

Standard for Equipment in Critical Care

Lead Authors:

Dr A.N. Thomas, Consultant in Intensive Care, Salford Royal Hospitals.

Email tony.thomas@srft.nhs.uk.

Dr J.C. Roberts, Specialist Registrar, North-West Regional Training Scheme

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Introduction

Critically ill patients are often absolutely dependent on the safe functioning complex medical equipment. Every Intensive Care Unit should therefore have clear policies for the management of this equipment, these policies should include:

1. Procurement and purchase of equipment.
2. Acceptance and commissioning of new equipment.
3. Record keeping and equipment registers.
4. Cleaning and decontamination of equipment.
5. Reporting and acting on patient safety incidents associated with equipment.
6. Training staff to use and manage equipment.
7. Storage of equipment.
8. Syringe pumps.
9. Plans to deal with electrical failure.
10. Standardisation.

These policies require management and leadership from within the department and will require the department to engage with other equipment users, trust managers and the E.B.M.E. (Electro-Biomedical Engineering) department. This is most likely to happen if there is a consultant clearly identified as the lead for medical equipment.

Equipment standards in critical care will be similar to those in anaesthesia, the Association of Anaesthetists have produced guidance for the management of anaesthetic equipment [1] and these have been referred to in writing these guidelines.

Departments should have policies for equipment management and an identified consultant medical equipment lead who should work closely with the clinical director and nursing staff.

Procurement and Purchase

New equipment is purchased for replacement of old equipment, to allow expansion in services or for new clinical indications. The Trust will prioritise equipment bids from different departments. A primary consideration that should be made by trusts is the risk of potential harm if the equipment is not purchased. This risk maybe defined by a risk register.

Risk registers normally score risks by the likely severity of injury (1 = minimal, 10 = Death / Catastrophic injury), likeliness of occurrence (1 = very unlikely, 10 = almost inevitable) and implementation of controls to reduce risk (1= all controls in place, 10 = no controls in place).

Risks may also be defined by previous patient safety incidents reported locally or nationally. Departments should record and monitor patient safety incidents reported locally and nationally. They should be able to quantify risks on a departmental risk register.

For replacement of equipment the following will be important in determining the need for new equipment: Withdrawal of continued support for servicing, increased maintenance costs, the development of alternative, superior, products, and opportunities to standardise equipment across departments and organisations.

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For new types of equipment trusts will consider national guidance (for example NICE guidance on ultrasound guided vascular access [2]) and guidance from learned societies as well as the results of controlled clinical trials.

All of this information should be used in producing a statement of need for new equipment to the Trust. This should include an estimate of lifetime costs for the equipment.

Departments should be able to produce statements of need for equipment based on an analysis of risk and best available evidence of effectiveness of new equipment so they can compete with other departments for scarce resources.

When the statement of need has been accepted the next stage is to choose the most appropriate device; a check list to help with this process is available at the MRHA website [3], this is summarised in Table 1.

Unfortunately the NHS does not provide detailed reviews of the whole range of equipment commonly used in intensive care units. Some information about syringe pumps and other devices is available at the Bath Institute of Medical Engineering [4]; otherwise contacts with other intensive care units and E.B.M.E. departments may be the only source of unbiased information.

About the device:	
1	What are the requirements for the device? (These must be completely and well described for any tending process).
2	What similar devices do we already have in the Trust: Are there opportunities for standardisation?
3	Are there external reviews or an evidence base to recommend the device?
4	How easy is the device to use and maintain?
5	How should the device be cleaned and decontaminated?
6	When is the device likely to be replaced by a new model?
7	What training is provided and required at initial purchase?
8	What training is provided and required following upgrades and for update training for new staff?
9	What training materials are provided with the product?
10	Does the device require battery back-up and is this built-in, how is the functioning of the battery to be assessed and will the time available allow you to deal with a power failure?

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About the costs:	
1	What are the costs of the device?
2	What are the costs of maintenance and servicing?
3	What are the costs of consumables, will the device require consumables only provided by the equipment manufacturer?
4	What are the costs of software upgrades and support?
5	What are the costs of depreciation and disposal?
6	What are the costs of releasing staff for training?
7	What are the storage costs?

