

Medical Devices Policy

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| Version number : | 4.0 |
| Consultation Groups | Medical Devices Committee |
| Approved by (Sponsor Group) | Lead Nurses , Nursing Development , CHS Policy Alignment Group |
| Ratified by: | Quality |
| Date ratified: | December 2019 |
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| Implementation Date : | March 2019 |
| Last Review Date | July 2019 |
| Next Review date: | September 2022 |

| Services | Applicable To |
|---------------------------|----------------------|
| Trust Wide | ✓ |
| Mental Health and LD | |
| Community Health Services | |

| Version | Date | Author | Status | Comment |
|----------------|---------------|---------------|---------------|---|
| 1.0 | March 2008 | DG | Final | Newham PCT Policy |
| 2.0 | July 2013 | CS | Draft | Trust wide Medical Devices Policy |
| 3.0 | November 2014 | CS | Draft | Inclusion of software as a medical device. Recognition of the trust wide provider of medical solutions. |
| 4.0 | July 2019 | BK | Final | Update to include community services and reformatted. |

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1. Introduction

ELFT attaches the greatest importance to the safety and care of its patients and considers it essential to provide effective and safe use of Medical Devices/equipment for patient care. We are also committed to ensuring safe systems of working, safe use of devices, and the provision of training and supervision to this purpose. Healthcare staff play a vital role in ensuring that medical devices are procured safely and used safely and effectively. They are vital for diagnosis, monitoring, rehabilitation and care. Effective management of this important resource is necessary to provide safe and high-quality patient care, clinical and financial governance, including minimising risks relating to adverse incidents.

The Medical Devices Policy is the overarching framework for the East London Foundation Trust (ELFT), which aims to provide clear guidance to staff on the acquisition, use and disposal of all reusable Medical Devices.

The growth of digital health, including artificial intelligence, software, and apps; combined with the implementation of the Medical Device Regulation (MDR), and the UK tech vision to build the most advanced health and care system in the world, all mean that it is an exciting time within the world of medical devices.

However, it must be recognised that failure, design flaws or incorrect use of such systems have the potential to cause patient harm. New digital tools and processes can also introduce new risks to clinical workflows. To help mitigate these risks, NHS Digital's Clinical Safety Team has developed clinical risk management standards to support the safe design, build, deployment and maintenance of health IT systems. These standards are mandated under section 250 of the Health and Social Care Act 2012 and should be considered and must be met by suppliers and health organisations when commissioning and deploying any new health IT system. They now align with the new medical device regulations for standalone software and thus apply to all health IT systems, including those regulated by the medical device regulations.

https://improvement.nhs.uk/documents/5472/190708_Patient_Safety_Strategy_for_website_v2.pdf

2. Medical Devices Definition

2.1 Introduction

The Medicines in Healthcare Regulatory Agency (MHRA) 2015 defines a Medical Device as any instrument, apparatus, appliance, material software or other article that may be used on a patient for the purposes of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury.
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

| Function | Examples |
|---|---|
| Diagnosis or treatment of disease | <ul style="list-style-type: none"> • Diagnostic laboratory device • X-ray machines • Magnetic resonance imaging (MRI) scanners • Vascular Catheters • Dressings • Surgical Instruments • Syringes • Hip replacement implants • Standalone software for diagnosis |
| Monitoring of patients | <ul style="list-style-type: none"> • ECG • Pulse oximeter • Apps on mobile device |
| Critical Care | <ul style="list-style-type: none"> • Infant incubators • Blood-gas analysers • Defibrillators • Ventilators • Vascular stents |
| Improve function and independence of people with physical impairments | <ul style="list-style-type: none"> • Hoists • Orthotic and Prosthetic appliances • Pressure care devices • Walking aids • Wheelchairs • Dressings • Domiciliary oxygen therapy systems |

2.2 Single Use Medical Devices

Medical devices designated for single use are not to be re-used under any circumstances. MDA 2000 (04) draws attention to the hazards and risks associated with re-processing and re-using single use items.

Single use: means that the manufacturer:

- Intends the item to be used once and then disposed of.
- Considers the item unsuitable for use on more than one occasion.

- Has insufficient evidence to confirm that re-use would be safe.

Single use Medical Devices should not be re-used as this affects the safety, performance and effectiveness of the device, and exposes staff and patients to harm.

3. Purpose

This policy describes the systems to manage and mitigate the risks associated with the acquisition, deployment, planned preventative maintenance, repair and disposal of medical devices within the organisation. It also gives guidance on user training and competence. Amongst others, this policy is based on the recommendations of the MHRA document Managing Medical Devices – Guidance for healthcare and social services organisations (April 2015). To enable clinical delivery of quality healthcare and compliance with clinical and financial governance, and to minimize risks of adverse events, this important resource requires effective and diligent management. Unless Medical Devices are managed proactively, reoccurrence of adverse incidents may happen. Safe and effective management will enhance the patient experience and reduce the risk of harm.

