Management of Point Of Care Testing (POCT) Devices Policy

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<th>Policy and Guideline Committee</th>
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**REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW**

August 2018 – review of V2, The policy has been completely rewritten to reflect current practice.

**KEY WORDS**

Point of Care Testing (POCT)
Near Patient Testing (NPT)
Medical Devices
Medical Equipment Management Service (MEMS)
1 INTRODUCTION AND OVERVIEW

1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trusts Policy and Procedures for the management of Point of Care Testing (POCT) devices.

1.2 POCT devices are used widely across UHL for diagnosis, monitoring and treatment. The aim of this policy is to ensure that POCT devices are subject to well governed processes to maximise benefits to the patients and minimise risks.

1.3 The Trust staff must comply with this policy and standards for the management of POCT devices.

1.4 This document provides a working directive for all areas that use POCT in their clinical management of patients thereby reducing the risk to patients and staff. This document sits in line with directives as outlined by the Medicines & Healthcare products Regulatory Agency (MHRA) and ISO Standards 15189 and 22870 and must be adhered to protect users and patients.

2 POLICY SCOPE —WHO THE POLICY APPLIES TO AND ANY SPECIFIC EXCLUSIONS

2.1 This policy applies to all staff users employed across UHL including bank staff and agency staff that are involved in the use and management of POCT devices and have received the appropriate training and assessed as competent to undertake this role.

2.2 This policy applies to all managers within their responsible clinical areas to ensure there is a governance process in place to monitor and audit compliance against this policy.

2.3 All staff using any any Point of Care device within UHL must be trained and competent to use them, and the evidence must be held by the Clinical/ward Manager in the clinical area.

2.4 This policy does not include any POCT Systems in the Alliance, primary care or in the community, although there may be scope to include these in the future.

2.5 This policy does not cover equipment for patient or patients’ relative self-monitoring POCT devices or any patients “own personal” POCT devices.

3 DEFINITIONS AND ABBREVIATIONS

a) A medical device is defined under EC directive 2007/47/ec as: “any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software intended by its manufacture to be used for human beings.”

b) Point of care testing device or “Near-patient testing” device is defined by Medicines and Healthcare products Regulatory Agency (MHRA) as: “any analytical test performed by a healthcare profession or non-medical individual outside the conventional laboratory setting.”

c) Single use device is the term used to describe any medical device intended to be used on an individual patient during a single procedure and then discarded. Items labelled or recommended by the manufacturer as single use must not be reprocessed and used on another patient.
d) **Medical Equipment Management Services (MEMS)** provide comprehensive technical support for medical equipment.

e) Medicines and Healthcare products Regulatory Agency (MHRA) is the governing body that advises the safe and correct use of POCT devices.

f) United Kingdom Accreditation Service (UKAS) is the accreditation body which assesses all Pathology departments to ensure adherence to the international standard ISO 15189:2012. They also outline POCT terms (ISO 22870:2016).

g) **Whole Life Costs** is the term used to describe all the costs associated with owning a piece of medical equipment; e.g. maintenance, consumables, training, as well as initial procurement of the actual device.

h) Internal Quality Control (IQC) is a method using control material of a known measure and concentration to test if a POCT device is operationally sound. These are ideally done on a daily basis or at least prior to the use of a device.

i) External Quality Assurance (EQA) is sent out by the POCT Team usually on a monthly or bi-monthly and it determines the safe operation of a POCT Device from operator to result. It also compares the result to other users across the UK.

### 4 ROLES – WHO DOES WHAT

#### 4.1 Executive Team

a) The **Medical Director** is responsible at Board Level for the management of medical devices throughout the Trust. The Medical Director acts in the role of Executive Lead for CQC and the Medical Equipment Executive (MEE) Committee.

b) The **Executive Team** will take responsibility for POCT devices in this policy. Issues relating to POCT will be reported to the executive team via the Executive Quality Board (EQB).

#### 4.2 UHL Committee (Medical Equipment Executive)

a) Providing assurance to the Trust that CQC Standards and MHRA guidelines relating to medical devices are being achieved. The Medical Equipment Executive is chaired by a senior clinician, with delegated authority from the Medical Director.

b) Identifying risks associated with the use of medical devices reported by the POCT Committee.

c) Supporting POCT Committee with issues relating to POCT devices and where required informing the Executive team of issues requiring their support.

