

## Point of Care Testing Policy

Date	Version
Jan 2017	5.2

**Purpose**

Plymouth Hospitals NHS Trust expects all Point of Care Testing to be carried out in a controlled manner, 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 (POCT) as part of their normal duties. Senior staff involved in the development and procurement of point of care testing new 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**

<b>Production</b>	The Point of Care Testing Section
<b>Review and approval</b>	The Point of Care Testing Governance Group
<b>Ratification</b>	Medical Director
<b>Dissemination</b>	The Point of Care Testing Governance Group
<b>Compliance</b>	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	23 <sup>rd</sup> January 2009	Approved by the Clinical Governance Steering Group
2	19 <sup>th</sup> August 2011	Document reviewed. Document Control and Monitoring Compliance Sections added
3	12 <sup>th</sup> 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

<b>5</b>	January 2017	Version adjusted for changes in since January 2014
<b>5.1</b>	March 2019	Extended for 12 months
<b>5.2</b>	November 2019	Extended to January 2021
<b>Last Approval</b>		<b>Due for Review</b>
January 2017		Extended to January 2021

*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.**

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## 1 Introduction

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). Advances in technology are eliminating the need for sample preparation procedures and allowing the use of whole blood for analysis and it is likely that the demand for and scope of POCT will increase.

## 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 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.

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 and, under the Consumer Protection Act (1987), the use of instruments for purposes other than those for which they were intended can lead to liability transfer from manufacturer to user.

## 3 Definitions

**Point of Care testing Clinical Lead-** A clinical biochemist or chemical pathologist who is in charge of the clinical effectiveness of the section 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 minimise health and safety and operational risk.

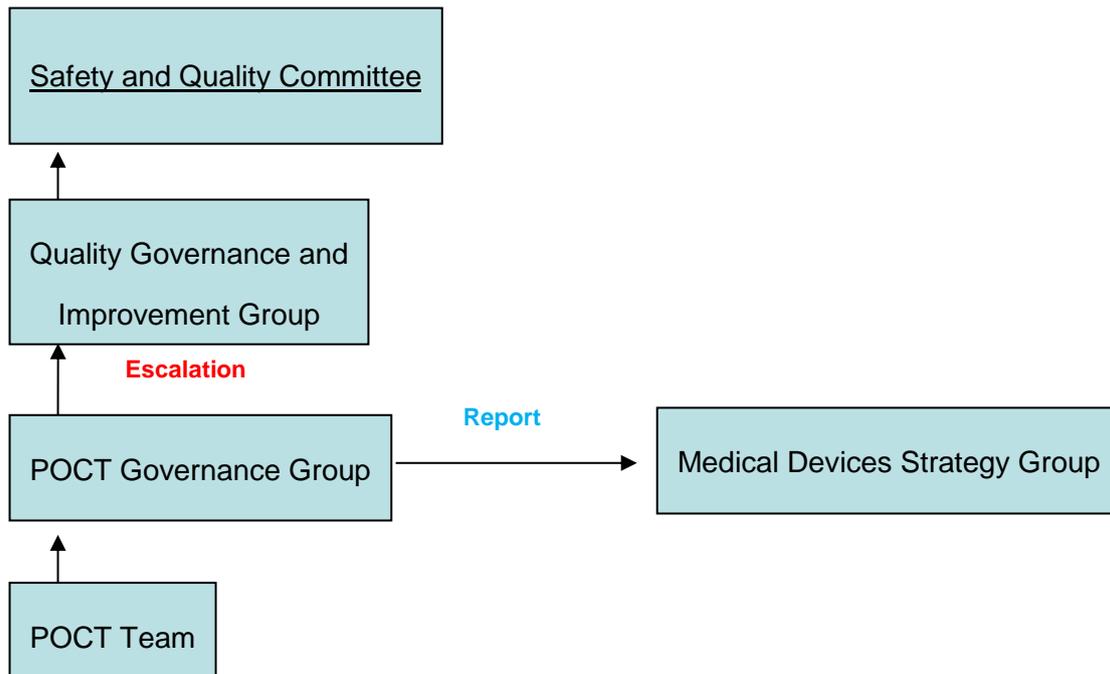
Note: There can be no other POCT sections, clinical leads or governance groups apart from the one established and based in DCL. Only the decisions and actions of this group are binding and covered by the authority of this policy.