4. Scope

This policy applies to all Medical Devices purchased by ELFT for use with inpatients and within the community services. It does not apply to Medical Devices purchased by individual patients for their own use. The policy applies to all ELFT staff, in particular those who use Medical Devices and are responsible for the procurement, deployment, maintenance and repair of such devices. The policy acts as a guide to good practice in the management of Medical Devices. It provides information on the “lifecycle” aspects of Medical Devices, from purchasing, deployment, maintenance and repair through to their final disposal.

This policy sets out standards to ensure compliance with Medicines and Healthcare Regulatory Authority (MHRA) Legislation and Care Quality Commission (CQC) and Regulation 15.2 for Medical Devices.

5. Implementation and Monitoring

The policy is posted on the Intranet with promotion via the Communications team to inform of the implementation of the policy with a request to managers to disseminate as appropriate in their areas. As this is a review of a policy, no specific training will be arranged.

All staff should be aware of their responsibilities/accountabilities with regards to Medical Devices which should be discussed both at local inductions and annual appraisals thereafter.

The local quality groups will monitor the implementation of this policy and report on the performance of medical equipment management via the Quality committee.

The Directorate Quality group will produce an end of year report for the Trust Virtual Medical Devices Group and specific to compliance as defined by the steps outlined in this policy.

6. Systems and Management

The Trust board is responsible for ensuring there are effective systems in place within the organisation.

The Chief Nurse is the executive responsible for Medical Devices; this responsibility is delegated to the Lead nurse on Physical Health.

The Operational Directors through their service managers are to ensure that those services directly managed by the Trust adhere to the standards set out in this policy.

Directors and Operational Managers are to ensure that all professionals are appropriately trained and competent in the use of the medical device and that training is formally recorded, reviewed and updated regularly.

The Associate Medical Director of IT & Systems will ensure that all new software applications that ELFT uses are reviewed in line with MEDEV 2.1/6 in order to assess whether or not it is likely to constitute a Medical Device

The Quality Committee oversees Medical Devices including adverse incident reporting and actions required on MHRA's Medical Devices alerts and manufacturers field safety notices. The Quality Committee oversee the development and implementation of the Medical Devices policy.

7. Duties

7.1 All Staff

Medical devices and equipment are used every day by most healthcare professionals to support the care and treatment of patients. All relevant staff have a role in ensuring that all equipment is used safely and for the purpose that it was intended for. It is the responsibility of all users of Medical Devices to ensure:

- It is suitable for its intended purpose.
- Its use is properly understood by the professional user.
- That staff are trained and competent in operating and decontaminating the device safely.
- That it is regularly maintained and safe for use.
- That It is procured following safe processes.
- That It is properly decontaminated.
- That staff ensure that patients who are issued Medical Devices understand how to use the equipment safely.
- The selection of the correct device for the intended use whilst ensuring that the device is appropriate the patient's condition.
- That the storage of all devices is practically safe to avoid unnecessary damage.
- That any battery-operated device is charged up where required.
- That any disposables are appropriate and safe to use.
- The agreed procedures and protocols are followed at all times.
- That the knowledge of how to respond a device and in the event of a problem and in order to reduce any risk to the patient.
- That all safety related incidents and potentially harmful products are reported, via Datix.

7.2 Matrons, Ward Managers and Team Leaders

- Will only purchase equipment have approved by the Medical Devices group and through the Trust E Procurement Department processes.
- Will ensure Medical Devices that meet the requirements of the care users are available and as a minimum they are to ensure the availability of mandatory Medical Devices
- Will highlight any deficit in equipment availability to their line manager and Service Director.
- Will ensure that all new equipment is reported to the Avensys department for acceptance testing and inclusion onto the audit and Medical Devices asset register.
- Will ensure decommissioned equipment is reported to the Avensys department for removal from the asset register.
- Will ensure that there is a log book in each area that contains accurate records for each piece of equipment.
- Will ensure that contractual warranties on specific items of equipment are kept safe.
- Will ensure that all new equipment is installed correctly and all the appropriate documentation logged into a logbook that is available to present as evidence for audits or inspection by both internal and external inspectors.
- Will ensure that there is provision of alternative facilities in the event of equipment failure.
- Will ensure that all staff are made aware of the Medical Devices Policy requirements and their responsibilities in this respect.
- Will ensure that staff know how to report faulty equipment.

- Will be competent to assess the competence of clinical and non-clinical staff in the use of Medical Devices.
- Will ensure that Medical Devices (including resuscitation equipment) is checked and records are available as evidence for audit or inspection from both internal and external inspectors.
- Will have systems and processes in their environments to ensure that Medical Devices are clean; all Medical Devices will have a cleaning schedule that is available as evidence for audit or inspection from both internal and external inspectors.
- Will ensure that equipment is replaced, when it is: worn out beyond economic repair, damaged beyond economic repair, clinically or technically obsolete, requiring repair but spare parts are no longer available.

8. Training

Ward managers and service leads are responsible for identifying training needs within their areas of responsibility and are responsible for organising appropriate training.

