

# Field Service Calibration Procedures

Technical Service Manual | Version 4.1 | October 2025

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## 1. Pre-Service Preparation

### 1.1 Equipment Checklist (Technician)

**Mandatory Tools:**

- ☐ Calibrated sound level meter (Class 1, < 1 year old)
- ☐ Calibration microphones (2.5cm & 1.2cm)
- ☐ Acoustic calibrator (IEC 60318-3 compliant)
- ☐ Impedance test cavity (for tympanometers)
- ☐ Digital multimeter
- ☐ Calibration software (latest version on laptop)
- ☐ Backup battery pack (charged)
- ☐ Cleaning supplies (isopropyl alcohol, lint-free wipes)
- ☐ Calibration stickers (with QR codes)
- ☐ Documentation kit (forms, pens, camera)

**Safety Equipment:**

- ☐ ESD wrist strap (electrostatic discharge protection)
  - ☐ Safety glasses
  - ☐ Disposable gloves (for hygiene)
  - ☐ Hand sanitizer
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### 1.2 Clinic Preparation Requirements

**24 Hours Before Visit:**

- Device must be powered on and warmed up (30 minutes minimum)
- Test room prepared:
  - Temperature: 20-25°C (68-77°F)
  - Humidity: 40-60% RH

- Ambient noise < 40 dBA
- Previous calibration certificate available
- Device usage log ready for review

**Day of Service:**

- Designated staff member available for handover
  - Device cleaned and ready (no patient data visible)
  - Access to power outlets confirmed
  - Parking/building access arranged
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## **2. Audiometer Calibration Procedure**

### **2.1 Standard Service Time**

**Duration:** 2.0 hours (standard)

**Breakdown:**

- Setup & documentation review: 15 minutes
- Physical inspection: 10 minutes
- Acoustic calibration: 60 minutes
- Electrical verification: 20 minutes
- Documentation & sticker: 15 minutes

### **2.2 Step-by-Step Process**

**Phase 1: Visual Inspection (10 minutes)**

1. Check device exterior for damage, corrosion, wear
2. Inspect cables, connectors, headphones
3. Verify serial number matches service order
4. Document any physical issues with photos

**Phase 2: Environmental Verification (5 minutes)**

5. Measure room temperature with digital thermometer
6. Measure humidity with hygrometer
7. Measure ambient noise with sound level meter

8. If conditions outside spec → Note in report, may affect results

### **Phase 3: Functional Check (10 minutes)**

9. Power on device, check for error messages
10. Test all frequency outputs (250Hz - 8000Hz)
11. Test all intensity levels (0 dB - 110 dB HL)
12. Verify tone presentation (continuous, pulsed, warble)
13. Check masking functionality

### **Phase 4: Acoustic Calibration (60 minutes)**

**For Each Frequency (250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz):** 14. Place calibration microphone on headphone cushion 15. Set device to specified frequency and level 16. Measure actual SPL with sound level meter 17. Compare to reference equivalent threshold SPL (RETSPL) 18. Adjust if deviation  $> \pm 3$  dB (per ISO 8253-1) 19. Re-measure to confirm adjustment 20. Record all measurements in calibration log

### **Headphone Types:**

- TDH-39/49: Most common, over-ear
- HDA 200: Circumaural, used for diagnostic
- Insert earphones (ER-3A): For infants/special needs

### **Tolerances (per ANSI S3.6):**

- $\leq 1000$  Hz:  $\pm 3$  dB
- $\begin{array}{|l} 1000 \\ 1000 \end{array}$  Hz:  $\pm 4$  dB
- Linearity:  $\pm 2$  dB across 10 dB steps

### **Phase 5: Electrical Verification (20 minutes)**

21. Check output impedance (match to headphone specs)
22. Test attenuator linearity (all 5 dB steps)
23. Verify frequency accuracy ( $\pm 1\%$  tolerance)
24. Test channel balance ( $< 1$  dB difference)
25. Check rise/fall time ( $< 20$ ms per ANSI S3.6)

