



HEALTH HOLDING

HAFER ALBATIN HEALTH
CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Facility Management and Safety		
Document:	Multidisciplinary Policy and Procedure		
Title:	Medical Equipment/Devices Management Plan		
Applies To:	All MCH Staff		
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1. PURPOSE:

1.1 This Medical Equipment plan describes the policies, procedures and testing of:

- 1.1.1 Initial check of new devices/equipments
- 1.1.2 Preventive maintenance
- 1.1.3 Corrective maintenance
- 1.1.4 Training medical equipment/devices users

2. OBJECTIVES:

- 2.1 Check, provide and maintain (per PM schedule) the medical equipment/ devices for safe and effective use for diagnosis, treatment) & care of patients
- 2.2 Organize a system and determine the responsibilities of PM works carried out by BMD in the Hospital for all medical devices/equipment.
- 2.3 Describe the policy & procedures for medical devices/equipment users as followed:
 - 2.3.1 In case of medical devices/equipment malfunction/failure.
 - 2.3.2 In case of expired date of check.
- 2.4 Organize a system and determine the responsibilities of medical device/ equipment purchase and import by the BMD for all medical device/ equipment.
- 2.5 Describe the policy & procedures of medical devices/equipment to be condemned.

3. GOALS:

- 3.1 Maintain medical devices/equipment to be compatible with the manufacturer company recommendation and specifications. This includes equipment repair and inspection.
- 3.2 Plan and implement an effective PM program in accordance with manufacturer company directions.
- 3.3 Provide pre-purchase engineering specifications of medical device/equipment.
- 3.4 Implement electrical safety program that includes testing of the devices connected to the patients, and to educate the staff and clinicians in the safe use of electricity in patient care areas.
- 3.5 Inspect all imported equipment before put into service.
- 3.6 Provide technical consultation to medical, clinical and administrative staff.
- 3.7 Reduce operation's costs through negotiation and monitoring, and evaluate maintenance contracts, as well as giving recommendation about the economical maintenance option

4. DEFINITIONS:

- 4.1 **Approved Adapter:**
 - 4.1.1 An adapter or converter that has been tested, approved, and tagged for PM by BMD.
- 4.2 **Electrically Powered Equipment:**
 - 4.2.1 Any equipment connected to electricity.
- 4.3 **Electrical connections:**
 - 4.3.1 Any heavy duty connection with built-in protection intended for use in patient care areas.
- 4.4 **Maintenance Requests:**

- 4.4.1 All maintenance activities carried out by BMD according to Maintenance Request Form which should be completed and submitted to Notifications' Officer.
- 4.5 **Physical and Information Risks for medical equipment.**
 - 4.5.1 Physical Risks are the possible consequences might be to the patient or operator if the equipment fails or malfunction such as disruption of the network by the device malfunction.
 - 4.5.2 Information Risks consider corruption of information.
- 4.6 **Typical Device Risk Levels**
 - 4.6.1 These levels are on based on the risks of injury caused by device failure or user error. They take into account both outcome probability and severity.
 - 4.6.1.1 High Risk Devices:
 - 4.6.1.1.1 Life support, key resuscitation, critical monitoring and other devices whose failure or misuse is reasonably likely to seriously injure patients or staff.
 - 4.6.1.2 Medium Risk Devices:
 - 4.6.1.2.1 Devices including many diagnostic instruments whose misuse, failure or absence (e.g. out of service with no replacement available) would have a significant impact on patient care, but would not be likely to cause direct serious injury.
 - 4.6.1.3 Low Risk Devices:
 - 4.6.1.3.1 Devices, whose failure or misuse is unlikely to result in serious consequences.

5. PROCEDURE:

- 5.1 **In case of Medical Devices Malfunction** : Call Biomedical Maintenance on duty technician through the Duty Manager during unofficial working hours and holidays.
- 5.2 It is not allowed to use electrical connections and tubing. And if for emergency need, the connection can be taken from the Biomedical Maintenance.
- 5.3 It is not allowed to use cellular phones in critical Units, ICU Units, OR and Cardiac Clinics

