Trust Policy

University Hospitals Plymouth NHS Trust

Point of Care Testing Policy

Issue Date	Review Date	Version
July 2021	Interim version 6 – July 2022	6

Purpose

University Hospitals Plymouth NHS Trust expects all Point of Care Testing to be carried out in a controlled way, by staff with sufficient understanding and training to do so in a safe and effective manner.

Who should read this document?

All Trust staff that perform, or are likely to perform Point of Care Testing as part of their normal duties. Senior staff involved in the development and procurement of point of care testing services and devices.

Key messages

The Chief Executive is responsible for the safe use and management of medical devices within the Trust. This responsibility has been delegated to the POCT section guided by a multidisciplinary committee acting within the framework of a Trust POCT policy and responsible to the Trust via clinical governance.

Accountabilities

Production	**The Point of Care Testing Section**
Review and approval	**The Point of Care Testing Governance Group**
Ratification	**Medical Director**
Dissemination	**The Point of Care Testing Governance Group**
Compliance	**The Point of Care Testing Governance Group**

Links to other policies and procedures

Medical Devices Training Policy

The Management and Use of Medical Devices.

The Point of Care Testing Audit Policy

The Point of Care Testing Training Policy

Service Level Agreement for Point of Care Services

Version History

1	January 2009	Approved by the Clinical Governance Steering Group
2	August 2011	Document reviewed. Document Control and Monitoring Compliance Sections added
3	June 2012	New format used. Addition of the terms POCT Governance Group and the Effective Care Group. Change to POCT team structure
4	January 2014	New version created in updated format and new content
5	January 2017	Version adjusted for changes in since January 2014

5.1	March 2019	Extended for 12 months
5.2	November 2019	Extended to January 2021
5.3	February 2021	Extended to May 2021
6	July 2021	Minor updates creating interim version whilst preparing for ISO accreditation

The Trust is committed to creating a fully inclusive and accessible service. By making equality and diversity an integral part of the business, it will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on the Trust Documents Network Share Folder (G:\TrustDocuments). Larger text, Braille and Audio versions can be made available upon request.

1 Introduction

Point of care testing (POCT) is defined as any analytical test performed by a healthcare professional or non-medical individual outside the conventional laboratory setting. POCT can be performed using non-instrument systems (e.g. urinalysis strips), small handheld analysers (e.g. blood glucose meters) or desktop analysers (e.g. machines for blood gas measurement).

2 Purpose, including legal or regulatory background

The Chief Executive of the Trust is responsible for the safe use and management of medical devices within the organisation. This responsibility has been delegated to the POCT section guided by a multidisciplinary committee acting within the framework of a Trust POCT policy and responsible to the Trust via the clinical governance structure.

The Trust POCT policy aims to safeguard a high standard of care by ensuring that

- all POCT in the Trust is regulated
- regulated POCT adheres to applicable statutory directives
- all staff using POCT are adequately trained and that training formally recorded

However, whilst an individual may take formal charge of a POCT programme, individual users trained and approved for POCT have legal responsibility for the results they produce. Incorrect use of POCT leading to inaccurate results may have medico-legal implications.

3 Definitions

Point of Care testing Clinical Lead- A clinical biochemist or chemical pathologist who is responsible for the clinical effectiveness of the service and chairs the POCT governance group.

Point of Care Testing (POCT)- this term refers to any analytical test performed outside of the traditional laboratory by a trained operator in a clinical area near to the patient.

Point of Care Testing Section- The section consists of management and clinical leads, biomedical scientists, associate practitioners and assistant technical officers who are responsible for the provision and support of the point of care testing service. The team is based in the Derriford Combined Laboratory (DCL).

Point of Care Testing Governance Group- this group is responsible for the governance of the point of care testing service within the Trust as detailed in section 4.

Standard Operating Procedure (SOP)- a document which presents the recognised process or procedure which must be followed in order to standardise the process, minimise health and safety and operational risk.

