University Hospitals of Derby and Burton
NHS Foundation Trust

TRUST POLICY FOR THE MANAGEMENT OF MEDICAL DEVICES

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	V3	June 2019	Mark Cannell, Thomas Spicer, David Wheatley	Joint UHDB policy
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Training and Dissemination: Training is provided for all identified clinical and medical staff in clinical areas as identified in local training needs analysis. Dissemination via the Trust Intranet				
To be read in conjunction with: Trust Policy for the Assessment and Management of Risk, Trust Policy and Procedures for Incident Reporting, Analysing, Investigating and Learning, Trust Policy for Decontamination, Trust Policy for the Competency and Training Connected with Medical Devices				
In consultation with and Date: Medical Devices Group June 2019.				
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Contact for Review			Clinical Specialist (Medical Devices), and Heads of Derby and Burton Clinical/Medical Engineering	
Executive Lead Signature			Medical Director	

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1 Introduction

Effective management of Medical Devices from efficient procurement, through effective use and maintenance to eventual disposal requires the full co-operation of all University Hospitals of Derby and Burton (UHDB) staff.

This Policy gives an overview of roles and responsibilities introduced by Trust to fulfil its "duty of care" to its patients and staff; whilst also ensuring compliance with the various Professional and Moral standards and current Legislation.

2 Purpose and Outcomes

These device management procedures are to ensure that whenever use is made of a medical device it will be:

- Suitable for its intended purpose.
- Properly understood by its user, and used safely and in a competent manner be they a member of staff, patient or carer.
- Maintained in a safe and reliable condition.

In order to manage the above identified risks associated with Medical Devices the Trust has a single practice and procedure which include the processes for:

- Acquisition (suitability, value and conformity with other products or constraints).
- Acceptance of a purchased device.
- Suitable decontamination.
- Maintenance.
- Repair.
- The training of authorised users.
- Application of Safety alerts (including Manufacturers recall).
- Replacement planning.
- Disposal.

These are reviewed in more detail in Appendix 1 through 9.

The definition of Medical Devices is too broad and for the purpose of simplicity and this policy is broken down into "Clinical Equipment" and "Consumables".
A third division of the definition will come under a further heading of "IT" as the definitions surrounding this aspect of "Device" are still in debate at Department of Health level, it is felt prudent and sufficiently important by the authors to be included.

3 Definitions Used

A Medical Device: is defined by the MHRA (Managing Medical Devices. April 2015) as any product used in the diagnosis, treatment, prevention or alleviation of illness or injury, of a patient.

Clinical Equipment: are mostly powered (and mostly reusable) Medical Devices, requiring Maintenance and Service as per manufacturer's instructions. These individual items have to be recorded separately for governance and maintenance reason rather than value and capital asset reasons (as can be occasionally singularly known despite being considered a group of components (e.g. Endoscope Stack contains multiple items and the cart). These items generally have an individual value such that they are bought and also recorded as Capital assets.

Consumables: are mainly "Single Use Medical Devices"; often very low cost, high volume products, occasionally associated with specific Clinical Equipment (then known as Dedicated Consumables). As low cost are often bought directly by clinical areas, as part of their revenue spends.

Single Use Medical Devices: All devices that are for single use or single patient use will not be re-used within the Trust. See Appendix 10, for detail and any relevant action plans.

Implanted Medical Devices: These products are single patient items that are as the title suggested integrated into the Patient via an invasive procedure; these can be inert such as a prosthetic implant (e.g. a hip joint) or active (e.g. Pacemaker).

Medical Devices related IT: this definition is still under debate as a number of applications/programmes can interact with medical equipment in such a way to change the manner of the Medical Devices function – these functions may have previously been performed via a direct control panel by a user, or by internal physical switches by Engineers. See Appendix 11, for detail and any relevant action plans.

Trust Equipment Database: there will be one single source of information relating to the inventory of Trust Clinical Equipment. (See Appendix 12, for detail and any relevant action plans). This will link to other Trust systems to allow diligence and remove repetition (i.e. Clinical Equipment Ordering systems, Financial Asset Management, Authorised User Training, Warrantee/Maintenance Management, Spares Management, Service Swap Management, Loan Management and Service Contracts). This is applicable to all capital Medical Devices, and those requiring service intervention or repair; it also includes externally serviced items and those under "Managed Services".