Ensuring that users of equipment have completed training and verifications of competency.

Staff can access the appropriate chapters in the Royal Marsden Manual of Clinical Nursing Procedures, available on line via the intranet page.

The purchaser will ensure there is a process of training in place to train staff in the use of new equipment.

9. Prescribers of Medical Devices

9.1 Introduction

As Medical Devices become more sophisticated and frequently used, there are risk implications for the healthcare professionals and patients who use them. Prescription of a Medical Device is the process that ensures only the most appropriate item of equipment is given to a patient or carer as part of an overall treatment plan. Clinical risk is reduced by permitting only appropriately trained healthcare professionals to prescribe a Medical Device for use by patients.

The person prescribing will need to have the knowledge and skills to ensure that:

- An appropriate device has been selected.
- The device has been appropriately maintained and decontaminated.
- It has been adjusted (if necessary) for the individual patient.
- The patient or carer is educated and supported in its use.
- Appropriate documentation has been completed. Competency in the correct use of Medical Devices will ultimately result in a reduction in clinical risk and the delivery of high-quality care.

9.2 Dispensing Prescribers

Prescribers who also dispense are responsible for maintaining a database that includes:

- Manufacturers details.
- Serial number.
- Warranty details.
- Date of distribution.
- End of life.

Prescribers are also responsible for:

- Registering the equipment with the appropriate provider company.
- Informing the GP.
- Ensuring the patient is trained.

9.3 Trust Medical Device Leads

- Monitor Medical Devices and other related contracts.
- Provide reports to relevant subcommittees as appropriate.
- Work with the Corporate Central Alert System Risk Manager on relevant alerts.
- Escalate to Trust board and MHRA as necessary.
- Agree processes for appropriate decommissioning and disposal of items not currently under agreed contracts.
- Liaise with Directorates on rolling programme of equipment replacement. Planned replacement of major items should be incorporated into business plans.
- Will run a quarterly report on all Medical Device Datix to identify themes and lessons learnt and create and annual review of key themes to inform future work plans.

10. Decontamination and Cleaning

Medical devices may serve as vehicles for the transmission of infection to susceptible hosts. Decontamination is the combination of processes (including cleaning, disinfection and sterilization) used to make a re-usable Medical Device safe for further use on patients and handling by staff. The effective decontamination of re-usable Medical Devices is essential in reducing the risk of transmission of infectious agents.

- All staff will clean/decontaminate any Medical Device after use in accordance with the manufacturer instructions.
- Staff will ensure that all disposable items for single use are disposed of after single use in the appropriate manner.
- Staff will ensure that all Medical Devices have a cleaning schedule and that is available as evidence for audit or inspection from both internal and external inspectors.
- Appropriate arrangements must be in place for the decontamination of all Medical Devices in service within the Trust. This includes contaminants from the normal use of the equipment, and from any other related activity that might affect it.
- Details of the arrangements and processes relevant to the decontamination of Medical Devices can be found in the Trust's Infection Prevention and Control Policy.

For support and advice about decontamination, contact the Infection Prevention and Control Team.

11. Replacement of Medical Devices

All devices have a set working life based on the technology and continuity in availability of spares/support from manufacturer. When a new device is accepted on inventory, seven years of life expectancy is recorded unless specified by the manufacturer or supplier based on the guaranteed availability of spares and services. Therefore, the database should highlight all the devices due for replacement based on the set parameters.

12. Operational Managers

Operational managers of healthcare services delivered on wards and departments within the Trust are the designated “owners” of a wide range of medical equipment and devices. They are responsible for ALL devices in use on their areas at all times. Therefore, as owners of this equipment, it is their responsibility to ensure that all their equipment is maintained adequately to the manufacturer’s recommendations and timeframe. Advice on equipment main issues can be sought from the Medical Device Lead.

Ward Managers and Service Leads must ensure an inventory of all medical equipment/devices owned or managed by their Department is maintained. This information will be centrally coordinated by the Medical Equipment Servicing contractor in order to enable the organisation to take appropriate action following manufacturer’s recall or the issue of hazard warning notices. The inventory will ensure that Medical Devices are examined annually for electrical safety, calibrated and/or serviced as necessary and that scheduled maintenance takes place.

13. Finance Department

The Finance Department will ensure that Medical Devices are procured in line with Trust Standard Financial Instructions.

They will also monitor and report on spending to the Board as follows: -

- New equipment.
- Replacement equipment.
- Repairs to equipment
- Consumables.
- Contract maintenance.
- Contracting and service level agreements with external stakeholders.
- Will ensure that contracts specify adherence to MHRA regulations

14. Local Log of Medical Devices

All clinical areas will have a logbook that details the lifespan of all equipment within the clinical area. This will include:

- Documentation on receipt of an item.
- Certificates of calibration.
- Warranties.
- Servicing history.
- Repairs history.
- Decontamination certificates if the item has been returned for repair outside the organization.
- Cleaning and checking schedules.
- Certificate of disposal.