#### 4.3 UHL POCT Committee (Point Of Care Testing)

a) Providing assurance to the Medical Equipment Executive that CQC standards and MHRA guidelines relating to POCT devices are being achieved. The POCT Committee is chaired by a senior clinician, with delegated authority from the Medical Director.

b) Identifying risks associated with the use of POCT devices.
c) Referring all issues relating to infection, prevention and control to the Infection Prevention Committee structure.

d) Advising the Trust on the device selection, procurement, maintenance, quality control (QC) and external quality assurance (EQA).

e) The periodic review of the POCT policy and the POCT Committee terms of reference (See Appendix 1).

f) Ensuring that the POCT policy is adhered to and followed when devices are being requisitioned and to ensure that POCT adds to the patient pathway by ensuring clinical effectiveness.

g) Overseeing the POCT working group to ensure all aspects of POCT within the organisation are included and to ensure compliance with external standards, with this group reporting to the POCT Committee and MEE.

h) Ensuring no POCT equipment is purchased or procured without the agreement of the POCT committee.

i) Removing any POCT device that have not been approved or managed by the POCT Committee following the event of an untoward incident involving that device. will be captured on the Datix system. The POCT Committee will have the authority and support of the Medical Director. Relevant risk assessment will be carried out before this action and will be discussed with CMG Directors and Heads of Nursing.

j) On discovery on the POCT device is not approved or managed correctly, a risk assessment must be carried out for devices to be approved by the POCT Committee. In the event of untoward incident reported as per Datix policy.

4.4 POCT Clinical Lead and POCT Manager is responsible for:

a) Liaising with users and manufacturers in the purchasing of new POCT devices.

b) Taking the lead for training of users (initial and competency).

c) Implementing, enrolling and managing of POCT EQA programmes.

d) Reviewing performance of IQC and EQA for POCT devices.

e) Organising and managing corrective and preventative actions as required to ensure optimum analytical performance of POCT devices.

f) Managing and control documentation and its review and update.

g) Managing procurement and selection of POCT devices.

h) Linking with the Clinical Management Group (CMG) Quality and Safety Board meetings.

4.5 Clinical Management Group (CMG) Clinical Directors, Heads of Operations and Heads of Nursing are responsible for ensuring the requirements of this policy are met and that staffs within their teams comply at all times. CMG senior managers are responsible for:

a) Ensuring equipment is procured in accordance with the Trust’s purchasing policy and procedures and is selected following approval by the POCT Committee for clinical suitability, quality and safety, and “whole life” costs.
b) Ensuring POCT devices intended for use on more than one patient must be decontaminated in line with the UHL Cleaning and Decontamination Policy B5/2006.

c) Ensuring POCT devices are used only by staff that have trained and been assessed as competent.

d) Ensuring copies of staff training records are sent to the POCT Team who must hold a central bank for all those trained.

e) Ensuring that there is appropriate focus within their CMG division and as advised by the MHRA, have a nominated individual within each CMG as a POCT Champion.

f) Ensuring safety information, adverse incidents, faulty products, recalls and MHRA alerts and bulletins are actioned and communicated to all relevant staff and acted upon in a timely manner.

g) Ensuring action is taken to address adverse incidents involving POCT devices in line with the UHL Policy for Management of Patient and Staff Safety A10/2002.

h) Ensuring faulty re-usable POCT devices are cleaned and decontaminated as set out in Cleaning and Decontamination for Infection Control UHL Policy B5/2006 and sent for repair to the medical equipment management service (MEMS) or POCT Team with a completed decontamination certificate that includes all relevant information to enable identification of the fault.

i) Ensuring the POCT device is CE marked and consumables are compliant with current health and safety legislation.

j) Ensuring that training records for service users are kept in the Ward Managers Office to evidence which staff are trained to use POCT devices. The folders will be provided by the POCT Team. This will be risk assessed and discussed with speciality Head of Service / CMG Clinical Director before the device is removed.

4.6 Line Managers are responsible for:

a) Arranging technical support from the Supplier or MEMS and ensure maintenance checks are being monitored where appropriate.

b) Ensuring all staff that use POCT devices are trained. (also see section 5.7 and 6)

c) Ensuring that training records are available and up to date evidencing that staff are trained to use POCT devices.(also see section 5.7 and 6)

d) Ensuring all trained staff is competency assessed every three years in line with the Core Training Policy For Statutory, mandatory and Essential to Job role Training (B21/2005).