Device Labelling: To ensure that the ownership and user requirements for service are easily understood and by use of good Human Factors based design, all products under the Clinical Equipment Banner will be labelled using one convention and set of rules. See Appendix 13, for detail and any relevant action/implementation plans.

4 Key Responsibilities/Duties

4.1 The Chief Executive

The Chief Executive has overall responsibility for the use and management of Medical Devices within the Trust.

4.2 The Trust Board

The Trust Board will seek independent assurance that an appropriate and effective system of managing Medical Devices is in place and that the necessary levels of controls and monitoring are being implemented.

4.3 The Medical Director

The Medical Director is the nominated Executive Director for Medical Devices, and has Board level responsibility for ensuring that there is clear and effective monitoring of all aspects of Medical Devices management, and that the Trust is in compliance with relevant legislation and Department of Health guidance with regards to Medical Devices.

4.4 The Chief Nurse

The Chief Nurse is the nominated Executive Director for Risk Management, and has Board level responsibility for ensuring that there is clear and effective monitoring of all aspects of Risk Management associated with Medical Devices.

The Chief Nurse is also the nominated Safety Alert Broadcast System (SABS) liaison officer for the Trust. Responsibility for ensuring that safety information relating to Medical Devices is disseminated throughout the organisation, and acted upon accordingly, is delegated to the Patient Safety and Risk Managers.

4.5 Risk Services

Risk services provide the resource of the incident recording systems for the Trust, receiving reports of incidents involving Medical Devices within the Trust, and work with specialist staff from all departments to investigate incidents and report findings. They are also the holder of the Trust Risk Register that includes details of identified risks associated with Medical Devices.

They receive and facilitate the Safety Alert Broadcast System (SABS)/Central Alerting System (CAS) information and alerts which are disseminated throughout the organisation. These include the Patient Safety and Medical Device Alerts (PSA & MDA respectively) distributed from MHRA and NHSi/e. They also act as a point of contact and record for the significant number of Field Safety Notices (FSA) from Manufacturers.
Risk Services provide Trust wide incident reporting training that includes the procedures and processes for reporting all incidents including those involving equipment or Medical Devices.

4.6 Clinical and Medical Engineering

The essential day to day repair and maintenance of the Trust clinical equipment is managed by these departments. They provide non-clinical advice and support for the acquisition and retention of Medical Devices; they manage the maintenance of equipment database, acceptance and disposal, monitoring/raising equipment performance or support issues and are part of the Safety Alerts cascade.

4.7 Procurement and Purchasing

These departments ensure that all equipment ordered (capital, lease, rental, loan etc.) has been properly approved by the relevant responsible party in accordance with this and relevant financial policies. They also track the procurement of all equipment and are an essential part of the Safety Alerts cascade and recall processes

4.8 Medical Devices Safety Officer (MDSO)

The Trusts nominated MDSO will liaise closely with the Medicines Safety Officer (MSO) and Risk Services to ensure prompt and appropriate responses to Safety Alert cascade notifications and act as the Trust connection with the MHRA on device related incidents and learning. They are also a member of the National Medical Devices Safety Network as required by MHRA and NHS England Patient Safety Alert NHS/PSA/D/2014/006 'Improving Medical Device Incident Reporting and Learning'
See Appendix 14, for detail, links to both Safety Alerts Policy and Medicines Safety Policy, also relevant action plans.

4.9 Medical Devices Training

Medical Device Training of authorised users is managed in a consistent and pragmatic way within the Trust, using a risk assessment process to identify equipment requiring significant assurance and specialist users only. This will link with procurement and Device safety. This will be managed and reported as per Policy.
See Appendix 15, for details, link to the Medical Devices Training Policy and any relevant action plans.

4.10 Medical Equipment Library's

The Trust's Equipment Library systems provide recognised efficient use of common equipment across the Trust, and cost savings in procurement. The system also allows for limited consumable rationalisation and management. Function and activity is reported through the MDPUG on exception.
The Equipment Library Team, with Procurement, and the Medical Device Engineering teams manage, regulate and support day to day equipment purchasing and standardisation.
See Appendix 16, for detail and any relevant action plans.

