medical devices or systems are purchased to meet clinical needs/integration with existing systems/infrastructure.
- **All Staff -** Responsible for following procedures and manufacturer's instructions and competency in using the equipment (includes Bank, agency staff). All staff will have responsibility for removal and replacement of depleted batteries where access to these batteries is by removal of a battery compartment cover that does not require any specific tools. Replacement of these batteries (consumable item) does not form part of

the maintenance of the device. Batteries must be disposed of in accordance with HS10 Waste Management Policy. Related responsibilities include functional check and inspection of related components (e.g., chargers) for damage in line with manufacturer's instructions, appropriate storage and retention of chargers and connectors and sufficient charging of batteries to support safe operation of medical devices.

- All devices and items found requiring service, repair or other technical intervention are decontaminated and brought to the attention of MPCE through the online Medical Devices Helpdesk.

4.0 Policy Detail

To have in place protocols that all Trust Divisions, Directorates and Departments will comply with to ensure that medical devices are managed to ensure both patient and staff safety including the cleaning/decontamination of these devices after each patient use in helping infection prevention. These protocols will put in place methods for:

Protocol 1 - Appropriate selection, purchase/replacement of medical devices

Protocol 2 - Trial, loan or lease of medical devices

Protocol 3 - Acceptance of medical devices

Protocol 4 - Procedure for medical device training

Protocol 5 - Transportation of medical devices (not limited to vehicular modes of transport).

Protocol 6 - Service, maintenance, repair and decontamination of medical devices

Protocol 7 - Reporting of Adverse Incidents - Medical Devices

Protocol 8 - Loaning medical devices to patients within the Trust or Community based healthcare

Protocol 9 – Replacement and disposal of medical devices

Protocol 10 - Company representative policy on medical devices

Protocol 11 - Medical device IT security

Protocol 12 - Procedure to cover loan of medical devices into the Trust from other organisations

Protocol 13 – Decontamination of Medical Devices

5.0 Financial Risk Assessment

1	Does the implementation of this policy require any additional Capital resources	No
2	Does the implementation of this policy require additional revenue resources	No
3	Does the implementation of this policy require additional manpower	No
4	Does the implementation of this policy release any manpower costs through a change in practice	No

5	Are there additional staff training costs associated with implementing this policy which cannot be delivered through current training programmes or allocated training times for staff.	No
	Other comments	No

If the response to any of the above is **'Yes'** please complete a standard business case report and which is signed by your Divisional Accountant and Directorate Manager for consideration by the Divisional Management Team before progressing to your specialist committee for approval. **Please retain all "yes" content in the final policy.**

6.0 Equality Impact Assessment – Completed.

7.0 Maintenance

This policy will be reviewed and maintained through the Medical Devices Group.

8.0 Communication and Training

- This policy and its requirements will be communicated to all areas through appropriate Governance channels.
- This policy will be brought to the attention of all staff when on the Trust NET through All User Bulletin email, presentation at Divisional meetings, Senior Managers Briefing and 'roadshow' staff awareness sessions.
- When medical devices are purchased or are on trial/loan, all staff must receive full information, instruction, training and supervision, this will include:
  - Users, Trainers and MPCE Clinical Technologists.
- All medical device training must be undertaken in line with HS11 – Protocol 4.
- All medical device training, other than exceptions detailed in Protocol 4, must be recorded on the MPCE Medical Device Training Database by the Trust's Medical Device Trainers.
- Medical Devices Helpdesk user training to be provided on Trust induction and supplemented through additional training session provided by the Medical Device Trainers.

9.0 Audit Process

Criterion	Monitoring Methods	Frequency	Group	Lead
CQC Fundamental Standards 12 and 15 (HS11 Protocol 4) Medical Device Training	• Audit of individual wards • New Starter List • Exceptions report	• Quarterly • Annual • Annual	• MDG	• Medical Device Trainers
CQC Fundamental Standards 12 and 15 (HS11 Protocol 6) Service and Repair	• Internal – f2 service and repair reports • External contracts Random audits	• Annual or on demand • Random audit with department or supplier	• MDG	• Head of clinical engineering • MDG co- chairs
CQC Fundamental Standards 12 and 15 (HS11 Protocol 1) Purchasing	• Capital Audit • Revenue Audit	• Quarterly • Quarterly	• TEG • Procurement	• MDSO
CQC Fundamental Standards 12 and 15 (HS11 Protocol 6) Decontamination	• Internal f2 service reports • External documentation	• Quarterly • Quarterly	• MPCE • Decontamination Group	• MDG/MDSO
CQC Fundamental Standards 12 and 15 (HS11 Protocol 9) Condemnation	• f2 records	• Annual	• MPCE	• MDG/MDSO
CQC Fundamental Standards 12 and 15 (HS11 Protocol 11) Security	• Audit physical security • Audit data security on a device	• Quarterly • Quarterly	• MPCE • CIS	• MDG/MDSO
MHRA 2010-001 Off Label Risks/non conformity procedures with medical devices	• Review of Datix reports	• Monthly	• MDG	• MDSO
Protocol 10 section 10.3 • SafeHands Badges used to track reps • Company Reps only to be on site if they have a prior appointment with a pre-agreed reason	• Reporting following a trial or implementation to either CPEG or TPEG depending on the products • Audit tool (Appendix 23)	• On completion of each trial • Quarterly	• CPEG and/or TPEG • MDG and/or CPEG/TPEG	• Senior Nurse Clinical Procurement • Head of Procurement

for visiting • Not to accept samples with a view to a clinical trial unless this has been agreed with Procurement or MPCE and Indemnity must be in place	• Clinical Trials protocol implementation audits	• Quarterly	• MDG and/or CPEG/TPEG	• Head of Procurement

10.0 Reference

- Health and Safety at Work Act 1974.
- Health and Social Care Act 2014.
- Medical Device Regulation UK MDR 2002:2019
- European Council Directive 93/42/EEC concerning medical devices.
- European Agreement Concerning the International Carriage of Dangerous Goods by Road 2013.
- The Provision and Use of Work Equipment Regulations (PUWER).
- Carriage of Dangerous Goods and Use of Transportable Pressure Equipment 2009 and 2011 Amendment Regulations,
- Waste Electrical and Electronic Equipment Regulations (WEEE Regulations).
- Artificial Optical Radiation Regulations (AOR) 2010.
- Managing Medical Devices 2021 – Guidance for Healthcare and Social Services Organisations.
- Sterilisation, Disinfection and Cleaning of Medical Equipment - Guidance on Decontamination from the Microbiology Advisory Committee to the Department of Health.
- BS EN 60601-x – Electrical safety testing for devices first entering the Trust as part of acceptance testing.
- BS EN 62353:2008 – Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment.
- ISO 80001-1:2010 - Application of risk management for IT-networks incorporating medical devices.
- ISO 27000-1 – Information security management.
- Reporting of Medical Device Adverse Incidents and Disseminating Medical Device Alerts, MDA/2011/001 MHRA.
- Institute of Physics and Engineering in Medicine (IPEM Report 95) Risk Management and its Application to Medical Device Management.
- CQC Fundamental Standards 12 and 15.
- MHRA 2010-001 Off-Label procedure.
- HS05 - Ionising Radiation Safety Policy.

- HS06 - Laser Safety Policy.
- HS10 - Waste Management Policy.
- HS12 - Decontamination Policy.
- HS33 - Driving for Work Policy.
- OP04 – Covid-19 Pandemic Support and Guidance.
- OP12 - IT Security Policy.
- OP13 - Information Governance Policy.
- OP41 - Induction & Mandatory Training Policy.
- OP85- Information Sharing Policy.
- OP95 Introduction of New Clinical Techniques and Interventional Procedures.
- OP109 Conflicts of Interest policy.

Part A - Document Control

Policy Number and Policy version: **HS11 version 7.1**	**Policy Title:** **Management of Medical Devices Policy**		**Status: Final**	**Author: Medical Devices Safety Officer** **Director Sponsor: Chief Medical Officer**
Version / Amendment History	Version	Date	Author	Reason
	1	Nov 2006	Head of Clinical Engineering	New policy
	2	Oct 2009	Head of Clinical Engineering	Reviewed
	3	Oct 2010	Head of Clinical Engineering	Minor changes
	4	Oct 2011	Head of Clinical Engineering	Incorporated HS37 - Medical device training
	5	July 2014	Head of Clinical Engineering	Minor changes.
	6	Feb 2018	Medical Devices Safety Officer	Reviewed, minor changes to existing Policy and inclusion of statement on BST/GMT, new audit process and new Protocols 10, 11 and 12.
	6.1	Sept. 2020	Medical Devices Safety Officer	Extension approved until September 2021 - due to COVID the medical devices regulations have been put back until May 2021 by the government.
	6.2	Oct. 2021	Trust Medical Devices Safety Officer	Extension approved until February 2022 whilst review is finalised.
	6.3	Jan.2021	Trust Medical Devices Safety Officer	Extension approved until May 2022 whilst review is finalised.
	7.0	May 2022	Medical Devices Safety Officer	Review of new Medical Device Regulations 2002-2019, review of all Protocols and addition of

				Protocol 13.
	7.1	June 2022	Medical Devices Safety Officer	Minor update to Protocol 7

Intended Recipients: Trust wide	
Consultation Group / Role Titles and Date: Medical Devices Group Health and Safety Steering Group Matrons Forum approved Union office Policy Committee Cyber Security Manager (Protocol 11)	
Name and date of Trust level group where reviewed	Trust Policy Group – May 2022 – Version 7.0 Trust Policy Group – Virtual Approval – June 2022 – Version 7.1
Name and date of final approval committee	Trust Management Committee – May 2022 Version 7.0
Date of Policy issue	June 2022
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	May 2025
Training and Dissemination: Induction, desktop, divisional governance	
Publishing Requirements: Can this document be published on the Trust's public page: Yes	
To be read in conjunction with: HS05, HS06, HS10, HS12, HS33, OP10, OP12, OP13, OP41, OP85, OP95, OP109, OP04.	
Initial Equality Impact Assessment (all policies): **Completed Yes** **Full Equality Impact assessment (as required):** **Completed Yes** If you require this document in an alternative format e.g., larger print please contact Central Governance Department on Ext 85114.	
Monitoring arrangements and Committee	Medical Devices Group, Directorate Management Governance Forum

Document summary / key issues covered:

To have in place protocols for all Divisions, Directorates, Departments, and Community based healthcare to comply with, to ensure that medical devices are properly managed to ensure patient and staff safety, including the cleaning/decontamination of these devices after each patient use in helping infection prevention. These protocols will put in place methods for:

- Purchase – the procurement and standardisation of medical devices
- Trial, loan or lease of medical devices from manufacturers/suppliers
- Acceptance of medical devices – asset registering, acceptance testing, commissioning and delivery of medical devices
- User training on medical devices
- Transportation of medical devices
- Service, repair, maintenance and decontamination of medical devices
- Reporting of Adverse Incidents - Medical Devices
- Loaning medical devices to patients within the Trust or Community based healthcare
- Replacement/disposal of medical devices
- Company representatives policy on medical devices
- Medical devices IT security
- Procedure to cover loan of medical devices into the Trust from other organisations
- Manufacturer's compliance
- Overview of medical devices decontamination

Key words for intranet searching purposes	Medical devices, HS11.
High Risk Policy? **Definition:** • Contains information in the public domain that may present additional risk to the public e.g. contains detailed images of means of strangulation. • References to individually identifiable cases. • References to commercially sensitive or confidential systems. If a policy is considered to be high risk it will be the responsibility of the author and chief officer sponsor to ensure it is redacted to the requestee.	**Yes** / ~~No~~ If Yes include the following sentence and relevant information in the Intended Recipients section above – In the event that this is policy is made available to the public the following information should be redacted: **This policy is commercially sensitive a redacted version will be made available for the public domain.**

Part B **Ratification Assurance Statement**

Name of document: **HS11 - Management of Medical Devices Policy**

Name of author: **Robert Millard** Job Title: **Medical Devices Safety Officer**

I, the above named author confirm that:

- The Strategy/Policy/Procedure/Guidelines (please delete) presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.
- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.
- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines(OP01).
- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.
- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.
- I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.
- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author: R Millard

Date: 9/3/22

Name of Person Ratifying this document (Chief Officer or Nominee):

Job Title: B McKAY, CHIEF MEDICAL OFFICER

Signature: 10/3/22

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to: The Policy Administrator

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and policy version: HS11v7.0	**Policy Title: management of Medical Devices Policy**	
Reviewing Group		**Date reviewed: May 2022**
Implementation lead: Robert Millard, Medical Devices Safety Officer		

Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead / s (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.	N\A	
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form	N\A	
Development of Forms, leaflets etc; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed	N\A	
Strategy / Policy / Procedure communication; Consider 1. Key communication messages from the policy / procedure, who to and how?	1. Trust comms, 2. Small presentations to HSSG & MSG & Matrons 3. MPCE staff	
Financial cost implementation Consider Business case development	N\A	
Other specific Policy issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation		

Protocol 1 - Appropriate Selection, Purchase and Replacement of Medical Devices

1.0 When procuring/purchasing medical equipment, Managers must ensure the medical device is:

- Suitable for the intended purpose/clinical application and
- Where possible, compatible with existing devices and any standardisation programmes.

1.1 For new makes or models of medical devices, Procurement will get a completed Pre-acquisition Questionnaire (PAQ) form from the company and forward it to MPCE for checking/approval. If companies have ticked section 11a/b) then form MDS2-RWT (Appendix 1) will also need to be completed by the company and checked by MPCE.

1.2 Consideration must also be given to the following.

a) Maintenance.

b) Routine cleaning methods, cleaning agents, disinfection or sterilisation methods and agents, suitability of fabric, and compliance with HS12. Decontamination of re-usable medical devices. For new make or type or model of devices to the Trust, a Decontamination Considerations Prior to Purchase of Medical Equipment form (HS12 Attachment 7) must be sent to the company by Procurement.. For devices requiring sterilisation or autoclaving, it is recommended the suppliers meet with Trust Sterilisation Dept. manager to clarify and agree cleaning requirements.

c) Device education and training material (user and technical) accommodating any staff disabilities, i.e., bespoke training or training materials or one to one training if required.

d) Support from manufacturer of the devices.

e) Enabling works on significant projects.

f) Consideration to any Estates issues, additional energy costs or implications for medical gas use.

g) IT in relation to any medical device that interfaces with any IT system or database servers – see Protocol 11. Consideration must be made regards archiving requirements, encryption/white listing devices and remote access requirements but not exhaustive.

h) Asset Tagging: identify funds to have key devices tagged enabling devices to be quickly located giving the following benefits: minimises delay for patient diagnosis, monitoring or treatment, helps compliance with Infection Prevention, and allows rapid location of devices affected by MHRA alerts to undertake remedial action.

1.3 **Modifying devices or using them for purposes not intended by the manufacturer** (off-label use) has safety and litigation implications and is not recommended. If the Trust's professionals judge that there is no alternative but to use a medical device off-label or modify an existing medical or non UKCA marked medical device, the following must be carried out in line with MHRA 2010/001:

- complete a risk assessment which must be sent to the Medical Devices Group for formal approval before placing the device in service;
- The risk assessment must be reviewed at suitable intervals, a responsible clinician will be identified and will ensure patient consent is recorded;
- consider the ethical and legal implications;
- implement suitable precautions to minimize the risk.

1.4 **Specialist medical devices** like lasers and x-ray equipment must be compliant with relevant policies and legislation, for example HS06 – Laser, UV and Optical Radiation Protection Policy, HS05 – Ionising Radiation Safety Policy or The Control of Artificial Optical Radiation at Work Regulations 2010.

1.5 Disposal of medical devices (in line with WEEE regulations and other hazardous waste in compliance with Trust policy HS10) to be included when purchasing medical devices.

1.6 When purchasing medical devices of a value ≥£50,000, a formal tender process must be followed and departments must involve Procurement and MPCE from the outset to ensure devices comply with the requirements of the Trust, standards and legislation. This will also ensure the relevant documentation is completed accordingly, i.e., equipment specifications, evaluation forms, indemnity forms, PAQ forms, etc.

1.7 A summary of the process and documentation to be followed and completed for all purchases/replacement of medical devices is illustrated in the flowchart in Appendix 2.

1.8 Purchase and, or replacement of medical devices with a value ≤ £5000 inc. VAT each that fall under a Revenue budget

1.8.1 HS11 Form (Request to Purchase Revenue Medical Equipment) (Appendix 3) Part A must be completed by the purchasing department or ward.

1.8.2 It must be saved as a Word document and emailed only to the address detailed within the form. A user guide is available for staff who need assistance in completing this form via Appendix 3A.

1.8.3 For medical devices that are additional purchases, the department or ward must identify funds of [redacted] of list price reoccurring per annum for the life of the equipment after the warranty period (unless otherwise stated by manufacturers cover), to be set aside for the service/maintenance of that equipment where costs are unknown.

1.8.4 MPCE will check and complete Section B to ensure the most appropriate make and model is identified and that it meets user requirements and complies with the Trust's equipment standardisation programme, addresses user training, and meets various medical device standards. If rejected, MPCE will send the form to the ward stating the reason why the medical device cannot be ordered. If approved the form will be sent back to the ward with a Reference Number completed.

1.8.5 The ward can then raise a Requisition stating the Reference Number on it along with the Request Form to Procurement to raise an order.

1.8.6 Procurement to complete Part C and email MPCE with a copy of the order generated.

1.9 **Replacement or additional or for service development or improvement with a value between £5k and £250k inc. VAT**- Trust departments and wards requesting medical devices must complete the Outline Business Case (OBC) form (Appendix 4) and Financial Proforma (Appendix 5). Senior Buyers in the Procurement Department must be contacted for advice relating to cost of equipment, consumables and /services and obtaining quotes from manufacturers and suppliers.

1.10 Advice from MPCE must be sought for all medical device maintenance costs, which may be in-house or provided under service contract by the manufacturer or other third-party service provider. For guidance purposes, if this is not known then [redacted] of the list price of the equipment must be identified on a reoccurring annual basis. Costs associated with any user or technical training must also be included. Consideration must be given to any Estates issues, additional energy costs or implications for medical gas use. This form must then be submitted to the Divisional Management Core Group, followed by Trust Equipment Group (TEG) for evaluation/prioritisation then to the Capital Review Group (CRG) for final approval to purchase.

1.11 For **Capital medical devices** prioritised for replacement by the Trust Equipment Group (TEG) with a total value between £5K and £250K (inc VAT), a **Replacement of Existing Capital Equipment form** (Appendix 6) will be initiated by TEG and sent to Trust department managers to complete along with a Financial Proforma (Appendix 5). The relevant Trust manager must liaise with Procurement to ensure correct quotes and tender processes are followed. This form along with the final quote/Financial Proforma must then be returned to TEG for approval. Once approved by TEG, it will be sent to CRG for funding approval.