These questions can be drafted into a pre-purchase questionnaire (PPQ) which should ask the supplier to formally respond to these questions [5]. The supplier should also be asked to provide evidence that the device is compliant with national and international standards [6] [7] and that the device has the appropriate CE marking [8], this will show that the device is compliant with EU legislation concerning medical devices [9].

Where equipment is loaned to the ICU for trial, it is important that the supplier provides indemnity in case of injury to patients or staff and also provides support to ensure the equipment is correctly used. The equipment should be checked by the E.B.M.E. department prior to use. The ICU should ensure that all relevant staff groups can evaluate the device and that questionnaires are used to establish ease of use, quality of performance and potential disadvantages of the device. The NPSA has issued guidance on how to assess the usability of equipment [10]. The E.B.M.E. department should also check and review the equipment and establish how easy it is to service and maintain.

When available options for equipment have been reviewed and assessed a tendering process should be commenced. Trusts will have standing financial instructions which give a threshold, (normally around £5,000) above which competitive tenders should be obtained. Above a threshold of £206,000 (2008) tendering will have to follow EU procurement directives. These directives allow free competition in the EU and legally binding and well described [11], they should be clearly understood by the Trust purchasing department. The main responsibility for intensive care staff is to be able to clearly define what the essential and desirable characteristics are that they require of a piece of equipment. Without this specification, the unit could end up with cheaper, but substandard, equipment.

There may be some advantages in entering into a longer term partnership with an equipment manufacturer so that, for agreeing to purchase their equipment over a period of time, the manufacturer would maintain a price discount. This could, for example, allow a Trust to standardise its monitoring equipment and allow a manufacturer to predict future demand.

When entering into discussions with manufacturers it is important that staff are seen to maintain

ethical standards with respect to accepting gifts or hospitality. It may be essential to visit manufacturer's facilities or be taken by manufacturers to other trusts. Expenses covered by the manufacturer should be reasonable and cleared with the Medical Director or appropriate trust body. Manufacturer's representatives should be treated with due respect and consideration. When in the clinical environment, company representatives should be reminded of their responsibilities for maintaining a professional and safe environment for patients.

An assessment of the environmental impact of purchasing decisions will become increasingly important as the importance of the environmental impact of health care is recognised [12].

When choosing between a range of available options, departments may wish to set criteria and then weight them by degree of importance and then score each criteria, multiplying the score by its importance weighting [13].

Departments should have policies based on MHRA and other guidance for the procurement of equipment and should work closely with the local E.B.M.E. department during the procurement process.

Acceptance and Commissioning of New Equipment

Once the tender has been accepted and the PPQ is checked there is a mandatory 10 day standstill period between the award decision and contract conclusion [11]. This allows unsuccessful bidders to be able to appeal against the tender decision. It is essential that a Trust keeps records that can demonstrate the tendering process has been fair to protect against appeals being successful, records of weighted scorings should be kept.

There should be a clear agreement about where equipment should be delivered and processes to document acceptance of equipment within the Trust [3]. Equipment should not be used until assembled, tested and recorded in appropriate asset registers. These are normally the responsibilities of the E.B.M.E. department.

Record Keeping and Equipment Registers.

Each device should have unique identification number. This should be linked to the life cycle of the device including its date of commissioning and service history [3]. Devices should be included in an asset register which lists all devices, date of commissioning, anticipated replacement date and service history. This allows planned maintenance and replacement [3] and is in line with level one standards for the clinical negligence scheme for trusts [14]. There are sophisticated commercial databases [15] [16] which manage these records which have been adopted by many Trusts to improve financial control and ensure correct equipment maintenance.

Equipment may also be radio linked to these databases using tagging devices so that their usage can be monitored and they can be easily located in the Trust to allow planned maintenance [17]. Many devices, for example syringe pumps, may be used very intermittently in some departments and better matching of supply of equipment to its use could result in significant cost savings [18]. Units should have up to date asset registers with service histories and expected dates of

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decommissioning; there are new IT solutions to maintaining these registers.

Cleaning and Decontamination of Equipment

Each NHS Trust will have a nominated lead, responsible for decontamination who is responsible to the executive of the Trust [19] [20].

Decontamination encompasses cleaning, disinfection and sterilisation.

Decontamination

A process which removes or destroys contamination so that infectious agents or other contaminants cannot reach a susceptible site in sufficient quantities to initiate infection or any other harmful response. Differing levels of decontamination are used depending on the device and the procedure involved. The levels of decontamination are:

- cleaning , cleaning followed by disinfection, cleaning followed by sterilization.