4.11 Divisional Directors

These individuals report to the Trust Board and the Chief Executive via the Chief Operating Officer. They are managerially responsible for the function of the Clinical Divisions, their Business Units and Wards, and are responsible to the Trust Board (via MDPUG and MDG) for the compliance of their staff to this, and associated Policies.

4.12 Business Unit Management

These Groups (Management, Nursing and Medical) report the Divisional Boards, responsible for the function of their subordinate service areas (Wards and departments)

and are responsible to their respective Divisional Board for the compliance of their staff to this, and associated Policies.

4.13 Ward and Departmental Management

These teams report the Business Unit Management; they are responsible for the function of their direct areas (Wards and departments) and are responsible to their respective Business Unit Board for the compliance of their staff to this, and associated Policies.

4.14 Users

This definition relates to authorised users of Clinical Equipment, this is detailed in the Medical Devices Training Policy, which includes all Trust Clinical Staff (Doctors, Nurses, Allied Health Professionals and non-trained support workers), Bank and Agency staff working in these roles, and Carers and Patients.

4.15 Medical Device Groups

A hierarchy of Device related groups exist in the Trust to assure levels of adoption of the policies and that the governance is embedded.

4.15.1 Medical Devices Group (MDG)

This is a sub group of Finance and Information Committee and receives escalations from MDPUG. The bids for Capital Equipment are debated and challenged in this forum. The links to Estates Prioritisation and Change in Clinical Practice forums are formal, and often bids require authorisation from at least 2 of these forums.

Quorate MDG is responsible for authorisation of ANY “Clinical Equipment” related trials and development of prioritised replacement plans.

See Appendix 17, for MDG terms of reference.

4.15.2 Medical Devices and Product User Group (MDPUG)

This is a division and business unit linked group, reviewing Training and Maintenance compliance levels and action plans. Non-compliance is an escalation to MDG. This group has close links to Decontamination Groups and management, also with the operational procurement meetings. The group manages, with clinical areas, any authorised trials of devices. This forum takes reports and monitors the operational policies; such as the Loans Protocols, Company Representative Codes of Conduct, Medical Devices Training Policy. The group with supplies manages the identification of standard products for supplies masking of consumables and recommendations to MDG of standardised clinical equipment.

See Appendix 18, for MDPUG terms of reference.

4.15.3 Theatre Supplies and Equipment Group

The Theatre Supplies Group explores the specialised procurement needs of the wider operating theatre establishment, looking for value and efficiencies by working as a Trust. They are responsible for developing long term strategies to maximise the use of equipment within a large department. They report issues by exception to MDPUG, and make capital bids via the Surgical Division Management route to MDG.

See Appendix 19, for this group’s terms of reference and any relevant action plans.

5 The Process for Control of the Risks Associated with the Management of Medical Devices

5.1 Establishing a need and implications

Prior to any purchase the Trust requires a purchaser to establish that there is a true need to have this device and not a “nice to have”, the procurement process will require that the local management team will have to commit resource to support this new equipment and identify its affordability, e.g. against tariff.

A new device, to be utilised within a new process or similar will require peer review and scrutiny at “Change in Clinical Practice”, to ensure the Trust is meeting minimum

standards, e.g. NICE. It will also require risk assessment to ensure the new process doesn't have problematic collateral effects.

Part of some purchases will be to ensure the users of the service and service providers are suitably safe during the use of this device, this may require the infrastructure and building to be modified to enable this, these costs will need to be identified and changes would need exploration and authorisation by ESPG (Estates and Services/Space Prioritisation Group), Health and Safety (H&S) – to explore any protective measures and IT (Information Technology) – to ensure the product efficiently, safely and securely integrates to existing Trust systems, without these consideration/authorisations MDG will not proceed or accept bids.

Consideration of the users that common equipment is more efficiently utilised through a pool system such as an "Equipment Library", so bids may be more effective to increase the Trust inventory of a product rather than a local stock.

The method of obtaining a product can be made more efficient than a simple purchase, e.g. rental of an infrequently used expensive product may be more cost effective than purchase options. This last part is a complex and hazardous process so must be supported by our procurement personnel.

5.2 Product choice

The Trust, where ever possible, will utilise a common product set across all of its areas of influence. Products from NHS supply chain will (where possible) be vetted and a process of masking products will be managed by our procurement team. This will support efficiencies and recall issues.