1.12 **Replacement or additional medical devices or medical devices for service development or improvement with a value between £250k and £500k inc. VAT**– Trust departments and wards requesting medical devices must complete the Full Business Case form (Appendix 7), and approach the Procurement and MPCE Departments as above for advice. Where maintenance costs are unknown, for guidance [redacted] of list price of the

equipment must be included. Costs associated with any user or technical training must also be included. Consideration must be given to any Estates issues, additional energy costs or implications for medical gas use. This form must be submitted to the Divisional Management Core Group, then TEG for evaluation/prioritisation and if accepted to the CRG.

1.13 If purchase has implications for high revenue or consumable costs or on other services or dependencies, then it must pass through the Contracting & Commissioning Forum (CCF) and Trust Management Committee (TMC) for final approval. **For equipment >£500K inc. VAT** the Full Business Case form (Appendix 7) must be completed and must go through all the groups/committees mentioned above then finally through Finance & Performance.

1.14 **Purchasing medical devices from Charitable Funds** – Procurement and MPCE must be involved following the same process depending on value of equipment, taking into account VAT is not paid on Charitable Fund purchases.

1.15 **Purchasing and /loaning of medical devices as part of a consumables/rental/lease deal package** – Procurement and MPCE must be involved to ensure compliance with this policy and there may be an administration charge by MPCE for the management of these devices. Follow the same process depending on value of equipment however excluding CRG.

1.16 **Purchase of medical devices maintained under external maintenance contract** – Procurement and MPCE must be involved to ensure compliance with this policy and there may be a standards compliance charge by MPCE for the management of these devices.

Protocol 2 - Trial, Loan or Lease of Medical Devices

2.1 When Trust departments or wards wish to trial, borrow or lease a medical device, it must be arranged with both Procurement and MPCE Departments. This is to ensure all safety, pre-use checks, user training and required indemnity and decontamination forms (PAQ/MDS2-RWT forms) are checked and that data sharing agreements are sought where applicable and that equipment labels are completed prior to the first use of the device. For all trial, loan or lease of medical devices, full information, instruction, training and supervision must be undertaken by the manufacturer or supplier prior to and during any trial or loan. Medical Device Trainers must be consulted and made aware so that any training can be captured and recorded. No trial, loan or lease will commence until all relevant documentation and checks are completed. Failure to comply with this procedure can adversely impact patient and, or staff safety and hence put the Trust at risk of litigation.

2.2 A summary of the process to be followed is shown in the flowchart 2 in Appendix 8.

2.3 MPCE must be informed when any trial, loan or lease equipment has been delivered so that an electrical safety check - BS EN 60601-x (if necessary) can be performed, following which an electrical safety sticker will be attached to the mains cable/device and an Equipment on Loan sticker attached to the equipment (Appendix 9).

2.4 If patient identifiable data (PID) is captured or stored on the trial, loan or lease device, this must be pseudonymised wherever possible. Seek clarification from the Clinical Information System team (MPCE). Where applicable, data sharing agreements must be completed by the company and sent back to MPCE and Information Governance.

2.5 Medical Devices that are on trial, loan or lease, as part of a tender evaluation, must have evaluation forms completed. These evaluation forms can either be from the manufacturers or suppliers or Trust departments/wards.

2.6 All documentation concerning the trial, loan or lease device must be retained by the Trust and must be forwarded to MPCE.

2.7 MPCE must be informed when a trial, loan or lease period is complete and prior to the equipment being returned to the manufacturer or supplier. This is to ensure that, wherever possible, all patient identifiable data (PID) has been backed up and securely and correctly deleted whilst still on Trust premises. Protocol 11 section 11.7.2 must be followed before the device leaves the Trust. The Trust has a duty to maintain the security and confidentiality of patient information in compliance with OP12 Information Security Policy and Protocol 11.

2.8 Clinical consumable trials will be conducted as per process and protocol detailed in Appendix 10.

2.9 Medical representatives from companies must conform to the above protocols and Protocol 10 in relation to trial, loan, lease or free purchase of medical devices, prior to acceptance by the Trust.

2.10 Any trials or loans that form part of a clinical research project must be discussed with the Research and Development Dept.

Protocol 3 - Acceptance of Medical Devices

3.1 When equipment has been purchased, it must undergo acceptance testing by MPCE (see the flowchart 3 in Appendix 8 and comply with Protocol 11 where applicable). Once testing is complete the equipment will be entered onto Trust f2 database, allocated an inventory number/GS1 label (Appendix 9) and a user training identification label (Appendix 11). Where applicable, an electrical safety test (BS EN 60601-x) will be carried out and a label attached to the mains cable or the device (Appendix 9). Any software configuration or default settings will be agreed with clinical users working closely with supplier application specialists and will be programmed into the device. All devices will be set to GMT. Exceptions will include networked devices or those clinically requiring adjustment to BST. MPCE will complete the acceptance check list in f2 database including the internal clock setting. End users will ensure they are aware of devices with agreed exceptions.

3.2 All equipment, except for large items, will be delivered to the relevant section of MPCE Department to allow all appropriate checks to be undertaken. Details of order number, ward and site must be forwarded to MPCE when the order has been raised; these details must be provided by Procurement or the Department Manager/Senior Sister/Senior Charge Nurse.

3.3 All acceptance and commissioning undertaken will follow the criteria stipulated in MHRA Managing Medical Devices.

3.4 **For devices on an external maintenance contract**, copy of the service contract from Procurement or Ward Manager must be sent to MPCE so it can be uploaded into f2 database, wards must retain locally and make available upon request copies of contract documents and service reports.

3.5 Staff training needs must be considered liaising with Medical Device Trainers where applicable and recorded accordingly before the devices are released to the department as per Protocol 4.

3.6 All new devices will be risk assessed (quarterly basis) against the criteria detailed in IPEM Report 95 and rated accordingly to determine if the device is place on a Planned Preventative Maintenance (PPM) schedule or risk managed with technical intervention taking place on breakdown only. In addition, at this meeting PID storage on devices will be assessed and identified.

Protocol 4 – Procedure for Medical Device Training

4.1 All medical devices will be risk categorised as high, medium and low risk. A label will be attached to each piece of equipment identifying its risk category (Appendix 11).

4.2 Each ward, area, and department can view a list of the devices used in their area on the Medical Device Competency Review Form which can be accessed via the electronic link on the intranet home page.

4.3 A baseline assessment of all new clinical staff will be undertaken with their manager or supervisor (taking into consideration any staff disabilities), using the Medical Device Competency Review which can be accessed via the electronic link on the intranet home page/Induction Packs. This identifies which medical devices the staff member uses (see flow chart in Appendix 12). Once completed, the form is saved to the Medical Device Training Team for recording on the Medical Device Training Database. A Training Needs Analysis (TNA) will be developed by Medical Device Training team for each area to determine training requirements for staff in that area. This will form the basis for appropriate training and updates.

Senior Sisters, Senior Charge Nurses, Departmental Managers and Clinical Supervisors are required to identify any training needs and notify Medical Device Trainers, who will coordinate and deliver training.

4.4 Medical Device Training Delivery

4.5 All Senior Sisters, Senior Charge Nurses, Department Managers and Clinical Supervisors have the responsibility to ensure that their staff have received training (staff disabilities are taken into consideration) on all medical devices relevant to their specific area and are competent and safe to use devices identified.

4.6 The training provided will be in the safe use of the device itself but **not** in the clinical interpretation of any result arising from the use of the devices.

4.7 Training on medical devices will be delivered by Medical Device Trainers and, or others as highlighted in sections 4.10-11-12-13. This may be delivered in groups or on an individual basis as deemed necessary; with relevant competency documents in the use of the device available as required. The frequency of update training is outlined in section 4.8-9 or sooner as determined by the trainers, and, or ward or departmental leads.

4.8 Training will be developed for all medical devices in all risk categories as follows:

- **For High-Risk Devices** e.g. all infusion devices.
  Training will be delivered and competency documents available to follow up with assessments in the clinical area by a nominated expert user or trainer (recommended). Updates and refresher training will be prompted for review on a 3 yearly basis via the TNA and retraining delivered as appropriate.

- **For Medium-Risk Devices** e.g. suction devices, ECG machines etc. Training will be delivered and competency documents available for assessment in the clinical area as required. Updates and refresher training will be prompted for review on a 6 yearly basis via the TNA and retraining delivered as appropriate.
- **For Low-Risk Devices,** e.g. tympanic thermometers, beds etc. Training is a one-off session with competency documents available for clinical assessment if required.

4.9 All devices in any category with identified training needs through incident management will be supported appropriately.

4.10 Training will be delivered by any of the following personnel:

- Manufacturers/Company Trainers,
- Medical Device Trainers,
- Specialist teams that have received manufacturers/company training, and
- Ward/Department Staff who have undertaken relevant link trainer sessions.

4.11 **Device Training Link Trainers.**

There will be nominated staff who will become Device Training Link Trainers. Link Trainers will receive appropriate training on the device from Company Trainers or Medical Device Trainers confirming competence. Link Trainers will be responsible for providing initial training and refresher training to any staff for whom there is a need to provide additional training.

4.12 Staff with a supervisory or managerial role within an area must take a lead role in supporting Link Trainers in the training of devices within their area of work and both must support junior staff in the use of devices.

4.13 Training (including update and refresher training) and any competency or observational based assessments can be undertaken either on the ward or in a simulated environment (i.e. training room).

4.14 Medical Device Training in Specialist Areas

4.15 Training with devices used in specialist areas where there is a concentration of specialist medical or clinical devices (i.e., ICCU, Theatres, NNU, Heart and Lung Centre, Obstetrics, Radiology, Renal Unit, Emergency Department, Endoscopy, and Therapy Services) will be delivered as outlined in 4.10-11-12-13 according to the frequency outlined in 4.8-9.

4.16 Usage of specialist devices outside of the specialist area will be kept to the absolute minimum. Where it is necessary for clinical reasons to use specialist devices in general areas, the devices will only be operated by a person who has received training in the safe use of that device.

4.17 Exemptions to the Medical Device Training Database

4.18 There are certain medical devices that the Medical Device Training Team do not deliver or coordinate training on and are not included on the Medical Device Training Database. These exemptions exist because there are specialist teams within the Trust to manage these devices, examples listed below (but not exhaustive):

- Cardiopulmonary resuscitation devices,
- Manual handling devices,
- Point of Care Testing (POCT) devices,
- Wound care therapy, and
- Clinical Applications (e.g., VitalPAC).

Exemption areas will be responsible for reporting device training compliance through relevant Governance channels and consideration for appropriate risk assessment.

4.19 MPCE Medical Devices Training Database

4.20 Staff will be entered onto the database by name, department and payroll number and in line with GDPR.

4.21 The Medical Device Training Database will record all completed Medical Device Competency Review Forms, all medical device training undertaken by staff, and any completed competencies. It will prompt the need for reassessments in line with the risk categorisation of the equipment as per 4.8-9.

4.22 All trainers and line managers will be responsible for collecting records on the training they deliver to or arrange for their staff and for ensuring that they are forwarded to Medical Device Trainers for entry onto the database. Exemptions under 4.18 will not apply.

4.23 A report of medical devices, and the training status for each member of staff required to use them will be developed for each ward, area and department and made available to the Senior Sisters, Senior Charge Nurses/ and Department Managers via the Training Needs Analysis reports (TNA) which they can view electronically via a secure log in and PIN specific to their areas. Senior Sisters, Senior Charge Nurses and Departmental Managers will be responsible for accessing training status of staff and actioning non-compliance,

4.24 The database will produce several levels of reports including Divisional Attainment and Service Group/Speciality Attainment Reports. These will be available to be provided to relevant Trust managers on request.

4.25 Maintenance and central administration of the training database will be carried out by designated staff within MPCE.

4.26 **Introduction of New Medical Devices**

4.27 **High-Risk Devices**: for new high-risk devices to be introduced to an area, the Senior Sister, Senior Charge Nurse/ or Department Manager will

ensure that at least 75% of identified users are trained in the safe use of the device prior to introduction.

4.28 **Medium- and Low-Risk Devices**: for new medium and low-risk devices, the Senior Sister, Senior Charge Nurse or Department Manager, in consultation with the training provider, will ensure that devices will only be used when users have received appropriate training on the safe use of the device. The number of users to receive training prior to the introduction of the new device is to be decided by the Senior Sister, Senior Charge Nurse or Departmental Manager after consulting with the Medical Device Trainers.

Protocol 5 - Transportation of Medical Devices (not limited to vehicular modes of transport)

5.0 All medical devices or equipment potentially contaminated with or containing infectious substances which are being carried for disinfection, cleaning, sterilization or repair must be carried in accordance with the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment 2009 and 2011 Amendment Regulations, and the European Agreement Concerning the International Carriage of Dangerous Goods by Road 2013. Medical devices that are free from contamination but either meet or contain items that meet the conditions of other classes of Dangerous Goods must also be transported in accordance with the Regulations and local procedures.

5.1 **Drivers will ensure that:**

- They are in accordance with the Trust's HS33 Driving for Work Policy,
- They fully understand and carry out their duties relating to the requirements of this procedure,
- They have a valid licence,
- Their vehicle is roadworthy.
- They have current MOT, road fund licence and have appropriate insurance cover which includes business usage.

5.2 Requirements when transporting medical devices

5.3 Health and safety of all personnel and manual handling procedures must be observed at all times.

5.4 Staff must make sure that the device has been decontaminated as per HS12 Decontamination of Medical Devices Policy and a Decontamination Label (Appendix 9) is attached.

5.5 If the device operates with fluids, make sure that they are emptied before transportation.

5.6 Always assess the load and the pathway before attempting the move.

5.7 Managers must ensure that risks associated with transporting devices are assessed and hazards are considered within the departmental risks. The Trust has a duty to maintain the security and confidentiality of patient information in compliance with OP12 Information Security Policy and Protocol 11 whilst transporting devices.

5.8 For transportation of medical devices, appropriate Personal Protective Equipment (PPE) must be used and safe transportation methods in compliance with local procedures including the use of relevant coloured polythene bags dependant on if it is clean or contaminated.

5.9 When carrying the device, staff must adhere to the manual handling procedures. If the device is heavy or awkward to handle, then assistance

must be sought, or a suitable number of staff must assist to handle the device. Where appropriate, undertake a suitable individual risk assessment.

5.10 The device must be safely loaded and secured to prevent excessive movement or risk of injury to the driver or passenger. If a number of devices are to be transported, then a secured transport box must be used.

5.11 When transporting devices on site, the route must be assessed to reduce the time a medical device is outside and for uneven surfaces. The device must also be assessed to determine if removal from a stand or trolley is appropriate. Devices must be decontaminated on arrival in the workshop or clinical area in accordance with HS 12 decontamination policy and manufacturer's guidelines.

5.12 Safety of individuals and /equipment

5.13 When leaving the vehicle unattended during working hours, all bags, devices and tools must be stored out of sight to reduce the risks of vandalism and theft (including theft or loss of PID). Where devices contain PID, ensure that Protocol 11 is adhered to.

5.14 Equipment must not be left in the vehicles overnight.

5.15 Mobile phones are NOT to be used whilst driving and no attempt must be made to operate them in any way.

5.16 In case of emergency due to breakdown, accident or inclement weather, staff must follow protocols as per – Driving for Work Policy, within this HS33 see Appendix 5, 6 and 7.

5.17 Staff are to refer to OP26 security policy and local lone working procedures where applicable.

Protocol 6 - Service, Maintenance, Repair and Decontamination of Medical Devices

6.0 A summary of the process to be followed is shown in the flowchart in (Appendix 13)

6.1 **Service and maintenance** – All maintenance and servicing of medical devices will be arranged through MPCE or by agreement the designated Senior Sister (for external maintenance contracts). This will also include arranging manufacturer or supplier servicing in conjunction with the device user. It is a requirement that devices are decontaminated with a status label attached (Appendix 9), all patient identifiable data must be backed up securely and correctly removed or deleted from the equipment prior to it being returned to the manufacturer or supplier for service or maintenance as per Protocol 11. Whenever possible, service and maintenance of devices carrying patient identifiable data must be carried out on Trust premises. Where, due to the condition or state of the device removal or deletion of patient identifiable data is not possible, transport of the device to manufacturer or supplier must be by an approved courier as per Attachment 4 of Trust policy OP12 Information Security Policy.

6.2 **External Contract Maintenance-**

The management of external contracts is the responsibility of the owner (the department that takes out the external maintenance contract on the medical device). The Ward Manager and Procurement must forward electronic copies of the contract and order details to MPCE for them to be uploaded onto f2 against the relevant medical devices. Compliance will be monitored through local Governance processes.

Manufacturer or supplier service sheets will be retained by MPCE, and the designated Senior Sister or Senior Charge Nurse (for external maintenance contracts) will forward all documentation to MPCE. All service and maintenance interventions will be recorded against the device on f2 unless stipulated and approved as an agreed exception. Compliance will be monitored through local Governance processes and audited and verified by the Trust's Medical Devices Group for compliance with regulations and standards. NOTE – all external third-party providers must remove old PPM labels and attached new in date PPM labels on completion of service interventions.

6.3 All devices known to MPCE will be risk assessed against the criteria detailed in Institute of Physics and Engineering in Medicine (IPEM Report 95) and rated accordingly to determine if the device is placed on a Planned Preventative Maintenance (PPM) schedule or risk managed with technical intervention taking place on breakdown only. All new and existing risks are assessed on a quarterly basis.

6.4 Only high and medium-risk rated devices will have a defined PPM schedule; these devices will be identified by a red or amber service label (Appendix 9) attached by the Clinical Technologist at the end of their intervention. (Excludes external maintenance contract devices.)

6.5 For devices on an external maintenance contract, a label 'External Maintenance Contract' will be attached to the device by MPCE staff, to make ward staff aware that the maintenance is carried out by the company and not MPCE.

6.6 **In-house maintenance and calibration** and planned servicing will be arranged and undertaken by MPCE in conjunction with the device user. It is the responsibility of the user, when notified, to make the device available within 5 working days to MPCE for service. When a pink 'Please Release Me' tag is identified on a medical device, a job must be raised on the Medical Devices Helpdesk as soon as the medical device becomes available from clinical use. After 10 working days, service request non-compliance reports will be generated by f2 and issued to the user for recording non-compliance in relation to CQC Fundamental Standards 12 and 15.

