File	**QUALITY MANAGEMENT SYSTEM RMT**
Scope of QMS	***DESIGN, DEVELOPMENT & MANUFACTURING OF INTRAVASCULAR DEVICES (MICROSPHERES)***
Domain	**QUALITY ASSURANCE**
Document Name	**MAINTENANCE**
Document Type	**STANDARD OPERATING PROCEDURE**
Document No.	**QA.SOP.06**
Language	**EN**
Version	**1.0**
Document owner	**REVIVE MEDITECH PVT LTD.**
Address	**BUILDING 2A, W1 STREET, RAWAT INDUSTRIAL ESTATE, ISLAMABAD, PAKISTAN (46220)**
Confidentiality level	**MODERATE**
Coming into effect	**20th November, 2024**

Purpose and goal:

This document is a part of the QUALITY MANAGEMENT SYSTEM folder of REVIVE MEDITECH PVT LTD. compiled for compliance of ISO 13485:2016 requirements.

ROLE	DESIGNATION	NAME	DATE	SIGNATURE
CREATOR	Assistant Manager Quality Assurance	Hafsa Inam Rao	14-10-2024	
REVIEWER	Chief Production Officer	Ammad Ahmed	24-10-2024	
REVIEWER	Chief Technology Officer	Ibraheem Raza	01-11-2024	
REVIEWER	Quality Manager	Suhail	17-11-2024	
APPROVER	Chief Executive Officer	Dr. Murtaza Najabat Ali	20-11-2024	

REVISION HISTORY

Revision	Status	Date	Description of Change
1.0	Obsolete	20-11-2024	Initial version

NOTE:

Document Status	Description	Marking Type	Document Type
DRAFT	Documents under creation, revision or review	In document background	Electronic
APPROVED	Approved documents in electronic Document Management System	In revision history table	Electronic
MASTER COPY	Approved documents in Quality Manager office	Stamped	Physical
CONTROLLED COPY	Approved documents sent to concerned department for reference	Stamped	Physical
OBSOLETE	Documents replaced by new revisions	Stamped/Moved to archive	Physical/Electronic

Table of Contents

1 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to establish a structured and compliant approach for performing all types of maintenance activities, on the infrastructure and utilities along with all equipment used in the "**Design, Development and Manufacturing of Intravascular Devices (Microspheres)**" at **Revive Meditech Pvt Ltd. (RMT)**. This procedure ensures that all relevant equipment operates within defined accuracy and reliability limits, minimizing the risk of errors that could compromise product quality, safety, and regulatory compliance. It ensures alignment with the requirements of **ISO 13485:2016.**

2 SCOPE

This SOP applies to all monitoring, measuring, testing, and production equipment used in the "**Design, Development, and Manufacturing of Intravascular Devices (Microspheres)**" at **Revive Meditech Pvt Ltd.** that requires maintenance to ensure proper function.

Included in the scope:

- Use of traceable reference standards
- Preventive maintenance
- Corrective maintenance (e.g., repair after breakdown or OOT event)
- Predictive and routine maintenance based on performance or manufacturer guidelines
- Documentation and traceability of all maintenance activities
- Evaluation and handling of out-of-tolerance or malfunctioning equipment

3 NORMATIVE REFERENCES

- **ISO 13485:2016** – Medical devices – Quality management systems – Requirements for regulatory purposes
- **ISO/IEC 17025:2017** – General requirements for the competence of testing and calibration laboratories
- **ISO 10012:2003** – Measurement management systems – Requirements for measurement processes and measuring equipment

4 DEFINITIONS AND ABBREVIATIONS

Preventive Maintenance (PM): Scheduled maintenance activities performed to reduce the likelihood of equipment failure or degradation. Includes cleaning, lubrication, and functional checks.

Corrective Maintenance: Unscheduled maintenance performed to restore a failed or malfunctioning device to its operational state. Often follows an OOT or breakdown incident.