Selection must be in accordance with the Medical and Healthcare Products Regulatory Agency and National Audit Office recommendations and subject to appropriate acceptance procedure. This also includes non-purchase of Medical Devices i.e. renting, borrowing, leasing, in-house manufacture, modification of in-house devices, refurbishment and 'cannibalising'. Decontamination issues must be considered at the time of purchase.

Non-stock products will (where possible) be standardised to allow efficiencies from contracted purchases and favourable servicing arrangements, this may also include consumable utilisation.

Details of standard products will be available from our procurement team.

Standard products will be recognised following an (MDG) authorised product evaluation following a set process, with involvement of appropriate trust expertise.

The common thread throughout the process above is to enshrine the principles that the equipment will be:

- Suitable for its intended purpose.
- Properly understood by its user, and used in a competent and safe manner.
- Maintained in a safe and reliable condition.

See Appendix 20, for detail of this review process and any relevant action plans.

5.3 Procurement and Purchasing

Purchase of a non-stock (i.e. non Supply Chain) Medical Device is via a purchase requisition and must be supported by the relevant budget holder's approval. Procurement is unable to process the request without this.

Products exceeding the revenue cap will be considered capital spends and will then need to be submitted to the area in question's Divisional Leads for them to be prioritised against the divisions other bids. This is then taken to MDG for final challenge and financial approvals.

See Appendix 1 for more information

5.4 Loan or evaluation

Any items loaned or given to the Trust for evaluation must have prior approval by the MDG for capital, or MDPUG for consumables items.

Use of such items is not covered by the Trust insurance and therefore must be identified and indemnity agreed under the Department of Health Master Indemnity Agreement – see Appendix 1 for details

5.5 Commissioning

All Medical devices require recognition of receipt and initial set up, therefore the delivery point for all new items of equipment should be Medical/Clinical Engineering.

The delivery will be checked against the purchase order (in accordance with MDA 2006(05)) and against other required standards, before they can be put into use, equipment details entered on the Medical Equipment database and issued with a Trust Identifier Number and label (Appendix 13). Acceptance checks are carried out, any configuration set and assembly or installation is completed correctly. At this point a maintenance plan will be established for the equipment.

The delivery point of large items should be agreed between Procurement team and Medical/Clinical Engineering prior to going to order, particularly for remote sites.

Medical/Clinical Engineering shall retain equipment until user training has been completed in line with the Medical Equipment Training Policy. Equipment will be labelled indicating that it is a new item and should not be used without training.

User training includes an understanding that they have a responsibility to confirm that the device is working correctly and as expected following any commissioning or repair.

5.6 Maintenance and repair

It is the personal responsibility of every equipment user to ensure the devices are fit for purpose prior to every use. This includes checking the item is within its identified service date.

It is the additional responsibility of the clinical department manager/lead to ensure all equipment used in the department is in good repair, and “in service”, making this equipment available for maintenance.

The Engineering Department will provide prompt lists on a regular basis, and have this available from the Trust information portals.

The information to allow measurement and compliance will be provided and each area will be responsible for reporting through Business units to division where compliance deficit action plans will be discussed before presentation at MDPUG, with non-compliance escalated to MDG.

The information available to the Areas and alike will be via Trust portals to the engineering databases. Please see Appendix 22 for details and availability of this data.

5.7 Reporting Faults

Wards and Departments should contact their local Clinical/Medical Engineering facility. Required information is the

- Equipment Identifier (Asset/Maintenance number) and a description of the equipment.
- A description of the fault
- The name and position of the person reporting the faulty equipment.
- If a declaration of contamination status has been completed.
- Collection or delivery of equipment is site and product dependant, this will be negotiated on contact with your local Clinical/Medical Engineering facility – see Appendix 5 for details.

5.8 Emergency Breakdowns

This process is area and often product specific.

An example is of an outpatient area with 12 thermometers and one breaks – this does not come under the Emergency Breakdowns process, for this follow fault reporting.

Details of this are in Appendix 5

5.9 Authorised Modification

The Off-label use of Medical Devices is where devices are used for purposes other than those intended by the manufacturer, this and the adaptation and use of non-medical products for clinical purposes must be avoided.

The consequence of this activity is that it cannot be assured that these devices are safe, suitable or effective and therefore exposes the users and patients to unacceptable risk.