19. Medical Device Maintenance and Repair

The majority of medical equipment maintenance in the Trust is provided by contracted companies Arjo and Avensys. Clinical departments will maintain a local inventory of all equipment serviced and maintained via external service contracts. It is their responsibility to ensure that all equipment is maintained to the manufacturer's recommendations and timescales.

The planned preventative maintenance system utilises a computerised register of medical equipment, which highlights equipment that is due for maintenance, the servicing that is required and also the timescale for completion of the work. All maintenance and calibration are as per manufacturer's guidance and timescales. It is therefore important for users, subject to their immediate clinical needs, to make their equipment available upon request for routine maintenance at any given time.

The contracted company has a duty to inform the local Operational Manager and the Medical Device Lead if there are any issues with servicing and equipment maintenance. Random audit will be carried out by the Medical Device Lead to ensure the contracted companies are compliant with contract terms and conditions and specifications. In the event of a fault occurring with an item of medical equipment, the user must remove the equipment from use and inform the appropriate maintenance provider.

Under no circumstances must users attempt to repair the equipment themselves. It is important for users to be mindful of the fact that items of re-usable medical equipment intended for repair and used in the treatment of patients may become contaminated with hazardous substances during use.

16. Medical Equipment Asset Register

All service areas should maintain accurate local registers of devices which are able to demonstrate their maintenance/service history from acquisition through to disposal. The maintenance contractors will maintain an external database (accessible by ELFT staff) of all ELFT Devices and agree on an annual program of planned Preventative Maintenance to ensure devices are safe and accurate.

All medical equipment will be entered onto the equipment management database by the Contractor Avensys detailing the following:

- Unique identifier for service organization.
- A full history, including date of purchase and where appropriate, when it was put into use, deployed or installed.
- Service schedule (if applicable, and to include calibration).
- Maintenance schedule.
- Supplier and manufacturer.
- Serial number.
- Purchase date and warranty period.
- Any specific legal requirements.

17. Electronics Software

The Deputy Director of Infection Control and Lead for Physical health will take the lead for co-ordinating and evaluating prospective physical medical devices that contain any software element, including internet of things (IT) devices. They will co-ordinate with relevant IT and clinical experts to evaluate the safety of these devices and that they comply with relevant medical device regulations. In addition, they will ensure that appropriate cyber security requirements are met in collaboration with IT and the information governance lead. The directorate proposing a project will prepare a report outlining benefits and risks together with any mitigations in place and deployment plan for submission to the Digital Strategy Board for approval.

The Director of IT & Systems will ensure that all new software applications that are ELFT uses are reviewed in line with MEDEV 2.1/6 in order to assess whether or not it is likely to constitute a Medical Devices.

All products that may be considered Medical Devices, including clinical information systems that are potentially subject to the Medical Device Regulations, shall undergo a process of review prior to deployment by the Trust.

An initial assessment will be made as to whether the device has no software element, includes software or is solely software.

In the case of products that are or include software the flow chart in MEDDEV 2.1/6 will be used to check whether a software application is or is not likely to constitute a Medical Device. Medical software that will be reviewed as to whether compliance is necessary includes Clinical Information systems, Decision Support Software, Information Systems,

Communication Systems, Web Monitoring Systems and in Vitro Diagnostic Systems. If compliance appears to be necessary, the Trust will seek appropriate documentation from the manufacturer and in cases of doubt will rely on the opinion of the Medical and Healthcare Products Regulatory Agency (MHRA) as to the applicability of the regulation.

Where the certified medical device consists solely of software (within for example the electronic health record, or a web application), the use of the certification of this device will be incorporated within the Clinical Safety Case for that digital solution and will fall under the remit of the IT clinical safety programme.

A responsible individual will review the supplier safety documentation, review the device with respect to potential risks and offer remedial consideration for the mitigation of risk, consider user and staff documentation, consider training requirements and produce a proposed deployment plan covering these matters.

Before deployment of these systems the Medical Devices group will in conjunction with IT and information governance evaluate the safety of these systems, provide guidance on mitigating risk and ensure that cybersecurity vulnerabilities that might compromise patient safety are addressed.

18. Tele Health

18.1 Tele Health

Tele health is the delivery of health services or information using telecommunications technologies. It uses devices to monitor people's health in their own home including monitoring vital signs (blood pressure, heart rate, blood oxygen levels, and weight). The monitoring includes blood glucose as well. The data can then be transmitted to a healthcare professional who can observe health status without the patient leaving home. Increasingly, this latter function could be placed on a server and software could be used to interpret the patient data. This could be considered a Medical Device.

Software used for Tele health purposes may or may not be classified as a Medical Device, under MEDEV 2.1/6 (f.4) Home care monitoring, wired or mobile. Standalone software intended for archiving patient results or for transferring results from the home environment to the healthcare provider is not an IVD device. The results are available, readable and understandable by the user without the intervention of the software, also (d.1.3) Home care monitoring, wired or mobile. The telecommunication system (mobile, wireless, wire, etc....) is not, as such, a Medical Device. Tele health systems that manipulate and act on data transferred can be regarded as Medical Devices.