### **Phase 6: Documentation (15 minutes)**

26. Complete calibration certificate (all fields)
27. Upload digital records to Data Fabric

28. Apply calibration sticker to device (with QR code)
  29. Calculate next calibration due date (+ 365 days)
  30. Handover: Explain results to clinic staff
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## **2.3 Complex Cases (3.5 hours)**

### **Additional Time Required For:**

- Multiple headphone types (add 30 min per type)
- Bone conduction calibration (add 45 min)
- Speech audiometry calibration (add 30 min)
- Repairs during calibration (add 60-120 min)

### **Common Repairs:**

- Replace worn headphone cushions: 15 minutes
  - Calibrate attenuator drift: 30 minutes
  - Fix loose connectors: 20 minutes
  - Update firmware: 25 minutes
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## **3. Tympanometer Calibration Procedure**

### **3.1 Standard Service Time**

**Duration:** 1.5 hours (standard)

#### **Breakdown:**

- Setup & documentation review: 10 minutes
- Physical inspection: 10 minutes
- Impedance calibration: 40 minutes
- Acoustic reflex verification: 20 minutes
- Documentation & sticker: 10 minutes

### **3.2 Step-by-Step Process**

#### **Phase 1: Visual Inspection (10 minutes)**

1. Check probe tips for damage or blockage

2. Inspect pneumatic system tubes for leaks
3. Verify pump operation (listen for smooth cycling)
4. Check display for pixel issues
5. Test printer (if equipped)

### **Phase 2: Pneumatic System Test (15 minutes)**

6. Connect to test cavity (0.5 cm<sup>3</sup>)
7. Initiate pressure sweep (-400 to +200 daPa)
8. Verify pressure accuracy ( $\pm 10$  daPa tolerance)
9. Check for air leaks (pressure should hold steady)
10. Test pump speed (< 10 seconds for full sweep)

### **Phase 3: Impedance Calibration (40 minutes)**

**Using Test Cavities** (0.5, 1.0, 2.0, 5.0 cm<sup>3</sup>): 11. Connect 0.5 cm<sup>3</sup> cavity to probe 12. Run tympanometry test 13. Measure compliance at peak (should be  $\sim 0.5$  mmho) 14. Adjust if deviation  $> \pm 0.1$  mmho 15. Repeat for 1.0, 2.0, 5.0 cm<sup>3</sup> cavities 16. Verify linearity across all cavities

**Acoustic Reflex Thresholds:** 17. Connect to acoustic calibrator 18. Verify 226 Hz probe tone level (85 dB SPL  $\pm 3$  dB) 19. Test reflex stimulus levels (500, 1000, 2000, 4000 Hz) 20. Confirm stimulus accuracy ( $\pm 3$  dB at all frequencies)

### **Phase 4: Functional Verification (15 minutes)**

21. Test on human subject (technician's own ear)
22. Verify normal tympanogram shape (Type A)
23. Check reflex detection sensitivity
24. Test auto-start feature (if equipped)
25. Verify data storage/export functions

### **Phase 5: Documentation (10 minutes)**

26. Complete calibration certificate
  27. Upload to Data Fabric
  28. Apply calibration sticker
  29. Calculate next due date (+ 365 days)
  30. Clinic handover & training (if new staff)
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### 3.3 Complex Cases (2.5 hours)

#### Additional Time For:

- Multi-frequency tympanometry (add 30 min)
  - Eustachian tube function tests (add 20 min)
  - Pneumatic system repairs (add 45 min)
  - Probe tip replacement & recalibration (add 30 min)
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## 4. Quality Assurance Standards

### 4.1 Acceptance Criteria

#### PASS:

- All measurements within tolerance
- No physical damage affecting function
- Environmental conditions met
- Previous issues resolved (if any)
- Device performs per manufacturer specs

#### CONDITIONAL PASS:

- Minor out-of-tolerance readings (< 5% deviation)
- Recommend recalibration in 6 months
- Usable for clinical purposes with caution note

#### FAIL:

- Critical measurements out of tolerance (> 10% deviation)
- Safety issues (electrical shock risk, radiation)
- Unrepairable damage
- Device must be taken out of service immediately

