|  |  |
| --- | --- |
| Department/Location/Project: Intensive Therapy Unit (ITU), ED, MAU, NICU, BBC, Children’s ward, Cath Lab, Respiratory ward, SAU and the laboratory; use of the ABL 90 blood gas analysers | SOP Document Reference Number: **SOP/POCT/62** |
| Risk Assessor(s): January Roque, Jacky Apps, Samantha Overton and Nicola Hodges | Highest Risk Rating Identified\*: 12 |
| Date of assessment: 26/04/2023 | Informed QM of any Risk Score >9: QM approver |

**\* Any identified risk which has a rating >9 must be communicated with the Quality Manager**

| **Description of risk** | **Existing control/ safe**  **System of work** | **Initial Risk**  **Rating**  **(S X L= RR)** | | | **What further action is required** | **Responsible person**  **and target date for completion** | **Final Risk**  **Rating**  **(S X L= RR)** | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| There is risk of transmission of infection, as a result of acquiring and handling of venous and arterial blood samples via:   * droplets * Blood spillages * Needle stick injury (via venepuncture)   Resulting in transmission of infection to ward staff, laboratory staff, and engineers who visit the analysers occasionally. | * Personal Protective Equipment (PPE) * Infection Control Policy [Standard Infection Control Precaution](https://webserver.ruh-bath.nhs.uk/staff_resources/governance/policies/documents/clinical_policies/yellow_infection_control/Yellow_622_Universal_Standard_Infection_Control_Policy.pdf) * Follow COVID 19 PPE flowchart in pandemic * Consider logistics, time frame and availability of machine. Check all blood parameters are green and machine is calibrated. * Ensure safety cap is on the blood gas syringe after obtaining sample. * Follow Trust procedure for spillages of blood. * Pathology Health and safety policy * [Sharps Policy](https://webserver.ruh-bath.nhs.uk/staff_resources/governance/policies/documents/clinical_policies/yellow_infection_control/Yellow_619_Medical_Sharps_Policy.pdf) * Seal and label sharps bin correctly. | 2 | 2 | 4 | N/A | N/A | **2** | **2** | **4** |
| There is a risk of erroneous results as a result of damage to the analyser and internal electrodes by cleaning the analyser with the incorrect wipes (green Clinell wipes) or products (wipes containing Benzalkonium). This could result in unnecessary treatment being given to patient or withholding of treatment when actually required for the patient. | * The SOP and quick user guide explain which are the correct wipes to use on the surfaces. * Supplies have listed these wipes for the wards that require them so will be stocked and topped up accordingly. * Any mild detergent could be used if these specific wipes were unavailable (i.e. washing up liquid and water on tissue). * Control access to ensure competency is reassessed at regular intervals (2 yearly). * Standardise training (SOP and competency assessment) * Data manager system to allow remote access to analysers to identify changes in performance | 4 | 1 | 4 | N/A | N/A | **4** | **1** | **4** |
| There is a risk of inaccurate results as a result of inadequate and/or diluted blood samples which may result in unnecessary treatment being given to patient or withholding of treatment when actually required for the patient. | * User guide is explicit on sample volume and this is covered in training. * Laboratory results can be requested if needed * Nursing team to maintain annual Arterial and IV competencies. * Access control allowing only trained & competent staff to use the analyser. * Traceability of analysis via electronic record of results or back up of results. * Competency assessment and SOP written recently by POCT, to be made available to ward. * Reassessment of competency for use of BGA | 4 | 1 | 4 | N/A | N/A | **4** | **1** | **4** |
| Analysis of samples or external quality assessment can pose a risk of infection to Equipment laboratory and ward staff when analysing the samples. | * PPE * Infection Control Policy [Standard Infection Control Precaution](https://webserver.ruh-bath.nhs.uk/staff_resources/governance/policies/documents/clinical_policies/yellow_infection_control/Yellow_622_Universal_Standard_Infection_Control_Policy.pdf) * Disposal into contaminated waste bins * Disinfecting/cleaning after procedure * EQA samples contain bovine haemoglobin solution and bovine albumin matrix – non human specimens. | 2 | 1 | 2 | N/A | N/A | **2** | **1** | **2** |
