Engineering Practice Report

4th July 2014

On the following pages is my completed Engineering Practice report to support my application to become a member of the VRCT. Copies of technical reports are contained within the appendices.
In my role at XXXX Hospitals NHS Foundation Trust I am responsible for the maintenance and repair of complex medical devices. I am the lead clinical technologist for the Neonatal Unit at the hospital and as such act as the technical link between my department (Clinical Engineering) and the clinical staff and management on the SCBU unit. (A8, C1, D1, E1)

It is my routine duty to provide technical guidance and assistance to staff both in the SCBU unit and across the Trust as a whole.

I am responsible for the acceptance testing and commissioning of complex medical equipment and for the decommissioning and disposal of old and obsolete equipment. (C3, C9)

I am routinely involved in the decision making process behind medical device assessment, testing and procurement and often provide an introspective on the technical connotations and consequences of selecting devices for use. I am often required to produce documentation to assist users of medical devices as well as technical and clinical protocol sheets. (A3, A5, A8, A9, B1, C1, C2, D1, D2, D3, D4)

It is my daily responsibility to conduct planned preventative maintenance (P.P.M.) on a range of complex medical equipment as well as providing responsive breakdown cover in the event of device failure. I use my technical experience to diagnose and repair devices in, often, high pressure environments, to reassure clinical staff to the validity of repairs and to the behaviour of devices in use. (A5, B1, B3, B4, C5, C6, C7, D1, D2)

I am responsible for the sub/annual service of a wide range of medical devices and this includes testing and calibrating devices to manufacturers dictated standards using calibrated and verified test equipment. See appendix 4 for job examples. (A3, B1, B4, C4, C5, C6)

I work in an ISO: 9001:2008 accredited department and as such all of my work is verified to be compliant with this quality system. Within this quality accreditation system I am routinely required to conduct quality system audits to ensure the continuing compliance of the system. (A3, B1, C10)

I am both Manual Handling risk assessor and Display Screen Equipment User risk assessor for my department. In the course of these roles I am required to undertake various competence based assessments of other staff members and to deliver both corrective and preventative training to the staff in my team. (A2, A5, A8, D1, E1)

It is my responsibility to maintain accurate digital equipment records, equipment risk assessments and manual handling/DSE risk assessments in line with Trust and quality system requirements. (A2, A6)

I am responsible for identifying and ordering spare parts to both facilitate repairs and to enable an effective PPM schedule. (A5, C3)

I have a strong commitment to continued professional development and academic achievement. I am currently studying for my MSc at XXXX University

I am member of the Institute of Healthcare Engineering and Estate Management (IHEEM) and am also registered as an Engineering Technician with the Engineering Council. I abide by and conform to all applicable codes of conduct from these institutions. (E1)

In my role I am committed to fulfilling the requirements of the Good Scientific Practice requirements. I use this document to ensure all aspects of my professional conduct are appropriate and delivered effectively. (E1)

I work within and fully understand the ISO: 9001:2008 quality management system and often undertake audits of this system’s effectiveness.

I am responsible for delivering both technical and user based training on a wide range of medical
devices to a wide range of audiences, from nursing staff to consultants and surgeons. (A5, A8, D1)

It is my remit as a senior member of staff within my department to train and guide junior staff members, to oversee and delegate work to them and to assist in their career progression as far as possible. (A8, E1)

I understand the need to put the patient first in all aspects of my work and to continuously develop my professional practice. (E1)

I am committed to developing both my scientific and my technical practice capabilities and have a CPD record to support this. (E1)
In March 2013 the Neonatal Unit at XXXX Hospitals NHS Foundation Trust undertook a substantial upgrade process. This process included a complete re-fit and upgrade of existing facilities, a reallocation of available clinical space, a re-purposing of other useable space and a substantial new build process.

The overall achievement of this process was that the unit increased its bed space capacity from 29 to 33 beds (cots) with an increase in space for each patient, an upgraded patient and family experience and a larger, more well equipped workspace for the staff operating the unit.

In my role at XXXX Hospitals NHS Foundation Trust I am the lead technician for the Neonatal Unit, I act as the departmental technical link and as such offer advice and guidance on all aspects of medical device procurement, acceptance, set up, testing and repair.