4.7 Clinical and Non-Clinical POCT Staff Users are responsible for:

a) Ensuring they are appropriately trained and assessed as competent in the use of POCT devices. Staff must not use a POCT device if they are not competent to do so.
b) Ensuring POCT Devices are appropriately stored when not in use to avoid any damage to the equipment.

c) Ensuring they follow the Trust’s decontamination procedures after use, between patients and prior to equipment being returned for repair or calibration.

d) Reporting any problems or issues with POCT devices to the MEMS or POCT Team.

e) Ensuring personal passwords or individual POCT barcodes are not shared with other staff and understanding their responsibility for adhering to this principle.

f) Ensuring procedures for POCT devices are followed as described in the Standard Operating Procedure (SOP) and Quick Guides.

g) Ensuring all generated patient results and quality control results are documented appropriately in the notes or logbooks.

h) Ensuring the responsible clinician or test requestor is notified of the test result.

i) Ensuring all adverse incidents is reported into the Datix incident reporting system and informing the line manager who will escalate to the POCT Team.

4.8 Medical Physics are responsible for:

a) Administering the asset inventory management system (AIMS).

d) Ensuring renewal for maintenance contracts relating to POCT devices.

e) Medical physics providing advice on training and development related to POCT Devices

BLOOD GAS ANALYSERS ONLY

b) Delivering first line support for the blood gas analysers during normal working hours.

c) Ensuring on-call support for specific blood gas analysers, out of hours.

4.9 Pharmacy is responsible for:

a) Overseeing the ordering, handling and distribution of some POCT reagents and consumables.

b) Liaising with users regarding the ordering and distribution of specific POCT reagents and consumables.

c) Liaising with the POCT Team for acceptance testing of reagents where appropriate.

4.10 Information Technology (IT) is responsible for:

a) Providing support for the use of IT systems used within Pathology and POCT including but not limited to Qpulse, ICE and AQure.

b) Upholding the service level agreement between Pathology and Trust IT.
5. POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS

5.1 The Point of Care Team

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

a) Establish the clinical need for POCT at the site
b) Advise in the selection of appropriate equipment including whether the equipment is fit for purpose
c) Advise a suitable environment for placing the equipment
d) Perform a comparison of the point of care analytical methods with the traditional laboratory method or existing POCT method
e) Liaise with Procurement in the purchase of new equipment including the tender process.
f) Liaise with the Suppliers and arrange installation of the devices
g) Provide technical support and perform maintenance where appropriate
h) Organise and/or perform training for POCT users
i) Ensure trained staff is competency assessed
j) Keep up to date records for staff training
k) Monitor Internal Quality Control (IQC)
l) Ensure External Quality Assurance (EQA) is performed and monitor performance.
m) Provide feedback and act on poor performance. Any repeated poor performance will be reported to the responsible person of the clinical area and could result in the removal of POCT device
n) Manage standing orders and/or provide information for ordering consumables.
o) Provide all documentation required for point of care testing including Standard Operating Procedure (SOPs), training record templates, database management, competency assessment, patient results record sheets, reagent log sheets, quality control log sheets and quick guides.
p) Perform audits on effectiveness of point of care processes.

5.2 Supporting Documentation

a) All documentation including quick guides and manufacturer manuals are available from the POCT Team.

5.3 Connectivity

a) 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

b) It also enables remote monitoring of:

- Patient results
- Quality control
- Calibration status
- Consumables
- Audit

c) All Point of Care devices across the Trust must be networked where possible so that the benefits of connectivity solutions can be realised. The cost of connectivity will be borne by the point of care area and should form part of the original business case.

5.4 The Introduction of New POCT activities

a) Before introducing new POCT device/activity the clinical need should be established by evaluating:

- 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

The application process for new or replacement point of care testing device must be followed by the requestor (see Appendix 2).

A Trust business case should then be drawn up and presented to the POCT Committee.

b) A proposal form for any new POCT device will need to be completed by the requester (see Appendix 3) and then submitted with any supporting documentation to the POCT Team for Committee approval. The final decision for approval may include other groups such as Trusts Revenue and Capital Investment Committees.