Cleaning

A process which physically removes infectious agents and the organic matter on which they thrive but does not necessarily destroy infectious agents. The reduction of microbial contamination depends upon many factors, including the effectiveness of the cleaning process and the initial bioburden. Cleaning is an essential prerequisite to ensure effective disinfection or sterilization.

Disinfection

A process used to reduce the number of viable infectious agents but which may not necessarily inactivate some microbial agents, such as certain viruses and bacterial spores. Disinfection does not achieve the same reduction in microbial contamination levels as sterilization.

Sterilization

A validated process used to render a product free from viable microorganisms (BS EN ISO 14937:2009)

Processes for decontamination are defined in the Microbiology Advisory Committee (MAC) Manual, published by the Microbiology Advisory Committee of the MHRA. This is under revision in 2010 and is published in 3 sections, basic principles, policies and procedures [21] [22] [23].

This guidance sets out that all equipment used on the ICU must be adequately cleared, including equipment which will then be disinfected or sterilised.

Units should ensure that they have systems in place to make sure medical equipment is appropriately cleaned. This will require:

1. Defining how equipment should be cleaned following manufacturer's recommendations and local infection control advice.
2. Providing staff with the correct cleaning equipment, cleaning agents and protective equipment.
3. Training staff in correct cleaning techniques.
4. Ensuring there are systems in place to identify what equipment has been cleaned and is ready to use and what still requires cleaning (This is often done using removable paper labels).
5. Ensuring staff know who should clean what, when and how.
6. Auditing the process to make sure devices are clean.

Detailed advice on cleaning medical equipment and decontamination of ventilators is described in

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the MAC manual volume 3 [23]. Mattresses are particular medical devices where decontamination may be inadequate. [24].

Trusts should undertake risk assessments that assign a risk category to equipment, which will determine the decontamination process [21].

1. High risk equipment should be sterilised.

Equipment introduced into sterile body areas or in close contact with broken mucus membranes or skin.

For example: Bronchoscopes.

2. Intermediate risk should be sterilised or disinfected.

Equipment In close contact with mucus membranes, contamination with virulent or transmissible organisms or prior to use with immunocompromised patients, for example: Laryngoscope blades.

3. Low risk should be cleaned.

Equipment in contact with healthy skin

For example: Monitoring cables.

The decontamination processes and agents must comply with manufacturer's recommendation which should be available at the time of purchase.

Bronchoscopes

Bronchoscopes cause particular problems with respect to decontamination; they enter sterile parts of the body so require sterilisation. Unfortunately they are also too delicate for normal sterilisation processes and the methods required may therefore pose risks to staff. They also should be immediately available on the unit to manage acute airway problems.

Suction and biopsy channels present within bronchoscopes make their decontamination particularly hazardous. Infection transmission as a result of inadequate cleaning and sterilization processes has been well documented. [25] [26] Extensive guidance on the disinfection of endoscopes can be found in various MHRA publications. [27] [28]. Bronchoscope decontamination must only be undertaken by those trained and familiar with the bronchoscope configuration. The pertinent points of the decontamination process are as follows:

- Air/ water channels must be irrigated with water immediately upon removal from the patient.
- The bronchoscope should be cleaned with warm neutral or enzymatic detergent solution.
- All channels and ports must be cleaned manually with appropriately designed, single endoscope use brushes.
- Bronchoscopes should be reprocessed within a validated automated endoscope reprocessor (AER) compliant with HTM2030, following a successful leak test. [29]
- On completion the bronchoscope should be purged with compressed air or 70% alcohol.
- Procedures that allow full traceability must be in place.

Storage of disinfected bronchoscopes

Endoscopes should be stored vertically in specifically designed storage cabinets. Endoscopes stored in excess of 3 hours should be reprocessed within an AER prior to next patient use. Units should have systems in place to ensure that equipment is decontaminated in line with published recommendations of the microbiology advisory committee of the MHRA. These processes should be checked and audited.

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Reporting and Acting on Patient Safety Incidents Associated with Medical Equipment.

Best practice in reporting patient safety incidents from critical care is described in the Intensive Care Society Guidelines on Critical Incident Reporting [30].