Maintenance and calibration will be carried out in line with manufactures' recommendations or locally agreed procedures. Planned preventative maintenance must include inspection of batteries, chargers, connector cables, plugs and sockets, and updating internal time settings i.e., GMT or BST dependant on the device. Users must clean or decontaminate the equipment in line with the Trust policy HS12, Decontamination of Medical Devices Policy, and attach a Decontamination /Equipment Status Label (Appendix 9) to all equipment requiring service or maintenance. On completion of servicing and maintenance, the device must be cleaned and, where applicable, an electrical safety test in accordance with BS EN 62353:2008 done. MPCE can provide the user if required with a copy of either a Service Report or a PPM Report via electronic communication, depending on the type of maintenance undertaken. MPCE will record all service/maintenance undertaken on f2 database. For transportation of medical devices appropriate Personal Protective Equipment (PPE) must be used and safe transportation methods in compliance with local procedures including use of relevant coloured polythene bag dependant on its clean or contaminated state.

6.7 Devices which cannot be located by the ward or MPCE, will follow the Clinical Engineering Local Procedure CESOP-11 15 Reporting Missing Medical Devices for devices classified as 'Missing in Service'. If the device contains PID then refer to Protocol 11.

6.8 **Repairs** – Defective and damaged equipment must be **removed from use immediately** and reported to the Medical Devices Helpdesk, (see user guide Appendix 14 on how to log faults). Users must affix a Decontamination/Equipment Status Label (Appendix 9) to all

defective/damaged equipment, tick the relevant decontamination method used to clean the equipment in line with the Trust policy HS12 Decontamination of Medical Devices Policy and give details of the defect.

6.9 **It is the responsibility of the user** to ensure that the faulty device is safely removed from use; this label is completed/attached to the device and reported on line via the Medical Devices Helpdesk (Appendix 14). Unless this label is completed and a Helpdesk call is correctly reported repair, service or maintenance will be delayed or not undertaken

6.10. **It is the responsibility of the user** to consider risk management and patient safety reporting in line with OP10 when applicable. Device inventory numbers reported through Datix must be referenced to assist with investigation and safeguarding

6.11 **It is the responsibility of the user** to declare the impact to service and the urgency of repair and to seek alternative equipment provision.

6.12 **For low-risk rated devices a Green label** on breakdown only will be attached by the Clinical Technologist (Appendix 9). (Excludes external maintenance contract devices)

6.13 Devices (particularly invasive type) that need to be sent back to the manufacturer for repair, inspection or service must have a Decontamination label (Appendix 9) completed by the users following the appropriate cleaning or decontamination of the equipment before these devices are sent away. The user must ensure that all devices with patient identifiable data are escalated to MPCE in accordance with Protocol 11 to ensure secure and correct removal or deletion from the equipment prior to being returned to the manufacturer or supplier.

6.14 The Trust has a duty to maintain the security and confidentiality of patient information in compliance with OP12 Information Security Policy. MPCE will be responsible for coordinating dispatch of these devices.

6.15 Devices intended for **single-use** only do not require decontamination, except where they are implicated in an adverse incident and may need to be sent to the manufacturer for investigation. In this situation, contact the manufacturer to find out the most appropriate method of decontamination.

6.16 MPCE reserves the right to return any medical device found to be contaminated back to the users for cleaning or decontamination before any repairs or maintenance is carried out.

6.17 Under normal circumstances, **pre-used parts** must not be used to repair a device. They may be acceptable in exceptional circumstances after a fully documented risk assessment, which must be attached in f2 for that device and approved by MPCE management. Consideration must be given to the part's length of time in service, age and repair or maintenance history. Pre-used parts may therefore increase the need for maintenance checks or reduce the overall life cycle of the device.

6.18 Any costs incurred, including labour, as a result of **user damage or missing parts will be charged back to the relevant department or ward**. All consumable purchases will be the responsibility of the user department. Please contact MPCE with reference to what is classed as a consumable item.

6.19 The Senior Sister or Senior Charge Nurse will be notified of any medical devices which are deemed beyond economical repair. This equipment will be condemned and in accordance with local MPCE SOP (CESOP-8). A PDF of the Work Request can be generated and issued to the clinical area on request.

6.20 Medical devices, once repaired along with clock settings as indicated on f2 (and tested in accordance with BS EN 62353:2008), will be cleaned prior to leaving the workshop and returned to the relevant department or /ward. A green service label for low risk rated devices will be attached by the Clinical Technologist, who will update f2 (Appendix 9).

Protocol 7 Reporting of Adverse Incidents – Medical Devices

7.0 Protocol Statement

7.1 This protocol is intended to rationalise the procedure for reporting and investigation of adverse incidents relating to medical devices. The policy must be implemented in conjunction with the MHRA Yellow Card Scheme and is vital in helping the MHRA monitor the safety of all healthcare products https://yellowcard.mhra.gov.uk/ It is supplementary to and must be used in conjunction with the Trust policy for Risk Management and Patient Safety Reporting OP10 Policy and Procedure 1 Incident Reporting and Monitoring.

7.2 To establish clear lines of responsibility for the implementation, control, reporting, audit and investigation of all adverse incidents pertaining to medical devices within a common framework for the Trust and Community based healthcare. This is governed within OP10 Policy and staff should refer to this policy for further instruction, detail, responsibilities and accountabilities.

7.3 Trust managers will ensure that a written procedure is in place in accordance with this policy, OP10 and the MHRA guidelines. The policy and procedures implemented are to contribute to the safety of patients, users and others.

7.4 Definitions Used

- **Liaison Officer -** Person within the Trust - Health, Safety and Improvement Co-ordinator (HSIC) - nominated with the necessary authority to take responsibility for dissemination and monitoring of the Central Alert System. HSIC must be informed when adverse incidents are reported by the Users to MHRA or other enforcing agencies along with any copies of the incidents submitted.
- **Adverse Incident:** An event which gives rise to, or has the potential to produce, unexpected or unwanted effects involving the safety of patients, users or other persons.
- **Medical Devices Safety Officer (MDSO):** One of the MDSO key roles is to promote the safe use of medical devices across their organisations and be the main point of reference for medical device safety. In summary the primary focus of this role is to:
  - be an active member of the National Medical Device Safety Network,
  - manage medical device incident reporting in the Trust, and improving the reporting and learning from them,
  - distribute device related safety alerts within the Trust, and
  - work as a member of the Medical Devices Group (a multi-professional group to support the safe use of medical devices in the Trust).

7.5 Detail

7.6 All incidents concerning medical devices that have led to any of the following must be reported.

- Death or serious injury,
- Medical or surgical intervention (including implant revision) or hospitalisation.
- Unreliable test results.
- Other minor safety or quality problems must also be reported as these can help demonstrate trends, such as highlighting inadequate manufacturing or supply systems.
- Incidents must be reported to MHRA via their Yellow Card scheme on their website within 24 hours by local areas and HSIC must be informed along with MPCE if medical equipment involved. There are currently no options to upload paper copies therefore an incident report must be completed online; a link to the MHRA webpage is included in Appendix 16. Appendix 17 indicates the correct notification route to follow depending on nature of faults produced/incidents.

7.7 All medical devices, including any packaging and, or consumables associated with the incident, **must** be quarantined and labelled '**Do Not Use – Under Investigation'**.

7.8 Trust departments and wards must ensure that action is taken as necessary to ensure safety of patients, users and others following any incident with a medical device. For example, this may include but is not be limited to: submission of Datix Incident Report (with direct reference to medical device inventory number), submission of MHRA Yellow Card, reporting to MPCE through Medical Devices Helpdesk, removal and quarantine of medical devices and consumables, data and, or event log downloads carried out by MPCE or third-party equipment maintenance provider, and reference to OP10.

7.9 The HSIC will initiate the appropriate method of investigation with the appropriate departments (Appendix 17) and, or enforcing authorities. In the absence of the HSIC the investigation and notification must be initiated by the Health and Safety Team (Appendix 17).

7.10 Trust departments and wards must ensure that procedures are in place for the policy to operate effectively and efficiently to demonstrate compliance with CQC Fundamental Standards 12 and 15.

7.11 Trust departments and /wards must ensure that a Trust Incident Report Form is completed and reported on the Datix system, the appropriate MHRA Adverse Incident Report Form is filled in, and, if required, a RIDDOR Report is submitted. Division must nominate a responsible officer to conduct a full investigation as per OP10 Policy.

7.12 The Trust's Health and Safety Team must inform the Receipts and Distribution Manager of any faulty consumables, and MHRA and Field

safety Notice (FSN) alerts who will liaise with the supplier and co-ordinate any returns.

7.13 No equipment, materials or substances must be brought back into service or use without the authority of the HSIC and, or MPCE, Estates and,or Procurement (Appendix 17).

7.14 Trust departments and wards must ensure that all staff, including bank, agency and contractors, at all levels are aware of their responsibilities, and of the procedures to be used with regard to the reporting of incidents, and isolation and retention of defective items.

7.15 Devices must only be decontaminated upon MHRA approval and prior to investigation; the Decontamination Label (Appendix 9) to be attached following approval. Under no circumstances can medical devices be sent through the post without prior decontamination. Devices that need to be dispatched must be sent via company employee or Trust approved courier service. Appropriate methods of decontamination must be identified through the manufacturers, HSIC or relevant department. Appropriate methods of decontaminations must be arranged through the Trust Sterilisation Services, MPCE or Estates (Appendix 18).

7.16 Medical devices that **contain patient identifiable data** that need to be sent to the manufacturer or supplier for investigation must follow step 11.7.6 of Protocol 11.

7.17 **MHRA Guidance – Return of Equipment**

- Equipment to be returned to the appropriate body (e.g., MHRA, manufacturer etc.) only upon receipt of MHRA instructions.
- Consumables - appropriate method of return to supplier to be arranged via Receipt and Distribution Manager.

Protocol 8 - Loaning Medical Devices to Patients

8.1 Wards and Departments that loan medical devices to patients for use outside of the Trust must maintain records of devices that are loaned and must include the following information.

- Patient's details – name, address, hospital number, NHS number, and telephone number (secured to comply with the data protection act).
- Device details – device, model number, serial number, inventory number, date loaned and date to be returned for service or replacement.
- Equipment requested from the Clinical Equipment Resource Library (CERL) must have a fully completed patient loan form prior to collection or despatch from the issuing ward or department. Any devices which cannot be recovered from the patient to whom the device was loaned will be off-costed to the issuing ward or department for replacement in CERL.

8.2 A summary of the process to be followed is shown in the flowchart 8 in Appendix 19. Records of loans must be completed on the Equipment Loaned to Patients Form booklet (Appendix 20), which consists of three copies: the white copy is to be given to the patient; the pink copy is to be sent to MPCE (in order that Loan Form Reference Number can be logged onto f2 and thus avoiding entry of Patient Identifiable Data) and the green copy is to be kept and filed by the ward.

8.3 It is the responsibility of the issuing ward or department to ensure that patients and, or their carers who borrow medical devices must be given sufficient information, instruction and training to allow safe use of the device.

8.4 Trust wards and departments loaning medical devices to patients must ensure they are given their contact details (i.e. phone, email etc.) in the case of emergency. It is the loaning ward or department's responsibility for ensuring these records are kept safe, passing relevant forms onto MPCE, to ensure that equipment is brought back for servicing when due. Equipment must be cleaned or decontaminated by the user and a decontamination label attached prior to sending the device for service to MPCE.

8.5 Wards and departments are responsible for procuring Patient Loan Forms from Clinical Illustration Department using reference MI_6290514_03.01.20_V_1

8.6 **Using Trust medical devices for purposes outside RWT** without prior agreement, contract and indemnity checks or disclaimers or approvals is strictly not permitted. In exceptional circumstances approval must be sought with senior management from Divisional, Legal and Governance departments. MPCE must be informed.

Protocol 9 – Replacement, Disposal & Condemnation of Medical Devices

9.0 The process to be followed is shown in the flowchart 9 in Appendix 19.

9.1 **Notification** – When a medical device has passed its life expectancy or there is unavailability of spare parts but is still usable, MPCE will issue the user with a Notification Form (Appendix 21), to inform them that they are required to initiate a replacement process if the device is to be replaced. This device can still be used until the stated date.

9.2 **Condemnation** – When a medical device is permanently removed from use, MPCE will issue the user with a Condemnation Service Report when requested, and physically remove the device following local Clinical Engineering Procedure - Removal of Equipment to Basement (CESOP-15). The Condemnation Certificate will be signed by a Senior Clinical Engineering Manager and countersigned by Head of Clinical Engineering or designated deputy when the device has been physically removed from service.

9.3 On request, a Condemnation Service Report will be issued for one of the following criteria:

a) worn out beyond economic repair,
b) damaged beyond economic repair,
c) unreliable through service history,
d) clinically or technically obsolete,
e) spare parts no longer available when a repair is required,
f) unable to be cleaned effectively prior to disinfection and, or sterilisation,
g) a device identified in accordance with Clinical Engineering Local Procedure - Reporting Missing Medical Devices (CESOP-11), or
h) Replacement of the medical device.

9.4 Once a Condemnation Service Report has been issued, under no circumstances must the device be brought back into clinical service.

9.5 **Disposal** – Disposal of medical devices can be arranged through MPCE in line with the guidance of MHRA Managing Medical Devices, however the cost of disposal must be met by the Division, Directorate, Department or RWT Primary Care. MPCE will ensure that all patient identifiable data is securely and correctly removed or deleted from the equipment prior to disposal as per Protocol 11. The Trust has a duty to maintain the security and confidentiality of patient information in compliance with OP12 Information Security policy and HS11 Protocol 11.

9.6 MPCE will remove all Trust identifiable labels attached to the medical devices before they are removed from Trust premises for disposal or sale through an approved auctioneer as per Clinical Engineering Local Procedure - Removal of Equipment to Basement (CESOP-15).

9.7 Devices will be either transferred to a Trust approved auctioneer or waste disposal agent in compliance with all national and legal requirements (WEEE regulations) for safe environmental disposal of the device(s).

9.8 If condemned devices are to be sold, transferred or donated to a charity or third party, the Form of Indemnity (Appendix 25) for sale of surplus equipment must be completed by the receiving party and sent back to MPCE so that it can uploaded to f2 database then sent to Procurement.

Protocol 10 - Company Representative Visits and Contacts (version 0.8)

Author - Senior Nurse Clinical Procurement

10.0 Protocol Statement

10.1 This Protocol sets out the key principles to be applied by Trust staff when dealing with company suppliers and the standards expected of company suppliers. This will ensure that the activity of suppliers within the Trust is appropriately co-ordinated and managed, and disruption to delivery of care and or service is minimised.

10.2 The Trust recognises that numerous suppliers visit the Trust to visit clinicians, nurses and other staff. This activity requires formal management and control to prevent inappropriate activity such as the introduction of more expensive or less effective products without appropriate approval and, or the trial of new products without collaboration with the Procurement Department and the Clinical Product Evaluation group members.

10.3 Definitions

10.4 **Trust Staff** - all employees, or other staff authorised to conduct activities on behalf of the Trust. In the context of this Protocol, this relates particularly (but not exclusively) to staff who have contact with company suppliers, including doctors, nurses, technicians, allied health professionals and heads of department.

10.5 **Company Suppliers** - any employee or agent of a supplier. This includes both existing and potential suppliers of products or services to the Trust.

10.6 **New / alternative products** - any product or service that is not currently being purchased by the department concerned. This applies to both new products on the market or products which have been on the market for some time but have not previously been used within the department concerned (but may already be used elsewhere within the Trust).

10.7 Throughout this Protocol reference to Medical Physics relates to any medical devices and any consumables required for that device, and reference to the Procurement Department relates to all other products and services.

10.8 Accountabilities

10.9 **The Director Sponsor** will be accountable for the revision of this Protocol which may be necessary from time to time.

10.10 **Directors** will be responsible for ensuring that this Protocol is fairly and consistently applied within their area of responsibility in the Trust.

10.11 **Divisional Managers and Clinical Directors** will be responsible for ensuring that this Protocol is communicated to all staff and applied to all relevant situations.

10.12 **Managers** will ensure that this Protocol is applied throughout their department(s) and that they have specified which members of their staff are authorised to engage with company suppliers.

10.13 **Employees** will be responsible for complying with the requirements of this Protocol and staff who engage with company suppliers are expected to make them aware of this Protocol.

10.14 Company Suppliers will abide by the ground-rules detailed in Appendix 22. This will be displayed in wards and departments and will be issued to suppliers electronically by the Procurement, and Medical Physics departments. Electronic copies will be available on the Trust intranet.

10.15 **Protocol Detail**

10.16 The aim of this Protocol is to effectively manage the activities of company suppliers when they visit the Trust to ensure consistency with Trust procurement strategy, to enforce compliance with infection prevention precautions (including proper hand hygiene on entry and exit to all clinical areas), and to maintain patient confidentiality.

10.17 Company suppliers may need to make non-promotional “service” visits to the Trust (e.g., to ensure that there are no problems with their product or to conduct staff training): in these cases, Trust staff are free to conduct such appointments, in accordance with the key principles detailed below, without prior reference to the Procurement or Medical Physics Departments.

10.18 All visits by company suppliers will be agreed in advance and will have an agreed specific purpose. When these visits involve the introduction of any new products, the visits must have been agreed in advance by the Trust Procurement Department or Medical Physics Department before any trial can commence.

10.19 Trust staff and company suppliers must follow these key principles for both personal visits to the Trust and, where relevant, telephone contacts: only see company suppliers if they have been authorised or delegated to do so by their line-manager.

10.20 Only see company suppliers who have made an appointment in advance.

10.21 Agree with the representative the specific purpose of the visit when making the appointment.

10.22 Where the purpose of the visit relates to the trial and, or introduction of a new product, this must be referred to the Procurement Department to agree the way forward prior to arranging or agreeing to the visit.

10.23 Prior to commencing any trials or implementations, on arrival at the Trust, company representatives must report to Procurement on the first day, and by appointment only.

10.24 Ensure that the representative’s attendance within the Department is registered in accordance with Department visitor policies.

10.25 Wherever possible conduct meetings with suppliers in private areas or offices and not in clinical areas and never in designated staff rest rooms where confidential patient discussions may take place.

10.26 Accept full responsibility for the conduct of the representative whilst he or she is within their department or clinical area.

10.27 Refer any discussions with suppliers relating to prices or other commercial arrangements to the Procurement or Medical Physics Department as appropriate depending on the product or service (see above).

10.28 Do not make any commitment to suppliers relating to the purchase of goods and services and ensure that such matters are referred to the Procurement or Medical Physics Departments.

10.29 Do not to agree any sponsorship arrangement (such as contributions towards training events) without the agreement of the Procurement or Medical Physics Departments.