5.5 POCT Device Selection

a) The POCT must be consulted when clinical areas are considering providing any point of care test. All POCT devices must be evaluated by the POCT team with regard to:

- appropriateness for clinical purpose
- analytical proficiency
- technical limits
- ease of use
- correlation of results with those of main Pathology laboratory or current POCT device
- cost effectiveness
training requirements

5.6 POCT Procedures

a) A standard operational procedure (SOP), written to UKAS ISO 15189 and ISO 22870 standards must be in place for each POCT device, and will include

- clinical background
- analytical principle
- manufacturer instructions
- health and safety information
  - information on COSHH (control of substances hazardous to health)
  - safe disposal of waste
  - control of infection
  - adverse incident reporting
  - risk assessment of patient harm prior to POCT use.

- pre-analytical considerations
- equipment
- reagents, standards, controls and quality assurance
- test procedure
- sample analysis
- calculation of results
- assay performance
- maintenance and calibration
- record-keeping
- references

b) SOPs will be developed by the POCT team and approved by the POCT clinical lead for their suitability in a clinical setting.

5.7 Personnel Considerations

a) All users of POCT must be trained in the use of any POCT Devices and deemed as competent. (Also see section 6) 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

b) On completion of training users all training will be recorded on HELM learning management system.

c) Users will also be required to complete and sign the POCT training form for evidence that training was delivered, received and accepted. The competency will be undertaken by the POCT Team, or Line Manager.

d) The POCT database of trained and authorised users will be maintained in a clearly identifiable folder located in the ward managers office. Any
update training will be arranged as deemed appropriate from which competency will then be assessed.

5.8 Quality Standards

a) Internal Quality Control (IQC) - Performance of IQC is essential to ensure the quality of the results produced is acceptable for patient management. The cost of IQC material will be borne by the point of care clinical area.

b) External Quality Assurance (EQA) - Enrolment in external quality assurance is required. Records of results and performance will be stored in the Point of Care office. The cost of EQA material and the monitoring of EQA will be borne by clinical area.

c) Device 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. Datix reports must be submitted.

If in the event that poor performance remains due to inappropriate use of equipment or continual poor technique, the POCT team will provide further training and competency assessment.

d) Device Audit- All incidences of poor performance or adverse events will be recorded by the POCT team for audit purposes. Datix reports must be submitted.

5.9 Maintenance and Repair of POCT Equipment

a) Users of POCT must follow written SOP procedures and quick guides for guidance on how to perform the daily, weekly and monthly maintenance.

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

c) 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 Results

a) Any POCT result produced should be acted upon appropriately as stated in local SOP or guidelines and documented into the patient health record.

b) The user must follow written SOP procedures and Trust Policy for the Management of Diagnostic Testing Procedures (Trust reference B7/2013) for the reporting of results which should include:
   - reference range of measurement
   - definition of critical values and limits
   - clear definition of action to be taken when abnormal results are obtained.
   - appropriate documentation with regard to confidentiality and permanency.

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

d) Production, handling and storage of patient results are subject to the Trust Information Policy B4/2004. Inappropriate use of or access to patient data is a clear breach of Trust policy and the contract of employment.

6 EDUCATION AND TRAINING REQUIREMENTS

a) Only users who are trained and competent will be permitted to use the relevant POCT device.

b) Device training is therefore mandatory for staff that are identified as users of the POCT device. To ensure safety and quality, the training records must be kept by the line manager and be readily available within the clinical area that the POCT device is to be used. The POCT Team will keep copies of the completed training forms.

c) A central training register for each clinical location and POCT device must be kept valid and available for inspection at any time. This will be kept in the POCT office in pathology.

d) The Line Manager for each clinical area with POCT device(s) must take responsibility for ensuring staff using the device are trained and maintain competency with competency re-assessment dates established.

e) Discussion and identification of any training and competency assessments required for POCT users will be included in their annual appraisal.

f) Training requirements will form part of the standard POCT application process and will be integrated in the tender process for procuring any new POCT devices.

7 PROCESS FOR MONITORING COMPLIANCE

7.1 Monitoring

The POCT Committee is responsible for monitoring compliance with this policy. The procurement team are responsible for ensuring that no new devices are procured without the formal approval of the POCT Committee. Once a new
service is in place the POCT Team are responsible for the quality management of the service and compliance with the POCT Policy.

7.2 Audit

The POCT Team with the assistance from the Pathology Service are responsible for the auditing of the POCT Service. An internal audit programme is scheduled throughout the year using the Pathology document management system Q-Pulse.