Where medical equipment has been involved in a patient safety incident, the equipment should be isolated and clearly labelled so that it cannot harm another patient and so that it can be analysed by the E.B.M.E. Department. Devices should not be disassembled and infusions should be left in place in infusion devices [31].

The incident should then be reported using the trust adverse incident reporting System. This should allow local investigation of the incident and the trust will also be required to forward the report to the NPSA.

An incident involving equipment should also be reported to the MHRA using their on-line reporting system [31]. The ICU and E.B.M.E. should agree who will be responsible for submitting these reports. The reporting of incidents to the MHRA should be coordinated in each Trust by a Medical Device Liaison Officer, who should also encourage the reporting of incidents by clinical staff [31].

The MHRA will investigate patient safety incidents and produce medical device alerts. These are disseminated via the Central Alerting System (CAS), each trust will have a CAS Liaison Officer (who will normally also be the Medical Device Liaison Officer and be a member of the EBME). The CAS Liaison Officer should disseminate alerts within the trust to the critical care unit. The ICU Equipment Officer should review these reports. The MHRA also maintains a webpage covering equipment issues relevant to critical care practitioners, which hosts relevant medical device alerts, drug alerts and MHRA Guidance and Publication [32]. The ICU equipment officer should review the advice provided by the MHRA.

Units should follow ICS general guidance on incident reporting and specific guidance issued by the MHRA on the handling of equipment involved in an incident and reporting of equipment associated incidents. The ICU equipment officer should be aware of, and act on, relevant medical device alerts and other guidance issued by the MHRA.

Training Staff to Use and Manage Equipment

Reviews of patient harm associated with equipment in critical care have consistently found that misuse of equipment is the most common cause of patient harm [33] [34]. In spite of this, until recently, little attention was given to training staff on how to use equipment [35].

It is a requirement for CNST approval that permanent staff should know how to use the equipment that they are required to use [14]. Unfortunately, the mechanisms by which staff should be trained and learnt to use equipment have been subject to almost no research. Training ICU staff to use equipment correctly presents major problems; there will be a large number of staff, who may need to use dozens of complex pieces of equipment. The staff will have had very variable previous

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training and education and the contributions of even the most inexperienced support workers may be critical to patient safety. In addition to this, many members of staff will only work on the unit for periods of a few days or months.

The problems are made worse because equipment will often not be designed to be easy to use [36] [37] and increasing complexity of some devices, for example ICU ventilators, is regarded as an advantage by many clinicians when purchasing equipment [38]. Dis-coordinated approaches to purchasing may also mean that staff moving between different hospital departments will have to use different makes of non-standardised equipment.

These problems have often been ignored where the blame for misusing equipment can easily be shifted to the staff involved, regardless of any lack of training provided or the poor usability of the equipment involved [39].

When dealing with these problems of providing staff training critical care units should:

1. Ensure they have a register of what equipment staff are expected to use, what they should know about each item of equipment (which will differ significantly for different staff groups) and what training and competency assessment each member of staff has had for each item of equipment [14].

Where staff are working for short periods in an intensive care unit (for example agency and locum staff) and they have used the same equipment in other units a self assessment of competency is a minimum standard that should be obtained.

2. Where temporary staff have been employed who are unfamiliar with the unit's equipment they will need clear instructions setting limits on what they can and cannot do and who they should expect to be able to ask for advice and to check equipment with.

3. Where new equipment is being introduced, there should be clear agreements with suppliers about who is responsible for training at the time of initial purchase and during subsequent equipment upgrades and during the induction of new staff [3].

4. Plan to assess and meet the training needs for all new starters from each staff group.

5. Provide "Just in time" training resources so that staff can access information easily when they use equipment that they have forgotten how to use or where an unexpected problem has occurred. This information should be where staff can find it; some information will be usefully presented as checklists [40].

6. Although we could find no specific evidence as to how to teach staff to use equipment, some basic educational principles should apply:

1. Learning is experimental - staff should have an opportunity to practice using the equipment [41].

2. Learning requires feedback - staff should be assessed and feedback provided [42].

3. Learning is contextual - It would be most effective in the workplace.

4. Learning decays - Just in-time training resources should be provided.

and update training may be required; the intervals suggested by studies of ALS training are measured in months [43].