In the case of Tele health services offered by the Trust, the Docobo Telehealth solutions is classified as a medical device and the Florence (Flo) simple Tele health system is not classified as a Medical device. The Medical and Healthcare Products Regulatory Agency (MHRA) advises that they found Florence most likely NOT to be a Medical Device, as it is effectively a transport and storage medium for raw data and most importantly does not de-skill the work of a clinician, by e.g. embellishing data or performing clinical algorithm calculations. The MHRA's advice is not definitive as to whether a device is or is not a Medical Device as this is something that can be tested in a court of law; nevertheless, as it is the regulatory authority, it is the best source of advice currently available

18.2 Home Telehealth Systems with Connected Monitoring Devices

MHRA requires individual devices to be CE marked as Medical Devices but does not require a system to be CE marked as a Medical Device unless it is placed on the market as a single product. Items such as the hub and possibly the motion detector (depending on the claims of the manufacturer) are not likely to be CE marked Medical Devices as they do not have a medical purpose. However, the software that runs on the server and interprets or interpolates the patient data is likely to be a Medical Device and would be regulated as such.

19. Instructions/Guidance

All users, end users and technical staff must have access to manufacturers' instructions. It is the responsibility of each Directorate to ensure user manuals are current for the device(s) in use in their area and that revised user manuals are requested when devices receive software upgrades after repair or service. Each device will have a risk log with appropriate mitigations in the use of the device available as part of the deployment of the solution.

20. Acquisition of Medical Devices

The selection process takes into account care objectives and priorities of the healthcare organisation and the needs of the patients. The process should consider whole life costs and follow the national acquisition policy and recommendations, including any regional or national aggregation of procurement where this results in best value for money.

The acquisition process should take the needs and reasonable preferences of all interested parties, including those involved in the use, commissioning, decontamination, maintenance and decommissioning of all Medical Devices.

The procurement department should ensure consumables are cost effective for the life of the device if applicable. This would include the cost of the device and its maintenance and the lifetime costs of consumables.

The procurement process should take account of the Trusts standardisation procedures, furthermore; Safety, quality and performance considerations are to be included in all acquisition decisions.

The recommendations of the MHRA and other appropriate bodies are to be considered before selection and acquisition.

Procurement should ensure that all acquisitions meet local and European regulations. Procurement must comply with 'Information Asset Privacy by Design Procedure' policy and ensure that cybersecurity vulnerabilities are addressed.

Where new equipment is to be sourced and a shortlist has been reached, equipment may be demonstrated or given a trial period of use and the opinion of all intended users considered. Before equipment is used for demonstration or trial, the Medical Devices department will be consulted to ensure there is an indemnity procedure in place.

21. Equipment Hire

Hire agreements must be checked to ensure that arrangements for insurance, maintenance, liability and the processes to be followed in the event of a fault are adequately covered.

Devices on loan from manufacturers or other organisations, including NHS organisations, should be subject to a written agreement which defines the device management requirements and responsibilities and liabilities.

Delivery receipt and pre-use procedures for hired and loan equipment should be the same as those for purchased equipment, unless otherwise specified in a written agreement.

An Asset register should be kept locally for these devices including any servicing logs.

22. New Reusable Equipment that Arrives in an Area

All reusable Medical Devices must be acceptance checked by the Medical Device contractor on arrival to an area for:

- Relevant documents,
- Instructions, compliance and calibration certificates, warranty details,
- Damage, appropriate CE markings, serial numbers for inventory requirements,
- Functional ability of the device,
- Electrical basic safety check prior to use,
- Device calibration prior to use,
- Installation requirements.

Equipment that has never before been used in an area, e.g. that staff are unfamiliar with, will require the senior nurse for that team to liaise with manufactures regarding a training programme for all relevant staff.

23. Maintenance, Repair and Calibration

23.1 Introduction

All Medical Devices require routine maintenance and/or calibration at a frequency recommended by the manufacturer whether it be checks by the user, maintenance by contracted company or maintenance by the manufacturer.

Maintenance The daily responsibility for the regular maintenance of Medical Devices is with staff.

Medical Devices will have one or more schedules for maintenance, servicing and calibration.

These are covered below.

23.2 User Servicing

User servicing is the responsibility of the user (staff or patient/client). This may involve daily checks e.g. syringe drivers, glucose monitoring machines, DEFIBs, regular cleaning, record

of checks and any findings. Users must have the appropriate training before carrying out these checks.

23.3 Scheduled Servicing

Scheduled servicing is planned and will be carried out by Avensys and Arjo on behalf of the Trust. Avensys has a database of all equipment used within the Trust that requires servicing and calibration. Newly purchased items are added to the database by Avensys. It is the responsibility of the manager to ensure that this information has been passed to Avensys or ARJO.

Avensys is responsible for servicing, maintaining and calibrating all Medical Devices within the agreed schedule. This is monitored via a contract group held between the Trust and Avensys every two months. The lead for this on behalf of the Trust is the Physical Health Lead Nurse. Problems or issues with this contract will be reported to the physical health lead.