#### 4.1 The Point of Care Testing Governance Group-

The POCT Governance Group was created in order to address issues with 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 and midwifery, paediatric care, maternity services, training and development and ward managers.

The group meets every two 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 our point of care sites and to approve or reject new POCT proposals.



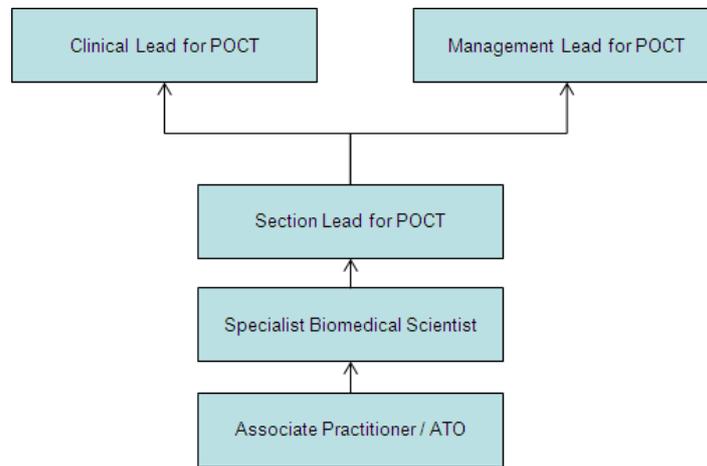
The clinical governance structure within the trust is constantly evolving and is currently under review. The POCT governance group escalates any serious POCT governance issues to the Quality, Governance and Improvement Group as detailed above.

#### 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 22870:2006 and ISO 15189:2012 and Trust Clinical Governance guidelines.

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 agreed through service level agreement the team will also support equipment placed in primary care. The point of care user will be responsible for the general upkeep and condition of the equipment.

The team is available between 09.00hrs and 17.30hrs Monday to Friday and can be contacted on ext. 52299.

## 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:

- Establish 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 comparisons of the point of care analytical method with the traditional laboratory method
- Liaise with Procurement in the purchase of new equipment to include tender processes
- Liaise with the suppliers and arrange installation
- Provide technical support and perform maintenance where appropriate
- Organise and/or perform training for POCT users
- Ensure trained staff are competency assessed on a regular basis
- Keep up to date records of staff training
- 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.
- Provide feedback and act on poor performance. Repeated poor performance will be reported to the Quality Governance and Improvement Group and could result in the removal of POCT equipment/tests.

- Manage standing orders and/or provide information for ordering 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 record sheets, reagent log sheets, quality control log sheets, quick guides etc.
- Perform audit of point of care processes
- Provision of these services is dependent on the signing of a Service Level Agreement (SLA).
- No POCT equipment must 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.

**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 and the support of the Medical Director to remove POCT devices and consumables where these are in use but not agreed with the POCT governance group.**

## **5.2 Supporting Documentation-**

A number of documents including quick guides, SOPs and control of substances hazardous to health (COSHH) documents are available on .

Navigate as follows:

**Open Internet Explorer > Click on Staffnet > Click on the ‘Departments’ drop down menu > Click on/Hover over ‘Plymouth Hospitals Departments [O-Z]’ > Click on ‘Pathology’ > Select the Pathology Point of Care Testing page.**

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 suitable 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. This will include the POCT team raising requisitions using the point of care site budget centre. 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 on the Combined Laboratory IT system. 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 the Combined Laboratory.

The cost of the services provided by the POCT section will be cross charged to the point of care site as set out in the SLA.

Through SLA, the external sites covered by the service will be subject to the same governance, quality and safety measures applied within the Trust. Clinical and managerial support will be available to these external sites in order to deliver the service in locations beyond the Trust.

