



BIOMEDICAL ENGINEERING MANUAL

Annual Documents adequacy & Change Requirements Review

Sr.No	SOP /Doc No	Documents Name	Issue. No	Rev.No	Review Date	Change	Rev No	Revision Date	Reason for Change	Amendment
1	SDH/BME/01	Content	1	1	05-Mar-21	No Any Change Review Completed	1	20-Nov-22	No Any Change Review Completed	No any Amendment History
2	SDH/BME/02	Departmental Organizational Chart	1	1	05-Mar-21		1	20-Nov-22		
3	SDH/BME/03	Roles And Responsibilities	1	1	05-Mar-21		1	20-Nov-22		
4	SDH/BME/04	Standard Operating Procedures	1	1	05-Mar-21		1	20-Nov-22		
5	SDH/BME/4.1	Equipment Purchase & Installation	1	1	05-Mar-21		1	20-Nov-22		
6	SDH/BME/4.2	Breakdown maintenance Activities	1	1	05-Mar-21		1	20-Nov-22		
7	SDH/BME/4.3	Preventive Maintenance System	1	1	05-Mar-21		1	20-Nov-22		
8	SDH/BME/4.4	Equipment & Assets Management	1	1	05-Mar-21		1	20-Nov-22		
9	SDH/BME/4.5	Calibrations Of Biomedical Equipment	1	1	05-Mar-21		1	20-Nov-22		
10	SDH/BME/05	Records	1	1	05-Mar-21			20-Nov-22		

	Original Date	Effective Date	Next date of revision	Issue NO		
	<u>05 March 2021</u>	<u>20 November 2022</u>	<u>20 November 2023</u>	1		

Reviewed & Prepared By		Recommended By	Approved By
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FMS HOD	Quality Co- ordinator	Chief Medical Administartor	Chairman & Managing Director
			

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10	SDH/BME/05	Records	1	1	20-Nov-22			20-Nov-23		
11	SDH/BME/06	Condemnation Policy	1	1	June 22	New Policy Added	1	20-Nov-23	As per NABH NC	New

Original Date	Effective Date	Next date of revision	Issue NO

05 March 2021

20 November 2023

20 November 2024

1

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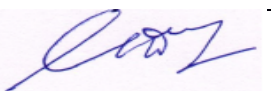
Chairman & Managing Director





SAIDEEP HOSPITAL BIOMEDICAL ENGINEERING MANUAL	Doc No	SDH/BME/01
	Issue No	01
	Rev No.	01
	Date	5/3/2021
	Page	1
Amendment Sheet		

Sr. No	Page No	Clause No	Date of Amendment	Amendment Made	Reasons	Signature of Approval Authority
1	8.1	FMS 4.H	June ,2022	Condemnation Policy	New Policy	

Recommended By	Signature	Approved By	Signature
Dr. Hrishikesh Kalgaonkar		Dr. S. S. Deepak	
Chief Medical Administrator		Chairman & Managing Director	





SAIDEEP HOSPITAL
BIOMEDICAL
ENGINEERING MANUAL

Doc No	SDH/BME/01
Issue No	01
Rev No.	01
Date	5/3/2021
Page	2

Amendment Sheet



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Dr. Hrishikesh Kalgaonkar		Dr. S. S. Deepak	
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SAIDEEP
HEALTHCARE & RESEARCH PVT. LTD.



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BIOMEDICAL ENGINEERING MANUAL

Doc No	SDH/BME/01
Issue No	01
Rev No.	01
Date	20 NOV 2023
Page	1

Contents

SR.NO	CONTENTS
1	Content
2	Departmental Organizational Chart
3	Roles And Responsibilities
4	Standard Operating Procedures
4.1	Equipment Purchase & Installation
4.2	Breakdown maintenance Activities
4.3	Preventive Maintenance System
4.4	Equipment & Assets Management
4.5	Calibration Of Biomedical Equipment
6	Records
7	Condemnation Policy

