Lebone Medical Supplies (Pty) Ltd trading as:
Amtronix Diagnostics

Xcelpark, N102 Second Floor
441 Rodericks Road, Lynnwood
Pretoria, Gauteng, 0081
P O Box 15025
Impala Park 1472
Tel: +27 12 054 5100
hear4u@amtronix.co.za
www.amtronix.co.za

The Why, The What and The Who of Audiological Equipment Calibration

Why do you need to Calibrate?

The regular calibration of audiometry equipment ensures that the hearing level and the frequencies that are indicated by the audiometry equipment complies with the strict values that are set by the South African National Standards (SANS), which is a division of South African Bureau of Standards (SABS) or the product manufacturer's specific references for hearing thresholds.

The calibration ensure that the audiometry equipment is accurate, the results are reliable and that the equipment is operating within the manufactures specifications.

What needs to be Calibrated?

The following equipment needs to be calibrated or certified at least once a year:

- Audiometers (Screening and Diagnostics)
- Tympanometers
- OAE equipment (Screener and Diagnostic)
- AEP equipment (including AARB, ARB, ASSR, VEMP, EcochG, etc)
- Hearing Aid Verification equipment
- Balance Assessment equipment
- Sound Booth (Certified)
- Any equipment that uses sound as a measurement

Who can Calibrate your equipment?

All audiometry equipment should be calibrated by a reputable service provider that has been trained and certified by the manufacture of the equipment. The service provider that provides the calibration service should have the necessary calibration equipment and procedures to perform the calibration of the audiometry equipment. The calibration equipment used for the calibration should have valid calibration certificate and traceable back to South African National Accreditation System (SANAS).

The calibration service provider must provide you with a calibration certificate that is in accordance with the South African National Standards (SANS) requirements.

The service provider that provider that offers the calibration service of your audiometry equipment should be registered and have a valid certificate issued by SAHPRA (South Africa Health Products Regulatory Authority)

Daily Checks

Audiometer

- Biological check of the equipment - pure tone at different frequencies
- Check for noise - static/hum
- Clean all equipment and transducers
- Clean all connectors. Booth interface cables etc.
- Check all cables and ensure they are not twisted
- Check patient response button - clicking
- Check monitor headset and talkback mic
- For industrial and medico legal testing these checks must be documented

Tympanometer and OAE equipment

- Listen to probe and reflex tones (pure tones, WBN, etc.)
- Check probe for debris and clean if necessary
- Check accuracy of cavity volume
- Perform biologic tympanogram and DPgram
- For industrial and medico legal testing these checks must be documented

Notice

Lebone Medical Supplies (Pty) Ltd t/a Amtronix Diagnostics management would like to reiterate the following regarding our products and services:

- Lebone Medical Supplies (Pty) Ltd t/a Amtronix Diagnostics has not authorized or certified any third parties to perform maintenance, repairs, calibrations, and servicing of any equipment supplied by Lebone Medical Supplies (Pty) Ltd t/a Amtronix Diagnostics.
- Lebone Medical Supplies (Pty) Ltd t/a Amtronix Diagnostics personnel are trained and certified in the maintenance, repairs, calibrations, and servicing of the devices and possess the requisite certification issued by the Original Equipment Manufacturer (OEM).
- All Lebone Medical Supplies (Pty) Ltd t/a Amtronix Diagnostics calibration equipment is SANAS certified and complies to the SANS requirements. *Certificates are available on request*.
- All the devices that Lebone Medical Supplies (Pty) Ltd t/a Amtronix Diagnostics supply into the market are CE certified and are registered with the Radiation Directorate, ensuring adherence to the safety and legal compliance requirements applicable to the devices. *Certificate is available on request*.
- Furthermore, Lebone Medical Supplies (Pty) Ltd t/a Amtronix Diagnostics is registered with the SAHPRA (South Africa Health Products Regulatory Authority) (the registration of all company for manufacturers, wholesalers, or distributors of medical devices is a requirement by law). This registration is mandatory for any South African company that supplies any medical equipment. *Certificate is available on request.* To check if a company is registered with SAHPRA, kindly follow the link below: https://www.sahpra.org.za/medical-devices-licences-issued/