Predictive Maintenance: Maintenance based on the analysis of equipment condition and performance data to predict failure before it occurs. Often supported by monitoring tools or trends.

Measuring Equipment: Any instrument or device used to assess a physical quantity (e.g., temperature, pressure, dimensions, and time) that may impact product quality or safety.

Monitoring Equipment: Equipment used to observe or record environmental or operational parameters (e.g., humidity sensors, temperature loggers), especially in storage or cleanroom areas.

Measurement Uncertainty: A parameter associated with the result of a measurement that characterizes the dispersion of values that could reasonably be attributed to the measurand.

Qualified Person: An individual trained, assessed, and authorized to perform calibration or maintenance activities under controlled procedures.

SOP: Standard Operating Procedures

ISO: International Standards Organization

QA: Quality Assurance

AM: Assistant Manager

OOT: Out of Tolerance

5 RESPONSIBILITIES

Role	Key Responsibilities	Designation
Initiator	Identify and report equipment/infrastructure requiring maintenance or found malfunctioning. Complete and submit Corrective Maintenance Request Form or Nonconformance Report. Isolate and tag faulty equipment as 'Do Not Use'.	All relevant employees
Implementation	Perform preventive, corrective, predictive, and routine maintenance per plan and manufacturer guidelines for equipment. Document all activities in Maintenance Log / Forms. Ensure only appropriate tools, spare parts, and lubricants are used. Coordinate with external service providers when needed.	Technician/Production Manager
Supervision	Ensure maintenance activities are executed on time. Verify that equipment under their department is properly maintained and fit for use. Review maintenance records for completeness and accuracy. Escalate recurring or critical failures to QA.	Production Manager/CPO
Implementation	Perform preventive, and corrective maintenance for infrastructure and utilities. Document all activities in Maintenance Log / Forms. Ensure only accessories are used for maintenance activities. Coordinate with external service providers when needed.	Assistant Manager Admin
Supervision	Ensure maintenance activities are executed on time. Verify that all infrastructure and utilities required for product is properly maintained and fit for use. Review maintenance records for completeness and accuracy. Escalate recurring or critical failures to QA.	Manager HR/Admin
Quality Assurance	Review maintenance plans and records. Review Corrective Maintenance Request Form and NC Reports. Ensure equipment status (fit / not fit for use) is controlled and documented. Verify that product impact is assessed when equipment malfunctions.	Assistant Manager Quality Assurance
	Approve maintenance plans and records. Review and approve Corrective Maintenance Request Form and NC Reports. Approve external service providers and ensure maintenance traceability. Escalate recurring maintenance issues to management during review meetings	Quality Manager
Top Management	Participate in management reviews Review maintenance effectiveness and trends during Management Review.	C-Level Personnel

Approving Authority	Ensure adequate resources (budget, personnel, vendors) for maintenance. Review maintenance effectiveness and trends during Management Review. Approve major equipment decommissioning or replacement	Chief Executive Officer

6 PROCEDURE

6.1 INFRASTRUCTURE MAINTENANCE

Revive Meditech Pvt Ltd. shall develop a maintenance procedure for all infrastructure elements and utilities critical for the "**Design, Development and Manufacturing of Intravascular Devices (Microspheres)**" in compliance with **ISO 13485:2016** and other applicable regulatory standards.

6.1.1 Preventive Maintenance

RMT shall develop and implement a preventive maintenance plan for all critical infrastructure elements and utilities that will be used in the "**Design, Development and Manufacturing of Intravascular Devices (Microspheres)**". Maintenance intervals shall be based on contractors' recommendations, operational usage and risk assessment. Each maintenance activity, either corrective or preventive, shall be documented in the Infrastructure Maintenance Log.

RMT shall conduct risk assessments to classify areas and utilities based on criticality to product quality and safety. Areas with a high impact on product conformity or safety shall be given priority in preventive maintenance planning.