7.3 Feedback

a) Audit results are reported to the POCT Committee through their bi-monthly meetings. Small non-compliances are managed by the POCT Committee who is responsible for drawing up an action plan to address these and report them to the Medical Equipment Executive Board (MEE) if urgent action is required.

b) The results from the monitoring and audit will be presented to the MEE Board in a quarterly report. The report will include details of current monitoring and audit results, any identified areas of good practice, improvements and any deficiencies. It will include the suggested recommendations and an action plan, any deficiencies identified, with named staff leads and timescales.

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<tr>
<th>Element to be monitored</th>
<th>Lead</th>
<th>Tool</th>
<th>Frequency</th>
<th>Reporting arrangements</th>
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<tr>
<td>All devices to be recorded on Medical Physics equipment AIMS database. (additions, disposals and transfers)</td>
<td>POCT Team / Medical Physics</td>
<td>AIMS (electronic system)</td>
<td>Monthly</td>
<td>POCT Lead / Team to work with Assigned leads for each clinical area. List to be updated monthly.</td>
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<tr>
<td>No new POCT device to be purchased without going through POCT process</td>
<td>POCT Team / Medical Physics / Procurement system</td>
<td>Procurement system</td>
<td>Bi-Monthly</td>
<td>POCT Lead / Team to work with leads for each clinical area New POCT devices</td>
</tr>
<tr>
<td>Reduction in the number of incident /serious untoward incidents relating to POCT device results</td>
<td>POCT Committee Chairperson / all device users</td>
<td>Incident database (DATIX)</td>
<td>On-going / six monthly review</td>
<td>Any patient safety issues or clinical governance issues to be discussed at POCT Committee and communicated to EQB via MEE.</td>
</tr>
<tr>
<td>Local Audits on POCT Devices</td>
<td>POCT Team Pathology Services</td>
<td>Q-Pulse system</td>
<td>Quarterly</td>
<td>Audit results are reported to the POCT Committee to develop an action plan to address any non-compliance. Any urgent action required to be communicated to MEE.</td>
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8 EQUALITY IMPACT ASSESSMENT

a) The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
b) As part of its development, this policy and its impact on equality has been reviewed and no detriment was identified.

## 9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES


Medicines and Healthcare products Regulatory Agency; Device Bulletin: Management and Use of IVD Point of Care Test Devices; DB2010 (02); February 2010.

www.mhra.gov.uk/home/groups/dts bi/documents/publication/con071105.pdf

www.mhra.gov.uk/Publications/Postersandleaflets/CON008382


Point of Care Testing (Near Patient Testing) Guidance on the Involvement of the Clinical Laboratory. IBMS guidance from IBMS website.

The Royal College of Pathologists: Guideline on point of care testing April 2004. Additional Standards for Point of Care Testing (POCT) Facilities from CPA (UK) Ltd. From www.cpa-uk.co.uk

A practical Guide to Point of Care Testing from NHS Improvement Website.

UHL Medical Devices Policy (Trust Ref B26/2005)

UHL Risk Management Policy (Trust Ref A12/2002)

Information Governance UHL Policy (Trust Ref B4/2004)

UHL Cleaning and Decontamination for Infection Control Policy (Trust Ref B5/2006).

UHL Policy for Management of Patient and Staff Safety (Trust Ref A10/2002).

Additional Standards for Point-of-Care Testing (POCT) Facilities; Clinical Pathology Accreditation (UK) Ltd v1.01 Nov 2010

Assortment of Point of Care Testing Policies from various NHS Trusts from UK, including 2008 Management of POCT devices policy from Nottingham University Hospitals (NUH) and Point of Care Testing Policy 2017 Plymouth Hospitals NHS Trust.

## 10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

a) This rewritten new policy will be reviewed in 18 months following approval or in response to any clinical risks identified to and by the POCT Committee.
b) The updated version of the Policy will then be uploaded and available through INsite Documents and the Trust’s externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system.

c) Previous electronic versions are archived on ‘Sharepoint’. Staffs working at the local level are responsible for destroying paper copies of previous iterations of this policy.
# UHL Committee (POCT) Terms of Reference

