


FACULTY OF HEALTH SCIENCES

UNIVERSITY OF CAPE TOWN

# Standards of medical equipment requirements and calibration for medical practices: Spirometry & Audiometry/Other

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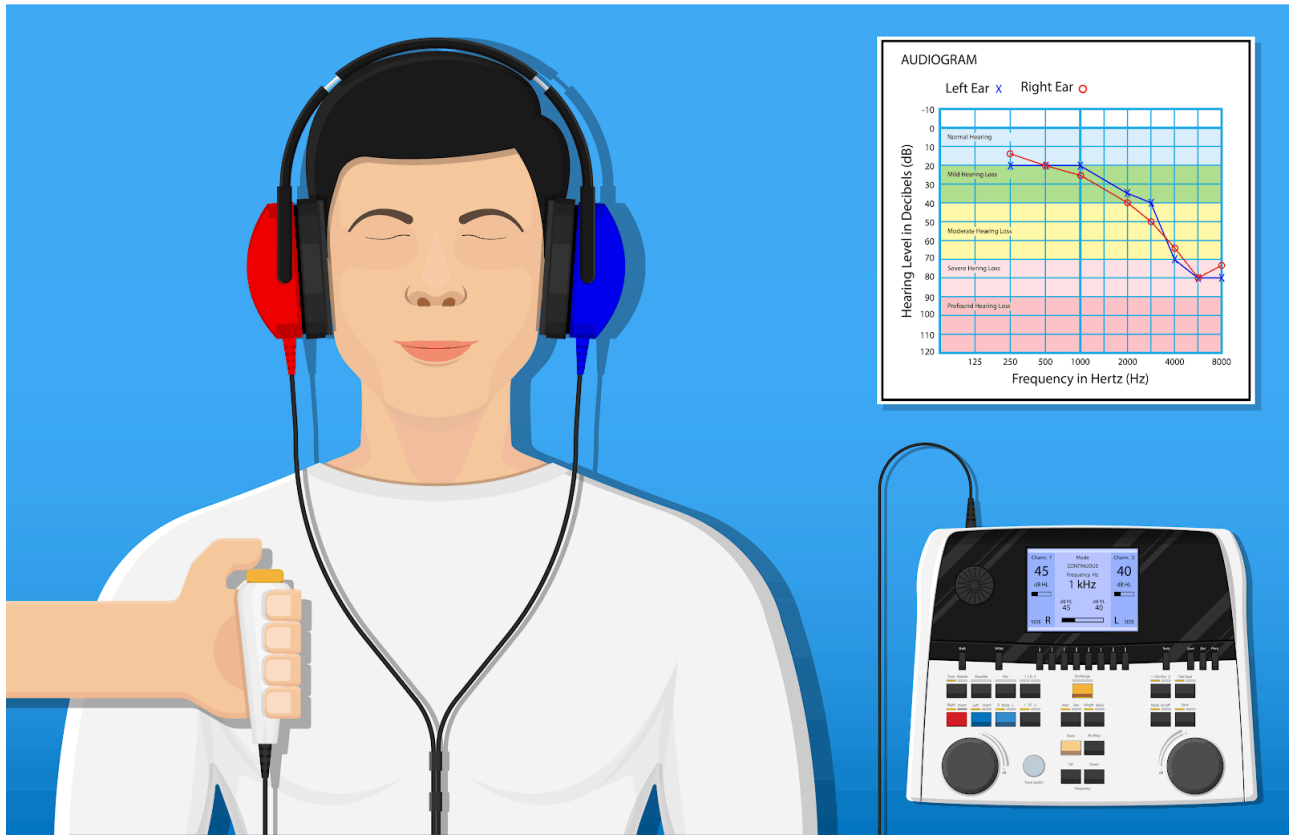
# Lecture Outline and Learning Outcomes

1. Audiometry equipment
2. Spirometry equipment
3. Vision testing equipment

- Overall structure
  - Introduction
  - Equipment/tools required
  - Checks and calibrations
  - Retention of records
  - Relevant standards and guidance
  - Legal requirements/regulations – records being kept

# Audiometry equipment



# Introduction

- Audiometry testing is performed to determine an individual's threshold of hearing at selected frequencies

- Most occupational health services offer screening vs diagnostic audiometry
  - Screening audiometry = only tests air conduction
  - Diagnostic audiometry = tests both air and bone conduction

- Aim is to detect deterioration in hearing thresholds before the individual is aware of any deficit