10.30 Do not to sign any documentation without the prior consent of the Procurement or Medical Physics Departments.

10.31 Do not agree with any company suppliers for the trial or demonstration of any new product and ensure that such matters are referred to the Procurement or Medical Physics Departments so that the Trust's Trials Protocol can be applied.

10.32 Do not accept samples with a view to a clinical trial unless this has been agreed with the Procurement or Medical Physics Departments, and indemnity must be in place.

10.20 Where offers to support training and education have been made, please refer to NHS guidance on business conduct and to local guidance: https://royalwolverhampton.mydeclarations.co.uk/.

10.21 Acceptance by staff of commercial sponsorship for attendance at relevant conferences and courses is acceptable, but only where the employee seeks permission in advance and the employer is satisfied that acceptance will not compromise purchasing decisions in any way. All sponsorship must be declared.

10.22 Where pertinent actions are agreed, or information is exchanged (for example notification of pending price or product changes or market intelligence) during meetings with suppliers they must be noted by the member of staff and reported to the Procurement or Medical Physics Departments.

Protocol 11 - Medical Devices IT Security

11.0 If a device stores or communicates Personal Identifiable Data (PID), additional measures identified in the protocol are required to ensure the Trust can guarantee data security.

11.1 Procurement

11.1.1 **Device security risk assessment ("base- lining").** Prior to procurement and where practicable the manufacturer or supplier will provide the Trust with a completed Manufacturer's Disclosure Statement for Medical Device Security (MDS2-RWT). This is supplementary to the Pre-Acquisition Questionnaire (PAQ) required by Procurement. Manufacturers and suppliers must use the RWT form (Appendix 1).

11.1.2 **Data Access**. Where the manufacturer or supplier requires access to device data, they must complete a Remote Access form through the IT helpdesk ServiceIT. Additionally, a completed Data Protection Impact Assessment (DPIA) will be required by Information Governance. Procurement will need to check.

11.1.3 **Register of Devices**. Copies of completed non-disclosure agreements, information sharing or data processing agreements together with remote access applications will form part of the device documentation held on f2.

11.2 Trials and Loan of Devices

11.2.1 At the end of the trial or loan, devices containing patient identifiable data must wherever possible have the data backed up and securely and correctly removed or deleted whilst still on Trust premises. The following steps must be followed.

11.2.2 Archive of data. The owner of the device will ensure MPCE are notified of all devices containing PID which are removed from service. Any PID data, system logs and configuration data remaining on the device will be saved to safe storage by either IT dept or CIS team. For PID storage and retention policies OP84 – 11.64 together with data protection guidelines will be observed.

11.2.3 PID Removal method. CIS team will contact the device manufacturer / supplier to securely remove the patient data where practicable in accordance with MHRA recommendations on Trust or Community site.

11.2.4 Documentation. Once the data has been securely removed by the manufacturer, the CIS team will file all documentation/certificates received into f2 against the device.

11.2.5 The device must have a decontamination label (Appendix 9) completed by the users and attached to the equipment following the appropriate cleaning

or decontamination of the equipment. The device can now be arranged for collection to go back to the manufacturer.

11.2.5 Where, due to the condition or state of the device, removal or deletion of patient identifiable data is not possible on site, secure transport of the device to the manufacturer or supplier must be arranged with them. Documentation regards service sheets and any certification of data removal must be saved in f2 against this device.

11.3 Delivery and Commissioning

11.3.1 Securing removable media. During commissioning, removable media (CD, DVD, BluRay, WORM or tape), not explicitly required will be disabled.

11.3.2 Controlling open data ports. Un-used open data ports (USB, Firewire, SD or Compact Flash cards) will be secured against misuse. Port blockers shall be used for non-utilised USB ports and covers to retain data cards. The integrity of the device must not be compromised.

11.3.4 Network configuration. The network type and configuration will be set during commissioning. Where possible steps shall be taken to ensure settings cannot be modified either accidentally or deliberately.

11.3.5 Remote diagnostics / monitoring. Where the manufacturer or supplier provides remote support or diagnostics, verify MPCE has received a completed PSDPA and forwarded a copy to network services for appropriate firewall configuration and authorisation.

11.3.6 User security. Where the device supports user access control or role-based security, user groups will be created and verified, using lowest rights necessary for operation.

11.3.7 User password settings. Where the device offers rules for password length, complexity, expiration and lock-out for incorrect passwords, they must be enabled.

11.3.8 User auditing. Where the device supports user logging and audit, it will be enabled.

11.4 Anti-virus.

11.4.1 Vendor supplied Anti-virus. Where the device is supplied with the approved anti-virus software the latest updates will be applied. Where automatic pattern file update is supported, this feature will be enabled.

11.4.2 Trust anti-virus. Where agreeable by the manufacturer or supplier, the Trust Cyber Security team will install anti-virus software using the manufacturer or supplier recommended configuration, e.g., real-time scanning, excluded file types and directories together with domain and non-domain exclusions. Any exceptions will be added to the Exception List maintained by MPCE and shared with IT.

11.4.3 No anti-virus supported. Where the manufacturer or supplier does not allow or recommend any anti-virus products, they must provide a risk management statement. Any exceptions will be added to the Exception List maintained by MPCE and shared with IT.

11.5 Data Encryption

11.5.1 Hard disk encryption. The manufacturer or supplier shall provide recommendations about hard disk encryption products supported on the device.

11.5.2 Removable media encryption. The manufacturer or supplier shall provide recommendations about media (e.g. USB, CD / DVD, BluRay, SD card etc.) encryption products supported by the device.

If either or both are types of encryption are not supported, the manufacturer or supplier must provide a risk management or mitigation statement. Any exceptions will be added to the Exception List maintained by MPCE and shared with IT.

11.5.3 Device configuration. All device security configurations, including exceptions and mitigations above, will be recorded in the device record held by f2.

11.6 Normal Operational

11.6.1 User training. Users must be made aware of the device's data security features and how to comply with Trust IT Security policy OP12 including highlighting the importance of reporting any exceptions or errors during device operation to MPCE.

11.6.2 Data storage requirements. User training must include information about backup and archive and the frequency with which this is required.

11.7 Service, Maintenance and Repair

11.7.1 The maintenance provider must do the following.

- Anti-virus update. Where the device has anti-virus software, routine maintenance will include a check of the anti-virus pattern file. Where necessary the latest pattern files will be installed.
- Log inspection. Any security related logs for the device will be checked for warnings of unusual activity and failed logins. If necessary. escalate through step 11.9 – Product upgrades.

11.7.2 Devices requiring return to the manufacturer or supplier. Wherever possible service, maintenance or repair of devices containing patient identifiable data must be carried out on Trust premises. A device that is required to be returned to the manufacturer or supplier for service, maintenance or repair

must have all patient identifiable data backed up and securely and correctly removed or deleted from the equipment before it is sent away. The following steps must be followed.

11.7.3 Archive of data. The owner of the device will ensure MPCE are notified of all devices containing Patient Identifiable Data (PID) which are removed from service. Any PID data, system logs and configuration data remaining on the device will be saved to safe storage by either IT dept or Clinical Information Service (CIS) team. For PID storage and retention policies Corporate Records Management Procedure (PRO02) together with data protection guidelines will be observed.

11.7.4 PID Removal method. CIS team will contact the device manufacturer or supplier to assess the most suitable method of securely removing the patient data in accordance with MHRA recommendations, one of the following will be carried out:

- Vendor or third-party to securely remove data, including. Certification, or.
- CIS team to securely remove or destroy data in line with manufacturer's recommendation.

11.7.5 Documentation. Once the data has been securely removed by the manufacturer, CIS team or approved third-party, the CIS team will record all documentation and certificates received, into f2. The device must have a decontamination label (Appendix 9) completed by the users and attached to the equipment following the appropriate cleaning or decontamination of the equipment before these devices are sent away. The device can now be securely sent for service, maintenance or repair to the manufacturer by MPCE staff via company employee or Trust approved courier service.

11.7.6 Where due to the condition or state or the device is involved in an adverse incident investigation (MHRA reportable) the removal or deletion of patient identifiable data is not possible on site, transport of the device (following a clean or /decontamination label attached) back to the manufacturer or supplier must be via company employee or Trust approved courier service as per section 4.8 of Trust policy OP13 Information Governance policy. The manufacturer or supplier must complete a Purpose Specific Information Sharing Agreement (PSISA) and return a copy to the Information Governance lead. Manufacturer or supplier service sheets will be retained by MPCE and the designated Ward Manager (for external maintenance contracts) will forward all documentation to MPCE. All service and maintenance interventions will be recorded against the device on f2.

11.8 Device Alerts / Safety Notices

11.8.1 MHRA. Cyber security concerns and issues raised by MHRA will be reviewed and acted upon in line with HS11 Protocol 7. Resultant

manufacturers field safety notices, or similar, will be acted upon as quickly as reasonably possible. All actions will be logged on f2.

11.8.2 CareCERT. Routine weekly and more urgent CareCERT bulletins (from NHS Information) will be monitored, and recommended action taken to minimise or eliminate data security risks. Where a device cannot be immediately removed from service the risk of restricted operation will be assessed and monitored until a satisfactory resolution found.

11.8.3 Operating System (OS) patching. Where the manufacturer or supplier permits user OS patching the monthly certified Trust updates are to be applied as soon as possible.

11.9 Product upgrades.

11.9.1 The manufacturer or supplier will provide release notes for software updates and a plan for roll back in the event of problems or unintended consequences. Devices will be tested prior to a wholesale application of updates. Where necessary the intended updates will be incorporated into the Trust IT Change Advisory Group requests for change.

11.10 Incident detection

11.10.1 Monitoring logs and error reports. If monitoring of device security logs identifies unexpected security concerns they will be escalated and reported to the manufacturer or supplier for further advice. If severe, the device will be removed from service pending a response. Incidents will be reported as per HS11 Protocol 7.

11.10.2 Anti-virus logs. Locally installed and monitored antivirus logs will be monitored frequently by MPCE. Trust installed antivirus software is monitored by IT security team. Any anomalies will be shared between the vendor, MPCE and IT security for discussion regarding appropriate action.

11.10.3 Network logs. Where concerns are raised over network activity MPCE will liaise with the Trust network team to monitor and log all traffic.

11.11 Incident Response

11.11.1 Action. If any Trust staff, patients or visitors raise concerns about device security, they must be investigated promptly: if the problem is confirmed, the device will be removed from service; if not possible, the service will be restricted, and the risk will be assessed and monitored until removal possible. The incident will be reported as per HS11 Protocol 7.

11.11.2 Remediation. In the event of a confirmed security issue the manufacturer or supplier must be contacted as soon as possible for their advice and recommendations.

11.11.3 Reporting. All confirmed security issues will be handled in accordance with policy HS11 Protocol 7.

11.12 Data Loss or Device Not Found

11.12.1 Data loss. Where there are concerns PID data has been extracted from the device as part of an attack, this must be reported to MPCE and Information Governance using their reporting form.

11.12.2 Device missing. Should a device holding or communicating PID be lost or not found, the potential data loss must be reported immediately to MPCE and Information Governance using their reporting form.

11.13 End of life

11.13.1 Archive of data. The owner of the device will ensure MPCE are notified of all devices containing PID which are removed from service. Any PID data, system logs and configuration data remaining on the device will be saved to safe storage by either IT dept or CIS team. For PID storage and retention Corporate Records Management Procedure (PRO02) together with data protection guidelines will be observed.

11.13.2 Device reusability. CIS team to seek advice from the device manufacturer or supplier to assess the suitability for re-sale.

11.13.3 PID Removal method. CIS team will contact the device manufacturer or supplier to assess the most suitable method of securely removing the patient data in accordance with OP12 – 4.14, one of the following will be carried out:

- Vendor or third-party to remove or destroy data including Certification, or.
- Trust IT will remove or destroy as per OP12 – 4.14.

11.13.4 Documentation. Once the data has been securely removed by the manufacturer or approved third party, the CIS team record all documentation and certificates received in f2. Where hard drives or storage media are sent for destruction, all storage device serial numbers will be recorded by CIS team for audit purposes.

11.13.5 Disposal or re-sale. MPCE will follow Clinical Engineering Local Procedure - Removal of Equipment to Basement (CESOP-15) for the device's secure disposal or re-sale.

Protocol 12 - Procedure to cover loan of medical devices into the Trust from other organisations

12.0 Procedure Statement (Purpose/Objectives of the Procedure)

12.1 This procedure is intended to manage medical device loans where no option exists other than loan of device(s). The loans within this procedure are outside of the Master Indemnity Agreement (MIA) process, i.e., from one NHS organisation to another NHS organisation and herein after will be referred to as 'loaner'.

12.2 **Accountabilities**

12.3 The Clinical Lead for the service that borrows the equipment – To take responsibility for determining the requirement to borrow, acceptance and continued use of a medical device through a documented risk assessment process. The risk assessment must also include reference to end-user training requirements.

12.4 The loaner – To take responsibility for decontamination of the medical device prior to transportation to the Trust and for organising safe transportation of the device to Trust. Upon request from the Trust, to provide documentation to demonstrate the device is safe, appropriately maintained and to support user training.

12.5 The loanee – Will take ownership and be responsible for the loaned medical device used in their areas during the entirety of loan period. The loanee will ensure full and timely communication with MPCE to ensure adherence with procedure.

12.6 Medical Physics and Clinical Engineering – To liaise with and support the end-user as required and communicate with Trust's Medical Device Trainers.

12.7 End User – Have a responsibility to ensure that they follow procedures and are competent to use equipment and work within sphere of professional practice.

12.8 Procedure Detail/Actions

12.9 A loan medical device may come in at any time of day or night; to reflect this, the following procedure will deal with loans during and outside of core Clinical Engineering hours.

12.10 **Transport of device**- The responsibility of the loaner, i.e., organisation loaning equipment to the Trust.

12.11 **Consumables** – The responsibility of the loanee to check the availability of a minimum of 7-day supply of consumables.

12.12 Delivery to the Trust - Delivery is to be to the point of use. The end-user is to inform MPCE of loan devices by raising a non-device call on Medical Devices Helpdesk. MPCE will be responsible for carrying out an electrical

safety test and attaching a 'loan' label to the device. MPCE will inform the Medical Device Trainers that the device is on site.

12.13 **After delivery, device has arrived on site** - Visual checks are to be carried out by the user and recorded as part of a documented risk assessment to support the clinical use of the device(s). The loanee, i.e., end-user, will check decontamination status. If the loanee decides that the device does not appear safe to use or is not functioning correctly, then a replacement must be requested from the loaner and the steps detailed under Protocol 12 followed. The end-user will document and record any handover training received and to inform Medical Device Trainers. Any training requirements on the device must be identified and undertaken prior to use. The loanee will liaise with MPCE to check to see if the Trust has a suitable device available and if so, the loaned device can be returned to loaner as soon as practicable.

12.14 **Ongoing support -** The loanee is responsible for the management of consumable supplies. The loanee must inform MPCE if the device develops a fault or goes past its Planned Preventative Maintenance (PPM) service due date. MPCE will inform the loaner that reactive maintenance or PPM is required.

12.15 **Whilst continuing in use** - Medical Device Trainers will review training support. The loanee to manage supply of consumables.

12.16 **End of loan -** The loanee must decontaminate the device as per the manufacturer's recommendations and label it accordingly. The loanee must also inform MPCE of the end of loan through a job raised on the Medical Devices Helpdesk. MPCE to ensure that any patient identifiable data is securely deleted as per Protocol 11 and OP12 before the device is taken off site. The loanee must arrange safe transport of the device back to the loaner, i.e. in accordance with the Trust's policy on transport of medical devices and HS11 Protocol 5. The loanee must inform the loaner that the device is being returned.

12.17 **Using \ loaning Trust medical devices for purposes outside RWT** without prior agreement or contract and indemnity checks or disclaimers or approvals is not permitted. In exceptional circumstances approval must be sought with senior management from Divisional, Legal and Governance departments. MPCE to have oversight and final approval of any such loans. A Loaning Medical Devices to other Trusts – Agreement Form (Appendix 15) must be completed and sent to MPCE for approval.

Protocol 13 – Decontamination of General Medical Devices

13.0 **Protocol Statement**

13.1 This protocol **excludes** medical devices and surgical instruments which are required to be processed by sterile services provider or where a SOP or Protocol exists for a specific make/model of medical device.

13.2 This protocol is intended to:

13.2.1 To improve the cleanliness and decontamination of near patient medical devices;

13.2.2 To help reduce the risk of healthcare associated infection (HCAI) cross contamination;

13.2.3 To embed the importance of cleaning into the everyday work routine of the ward;

13.2.4 To improve patient confidence.

13.3 Medical devices which cannot be cleaned must be risk assessed on a need to use basis, or alternatively designated for single patient use. Local decontamination guidance from the Trust's Infection Prevention Team and Medical Physics and Clinical Engineering departments will be sought.

13.4 Single use items **must not** be re used.

13.5 All staff must be aware of their roles and responsibilities with regard to cleaning and decontamination.

13.6 Ward and department staff undertaking the cleaning of medical devices must be trained in the correct cleaning and decontamination procedures as determined by the Trust.

13.7 Similarly, all staff undertaking cleaning duties must have access to the appropriate cleaning materials and products at all times.

13.8 A clutter free environment will provide the foundation for delivering high quality care in a clean, safe place.

13.9 When new medical devices are considered for purchase, the manufacture's advice on cleaning must be sought, and training, if necessary, must precede use. Careful consideration must be given to the consequences of the purchase of any medical device that is not capable of being disinfected by chlorine or other sporicidal agents.

13.10 Clear identification of cleaned items and a visibly clean environment will provide reassurance to patients that they are receiving safe care in a clean environment.

13.11 Trusts must ensure that appropriate designated areas and cleaning products are available for the cleaning of medical devices and storage to take place.

13.12 **Cleaning medical devices after use by or on a patient**

Location of cleaning activity	Patient medical devices located in isolation areas must be cleaned prior to its removal from that area.
Correct hand hygiene	Decontaminate hands before and after cleaning medical devices.
Personal protective equipment	Correct personal protective equipment (PPE) (gloves and apron as necessary) is worn. PPE is disposed of correctly (in line with local policy) after use and hand decontamination completed.
Cleaning and decontamination	Cleaning and decontamination are carried out immediately following use of the medical device by the patient or staff member. - Medical device is cleaned with a natural detergent followed by a 1,000 ppm chlorine containing disinfectant solution or other sporicidal product, using a disposable cloth or equivalent wipe (products containing both detergent and chlorine can also be used). 5,000ppm routine cleaning of the room and fittings when treating a patient identified with Carbapenemase-Producing Enterobacterales (CPE), 10,000 ppm decontamination of blood and body fluids spills. Refer to IP 19 Blood & Bodily Fluid Spillage Management for additional. Systematic cleaning of items (top down) is carried out in line with local policy if available; if the local policy is not available, follow manufactures guidance.
Storage	Cleaned and decontaminated medical devices are stored separately from used items and away from areas where cleaning is taking place, to reduce risk of recontamination.
Documentation	Cleaning is documented by the person who cleaned the item and the item is labelled as clean.