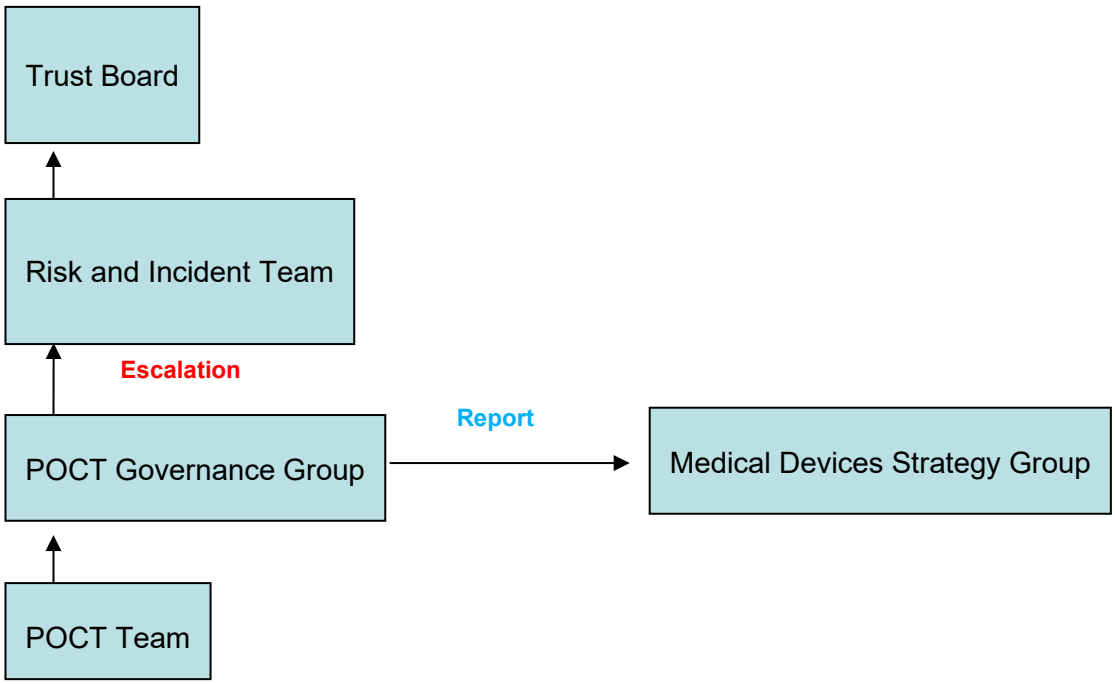
4 Duties

4.1 The Point of Care Testing Governance Group-

The POCT Governance Group provides oversight of the clinical governance of point of care testing within the trust.

The membership includes representatives from critical care, medical specialties, pharmacy, procurement, risk management, theatres, emergency medicine, nursing, paediatric care, maternity services, training and development and ward managers.

The group meets every three months to discuss actions to be taken to improve patient care and the quality of the point of care service. The remit of the group is to effectively implement Trust policies across point of care sites under UHP governance and to approve or reject new POCT proposals.



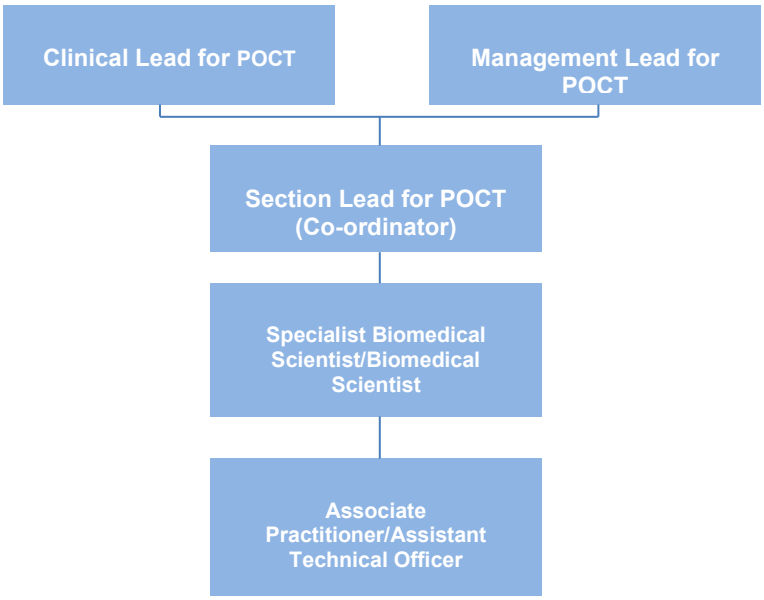
The clinical governance structure within the trust changes frequently in response to operational requirements. The POCT governance group escalates any serious POCT governance issues to the Risk and Incident Team who will advise on where the issue should be managed.