- **Legal requirement**: Noise Induced Hearing Loss Regulations

# Faulty equipment – an issue

- Audiometric testing is performed in variety of settings which may influence test result
- Faulty equipment will also lead to inaccurate test results being recorded
- Influences medical surveillance (baseline, periodic and exit audiograms), action by employers and compensation claims
- It's **essential** that correct equipment is used and calibrated

# Equipment required

- Audiometer must comply with South African National Standards (SANS) SANS 10083:2013 and IEC 60645-1

- **Pure tone screening audiometers**
  - Most commonly used audiometers in industry
  - Performed by audiometrists, OHNP, MO/OMP & Audiologist (HPCSA registered)
  - Must be able to test audio frequencies of 500Hz and 1, 2, 3, 4, 5, 6, and 8 kHz
  - Measure intensity of tone/decibels from 0 to 90 dB
  - Have matched earphones with insulating ear muffs
  - Patient response mechanism
  - Tone interrupt switch for tone presentation
  - Allow for self recording/automatic and manual techniques

# Equipment required

- **Diagnostic audiometers**
  - Used mostly by audiologists
  - Must comply with IEC 60645-1 requirements
  - Used to conduct bone, masking and speech discrimination tests

- **Testing environment (“sound booths”)**
  - Reliable test results require noise proof environment & reliable equipment
  - Several commercially available (meet set standards)
    - ISO standards (ISO 8253-1:2010)
    - SANS 10182:2013 standard
  - Should be noise proof enough to reduce ambient noise to acceptable testing levels
  - Testing outside booth acceptable if ambient noise levels have been measured and conform to SANS10182:2013 requirements

# Equipment required

- **<u>Other “tools” to remember</u>**
- **Screening questionnaires**
  - Record med and occ hx
  - Noise exposure hx (recent/past)
  - Risk factors for hearing loss
  - Symptoms

- **Clinical examination tools**
  - Otoscope
  - Tuning forks (Rinne and Weber tests)

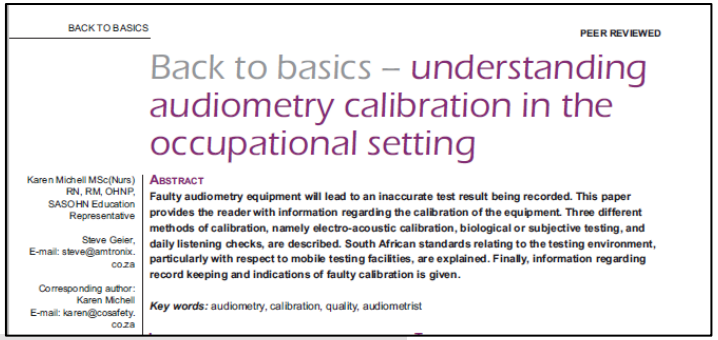
# Checks and calibration

- Calibration ensures tones and decibels presented to client are within required parameters

- Un-calibrated audiometers may present inaccurate tones and/or decibels

- Three different methods of calibration regularly completed at predetermined intervals
  1. Electro-acoustic calibration (annual)
  2. Biological or subjective testing (weekly)
  3. Daily listening checks

# Checks and calibration



BACK TO BASICS

PEER REVIEWED

Back to basics – understanding audiometry calibration in the occupational setting

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ABSTRACT

Faulty audiometry equipment will lead to an inaccurate test result being recorded. This paper provides the reader with information regarding the calibration of the equipment. Three different methods of calibration, namely electro-acoustic calibration, biological or subjective testing, and daily listening checks, are described. South African standards relating to the testing environment, particularly with respect to mobile testing facilities, are explained. Finally, information regarding record keeping and indications of faulty calibration is given.

*Key words:* audiometry, calibration, quality, audiometrist

**Table 1. Comparisons of the three forms of calibration as explained in SANS 8253-1[2]**

| | Type A | Type B | Type C |
|---|---|---|---|
| SANS 8253-1 title | Routine checking and subjective tests. | Periodic objective checks. | Basic calibration tests. |
| Common title | Daily listening checks and biological calibration. | Electro-acoustic calibration. | Factory calibration. |
| Interval | Daily and weekly (or as required for mobile testing). | Annual if A is done regularly. | When required i.e. after a major fault and audiometer found not calibrated. |
| Purpose | To ensure equipment is working correctly and calibration is not altered, and that attachments are free from defects. | To measure and compare results for frequencies and ensure decibels are within accepted standards. | To return equipment to calibration after a major failure. |
| Note | Subjective tests are very important. Ambient noise during a subjective test to be no worse than it would be at normal testing. | Recommended that a calibration check label be attached to indicate date of next objective check. | Only required when the equipment cannot be calibrated on site due to a major failure. |