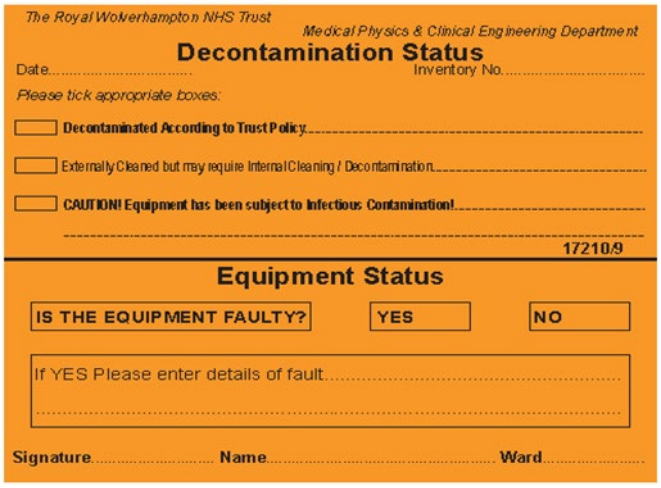
13.13 Decontamination Label

13.13.1 This label (Appendix 9) is shown below; it must be completed by the ward or department staff before any medical device is released for maintenance or disposal.

13.13.2 If the label is NOT attached to the medical device that is to be collected, repaired or serviced, then it will not be collected. Any contamination incidents will have Incidents logged against the Ward/Department concerned.

13.13.3 Similarly, no member of staff will accept any medical device for repair, or from repair, that does not have a Decontamination Status label, correctly completed and attached to it.

13.13.4 The label is available to order using the following details; Orange Decontamination/Equipment Status label from Fine Cut Group Ltd – Part number 17210/9, Quote – 29055/KP.


The Royal Wolverhampton NHS Trust

Medical Physics & Clinical Engineering Department

Decontamination Status

Date..... Inventory No.....

Please tick appropriate boxes:

☐ **Decontaminated According to Trust Policy**

☐ Externally Cleaned but may require Internal Cleaning / Decontamination

☐ **CAUTION! Equipment has been subject to Infectious Contamination!**

17210/9

Equipment Status

IS THE EQUIPMENT FAULTY?	YES	NO

If YES Please enter details of fault.....

.....

Signature..... **Name**..... **Ward**.....

The Royal Wolverhampton NHS
NHS Trust

V 4

Manufacturers Disclosure Statement for Medical Device Security

Device Information

Device Category *Enter category.*	*Manufacturer* *Enter manufacturer.*	*Document Number* *Enter document number.*	*Release date* *Enter release date*
Device Model *Enter model.*	*Software Revision* *Enter software revision.*		*Software Release Date* *Enter date.*
Vendor Contact info *Enter vendor information.*	*Company Name* *Enter name.* *Representative Name / Position* *Representative.*	*Manufacturer Contact Information* *Manufacturer information.*	
Intended use of device in network connected environment: *Intended use.*			

Please select response from drop down list. Add any notes at end of section, reference in column.

Management of Personal Data

			Y, N, N/A	Note No.
A	Can the device and or application display, transmit or maintain Personal Identifiable Data (PID)		-	-
B	Types of Personal Data			
	B.1	Demographic (name, address, phone number)	-	-
	B.2	Medical Record (hospital number or NHS number)	-	-
	B.3	Diagnostic data (image, test results)	-	-
	B.4	Free text entered by user	-	-
	B.5	Biometric data	-	-
C	Maintaining Personal Identifiable Data			
	C.1	Maintain PID in temporary volatile memory (cleared at power off)	-	-
	C.2	Store PID persistently on local media	-	-
	C.3	Import / export PID with other systems	-	-
D	Mechanisms for transmitting Personal Identifiable Data			
	D.1	Display PID (eg. Video Display)	-	-
	D.2	Generate hard copy reports or images containing PID	-	-
	D.3	Retrieve or record PID to or from removable media containing PID	-	-
	D.4	Transmit / receive or import / export PID via direct cable connection	-	-
	D.5	Transmit / receive or import / export PID via wired network connection	-	-
	D.6	Transmit / receive or import / export PID via integrated wireless connection	-	-
	D.7	Import PID via scanning	-	-
	D.8	Other	-	-

Notes / Comments:
Click here to enter text.

Security Capabilities						
					Y, N, N/A	Note No.
1	Auto logoff					
	1.1	Can the device and or application be configured for auto log off / password screen lock			-	-
		1.1.1	Is the inactivity time user or administrator configurable		-	-
		1.1.2	Can auto logoff / screen lock be invoked manually		-	-
Notes / Comments: **Click here to enter text.**						
2	Audit Controls					
	2.1	Can the device and or application create an audit log			-	-
	2.2	Indicate which of the following are logged				
		2.2.1	Login / logout		-	-
		2.2.2	Display / presentation of data		-	-
		2.2.3	Creation / modification / deletion of data		-	-
		2.2.4	Import / export of data from removable media		-	-
		2.2.5	Receipt / transmission of data from / to external connection		-	-
			2.2.5.1	Remote service activity	-	-
		2.2.6	Other events		-	-
	2.3	Indicate how log entries identified				
		2.3.1	User ID		-	-
		2.3.2	Date / Time		-	-
Notes / Comments: **Click here to enter text.**						
3	Can the device and or application determine authorisation of users					
	3.1	Can the Device and or application prevent access to unauthorised users through login mechanism			-	-
	3.2	Can users be assigned different privilege levels – role based			-	-
	3.3	Can the owner / operator be assigned unrestricted (root) permissions			-	-
Notes / Comments: **Click here to enter text.**						
4	Configuration of Security Features					
	4.1	Can the device and or application owner / operator reconfigure security capabilities			-	-
Notes / Comments: **Click here to enter text.**						
5	Cyber Security Upgrades					
	5.1	Can O/S and device and or application security patches be applied as available			-	-
		5.1.1	Can security patches be installed remotely		-	-
Notes / Comments: **Click here to enter text.**						
6	Anonymisation / Pseudonymisation					
	6.1	Does the device and or application provide capabilities to de-identify personal data			-	-
Notes / Comments: **Click here to enter text.**						
7	Backup and Data Recovery					

	7.1	Does the device and or application have an integral data backup capability (backup on remote storage or removable media)		-	-
Notes / Comments: **Click here to enter text.**					
8	Emergency Access				
	8.1	Does the device and or application incorporate an emergency access feature		-	-
Notes / Comments: **Click here to enter text.**					
9	Data integrity and Authenticity				
	9.1	Does the device and or application ensure integrity of stored data with implicit or explicit error detection / correction technology		-	-
Notes / Comments: **Click here to enter text.**					
10	Malware/ Virus Protection / Detection				
	10.1	Does the device and or application support the use of anti-virus software or other anti-malware mechanism		-	-
		10.1.1	Can the user configure anti-malware settings	-	-
		10.1.2	Notification of malware / virus detected in user interface	-	-
		10.1.3	Can only manufacturer repair when malware detected	-	-
	10.2	Can owner / operator update virus definitions on manufacturer installed anti-virus software		-	-
	10.3*	Can owner install own anti-virus software		-	-
		10.3.1*	Which anti-virus / end point protection products supported	-	-
		10.3.2*	Is real-time / on access scanning supported	-	-
		10.3.3*	Should file types or directories be excluded from scanning	-	-
Notes / Comments: **Click here to enter text.**					
11	Node authentication - DICOM				
	11.1	Does the device and or application provide / support node authentication for data transfer		-	-
Notes / Comments: **Click here to enter text.**					
12	Person Authentication				
	12.1	Does the device and or application support user / operator username and password		-	-
		12.1.1	Does the device and or application support unique ID's and passwords for multiple users	-	-
	12.2	Can the device and or application be configured to authenticate through external service (e.g. AD, LDAP etc.)		-	-
	12.3	Can the device and or application be configured to lock out users after failed attempts		-	-
	12.4	Can default password be reconfigured at installation		-	-
	12.5	Are any shared user ID's used by the system		-	-
	12.6	Can the device and or application be configured to enforce password complexity rules		-	-
	12.7	Can the device and or application be configured for password expiration		-	-
Notes / Comments: **Click here to enter text.**					
13	Physical Security				

	13.1	Are all the device and or application components holding PID physically secure		-	-
Notes / Comments: **Click here to enter text.**					
14	Future plans for 3rd Party Components				
	14.1	In the notes list the provided or required operating systems and version		-	-
	14.2	Is a list of other third party applications provided by the manufacturer available		-	-
Notes / Comments: **Click here to enter text.**					
15	System and Application Hardening				
	15.1	Does the device employ any hardening measures		-	-
	15.2	Does the device employ any mechanism to ensure program / update is manufacturers authorised version		-	-
	15.3	Does the device have external communication capabilities (modem)		-	-
	15.4	Does the file system implement file level access control		-	-
	15.5	Are all accounts not intended for use disabled or deleted		-	-
	15.6	Are all shared resources not required for intended use disabled / deleted		-	-
	15.7	Are all communication ports not required for use closed / disabled		-	-
	15.8	Are all services not required for use deleted / disabled		-	-
	15.9	Are all applications not required for use deleted / disabled		-	-
	15.10	Can the device boot from uncontrolled removable media		-	-
	15.11	Can software or hardware not authorised by manufactured be installed without the use of tools		-	-
	15.12*	Does the device and or application support local hard disk encryption		-	-
	15.13*	Does the device and or application support removable media encryption		-	-
	15.14*	Can the device become a member of owners security domain or the application support active directory		-	-
		15.14.1*	Are domain policies supported	-	-
		15.14.2*	Does the device and or application have policy requirements / exceptions	-	-
Notes / Comments: **Click here to enter text.**					
16	Security Guidance				
	16.1	Are security related features documented for device and or application user		-	-
	16.2	Are instructions available for device / media data cleansing / removal		-	-
Notes / Comments: **Click here to enter text.**					
17	PID Data Confidentiality				
	17.1	Can the device and or application encrypt data at rest		-	-
		17.1.1*	Can the owner install disk encryption software	-	-
		17.1.2*	Can the owner install media encryption software	-	-
Notes / Comments: **Click here to enter text.**					
18	Transmission Confidentiality				
	18.1	Can PID be transmitted over point to point links		-	-
	18.2	Is PID encrypted prior to transmission via network or removable media, please provide details		-	-

	18.3	Is PID data transfer restricted to fixed list of network connections		-	-
Notes / Comments: **Click here to enter text.**					
19	Transmission Integrity				
	19.1	Support mechanism to ensure data not modified in transmission		-	-
Notes / Comments: **Click here to enter text.**					
20	Other Security Considerations / requirements				
	20.1	Can the device and or application be serviced remotely		-	-
	20.2	Can the device and or application restrict remote access from / to specified addresses		-	-
		20.1.1	Can the device and or application be configured to require user to accept or initiate remote access	-	-
		20.1.2*	Has the vendor completed data processing agreement	-	-
	20.3*	Will the vendor process device data for Trust		-	-
		20.3.1*	Has the vendor completed an information agreement	-	-
Notes / Comments: **Click here to enter text.**					
21*	UK / EU Regulation				
	21.1*	Does the device and or application support GDPR requirements		-	-
		21.1.2*	Are additional measures needed (e.g. privacy shield)	-	-
	21.2*	Does the device s and or application upport Caldicott 2.0 recommendations		-	-
	21.3*	Is all diagnostic / performance date held in EU		-	-
		21.3.1*	If not is there a safe harbour agreement in place	-	-
	21.4*	Vendor accreditation			
		21.4.1*	Has the vendor achieved HSCIC IG Toolkit level 2 or NHS Digital Data Security & Protection Toolkit (DSP) equivalent	-	-
		21.4.2*	Is the vendor ISO 27001 accredited	-	-
	21.5*	Has the vendor an existing Trust Non-Disclosure agreement		-	-
Notes / Comments: **Click here to enter text.**					
Items marked with * are additional to NH 1-2013					

1) PURCHASE / REPLACMENTOF MEDICAL DEVICES

Consult Procurement Dept & MPCE
To ensure correct process is followed and relevant documentation is completed i.e. Indemnity/Specifications/Evaluations/PAQ/ Training needs assessed/recorded

<£5K inc. Vat
Request for Purchase of Medical Equip <£5K Form (HS11 form). Ward to complete Part A and email to MPCE)

MPCE (Part B) – compliance/costs for – compliance with standards, maintenance, training etc. On approval Form sent back to Ward.

Ward raises Requisition and email Request Form to Procurement

Procurement raise Order and completes (Part C), a copy of the Order must be emailed rwh-tr.clinicalengineering@nhs.net

£5K to £250K inc. Vat
Outline Business Case form. Proc. Dept. - cost of equip /consumables/ services/ additional energy costs i.e. electrical /medical gas. MPCE – maintenance assessment/costs

Divisional Management Core Group
I
Trust Equipment Group
I
Capital Review Group

£5K and £250K in Vat
Replacement of capital medical devices, a Replacement of existing capital equipment form

Divisional Management Core Group
I
Trust Equipment Group
I
Capital Review Group

£250K to £500K inc. Vat
Full Business Case form. Proc. Dept. - cost of equip/consumables/ services/additional energy costs i.e. electrical /medical gas. MPCE – maintenance assessment/costs

Divisional Management Core Group
I
Trust Equipment Group
I
Capital Review Group
I
Contracting & Commissioning Forum
I
Trust Management Committee

>£500K inc. Vat
Full Business Case form. Proc. Dept. - cost of equip/consumables/ services/ additional energy costs i.e. electrical /medical gas. MPCE – maintenance assessment/costs

Divisional Management Core Group
I
Trust Equipment Group
I
Capital Review Group
I
Contracting & Commissioning Forum
I
Trust Management Committee
I
Trust Board Public

Charitable Fund purchases
Follow same process depending on value of equipment. Plus Charitable Funds Committee

Lease/Rental/ Consumable deals
Follow same process depending on value of equipment but exclude CRG.

Ref No:
(MPCE will issue above number after Part A completed)

The Royal Wolverhampton NHS Trust

HS11 Form - Appendix 3

REQUEST FOR PURCHASE OF REVENUE MEDICAL EQUIPMENT <£5K inc Vat

Devices ≥£5K inc vat complete an OBC form and submit to Trust Equipment Group

Part A – WARD TO COMPLETE

Ward/Dept: Division:

Ward Manager: Tele: Date:

Description: Model:

Supplier: Quantity:

Cost:
(inc Accessories, excl Vat)

Source of funding: Ward Revenue ☐ Charitable Funds/TF ☐ Rental/Lease ☐ Consumable deal ☐ Other ☐

Replacement Equipment ☐ ·····➔ Inventory No of old device:
Condemnation/Notification No:

After completing above section, no further details required. Save as Word Document and email to: rwh-tr.clinicalengineering@nhs.net

OR

New Type/Additional Equipment ☐ *By ticking the box you are agreeing to the relevant terms below, then email form to:* rwh-tr.clinicalengineering@nhs.net

- If equipment is new to the Trust, the Supplier must complete the Decontamination Considerations Prior to Purchase form. *(HS12 Attachment 7)*
- If equipment is new to the Trust and maintenance is to be carried out by MPCE any technical training costs must be funded by the Ward. *(Procurement Dept will endeavour to get this foc)*[1]
- Maintenance costs – for budgetary purposes normally [redacted] of list price must be identified on re-occurring annual basis.
- For equipment on external maintenance/lease/rental contracts, a Standards compliance admin fee (MHRA/CQC) must be funded for MPCE.

Part B - MPCE TO COMPLETE

If device is new to Trust, PAQ completed and checked? YES/NO *(if non-compliance to Standards seek alternative device)*
State any non-compliances:
Any specialist safety requirements i.e. ionising radiation, laser etc YES/NO
If yes make relevant Physicist aware and give details:

Warranty period:
Maintenance by: MPCE ☐ Partnership ☐ External contract/Rental/Lease ☐
MPCE costs: Contract costs:
i.e. commissioning calibration, service, training etc

User training implications:

Checked by Medical Device Trainer name:
Deliver to workshop from Central Stores [2]

Approved ☐ Send form to Ward/Procurement. Ward to send Requisition with Ref No on it to Procurement.
Rejected ☐ Send form to Ward. Reason:

Sign: Print: Date:
(Head of Clinical Engineering or Operational Manager)

Part C – PROCUREMENT TO COMPLETE

List cost (inc vat): Discounted cost (inc vat):

Requisition No: Order No:
Email copy of Order to: rwh-tr.clinicalengineering@nhs.net

Sign: Print: Date:

[1] *Negotiate technical training as part of purchase.*

[2] *Devices to be taken to the relevant Commissioning workshop following delivery to Receipts & Distribution Centre.*

Guidance notes for Appendix 3:

REQUEST FOR PURCHASE OF REVENUE MEDICAL EQUIPMENT <£5K inc. Vat FORM

Wards/Depts to complete section A of the form only:

- Complete ward/dept. and medical equipment details.
- Click on the appropriate box for the source of funding.
- Is new equipment - a Replacement **OR** a New type/additional?

Replacement Equipment

- Click the Replacement Equip box
- Enter Inventory number and Condemnation/Notification number of old equipment
- If details not known contact your MPCE Technician for help.
- Save the form on your computer by renaming the file i.e. ward name or equip name-date
- Email the form to MPCE at:

  rwh-tr.clinicalengineering@nhs.net

New Type/Additional Equipment

- Click the New Type/Additional Equip box
- Read the next 4 points i.e. decontamination considerations, technical training, maintenance, admin fee.
- For queries regarding these points please contact a MPCE managers at: **rwh-tr.clinicalengineering@nhs.net**
- Save the form on your computer by renaming the file i.e. ward name or equip name-date etc.
- Email the form to MPCE at:

  rwh-tr.clinicalengineering@nhs.net

MPCE will complete section **B.**

- MPCE will liaise with Ward Manager on any queries i.e. standardisation requirements/revenue costs associated with device/s requested.
- If approved a unique number will be entered in the Ref No at the top of form and then emailed back to sender/Ward Manager.

Ward to generate Requisition and attach this form electronically to be sent to Procurement Dept.