6.1.2 Corrective Maintenance

- In case of any malfunctions or breakdowns, it shall be reported immediately to the Admin and Quality Department.
- A corrective maintenance work order shall be initiated and addressed promptly to minimize downtime.
- Root cause analysis shall be conducted where appropriate to prevent recurrence.
- All corrective actions shall be verified and documented.

6.1.3 Verification and Review

Post-maintenance verification shall be performed by designated personnel to ensure facility returns to full operational status. The effectiveness of the preventive and corrective maintenance program shall be reviewed periodically by Quality and Production teams.

6.1.4 Record Retention

All infrastructure maintenance logs and associated records shall be retained for a minimum period of 5 years or as per regulatory requirement. Records shall be readily available during audits and inspections.

REFERENCE:

- SOP- Control of Records

6.2 EQUIPMENT MAINTENANCE

6.2.1 Preventive Maintenance

Preventive Maintenance (PM) and Routine Maintenance shall be performed to ensure the continued functionality, reliability, and safety of all critical equipment used in the "**Design, Development and Manufacturing of Intravascular Devices (Microspheres)**".

PM activities shall be defined based on:

- The manufacturer's recommended maintenance procedures and intervals, as documented in equipment user or service manuals.
- The organization's internal preventive maintenance plan, which shall consider:

- Criticality of the equipment to product quality,
- Frequency of use, and
- Environmental exposure (e.g., humidity, vibration, cleanroom conditions)

6.2.1.1 Preventive Maintenance Activities

PM tasks shall include, but are not limited to:

- Lubrication of mechanical parts as required,
- Inspection and replacement of consumables or parts such as seals, filters, or gaskets,
- Alignment and calibration checks for moving parts or sensors,
- Environmental conditioning tasks (e.g., HVAC filter checks).

6.2.1.2 Routine Maintenance Activities

Routine maintenance activities at RMT shall be scheduled at fixed intervals, regardless of equipment condition and may include:

- General visual inspections,
- Basic functionality tests,
- Cleaning of accessible surfaces,
- Checking for signs of corrosion, leakage, or loose parts.

Any abnormalities identified during routine checks shall be escalated to QA for further evaluation or corrective action.

6.2.1.3 Documentation and Records

All maintenance activities shall be recorded in the Equipment Maintenance Log.

Maintenance records shall be retained and **s**hall be readily available during internal audits, external audits, and inspections. Equipment shall not be used in production or testing if preventive maintenance is overdue.

6.2.2 Corrective Maintenance

Revive Meditech Pvt Ltd. shall perform Corrective Maintenance to restore the functionality of monitoring and measuring equipment in response to unexpected failures, deviations, or malfunctions that may affect the quality, performance, or regulatory compliance of **Intravascular Devices (Microspheres).** Corrective maintenance ensures operational continuity and supports RMT's commitment to product safety and reliability.

6.2.2.1 Triggers for Corrective Maintenance

Corrective maintenance Request at RMT shall be initiated under the following conditions:

- Equipment failure during production, testing, or storage processes,
- Abnormal readings, alarms, or error messages generated during equipment use,
- Discovery of out-of-tolerance (OOT) results during calibration,
- Reported equipment malfunction, wear, or damage by operators or QA personnel,
- Any incident where equipment performance may be compromised or unverified.

RMT personnel shall submit Corrective Maintenance Request Form to the Quality department immediately for timely corrective action.

6.2.2.2 Corrective Maintenance Activities

Corrective maintenance activities at RMT shall include but not limited to:

- Equipment troubleshooting and fault diagnosis
- Repair or replacement of faulty components (e.g., pressure sensors, temperature probes)
- Software reset or firmware updates, where applicable
- Mechanical realignment, cleaning, or internal adjustments
- Re-verification and functional testing after repair
- Calibration (if required) following corrective intervention

Only authorized and trained personnel or approved third-party service providers shall perform corrective maintenance activities at RMT.

