

Standard Operating Procedure (SOP)

Medical Equipment Maintenance and Calibration

1. Purpose

This SOP details the procedures for **medical equipment maintenance and calibration**, including routine inspection schedules, preventive maintenance tasks, calibration standards adherence, documentation of maintenance activities, troubleshooting protocols, and ensuring equipment accuracy and reliability. The goal is to guarantee optimal performance, safety, and compliance of all medical devices used in clinical settings.

2. Scope

This SOP applies to all staff responsible for the maintenance, calibration, and documentation of medical equipment within the facility.

3. Responsibilities

- **Biomedical Engineering/Technicians:** Conduct all maintenance, calibration, and troubleshooting tasks, and complete documentation.
- **Department Heads/Managers:** Ensure staff compliance with SOP and schedule adherence.
- **Clinical Users:** Report equipment issues or irregularities immediately.
- **Quality Assurance:** Periodically review adherence and documentation.

4. Definitions

- **Maintenance:** Scheduled activities conducted to ensure equipment operates as intended and to prevent breakdowns.
- **Calibration:** The process of adjusting equipment to meet prescribed standards of accuracy.
- **Preventive Maintenance (PM):** Routine and scheduled checks and servicing of equipment.
- **Corrective Maintenance (CM):** Actions taken after equipment failure or when a problem is identified.

5. Procedure

5.1 Inspection and Preventive Maintenance Schedule

- Identify all medical equipment and assign unique identification numbers.
- Create a maintenance and calibration schedule (see example table below).
- Inspect equipment following manufacturer's recommendations and regulatory guidelines.

Equipment	Frequency	Task	Responsible
Defibrillator	Monthly	Functional check, cleaning, battery check, calibration	Biomedical Technician
Infusion Pump	Quarterly	PM as per manual, accuracy test	Biomedical Technician
Patient Monitor	Biannually	Visual inspection, calibration, function test	Biomedical Technician

5.2 Calibration Procedures

- Calibrate equipment in accordance with manufacturer and applicable regulatory standards using certified calibration tools.
- Record pre-adjustment readings, make necessary adjustments, and document final readings.
- Ensure reference standards used are within current calibration validity.
- Affix calibration labels with last and next calibration dates.

5.3 Documentation

- Maintain logs for each device, recording:
 - Date of maintenance or calibration
 - Tasks performed
 - Results/values obtained

- Personnel involved
- Anomalies and actions taken
- Update electronic maintenance management system, if available.

5.4 Troubleshooting and Corrective Actions

- Investigate any reported malfunction promptly.
- Perform root cause analysis and implement corrective measures.
- Document troubleshooting steps and solutions applied.
- If equipment cannot be repaired immediately, remove from service and apply “Out of Service” label.

6. Safety and Compliance

- Use appropriate personal protective equipment (PPE) during all procedures.
- Comply with relevant regulatory, accreditation, and manufacturer guidelines at all times.
- Ensure regular training for all personnel involved in maintenance and calibration.

7. Review and Update

- The SOP shall be reviewed annually or upon significant regulatory changes or equipment updates.
- All changes must be documented and communicated to relevant staff.

8. References

- Manufacturer's manuals and service guides for all equipment
- ISO 13485:2016 - Medical Devices Quality Management Systems
- Relevant local and national regulations governing medical equipment calibration and maintenance

9. Attachments/Forms

- Sample Maintenance Log Sheet
- Calibration Certificate Template
- Annual Maintenance Schedule