Procurement will place order and complete section **C** and send copy of PO to **rwh-tr.clinicalengineering@nhs.net**

(Please note failure to fully complete relevant section of the form may result in delay of processing and purchase of equipment)

Outline Business Case

TITLE OF PROPOSAL	
DIRECTORATE	**PROJECT LEAD (ACCOUNTABLE OFFICER)**

BACKGROUND INFORMATION *(where are we now including drivers for change) - Information to help the reader unfamiliar with the service to understand the service and impact of the improvement)*

CASE FOR IMPROVEMENT *(where do we want to get to) - include quantitative data showing the performance gap and how the proposal fits with Trust Strategy)*

OPTIONS *(Brief description of alternative ways to achieve the improvement)*

BENEFITS OF PREFERRED OPTION *(What will this do for Performance (targets, payment, costs), Commissioners (GP, PCTs), Patients (quality, time, perception, environment – including impact on space utilisation), Process (productivity, legal, innovation) and Staff (release potential, involvement, learning & development, environment) i.e. quantifiable measures so that we will know when the benefits have been delivered)*

Benefit	*Measure and approach*	*Date benefit will be realised*
e.g. Increased income associated with activity	*50 cases per annum*	*1st December 09*

RESOURCE IMPACT *(Staffing, time, costs -capital and revenue, source of funding)*
Attach financial proforma (Add hyper-link for Financial Proforma)

RISKS AND DEPENDENCIES *(Partners, other projects in progress, availability of resource/people, Service Improvement capability within team, contingency plans & mechanism to stop the improvement if benefits cannot be delivered i.e. exit strategy, Risk Register implications)*

Risk	***Grade (R,A,G)***

PUBLIC CONSULTATION – *(determine which level of consultation, if any, is appropriate)*

EQUALITY IMPACT ASSESSMENT

HIGH LEVEL IMPLEMENTATION PLAN

Key Actions	Person responsible	Timescale

SUBMITTED BY:

Clinical Director ……Matron…..……Dir. Mgr…….

Date……..

APPROVED BY:

Divisional Director…… Divisional Manager …….

Divisional Accountant…… Head of Nursing …….

Date……..

APPROVED BY TRUST EQUIPMENT GROUP:

Chairman (or Deputy) of Trust Equipment Group ……Date……..
(On behalf of Trust Equipment Group)

FOR CAPITAL INVESTMENT ONLY

Director of Estates Development …….. Date……..
(On behalf of Capital Review Group)

THE ROYAL WOLVERHAMPTON HOSPITALS NHS TRUST

Business Case / Service Change Costing :

CAPITAL COST:-	Capital £ Year 1	Life Years	Capital £ Year 2	Life Years	Total Captial £
TOTAL CAPITAL	***0***		***0***		***0***

ACTIVITY & OTHER INCOME:-	Activity Year 1	Activity Year 2 FYE	Tariff Year 1	Tariff Year 2 FYE	Income Year 1	Income Year 2 Recurring
Description			£	£	£	£
Activity Income must be entered by Point of Delivery						
TOTAL INCOME					**0**	**0**

REVENUE COST:-
Note: All entered as minus values (-£)

Pay Costs Description	Department	Date wef	Pay Band	PAs/ Other	Cost per WTE £	WTE	Spend Year 1 £	Spend Year 2 Recurring £
Pay - Direct Clinical								
						0.00	0	0
Pay - Clinical Support								
						0.00	0	0
Total Pay Costs						0.00	0	0
Non Pay Costs								
Non Pay - Direct Clinical								
						0.00	0	0
Non Pay - Clinical Support								
						0.00	0	0
Total Non Pay Costs						0.00	0	0
TOTAL CLINICAL AND CLINICAL SUPPORT COSTS						**0.00**	**0**	**0**

TOTAL CONTRIBUTION TO TRUST OVERHEADS	**0**	**0**
AS PERCENTAGE (Should be 20% or above)	#DIV/0!	#DIV/0!

OVERHEAD COSTS:-		
TOTAL OVERHEAD COSTS	**0**	**0**
TOTAL EBITDA	**0**	**0**

MARGIN AS PERCENTAGE (Should be [redacted] or above)	#DIV/0!	#DIV/0!
CAPITAL CHARGES:-		
Note: All entered as minus values (-£)		
Impairment		
Depreciation		
Rate of Return		
TOTAL COST OF CAPITAL	**0**	**0**
NET SURPLUS	**0**	**0**
MARGIN AS PERCENTAGE (Should be 3% or above)	#DIV/0!	#DIV/0!

Divisional Accountant	**Divisional Manager / Director**
Name:	Name:
Date:	Date:

HS11 Appendix 6

The Royal Wolverhampton NHS Trust

REPLACEMENT OF EXISTING CAPITAL EQUIPMENT FORM £5,000 - £250,000 (INCLUDING VAT)

(For additional/new equipment or >£250,000 inc. VAT please complete an OBC form instead and submit to Division)

PART A – TEG TO COMPLETE			
Supplier / Equipment Description			
Model		**Quantity**	
Inventory No's		**Existing equipment list attached** ☐	
Cost Each (in F2)		**Year of Purchase**	
What year is the equipment due for replacement?			

Replacement Equipment Rating Score	A - Usage/Fatigue (input from Users)	B - Reliability and number of repairs, uptime	C - Availability of Spare parts	D - Not meeting clinical/technology requirements (input from Users)	E - Years left of expected life span (ELS)	F - Company notification end of sale life

Comments	

PART B – SUBMITTED BY			
Ward / Department		**Is this on your Risk Register?**	
Group Manager		**Risk Rating**	
Clinical Lead		**Risk Number**	
Justification for replacement (frequency / clinical application of use):			
Clinical impact if not replaced (do nothing):			

PART C – PROCUREMENT APPROVAL			
Quotation Attached?		**Estimated lead time for delivery**	
Procurement Approval (Name)		**Date**	
Comments			

PART D – TEG APPROVAL

TEG Approval (Name)		**Date**	

PART E – DIVISIONAL APPROVAL			
Divisional Accountant (Name)		**Date**	
Divisional Manager (Name)		**Date**	

PART F – CAPITAL APPROVAL			
Estates Developments (Name)		**Date**	

Full Business Case Proposal HS11 Appendix 7

TITLE OF PROPOSAL

EXECUTIVE SUMMARY

PROJECT LEAD (ACCOUNTABLE OFFICER)

BACKGROUND INFORMATION (where are we now)

Quantify the present service model e.g.

- *Catchment population*
- *activity levels*
- *capacity e.g. staffing, theatre sessions, outpatient clinics, beds, equipment, technology*
- *waiting times*
- *length of stay*
- *performance*
- *budgets*

Service development priorities and drivers for change e.g.

- *Growth*
- *Market Assessment/Commissioner Support*
- *Technology trends*
- *Research – evidence base*

CASE FOR IMPROVEMENT (where do we want to get to). *This section should state:-*

- *Desired future performance/activity targets e.g.*
  - *LOS*
  - *Day Case Rates*
  - *Throughput – Theatres & Out-patients*
- *Fit with Trust vision and corporate/local business plan*
- *Fit with Trust Capital Programme*
- *Impact on partner organisations*
- *Impact on other services, clinical and non-clinical*
- *Physical solution requirements – e.g. major equipment/estates provision*

OBJECTIVES

- *Healthcare outputs/outcomes e.g. achievement of targets*
- *Risk reduction*
- *Resource utilisation (estate, workforce etc)*
- *Improved quality*

OPTIONS

For each alternative considered (including "Do Nothing & Do Minimum"), quantitative analysis must be presented clearly showing the financial and activity implications for each option, key constraints, benefits, dis-benefits, risks, sensitivity analysis and conclusion for each.

NON-FINANCIAL OPTION APPRAISAL

(In case of significant capital schemes i.e. between £250K & £8million, completion of the Non-financial evaluation process template will be necessary). ***For Capital schemes above £8m refer to Director of Estates Development as an SHA process will need to be followed.***

KEY: **0=objective will not be achieved** **1=objective will be partially achieved**
2=objective will be mostly achieved **3=objective will be fully achieved**

	Option1	Option2	Option3	Option4
Objective 1				
Objective 2				
Objective 3				
TOTAL				

FINANCIAL SUMMARY *(will be derived from the full financial proforma; an economic appraisal may be required – seek guidance from your Divisional Accountant)* Attach financial proforma (Add hyper-link for Financial Proforma)

	1ST YEAR	Recurrent	Capital	Revenue
	Surplus/(Deficit)	**Surplus/(Deficit)**		
Current				
Option 1				
Option 2				
Option 3				
Option 4				

A statement confirming the resulting preferred option must be provided.

PUBLIC CONSULTATION– *(determine which level of consultation, if any, is appropriate)*

EQUALITY IMPACT ASSESSMENT

BENEFITS (of the preferred option) - *The benefits must have a means by which their achievement can be measured. No benefit should be included that cannot be quantified i.e. where there is no data that can be presented to demonstrate that the benefit (objective) has been achieved.*

Benefit	*Measure and approach*	*Date benefit will be realised*	*Responsible for Review*
e.g. Increased income associated with activity	*50 cases per annum*	*1st December 09*	

RISK MANAGEMENT APPROACH (of the preferred option) *– complete a risk log/assessment of all key risks - hyperlink*

DETAILED IMPLEMENTATION PLAN – hyperlink to Project Plan Template

Key Actions	Person responsible	Timescale

AGREED BY:

	Date
IT Strategy Group	
Trust Equipment Group	
Capital Review Group	
Division One	
Estates & Facilities	
Procurement	
Others – please state	

	Date
Medicines Management	
NICE Implementation Group	
Division Two	
Human Resources	
Education	

APPROVED BY: **Divisional Director…… Divisional Manager ……** **Divisional Accountant…… Head of Nursing ……**
APPROVED BY TRUST EQUIPMENT GROUP: **Chairman (or Deputy) of Trust Equipment Group ……. Date……** **(On behalf of Trust Equipment Group)**
APPROVED BY: **Contracting & Commissioning ……....Name……Date……**
APPROVED BY **Trust Management Team ……..……....Name……Date……**
APPROVED BY **Trust Board ……..……....Name……..……Date……**

2) TRIAL / LOAN / LEASE OF MEDICAL DEVICES

Consult Procurement Dept. & MPCE
To ensure correct process is followed and relevant documentation is completed i.e.
Indemnity/Specifications/Evaluations/PAQ/ Data sharing agreements/MDS2-RWT/Decontamination considerations/ training needs considered

On delivery of equipment
MPCE – electrical safety test, labeled
Indemnity forms completed, PAQ's checked, training assessed/scheduled.
Devices logged on f2 database and inventory number attached to devices and any documentation for these devices uploaded against them.

If patient identifiable data is to be captured/stored on device – this must be pseudonymised where possible. Data sharing agreements completed and copies sent to Information Governance dept

During trial
Where applicable evaluation forms completed and any training recorded.

End of trial/loan
Inform MPCE prior to returning equipment, any patient identifiable data must be backed up and securely removed/deleted as per Protocol 11.

3) ACCEPTANCE OF MEDICAL DEVICES

On purchase of medical equipment.
Procurement to send order details to MPCE.
MPCE – commissioning/acceptance tested, inventory and training risk labels attached, devices added to f2 database. Device clocks set to GMT except networked/clinical requirement for BST to be set. Where applicable Protocol 11 must be followed.

Staff training must be considered liaising with Medical Device Trainers

Equipment delivered to Ward/Dept.

Equipment On Loan Label

The Royal Wolverhampton NHS
NHS Trust

EQUIPMENT ON LOAN

This device has been tested by MPCE.

Indemnity No: _____

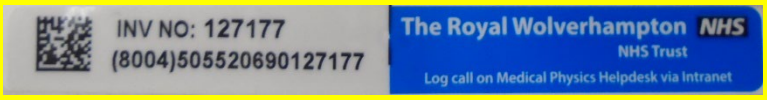
Do not use after: ____/____/____

Please contact MPCE if date has expired.

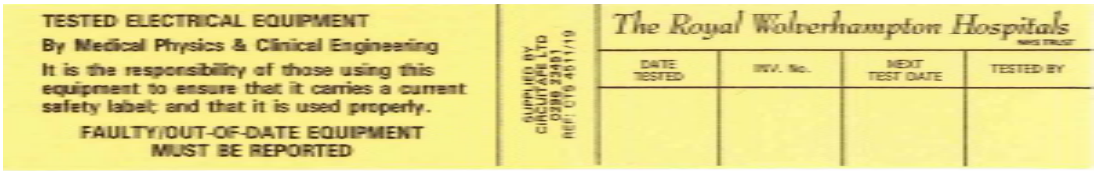
Decontamination/Equipment Status Label

Order Orange Decontamination/Equipment Status label from Fine Cut Group Ltd – Part number 17210/9, Quote – 29055/KP

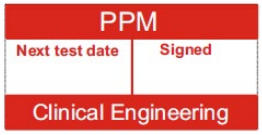
Inventory Labels

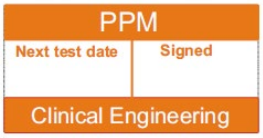


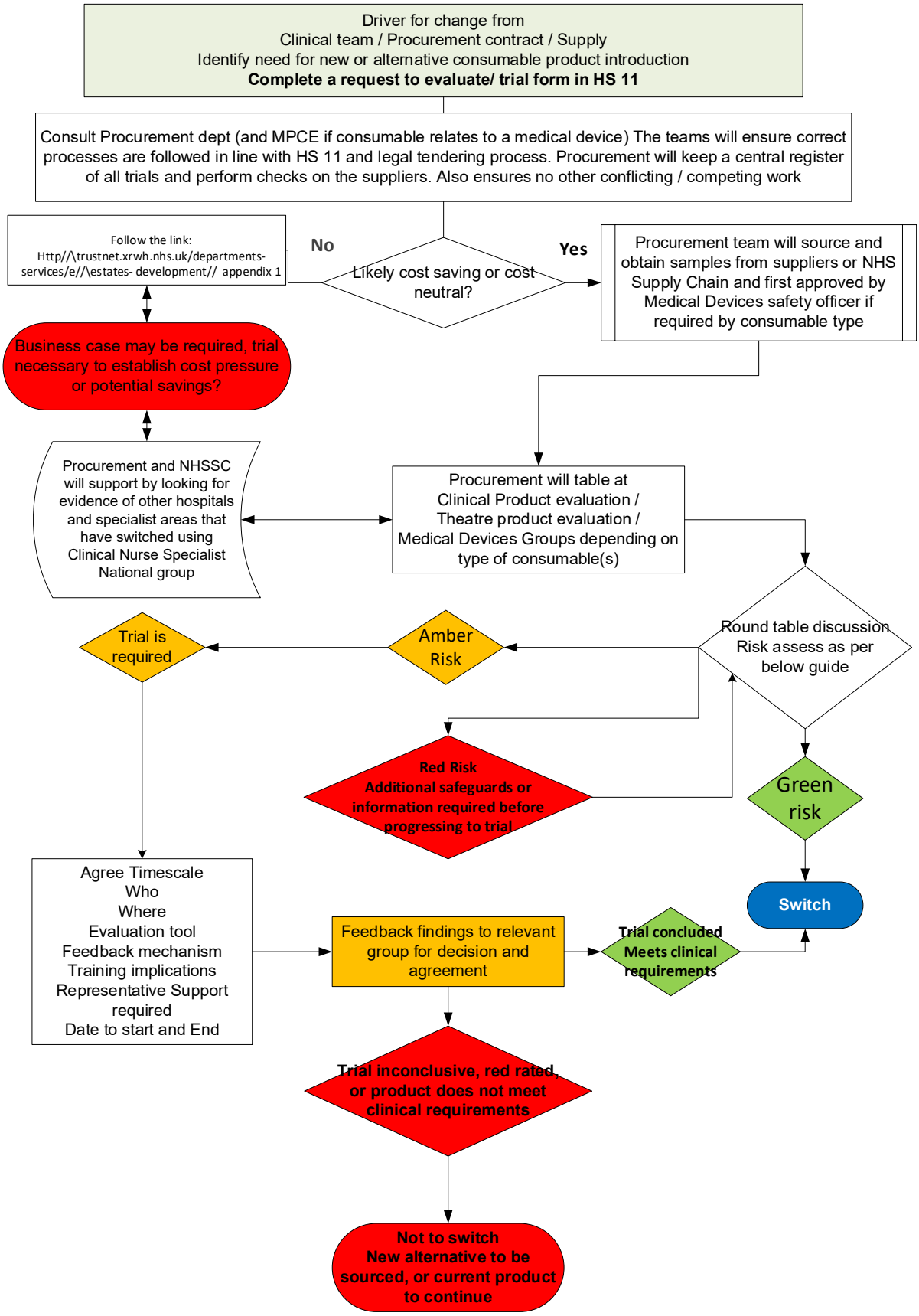
Electrical Safety Test Labels



Service Labels






Driver for change from
Clinical team / Procurement contract / Supply
Identify need for new or alternative consumable product introduction
Complete a request to evaluate/ trial form in HS 11
Consult Procurement dept (and MPCE if consumable relates to a medical device) The teams will ensure correct processes are followed in line with HS 11 and legal tendering process. Procurement will keep a central register of all trials and perform checks on the suppliers. Also ensures no other conflicting / competing work
Follow the link: Http//\trustnet.xrwh.nhs.uk/departments-services/e//\estates- development// appendix 1
No
Likely cost saving or cost neutral?
Yes
Procurement team will source and obtain samples from suppliers or NHS Supply Chain and first approved by Medical Devices safety officer if required by consumable type
Business case may be required, trial necessary to establish cost pressure or potential savings?
Procurement and NHSSC will support by looking for evidence of other hospitals and specialist areas that have switched using Clinical Nurse Specialist National group
Procurement will table at Clinical Product evaluation / Theatre product evaluation / Medical Devices Groups depending on type of consumable(s)
Round table discussion Risk assess as per below guide
Trial is required
Amber Risk
Red Risk Additional safeguards or information required before progressing to trial
Green risk
Switch
Agree Timescale
Who
Where
Evaluation tool
Feedback mechanism
Training implications
Representative Support required
Date to start and End
Feedback findings to relevant group for decision and agreement
Trial concluded Meets clinical requirements
Trial inconclusive, red rated, or product does not meet clinical requirements
Not to switch New alternative to be sourced, or current product to continue

The Royal Wolverhampton NHS
NHS Trust

HS11 APPENDIX 11
MEDICAL DEVICE
TRAINING RISK CATEGORISATION

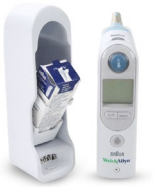
RED TRIANGLE

All Medical Devices in this group are **HIGH RISK** and must only be operated by Staff who have received Training in the safe use of the device and feel competent to use it.
Refresher training is required Every Three Years

