Title: Evaluation of the Kuduwave 5000 audiometer for compliance with standards for hearing conservation purposes

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Abstract

The Kuduwave 5000 audiometer is a South African manufactured computer-software-controlled audiometer that uses insert earphones covered by circumaural earphones fitted with internal and external microphones to monitor ambient noise levels. This article presents an evaluation of the audiometer's compliance with standards and regulations for use of this device in health surveillance in hearing conservation programmes.

The requirements for audiometry in a hearing conservation programme as specified by the internationally accepted standards are compared with the technical specifications and observed use of the Kuduwave 5000 audiometer.

The technical specifications of the Kuduwave 5000 audiometer were found to comply with the relevant standards for hearing conservation programme purposes. The audiometrist must ensure compliance with the calibration requirements annually, or three-monthly if used as a mobile device, and that the ambient noise levels in the test room comply with the standards set for the test environment for the Kuduwave 5000 headset.

Key words: Audiometry, hearing conservation programme, standards

[148 words]

Introduction

The Kuduwave 5000 audiometer is manufactured by eMoyoDotNet (Pty) Ltd (previously manufactured by GeoAxon). It is a computer-software-controlled audiometer connected to a laptop via a USB port, which is equipped with circumaural earphones that are placed over insert earphones to increase the attenuation of environmental sound. During testing with the Kuduwave 5000, the noise levels can be monitored by the device with an external microphone (on the outside of the circumaural earphone cup) and internal microphone (on the inside of the circumaural earphone cup) to ensure test compliance[1]. The Kuduwave 5000 audiometer has the facility to test air and bone conduction and can be used for manual testing or

automated testing. The Kuduwave has been shown to provide accurate diagnostic audiometric results[8,9,10].

Surveillance testing for hearing conservation programme (HCP) purposes is regulated in the South African context by SANS 10083:2012 and is used to track any changes in a worker's hearing so that appropriate intervention can prevent further hearing loss[2]. The required annual air conduction pure-tone audiometry results are also used to calculate the baseline percentage loss of hearing (PLH) when a worker enters an occupation where s/he will be exposed to noise levels of above 85 dBA. This baseline PLH is compared with future test results and to calculate if a worker is eligible for compensation for noise-induced hearing loss (NIHL) as a result of hazardous workplace exposure[6].

Typically in South African industrial settings, annual pure-tone audiometry is conducted in a soundproof booth. In some cases a mobile sound-treated facility is used. The annual tests are typically conducted by an audiometrist or occupational health practitioner using automated audiometry. To cope with large numbers of employees needing to be tested often more than one person is tested at a time by placing a number of sound booths in one testing location.

This study evaluates the use of the Kuduwave in the context of hearing conservation specifically within the South African legal and regulated industrial context. The South African standards are all strictly based on international standards and compliance with South African standards can therefore imply compliance with international standards. The rationale for the evaluation is to establish whether, from the perspective of all applicable standards and regulations, a practitioner is legally compliant when using a Kuduwave 5000.

Standards and regulations relevant for hearing conservation purposes

Through the application of national and international standards, governments, procurers and consumers can have confidence in calibration and test results, inspection reports and certifications.

The International Electrotechnical Commission (IEC) is the world's leading organisation for the preparation and publication of international standards for all electrical, electronic and related technologies. All IEC standards are fully consensus-

based and represent the needs of key stakeholders of every nation participating in IEC work. The IEC has an Affiliate Country Programme that allows affiliated countries to adopt the IEC standards for increased awareness and use of internationally accepted standards[2].

Accreditation is the independent evaluation of the conformity of assessment bodies against recognised standards to ensure their impartiality and competence. Accreditation bodies are established in many countries with the primary purpose of ensuring that conformity assessment bodies are subject to oversight by an authoritative body. Accreditation bodies, which have been evaluated by peers as competent, sign agreements that enhance the acceptance of products and services across national borders, thereby creating a framework to support international trade through removing technical barriers. These agreements are managed by the International Accreditation Forum (IAF) in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment and the International Laboratory Accreditation Cooperation (ILAC) in the field of laboratory and inspection accreditation.

In South Africa the South African Bureau of Standards (SABS) manages standards and accreditation. The SABS is affiliated to both the IAF and the ILAC and facilitates product certification for South African manufacturers. In most cases the SABS standards are exact replicas of the international standards and often have a South African National Standards (SANS) number, which refers to the international standard's number; e.g. the IEC or the International Standards Organisation (ISO).

Currently the SABS does not have a functioning acoustics unit that is able to certify equipment and calibrate equipment[12]. Therefore, manufacturers and suppliers of acoustic-related equipment such as audiometers typically use international training and equipment for the manufacture and calibration of audiometers. The laboratories where calibration of equipment takes place are also typically based on international manufacturers or suppliers of the parts or complete equipment. However, factories/laboratories can subject themselves to a process where auditors visit the factory/laboratories, certify the production of the product against accepted standards and provide a permit/certificate of accreditation for three years.

The eMoyoDotNet (Pty) Ltd product is tested by Intertek and its manufacturing management system certified by Lloyd Register Quality Assurance. Both

organisations are members of the certification bodies for the United Kingdom (UK) Accreditation Services and therefore signatories to the IAF and both have a Mutual Recognition Agreement with the SABS. This appears to be typical practice for audiometer suppliers/manufacturers in South Africa (personal communication SABS representative, 2013).