Please contact your local Clinical/Medical Engineering department for advice.

5.10 Management of Devices involved in incidents

Please refer to the Incident Management Policy and Process.

It is essential that any equipment or device involved is quarantined, settings not changed, consumables and packaging retained.

The device must be reported to Clinical/Medical Engineering for technical investigation. The Clinical/Medical Engineering Manager will be responsible for the production of any necessary technical report for the investigation, in collaboration with the Medical Devices Training personnel

The MDSO will be automatically notified via the Trust Incident reporting system of all incidents involving Medical Devices and will monitor for incident trends, advise in investigations and report as required to the MHRA.

In all cases of harm, suspect items should not be repaired in-house, by a third party, returned to the manufacturer/supplier or discarded before the local investigation has been carried out.

5.11 Staff Disciplinary Action

Any attempt by any member of staff to interfere with the correct working of a medical device, or to alter its basic electronic configuration without proper authority, may result in disciplinary action.

Any attempt to gain access to the internal workings of, or to repair, or attempt a repair, on a medical device, by any unauthorised member of staff may result in disciplinary action.

5.12 Acceptable behaviour of Company Representatives on Trust Premises

Hospitals buildings are privately owned by their respective Trusts. It is the expectation that whilst Device Manufacturer's agents are on Trust Property, they are to behave in a manner supportive to our Trust's best interests. For further detail please see the Trust Policy on Commercial Representatives.

5.13 Equipment disposal

All Clinical Equipment has to be disposed of in a safe, responsible and appropriate manner. The initial part of the process is to identify if the device has use elsewhere within our Trust, then Disposal may be by either Transfer of ownership (by sale via an approved auction house) or Disposal as waste.

The selling of Medical Devices must be notified through the Medical Devices Group and the Director of Finance to ensure the asset is written off as appropriate in accordance with Standing Financial Instructions.

All require the involvement of the local Clinical/Medical Engineering Department, following the ‘Local Disposal Policy’ must be followed to facilitate updating the Trusts Asset Register.

The Clinical/Medical Engineering Department will decommission all Medical Devices prior to disposal. Decommissioning will ensure that the medical device is risk and environmentally safe for disposal and any electronic patient data has been removed.

Any medical device, which through age, inability to effectively fulfil its intended purpose, becomes unreliable in use, uneconomical to maintain or cannot be easily cleaned, will be reported to the Clinical/Medical Engineering Department for investigation prior to possible withdrawal from service and replacement action being taken.

5.14 British Summertime and Clocks

Please see Appendix 23

6 Monitoring Compliance and Effectiveness

Monitoring Requirement :	• Health and Social Care Act 2008
	• The Medicines and Healthcare Product Regulatory Agency (MHRA) document 'Managing Medical Devices – April 2015'
	• IEC 62353:2014 'Medical Electrical Equipment – Recurrent test and test after repair of medical electrical equipment'
	• NHS Resolution (NHSR) Risk standards The risk standards impacting on medical devices management are:
	  • Standard 5, criterion 4: Maintenance of medical devices and equipment
	  • Standard 5, criterion 5: Medical devices training
	• Health and Safety at Work Act 1974
	• The Provision and Use of Work Equipment (1998) regulations require all equipment to be maintained such that it is safe and regularly inspected to ensure the same.
	• The Electricity at Work Regulations (1989) requires that electrical equipment is tested at regular intervals to ensure that it is electrically safe.
	• CQC Outcome 8 (St12) Cleanliness and infection control
	• CQC Outcome 11 (St16) Safety, availability and suitability of equipment

Monitoring Method:	The MDPUG will monitor a number of metrics via reports from Divisional and Business unit representation as fixed agenda items, this will include • Medical Devices training compliance and action plans • Medical Device servicing compliance and action plans • Equipment decontamination compliance • Equipment Library use and returns compliance • Safety Alerts response compliance and action plans • Incidents relating to medical devices reporting
Report Prepared by:	Chair of MDPUG
Monitoring Report presented to:	Exception Escalation to MDG ad hoc 6 monthly Medical Devices Group, to F&IC
Frequency of Report	Six Monthly

7 References

References – related/further reading.