4.2 Point of Care Testing Team Structure-

The POCT team consists of state registered Biomedical Scientists, Clinical Scientists, Chemical Pathologists, Associate Practitioners and Assistant Technical Officers.

Governing this team is a management and clinical structure in line with the requirements of ISO 22870:2016 and ISO 15189:2012.

The team structure is shown below-



The structure of the POCT team may change at any time and is dependent on the point of care service requirements.

4.3 POCT Team Responsibilities-

The POCT team will support the introduction and monitoring of POCT equipment in the Trust where approved by the POCT governance group. Where agreed through service level agreement (SLA) the team will also support equipment placed in the community. The point of care user will be responsible for the general upkeep and condition of the equipment. Service users are directly responsible for the safe use of the equipment.

The team is available between 09.00hrs and 17.30hrs Monday to Friday excluding bank holidays, and can be contacted on ext. 33327/33328.

5 Key elements (determined from guidance, templates, exemplars etc)

5.1 The Point of Care Testing Service-

The POCT team will provide a full support service for the users of, and potential user of POCT equipment. As part of this service the team will:

- Review the clinical need for POCT at the site
- Advise in the selection of appropriate equipment including whether the equipment is fit for purpose
- Select a suitable environment for placing the equipment
- Perform validation and verification of the point of care analytical method with the traditional laboratory method where one exists. Where there is no comparable method the equipment will be assessed for safe use.
- Liaise with Procurement in the purchase of new equipment to include tender processes and development of equipment specifications
- Liaise with the suppliers and arrange installation and implementation
- Provide technical support and perform maintenance where appropriate
- Organise and/or perform training for POCT users and clinical educators
- Ensure trained staff are competency assessed on a regular basis as defined in the POCT Training Policy
- Keep up to date records of staff training and competency
- Monitor Internal Quality Control (IQC)

- Provide External Quality Assurance (EQA), monitor performance and ensure compliance in our own departments and also in third party organisations where applicable.
- Provide feedback and act on poor performance. Repeated poor performance will be reported to the POCT Governance Group and could result in the removal of POCT equipment/tests.
- Work with procurement and materials management for the provision of consumables.
- Provide all documentation required for the point of care test including Standard Operating Procedures (SOPs), training records and database management, competency assessment, patient result log books, quick guides etc.
- Perform audit of point of care processes as described in the POCT Audit Policy and the Audit calendar in the laboratory quality management system (QMS).
- Provision of these services is dependent on the signing of a Service Level Agreement (SLA) at Care Group level or external site.
- POCT equipment must not be purchased without the agreement of the point of care team. The Trust procurement team will not place orders for POCT items without knowledge of this agreement and approval by the POCT Governance Group.

Staff who allow the use of medical equipment that has not been approved by the POCT Governance Group may be made personally liable by the Trust in the event of an untoward incident involving that equipment. The POCT section will have the power to remove POCT devices and consumables where these are in use but not agreed with the POCT governance group with the support of the Medical Director.

5.2 Supporting Information-

For further POCT information visit the Trust POCT webpage. Navigate as follows:

Open Internet Explorer > Click on Staffnet > Click on the 'Departments' tab > Click on 'Pathology' > Select the Pathology Point of Care Testing link.

Or from your web browser:

Type: www.plymouthhospitals.nhs.uk, select P under A-Z of our services, select Pathology, select the Point of Care Testing link

POCT policies and competency paperwork can be located on the network drive (G:) in the Trust Document Library.

All documentation available at this location is valid only on the day of printing. The version accessed at this location is the current version authorised by the POCT team. No other versions are permitted for use.

5.3 Service Level Agreements (SLA)-

SLAs will be formulated by the POCT section in conjunction with the point of care site. This document will clearly illustrate the responsibilities of the POCT section and the point of care user for that site. In signing the SLA the POCT site agree to the POCT section ordering items using the site's budget.

Copies of the SLA will be made available at the point of care site and stored in the DCL QMS. This document must be signed by both the POCT section and the appropriate member of staff responsible for provision of point of care testing at the point of care site. The original signed copy of the SLA will be kept in the point of care office in DCL.