6. Developments in IT, E-Learning[44] and Simulation[45] may provide opportunities to improve training and departments should invest in these resources.

Units must invest in appropriate staff training so that staff can use equipment safely. Ways in which this is delivered should be based on rational educational theory.

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Storage of equipment

In a detailed review of syringe pump usage the NPSA found the storage of equipment be highly unsatisfactory [18]. Many ICUs have expanded clinical services but have been unable to provide space to store equipment. HBN 57 [46] describes basic requirement for storing equipment and should be followed in new designs. For units where rebuilding is not an option, old equipment should not be kept after it is no longer used, unnecessary clutter should be removed, unnecessary stock should not be kept and space should be used as appropriately as possible.[47](reference productive ward)

New builds should provide storage space in line with Hospital Building Note 57 and where rebuilding is not an option, space should be used as appropriately as possible as set out in the principles of the productive ward.

Equipment Libraries

Many hospitals have developed equipment libraries in line with advice from the NPSA [48]. These libraries provide a central storage point for equipment, and have the following potential advantages:

1. Less equipment is required for a hospital as each department does not have to have enough equipment to cover exceptional periods of demand in that department.
2. Equipment can be cleaned when returned and stored and charged correctly.
3. It is easier to locate equipment for servicing.
4. Equipment can be rotated to ensure constant levels of use for all individual devices.

Unfortunately there are reasons why equipment libraries have not been universally adopted.

These include:

1. Equipment may be difficult to access out of hours.
2. There is a cost in moving equipment into and out of the library.
3. There are costs in maintaining and running the library and providing staff.

We were unable to identify a current evaluation of the longer term benefits and costs of equipment libraries.

Trusts should consider the advantages and disadvantages of establishing an equipment library.

Syringe Pumps

Syringe pumps are the most commonly described devices in patient safety reports [33]. For this reason the, NPSA conducted a review of best practice for management of syringe pumps [18] and has issued guidance in best practice in infusion pump design [49]. Units should consider this advice.

Departments should review NPSA guidance on the management of syringe pumps and infusion pump design.

Electrical failure

Electrical supply to critical care units should be supported by backup generators, however, in the same way that a unit can be at risk of fire [50], there will always be a small risk of electrical failure [33].

Intensive Care Units are designated category 5 (life support) for patient clinical risk (Ref HTM 06-01 Part A) [51] and will have emergency generator supply back-up in the event of an external

mains supply failure.

However, a contingency plan (similar to fire response [50]) should be made for total power failure as mains and generator supplies can both fail [33].

Such a plan should include consideration of the following:

1 UPS (uninterruptible power supply) installation to bedside or pendant sockets to which essential equipment is connected. UPS will provide usually approx. 60 minutes supply via batteries and AC inverter. This will eliminate any disruption of power supply to all connected electrical devices within the specified time limit. However, installation of comprehensive UPS may only be feasible in a new build due to cost and access.

2 Assessment of which items of equipment have internal battery back-up. This is normal for portable devices (such as infusion pumps) but may not be provided in ventilators, mounted monitoring screens, cardiac output monitors, haemofiltration machines or beds.

3 Evaluation of how other services in the building could be affected (piped gas & vacuum supply, lighting, lifts, electrically operated doors, telephones, computers, printers).

4 In the event of prolonged total power failure, emergency evacuation and relocation to an alternative area with mains electricity may be unavoidable. Adequate portable equipment including, monitors, infusion pumps, ventilators, torches and suction devices should be available.

Units should have a plan to allow evacuation of the unit if there is a localised electrical power failure and should have the facilities to provide battery powered lighting and the ability to manually ventilate patients.

Standardisation of equipment

Unnecessary variation in the provision of health care tends to increase patient harm [51]. There are strong potential advantages to standardisation:

1. Ease of training staff, particularly when moving between departments.
2. Reduced maintenance costs.
3. Equipment can be moved between departments to cover fluctuations in demand so reducing the total number of devices required.
4. There may be cost reductions for placing large orders and for entering into long term arrangements with suppliers.

There are also some risks:

1. If the equipment proves unreliable or otherwise unsuitable, then the consequences will be more significant than if there was a range of equipment.
2. There will be a smaller range of equipment that would be helpful in dealing with special indications.

Trusts should aim to standardise equipment where the advantages and disadvantages of standardisation have been assessed.

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