YELLOW CIRCLE

All Medical Devices in this group are **MEDIUM RISK**
and must only be operated by staff who have received Training in the safe use of the device and feel competent to use it.
Refresher training is required every Six Years

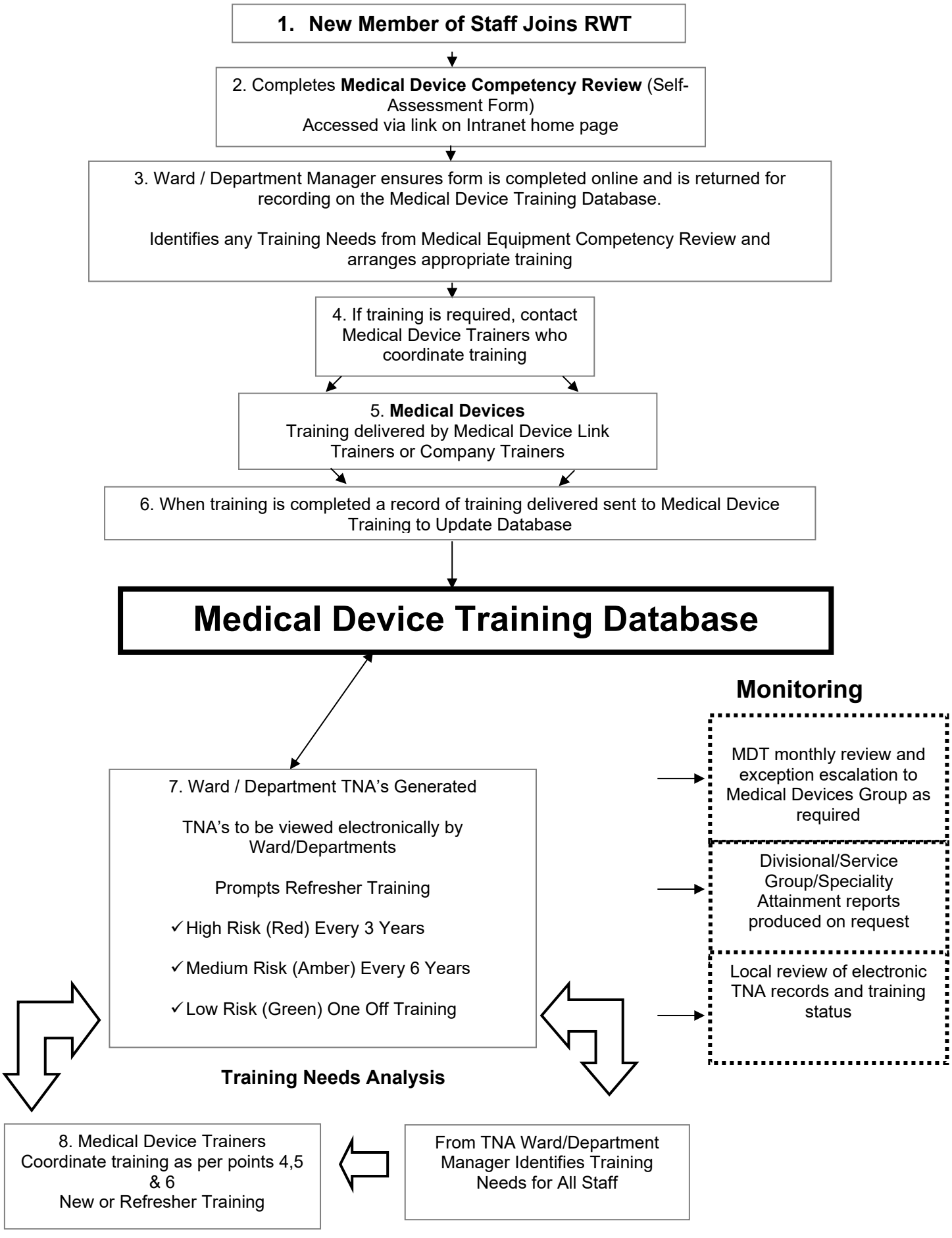
GREEN SQUARE



All Medical Devices in this group are **LOW RISK**. The user is required to attend a one off training session or has self assessed as competent to use the device.

For Details Contact Medical Device Training Team Ext 85530

Protocol 4 - USER TRAINING ON MEDICAL DEVICES – FLOW CHART



6) SERVICE/MAINTENANCE/REPAIR & DECONTAMINATION OF MEDICAL DEVICES

SERVICE / MAINTENANCE / DECONTAMINATION

Arranged through MPCE or Ward Manager for locally held external contracts.

Responsibility of Ward to make devices available (including when pink 'release me' tags are attached) for service ensuring these are cleaned/decontaminated prior to service by User, Decontamination/Status label attached.

Any medical device to be **sent off site for service**, all patient identifiable data must be backed up and securely deleted as per Protocol 11.

Invasive type devices to be sent away must have Certificate of Decontamination completed following clean/decontamination.

MPCE will service **High and Medium risk** devices and relevant service labels attached followed by a clean.

Service undertaken by MPCE or Manufacturer PPM reports completed, recorded onto **F2 Database**

REPAIR / DECONTAMINATION

Defective/damaged medical device must be removed from use immediately, quarantined and reported to the **MPCE Helpdesk**. Faulty equip taken out of service must be cleaned/decontaminated and a Decontamination/Status label attached.

Invasive type devices to be sent away must have a decontamination label attached following a clean / decontamination.

MPCE to assess/collect equip for repair, complete repair, attach appropriate service label, service sheet/logged on f2, then returned back to ward once fixed prior to it being cleaned.

Any medical device to be **sent off site for repair**, all patient identifiable data must be backed up and securely deleted as per Protocol 11.

Consumables/user damage/lost parts charged back to Ward/Dept.

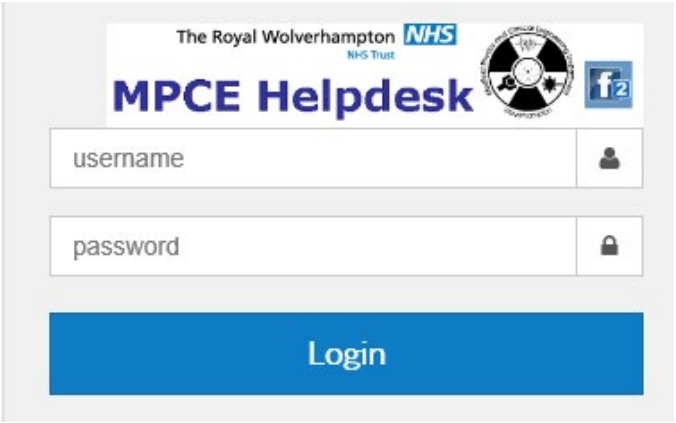
Devices **beyond economical to repair** will be condemned and Ward Manager notified

Medical Devices (MPCE) Helpdesk User Guide (complete revision)

Contact Ext : 85762 if you need assistance

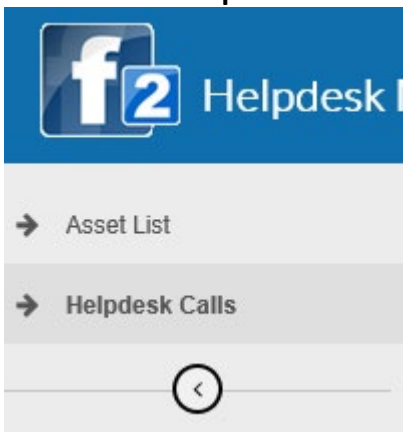
Reporting Issues / Faults with Medical Devices on the Helpdesk

- **Access Helpdesk through Trust NET**
- On home page go to Computer Systems (top of page)
- Click on **M** and select **Medical Devices Helpdesk**
- Log in box will appear
- **Enter details in log in box**

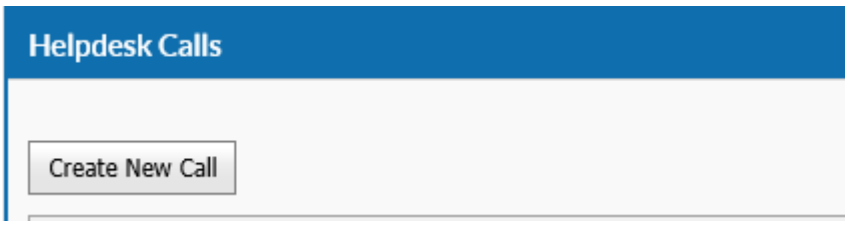


1. Username :
2. Password : **f2Helpdesk**

- **Select Helpdesk Calls at top left (if not already highlighted)**



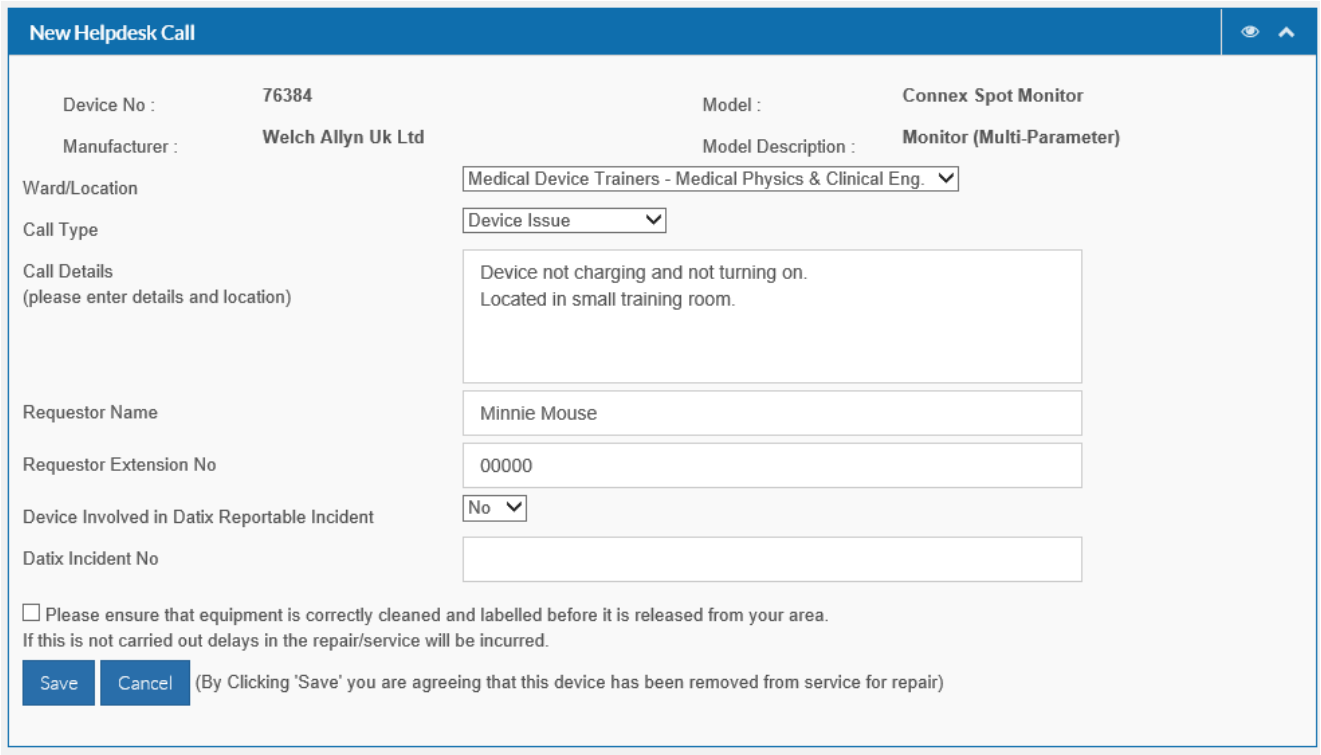
- **Select Create New Call**



1. Enter the Device number into the white rectangle box (device number in small orange/brown/blue label on device) *if this number starts with “0” then you may have to omit the “0” and just enter the remaining digits.

2. If no device number present or it is a new device then tick box next to “This is a Non-Device call”, and follow process below.
3. Click on Next

- **Enter all information requested (see EXAMPLE below)**
  1. Select the correct location from the drop-down list
  2. Call Type is Device Issue
  3. Enter fault / problem / request in Call Details section. Please give as much information as possible. State where device can be located in the clinical area e.g./ Sister’s office
  4. Complete Requestor name
  5. Complete contact phone number
  6. Device involved in Incident (i.e./ reported on Datix) select Yes or No
  7. If Yes then enter Datix Incident number
  8. Tick box to confirm device has been cleaned and labelled ready for collection
  9. Click on Save



- **To check progress of the job logged**
  1. Click on “Helpdesk Calls” on first page to view jobs already reported for your area

New Cross Hospital
Wolverhampton Road
Wolverhampton
West Midlands
WV10 0QP

Tel: 01902 307999

HS11 Appendix 15

The Royal Wolverhampton NHS Trust

LOANING MEDICAL DEVICES TO OTHER TRUSTS – AGREEMENT FORM

Equipment Description	
Model	
Manufacturer	
List of Serial numbers attached?	Yes / No

Loaning-Out Organisation	The Royal Wolverhampton NHS Trust (RWT)	**Borrowing Trust & Department**	
Location of Dept.		**Location of Dept.**	
Responsible Person loaning out		**Responsible Person borrowing**	
Designation		**Designation**	
Contact Details		**Contact Details**	

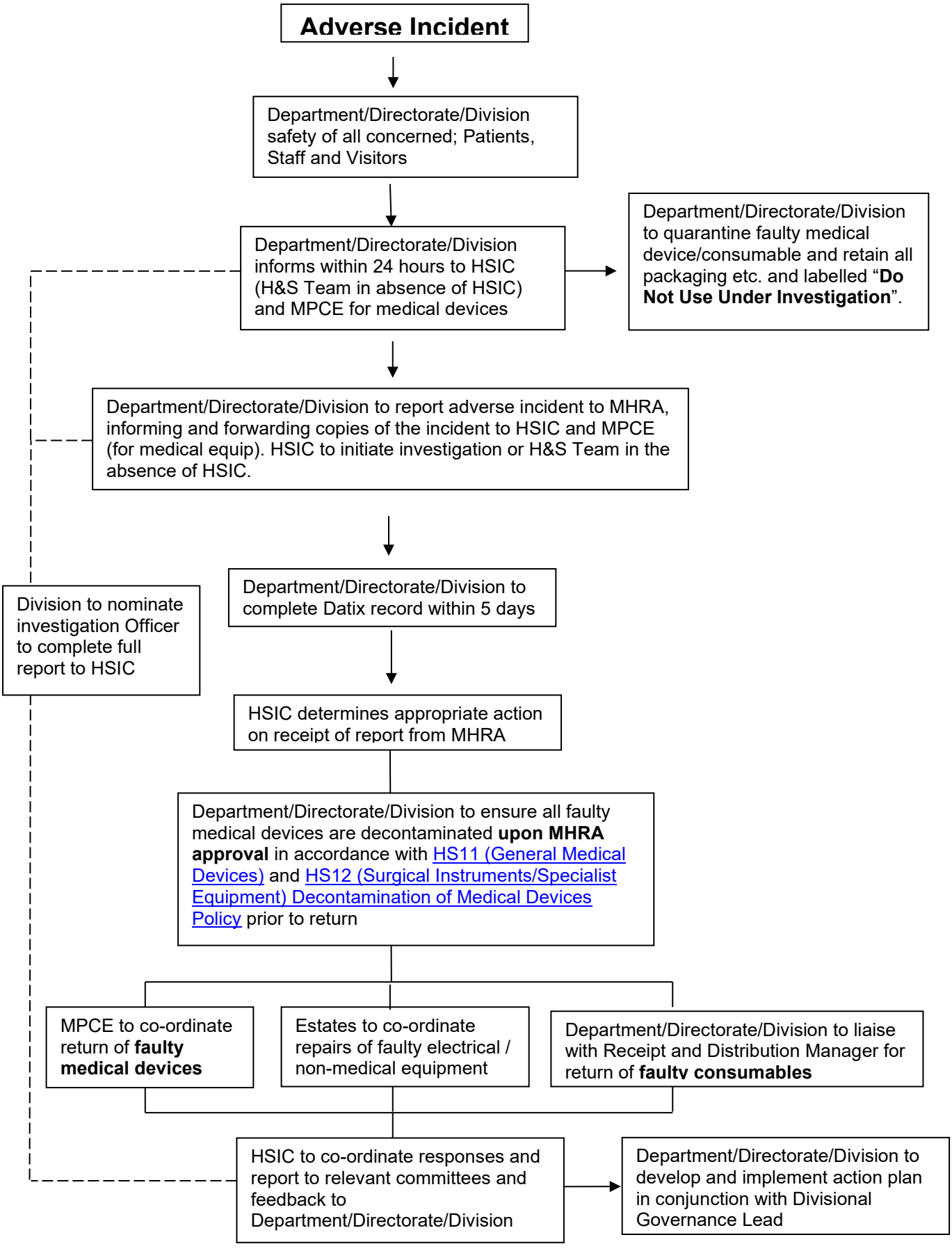
Duration of Loan:	

Statement by Responsible Person Loaning out (RWT)	• I certify that this equipment is in good working order and has been decontaminated. • I certify that I have supplied with instructions (if applicable) to use with the equipment. • The configuration of the device setting must be checked prior to use as it is specifically programmed to RWT clinical requirements only. • Add any other relevant info here…….	**Signature:** **Date:**
Statement by Responsible Person Borrowing the devices.	• I certify that the equipment will only be used by competent persons. • I certify the configuration of these devices will need to be adjusted to suit the clinical needs of the relevant department intended use by the Borrowing Trust. • My department accepts financial responsibility for any loss or damage to the devices, whist on loan and will put right before returning the devices, including decontamination. • I certify if due to patient needs the loan devices are required back by RWT before end of loan period, devices will be returned as quickly as possible. • I undertake to ensure that all the conditions of the loan are adhered to.	**Signature:** **Date:**

Incidents must be reported to MHRA via their Yellow Card scheme on their website within 24 hours by local areas and HSIC is informed along with MPCE if medical equipment involved.

