



HEALTH HOLDING

HAFER ALBATIN HEALTH
CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Biomedical Department		
Document:	Departmental Policy and Procedure		
Title:	Biomedical Equipment Management Plan		
Applies To:	All Biomedical Staff		
Preparation Date:	January 05, 2025	Index No:	BIO-DPP-005
Approval Date:	January 19, 2025	Version :	2
Effective Date:	February 19, 2025	Replacement No.:	BIO-DPP-005(1)
Review Date:	February 19, 2028	No. of Pages:	05

1. PURPOSE:

- 1.1 To insure that all medical equipment have been checked, monitored, repaired and functional test.

2. DEFINITIONS:

- 2.1 **Biomedical Chief** – communicates closely with the site manager, engineers, technicians, and computer operator for any major decision needs to be done such as condemnation of old machine, purchasing or replacement of new medical equipment.
- 2.2 **Biomedical Supervisor**– communicates closely with the site manager, engineers, technicians and computer operator. Check pending job orders. Communicates with medical equipment distributor for under warranted machines.
- 2.3 **Biomedical Site Manager (Sub – Contract)** – communicates closely with the biomedical staff such as engineers, technicians and computer operator for any decisions related to medical equipment such as requesting of spare parts, PPM and other function related to maintenance of medical equipment.
- 2.4 **Biomedical Engineer** – responsible for the repair and maintenance of medical equipment. Reports directly to the site manager or supervisor regarding any problem related to medical equipment.
- 2.5 **Biomedical Technician** – responsible for the repair and maintenance of medical equipment. Reports directly to the site manager or supervisor regarding any problem related to medical equipment.
- 2.6 **Computer Operator** – responsible for receiving job orders, encoding of data to the database. Also responsible for the maintenance of database. Reports directly to the site manager and supervisor.
- 2.7 **End Users** – users of the medical equipment.
- 2.8 **PPM** – Periodic Preventive Maintenance.
- 2.9 **CM** – Corrective Maintenance.
- 2.10 **Biomedical Store:** to keep spare parts, providing immediate respond to solve the problems.
- 2.11 **Medical Supply Store:** to receive all medical, non – medical equipment and consumable material from supplier or HCH and supply them to the hospital departments.
- 2.12 **Medical Device Life Cycle Plan** – to receive the MDELS, MDMA certificate from supplier and keep the records for all disposal medical devices for at least 2 years.
- 2.13 **Reporting Incidents** – to report and record the adverse events to SFDA – NCMDR with actions taken.

3. POLICY:

3.1 Periodic Preventive Maintenance

- 3.1.1 The PPM are based on the following criteria:
 - 3.1.1.1 Manufacturer's Recommendations
 - 3.1.1.2 Risk Levels
 - 3.1.1.3 Current Hospital Experience
- 3.1.2 It is done according to schedule prepared from the first PPM done. Agents, technicians or engineers did PPM by using checklist (attached) which is clarified by criteria above.
- 3.1.3 Medical equipment are divided into 3 classes: Class A, Class B and Class C.