Through SLA, the external sites covered by the service will be subject to the same governance, quality and safety measures applied within the Trust.

5.4 Connectivity-

The introduction of connectivity solutions within the Trust and the community is a necessity for the POC team to effectively monitor equipment and to provide a timely response for analyser support. It also offers greater functionality in terms of:

- Long term data storage
- Remote technical support of equipment
- Managing user access

It also enables remote monitoring of the following:

- Patient results
- Quality control
- Calibration status
- Consumable management
- Supporting audit

All Point of Care equipment in the Trust must be networked if possible so that the benefits of connectivity solutions can be realised. The cost of connectivity will be borne by the point of care site and should form part of the original business case.

5.5 The Introduction of New POCT activities-

Before introducing new POCT activity clinical need should be established by evaluating:

- the critical nature of the result
- potential for improving patient care
- assessment of the laboratory's ability to provide satisfactory turnaround times currently or through process improvements
- demonstration that reliable technology exists
- cost/benefit outcome

A business case should then be drawn up and presented to the POCT governance group for approval using POCDOC19 Application for Point of Care Testing (POCT), provided by the POC team.

5.6 Instrument Selection-

The Point of Care Team must be consulted when point of care sites are considering providing any point of care test. All instruments for POCT must be evaluated by the POCT team with regard to:

- appropriateness for clinical purpose
- risk to patient care optimisation
- analytical proficiency
- technical limits
- ease of use
- correlation of results with those of main laboratory where applicable
- cost effectiveness

5.7 POCT Procedures-

A standard operational procedure (SOP), compliant with ISO 15189/22870 standard requirements must be in place for each POCT performed, and will reference the following

- clinical background
- analytical principle
- health and safety information
- pre-analytical considerations
- equipment
- reagents, standards, controls and quality assurance
- test procedure
- maintenance
- record-keeping
- references

SOPs will be developed by the POCT team and countersigned by clinical leads for their suitability in the intended clinical setting.

5.8 Personnel Considerations-

All users of POCT must be trained and certified, and their competence observed and subject to review. Training should cover pre-analytical, analytical and post-analytical factors and include:

- specimen requirements
- operational factors
- quality assurance and quality control
- Consumable requirements
- health and safety
- appropriate action on obtaining results

On completion of training users will be registered as described in the POCT Training Policy. Users will also be required to sign that they recognise the legal responsibilities of the tests being undertaken. The database of trained and authorised users will be maintained and update training arranged as appropriate from which competency will be assessed.

5.9 Standards/Key Performance Indicators-

5.9.1 Internal Quality Control (IQC)- Performance of IQC is essential to ensure the quality of the results produced are acceptable for patient management.

5.9.2 External Quality Assurance (EQA)- Participation in external quality assessment is mandatory. Records of results and performance will be stored in the scheme web portals, accessible at any time by the POCT team. The cost of EQA material and the monitoring of EQA will be borne by the point of care site and communicated to the user on a regular basis.

5.9.3 Poor Performance- The POCT team will monitor the quality of point of care processes and investigate incidences of poor performance. In the event that poor performance occurs the POCT team will identify the cause, whether process based, equipment error or user error, and act accordingly to restore acceptable performance.

In the event that poor performance remains, due to inappropriate use of equipment or continual poor technique following official training, the POCT team may advise the removal of the point of care process from the point of care site.

5.9.4 Audit- All incidences of poor performance or adverse incidents will be recorded by the POCT team for audit purposes and corrective action. Datix reports shall be raised in line with DCL guidance. Minor incidents shall be recorded by the POCT section and where non-conformance is identified this will be logged in the CAPA module of DCL QMS.

5.10 Maintenance and Repair of POCT Equipment-

Clinical Engineering (formerly MEMS) are not involved in the upkeep of POCT devices.

Users of POCT must follow the manufacturer's recommendations for maintenance as stated in the SOP for that device, and written records of maintenance programmes will be kept by the point of care team for audit purposes. The POCT team may be responsible for maintenance of equipment, arranging service contracts, coordinating service visits, storing service reports and requesting engineer assistance.

The POCT team will coordinate periodic supplier maintenance visits in line with the service contract.

