Medical Equipment Quality Assurance

A Condensed Practical Reference & Preventive Maintenance Checklist Set for Healthcare Facility Biomedical Engineering Teams

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Important note on scope and use: *This document is an original, independently written condensed reference and checklist toolkit. It reflects general, widely-published clinical/biomedical engineering practice for medical equipment quality assurance (QA) and preventive maintenance (PM) programs — including well-known risk-based maintenance scheduling concepts used across the profession — expressed in the author's own words. It is* ***not a reproduction of any copyrighted textbook, manual, or proprietary institutional procedure****, and is not a substitute for a facility's own validated PM procedures, manufacturer service manuals, or applicable regulatory/accreditation requirements (e.g., IEC 60601-1, IEC 62353, NFPA 99, and accreditation body standards such as The Joint Commission). Facilities should adapt intervals, acceptance limits, and test methods to their own equipment management plan.*

1. Purpose of a Medical Equipment QA / PM Program

A medical equipment quality assurance program exists to keep equipment safe, accurate, and ready for patient use throughout its service life. It typically sits inside a broader equipment management program that also includes corrective maintenance/repair, asset and inventory control, technology planning, staff education, and patient-safety incident follow-up.

A well-run program generally includes four components:

- A defined **inventory** of equipment requiring scheduled maintenance (a "managed inventory").
- A **risk-based schedule** that sets inspection/testing frequency according to the equipment's clinical role and risk profile rather than a single fixed interval for everything.
- **Written procedures** for each device type or device family covering visual inspection, electrical safety testing, and performance/functional testing, with clearly defined acceptance limits.
- **Documentation** of every inspection, test result, and repair in the equipment's service history, supporting both patient safety and regulatory/accreditation review.

2. Risk-Based Maintenance Scheduling

A widely used approach in clinical engineering (originating from published risk-criteria scoring models used across the profession) sets maintenance frequency by scoring each device type against several risk factors, rather than treating all equipment the same. The general logic is summarized below; facilities typically formalize this in a maintenance strategy worksheet.

Risk factor	What it captures
Equipment/clinical function	How critical the device's function is to patient care (e.g., life-support and therapeutic devices score higher than simple diagnostic aids).
Physical risk of failure	The severity of harm that could result if the device fails or malfunctions during use.
Failure/problem probability	How likely the device type is to fail, based on historical repair and maintenance data.
Incident history	Whether this device type has been associated with adverse events, recalls, or repeated faults.
Regulatory / manufacturer requirement	Any mandatory testing frequency required by regulation, accreditation body, or the manufacturer.

Each factor is scored numerically and totalled per device type; the total then maps to a maintenance tier — commonly something like: higher combined scores justify semiannual testing, mid-range scores justify annual testing, and lower scores justify extended intervals or user-check-only strategies for low-risk, high-reliability devices. Life-support equipment is generally treated as automatically highest-priority regardless of score. Exact thresholds and scoring scales vary by institution and should be set through the facility's own equipment management committee.

3. General Inspection / PM Procedure Structure

Regardless of device type, a sound PM/inspection procedure generally follows the same broad sequence. Device-specific checklists in Section 5 build on this common structure.

- **Pre-check / paperwork:** confirm work order, pull prior service history, gather correct test equipment and consumables/accessories for the device type.
- **Visual and physical inspection:** enclosure, power cord, connectors, casters/mounts, labels, and accessories checked for damage, contamination, or wear.
- **Electrical safety testing:** earth/ground continuity, insulation resistance, and leakage current measurements against the applicable limits for the device's classification.
- **Functional / performance testing:** device-specific clinical parameters verified against manufacturer tolerance (e.g., accuracy, timing, output, alarm thresholds).
- **Calibration** (where applicable): adjustment or verification against a traceable reference standard.
- **Alarm and safety-interlock verification:** audible/visual alarms and any safety interlocks triggered and confirmed.
- **Disposition and documentation:** pass/fail determination, corrective action if failed, PM/inspection tag applied, and results recorded in the equipment history / CMMS with the next due date scheduled.