- 3.1.3.1 Class A and Class B – machines which have a contract with the supplier or under the warranty period. PPM should be done by the supplier of the machine (AGENT).
 - 3.1.3.2 Class C – machines which do not have a contract with the supplier or the warranty period has already expired then PPM should be done by the biomedical staff.
- 3.2 Repair**
- 3.2.1 At time of CM, receive Service Calls from end user. The responsible person (engineer or technician) will visit the department to solve the problem. Then he will close the Job number. Medical equipment are divided into 3 classes. Class A, Class B and Class C Class A and Class B machines which have a contract with the supplier or under the warranty period. Repair should be done by the supplier of the machine (AGENT). Class C – machines which do not have a contract with the supplier or the warranty period has already expired then Repair should be done by the biomedical staff.
 - 3.2.2 Medical devices shall be serviced by a certified personnel only.
 - 3.2.3 Function and calibration tests shall be conducted as per the manufacturer recommendations.
 - 3.2.4 All CM reports /orders must be signed off by the end – user.
- 3.3 Tagging**
- 3.3.1 All medical equipment used in hospital must be tagged by the Biomedical Department before use.
- 3.4 Condemnation**
- 3.4.1 Machines are considered condemned if:
 - 3.4.1.1 The device is in poor condition.
 - 3.4.1.2 Unsafe and department no more need it.
 - 3.4.1.3 The machine is already obsolete as declared by the supplier with supporting paper from the manufacturer.
 - 3.4.1.4 Not meet the required purposes.
 - 3.4.1.5 The price of the spare parts is more than 50% of the actual price of the machine.
 - 3.4.1.6 The machine is very old which more than 10 years is and the parameters available on the machine are no longer suitable for the current diagnostic procedure.
 - 3.4.2 The head of the department will bring this report together with the condemned machine to the store. Copy of the report should be given on the following: Biomedical Chief, Site Manager and Head of the department.
- 3.5 Identifying, Evaluating and Taking Inventory of Medical Equipment**
- 3.5.1 All mechanical and electrical patient care equipment will be evaluated prior to use, based on function including diagnosis, care, treatment and monitoring; physical risks associated with use to both patients and operators, maintenance requirements and history of equipment incidents. All incoming and existing equipment meeting the evaluation criteria are included in the equipment management program.
 - 3.5.2 All new equipment shall be inventoried and inspected prior to use for patient care or any other use. Equipment that fails electrical safety tests shall not be approved for use until the deficiencies have been corrected. There is a current inventory of all equipment included in the equipment management program.
- 3.6 Hazard Notices and Recalls:**
- 3.6.1 All product safety alerts, hazard notices and recalls will be directed to the Director of Biomedical Engineering. In the event the notices are not directed to the Director of Biomedical Engineering, the notices will be immediately rerouted to the Director of Biomedical Engineering. The Director of Biomedical Engineering will check the clinical equipment inventory to screen for equipment matches and will evaluate the severity of the risk. In most cases, the notices may be addressed without removing equipment from service. In the event equipment must be removed from service, the equipment is replaced with a safe effective substitute. The Biomedical Engineering Department will impound equipment removed from use due to recall notices until it can be rendered safe.
 - 3.6.2 The Risk Manager will report quarterly to the Safety Committee on any hazard notices and recalls affecting the hospital and all follow up activities undertaken.
 - 3.6.3 Following up and recording of communication with SFDA field safety notice.

- 3.6.4 Records of closing corrective actions associated with safety notices for medical devices.
- 3.7 Single Use (Disposable) and Reprocessing the Medical Devices.
 - 3.7.1 Prohibit the reuse of single use medical devices.
 - 3.7.2 As per the manufacturer recommendations, **REPROCESSING** Medical Devices conducted with respect to the suitability process, conditions, and lifespan.

4. PROCEDURE:

- 4.1 **Periodic Preventive Maintenance** – will be carried out according to the PPM schedule and ID card. PPM will follow the flow chart.
 - 4.1.1 Before performing PPM, the device shall be clean, decontaminated (if needed), and working in a good condition.
 - 4.1.2 The medical devices must be calibrated after the PPM. Yet, if the PPM to be done by the manufacture, a calibration certificate should be given to the Biomedical department.
 - 4.1.3 If the machine under Warranty – contact the vendor about the due date of the PPM through the site manager to perform the PPM according to the checklist. In case, the agent engineer not come on the due date, official letter will be sent through HCH, stated clearly that delay time will be added to the warranty period.
 - 4.1.4 Equipment under contract service – contact the vendor about the due date of the PPM through site manager to perform the PPM, according to PPM schedule. In case, not done on due date. There will be penalty on contractor by HCH law.
 - 4.1.5 PPM by Biomedical Staff – The site manager will issue the schedule list to perform the PPM on due PPM.
- 4.2 **Repair**
 - 4.2.1 If the machine under Warranty – contact the vendor about the problem. If the vendor want to take the machine out of hospital fill the form of pulling equipment.
 - 4.2.2 In the case of medical device malfunction at the time of the official working hours:
 - 4.2.2.1 Check the machine needs spare parts or NO.
 - 4.2.2.2 Require spare parts are available in store or NO.
 - 4.2.2.3 In – case, spare parts are not available in store, request for quotation from agent.
 - 4.2.3 In the case of medical device malfunction during on call time inform the engineer or technician in charge.
 - 4.2.3.1 Biomedical engineer or technician will response to the mobile called by department.
 - 4.2.3.2 Biomedical engineer or technician will make service report either machine repair or need spare parts or need a service from the agent.
- 4.3 **Tagging**
 - 4.3.1 Identification Tag – When the new machine is received. Register the following information into the database:
 - 4.3.1.1 Manufacturer
 - 4.3.1.2 Model
 - 4.3.1.3 Serial Number
 - 4.3.1.4 Warranty Time
 - 4.3.1.5 Vendor Name
 - 4.3.1.6 Department
 - 4.3.1.7 Inventory Number
 - 4.3.2 Electrical Safety Tag – when the new machine is received by hospital, Biomedical Department must ensure.
 - 4.3.2.1 Installation done properly.
 - 4.3.2.2 Electrical safety test done.
 - 4.3.2.3 After that the electrical safety tag will be put on the machine.
 - 4.3.3 Periodic Maintenance Tag – the PPM is done as:
 - 4.3.3.1 Recommendation of the Manufacturer.
 - 4.3.3.2 Experience to Prevent Fault.
 - 4.3.3.3 Risk Level.