If a point of care device has developed a fault which cannot be addressed by the point of care testing team, the manufacturer or distributor will be contacted by the POCT team to log the fault.

Depending on whether a service contract has been purchased the fault will be rectified in one of the following ways:

- An engineer visit will be arranged who will restore functionality
- The equipment will be returned to the manufacturer for repair
- The manufacturer will provide an alternative device on loan until the fault has been fixed
- The POCT team will make other arrangements to limit the impact of the device not being available, including access to devices of the same type within the organisation.

5.11 POCT Equipment Inventory-

An inventory of all Trust and outlying site POCT equipment is kept electronically by the POCT team. This is in the form of spreadsheets and other electronic solutions such as the eQuip database, which are updated as and when serial numbers or model types are changed or acquired.

All asset numbers, where available and appropriate, are recorded in the spreadsheets along with their location.

5.12 POCT Results-

The user must follow local procedures for the reporting of results which should include:

- reference range
- definition of critical values/phoning limits
- clear definition of action to be taken when abnormal results are obtained
- appropriate documentation with regard to confidentiality and permanency

The UHP POCT service is not fully connected due to the capability of some devices in use.

- Devices connected to middleware, where interfaced, will send results directly to the hospital network IT systems (HIS) and be available to clinical staff for review and action.
- Some non-connected devices will produce a result print out which are recorded in the patient notes and bedside charts.
- Some tests are interpretative and read by eye. These results are recorded in patient notes or result log books provided by the POCT team.

All analyses must be recorded in the patient health record, POCT result logbook or on POCT middleware or electronic patient record. This includes the full range of results obtained regardless of whether the result is normal or abnormal.

Production, handling and storage of patient results are subject to the Data Protection Act (1998). Inappropriate use of or access to patient data is a clear breach of Trust Information Governance policy and the contract of employment.

6 Overall Responsibility for the Document

This document is subject to ratification by a medical director within the trust clinical governance structure.

The development and periodic review of the document is the responsibility of the section lead for POCT. The content of the document is subject to approval by the POCT Governance Group.

7 Consultation and Ratification

The Point of Care Testing Policy is subject to input and approval from the following Groups-

POCT Governance Group

DCL POCT Team

POCT Stakeholders

All issues regarding Point of Care equipment are subject to consultation with the following Groups-

Clinical Engineering

Medical Devices Strategy Group

Ratification of this document is provided by the Medical Director for University Hospitals Plymouth NHS Trust (UHP)

8 Dissemination and Implementation

Following approval and ratification, this policy will be published in the Trust's formal documents library. The POCT team will disseminate the document to users of the service and cover specific elements of the policy during training sessions.

Document control arrangements will be in accordance with The Development and Management of Trust Wide Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document and detail this in the POCT Training Policy.

Implementation of the policy will be driven by the section lead for POCT in partnership with Care Group/Service Line Managers through to Ward Managers and team leads.

It is the responsibility of all Trust staff who engage in POCT activities to be aware of the content of this document, which will be enforced during training sessions provided by the POCT team.

9 Monitoring Compliance and Effectiveness

Compliance with the policy will be monitored through regular audit of point of care processes performed by users covered by the policy. Audits will be conducted as defined in the POCT Audit Policy and managed through the audit calendar in DCL QMS.

Audits will be performed by members of the Point of Care Testing team or individuals appointed by them to conduct them on the team's behalf. The findings of the audit programme will be held electronically within the DCL QMS and the actions generated from these audits raised as non-conformances to be addressed by point of care staff. Root cause will be established and preventive and corrective actions will be taken to avoid recurrence. The extent and impact of the non-conformance will also be considered.

10 References and Associated Documentation

Medical Devices Training Policy (if in use need the reference number)

The Management and Use of Medical Devices as above

POCT Audit Policy

POCT Training Policy

Service Level Agreement for Point of Care Services Are these current? Suspect not so need to re-issue to Care Group level for signing

ISO 22870:2016 and ISO 15189:2012

Dissemination Plan | Appendix 1

Core Information	
Document Title	Point of Care Testing Policy
Date Finalised	07/07/2021
Dissemination Lead	Richard Kua
Previous Documents	
Previous document in use?	YES, For removal immediately upon release of this version
Action to retrieve old copies.	Electronic copy removed from Trust Documents. No paper copies exist.