4. Electrical Safety Testing — Quick Reference

Electrical safety testing is a required part of most PM procedures and is typically performed per a recognized in-service testing method (e.g., IEC 62353) aligned with the device's IEC 60601-1 classification. Core measurements generally include:

- **Protective earth resistance** — continuity of the protective earth conductor for Class I equipment.
- **Insulation resistance** — resistance between live parts and accessible/earthed parts.
- **Earth leakage current** — current flowing to earth under normal and single-fault conditions.
- **Enclosure (touch) leakage current** — current available at accessible enclosure parts.
- **Patient leakage / patient auxiliary current** — for equipment with applied parts (type B/BF/CF), measured under normal and relevant single-fault conditions.

A more detailed condensed reference on IEC 60601-1 classification and electrical safety limits is covered in the companion document, "IEC 60601-1 Condensed Reference & Field Checklists."

5. Device-Specific Practical PM / Inspection Checklists

The checklists below cover commonly maintained general-ward and critical-care device categories. Each is a condensed, practical starting template reflecting generally known inspection themes for that device type — adapt acceptance limits, accessories, and test steps to the specific make/model's service manual and your facility's risk-based interval.

General Equipment (baseline, any device) — Typical PM interval: Per risk tier

Check Item	Result
■ Enclosure, cord, and connectors free of damage or contamination.	P / F / NA
■ Labels, ratings, and warning symbols legible and intact.	P / F / NA
■ Power-on / self-test completes without error.	P / F / NA
■ Electrical safety test performed and within limits for device class.	P / F / NA
■ Basic functional check appropriate to device purpose completed.	P / F / NA
■ Accessories present, undamaged, and compatible.	P / F / NA
■ PM label applied and service record updated.	P / F / NA

Apnea Monitor — Typical PM interval: Annual / per risk score

Check Item	Result
■ Sensor/belt and cabling intact, no fraying.	P / F / NA
■ Apnea alarm delay setting verified against specification.	P / F / NA
■ Alarm triggers correctly on simulated apnea condition.	P / F / NA
■ Battery backup (if present) holds charge and alarms on AC loss.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Aspirator / Suction Unit — Typical PM interval: Annual

Check Item	Result
■ Vacuum level achieves and holds manufacturer-specified range.	P / F / NA
■ Overflow/shut-off float valve functions correctly.	P / F / NA
■ Canister and tubing free of cracks, proper seal confirmed.	P / F / NA
■ Filter (if present) inspected/replaced per schedule.	P / F / NA
■ Electrical safety test passed (if electrically powered).	P / F / NA

Cardiac Output Unit — Typical PM interval: Annual

Check Item	Result
■ Injectate temperature sensing verified against reference.	P / F / NA
■ Cable/connector continuity to catheter interface confirmed.	P / F / NA
■ Calculation/display accuracy checked against simulator.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Central Station Monitoring System — Typical PM interval: Annual

Check Item	Result
■ Network/telemetry connectivity to bedside monitors verified.	P / F / NA
■ Alarm annunciation (visual/audible) at central station confirmed for each linked bed.	P / F / NA
■ Data/waveform display accuracy spot-checked against a bedside unit.	P / F / NA
■ Backup power / failover behavior verified if applicable.	P / F / NA
■ Cybersecurity/software patch status reviewed per IT policy.	P / F / NA

Compression (Sequential/DVT) Unit — Typical PM interval: Annual

Check Item	Result
■ Cuff/sleeve inflation pressure verified against specification.	P / F / NA
■ Cycle timing verified against specification.	P / F / NA
■ Tubing/connectors free of leaks or cracking.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Defibrillator (incl. AED/monitor-defib) — Typical PM interval: Semiannual (high risk)

Check Item	Result
■ Energy delivery accuracy verified across selected energy levels using a defibrillator analyzer.	P / F / NA
■ Charge time within manufacturer specification.	P / F / NA
■ Paddles/pads and cables inspected; synchronized-cardioversion mode tested.	P / F / NA
■ Battery capacity/runtime test performed; spare battery checked.	P / F / NA
■ Self-test log reviewed; audible/visual fault indicators confirmed functional.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Electrocardiograph (ECG) — Typical PM interval: Annual