23.4 Equipment Faults

Medical Devices and equipment that becomes faulty must be removed from service and isolated as soon as practicably possible. Faulty items must be labelled as such and tagged or marked to ensure they are not inadvertently put back into service and they must also be cleaned in accordance with the Decontamination Policy and have attached a Declaration of contamination status form. The fault should be reported to **Avensys 01562 745858**

Avensys will arrange for an engineer to investigate the fault and report back to the manager for appropriate action.

If the equipment has become faulty and caused injury (or could have done) to a member of staff or a patient/client this must be reported through the completion of an incident report and maybe subject to a report to the MHRA – see Incident reporting and management procedure.

It is the responsibility of each individual to ensure the equipment they use is in a serviceable state prior to clinical use. Serviceable state would mean there is no visible damage to the equipment, the equipment passes pre-use checks, the equipment hasn't been reported as faulty and that the service due date hasn't expired. All maintenance procedures must be in line with the manufacturer's recommendations.

The expected life cycle of a device/piece of equipment should be held in the database and regularly reviewed against the usage, maintenance and repair record to see if the end date needs to be adjusted. Heavy use or irregular maintenance may reduce the life cycle; limited use may extend it. Manufacturers recall of a device will take precedence over other considerations.

Factors to consider include:

- Whether the device is damaged or worn out beyond economic repair.
- Its reliability (check service history).
- Clinical or technical obsolescence.
- Changes in local policies for device use.
- Absence of manufacturer/supplier support.
- Non-availability of correct replacement parts.
- Non-availability of specialist repair knowledge.
- Users' opinions.

- Possible benefits of new model (features, usability, more clinically effective, lower running costs).
- Lifecycle of the Medical Device.

24. Decommissioning and Disposal

Decommissioning aims to make equipment safe and unusable, while minimising damage to the environment. Equipment deemed unfit for use should be decommissioned. This should include decontamination, making safe and unusable. This is to ensure that inappropriate persons do not use the equipment and expose themselves or others to hazards. Users should consult the Medical Engineering Department or the Estates department for advice before decommissioning commences. Disposal of electrical/electronic equipment should comply with the Waste Electrical and Electronic Regulations 2013. Consult the Medical Engineering Department or the Estates Department in the first instance. Some waste products need specialised disposal.

Examples include:

- Wastes containing certain metals (e.g. Mercury above 3% and some batteries)
- Oil wastes.
- Wastes from coolants.
- Radioactive waste.
- Healthcare waste from human or animal origin.
- Human waste from care, diagnosis, treatment or prevention of disease. Where applicable, equipment should be decontaminated before disposal or transfer to a third party and supplied with a certificate of decontamination. When returning Medical Devices to the manufacturer at end of life, or when transporting devices, ensure that they are appropriately packaged and secured. Issues that should be addressed include: strength of packaging materials, protecting sharp edges and ensuring that the device cannot get damaged during transit. Legislation applies to the transport of goods by road and rail.
- The carriage of dangerous goods and use of transportable pressure equipment (amendment) regulations 2011
- Chemicals (hazard information and packing for supply) regulations 2009
- The radioactive material (road transport) regulations 2002
- If a device stores patient identifiable data, this should be securely erased or hard drives removed and sent to IT for destruction when the device is decommissioned. Data on any device should be forensically unrecoverable.

25. Risk Assessment

Risk assessments are to be conducted or reviewed as appropriate, prior to new devices being accepted into Trust service and prior to being allocated to a service user in the community for individual use. These risk assessments should be implemented;

- post incident review
- change of model or function
- as advised by the Trust or legislation

Risk assessments are to be logged – a copy retained within the service and are to be brought to the attention of “users” at the earliest opportunity.

Medical Devices are to be risk assessed, by a competent person delegated by Service Lead and documented to ensure that any hazards and risks identified are appropriately recorded and mitigating actions taken in relation to such as: usage (including assembly and disassembly & accessories), training, maintenance, servicing, decontamination and disposal associated with a particular device.

26. Reporting Adverse Incidents and Dissemination Medical Device Alerts

For all incidents involving Medical Devices that occur within the Trust.

In the first instance the Staff are to ensure that any patient and/or staff wellbeing or safety is not compromised, then immediately remove the item from use. The department manager must then be informed as soon as possible after the incident. Staff must complete a Datix Incident form and retain the device should an investigation be required. There is also a requirement to report incidents involving Medical Devices to various external agencies where it is implicated in a serious incident.

Once equipment involved in an incident has been removed from use, users must do the following:

- Quarantine the suspect device, together with any associated consumables.
- Inform Medical Device Lead as soon as possible after the event.
- The equipment should clearly label '**FAULTY EQUIPMENT – DO NOT USE**'.
- The department manager should then liaise with the Medical Device Lead and the Physical Health Lead who will determine if the equipment is safe to use.