| There is a risk that incorrect patient ID is logged into analyser when running a sample. This can lead to incomplete audit trail and trends for a patient so cannot be reviewed properly which may affect the patients treatment (ie.giving blood component, electrolytes, changing ventilator settings, etc.). | * Radiometer prompts for patient ID including medical record number for every test * Only trained competent staff to use the radiometer * Staff should not share log in codes. * Samples should be accompanied by patient ID sticker/notes * Cover the importance of patient ID during training. * Control access to ensure competency is reassessed at regular intervals (2 yearly). * Standardise training (SOP and competency assessment). * Decision to transfuse not to be solely based on Hb result – Hb result should be lab Hb. | 4 | 3 | 12 | * Bi directional connectivity to patient records included as part of the MES due to complete summer 2023 | * Department lead for analyser and POCT coordinator 2023 | **1** | **4** | **4** |
| There is a risk of insufficient stock levels of consumables for analyser due to:   * Out of date consumables * Insufficient stock   Resulting in Interruption of availability of 1 or more analysers.  These can cause 1 or more analysers to be out of action until stock can be delivered. Patients may need to be re bled or a delay is analysis may cause erroneous results. No results may affect patient treatments. | * Rotate stock to ensure short shelf life stock used first * Check amber warning on analyser when consumables are about to expire or available tests are running low. * Prepare for planned (annual leave) time key staff are away from department. * POCT staff also review the on board stock levels remotely and can contact ward to make changes if required * POCT staff will check stock levels held on the ward to ensure there is always a replacement consumable available. * Stock held and managed from POCT lab is reviewed weekly, bi monthly deliveries received from Radiometer. * Ad hoc orders available outside of scheduled deliveries. | 2 | 1 | 4 | N/A | N/A | **2** | **1** | **2** |
| There is a risk of incorrect transcription of results into patient notes as a result of:   * Writing down wrong results on paper charts/patient notes. * Writing down results on incorrect patient record/notes * Misinterpretation of reading results incorrectly   This could lead to unnecessary treatment being given to patients or withholding of treatment when actually required for the patient. | * All entries on paper chart need to be signed off by respective staff. * Confirmatory laboratory results can be done as/where applicable. * Results are held on the analyser and in the Aqure system if retrospective access is required. | 4 | 3 | 12 | * Bi directional connectivity to hospital patient record – to allow results to transfer automatically. | * Summer 2023 as part of the MES. | **4** | **1** | **4** |
| There is a risk of loss of patient results that should be held for 30 years. Loss of results can affect patient treatment (giving blood components, electrolytes, changing ventilator settings, etc.) if previous results are not available. | * All analysers connect to Aqure middleware system, which is on a trust server that is backed up daily. * Whilst the Aqure is not linked to EPR the results are also being transcribed into the patient paper notes. | 3 | 1 | 3 | * Bi directional connectivity to hospital patient record – to allow results to transfer automatically – offering a second level of electronic storage of results into the EPR. | * Pathology IT and POCT coordinator - Summer 2023 as part of the MES. | **3** | **1** | **3** |
| There is a risk of electrocution to laboratory and ward staff. Caused through faulty connection to mains electricity. | * PAT testing performed on all hospital equipment in the department. | 3 | 2 | 6 | * Confirm PAT test current | Local – ensure this is included with whole department | **3** | **1** | **3** |