Recommended By	Signature	Approved By	Signature
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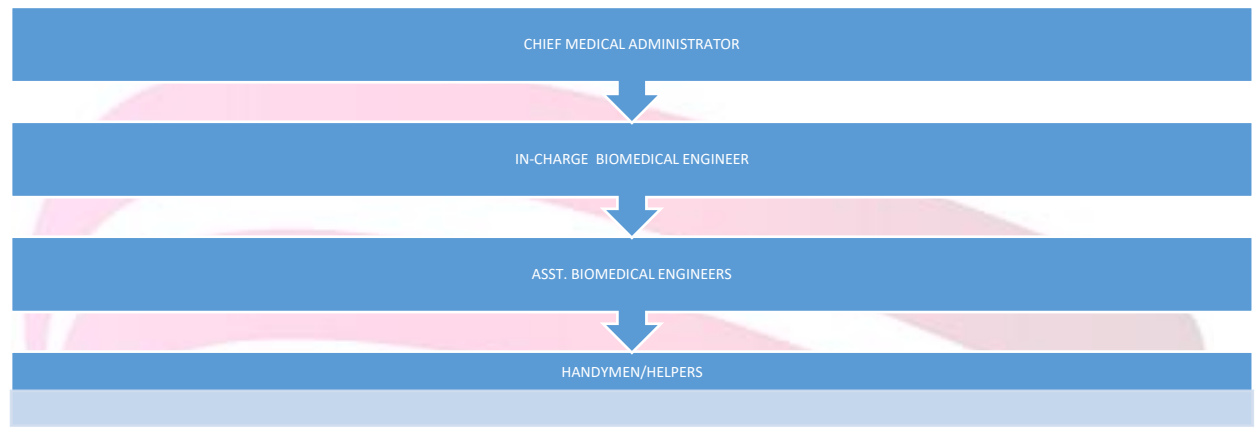


SAIDEEP HOSPITAL
BIOMEDICAL ENGINEERING
MANUAL

Doc No	SDH/BME/02
Issue No	01
Rev No.	01
Date	5/3/2021
Page	1

Organisational Chart – BME

Saideep Healthcare & Research Pvt. Ltd. has outsourced the responsibility of Bio-Medical engineering department to an external agency. An MOU has been signed with the agency.



Organisational structure: The overall responsibility lies with the Chief Medical Administrator.

In-Charge Bio-Medical engineer:

Diagnoses and corrects system and equipment malfunctions by making alterations, repairs or replacements to ensure that medical equipment and internal circuitry meet specified requirements; make necessary calculations for computing circuit elements necessary to adjust circuitry to specified requirements as instructed.

Responds to breakdown calls from various user departments.

Performs regularly scheduled preventive maintenance work on patient care systems and equipment in assigned departments or areas; maintains a log of repairs, electrical safety testing, and maintenance actions; keeps accurate records of time and materials utilized in the performance of these duties.

Provides technical assistance and instruction to the concerned personnel in the maintenance and operation of equipment; recommend the purchase or acquisition of biomedical equipment or related accessories; advise supervisor of equipment deficiencies as required.

Liaise with clients, other engineers, technical officers, technicians, trades people and other workers. Coordinate and evaluate the work performed by service contractors to include maintenance, calibration, installation and verification of service documentation. Examine installations to ensure they meet contract conditions

- Validates, mates, adjusts and synchronizes system controls and recording devices utilized in tests or related analyses as required.
- Trains new employees and reviews the work of lower level employees.

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SAIDEEP HOSPITAL
BIOMEDICAL ENGINEERING
MANUAL

Doc No	SDH/BME/02
Issue No	01
Rev No.	01
Date	5/3/2021
Page	2

Organisational Chart – BME

- Participates in on-the-job training to advance and acquire new skills regarding sophisticated and specialized electronic equipment.
- Provides a systematic preventive maintenance program for complex integrated diagnostic systems and related biomedical equipment; provides engineering and technical counsel on codes to ensure compliance with electrical safety standards; maintains preventive maintenance records and prepares reports as required.
- Performs other related duties incidental to the work described herein

Assistant Bio-Medical Engineer: Assembles repairs and maintains mechanical / pneumatic devices according to specifications.

