

Medical Device Calibration Rules & Guidelines

Version 2.1 | Effective Date: October 2025

1. Device Calibration Intervals

1.1 Audiometers

- **Standard Calibration Interval:** 365 days (12 months)
- **Manufacturer Recommendation:** Annual calibration mandatory
- **Regulatory Requirement:** ISO 8253-1:2010 compliance
- **Critical Equipment:** Yes - affects patient diagnosis

1.2 Tympanometers

- **Standard Calibration Interval:** 365 days (12 months)
 - **Manufacturer Recommendation:** Annual calibration mandatory
 - **Regulatory Requirement:** IEC 60645-5:2004 compliance
 - **Critical Equipment:** Yes - diagnostic device
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2. Pre-Calibration Planning Thresholds

2.1 Status Classification Rules

OVERDUE Status

Trigger: `current_date > next_calibration_due`

Actions Required:

- **Priority:** CRITICAL (Priority 1)
- **Response Time:** Immediate (within 24 hours)
- **Escalation:** Notify compliance officer
- **Device Usage:** PROHIBITED until calibration completed
- **SLA Impact:** Potential regulatory violation

Notes:

- Device MUST be taken out of service immediately

- Facility notified of compliance breach
 - Emergency calibration scheduling required
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URGENT Status (Red Zone)

Audiometers:

- **Trigger:** `days_until_due <= 14`
- **Rationale:** Allow 2-week scheduling window before expiration
- **Priority:** High (Priority 1-2)
- **Response Time:** Schedule within 7 days
- **Technician Assignment:** Immediate

Tympanometers:

- **Trigger:** `days_until_due <= 7`
 - **Rationale:** Shorter window due to simpler calibration process
 - **Priority:** High (Priority 1-2)
 - **Response Time:** Schedule within 3 days
 - **Technician Assignment:** Immediate
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SCHEDULED Status (Yellow Zone)

Audiometers:

- **Trigger:** `15 <= days_until_due <= 30`
- **Priority:** Medium (Priority 2-3)
- **Response Time:** Schedule within 14 days
- **Planning Window:** Normal batch scheduling allowed

Tympanometers:

- **Trigger:** `8 <= days_until_due <= 21`
 - **Priority:** Medium (Priority 2-3)
 - **Response Time:** Schedule within 10 days
 - **Planning Window:** Normal batch scheduling allowed
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ACTIVE Status (Green Zone)

All Devices:

- **Trigger:** `days_until_due > 30` (Audiometer) or `> 21` (Tympanometer)
 - **Priority:** Low (Priority 4-5)
 - **Action:** No immediate action required
 - **Planning:** Include in quarterly planning review
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3. SLA (Service Level Agreement) Rules

3.1 Clinic-Level SLA

24-Hour SLA (Hospitals - Critical Care):

- **Overdue Devices:** Respond within 4 hours
- **Urgent Devices:** Schedule within 24 hours
- **Scheduled Devices:** Schedule within 7 days
- **Penalty:** €500/day for missed SLA

48-Hour SLA (General Hospitals):

- **Overdue Devices:** Respond within 8 hours
- **Urgent Devices:** Schedule within 48 hours
- **Scheduled Devices:** Schedule within 10 days
- **Penalty:** €300/day for missed SLA

72-Hour SLA (Clinics - Outpatient):

- **Overdue Devices:** Respond within 12 hours
 - **Urgent Devices:** Schedule within 72 hours
 - **Scheduled Devices:** Schedule within 14 days
 - **Penalty:** €150/day for missed SLA
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4. Priority Matrix

Device Status	Clinic SLA	Final Priority	Max Response Time
OVERDUE	24h	1 (Critical)	4 hours

Device Status	Clinic SLA	Final Priority	Max Response Time
OVERDUE	48h	1 (Critical)	8 hours
OVERDUE	72h	1 (Critical)	12 hours
URGENT	24h	1 (High)	24 hours
URGENT	48h	2 (High)	48 hours
URGENT	72h	2 (Medium)	72 hours
SCHEDULED	24h	2 (Medium)	7 days
SCHEDULED	48h	3 (Medium)	10 days
SCHEDULED	72h	3 (Normal)	14 days
ACTIVE	Any	4-5 (Low)	30 days

5. Batch Scheduling Guidelines

5.1 When to Batch Services

ALLOWED for:

- SCHEDULED status devices only
- Same clinic location
- Same technician specialization
- Within 30-day planning window

NOT ALLOWED for:

- OVERDUE devices (emergency only)
- URGENT devices with 24h/48h SLA
- Cross-city batching (travel time priority)

5.2 Optimal Batch Size

- **Target:** 3-4 devices per clinic visit
- **Maximum:** 5 devices per clinic visit
- **Rationale:** Minimize travel, maximize technician efficiency

6. Quality Assurance Requirements

6.1 Pre-Calibration Checks

- Device visual inspection
- Environmental conditions verification (temp: 20-25°C, humidity: 40-60%)
- Previous calibration report review
- Spare parts availability confirmation

6.2 Calibration Standards

- **Audiometers:** ANSI S3.6-2010, ISO 8253-1:2010
- **Tympanometers:** ANSI S3.39-1987, IEC 60645-5:2004

6.3 Post-Calibration Documentation

- Calibration certificate (mandatory)
 - Measurement data log
 - Device sticker update (next calibration date)
 - Digital record upload to Data Fabric
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7. Emergency Procedures

7.1 OVERDUE Device Protocol

Step 1: Immediate notification

- Email to clinic contact
- Phone call to facility manager
- Compliance team notification

Step 2: Device quarantine

- Physical "OUT OF SERVICE" tag applied
- Software system lock (if applicable)
- Patient appointments rescheduled

Step 3: Emergency dispatch

- Technician dispatched within SLA window
- Expedited calibration procedure

- Same-day reporting required
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8. Technician Specialization Requirements

8.1 Audiometer Calibration

- **Required Certification:** ISO 8253 Certified Audiologist Technician
- **Experience:** Minimum 2 years
- **Specialization:** "Audiometry" or "All"

8.2 Tympanometer Calibration

- **Required Certification:** IEC 60645 Tympanometry Specialist
 - **Experience:** Minimum 1 year
 - **Specialization:** "Tympanometry" or "All"
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9. Cost & Time Estimates

9.1 Service Duration

Device Type	Standard Duration	Complex Cases	Travel Time
Audiometer	2.0 hours	3.5 hours	+0.5-2h
Tympanometer	1.5 hours	2.5 hours	+0.5-2h

9.2 Pricing Structure

- **Audiometer Calibration:** €350 (standard), €500 (emergency)
 - **Tympanometer Calibration:** €280 (standard), €420 (emergency)
 - **Travel Fee:** €0.50/km (charged once per visit, not per device)
 - **Emergency Surcharge:** +40% for same-day service
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10. Reporting & Compliance

10.1 Daily Reports

- Devices reaching URGENT status
- Overdue devices count
- Scheduled visits completion rate

10.2 Weekly Reports

- SLA compliance metrics
- Technician utilization rates
- Cost analysis per clinic

10.3 Monthly Reports

- Calibration trend analysis
 - Device failure patterns
 - Clinic satisfaction surveys
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Document Control

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Document Owner: Quality Assurance Department

Approved By: Medical Device Compliance Officer

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- v2.1 (Oct 2025): Updated SLA thresholds for Tympanometers
 - v2.0 (Jan 2025): Added emergency procedures section
 - v1.5 (Jul 2024): Initial structured guidelines
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