## **5.4 Connectivity-**

The introduction of connectivity solutions within the Trust and primary care is a necessity for the effective monitoring of equipment and timely response for analyser support. It also offers greater functionality in terms of:

- Long term data storage
- Remote technical support of equipment
- Trained user password feature

It also enables remote monitoring of:

- Patient results
- Quality control
- Calibration status
- Consumables
- 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 plan.

## **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 laboratories ability to provide satisfactory turn-around-times currently or through improvement
- 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.

## **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 laboratory with regard to:

- appropriateness for clinical purpose
- analytical proficiency
- technical limits
- ease of use
- correlation of results with those of main laboratory
- cost effectiveness

The POCT team must countersign/authorise any purchase of Trust POCT equipment/reagents.

## **5.7 POCT Procedures-**

A standard operational procedure (SOP), written to ISO 15189 standards must be in place for each POCT performed, and will include

- clinical background
- analytical principle
- health and safety information
  - information on COSHH (control of substances hazardous to health)
  - safe disposal of waste
  - control of infection
  - adverse incident reporting
- pre-analytical considerations
- equipment
- reagents, standards, controls and quality assurance
- test procedure
- sample analysis
- calculation of results
- assay performance
- maintenance
- record-keeping
- references

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

## **5.8 Personnel Considerations-**

All users of POCT are trained and certified and their performance subject to review. Training should cover pre-analytical, analytical and post-analytical factors and include:

- specimen collection
- operational issues
- quality assurance
- health and safety
- appropriate action on obtaining results

On completion of training users will be registered on the Trust approved Oracle Learning Manager (OLM) database. 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. The cost of IQC material will be borne by the point of care site.

**5.9.2 External Quality Assurance (EQA)-** Enrolment in external quality assessment is required. Records of results and performance will be stored in the Point of Care office in the Combined Laboratories. The cost of EQA material and the monitoring of EQA will be borne by the point of care site.

**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. Datix reports shall be raised if appropriate. Minor incidents shall be logged by the POCT section.

## **5.10 Maintenance and Repair of POCT Equipment-**

Users of POCT must follow the manufacturer's recommendations for maintenance and written records of maintenance programmes should be kept at the point of care site for audit purposes. Where stipulated in the SLA the POCT team may be responsible for maintenance of equipment, arranging service contracts, coordinating service visits, storing service reports and requesting engineer assistance.

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

### **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 documents 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 produce written 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

All analyses must be recorded in the patient health record, POCT result logbook or on laboratory IT or electronic patient record.

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 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 of the document is the responsibility of the section lead for POCT. The content of the document will be developed by the POCT Governance Group.

The Executive Member (Chair) of the POCT Governance Group will submit the document to the Quality Governance and Improvement Group or Medical Director for approval.

## **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

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

Quality Governance and Improvement Group

Medical Devices Strategy Group

## **8 Dissemination and Implementation**

Following approval and ratification, this policy will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

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 with the named Executive Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

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.

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.

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 Combined Laboratory quality database and the actions generated from these audits will be carried out by point of care staff. Preventive and corrective actions will be recorded on the quality database also.

Audits will include compliance with quality programmes, maintenance and upkeep of equipment, recording of patient results, reporting of problems through Datix or to the POCT team and involvement of the POCT team in developing new services. The failure to comply with the policy may result in reports being presented to the Effective Care Group or the POCT Governance Group for action. The effectiveness of the policy and point of care issues are discussed at the Point of Care Testing Team meetings and the Point of Care Testing Governance Group meetings which are held on a regular basis.