Diagnosis and correction of life support system and equipment malfunctions by making repairs or replacements.

Performs regularly scheduled preventive maintenance work on patient care systems and equipment in assigned departments or areas; maintains a log of repairs, electrical safety testing, and maintenance actions; keeps accurate records of time and materials utilized in the performance of these duties.

Responds to breakdown calls from various user departments.


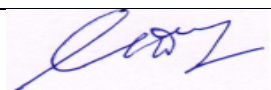
Documents and verifies the introduction of new therapeutic and diagnostic equipment, corrective and preventive maintenance actions and special requests as required.

Participates in on-the-job training to advance and acquire new skills regarding sophisticated and specialized electronic equipment.

Trains new employees on bio-medical equipments

Performs other related duties incidental to the work described herein.

Handymen/Helpers: Assist in all the relevant jobs and perform non Bio-medical repairs under FMS team guidance.

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SAIDEEP HOSPITAL
BME MANUAL

Doc No	SDH/BME/03
Issue No	01
Rev No.	01
Date	5 /3/2021
Page	1

Roles & Responsibilities – BME

Biomedical Engineer

Coordination Responsibilities

- Overall management and coordination of daily activities.
- Organizing and coordinating in equipment installations.
- Annual plan development for maintenance of equipment.
- Arranging gate pass/ correspondence letters and sending equipment for service.
- Regular follow-ups regarding service, supply of spares, AMC.
- In support of new equipment purchase, identifying vendors, arranging demonstrations (if necessary), providing feedback on the demonstrated equipment.
- Preparing and getting approving store indents.
- Creating master entry of new equipment and entry of inspection reports, obsolete equipment, equipment department transfer, and equipment returned to company and AMC.

Maintenance and Other Responsibilities

- Attending service calls and documentation of services.
- Issue of new accessories and spares.
- Carrying out maintenances and calibrations as per schedule and documenting the same.
- Accompanying company engineers and co- coordinating in carrying out the service/maintenance and installation of equipment.
- Informing the top management in case of non-availability of spare or pending service for further processing.
- Receiving machine/accessories from wards/departments for service and returning them back after service

Working Hour and Service Schedules

Biomedical Engineering facility service is available in the hospital through normal shifts and provision of On-call facility. Bio Medical Engineer is available between 9 am-5pm for regular working hours to render this service.

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SAIDEEP HOSPITAL
BIOMEDICAL ENGINEERING
MANUAL

Doc No	SDH/BME/4.1
Issue No	01
Rev No.	01
Date	5/3/2021
Page	1

Biomedical Equipment Purchase & Installation

Objective Stream lined processing of purchase and equipment installations ensuring best fit for the hospital and maximizes the benefits as per contracted services from the selected vendors / OEM

Scope: BME participation in equipment selection and purchase process, Acceptance and Installation of purchased equipment, User demonstration and training

Expected Outcomes: Timely installation of equipment as per terms of purchase

- Ensure smooth handover and user acceptance of new equipment

No	Process Step / Activity	Responsibility	Outputs / Records
1	On requirement of any high budget equipment, in any department/ward, an indent is placed to the Manager – Materials Management	HOD/ Manager Materials Management	
2	The Manager Materials Management discuss the same with Chief Administrative Officer of the hospital who shall obtain approval from Managing Director	CAO/MD	
3	A feedback on the same is provided by the BME department , and decided whether they have to be purchased or to be moved from any other department or shared	BME	
4	In support of new equipment purchase, identifying vendors, arranging demonstrations (if necessary), providing feedback on the demonstrated equipment are done by the BME Department.	BME	
5	Equipment are purchased after the Equipment negotiation meeting with the vendors and Equipment purchase and material management committee members	CAO	
Equipment Installation and Acceptance			
6	Installation requirements are provided by the suppliers prior to installation, and they are arranged seeking inter department support, through proper approvals	BME	
7	The new materials are checked at the biomedical department with the purchase order to confirm the ordered specifications and quantity are received as stated	BME	