**Risk assessment matrix**

**Acceptable Risk**

Risk is tolerable as long as it is well managed and controlled. In addition to identified hazards, all incidents claims and complaints will be risk assessed according to the following process and investigated according to the severity or the consequence and likelihood of (re)occurrence.

**All Risk Assessments within the Trust will identify:**

1. The hazards within the Task/ area being assessed inherent in the work undertaken
2. who and how many people would be affected
3. how often specific events are likely to happen (may be based on frequency of previous occurrence):
4. how severe the effect or consequence would be
5. how controllable the hazards are.

Acceptable risk will be determined using the following traffic light system:

**Severity/consequence**

Given the (in) adequacy of the control measures, how serious the consequences are likely to be for the group, patient or Trust if the risk does occur (using the matrix).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Consequence score (severity levels) and examples of descriptors** | | | | |
|  | **1** | **2** | **3** | **4** | **5** |
| **Domains** | **Negligible** | **Minor** | **Moderate** | **Major** | **Catastrophic** |
| **Impact on the safety of patients, staff or public (physical/**  **psychological harm)** | Minimal injury requiring no/minimal intervention or treatment.  No time off work | Minor injury or illness, requiring minor intervention  Requiring time off work for ≤3 days  Increase in length of hospital stay by 1-3 days | Moderate injury requiring professional intervention  Requiring time off work for 4-14 days  Increase in length of hospital stay by 4-15 days  RIDDOR/agency reportable incident  An event which impacts on a small number of patients | Major injury leading to long-term incapacity/ disability  Requiring time off work for >14 days  Increase in length of hospital stay by >15 days  Mismanagement of patient care with long-term effects | Incident leading to death  Multiple permanent injuries or irreversible health effects  An event which impacts on a large number of patients |
| **Quality/complaints/**  **audit** | Peripheral element of treatment or service suboptimal  Informal complaint/inquiry | Overall treatment or service suboptimal  Formal complaint (stage 1)  Local resolution  Single failure to meet internal standards  Minor implications for patient safety if unresolved  Reduced performance rating if unresolved | Treatment or service has significantly reduced effectiveness  Formal complaint (stage 2) complaint  Local resolution (with potential to go to independent review)  Repeated failure to meet internal standards  Major patient safety implications if findings are not acted on | Non-compliance with national standards with significant risk to patients if unresolved  Multiple complaints/ independent review  Low performance rating  Critical report | Totally unacceptable level or quality of treatment/service  Gross failure of patient safety if findings not acted on  Inquest/ombudsman inquiry  Gross failure to meet national standards |
| **Human resources/ organisational development/ staffing/ competence** | Short-term low staffing level that temporarily reduces service quality (< 1 day) | Low staffing level that reduces the service quality | Late delivery of key objective/ service due to lack of staff  Unsafe staffing level or competence (>1 day)  Low staff morale  Poor staff attendance for mandatory/key training | Uncertain delivery of key objective/service due to lack of staff  Unsafe staffing level or competence (>5 days)  Loss of key staff  Very low staff morale  No staff attending mandatory/ key training | Non-delivery of key objective/service due to lack of staff  Ongoing unsafe staffing levels or competence  Loss of several key staff  No staff attending mandatory training /key training on an ongoing basis |
| **Statutory duty/ inspections** | No or minimal impact or breech of guidance/ statutory duty | Breach of statutory legislation  Reduced performance rating if unresolved | Single breech in statutory duty  Challenging external recommendations/ improvement notice | Enforcement action  Multiple breeches in statutory duty  Improvement notices  Low performance rating  Critical report | Multiple breeches in statutory duty  Prosecution  Complete systems change required  Zero performance rating  Severely critical report |
| **Adverse publicity/ reputation** | Rumours  Potential for public concern | Local media coverage –  short-term reduction in public confidence  Elements of public expectation not being met | Local media coverage –  long-term reduction in public confidence | National media coverage with <3 days service well below reasonable public expectation | National media coverage with >3 days service well below reasonable public expectation. MP concerned (questions in the House)  Total loss of public confidence |
| **Business objectives/ projects** | Insignificant cost increase/ schedule slippage | <5 per cent over project budget  Schedule slippage | 5–10 per cent over project budget  Schedule slippage | 10–25 per cent over project budget  Schedule slippage  Key objectives not met | Incident leading >25 per cent over project budget  Schedule slippage  Key objectives not met |
| **Finance including claims** | Small loss Risk of claim remote | Loss of 0.1–0.25 per cent of budget  Claim less than £10,000 | Loss of 0.25–0.5 per cent of budget  Claim(s) between £10,000 and £100,000 | Uncertain delivery of key objective/Loss of 0.5–1.0 per cent of budget  Claim(s) between £100,000 and £1 million  Purchasers failing to pay on time | Non-delivery of key objective/ Loss of >1 per cent of budget  Failure to meet specification/ slippage  Loss of contract / payment by results  Claim(s) >£1 million |
| **Service/business interruption Environmental impact** | Loss/interruption of >1 hour  Minimal or no impact on the environment | Loss/interruption of >8 hours    Minor impact on environment | Loss/interruption of >1 day  Moderate impact on environment | Loss/interruption of >1 week  Major impact on environment | Permanent loss of service or facility  Catastrophic impact on environment |

**Likelihood**

Given the (in) adequacy of the control measures for each risk, decide how likely the risk is to happen according to the following guide. Scores range from 1 for rare to 5 for very likely.

|  |  |  |
| --- | --- | --- |
| **Score** | **Descriptor** | **Description** |
| **1** | **Rare** | Extremely unlikely to happen/recur – may occur only in exceptional circumstances – has never happened before and don’t think it will happen (again) |
| **2** | **Unlikely** | Unlikely to occur/reoccur but possible. Rarely occurred before, less than once per year. Could happen at some time |
| **3** | **Possible** | May occur/reoccur. But not definitely. Happened before but only occasionally - once or twice a year |
| **4** | **Likely** | Will probably occur/reoccur. Has happened before but not regularly – several times a month. Will occur at some time. |
| **5** | **Very Likely** | Continuous exposure to risk. Has happened before regularly and frequently – is expected to happen in most circumstances. Occurs on a daily basis |

**Risk Score is determined by Severity x Likelihood**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Consequence** | | | | |
| **Likelihood** | **1**  **Insignificant** | **2**  **Minor** | **3**  **Moderate** | **4**  **Major** | **5**  **Catastrophic** |
| **5 – Almost certain** | **5** | **10** | **15** | **20** | **25** |
| **4 - Likely** | **4** | **8** | **12** | **16** | **20** |
| **3 – Possible** | **3** | **6** | **9** | **12** | **15** |
| **2 – Unlikely** | **2** | **4** | **6** | **8** | **10** |
| **1 - Rare** | **1** | **2** | **3** | **4** | **5** |

