Medical Device Maintenance Guidelines

The following should be taken into account when considering medical device maintenance

- the repair and maintenance, including preventative maintenance of a device is considered at the purchase stage
- all the information necessary to undertake a repair or to maintain a device safely is made available
- any changes to repair and maintenance methods are brought to the attention of the repairer
- the repairers are appropriately trained and up-to-date with their knowledge of repair and maintenance methods
- the instructions used should be as specified by the manufacturer
- replacement parts should match those specified by the manufacturer
- the use of alternative instructions, methods and parts should be demonstrated to be equivalent and take into account all risks to patients and clients and fully documented
- all replacement spare parts and critical components used in a repair or maintenance are traceable
- all associated repair and test equipment is suitable for its purpose and is appropriately maintained and calibrated
- repairers are made aware of any changes in circumstance which may affect repair and maintenance and assess the impact of those changes to ensure that agreed specifications continue to be met
- there is a system in place to manage device repair and maintenance activities.
- the device itself remains identifiable
- all records relating to the repair and maintenance of any device are accurate, detailed and readily accessible
- regular audit and review of the repair and maintenance process
- report device failures to the MHRA
- there is a contract with the repairer defining responsibilities for repair and maintenance
- all devices intended for repair or maintenance are safe to handle

1.0 INTRODUCTION

The Trust has entered into a contract with Althea to provide a comprehensive medical equipment maintenance service for all departments.

All medical equipment relevant to the contract will be labelled with a unique asset number. A planned preventative maintenance (PPM) programme will be in place to ensure that all high-risk equipment is serviced at least once a year or as per manufacturer’s recommendations.

When a PPM is being carried out, any items of equipment found to be unsafe by the engineer will be removed from use. If the equipment cannot be repaired or is not cost effective a condemnation certificate will be issued. It is then the responsibility of the budget holder to replace the item if required
Examples of TBSGB (Previous contractor) Stickers that still may be found on devices within EPUT are shown below:

With time these will be replaced by Althea Stickers:
2.0 GUIDELINES FOR MEDICAL DEVICE REPAIRS

EPUTs main medical devices contractor is Althea, there are some smaller/specialist contracts in place. Labelling on the Medical Device will indicate which contractor is responsible for the equipment. Records for the smaller contracts will be held locally.

When an item of medical equipment develops a fault the following procedure must be followed:

- Contact Althea (UK & Ireland Ltd UK Customer Care Centre)
  
  EMAIL: uk.endoscopy@althea-group.com
  TELEPHONE: +44 (0)118 900 8140

The following information is required:

- Asset Number: (You will find this on the Althea Asset label and will proceed with EPUTXXXXXX, if this is not available then a serial number)
- Reported fault: (Problem/service/asset request etc.)
- Location of device (Where we are expected to attend)
- Caller/contact name
- Telephone number
- Email
- If there are preferred days for the visit/call due to clinic opening times then please state.

Your call will be logged, and a job number will be assigned.

Keep the equipment in the department/on site with a large notice in red writing that clearly states that the equipment is “not for use” and that Althea have been informed. One of the benefits of this contract is that where possible repairs will be carried out on site.

All equipment for service or repair must be decontaminated as per the Trust’s policy. If decontamination has not taken place, the medical device must be labelled to inform the engineer of this.

Once you have reported your repair the engineer from Althea will attend to facilitate the repair. If a repair cannot be done on site the item will be taken to an Althea service centre.

**PLEASE ENSURE YOU OBTAIN A RECEIPT IF EQUIPMENT IS REMOVED FROM YOUR PREMISES.**

Parts up to the value of £250 will be automatically approved. However, if the costs of parts are estimated to be in excess of this, budget holder authorisation will be sought by Althea via EPUT’s Medical Device Officer. Similarly, if it would be cheaper to replace rather than repair the purchasing department will be advised.
3.0 GUIDELINES FOR WHEN MEDICAL EQUIPMENT IS DELIVERED

When a new piece of medical equipment is delivered staff must phone Althea to check it has been acceptance tested and has a sticker on it before it is used and added to the equipment database. If it has not, contact Althea.

When the item is tested it will be asset labelled and this will ensure it will be included for maintenance and servicing in future years.

Ward and Department Managers have the responsibility to ensure all medical equipment in their area is safely used and maintained. To facilitate this it is good practice to:

   a. Ensure equipment is checked for visible signs of damage after transit.

   b. Ensure all new medical equipment (whether purchased, leased, on loan or on trial) is tested and labelled by Althea.

   c. Ensure instruction manuals are received and kept with the equipment, these must be available to all those who use the equipment and should be read fully before the equipment is used.

   d. Ensure staff and patients are adequately trained on the use of the equipment.

   e. Ensure all medical equipment is stored in a safe, clean and dry environment.

   f. Ensure risk assessments are completed for all items of medical equipment, before they are used.

4.0 PROBLEMS / COMPLAINTS

If any staff experience problems with the service offered by Althea please advise the Associate Director of Risk & Compliance & MDSO via email at epunft.risk@nhs.net