1) Guidance about compliance. Essential standards of quality and safety. Care Quality Commission, March 2010
2) NHSLA Risk Management Handbook, 2011/12. NHS Litigation Authority, February 2011.
3) NHSLA Risk Management Standards for NHS Trusts providing Acute, Community or Mental Health & Learning Disability Services and Independent Sector Providers of NHS Care, 2011/12. NHS Litigation Authority, January 2011.
4) Medical Electrical Installation Guidance Notes, (MEIGaN) (2007), Medicines and Healthcare Products Regulatory Agency, London
5) Single-Use Medical Devices: Implications and Consequences of Reuse MHRA DB2006(04) v2.0
6) Management of In Vitro Diagnostic Medical Devices MDA DB2002(02) Medical Devices Agency, London
7) Management and use of IVD Point of Care Test Devices MDA DB 2002(03) Medical Devices Agency, London
8) Reporting Adverse Incidents and Disseminating Medical Device Alerts MHRA /2004/001. Medical Devices Agency, London
9) Safeguarding Public Health: The Medical Devices Regulations: Implications on Healthcare and other related Establishments Bulletin 18. Medicines and Healthcare products Regulatory Agency (2003), London
10) Managing Medical Devices: Guidance for healthcare and social services organisations - April 2015 Medicines and Healthcare products Regulatory Agency, London
11) The Management of Medical Equipment in NHS Acute Trusts in England National Audit Office (1999), London
12) For The Record - Managing records in NHS Trusts and Health Authorities HSC 1999/53 1999 NHS Executive
13) The Ionising Radiations Regulations 1999, SI 1999/3232 Stationery Office 1999 ISBN 0 11 085614 7
14) Guidance on the safe use of lasers, IPL systems and LEDs – MHRA DB 2008(03)
15) BS EN 60825-1:2007 Safety of Laser Products – Part 1: Equipment classification and requirements
16) BS EN 60825-8:2006 Safety of Laser Products – Part 8: Guidelines for the safe use of laser beams on humans
17) BS EN 60825-14:2004 Safety of Laser Products – Part 14: A user's guide
18) BS EN 207:1999 Personal Eye-Protection – Filters and eye-protectors against laser radiation (laser eye protectors)
19) BS EN 60601-1:2006 Medical Electrical Equipment, General Requirements for Basic Safety and Essential Performance
20) IEC 62353:2014 'Medical Electrical Equipment – Recurrent test and test after repair of medical electrical equipment',
21) BS EN 60601-2-22:1996 Medical Electrical Equipment Part 2: Particular requirements for safety – Section 2.122 Specification for diagnostic and therapeutic laser equipment
22) Health and Safety at Work Act HMSO 1974 ISBN 0 10 543774 3
23) Safe Use of Work Equipment, Provision and Use of Work Equipment Regulations 1998. Approved Code of Practice and Guidance L22 HSE Books 1998 ISBN 0 7176 1626 6
24) Electricity at Work Regulations 1989 SI 1989/635 HMSO 1989 ISBN 0 11 096635 X
25) Health and Social Care Act 2008 (regulated Activities) Regulations 2009
26) Lifting Operations and Lifting Equipment Regulations (LOLER) 1998

8 Appendices

Please Note: These will be links to the separate Documents as developed, in the interim (Whilst Red) please contact either RDH Campus Clinical Engineering Manager (Thomas Spicer), QHB Campus Medical Engineering Manager (David Wheatley) or the Trust's Equipment Clinical Specialist (Mark Cannell),

8.1 Acquisition (suitability, value and conformity with other products or constraints)

8.2 Acceptance of a purchased device

8.3 Suitable decontamination

8.4 Maintenance

8.5 Repair

8.6 **Now in Appendix 15

8.7 **Now in Appendix 14

8.8 Replacement planning

8.9 Disposal

8.10 Single Use Medical Devices

8.11 Medical Devices related IT

8.12 Trust Equipment Database

8.13 Device Labelling

8.14 Safety Alerts Policy

8.15 Medical Devices Training Policy

8.16 Medical Equipment Library

8.17 Medical Devices Group Terms of Reference

8.18 Medical Devices and Product User Group Terms of Reference

8.19 Theatre Supplies and Equipment Group Terms of Reference

8.20 Product Evaluation Process

8.21 Company Representative Policy

8.22 Process for dealing with device related incidents

8.23 British summertime and Clocks