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SAIDEEP HOSPITAL

BIOMEDICAL ENGINEERING MANUAL

Doc No	SDH/BME/4.1
Issue No	01
Rev No.	01
Date	5/3/2021
Page	2

Biomedical Equipment Purchase & Installation

8	Installation is carried out at the site. The equipment are handed over to the concerned department and the Equipment Acceptance form (Annexure 1) will be filled at the time of installation as a token of acceptance. The supplier makes an installation report and an Equipment installation checklist (Annexure B) is compiled, they are accepted by the Biomedical Engineer.	BME	Equipment Acceptance Form
9	Incomplete installations due to wrong supply or short shipment of accessories, equipment identified as defective during installation are communicated to the Material Management Manager and duly followed-up.	BME / Materials Management Manager	
10	All the Bio-medical Equipment of the hospital shall be identified and tracked using a unique identification number issued by BME department. This number shall be visibly labeled on all the biomedical equipment.	BME	


Equipment Working Demonstrations & User Training

11	Demonstration and training is conducted by the equipment suppliers to the users. Application demonstration is given to the Doctors, Nurses and technicians who will be using the equipment. Training on machine usage, alarm management, user settings are given to the staff/technician. Technical, service and basic trouble shooting demonstration is given to the Biomedical Engineers. After each installation, the list of persons, who attended the training session, is documented. The installation is completed with the filling in of the equipment installation report	BME	Training Attendance Sheet Biomedical Equipment Installation Report
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Records

Record ID	Name	Type	Responsible Person	Retention Period
SDH-BME-01	Biomedical Equipment Acceptance Form	Form / File	BME	Till equipment condemnation

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		Issue No	01
		Rev No.	01
		Date	5/3/2021
		Page	1
Breakdown Maintenance of Biomedical Equipment			

Objective

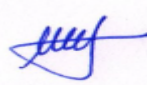
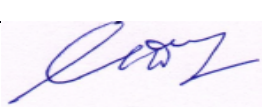
- To ensure a round the clock breakdown maintenance system to support 24 X 7 patient care activity at the hospital

Scope: Breakdown maintenance system for biomedical equipment's

Expected Outcomes

- Effective system for reporting and attending to breakdown calls for biomedical equipment
- Minimize critical equipment down time through faster turnarounds in cases of breakdown

No	Process Step / Activity	Responsibility	Outputs/ Records
1	A written complaint notification is received from the concerned department, stating the equipment, complaints and the fault date, with the approval of their in-charge	Various Units / Departments	BME Equipment Breakdown Request
2	The equipment/accessories sent from the concerned department for breakdown service is checked and received and the equipment details and quantity are recorded in the Complaint Register. In case of emergencies, a verbal complaint (direct or telephone) is accepted and it is registered in the complaint register furnishing the above details along with the name of the complaint reporter	BME	BME Complaints Register
3	The problem is duly attended by a biomedical engineer/ Biomedical Engineer-Trainee and rectified. In case the job is not completed on the same day, reason for the delay (like spares required, company support required, etc) is communicated to the concerned department. To minimize the downtime of the equipment, a few spares which are frequently used are maintained in the biomedical department stock.	BME	
4	While in need of OEM/Vendor company support, complaints are taken to the notice of Materials Management Manager / CAO. After CAO approval, Service charge estimate is received	BME / Manager Materials Management /	

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SAIDEEP HOSPITAL
BIOMEDICAL ENGINEERING
MANUAL

Doc No	SDH/BME/4.2
Issue No	01
Rev No.	01
Date	5/3/2021
Page	2

Breakdown Maintenance of Biomedical Equipment

	from the company and is submitted to the Materials Management Manager. Work order is released and service of company is sought and the job is closed after rectification. In case, the problem cannot be rectified in-house, the unit is taken to the company site. Documents supporting each activity are filed.	CAO	
5	Functions of the equipment are checked and finally handed over to the department, and documented in the Complaint Register. Suggestions or advice regarding the equipment handling, if any are also communicated to the user.	BME	
9	Incomplete installations due to wrong supply or short shipment of accessories, equipment identified as defective during installation are communicated to the Material Management Manager and duly followed-up.	BME / Materials Management Manager	
10	All the Bio-medical Equipment of the hospital shall be identified and tracked using a unique identification number issued by BME department. This number shall be visibly labeled on all the biomedical equipment.	BME	