Throughout the refurbishment process I was required to frequently attend the Unit to provide technical support regarding the new and existing medical equipment, its use, its installation and its commissioning.

It was also necessary to select and procure a new patient monitoring solution for the unit. I was heavily involved in this process.

The technical report for this project is attached in appendix 1 of this report.
In August 2013 it was noticed that XXXX Hospitals NHS Foundation Trust Neo-Natal unit’s Draeger C2000 incubators were having a high level of humidity failure events. These failures endangered the neonates receiving therapy in the incubators, leaving potentially very serious consequences, and causing major disruption of the service delivered. The severity of these failures mandated that an incident report be produced and submitted via the Trusts incident reporting system.

As the lead for the Neonatal unit it was my responsibility to initiate, investigate, report on and rectify all issues surrounding these failures. I reported the failures to my line manager who agreed with my decision to report the incident formally. Once the incident was reported I was assigned as the investigator for the issue.

The technical report for this incident is attached in appendix 2 of this report.
In April 2013 I was contacted by Consultant Neonatologist Dr. Y of the Neonatal Unit at XXXX Hospitals NHS Foundation Trust. Dr. Y required that an analysis of baby warming techniques available to him on the Neonatal unit be carried out in order to attain a comparison of which of the methods were most effective.

I suggested that a comparison could be drawn by using a calibrated digital thermometer to test the effectiveness of each method in warming a 1L saline solution bag (simulating a patient mass) over 120 minutes. As a benchmark I would also run a background test to monitor the temperature of the solution as it warmed at room temperature.

The test would require controlled circumstances and identical environments to ensure that the warming methods checked were scientifically accurate.

The technical report for this investigation is attached in appendix 3 of this report.
Appendix 1:

Neonatal Unit new build report

Introduction

In March 2013 the Neonatal Unit at XXXX Hospitals NHS Foundation Trust undertook a substantial upgrade process. This process included a complete re-fit and upgrade of existing facilities, a reallocation of available clinical space, a re-purposing of other useable space and a substantial new build process. The overall achievement of this process was that the unit increased its bed space capacity from 29 to 33 beds (cots) with an increase in space for each patient, an upgraded patient and family experience and a larger, more well equipped workspace for the staff operating the unit.

In my role at XXXX Hospitals NHS Foundation Trust I am the lead technician for the Neonatal Unit, I act as the departmental technical link and as such offer advice and guidance on all aspects of medical device procurement, acceptance, set up, testing and repair. (A5)

Throughout the refurbishment process I was required to frequently attend the Unit to provide technical support regarding the new and existing medical equipment, its use, its installation and it’s commissioning.(A5, C8, E1)

Movement Process

It was necessary, throughout the build, to remove and reposition medical equipment within a changing, challenging environment. This work required that new cot spaces be ‘created’ where there were previously no spaces allocated/available. In creating these new spaces it was necessary to undertake a number of risk assessments to ensure that the new environment was safe and suitable for use in such a critical care area. These risk assessments also had to be tailored to the fact that the created spaces were ‘ad-hoc’ and temporary. (A1, A2, A5, A6) I undertook these assessments on a daily basis throughout the build process.

As each cot space was moved and re-created it was essential that a full clean of the area and equipment was completed, this is standard procedure in a hospital environment, but is especially important in the Neonatal environment due to the nature of the patients and their susceptibilities. I was involved in this infection management process on a daily basis and had to be keenly aware of infection control procedures.