### 4.2 Calibration Certificate Requirements

#### Mandatory Fields:

- Device information (make, model, serial number)

- Clinic information (name, address, contact)
- Calibration date & time
- Technician name & certification number
- Environmental conditions during test
- All measurement data (tabular format)
- Pass/Fail decision with justification
- Next calibration due date
- Technician signature (digital or wet)
- Company stamp/QR code

**Digital Upload:**

- PDF certificate → Data Fabric (ServiceOrders attachment)
- Raw measurement data → CSV format
- Photos of device & sticker → Image files
- All files linked to equipment\_id

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## 5. Troubleshooting Common Issues

### 5.1 Audiometer Problems

Issue	Possible Cause	Solution	Time
Output drift	Attenuator wear	Re-calibrate, replace if needed	30min
No sound	Broken cable	Replace headphone cable	15min
Distortion	Speaker damage	Replace transducer	60min
Frequency error	Crystal oscillator drift	Factory service required	N/A

### 5.2 Tympanometer Problems

Issue	Possible Cause	Solution	Time
Air leak	Worn probe tip	Replace tip	10min
Noisy trace	Probe blockage	Clean probe tube	15min
Pump failure	Motor wear	Replace pump assembly	90min
Compliance error	Calibration drift	Recalibrate with cavities	40min

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## 6. Safety Protocols

### 6.1 Electrical Safety

- **Always** verify device is unplugged before opening case
- Use ESD protection when handling internal components
- Check for exposed wires or damaged insulation
- Test ground continuity before returning to service

### 6.2 Acoustic Safety








- **Never** expose technician's ears to > 85 dB SPL without hearing protection
- Use calibration microphone, not human ears, for measurements
- Warn clinic staff before generating test tones
- Keep probe tips away from face during tympanometry

### 6.3 Hygiene Standards

- Clean all patient-contact surfaces with 70% isopropyl alcohol
  - Use new disposable probe tips for tympanometry
  - Sanitize headphones between uses (if testing on humans)
  - Wash hands before and after handling equipment
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## 7. Post-Service Requirements

### 7.1 Immediate Actions (Before Leaving Clinic)

1.  Calibration sticker applied and clearly visible
2.  Certificate signed and delivered to clinic contact
3.  Digital records uploaded to Data Fabric
4.  ServiceOrder status updated to "Completed"
5.  Equipment. next\_calibration\_due updated in database
6.  Clinic staff trained on any changes/repairs
7.  All tools and test equipment packed and accounted for

### 7.2 Within 24 Hours

8. Expense report submitted (mileage, tolls, parking)



9. Time sheet updated (actual hours worked)
10. Any device failures reported to manufacturer
11. Follow-up email sent to clinic (thank you + certificate attachment)

## **7.3 Weekly Reporting**

12. Technician submits weekly summary to manager
  13. Average service time tracked (identify training needs)
  14. Equipment condition trends noted
  15. Recommendations for process improvements
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## **8. Continuous Improvement**

### **8.1 Technician Training Requirements**

#### **Annual Certification:**

- ISO 8253-1:2010 Audiometry (16 hours)
- IEC 60645-5 Tympanometry (8 hours)
- Electrical Safety (4 hours)
- Customer Service (4 hours)

#### **Quarterly Updates:**

- New device models (as needed)
- Software updates (as released)
- Regulatory changes (as published)

### **8.2 Equipment Maintenance**

#### **Calibration Tools** (technician's own equipment):

- Sound level meter: Annual calibration (traceable to national standard)
  - Acoustic calibrator: Annual verification
  - Test cavities: Annual dimensional check
  - Multimeter: Bi-annual calibration
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# Document Control

**Version:** 4.1

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**Document Owner:** Chief Technical Officer

**Approved By:** Quality Assurance Manager

**Revision History:**

- v4.1 (Oct 2025): Added troubleshooting section
- v4.0 (Jul 2025): Major rewrite - aligned with ISO/IEC standards
- v3.5 (Jan 2025): Updated tympanometer procedures

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