<table>
<thead>
<tr>
<th>Title</th>
<th>POCT Committee Terms of Reference</th>
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<tr>
<td><strong>Purpose</strong></td>
<td>The primary purpose of the Point of Care Testing Committee is to ensure good clinical and laboratory practice in POCT, which includes any analytical test performed outside the conventional laboratory setting.</td>
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| **Key responsibilities** | 1.1 Acting as a multidisciplinary forum to discuss POCT issues and co-ordinate proposed actions, recommendations and representations.  
1.2 Determining if POCT is justified at a particular location or for a particular application, by demonstration of clinical benefits over alternative options.  
1.3 Actively assessing and promoting new patterns of service, including POCT, when benefits to the Trust have been objectively established.  
1.4 Ensuring all POCT equipment (analysers/devices and consumables) are approved by the committee and fit for purpose.  
1.5 Taking steps to notify those responsible for unsafe or ineffective POCT procedures and escalating significant risks via the Trust Quality and Performance review group.  
1.6 Establishing systems for continuing audit and assessment of POCT.  
1.7 Acting as a communication channel between users of POCT and senior professionals and managers, to ensure all are aware of issues affecting good practice and quality of service.  
1.8 Establishing and maintaining systems of accountability for users of POCT.  
1.9 Liaising and making representations to the community, primary care, patients and manufacturers as appropriate, to promote good practice.  
1.10 Ensuring that all users are appropriately trained and accredited for use of specific POCT applications. Training will include all contra-indications and limitations of POCT applications.  
1.11 Ensuring that appropriate internal quality control (IQC) and external quality assessment (EQA) schemes are employed effectively and ensuring that POC equipment meets the requirements of such quality assurance schemes.  
1.12 Ensuring funding mechanisms for training, quality assurance and maintenance of POCT, are included, preferably as part of the procurement process.  
1.13 Acting as a channel for notification of defects in POCT devices to the MHRA via Trust procedures and, alongside other Trust management channels, in the dissemination of information about MHRA/DH Hazard notices. |
## Membership

Appropriate representation from clinical areas and CMGs using POCT including:

- Medical Consultants
- Nursing Managers
- Nursing Sisters/Educators /Specialist Nurses

Representatives and or co-opted membership of departments providing technical support for POCT, including:

- Department of Chemical Pathology and Metabolic Disease
- Haematology Department
- Microbiology Department
- Pharmacy Department
- Medical Physics Department
- Supplies Department
- Procurement and finance
- IT Department
- Patient Representative

In addition to formal and co-opted membership listed above, the POCT committee will work in close collaboration with the:

- UHL Infection Control Team
- Primary Care Trust Representative
- Head of Nursing Representative (HON CSI CMG)
- Clinical Governance Representative
- Clinical Risk Management Representative
- Medical Devices Training Manager
- Managers and other Professionals with an interest in POCT

The above list is not exhaustive.

## Delegated responsibility / Chairman’s action

In exceptional circumstances and in urgent situations where a decision needs to be made before the next committee meeting is due, the appropriate action will be taken by the chairperson and / or the nominated trust clinical lead for point of care testing on behalf of this committee.

Non-Trust representatives may attend for relevant agenda items at the invitation of the Chair.

## Quorum

A quorum shall consist of five members, including the Chair or their nominated Deputy.

## Attendance at Meetings

The inaugural Chair will be a consultant appointed by the Medical Director. The term of office of the Chair shall be five years, although the Committee can elect to extend this period. Future Chair shall be a Committee member nominated by the Committee and appointed by the Medical Director. The Chair or members of the Committee may request, in advance of a meeting, a change in the Chairmanship to be considered.

- The Chair may invite non-members to attend.
- In their absence, members should ensure that a deputy is sent where appropriate.
- The Chair shall recruit a member to act as Secretary as required.
<table>
<thead>
<tr>
<th>Accountability</th>
<th>This group is accountable and reports to the Medical Equipment Executive.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting</td>
<td>Minutes are circulated to members of the Group and are available on Q-Pulse</td>
</tr>
<tr>
<td>Chair</td>
<td>Dr Prashanth Patel – Consultant Metabolic Physician/ Chemical Pathologist</td>
</tr>
</tbody>
</table>
Appendix 2

Application Process for New or Replacement Point of Care Testing Device

**POCT Device Application Process**

**June 2018**

**Pathology/POCT Lead/Team**

- Discussion with Acquiring Manager – provide support with Application process

**Acquiring Manager**

- Need for new/replacement device identified
- Ensures completion of: Cost and benefit analysis. Site survey. Risk Assessment
- Application Form completed and submitted
- Receives approval for new/replacement device
- Contact external company to support or install device.
- Ensures Devices Users are trained and competent. Training Record updated.
- Completes device training.
- Uses device in accordance with Standard Operating Procedures and POCT Policy

**Device User**

**POCT Committee**

- Application Tracker initiated
- Discussion at meeting. Formal Minutes to be taken.
- Outcome communicated to Acquiring Manager/Pathology Lead/Team
- Receives copy of Minutes

**Governance and Risk Management Committee**

- Communication with: Trust Clinical Directors via Trust Exec
APPENDIX 3

APPLICATION FOR NEW POINT OF CARE TESTING DEVICE

Please fill in all required sections and return to **Pathology POCT Manager, Level 2, Pathology, Leicester Royal Infirmary Hospital** or email PDF to **POCT.team@uhl-tr.nhs.uk**.