Anyone can report concerns about a medicine or medical device to it via its Yellow Card scheme.

The National Patient Safety Alerting Committee (NaPSAC,) set up 2018 is developing common standards and will ensure alerts are received and identified actions completed.

These standards and thresholds agreed by NaPSAC will underpin CQC's inspection of National Patient Safety Alerts and any regulatory response to non-compliance.

The role of NaPSAC

- Developing common standards and thresholds for National Patient Safety Alerts
- Developing a single recognizable consistent format for National Patient Safety Alerts
- Overseeing the development of a process to ensure all alert issuers reach these common standards and thresholds.

Central Alert System (CAS) from the Medical and Healthcare Product Regulatory Agency (MHRA) and National Patient Safety Agency (NPSA).

The Trust generates and also receives medical device safety alerts from external agencies such as the Medicines and Healthcare Products Regulatory Agency (MHRA), the National Patient Safety Agency (NPSA) and others through the Central Reporting System. Corporate Central Alert System Risk Manager distributes to the relevant leads, ensuring they are disseminated throughout the organisation and followed up on the implementation of actions required by information received from alert notices and recorded on 'Datix Alerts Module'. The Risk manager provides a report to the Trust Medical Devices group and Quality Committee of all alerts received via CAS for compliance/governance purposes. This includes monitoring responses within the given deadlines and transmits all responses to the Medical

Devices Agency (DH) and provides monitoring data to Clinical Commissioners. All staff are responsible for ensuring they read and act upon any safety alerts that are distributed to them.

ELFT'S response to these alerts is monitored by both the CQC and Commissioners who can impose financial penalties on the organisation if these alerts are not actioned within the deadlines stated in the alert. The policy for the Alerts system outlines the procedures and process for providing assurance to the trust that alerts have been actioned as documented a recorded the 'Datix Alerts System'.

Managing Medical Devices, (April 2014) a Crown Publication, which includes the following:

“Acceptance” Testing – When a new medical equipment is delivered to the Trust an “acceptance” test is to be carried out to ensure that the equipment is correct and complete on delivery, the test will identify any fault with the equipment and any damaged caused during transit. **Manufacturer’s Instructions** – The “User” should have access to the manufacturer’s operating instructions and DME&P&P to the manufacturer’s service / maintenance instructions.

Handling / Storage – Information will be made available to “Users” on the appropriate methods for handling / storing Medical Equipment & accessories. There will also be guidance on how internal batteries should be charged.

Avensys and Arjo Contractors have the delegated responsibility for maintaining medical equipment/ devices within ELFT will report any actions taken using a unique device identifier, the identifier will allow the device to cross referenced with contractor databases by their asset numbers for fault repair, audit and Planned Preventative Maintenance (PPM)

- Maintain a trust-wide Medical Devices asset register for tracking purposes.
- Respond to requests for repairs of faulty equipment.
- Carry out 'acceptance testing' on all new devices/equipment prior to use.

Planned Preventative Maintenance (PPM) – The PPM always follows the manufacturer’s guidance with the identified service organisation documented within the equipment database, which will also point to the level of maintenance support required.

The User is responsible for routine maintenance on the equipment i.e. regular cleaning, preparation for use and performing User checks.

Damaged / malfunctioning medical devices – must be removed from service immediately, clearly labelled and reported to the DME&P&P help desk, who will organise the necessary action.

Decontamination – All Medical Devices requiring PPM, repair, removal, loaned, disposal etc. must be decontaminated. The decontamination procedure will follow the manufactures / supplier’s instructions or the Trust Decontamination Policy before release by the “User” or clinical service.

Equipment Disposal – The manufacturer will provide details for the best methods for waste disposal, the process will be carried out in compliance with the Trusts: Standing Financial Instruction, the Waste Management Policy and the Waste Electrical and Electronic Equipment (WEEE) Regulations 2006.

Please refer to Appendix 23 Medical Devices Flow Chart for reporting on Datix and Contacting Avensys

References

Associated Documents and Supporting References

Controlled Assurance Medical Devices Management Standard (Decontamination section) DH, social services and public safety <http://www.dhsspsni.gov.uk/cas-decontamination.pdf>

CQC Essential Standards of Quality and Safety – regulation15: Premises and Equipment
<https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-15-premisesequipment#guidance>

Department of Health, Medicines and Healthcare products Regulatory Authority - Managing Medical Devices - Guidance for healthcare & social services organisations April 2015
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/421028/Managing_medical_devices_-_Apr_2015.pdf

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Health and Safety at Work Act 1974 <http://www.hse.gov.uk/work-equipment-machinery/purchaser.htm>

MHRA2006 - Directive 2007/47/EC. Transposed into UK law by the Medical Devices Amendment Regulations SI2008

<http://www.mhra.gov.uk/home/groups/esera/documents/regulatorvnews/con049176.pdf>

MHRA. (2017). Medical devices: EU regulations for MDR and IVDR. Available:
<https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr>. Last accessed 9th July 2019.