Replacement monitors

The new build process also, coincidentally, coincided with the need to replace a substantial quantity of the departmental Patient Monitoring devices, these monitors were to be replaced under XXXX Hospitals NHS Foundation Trust’s ‘Capital Replacement Program’ this is a program that aims to replace and replenish high value medical devices at the end of their working life cycle. It was necessary for me, in my role as technical lead, to liaise with the senior medical practitioner staff, consultants and medical device manufacturers to facilitate trials of possible replacement monitors.(A3, A4, B2, C2, D2) This entailed having manufacturers provide devices to site for a two week trial to provide time for the medical staff on the unit to experience the monitors and to form opinions on the available choices. We trialled 4 different manufacturers (with a total of 7 different monitors) across three months, at the end of the trial period I attended a meeting of senior staff to try and come to a consensus on the replacement monitors to be purchased. We compared the devices on numerous factors including – functionality, ease of use, configurability, screen size, connectivity, ease of maintenance and cost. After this meeting, in agreement with all parties, it was decided
that we would purchase the Philips MX700 Patient Monitoring system. My role in the process was to advise on the technical aspects of the replacement procedure, this involved comparing and advising on the technical abilities of each monitor, their repair processes, their reliability, their ease of use and their connectivity. My opinion was counted toward the overall consensus on the replacements. (E1)

Once the replacements had been decided on it was my responsibility to order the new monitors. (A3, C1) This ordering process required that I liaise with Philips Healthcare to ensure that delivery dates could be met and that the device install team (for networking) could attend at the correct juncture in the new build process. (A4) Once I had all of the assurances needed from Philips Healthcare I placed the order for 10 new patient monitors through my departmental standard ordering process. I continued to liaise with Philips Healthcare throughout the ordering process to ensure that delivery times remained on target. All of the monitors were delivered in time for acceptance into the new build environment.

Upon delivery of the monitors I was required to carry out an acceptance testing procedure, this involves unpacking and assembling the device, checking for any transit damage, asset registering (asset labels are required for any device with a value of more than £5000) and equipment database labelling, functional testing and electrical safety testing. These tests all need to be carried out prior to a device being released into use. (A3, A4, B3, C1, C3)

It was also my responsibility to ensure that the XXXX Hospitals NHS Foundation Trust training requirements were met. The training policy states that more than 70% of staff in a department must be trained and competent in the use of a device before it can be released for use. To ensure that the 70% target was achieved in time for the ‘Go Live’ date for the new unit I was required to liaise with the technical trainer at Philips Healthcare and ensure that she attended the Neonatal Unit several times throughout the process to capture as many trainees as possible. (A3, A8, D1) This also required negotiating that the trainer visited in the evening as early in the morning, so as to train staff members who happened to be working night shifts etc. I negotiated to have two ‘demonstrator’ monitors delivered for a loan period, so that the clinical staff on the unit could become familiar with the use and layout of the new monitors, so as to alleviate any teething problems that may arise once the new monitors are used in a live environment, these monitors were duly delivered and accepted under a loan indemnity agreement. I also liaised with the Philips Healthcare trainer to have copies of all training records forwarded to me so that I could enter them, digitally, on our electronic equipment inventory (E-Mat) system’s training sector. During this period I underwent both user and full technical training on the MX700, this ensured that I could confidently act as a technical lead for the devices in the unit, acting as a key trainer for the technical (non-clinical) elements of the monitors. (A4, D1) I was able to provide assistance with the setting up of the monitors to provide specific measurements and telemetry, as well as remote viewing and teaching staff how to access many of the monitor’s new functions. Completing all of this training ensured that the department were entirely compliant with the requirements of the Trust’s training policy.

Once all of these factors had been satisfied I was able to release the monitors to the unit so they could be used in the new buildings. (A4)

The release of the monitors required that I install the into the new nursery environment, this meant attaching a mounting solution to the existing infrastructure and setting the monitors safely and securely to the new mountings (A1, A8, D3) Special considerations had to be made to this positioning as the new monitors are entirely touch screen interfaced and as such nursing staff need to be able to reach the extremes of the screen. This was a challenge due to the fact that all of the monitors need to be visible from anywhere in the nursery, which contains a lot of other equipment. The monitors needed to be high enough to be seen, but low enough to be used effectively. The solution to this was found somewhat from analysing the heights of the probable working staff members and the height of the equipment in the room, we found that the majority of users could operate the devices at a height that allowed the screen to be clearly viewed from any location. For the instances where visual contact was not possible we commissioned a ‘remote view’ facility within the monitors, this enabled nursing staff to bring up, in a separate window, direct display information from a monitor in
another location within the department. This was deemed an acceptable solution after consultation with the senior staff members on the unit. (D4) The final task in the replacement of the monitors was to remove, and dispose of, the old monitors. (A3, A4, A9, B3) The required that the old monitors be taken from their mountings in the current locations and decommissioned in line with our departmental procedures. The monitors were removed to the Clinical Engineering premises, all identifying markers were removed from the devices and they were removed from the Trust equipment database and asset register. The devices were deemed (after consultation with my line manager) to be of resale value and as such were sent to a specialist auction house for resale. Two of the monitors were deemed to be unsuitable to be sent to auction, so these devices were disposed of following WEEE Regulations.