Check Item	Result
■ Lead/cable continuity and signal quality verified with a patient simulator.	P / F / NA
■ Calibration signal (1 mV) amplitude and paper/trace speed verified.	P / F / NA
■ Printer/recorder output legible and correctly scaled.	P / F / NA
■ Electrical safety test passed, including patient leakage current.	P / F / NA

Electrosurgical Unit (ESU) — Typical PM interval: Semiannual (high risk)

Check Item	Result
■ Output power verified at representative settings using an ESU analyzer/load.	P / F / NA
■ Return-electrode monitoring (REM) / contact quality alarm function tested.	P / F / NA
■ Footswitch and handpiece activation confirmed reliable.	P / F / NA
■ Isolation/leakage current test passed for both active and return paths.	P / F / NA
■ Cables and connectors inspected for insulation damage.	P / F / NA

Enteral Feeding Pump — Typical PM interval: Annual

Check Item	Result
■ Delivery rate accuracy verified across low/mid/high settings using a graduated cylinder or flow analyzer.	P / F / NA
■ Occlusion alarm (upstream/downstream) triggers correctly.	P / F / NA
■ Air-in-line alarm (if equipped) tested.	P / F / NA
■ Battery backup runtime checked.	P / F / NA
■ Electrical safety test passed.	P / F / NA

External Pacemaker (Transcutaneous) — Typical PM interval: Semiannual (high risk)

Check Item	Result
■ Output current/rate accuracy verified using a pacer analyzer.	P / F / NA
■ Capture/sense indicators function correctly on simulated signal.	P / F / NA
■ Battery backup tested.	P / F / NA
■ Electrical safety test passed, including patient leakage current.	P / F / NA

Fetal Monitor — Typical PM interval: Annual

Check Item	Result
■ Ultrasound transducer and toco transducer signal quality verified.	P / F / NA
■ Heart-rate accuracy verified against a fetal simulator.	P / F / NA
■ Paper feed / trace output legible and correctly scaled.	P / F / NA
■ Alarm limits configurable and trigger correctly.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Hypo/Hyperthermia Unit — Typical PM interval: Annual

Check Item	Result
■ Blanket/pad temperature accuracy verified against a reference thermometer.	P / F / NA
■ Over-temperature cutoff/alarm tested.	P / F / NA
■ Water circulation (if applicable) free of leaks; reservoir level sensor checked.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Infant Incubator — Typical PM interval: Semiannual (high risk)

Check Item	Result
■ Air/skin temperature accuracy verified against a reference probe at multiple setpoints.	P / F / NA
■ High-temperature alarm triggers within specified range.	P / F / NA
■ Humidity system (if equipped) verified.	P / F / NA
■ Alarm for sensor disconnect/probe failure confirmed.	P / F / NA
■ Noise level and access-port seals checked.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Infusion Pump — Typical PM interval: Semiannual (high risk)

Check Item	Result
■ Flow-rate accuracy verified at low/mid/high rates using a flow analyzer.	P / F / NA
■ Occlusion (upstream/downstream) alarm pressure verified.	P / F / NA
■ Air-in-line detection tested.	P / F / NA
■ Free-flow protection (door/clamp) verified.	P / F / NA
■ Battery backup runtime checked.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Non-Invasive Blood Pressure (NIBP) Monitor — Typical PM interval: Annual

Check Item	Result
■ Pressure accuracy verified against a calibrated reference manometer/simulator.	P / F / NA
■ Cuff inflation/deflation timing and over-pressure cutoff tested.	P / F / NA
■ Cuff and tubing inspected for leaks.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Patient Monitor (Multiparameter) — Typical PM interval: Annual

Check Item	Result
■ ECG, SpO2, and NIBP modules each verified against an appropriate simulator.	P / F / NA
■ Alarm limits configurable and audible/visual alarms confirmed for each parameter.	P / F / NA
■ Display accuracy and waveform rendering checked.	P / F / NA
■ Battery backup and network/telemetry link verified.	P / F / NA
■ Electrical safety test passed, including patient leakage current.	P / F / NA