Records

Record ID	Name	Type	Responsible Person	Retention Period
SDH-BME-F03	BME Equipment Break down Service Request	Form / File	Departments	1 Years
SDH-BME-F04	BME Complaints Register	Register	BME	2 Years

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SAIDEEP HOSPITAL
BIOMEDICAL ENGINEERING
MANUAL

Doc No	SDH/BME/4.3
Issue No	01
Rev No.	01
Date	5/3/2021
Page	1

Preventive Maintenance System for Biomedical Equipment

Objective

- To establish a effective system for preventive maintenance of biomedical equipment minimizing interruption of hospital services and increasing key equipment life

Scope

- Annual Maintenance Contract / Comprehensive Maintenance Contract / Equipment Warranty Management
- Internal Preventive Maintenance Activities

Expected Outcomes: Reduction of equipment down time

Increase in equipment life

No	Process Step / Activity	Responsibility	Outputs/ Records
	<p>For the purpose of preventive maintenance planning and execution Biomedical Equipment are categorized as</p> <ol style="list-style-type: none"> 1. AMC/CMC Equipment 2. Non-AMC Equipment <p>Preventive Maintenance Planning is done based on the category of the equipment in each department at the end of every year for the next year (December).</p>	BME	Annual Preventive Maintenance Plan
Preventive Maintenance System for Equipment Under AMC/CMC			
3	For equipment under AMC / CMC, details of the contract are available in the Equipment's history. Same is checked for validity and renewed when necessary with approval of CAO	BME / CAO	
4	Preventive maintenance plan is prepared based on the number of PM visits committed as per the contract for each of the above equipment	BME	
5	First day of every month, list of equipment for which the PM is due and whose AMC is about to expire is displayed on the department notice board and reminded about the same to the concerned company.	BME	

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SAIDEEP HOSPITAL

**BIOMEDICAL ENGINEERING
MANUAL**

Doc No	SDH/BME/4.3
Issue No	01
Rev No.	01
Date	5/3/2021
Page	2

Preventive Maintenance System for Biomedical Equipment

9	Preventive Maintenance is carried out by the company engineer in the presence of a biomedical engineer/Biomedical Engineer-Trainee and it is acknowledged with a service report. A entry of the same is made in the Preventive Maintenance Record maintained in the equipment file	BME	Company Service Reports/ BME Maintenance Repo
10	If any PM visit planned is missed out an incident report is raised and corrective action is ensured.	BME / CAO	Incident Report
Preventive Maintenance of Equipment Not Under AMC/CMC			
11	Equipment's are listed department wise and preventive maintenance is planned for each equipment for subsequent year every December	BME	Annual Preventive Maintenance Plan
12	In the first 2-3 days of every month; department wise list of equipment due for preventive maintenance is listed and days scheduled in consultation with the user departments. The final monthly schedule is shared with each department for planning and coordination	BME	Monthly Internal B PM Schedule
13	Preventive maintenance is carried out as per the Equipment maintenance protocol (Check list), by the biomedical engineer/ Biomedical Engineer-Trainee. It is documented in the PM log.	BME	BME Maintenance Report

Records

Record ID	Name	Type	Responsible Person	Retention Period
SDH-BME-F05	BME Annual Preventive Maintenance Plan	Form / File	BME	2 Years
SDH-BME-F05	BME PM Log Chart	Form / Chart	BME	Till equipment Condemnation

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SAIDEEP HOSPITAL
BIOMEDICAL ENGINEERING
MANUAL

Doc No	SDH/BME/4.4
Issue No	01
Rev No.	01
Date	5/3/2021
Page	1

Preventive Maintenance System for Biomedical Equipment

Objective

- To establish a system for tracing biomedical equipment assets of the hospital and create a system of equipment history tracking to ensure longer life and better utilization