### Section 1

<table>
<thead>
<tr>
<th>Contact Details of Requester</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Requestor:</td>
</tr>
<tr>
<td>Location:</td>
</tr>
<tr>
<td>Ward Manager:</td>
</tr>
<tr>
<td>Lead User for Device:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Details for Person(s) Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Responsible for Health and Safety:</td>
</tr>
<tr>
<td>Contact Responsible for Risk Assessment:</td>
</tr>
<tr>
<td>Contact Responsible for COSHH Assessment:</td>
</tr>
</tbody>
</table>

### Section 2

<table>
<thead>
<tr>
<th>Device Requested Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device full name:</td>
</tr>
<tr>
<td>Supplier Contact details:</td>
</tr>
</tbody>
</table>

*Continued overleaf*
Clinical Need for Device (also MUST attach specific National Guidelines appropriate to request and indicate exact pages that are appropriate):

*Continue onto additional pages if more space required.

Have alternative solutions been considered? (I.e. can the laboratory offer the test, and what is the turnaround time for this test? Have alternative ways of working been considered?) Please give details.

Have alternative suppliers been considered? Please give details of others suppliers of device and associated costs.

Staff Usage and Training Information

<table>
<thead>
<tr>
<th>Total number of probable users for device (state number for each ward area):</th>
<th>Number of authorised trainers required for implementation (for each ward area):</th>
</tr>
</thead>
</table>

Continued overleaf
### Section 3

**Cost Implications**

<table>
<thead>
<tr>
<th>Purchase price of IT connected Device</th>
<th>Other costs of IT connectivity (including data point):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consumables (include itemised and annual costs, and must include number of predicted weekly tests):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Internal Quality Control Solutions (include itemised and annual cost, and testing frequency):</th>
<th>External Quality Assurance samples:</th>
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</thead>
<tbody>
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<td></td>
<td></td>
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</tbody>
</table>

**Documentation**

*Please state members of staff responsible for writing the following:*

<table>
<thead>
<tr>
<th>Standard Operating Procedure:</th>
<th>Trust Competency:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk Assessment:</th>
<th>COSHH Assessment:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Are Material Safety Data Sheets available?</th>
<th>Please attach any relevant documentation to this form.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Urgency (proposed realistic implementation date):**

*Please note all devices will have to be commissioned by Clinical Engineering before implementation.*

---

Print Name: .................................................................................................................

Signed: ......................................................................................................................
*If attaching additional documentation, please ensure it is fastened to the form securely.

<table>
<thead>
<tr>
<th>For Official Use Only</th>
<th>Delete as Appropriate</th>
<th>Date</th>
<th>Signed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussed with requester</td>
<td>Yes / No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk assessment received</td>
<td>Yes / No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discussed/Accepted at POCT Group</td>
<td>Yes / No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discussed/Accepted at MDEC</td>
<td>Yes / No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Request</td>
<td>Accepted / Rejected</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Requester informed of decision</td>
<td>Yes / No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COSHH Assessment received</td>
<td>Yes / No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard Operating Procedure authorised</td>
<td>Yes / No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trust Competency Statement authorised (by MDTG)</td>
<td>Yes / No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SLA/Cross-charging set-up</td>
<td>Yes / No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IQC set-up</td>
<td>Yes / No</td>
<td></td>
<td></td>
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<tr>
<td>EQA subscription set-up</td>
<td>Yes / No</td>
<td></td>
<td></td>
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</tbody>
</table>

Notes:
Appendix 4

A list of POCT Devices used at UHL

Blood Gas Analyser
Blood Glucose Meter
Blood Haemoglobin Meter
Blood INR Meter
Blood Ketone Meter
Urine Analyser
Coagulation Analysers
Blood HbA1C analysers
Blood HIV Testing
Pregnancy testing
pH testing
Flu testing