6.2.2.3 Documentation and Traceability

A completed Corrective Maintenance Request Form including request and maintenance details.

All corrective maintenance conducted at RMT shall be recorded in the Equipment Maintenance Log.

Corrective maintenance records shall be reviewed and approved by the Quality department and retained as per **SOP-Control of Records**.

If the equipment cannot be successfully repaired, RMT shall safely remove it from active use and update the Equipment Master List accordingly.

6.2.3 Predictive Maintenance

Revive Meditech Pvt Ltd. shall implement Predictive Maintenance strategies to minimize the risk of equipment failure and optimize equipment performance based on condition trends and scheduled inspections. These activities support operational continuity and ensure sustained compliance with product quality and safety requirements.

6.2.3.1 Predictive Maintenance

Predictive maintenance at RMT shall involve monitoring equipment conditions to identify potential failures before they occur. This includes:

- Tracking parameters such as vibration, temperature, pressure, noise, or cycle count,
- Analyzing trends and wear patterns to predict when maintenance is required,
- Utilizing historical data from previous breakdowns or deviations.

All predictive maintenance activities shall be recorded in the Equipment Maintenance Log. Records shall be reviewed periodically by QA to identify trends and adjust maintenance schedules accordingly.

6.2.4 Nonconforming Equipment

Nonconforming equipment refers to any equipment or device including monitoring and measuring equipment that fails to meet defined calibration tolerances, performance specifications, functional requirements or requires maintenance. **Revive Meditech Pvt Ltd.** shall ensure that such equipment is promptly identified, controlled, and addressed to prevent the use of inaccurate or unreliable instruments in the production or testing of medical devices.

6.2.4.1 Identification and Isolation

Any equipment identified as Out of Tolerance (OOT), malfunctioning, or non-operational shall be immediately labeled as “Do Not Use” and physically segregated from operational areas to prevent inadvertent use. The responsible personnel shall initiate an Corrective Maintenance Request and notify the relevant department for further action.

6.2.4.2 Investigation and Impact Evaluation

- The relevant department shall perform an investigation to determine the extent and nature of the nonconformance.

- A retrospective review shall be conducted to evaluate whether the nonconforming equipment was used during the production, inspection, or testing of any in-process or released lots.
- If there is a possibility that nonconforming/OOT equipment affected product quality or compliance, the affected product shall be evaluated for disposition (e.g., re-inspection, rework, or rejection), and a Nonconformance Report shall be initiated as per **SOP Nonconformance of Product**.

6.2.4.3 Corrective and Preventive Action (CAPA)

If the nonconformance is found to have a significant impact on product quality, safety, or regulatory compliance, a Corrective and Preventive Action (CAPA) shall be initiated.

The CAPA shall address:

- Root cause analysis for equipment failure or drift,
- Actions to correct the equipment condition (e.g., repair, recalibration),
- Preventive measures to avoid recurrence (e.g., more frequent calibration, equipment upgrade).

6.2.4.4 Disposition of Equipment

Nonconforming equipment shall be either:

- Re-calibrated and verified to meet acceptance criteria before return to service, or
- Sent for maintenance and repair to a qualified and approved service provider, or
- Permanently removed from service and decommissioned if it fails to meet the required performance after corrective actions.

All actions and decisions regarding nonconforming equipment shall be documented in the Equipment Maintenance Log and linked with the corresponding Nonconformance and CAPA records.

REFERENCES:

- SOP- Nonconformance of Product
- SOP- Corrective Actions & Preventive Actions

7 TRAINING

Revive Meditech Pvt Ltd. shall ensure that all employees involved in the maintenance activities related to infrastructure, utilities and equipment used in the "**Design, Development and Manufacturing of Intravascular Devices (Microspheres)**" shall be trained on this SOP and other maintenance processes as required in compliance with **ISO 13485:20176**. The HR department shall be responsible for all the training-related activities and shall maintain training records.

REFERENCE:

- SOP- HR Management