Karen Michell. 2009. Back to basics – understanding audiometry calibration in the occupational setting

# Mobile audiometric test facilities

- Now common for practitioners to set up mobile audiometry testing facility and move this to different locations
- Important that specially designed mobile facilities for onsite screening audiometry must meet SANS10182:2013 requirements

- The mobile testing facility must:
  - Have audiometers mounted on suitable anti-vibration platforms
  - Audiometers mounted to prevent exposure to environmental exposures (set up far away as possible from noise)
  - Perform biological calibration before actual audiometry testing and upon completion
  - Ensure sound booth have adequate lighting and ventilation
  - Lighting, ventilation system, sound pressures inside test booth must comply with ambient noise stipulated in SANS10182: 2013

# Record keeping

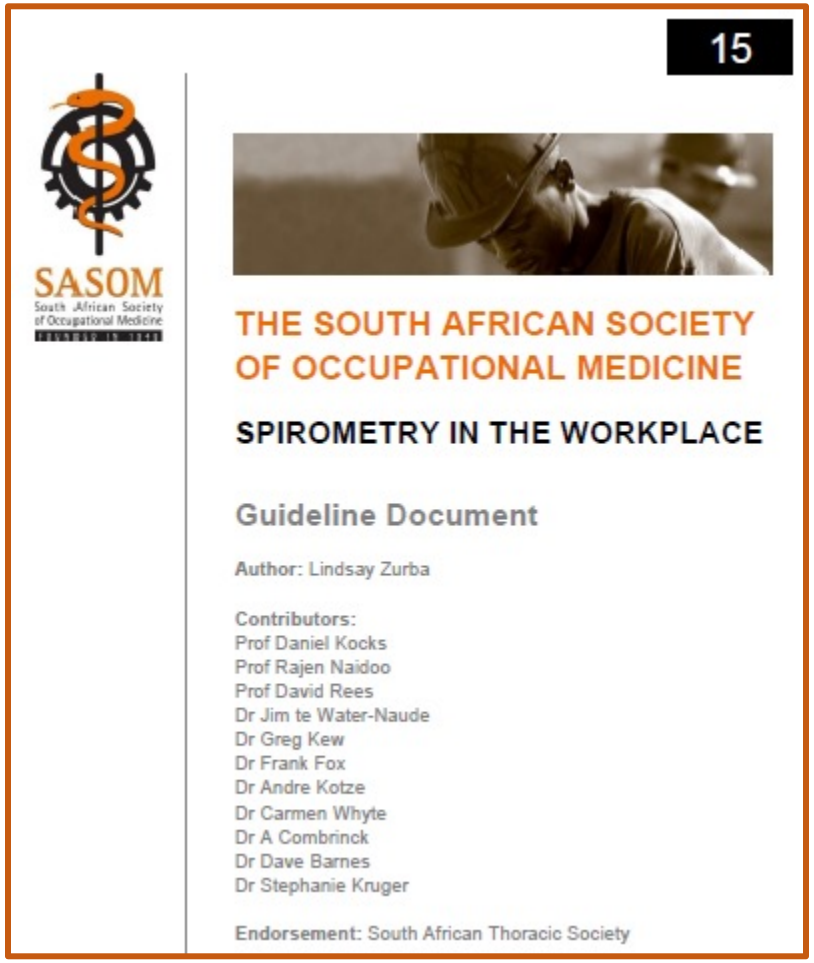
- All records must be kept for 40 years
- Essential to validate audiometric test in case of dispute
- Claims may arise years after employment ends
- Important for inspection purposes (Dept of Employment and Labour)
- Copy of calibration record could be given to the client

- **Keep records documentation**
  - Site calibration (biological calibration)
  - External noise measurement (a-weighted sound pressure levels observed inside and outside)
  - Site selection/evaluation procedures

# Spirometry equipment

# Introduction

- Spirometry: widely used in the assessment of lung function to provide objective info used in the diagnosis and monitoring of lung health
- Office spirometry integral to comprehensive respiratory evaluation of workers
- Various guidelines available: aimed at improving the quality, standardization



# Introduction

- For accurate result – various specific testing process required

- These include:
  - Equipment performance (equipment specifications/ calibration)
  - Quality of the test
  - Test performance and infection prevention
  - Client preparation
  - Human resources
  - Record keeping and audits

- Above have potential to influence results if not adequately controlled.