Below is a copy of a risk assessment done for the purpose of this investigation – (A1, A2)
## Clinical Engineering Risk Assessment

<table>
<thead>
<tr>
<th>Equipment Type:</th>
<th>Temporary cot space set up</th>
<th>Model:</th>
<th>Multiple</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital:</td>
<td>BRI</td>
<td>Department/ Location:</td>
<td>SCBU</td>
</tr>
<tr>
<td>Description:</td>
<td>Setting up temporary environments to facilitate building work</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risks:</td>
<td>Manual handling, exposure to biohazard, Lifting &amp; Handling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Author:</td>
<td>SL</td>
<td>Date:</td>
<td>29-Apr-14</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of Hazard/ Operation</th>
<th>Initial Risk Consequence x Likelihood</th>
<th>Control measure/ Comments</th>
<th>Residual Risk Consequence x Likelihood</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C  L  R</td>
<td></td>
<td>C  L  R</td>
</tr>
<tr>
<td>Slip trip or fall, same level</td>
<td>2  2  4</td>
<td>Good working practice, clear working area</td>
<td>2  1  2</td>
</tr>
<tr>
<td>Contact with Electricity</td>
<td>2  1  2</td>
<td>Good working practice, no working on exposed live parts</td>
<td>1  1  1</td>
</tr>
<tr>
<td>Manual handling/ lifting</td>
<td>3  2  6</td>
<td>Mandatory E Learning and Practical Manual Handling Training carried out</td>
<td>3  1  3</td>
</tr>
<tr>
<td>Exposure to harmful Substances (Coshh)</td>
<td>1  1  1</td>
<td>Good working practice, use of PPE</td>
<td>1  1  1</td>
</tr>
<tr>
<td>Exposure to Biohazard</td>
<td>3  1  3</td>
<td>Not working on contaminated equipment, Follow local guidelines and policies, use of PPE</td>
<td>3  1  3</td>
</tr>
<tr>
<td>Sharps Injury</td>
<td>1  2  2</td>
<td>Good working practice, E learning training</td>
<td>1  1  1</td>
</tr>
<tr>
<td>Risk to Patient/ User</td>
<td>3  2  6</td>
<td>Follow local guidelines and policies, Liase with users</td>
<td>3  1  3</td>
</tr>
<tr>
<td>Working in confined spaces</td>
<td>1  1  1</td>
<td>Good working practice</td>
<td>1  1  1</td>
</tr>
<tr>
<td>Working in restricted areas</td>
<td>1  3  3</td>
<td>Coordination and assistance from users</td>
<td>1  1  1</td>
</tr>
<tr>
<td>working with restrictive posture</td>
<td>3  2  6</td>
<td>Mandatory E Learning and Practical Manual Handling Training carried out</td>
<td>3  1  3</td>
</tr>
<tr>
<td>Working above shoulder height</td>
<td>2  1  2</td>
<td>Mandatory E Learning and Practical Manual Handling Training carried out</td>
<td>1  1  1</td>
</tr>
<tr>
<td>Lone working</td>
<td>1  5  5</td>
<td>Coordination and assistance from users</td>
<td>1  1  1</td>
</tr>
</tbody>
</table>
Appendix 2:

Neonatal Unit Incubator humidity incident report

Introduction
In August 2013 it was noticed that XXXX Hospitals NHS Foundation Trust Neo-Natal unit’s Draeger C2000 incubators were having a high level of humidity failure events. These failures endangered the neonates receiving therapy in the incubators, leaving potentially very serious consequences, and causing major disruption of the service delivered. The severity of these failures mandated that an incident report be produced and submitted via the Trusts incident reporting system. (A7)