- 4.3.4 When the new machine is received by Maternity and Children Hospital, Hafer Al Batin, Biomedical Department will put a sticker "PPM After receiving complete information from the supplier along With checklist procedure.
- 4.3.5 Label Machine Keep Battery Charge Tag – when the new machine is received by HCH, if the machine has a built in battery to keep the battery charge or to increase the life of the battery, the plug of the machine must plug. Biomedical Department will put on the machine a yellow tag "Keep Battery Charge".
- 4.3.6 Discard Tag – when machine has been discarded. The tag Red will be put on the machine after completion of the legal procedure to forward to medical store.
- 4.4 **Condemnation** – the machine will be condemn when fulfil the following conditions.
 - 4.4.1 Accuracy is not okay.
 - 4.4.2 Consumables are not available.
 - 4.4.3 Availability of new machine.
 - 4.4.4 If model is obsolete.
 - 4.4.5 If the cost of spare parts to repair the machine is more than 50% of the cost of the machine.
- 4.5 **Orientation and Education Program for Equipment Maintenance and Users:**
 - 4.5.1 Thorough training will be provided to equipment maintainers upon hire and as needed thereafter regarding the maintenance and care of medical equipment.
 - 4.5.2 All equipment maintainers will be tested for their knowledge and skills necessary to perform equipment repair and maintenance according to their job specifications.
 - 4.5.3 Staff will be oriented and educated on the reporting process for equipment management problems, failures and user errors.
- 4.6 Monitoring and reporting of medical device incidents resulting in death, serious injury or serious illness of any individual in Maternity and Children Hospital, Hafer Al Batin has established methods for reporting these events:
 - 4.6.1 The appropriate personnel will be notified immediately.
 - 4.6.2 All packaging and disposable materials will be returned.
 - 4.6.3 The device will be inspected and control settings and any damage will be recorded. The equipment will be bagged, tagged and sequestered by BIOMED.
 - 4.6.4 An investigation shall be conducted.
 - 4.6.5 Reporting adverse events related to medical device to SFDA-NCMDR and perform the defined duties identified by the SFDA.
 - 4.6.6 Record of reported adverse events to SFDA with the actions taken.

5. MATERIALS AND EQUIPMENT:

N/A

6. RESPONSIBILITIES:

- 6.1 All Biomedical Staff

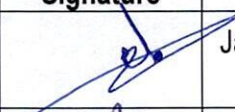

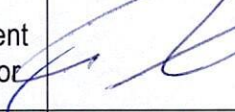



7. APPENDICES:

N/A

8. REFERENCES

- 8.1 Total Safety Quality Center for Training and Consultancy (TSQCTC)
- 8.2 Kingdom of Saudi Arabia, Ministry of Health, Bisha General Hospital

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Engr. Wafi Abdoo Elgaleel	Head of Biomedical Department		January 05, 2025
Reviewed by:	Mr. Waleef Hajjaj Alshammary	Biomedical Department Director		January 07, 2025
Reviewed by:	Mr. Mishari Fahad Al Mutairi	Facility Management and Safety Director		January 08, 2025
Reviewed by:	Mr. Abdulelah Ayed Almutairi	QM&PS Director		January 08, 2025
Reviewed by:	Mr. Thamer Nasser Alanizi	Assistant for Administrative and Operating Services		January 12, 2025
Approved by:	Mr. Fahad Hazam Al - Shammari	Hospital Director		January 19, 2025