Dissemination Plan

Recipient(s)	When	How	Responsibility	Progress update
All staff	Oct 2016	Trust Documents	Document Control	
All staff	July 2021	Trust Document Library	Document Control	

Review and Approval Checklist | Appendix 2

Review		
Title	Is the title clear and unambiguous?	Y
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Y
	Does the style & format comply?	
Rationale	Are reasons for development of the document stated?	Y
Development Process	Is the method described in brief?	Y
	Are people involved in the development identified?	Y
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Y
	Is there evidence of consultation with stakeholders and users?	Y
Content	Is the objective of the document clear?	Y
	Is the target population clear and unambiguous?	Y
	Are the intended outcomes described?	Y
	Are the statements clear and unambiguous?	Y
Evidence Base	Is the type of evidence to support the document identified explicitly?	Y
	Are key references cited and in full?	Y
	Are supporting documents referenced?	Y
Approval	Does the document identify which committee/group will review it?	Y
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	Y
	Does the document identify which Executive Director will ratify it?	Y
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Y
	Does the plan include the necessary training/support to ensure compliance?	Y
Document Control	Does the document identify where it will be held?	Y
	Have archiving arrangements for superseded documents been addressed?	Y
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Y
	Is there a plan to review or audit compliance with the document?	Y
Review Date	Is the review date identified?	Y
	Is the frequency of review identified? If so is it acceptable?	Y
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Y

Core Information	
Manager	Tony Cambridge
Directorate	Pathology
Date	July 2021
Title	Point of Care Testing Policy
What are the aims, objectives & projected outcomes?	Point of care testing (POCT) is defined as any analytical test performed by a healthcare professional or non-medical individual outside the conventional laboratory setting. POCT is currently performed in many clinical areas using non-instrumental systems (e.g. urinalysis strips), small analysers (e.g. blood glucose meters) or desktop analysers (e.g. machines for blood gas measurement). The Trust POCT policy aims to safeguard a high standard of care by ensuring that • all POCT in the Trust is regulated • regulated POCT adheres to applicable statutory directives • all staff using POCT are adequately trained and competent and that training is formally recorded However, whilst an individual may take formal charge of a POCT programme, individual users trained and approved for POCT have legal responsibility for the results they produce. Incorrect use of POCT leading to wrong results could have medico-legal implications.

Scope of the assessment
This assessment covers the impact the policy will have on patients and staff.

Collecting data	
Race	There is no evidence to suggest there is a disproportionate impact on race. However, data collection will be monitored through incidents and complaints on Datix. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.
Religion	There is no evidence to suggest there is a disproportionate impact on religion and belief. However, data collection will be monitored through incidents and complaints on Datix. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.

Disability	There is no evidence to suggest there is a disproportionate impact on disability. Consideration for reasonable adjustment requests from staff for training will be made. Data collection will be monitored through incidents and complaints on Datix. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.
Sex	There is no evidence to suggest there is a disproportionate impact on sex. However, data collection will be monitored through incidents and complaints on Datix. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.
Gender Identity	There is currently no data collected for this area, however, data collection will be monitored through incidents and complaints on Datix.
Sexual Orientation	There is no evidence to suggest there is a disproportionate impact on sexual orientation. However, data collection will be monitored through incidents and complaints on Datix. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.
Age	There is no evidence to suggest there is a disproportionate impact on age. However, data collection will be monitored through incidents and complaints on Datix. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.
Socio-Economic	There is currently no data collected for this area, however, data collection will be monitored through incidents and complaints on Datix.
Human Rights	There is no evidence to suggest that there is a disproportionate impact on human rights regarding this policy
What are the overall trends/patterns in the above data?	There is no data or trends identified at this time
Specific issues and data gaps that may need to be addressed through consultation or further research	There is no data currently collected for gender identity or socio-economic
Involving and consulting stakeholders	
Internal involvement and consultation	Previous consultation with internal stakeholders. This version 6 is an interim version and the next ratified document will go through full stakeholder consultation
External involvement and consultation	No external consultation was undertaken on this version
Impact Assessment	

Overall assessment and analysis of the evidence	Consideration for reasonable adjustment requests from staff for training will be made. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.

Action Plan

Action	Owner	Risks	Completion Date	Progress update