Scope

- Assets Register
- Equipment Management records

Expected Outcomes

- Effective tracking of biomedical equipment

No	Process Step / Activity	Responsibility	Outputs/ Records
1	<p>Assets Register</p> <p>Each biomedical equipment is uniquely numbered and labelled by the biomedical department. The labelling consists of Equipment ID No, Date of Installation / Commissioning, User Department and also Manufacturer Serial No if not displayed on the equipment.</p> <p>The equipment is listed under the equipment Asset register with details of user department the equipment is issued for custody and use</p> <p>No equipment is allowed to be transferred from one department to another with out permission from CAO and intimation to BME. In such cases the new details are updated in BME Assets register</p>	BME	BME Assets Register

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SAIDEEP HOSPITAL
BIOMEDICAL ENGINEERING
MANUAL


Doc No	SDH/BME/4.4
Issue No	01
Rev No.	01
Date	5/3/2021
Page	2

Preventive Maintenance System for Biomedical Equipment

2	<p>Equipment Manuals</p> <p>The Bio-medical engineering section shall maintain the relevant service and operation manuals (hard or soft copies) of various biomedical equipment.</p> <p>A catalogue of manuals under its custody is maintained by BME Department</p> <p>The manuals are arranged in cupboards / shelves under lock and key for easy reference and to prevent their loss / misplacement</p>	BME	
3	<p>Equipment History Files</p> <p>Information and history of each equipment is maintained as file by the BME. A single file shall be maintained for high value equipment and category wise box files with separators maintained for others</p> <p>Each equipment file shall have the following details</p> <ol style="list-style-type: none">1. Purchase Orders Copy/Reagent rental Agreement contract copy2. Equipment Acceptance Form3. Equipment Installation Report4. Installation Report (Manufacturer / Service Agent Provided)5. Quotations & Invoice (For spares, maintenance)6. Copy of AMC/CMC7. Service Reports8. Copy of Correspondence with company / vendors9. Equipment Maintenance History	BME	

Records: Nil

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	BIOMEDICAL ENGINEERING MANUAL		Issue No	01
			Rev No.	01
			Date	5/3/2021
			Page	1
Preventive Maintenance System for Biomedical Equipment				


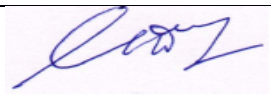
Objective


- To establish a calibration system for biomedical equipment of the hospital
- **Scope**
- External calibrations
- Internal calibration

Expected Outcomes

- Timely calibration of equipment

No	Process Step / Activity	Responsibility	Outputs/ Records
	The calibration activities for biomedical equipment is divided into two; External Calibrations External calibration is done by contracted vendors (OEM of otherwise) for those biomedical equipment which cannot be calibrated by the hospitals own BME team Internal calibrations / verifications are those done by the hospitals own BME team using master calibration equipment	BME	Annual Preventive Maintenance Plan
2	Calibration Planning Not all Biomedical equipment require calibrations. That biomedical equipment which work on hydraulics (OT Tables, Dental Chairs), Optics (Endoscopes) etc may not require calibration BME team draws up a list of equipment requiring calibration with details like frequency of calibrations, mode (eternal vs internal), vendors etc. Where possible OEM suppliers may be relied on for provision of calibration of the equipment Based on discussions with OEM and service providers, independent external calibration agencies the BME draws up a annual calibration plan every December for the subsequent year along with budget for calibration The CAO reviews the same and obtains approval of same from Managing Director	BME / CAO	
3	On approval of the Annual Calibration Plan the calibration plan and budget; activities shall be undertaken in liaison with	BME	


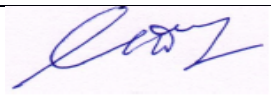
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	BIOMEDICAL ENGINEERING MANUAL		Issue No	01
			Rev No.	01
			Date	5/3/2021
			Page	2
Preventive Maintenance System for Biomedical Equipment				