As the lead for the Neonatal unit it was my responsibility to initiate, investigate, report on and rectify all issues surrounding these failures. I reported the failures to my line manager who agreed with my decision to report the incident formally. Once the incident was reported I was assigned as the investigator for the issue. (E1)

Investigation

I began my investigation by liaising with the staff members on the Neonatal unit to see if there was any information to be gained from them, and to see if there were any out of the ordinary procedures being carried out at the time of failure. (E1) This line of enquiry was unsuccessful so my investigation turned to the actual incubator, to search for mechanical or electronic failures. During the course of this investigation I isolated the cause of the failures to be the humidification chamber and boiler within the C2000. The failures of the humidifiers were then further investigated to ascertain the true cause of the failures. (C6) Upon this investigation I discovered that the boiler chambers had become coated with a mineral ‘scale’. This scaling was causing the heater to cut out prematurely, as the temperature sensors were not conducting heat from the water effectively.

Upon discovering this issue I contacted the manufacturer of the units to seek guidance on the matter. The manufacturer advised to check that the water being used for humidification was of the correct mineral density. I obtained a specification sheet of the required mineral content and proceeded to investigate the mineral content of the water in use in the Neonatal unit. After consultation with the neonatal department and the pharmacy department I discovered that the mineral content of the water was indeed too high, causing excess scaling of the units.

Remedy

Once the mode of failure had been identified I was able to work with the infection control team, pharmacy and the neonatal unit to procure a suitable replacement water option (distilled, rather than sterile) and oversaw its implementation into standard use.

I stripped down the incubators and replaced the damaged humidifiers with new units, I then ran a series of reheating and humidification tests on each incubator to verify that the repair had been successful. This required that the temperature and humidity be checked and verified against and external measure, over a 3 hour period. (A3, B1, B4, D2) The external measures I used were a calibrated digital thermometer and a calibrated digital humidity meter. (C4) Once the performance had been verified I was required to carry out an electrical safety test before the unit went back into service, this included testing the earth bonding resistance, touch current values, earth leakage current and patient applied part leakage. All of these repairs and tests were recorded on the Clinical Engineering database for traceability purposes.

Before the units were allowed to return to service it was necessary for me to produce some guidance literature for the staff on the Neonatal unit to help ensure that the issues didn’t reoccur in the future. (A9, D1, E1) This consisted of a guidance ‘checklist’ reminding staff to
ensure the water used in the humidity chambers was distilled and not just sterile. It also asks that to extend the life of the boiler units staff be vigilant against letting the boiler chambers run dry, as this puts extra strain on the heating element in the unit. Due to this guidance and the new water and boiler repairs the issue, at least in the short term, has been solved. (A8) The longer term performance of the humidifiers with the new water type will be audited yearly during the planned preventative maintenance visits, on this basis the incubators have just undergone the first annual service since the incident and during the course of the PPM checks carried out I found that the humidifiers are scale free and functioning as per manufacturers specification. (A3, B1, B3)
Appendix 3:

Baby warming method analysis report

Introduction

In April 2013 I was contacted by Consultant Neonatologist Dr. Y of the Neonatal Unit at XXXX Hospitals NHS Foundation Trust. Dr. Y required that an analysis of baby warming techniques available to him on the Neonatal unit be carried out in order to attain a comparison of which of the methods were most effective. (E1)

I suggested that a comparison could be drawn by using a calibrated digital thermometer to test the effectiveness of each method in warming a 1L saline solution bag (simulating a patient mass) over 120 minutes. As a benchmark I would also run a background test to monitor the temperature of the solution as it warmed at room temperature. (C2, E1)

The test would require controlled circumstances and identical environments to ensure that the warming methods checked were scientifically accurate.

Background

As a Trust, XXXX Hospitals NHS Foundation Trust has, historically, used an electronic device to warm infants after birth. The system we use is the Inditherm Medical CCU200 which uses a contact mat to provide electrical heating to the infant placed onto the device. The alternative method available to Dr. Y was a chemical heating system known as a TransWarmer, which uses a chemical reaction to generate heat within a sealed ‘gel’ type pad. Both systems have to have the infant placed on top of their respective heat delivery systems, with a blanket barrier to avoid any contact burns.