# Equipment

- Needs to meet predetermined technical specifications: SANS 451

- Guidelines for equipment used in RSA (SANS 451)
  - Equipment needs to be able to conduct calibration checks daily in workplace/field
  - Has appropriate reference values used in South Africa (European Community of Coal & Steel Workers)
  - Measurable volume of 0.5 to 8 litres
  - Has flow range of 0 to 14 litres/second
  - Can measure effort for 14 seconds
  - Able to convert the volume of gas exhaled measured at ambient temperature and pressure (ATPS) to body temp and pressure saturated with water vapour (BTPS)
  - Ability to store results in order to access in future

# Equipment: quality control and maintenance

- Once spirometer complies with guidelines
  – standards should be maintained!

- Have a written quality control program for your practice
- Perform maintenance according to manufacturers recommendations
- Disposable parts – must be changed as required
- Keep records of maintenance and service (must be readily available)

# Equipment: calibration

- Main part of the quality control process – **MUST be done**
- Checks accuracy and precision of spirometer for flow volume and time
- Check before each testing session – some cases may be required > once/day (large numbers of workers or humid weather)
- Spirometer manufacturers manual will indicate procedure to be followed

- Equipment needed for calibration checks
  - Spirometer
  - 3-liter calibration syringe
  - Accessories: e.g. bacterial filters
  - Weather meter
  - Calibration file
  - Pen and calculator

# Equipment: calibration

When calibrating equipment - the following standards should be met:

- Calibrated with a volume of at least 3 litre
- Calibrated to an accuracy of 3% or 50 ml (whichever is the greater)
- Corrected to Body Temperature Pressure and Saturation(BTPS).
- Record of calibration is kept in a logbook.
- Preventative maintenance records are stored.
- Evidence of biological calibration is recorded.

The following should be recorded on the calibration

- Signature
- Full name
- Date
- Whether calibration was successful or not

# Infection prevention and control

- Use practical and sensible measures
  - Ensure good ventilation
  - Hand washing before/after testing
  - Disinfection of surfaces & spirometer
  - Use of disposable filters and mouth pieces
  - Gloves when handling contaminated equipment
  - Client to blow away from spirometrist

**COVID-19 Specific IPC Measures (SASOM Guideline)**

**Special IPC Measures (hierarchy of controls) to consider during COVID**

- Isolation (Perspex barrier, separate room)
- Ventilation (fresh air via open windows, HVAC, or even extraction – or perform the test outside!)
- Elimination
  - cleaning & disinfection practices of the area plus the equipment - between cases and daily.
  - consider properly installed UV-C germicidal light as an adjunct to ventilation.
  - spirometrist should have had the COVID-19 vaccine.
- Substitution (use a questionnaire-based screen plus clinical exam where possible, as a substitute for spiro's).
- Administrative (increase time between spiro's, fewer spiro's, safe work procedure).
- PPE for operator (FFP2 / FFP3 / N95) mask, goggles, apron).

# Equipment: general

- **Human resources**
  - Ensure all staff involved hold certificates of competence in spirometry
  - To undergo refreshers every 3 to 5 years

- **Worker safety**
  - Ensure no contra-indications to spirometry
  - Chair available – in case of dizziness/syncope

- **Spirometry record keeping and audits**
  - Quarterly review of spirometrists by supervisors
  - Keep calibration records for 40 years and log of technical problems found & solved
  - Changes in protocol, computer software or equipment

# Other equipment/devices

# Other equipment/devices

- **Vision testing in occupational health**
- Visual acuity (VA) testing
  - Electronic VA tester
  - Hand held lens device
  - Wall mounted reading card with standardized images (e.g Snellen Chart)
  - Snellen chart – best value for money, meets legal standard

# Other equipment/devices

- **Vision testing in occupational health**
- Peripheral vision (visual fields)
- Colour vision
- Depth perception (&stereopsis)
- Night vision

# Conclusion, Take home messages and Resources

- Important to carefully select equipment used in practice
- Ensure meets required standards (SANS, ISO etc)
- Ensure standard protocol is followed by trained staff
- Ensure adequate record keeping (40 years) of results and calibration, maintenance of equipment


thank you
danke
謝謝
ngiyabonga
рахмат
teşekkür ederim
Баярлалаа
спасибо
gracias
dank je
tapadh leat
bedankt
dziękuję
hvala
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go raibh maith agat
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- South African Society of Occupational Medicine Guidelines
  - Spirometry in the workplace
  - Vision testing