There are currently no options to upload paper copies therefore an incident report must be completed online, a link to the MHRA webpage is shown below (press Control on your keyboard and click below):

Yellow Card | Making medicines and medical devices safer


Adverse Incident
Department/Directorate/Division safety of all concerned; Patients, Staff and Visitors
Department/Directorate/Division informs within 24 hours to HSIC (H&S Team in absence of HSIC) and MPCE for medical devices
Department/Directorate/Division to quarantine faulty medical device/consumable and retain all packaging etc. and labelled "Do Not Use Under Investigation".
Department/Directorate/Division to report adverse incident to MHRA, informing and forwarding copies of the incident to HSIC and MPCE (for medical equip). HSIC to initiate investigation or H&S Team in the absence of HSIC.
Department/Directorate/Division to complete Datix record within 5 days
Division to nominate investigation Officer to complete full report to HSIC
HSIC determines appropriate action on receipt of report from MHRA
Department/Directorate/Division to ensure all faulty medical devices are decontaminated upon MHRA approval in accordance with HS11 (General Medical Devices) and HS12 (Surgical Instruments/Specialist Equipment) Decontamination of Medical Devices Policy prior to return
MPCE to co-ordinate return of faulty medical devices
Estates to co-ordinate repairs of faulty electrical / non-medical equipment
Department/Directorate/Division to liaise with Receipt and Distribution Manager for return of faulty consumables
HSIC to co-ordinate responses and report to relevant committees and feedback to Department/Directorate/Division
Department/Directorate/Division to develop and implement action plan in conjunction with Divisional Governance Lead

Defective or Contaminated Items and Evidence
[Abstract taken from Annex C MDA A.I.C]

Evidence:

1. All material evidence should be labelled, appropriately bagged and kept secure including products and, where appropriate packaging material or other means of batch identification.
2. The evidence is not to be interfered with in any way except for safety reasons or to prevent loss. If necessary, a record should be made of all:-
    - readings
    - settings
    - position of switches
    - valves
    - dials
    - gauges
    - indicators
3. Photographs may be taken where appropriate.
4. All persons involved must make witness reports.
5. In serious cases witness reports are to be countersigned by another person.

Defective Items:

1. Must not be repaired before investigation.
2. Must not be returned to supplier or discarded before investigation.
3. Must be appropriately decontaminated only after approval by MHRA prior to any investigation and before being allowed to move within or outside of the Trust, in which case use approved Trust Courier where applicable.
4. The manufacturer or supplier must be informed promptly of the incident, by the HSIC.
5. The manufacturer or supplier must not be allowed to inspect the item without the presence of the HSIC or relevant Department, i.e. MPCE, Estates, Procurement.
6. The manufacturer or supplier must not to be allowed to exchange, interfere with or remove any part of the product without the approval of the HSIC or relevant Department, i.e. MPCE, Estates, Procurement.

8) LOANING MEDICAL DEVICES TO PATIENTS

Equipment Loaned to Patients Form completed by Ward staff, with one copy to Patient/Ward/MPCE. Appropriate training given to Patient/Carer

Ward responsibility to organise return/clean/decontamination of devices requiring servicing by MPCE when requested.
Devices that cannot be recovered will be off-costed to issuing Ward

9) REPLACEMENT / DISPOSAL OF MEDICAL DEVICES

Notification completed for the temporary use of old equipment whist replacement is sort.

Condemned Equipment – Condemnation service report issued by MPCE. Equipment taken out of service and cannot go back into use.

Disposal – MPCE will arrange either disposal (WEEE Regs) or transfer to Trusts approved Auctioneers for equipment to be sold. All patient identifiable data will be securely deleted as per Protocol 11 and Trust labels removed.

0501

NHS
The Royal Wolverhampton
NHS Trust

Please keep this form with your equipment

White copy - Patient
Pink copy - Medical Physics
Green copy - Issuing Ward or Department

Surname	Unit No
Forename	NHS No
Address	DOB
Postcode	(or affix patient label)

Equipment Loaned to Patients

The medical equipment detailed/listed below is being loaned to you as part of ing treatment. The instructions set out on the back of this form should be read carefully. If or you have any queries about the equipment or its use, please ask the member of st with it.

Details of Equipment:

Type: Descri

Serial No:

Inventory No:

Patient's contact telephone number:

Ward / Department issuing equipme

Consultant / Nurse in Charge:

Date loaned: eturn Date:

GMC/Register

If y **c:**

Name:

Ward / Depa Tel:

PLEASE NOTE – R air or replacement is only available between the hours of 08.00 – 16.00 Monday – Friday (excluding Bank Holidays.

List of Loaned Equipment:

Service Dates:	1	2	3	4
Due Date Serviced by Date				
Due Date Serviced by Date				

Issued by (Sign and print): _____

Received by or signed on behalf of (Sign and print): _____

Please Note:

1. The equipment is only being loaned to you and remains the property of The Royal Wolverhampton NHS Trust.

2. When it is handed over to you Trust staff will give you full instruction and training on how to use the equipment correctly and safely. If you do not fully understand these instructions, please ask.

3. A user guide may be supplied with the equipment. If so this should be read carefully before the equipment is used and retained for future reference.

4. Accessories and consumables such as giving sets, pads, electrodes, etc. which may be supplied with the equipment should be used as instructed. No other types of accessories or consumables may be used without the approval of the ward or department who supplied the equipment.

5. When the equipment is loaned to you it will have been fully checked for operation and safety. It may be necessary to return the equipment at regular intervals for routine servicing and safety checks (it may be possible to service some equipment in your home). The ward or department issuing the equipment or the Medical Physics and Clinical Engineering Department will contact you to arrange for service. Equipment will normally be serviced every 12 months. If necessary replacement equipment will be made available during the service. The ward or department issuing the equipment will advise you of the service dates when the Medical Physics and Clinical Engineering Department will carry out maintenance.

6. In the event of any problems including a breakdown, the appropriate ward or department should be contacted and arrangements will be made to repair or replace the equipment as soon as possible.

Please note:

i. **Repair or replacement is only available between the hours of 08.00 – 16.00 Monday – Friday (excluding Bank Holidays).**

ii. **Repairs of any kind must not be made by anyone other than the Medical Physics and Clinical Engineering Department who are based at New Cross Hospital.** This includes repairs to items such as plugs, fuses, mains leads, etc.

7. When the equipment is no longer required it must be returned together with any unused accessories/ consumables to the ward or department from which you obtained it, details are shown on the front of this form. It must be returned in a clean and undamaged condition.

8. **Please note that the Trust reserves the right to charge for any loss of or damage to equipment that has been issued to you until such time that it is returned in its original condition to the issuing ward or department.**

Department of Medical Physics & Clinical Engineering

Form No	

Notification of Need for Replacement of Medical Equipment

Hospital: Directorate:

Ward/Dept:

Description of Equipment:

Manufacturer: Date Purchased:

Model No: Inventory No:

Serial No:

Reason for Notification:

Equipment Assessed by: Date:

Assessment enclosed: No

Assessment checked by ..... *Operational Manager* Date:

Recommended **maximum** remaining life

Comments: I

The above equipment has been assessed and recommended for replacement. Failure to replace the equipment within the remaining life may necessitate the issue of a **Condemnation service report, and the consequent removal of the equipment from clinical use**. The Clinical Director is asked to ascertain the need for replacement and, if necessary, to process a requisition in the usual way.

Signed ..... *Head of Clinical Engineering* Date:

Copies to: Clinical Director
Business Manager
Director of Capital & Estates

NOTICE TO COMPANY SUPPLIERS

Trust Policy HS 11 requires all company suppliers to adhere to the following principles and applies to all contact with Trust staff by suppliers, either by telephone, or during visits to Trust sites:

- **Suppliers MUST NOT visit any Trust site at all if they have been unwell in the last 48 hours with flu like symptoms or diarrhoea and or vomiting.**
- Prior to visiting any clinical or patient area, outer coats and jackets must be removed and hands must be decontaminated using alcohol hand rub or soap and water if hands are visibly dirty. Suppliers must be "bare below the elbow" i.e., short sleeves or long sleeves rolled up above the elbow, no stoned rings, wrist watches or other jewellery other than a simple gold band. It is permissible to wear a kara.
- **Visits must only be made by a prior appointment, and when requesting appointments suppliers must indicate the specific purpose of the visit.**
- Trials or demonstration of products must not be made to wards, departments or clinicians without the prior consent of the Procurement Department or Medical Physics Department (indemnity form required).
- Only Trust staff who have been authorised to do so by their line-manager will see company suppliers and appointments should only be made with such authorised members of staff.
- Suppliers must comply with departmental visitor policies when attending wards and departments and must comply with Trust policies including infection prevention and control and health and safety regulations. Policies are available on the Trust intranet if suppliers wish to read them.
- Suppliers are expected to conduct themselves in a professional manner.
- Ward and department staff and clinicians are not authorised to agree to any commercial arrangements including the ordering of product or sponsorship arrangements. All such matters must be referred to the Procurement Department or the Medical Physics Department.
- Product samples must not be left on wards or departments or with junior clinicians without the prior agreement of the Procurement Department or the Medical Physics Department or the clinical expert leading the trial.
- Any safety issues with a medical device presented by a Rep must be notified to the Trust's Medical Device Safety Officer (MDSO) prior to use, trial or loan
- Whilst on Trust premises, suppliers should display their own identity badges.
- Suppliers should not enter clinical areas unless specifically invited to do so by the authorised Trust staff member on the ward or department concerned.
- Suppliers should not enter designated staff rest areas – many discussions of confidential clinical matters occur in these areas.
- Unsolicited mail, leaflets and posters must not be distributed or displayed in clinical areas unless approved by the Procurement, Medical Physics Department and agreed with the authorised staff member on the ward or department concerned.
- Gifts and hospitality should not be offered to Trust staff.

Note – In the context above, reference to Medical Physics relates to all medical devices and consumables relating to those, and Procurement Department relates to all other products and services.

HS11 APPENDIX 23

Policy Audit tool

Auditor Name		**Auditor role**		**Date**	**Time**	**Signature**	
Area Visited	Are any representatives present in the area today Yes/ No	Was person in charge expecting them (yes/ no)	For what purpose is their visit? **	Is the rep wearing an ID badge	Has the rep brought in any new products with a view to trial	Are procurement aware of the appointment if a trial is underway?	Do staff know where to find the reps protocol

** Education (E) Implementation (Imp) Innovation (Inn) Trial (T)

NON DISCLOSURE & CONFIDENTIALITY AGREEMENT dated [Enter date]

BETWEEN
(1) The Royal Wolverhampton NHS Trust (RWT) New Cross Hospital
Situated at New Cross Hospital – **"the Data Controller"**

(2) Name of Company
Registered Number XXXXXX whose registered office is situated at [INSERT ADDRESS] - **"THE RECIPIENT"**

DETAILS
The following terms apply where an organisation or its staff may gain access to, or have provided to it, personal identifiable information (defined within the terms of the Data Protection Act 1998) when working for, or with RWT (the "data controller"). It also applies where the contracted third party is privilege to commercially sensitive information, security related information and any intellectual property of the contracting organisation.

The access referred to above may include:
- Access to or sharing of information held in any electronic format or on paper
- Information that is part of verbal discussions

(A) The Data Controller has appointed the Recipient as its sub-contractor for [enter system(s) name here]

(B) In order to perform the Services on the Data Controller's behalf, the Recipient will have the ability to access Personal Data when providing support to the servers running the applications (i.e. [Enter systems name(s) here])

(C) Under the Data Protection Act 1998, the Data Controller is required to put in place an agreement between the Data Controller and any organisation which processes or has access to personal data on its behalf governing that data.

CONFIDENTIALITY AGREEMENT
1. DEFINITIONS AND INTERPRETATION

1.1 The following words and phrases used in this Agreement and the Schedules shall have the following meanings except where the context otherwise requires:

"Master Contract" means the main contract between the Data Controller and the Recipient setting out the terms and conditions for the services to be provided by the Recipient.

"Personal Data" means data which relate to a living individual who can be identified from

"Services" means the services to be carried out by the Recipient under the terms of the master Contract.

1.2 This Agreement shall continue in full force and effect for the same period as the Master Contract, unless terminated for breach by either party.

2. OBLIGATIONS OF THE DATA CONTROLLER
2.1 The Data Controller shall provide access for THE RECIPIENT together with such other information as the Recipient may reasonably require in order for the Recipient to provide the Services.

3. OBLIGATIONS OF THE RECIPIENT
3.1 Any information (personal or organisational) will only be used for purposes agreed between the organisations. Information will be retained for a period agreed between the parties and destroyed by an agreed method.

Agreed Purposes are:	Agreed Retention period:	Agreed Destruction method
[Document agreed purpose		

here and complete columns to the right]		

3.2 Any work involving access to personal identifiable information will be done by formally authorised staff of the organisation (except as provided in paragraph 3.3 below). The organisation shall keep a record of all such authorisations.

Information containing a unique number (e.g. NHS, NI or organisational) or a combination of items from the following list is personal identifiable data: Name, Address, Postcode, Date of Birth, Other Dates (i.e. death, diagnosis), Sex, Ethnic Group or Occupation.

How access to be provided	Via	Process
Remote	[Specify method here e.g. Use of specified userid(s) via N3 over remote desktop protocol, via the Trust's SSL VPN using advanced authentication]	[Specify any changes to this standard] Remote access will normally remain 'disabled' when access required – this needs to be pre-arranged with the assigned [enter responsible officer/post].
Physical	[Specify any changes to this standard] This agreement acknowledges that there may be certain circumstances where a formal prior agreement for physical access would be detrimental to the support of services. When physical access is required as a matter of urgency the following procedure applies – contact the assigned [enter responsible officer/post]. .	[Specify any changes to this standard] Physical Access – The Recipient will be required to - agree a convenient time/date before being granted physical access to the servers in [enter location].

3.3 The recipient will not sub-contract any work it is doing on behalf of RWT under the master agreement without explicit written agreement of the Data Controller.

3.4 All personal identifiable information will be treated as confidential and will not be disclosed to any other persons outside the requirements of the above agreed purpose(s), without agreement of the 'data controller'. Any organisational information marked as 'commercial' or 'sensitive' or by implication of the subject could prejudice the commercial interests of either party will be treated as confidential.

3.5 Where the activities performed by the recipient do not require them to process information but they may become party to it by overseeing or overhearing, they will be required to keep such information confidential.

3.6 Any breach of the terms of this agreement may result in termination of arrangements (including formal contracts) and legal action may be taken.

3.7 The Recipient is responsible for ensuring their staff/sub-contractors adhere to the terms of this agreement.

3.8 The Recipient in must adhere to the Trust's change management process to obtain agreement for changes to RWT systems and/or data.

3.9 The Recipient will provide RWT with the name of the principal person responsible for maintaining the agreed support.

For the purposes of this agreement – the following employees will be responsible for maintaining the agreed support	
e.g. [INSERT EMPLOYEES WITH ACCESS]	

3.10 Userids and authentication devices are for an individual's use only and Recipient will be accountable for all actions undertaken by any allocated userid and authentication device.

3.11 The Recipient will NOT transfer the Personal data outside of the United Kingdom; Remote access will only be permitted from within the United Kingdom, any access from outside of the UK by THE RECIPIENT or any sub-contractor etc. will only be permitted with the express permission of INSERT NAME HERE It is a requirement of any third party outside the UK that they will hold any relevant certification for processing data on behalf of a UK business e.g. Safe Harbor and that they will comply with the principles of the UK's Data Protection Act and NHS data security policies when accessing and processing RWHT data.

3.12 The Data Processor agrees that, where it is permitted to sub-contract, it will ensure that any sub-contractor it uses to process the personal data complies with the terms of this agreement. Where a sub-contractor is used, the Data Processor agrees that the Data Controller may, upon giving reasonable notice and within normal business hours, carry out compliance and information security audits and checks of the sub-contractor to ensure adherence to the terms of this agreement

3.13 THE RECIPIENT will employ appropriate operational and technological processes and procedures to keep the Personal Data safe from unauthorised use or access, loss, destruction, theft or disclosure. The organisational, operational and technological processes and procedures adopted are required to comply with the requirements of ISO/IEC 27001:2005 as appropriate to the services being provided to the Data Controller. The Data Controller will use ISO/IEC 27002:2005 as a basis for auditing compliance with the guarantees the Data Processor provides in relation to this obligation;

Where information is accessed or transferred electronically THE RECIPIENT will ensure that any programs including updates or data supplied or directly input to the system(s) by them is malware free by ensuring that an up-to-date malware scanner is used to check files prior to their input on to RWT system(s) (as a minimum malware scanning is to include checks for viruses, trojans and spyware).

3.14 RWT cannot be held responsible for the results of any cyber attack which may occur as a result of a remote access connection.

3.15 The Recipient will not keep the personal data on any laptop or other removable drive.

3.16 The Data Controller reserves the right upon giving reasonable notice and within normal business hours to carry out compliance and information security audits of the Recipient in order to satisfy itself that the Recipient is adhering to the terms of this agreement.

4. INDEMNITIES

4.1 Each party shall indemnify the other against all costs, expense, including legal expenses, damages, loss, including loss of business or loss of profits, liabilities, demands, claims, actions or proceedings which a party may incur arising out of any breach of this Agreement howsoever arising for which the other party may be liable.

5. GOVERNING LAW

5.1 This Agreement shall be governed by and construed in accordance with English law and each party hereby submits to the non-exclusive jurisdiction of the English courts.

Party Name:	Name of Person responsible for confirming agreement with this non-disclosure and confidentiality agreement	Date of Agreement:
THE RECIPIENT	Name: …… Signature: ……	[Enter date here]
RWT Sponsor	Name: …… Signature: ……..	[Enter date here]

HS11 APPENDIX 25

FORM OF I N D E M N I T Y

I, the undersigned, hereby confirm that I have purchased the following item(s)

……

……

On the clear understanding that, should I wish to re-use the item(s), I will be responsible for arranging and paying for any testing of, repairs to, or future maintenance of the items and understand that, the Royal Wolverhampton NHS Trust is selling the products without any guarantees as to their condition and without any liability, as to their future use and that they are: -

a) of no further use to the Trust, because the product could not be repaired economically,

or

b) as “surplus to requirements”.

In either case, the item(s) may not have been continually maintained.

The Purchaser should note that, in accordance with WEEE Regulations 2006, in the event of the electrical/electronic equipment being sold for re-use to a secondary user, the responsibility for recovery and recycling will remain with the ‘Producer’ of the Equipment.

The Purchaser undertakes to – where electrical/electronic equipment purchased will be disposed of as scrap – dispose of the equipment through an Authorised Treatment Facility (ATF) in accordance with WEEE Regulations 2006.

In accordance with EEC Regulations any equipment intended for re-use within the European Community must comply with IEC 601 Part 1 and (if applicable) IEC 601 Part II, together with the Health and Safety at Work Act.

SIGNED: ……..

NAME: ……..

DATE: ……..

(*) Delete where applicable

RETURN TO DEPARTMENT OF PROCUREMENT, NEW CROSS HOSPITAL, WOLVERHAMPTON, WV10 0QP WHEN COMPLETED.