MONITORING AND MAINTENANCE OF MEDICAL, ELECTRICAL & MECHANICAL EQUIPMENT

PURPOSE

To outline a systematic approach to the management of all aspects of the lifecycle of medical, electrical & mechanical devices, to ensure that all risks associated with the acquisition, use, monitoring, record integrity, reprocessing, modification, maintenance, record generation, storage, disposal of devices are prevented/minimised.

MEDICAL DEVICE

The term 'medical device' is any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer, to be used on human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease; or,
- Diagnosis, monitoring, treatment of, or compensation for an injury or handicap; or,
- Investigation, replacement or modification of the anatomy or physiological process;

OWNERSHIP & RESPONSIBILITY

The Medical Director/ Lead School Nurse has overall responsibility for the safe management of all medical, electrical & mechanical devices and compliance with relevant regulation.

ROLE OF HEALTHCARE PROFESSIONALS

It is the responsibility of HCP involved in the use of medical devices to ensure:

- Familiarise with the use of Medical, Electrical & Mechanical Devices
- Trained and competent in the use of medical devices
- Training records are maintained and updated.
- Use medical devices if authorised to do so
- Check the maintenance due label before using the device
- Properly decontaminated after each patient use
- Adequately stored and maintained when not in use
- Follow procedures regarding the management and use of medical devices
- Report any defects or faults with equipment immediately
- Clearly label defective devices and ensure they are not in use.
- Endeavour to make devices available for maintenance
- Report all adverse events to line manager immediately for possible replacement or repair.

STANDARDS & PRACTICE

Care of Equipment by Users

- Users must follow the manufacturer's guidelines on the care and user maintenance of equipment and devices. Regular basic checks must be performed by users prior to use. These should consist of, as a daily checking for any obvious signs of damage, cleanliness and faults affecting performance or safety. Maintenance labels must be checked to ensure servicing is not overdue.
    - ✓ Abonemed is the responsible company for maintenance & to check the functionality of medical, electrical & mechanical devices in the clinic.
- Faults are to be reported as per the guidelines issued by the relevant maintenance provider. Clear labelling of any fault is required to aid in a prompt turn-around of equipment.
- Equipment must be decontaminated and labelled as such prior to being sent for repair.

Maintenance

- Maintenance may consist of Planned Preventive (PPM), reactive repair and/or Inspection/Performance checks. The frequency and level of maintenance may be adjusted at the recommendation of DHA and will be evidence based and risks assessed.
- Medical Director must ensure that medical devices are made available for Planned Maintenance at the appropriate time in accordance with the manufacturers' instructions .
- Where a contracted service provider carries out maintenance on medical devices on site, a record of the visit and work done must be kept by the Clinic where it was carried out. This would normally be a copy of the company service report.
- Maintenance and repair of reusable medical devices must only be carried out by competent persons recognised as having sufficient technical knowledge and experience.

Decontamination

- The purpose of decontamination of medical equipment to provide safe and clean, disinfected or sterilised equipment to control the spread of microorganisms.
- Users of medical devices are responsible for the decontamination of the equipment after use.
- Any equipment that has been decontaminated must be labelled as such.

Single-use Device

Medical devices that are designated for 'single use' by the manufacturer and labelled as such should not be reprocessed and reused. This will include those devices that have been opened in error although not used. Single use medical devices should not be reprocessed or reused under any circumstances.

Replacement and disposal of Equipment

- Equipment must be replaced when it becomes unsafe to use, is no longer producing clinically acceptable results or is no longer supportable.
- Disposal of old equipment must be carried out in a safe manner and follow the DM Guidelines