Medicines and Medical Devices Regulations - What you need to know
<http://www.mhra.gov.uk/home/groups/commsic/documents/websiteresources/con2031677.pdf>
<http://www.mhra.gov.uk/Howweregulate/Devices>

Medical Devices Regulations 2002 - Regulation 16 of the Health and Social Care Act 2008

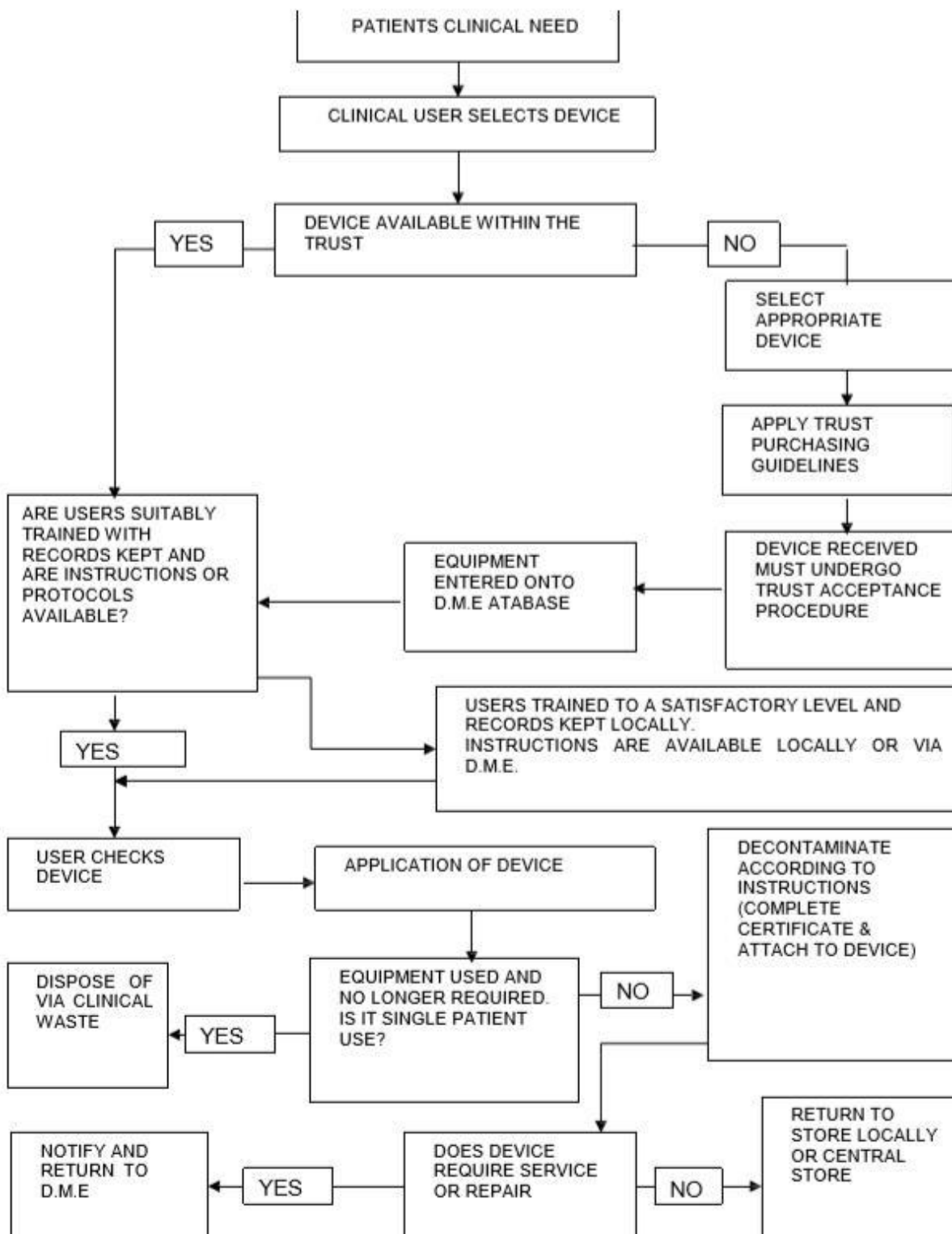
(Regulated Activities) Regulations 2012 <http://www.legislation.gov.uk/ukdsi/2012/9780111522752>
<https://www.gov.uk/government/publications/report-a-non-compliant-medical-device-enforcementprocess/how-mhra-ensures-the-safety-and-quality-of-medical-devices>

MHRA2006 - Directive 2007/47/EC. Transposed into UK law by the Medical Devices Amendment Regulations SI2008 <http://www.mhra.gov.uk/home/groups/esera/documents/regulatorvnews/con049176.pdf>

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<http://www.mhra.gov.uk/Howweregulate/Devices>

Medical Devices Regulations 2002 - Regulation 16 of the Health and Social Care Act 2008

Appendix 1 Summary of Medical Devices Management



Appendix 2 Medical Device Reporting Flow Chart

Reporting on Datix & contacting Avensys or ARJO