	Manufactures / AMC service providers / Calibration Agencies and the calibration certificates kept in the Equipment file, a copy of which is maintained in the concerned department		
4	First day of every month, list of equipment for which the calibration is due in the month is drawn up and same is informed to the department with scheduled dates (after consulting with user department)	BME	
5	<p>Calibration is carried out by the external calibration technicians in the presence of a biomedical engineer.</p> <p>Based on the activity a calibration report is provided by the agency with traceability to applicable national / international standards as applicable</p> <p>The calibration report original is stored with BME and copies provided to user department</p>	BME	Company Service Reports/ BME Maintenance Report
6	<p>Internal Calibration is carried out by BME team using Work Instruction / Checklist for calibration for each equipment as per manufacturer recommendations.</p> <p>Internal calibrations / verifications are done using master equipment which are calibrated externally with calibration certificate establishing traceability</p> <p>Based on the activity internal calibration report is generated.</p> <p>The calibration report original is stored with BME and copies provided to user department</p>	BME	<p>Work Instruction for Calibrations / Internal verifications</p> <p>Internal calibration / verification Report</p>

Records

Record ID	Name	Type	Responsible Person	Retention Period
SDH-BME-F07	Internal Calibration Report	Form / File	BME	2 Years

Recommended By	Signature	Approved By	Signature
Dr.Hrishikesh kalgaonkar		Dr.S.S.Deepak	
Chief Medical Administrator		Chairman & Managing Director	

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		Issue No	02
		Rev No.	00
		Date	1 Nov 20
		Page	1
<p>Policy and Procedure for Identification and Disposal (Condemnation) of Equipment and Materials Not Used</p>			

Purpose


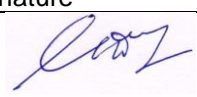
To develop a system to condemn and dispose in a systematic manner the materials not in use such as non-functioning items, excess unwanted material, general waste, scrap materials etc


Policy

- The Condemnation Committee shall meet annually once and complete the condemnation of all the unused items.
- Wherever buy-back policy for equipment is offered, the committee shall consider the same before approving the condemnation.
- All stores including steel items, empty containers of drugs and dressings that are found to be unserviceable inwards / Theatres / Department / Nurses station etc., should be returned to the main stores. The in-charge of main stores should take steps to condemn them which are beyond repairs.
- Linen items which are worn out due to wear and tear in the wards, theatres and department shall be listed out and consolidated by the Nursing Superintendent and should be placed before the condemnation committee for its approval.
- Scrap sales, old equipment sales beyond value of 2 Lakhs rupees shall be based on inviting minimum three quotes from different vendors and the analysis of same.

Procedure

- All the items condemned should be noted in the general disposal register The entries in the general disposal register should tally with the items condemned and reduced in the main stock register of instruments, accessories, furniture etc.,. The stock in the general disposal register shall be reduced as and when such items are disposed.
- The list of items to be condemned should be approved by a condemnation committee which meet once in three months
- **Hospital Condemnation Committee Members**
 - Chairman (Medical Director)
 - Medical Superintendent
 - Medical Administrator
 - Nursing Superintendent
 - Materials Management In-Charge



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Dr. Hrishikesh Kalgaonkar		Dr. S.S. Deepak	
Chief Medical Administrator		Chairman & Managing Director	

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		Date	1 Nov 20
		Page	2
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- FMS In-Charge / Senior Engineer
 - Biomedical Engineer
- If it is not possible to co-opt any of the Technical Professional persons, an Inspection report on the irreparable state of the item may be obtained and the same may be considered by the condemnation committee.
 - Minutes of meeting will be met and list of items approved will be passed on to Manager – Materials Management for disposal / salvage/ sales
 - Copies of sale letters with value should be forwarded to accounts.

STANDARD REFERENCE

FMS- 1D

Recommended By	Signature	Approved By	Signature
Dr. Hrishikesh Kalgaonkar		Dr. S.S. Deepak	
Chief Medical Administrator		Chairman & Managing Director	