6. POLICIES:

- 6.1 Staff shall refer to, and comply with medical equipment / devices management plan.
- 6.2 **Medical equipment/devices needed to be purchased should be evaluated.** Medical equipment /devices should be received from the Main Store with service and operation manual. Testing, installation and users training will be given by the product engineer.
 - 6.2.1 Medical equipment/devices needed to be purchased should be evaluated according to user requirements.
 - 6.2.2 Medical equipment /devices should be received from the Main Store with service and operation manual.
 - 6.2.3 Testing and installation should be carried out by Import Company Engineer.
- 6.3 PM, testing date and maintenance due date should be determined according to manufacturer's Schedule and specifications. The performance should be analyzed and tested and corrective action taken as necessary for any deficiencies which could increase the safe and acceptable performance of medical equipment/devices and reduces unscheduled repairs.
- 6.4 All medical equipment should be inventoried with code number, serial number, model and location with the use of a sticker as a coding color for inventory.
- 6.5 Procedures should be implemented according to the scheduled plan for all Hospital medical devices/ equipment that are distributed throughout the year and executed under supervision of Medical Maintenance.
- 6.6 Biomedical Chief responsible for follow-up of maintenance procedures according to the scheduled plan for all departments.
- 6.7 **Identification stickers have been specialized as follow:**
 - 6.7.1 Sticker for completed PM

- 6.7.2 Sticker for electrical safety testing
- 6.7.3 Sticker for equipment identification inventory
- 6.7.4 Sticker for equipment charged by batteries
- 6.7.5 Sticker for equipment out of service (under repair sticker)
- 6.7.6 Sticker for condemned equipment
- 6.8 Lectures should be given for the medical team to clarify the importance of equipment tagging and how to execute the procedure.
- 6.9 All procedures implementation forms should be approved by BMD Chief. It should be approved by the department wherein the procedure done then to be approved by BMD Chief form.
- 6.10 **Medical equipment/devices training should be as followed:**
 - 6.10.1 Medical equipment/devices users; Physicians, Nursing staff, BMD Technicians and Engineers should be trained on the new medical equipment/ devices; the user trained on how to use it properly, and BMD Technicians and Engineers trained on using and operation.
 - 6.10.2 Staff should be trained in case of transfer to another department.
 - 6.10.3 New staff should be trained on the medical equipment/devices used in their departments as requested by Department Chief.
 - 6.10.4 If medical equipment/devices misuse detected, the staff should be re-trained to correct the operational errors/mistakes of the equipment
- 6.11 All medical equipment/devices users should attend or receive required orientation and training on how to use these equipment and to fill-in Educational Activity Form.
- 6.12 BMD should inspect and approve electrical wire extension, adapters'/ converters' plugs/tubing, and to permit using in patient care areas. Only heavy-duty three-wire extension is permitted to be used in patient care areas for a temporary period.
- 6.13 Equipment/ device should be condemned in case of :
 - 6.13.1 Expired assumption life of the device.
 - 6.13.2 Equipment/device repair cost is more than half of the device total cost.
 - 6.13.3 Unavailable spare parts by the manufacturer company.
 - 6.13.4 User request equipment/devices more developed technically for patient examination.

7. RESPONSIBILITIES:

- 7.1 **BMD Chief shall:**
 - 7.1.1 Follow-up and supervise Hospital Medical Equipment / Devices Operation Companies.
 - 7.1.2 Implement the Medical Equipment / Devices Management Plan.
 - 7.1.3 Supervise Medical Maintenance
 - 7.1.4 Audit the monthly costs of manpower, sub-contract and spare parts.
- 7.2 **Hospital Operation Company (Major Contractor):**
 - 7.2.1 Carry out PM works procedure and distribute the executors' responsibilities and approve the attached documents.
 - 7.2.2 Ensure that at least 95% of the medical equipment/ devices identified, prioritized and received initial inspection and PM according to the schedule.
 - 7.2.1.1 High Risk devices/ equipments should be maintained by the Agent through the Operation Company.
 - 7.2.1.2 Medium Risk devices/ equipments should be maintained by the Agent or Specialized Company through the Maintenance Department.
 - 7.2.1.3 Low-Risk devices / equipments should be maintained by the Maintenance Department in of the hospital.
 - 7.2.3 Direct BMD staff in regard to the submitted work requests by the staff for the inspection, testing, repair, operation or tagging, etc. of medical equipment/devices, wire-extensions, adapters and used power in patient care areas.
 - 7.2.4 Notify users promptly about medical equipment/devices' recalls and take the necessary procedures such as inspection, testing, repair or condemn.
 - 7.2.5 Direct BMD staff in the maximum and routine utilization of medical equipment, and to distribute information as necessary to medical equipment/devices users.