Investigation

To ascertain which, if any, method was most effective for the heating of newborns it was necessary to undertake an experiment, in controlled circumstances, to discover the most effective technique available.

I set up the experiment in an office in the Neonatal unit, away from draughts, airconditioning and strong sunlight. The experiment used 3 cots, each with a standard mattress covered in a blanket, a 1L saline bag which had been chilled to 3 degrees in the nursery fridge and another covering blanket as means of insulation. The test set up for the experiment consisted of calibrated digital thermometers inserted onto the surface of the saline solution bag. It was ensured that each probe was 75mm from the neck of each bag so as to provide a consistent approach. (C2, B4)

The bags were removed from the fridge at the same time, placed on the two heating sources at the same time (a third was placed onto the mattress/blanket only) and the heating systems were started simultaneously. The bags were covered with another blanket and left to warm for a little over two hours. Measurements were taken from each thermometer at 15 minute intervals throughout the process and the results were recorded in the table (Table 1) below. (C10) The initial temperature drop can be explained by the cooling of the temperature probe from room temperature to the temperature of the surface of the saline solution bag.

Results

Once the test had concluded I was able to plot all of the data in a table (Graph 1) to demonstrate the effectiveness of each warming technique. The clear winner was the chemical based TransWarmer system which achieved a warming of 8.6°C across the test. The Inditherm managed an increase of only 5.4°C in the same time and room temperature warming gained 3°C. (C10) The lack of heating gained from the Inditherm was concluded to
be due to lack of mass on the conductive pad, but as the Neonatal unit’s patients are often remarkably small/light there exists the possibility of lack of heat transfer due to lack of contact with the conductive pad.

Table 1

<table>
<thead>
<tr>
<th>Time (Minutes)</th>
<th>Inditherm</th>
<th>TransWarmer</th>
<th>No Heating</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Ambient</td>
<td>Ambient</td>
<td>Ambient</td>
</tr>
<tr>
<td>15</td>
<td>12.0°C</td>
<td>11.1°C</td>
<td>11.5°C</td>
</tr>
<tr>
<td>30</td>
<td>7.3°C</td>
<td>10.5°C</td>
<td>7.5°C</td>
</tr>
<tr>
<td>45</td>
<td>8.0°C</td>
<td>12.1°C</td>
<td>7.9°C</td>
</tr>
<tr>
<td>60</td>
<td>8.7°C</td>
<td>15.2°C</td>
<td>8.5°C</td>
</tr>
<tr>
<td>75</td>
<td>9.6°C</td>
<td>16.5°C</td>
<td>9.0°C</td>
</tr>
<tr>
<td>90</td>
<td>10.6°C</td>
<td>17.5°C</td>
<td>9.4°C</td>
</tr>
<tr>
<td>105</td>
<td>11.5°C</td>
<td>18.2°C</td>
<td>9.7°C</td>
</tr>
<tr>
<td>120</td>
<td>12.0°C</td>
<td>18.6°C</td>
<td>10.2°C</td>
</tr>
<tr>
<td>135</td>
<td>12.7°C</td>
<td>19.1°C</td>
<td>10.5°C</td>
</tr>
</tbody>
</table>

- Tests carried out using 1L saline from fridge.
- Saline bags placed in cot, on single blanket, covered by two blankets
- Initial temperature drop due to thermometer probe cooling
Conclusion/Implications

The implications of this study are that there exists the possibility of a neonatal patient not receiving adequate heat transfer form the current baby warming system in place at XXXX Hospitals NHS Foundation Trust, this could lead to significant detriment to the patient and an increased hospital stay. This is an unacceptable risk and as such the decision was made to change from the Inditherm heating system to the chemical TransWarmer system for the more serious cases on the Neonatal unit. The TransWarmer is seen as the preferred method due to its quick heat up and consistent contact method. The TransWarmer is now used as a direct result of the work conducted in this experiment (D4)
Appendix 4

Note – Copies of service reports have been removed in order to anonymise this report. The actual report contained copies suitable to demonstrate that the RCT applicant is working to the required level.