## **10 References and Associated Documentation**

Medical Devices Training Policy

The Management and Use of Medical Devices

POCT Audit Policy

POCT Training Policy

Service Level Agreement for Point of Care Services

ISO 22870:2006 and ISO 15189:2012

<b>Core Information</b>				
<b>Document Title</b>	Point of Care Testing Policy			
<b>Date Finalised</b>	11 October 2016			
<b>Dissemination Lead</b>	Richard Kua			
<b>Previous Documents</b>				
<b>Previous document in use?</b>	YES, For removal immediately upon release of this version			
<b>Action to retrieve old copies.</b>	Electronic copy removed from Trust Documents. No papy copies exist.			
<b>Dissemination Plan</b>				
<b>Recipient(s)</b>	<b>When</b>	<b>How</b>	<b>Responsibility</b>	<b>Progress update</b>
All staff	Oct 2016	Trust Documents	Document Control	

Review		
<b>Title</b>	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?	
<b>Rationale</b>	Are reasons for development of the document stated?	Y
<b>Development Process</b>	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
<b>Content</b>	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
<b>Evidence Base</b>	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
<b>Approval</b>	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
<b>Dissemination &amp; Implementation</b>	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
<b>Document Control</b>	Does the document identify where it will be held?	Y
	Have archiving arrangements for superseded documents been addressed?	Y
<b>Monitoring Compliance &amp; Effectiveness</b>	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
<b>Review Date</b>	Is the review date identified?	Y
	Is the frequency of review identified? If so is it acceptable?	Y
<b>Overall Responsibility</b>	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Y

Core Information	
<b>Manager</b>	Anthony Cambridge
<b>Directorate</b>	Pathology
<b>Date</b>	11 October 2016
<b>Title</b>	Point of Care Testing Policy
<b>What are the aims, objectives &amp; projected outcomes?</b>	<p>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). Advances in technology are eliminating the need for sample preparation procedures and allowing the use of whole blood for analysis and it is likely that the demand for and scope of POCT will increase.</p> <p>The Trust POCT policy aims to safeguard a high standard of care by ensuring that</p> <ul style="list-style-type: none"> <li>• all POCT in the Trust is regulated</li> <li>• regulated POCT adheres to applicable statutory directives</li> <li>• all staff using POCT are adequately trained and that training formally recorded</li> </ul> <p>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 and, under the Consumer Protection Act (1987), the use of instruments for purposes other than those for which they were intended can lead to liability transfer from manufacturer to user.</p>
Scope of the assessment	
This assessment covers the impact the policy will have on patients and staff.	
Unable to show data	
Collecting data	
<b>Race</b>	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.
<b>Religion</b>	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.

<b>Disability</b>	<p>There is no evidence to suggest there is a disproportionate impact on disability.</p> <p>Consideration for reasonable adjustment requests from staff for training will be made.</p> <p>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 &amp; diversity.</p>
<b>Sex</b>	<p>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 &amp; diversity.</p>
<b>Gender Identity</b>	<p>There is currently no data collected for this area, however, data collection will be monitored through incidents and complaints on Datix.</p>
<b>Sexual Orientation</b>	<p>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 &amp; diversity.</p>
<b>Age</b>	<p>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 &amp; diversity.</p>
<b>Socio-Economic</b>	<p>There is currently no data collected for this area, however, data collection will be monitored through incidents and complaints on Datix.</p>
<b>Human Rights</b>	<p>There is no evidence to suggest that there is a disproportionate impact on human rights regarding this policy</p>
<b>What are the overall trends/patterns in the above data?</b>	<p>There is no data or trends identified at this time</p>
<b>Specific issues and data gaps that may need to be addressed through consultation or further research</b>	<p>There is no data currently collected for gender identity or socio-economic</p>
<b>Involving and consulting stakeholders</b>	
<b>Internal involvement and consultation</b>	<p>Discussion with GU health about providing governance to external organisations. (including voluntary sector)</p>
<b>External involvement and consultation</b>	<p>No external consultation was undertaken on this policy</p>
<b>Impact Assessment</b>	

<b>Overall assessment and analysis of the evidence</b>	<p>Consideration for reasonable adjustment requests from staff for training will be made.</p> <p>Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality &amp; diversity.</p>
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<b>Action Plan</b>				
Action	Owner	Risks	Completion Date	Progress update