- 7.2.6 Monitor, direct if necessary, and re-orient user training as related to user errors. Report all user errors to the Safety Officer or directly to the Safety Committee for evaluation and documentation by using OVR form.
- 7.2.7 Ensure that BMD staff (referred to on-call BMD Engineering Technician) is on call during the unofficial working hours and can be reached by calling the hospital Duty Manager.
- 7.2.8 Direct BMD staff to identify user errors and input entry into the OVR for tracking and reporting.
- 7.2.9 Maintenance staff should be monitored by BMD Director during medical equipment/ device numbering which has constant assets in inventory lists that have been saved in the computer.
- 7.2.10 Carry out and follow-up medical device purchase procedures, distribute the executors' responsibilities and approve the attached documents.
- 7.2.11 Prepare Check file for each device/equipment to maintain the documents of maintenance, failures and repair procedures.
- 7.3 **Electronic Technician:**
 - 7.3.1 Each in the scope of service to implement and follow-up the procedure in specialty, or any dependent technician, and to suggest modifications as necessary for performance improvement
- 7.4 **Support Service Director:**
 - 7.4.1 Ensure the necessary funds, equipment, staff training are available to implement the Medical Equipment / Devices Management Plan.
 - 7.4.2 Review and approve lists of prioritized medical equipment/devices tested by BMD to be included in PM Program which detail frequent or intervals equipment/devices maintenance.
 - 7.4.3 Receive, evaluate and document any received OVR about medical equipment/devices or users' failures.
- 7.5 **Store Officer:**
 - 7.5.1 Follow up the procedure, and suggest modifications as necessary for performance improvement.
- 7.6 **Department Heads:**
 - 7.6.1 Ensure that medical equipment/devices users shall develop emergency procedures that address:
 - 7.6.1.1 Specific procedures to be followed in case of medical equipment/ devices failure.
 - 7.6.1.2 When and how to perform emergency clinical interventions when medical equipment/devices fail.
 - 7.6.1.3 Availability of back-up medical equipment/devices.
 - 7.6.1.4 Procedures to obtain back-up services.
- 7.7 **Nursing Supervisors shall:**
 - 7.7.1 Ensure from the operation of the backup equipment if available. If backup equipment is not available, contact on-call BMD Technician for emergency services procedures.
 - 7.7.2 Ensure that the (Work Request) form is available in the department if an emergency service is required.
 - 7.7.3 Monitor procedure implementation and suggest modifications as necessary for performance improvement.
- 7.8 **On-Call Technician(s):**
 - 7.8.1 BMD Chief shall prepare on-call Rota and be sure that the on-call technician is available for 24 hours per day 7days weekly.
 - 7.8.2 Provide on-site service within 60 minutes from receiving the request for an emergency service.
 - 7.8.3 Note: An emergency service is defined as a service provided when unforeseen malfunction of medical equipment/ device occurs which places patients in a threatened condition. Such circumstances include, but are not limited to, life and death, undue suffering or inability to diagnose, treat or monitor patient during critical situations.
 - 7.8.4 Make all reasonable attempts to quickly repair and reinstate equipment.
 - 7.8.5 Collect and complete (Work Requests) forms from supervisor or area where emergency service call originated.
 - 7.8.6 Document emergency service calls into a logbook.
- 7.9 **Quality Manager shall:**

- 7.9.1 Inquire, receive and notify Safety Manager and BMD Chief about any occurrence involving serious injury or death of patients or staff resulting from misuse or malfunction of medical equipment/devices.
- 7.10 **Head Nurses** (in operational areas where medical equipment/devices are in use) **shall:**
 - 7.10.1 10.1 Immediately report to the Quality Manager and BMD Chief about all occurrences involving failure of medical equipment/devices or user failure which results in serious injury or death to a patient, staff member, visitor, etc.
 - 7.10.2 Fill-in/Complete (Work Request) form and submit it to BMD for inspection, testing, repair, processing tagging, etc. of medical equipment/devices and wire-extensions, adapters and power used in patient care areas.
 - 7.10.3 Immediately report to the Quality Manager and BMD Chief about all occurrences involving failure of medical equipment/ devices or user failure which results in serious injury or death to a patient, staff member, visitor, etc.
 - 7.10.4 Notify all employees working in areas of risk medical equipment/ devices. Take whatever action necessary (such as removal or replacement of the equipment) to protect patients, staff, and property.
 - 7.10.5 Assist BMD staff to determine the site of the equipment due for PM.
 - 7.10.6 Report repeated equipment malfunctions to the BMD chief.
 - 7.10.7 Notify the BMD about any equipment requires a sticker or an updated sticker.
- 7.11 **Nursing staff should:**
 - 7.11.1 Inspect medical equipment/ devices for proper functioning prior to each use.
 - 7.11.2 Report any risk malfunctions or equipment due for PM to the Supervisor immediately.
 - 7.11.3 Attend the required training.
 - 7.11.4 Not use equipment/devices with expired date for due PM and report to BMD about delay of equipment maintenance date.
- 7.12 **Staff – Patients – Visitors :**
 - 7.12.1 In a polite manner ask anyone observed using a cellular phone or other transmitting device inside Critical Units, ICU, and Cardiac Clinic to turn-off the device while inside the facility, and if the person refused to do so, notify the Security.
- 7.13 **Steps of Purchase and Import a new Medical Equipment/Devices**
 - 7.13.1 **Direct purchase**
 - 7.13.1.1 The concerned department should submit a request to purchase a new equipment with determined specifications and manufacturer area, and forward it to BMD Chief.
 - 7.13.1.2 The BMD Chief put the equipment technical specifications that are compatible with Hospital specifications, and forwards the request to the Hospital Director for initial approval.
 - 7.13.1.3 The support service director forwards the request to the Hospital Director for final approval.
 - 7.13.1.4 After Hospital Director approval, the transaction addressed to Purchase Officer in the Hospital.
 - 7.13.1.5 The Purchase Officer sends the purchase request to the imported companies and a copy of it to Purchase Representative to look for it in the Local Market (for urgent requests) and waits for price offer/s from any of them.
 - 7.13.1.6 After receiving price offer/s, it should be presented to Hospital Administration for final approval.
 - 7.13.1.7 After approval of one of the offers by the Administration, the offer should be sent to Purchase Officer who will fill-in form of approved purchasing order from the requested equipment/device then to be reviewed by the (Engineer/Technician) and signed by the Administration.
 - 7.13.1.8 After Administration approval to purchase the requested equipment/ device and submitted form to Store Officer for approval, the Store Officer should submit it to