PCA (Patient-Controlled Analgesia) Pump — Typical PM interval: Semiannual (high risk)

Check Item	Result
■ Dose/rate accuracy verified using a flow analyzer.	P / F / NA
■ Lockout interval enforced correctly.	P / F / NA
■ Dose-limit and occlusion alarms tested.	P / F / NA
■ Key/lock or access-control mechanism verified functional.	P / F / NA
■ Battery backup runtime checked.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Phototherapy Unit — Typical PM interval: Annual

Check Item	Result
■ Irradiance output measured with a radiometer against specification.	P / F / NA
■ Timer function verified.	P / F / NA
■ Eye-shield/patient-protection hardware present and intact.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Pneumatic Tourniquet — Typical PM interval: Annual

Check Item	Result
■ Pressure accuracy verified against a calibrated reference gauge.	P / F / NA
■ Pressure-hold (leak-down) test performed over a defined period.	P / F / NA
■ Timer and alarm function verified.	P / F / NA
■ Cuff/hose inspected for leaks or damage.	P / F / NA

Pulse Oximeter — Typical PM interval: Annual

Check Item	Result
■ SpO2 and pulse-rate accuracy verified against a functional tester/simulator.	P / F / NA
■ Low-SpO2 and low-perimeter alarm thresholds tested.	P / F / NA
■ Sensor cable continuity checked.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Radiant Warmer — Typical PM interval: Semiannual (high risk)

Check Item	Result
■ Skin-temperature accuracy verified against a reference probe.	P / F / NA
■ High-temperature alarm/cutoff tested.	P / F / NA
■ Manual mode power output verified.	P / F / NA
■ Sensor-disconnect alarm confirmed.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Sphygmomanometer (Manual/Aneroid) — Typical PM interval: Annual

Check Item	Result
■ Pressure accuracy verified against a calibrated reference manometer across the scale.	P / F / NA
■ Cuff and bulb inspected for leaks.	P / F / NA
■ Needle/dial zeroes correctly at rest.	P / F / NA

Therapeutic Stimulator (e.g., TENS/NMES) — Typical PM interval: Annual

Check Item	Result
■ Output amplitude/frequency accuracy verified against specification.	P / F / NA
■ Timer and mode-selection functions verified.	P / F / NA
■ Lead wires and electrodes inspected for continuity/damage.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Therapeutic Ultrasound Unit — Typical PM interval: Annual

Check Item	Result
■ Output power verified with a power meter against specification.	P / F / NA
■ Timer function verified.	P / F / NA
■ Applicator head inspected for cracking/wear.	P / F / NA
■ Electrical safety test passed.	P / F / NA

Ventilator — Typical PM interval: Semiannual (high risk)

Check Item	Result
■ Delivered tidal volume, rate, and pressure verified against a calibrated test lung/analyzer.	P / F / NA
■ FiO2 accuracy verified against a calibrated oxygen analyzer.	P / F / NA
■ High/low pressure, disconnect, and power-failure alarms tested.	P / F / NA
■ Battery backup runtime and switchover behavior verified.	P / F / NA
■ Circuit/valve assemblies leak-tested.	P / F / NA
■ Electrical safety test passed.	P / F / NA

6. Related Standards & Reference Frameworks

PM procedures for the device types above are typically developed with reference to the following standards and frameworks (consult the current official text of each for authoritative requirements):

- **IEC 60601-1** — general requirements for basic safety and essential performance of medical electrical equipment (see the companion condensed reference document).
- **IEC 62353** — recurrent/in-service electrical safety testing methodology for medical electrical equipment already in clinical use.
- **NFPA 99** — health care facilities code, including requirements relevant to electrical systems and medical gas/vacuum systems in the US context.
- **Accreditation body requirements** (e.g., The Joint Commission in the US, or the relevant national healthcare accreditation body) — requirements for documented equipment management programs, inventory, and maintenance records.

Reminder: *acceptance limits, test frequencies, and specific test methods above are illustrative and must be validated against the manufacturer's service manual, applicable national regulation, and the facility's own risk-based equipment management plan before use in a formal QA program.*