the Financial Administration for final approval then to be sent back to Purchase Officer.

- 7.13.1.9 The Purchase Officer should send a request to provide the equipment/ device to the Importer who's price offers approved and signed by BMD Director, and to maintain the original copy and the original copy of the approved form in a File of Approvals Waiting for Import.
 - 7.13.1.10 For urgent requests, the Purchase Officer submitted a copy of the approved form to Purchase Representative to bring the equipment/device from the Local Market (for urgent requests).
 - 7.13.1.11 The Purchase Officer should maintain the approved copy of form in the Approvals File during price offer valid period until the import.
 - 7.13.1.12 When the equipment/device imported to the Hospital Store, the Store Officer should fill-in Equipment/Device Temporary Receiving form no and to approve its arrival by the Administration, that is after the necessary technical check by the Engineer/Technician.
 - 7.13.1.13 Store Officer should complete the invoices/bills and price offers and to attach it with the form and Temporary Receiving Form to prepare financial amount reimburse transaction.
 - 7.13.1.14 Store Officer should submit the equipment/device to the Imported Company and BMD engineers for install and operation of the equipment/device in the concerned department.
 - 7.13.1.15 The imported Company Engineer should install and operate the equipment/device, and to train the medical team on the optimal use in the attendance of Hospital Medical Engineer.
 - 7.13.1.16 Hospital BMD Engineer should fill-in Install and Operation Certificate Form to install and operation, as well as, Operation, Training, Completed Maintenance Works and Guaranty Certificate Form, and to submit the transaction to the Administration for signing, and maintain a copy of it in the equipment/device File.
 - 7.13.1.17 All data of new equipment/device such as serial no., model no., and site & code no. included in the inventory process and maintained in BMD computer.
 - 7.13.1.18 The Hospital should make an agreement in the purchase contract which obliged the company to train equipment users in the Hospital; either in its location or to send one of its engineers to the Hospital to complete the training process.
- 7.14 Enhance and Update Hospital Medical Equipment/Device Level:**
- 7.14.1 BMD Chief should distribute Equipment/devices Request Form to all departments for filling-in and counting the equipment/devices to be purchased and imported for the department as needed.
 - 7.14.2 After completion of Form By the departments, a Committee of BMD Chief, support services Director and Medical Director studies the requests and classifies it according to its priority and importance and in the committee but it's recommendation will be forwarded to Hospital for final approval.
 - 7.14.3 Approved requests should be sent to the Purchasing department to offer import and purchase competition.
 - 7.14.4 Import procedures from item 12-18 of Direct Purchase article should be carried out by the store.

8. ACCOUNTABILITY:

- 8.1 Medical staff (Physicians-Nursing-BMD)

9. APPENDICES:

- 9.1 Emergency Bag Checklist
- 9.2 Repair Registry of Medical Equipment

10. REFERENCES:

- 10.1 Herra General Hospital Policy and Procedures
- 10.2 Baish General Hospital Policy and Procedures

11. APPROVAL:

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