Kuduwave compliance with standards and regulations

Compliance with standards for hearing conservation purposes is guided by SANS 10083:2012, which is entitled *The measurement and assessment of occupational noise for hearing conservation purposes*, and the legislation pertaining to both the mining industry (the Mine Health and Safety Act) and other industries (Occupational Health and Safety Act) refer to this standard[3,6]. SANS 10083:2012 refers to the other relevant standards: SANS 8253-1:2011 (*Acoustics – Audiometric test methods. Part 1: Basic pure tone air and bone conduction threshold audiometry*)[4]; SANS 10154:2012 (*Calibration of pure tone audiometers. Part 1: Air conduction*)[5]; and SANS 10182:2006 (*The measurement and assessment of acoustic environments for audiometric tests*)[7].

When evaluating the compliance of the Kuduwave 5000 with the standards that will ensure good hearing conservation, the audiometrist must adhere to:

- the audiometer specifications (SANS 8253-1:2011);
- the earphone/inserts specifications (SANS 8253-1:2011);
- the calibration of the audiometer and of the headphones (SANS 10154:2012); and
- the suitability of the test environment (SANS 10182:2006).

Each of these aspects is dealt with separately in the sections below.

1. Audiometer specifications

Table 1 The Kuduwave (KW) evaluated against the required audiometer specifications

SANS 8253-1 requirements	Kuduwave complies		Evidence
	Yes	No	
1. Can the KW perform an audiometric	√		Specifications and observed and

test manually?			references 10 and 11
2. Can KW perform an audiometric test with automatic-recording?	√		Specifications and observed
3. When testing automatically is the order of presentation of test tones from 1,000 Hz upwards, followed by the lower frequency range, in descending order?	√		Specifications and observed
4. Is a repeat test carried out at 1,000 Hz on the ear tested first?	√		Specifications and observed
5. Does the KW use either the bracketing or the ascending method of test tones presentation?	√		Specifications and observed both. The shortened ascending method (Hughson-Westlake) is also used[4]
6. Is the KW constructed in accordance with IEC60645-1?	√		Certificates from Intertek
7. Is the KW at least a Type 4 audiometer?	√		Specifications and observed Type 2 (Type 2 performs better than Type 4)
8. Can the KW present at least the frequencies 0.5, 1, 2, 3, 4, 6 and 8 kHz tones?	√		Specifications and observed
9. Can the KW present the 8,000 Hz tone at least at 70 dB?	√		Specifications and observed
10. Can the KW present all other tones from 0 to 70 dB?	√		Specifications and observed
11. Can the KW present tones in 5 dB steps?	√		Specifications and observed
12. Does the KW have dual fixed headphones?	√		Specifications and observed
13. Does the KW have a stimulus button?	√		Specifications and observed
14. Does the KW have a patient response button?	√		Specifications and observed
15. Can the KW present pulsed tone and continuous tones?	√		Specifications and observed

2. Earphone/insert specifications

The path of delivery of sounds to the ears is typically, in the South African context, via a set of circumaural earphones but, in internationally accepted audiometry, insert earphones are also used. The SANS 10154 standard specifies the compliance requirements for either insert earphones or typical circumaural earphones. In the

case of the Kuduwave, insert earphones are used and therefore at the time of the electro-acoustic calibration the inserts must be calibrated using Table 2 in SANS 10154-1 (Table 2).

Table 2 Reference values for frequencies and sound pressure levels, for insert earphones as specified in ISO 389-2, in an acoustic coupler that complies with IEC 60318-5 (Source SANS 10154-1 Table 2)

Frequency Setting (Hz)	Permissible range of frequencies (Hz)	Nominal sound pressure level at a setting of 70 dB (dB)	Permissible range of sound pressure levels at a setting of 70 dB (dB)
250	242 – 258	84,0	81,0 – 87,0
500	485 – 515	75,5	72,5 – 78,5
1 000	970 – 1 030	70,0	67,0 – 73,0
2 000	1 940 – 2 060	73,0	70,0 – 76,0
3 000	2 910 – 3 090	73,5	70,5 – 76,5
4 000	3 880 – 4 120	75,5	72,5 – 78,5
6 000	5 820 – 6 180	72,0	67,0 – 77,0
8 000	7 760 – 8 240	70,0	65,0 – 75,0

To avoid masking test tones, the ambient sound levels in the room/audiometric booth or mobile unit where the test using insert earphones is conducted must comply with the maximum permissible sound pressure levels set out by SANS 10182. The Kuduwave uses circumaural earphones over the insert earphones known as the Ambidome. The effect of the Ambidome on the suitability of the test room is discussed in Section 4.

3. Calibration of the audiometer and of the headphones

Calibration of audiometric equipment against an accepted standard is aimed at verifying that the frequencies of the tones presented and the intensity of the tones presented to the client from the audiometer are within the required parameters. SANS 8253-1 specifies three methods of calibration that must be conducted at predetermined intervals[11]. Table 3 summarises the requirements of SANS 8253-1.

Table 3 Calibration methods required by SANS 8253-1 (Source: Michell & Geier, 2009)[11]

	Type A	Type B	Type C
SANS 8253-1 title	Routine checking	Periodic objective	Basic calibration

	and subjective tests	checks	tests
Common title	Daily listening checks and biological calibration	Electro-acoustic calibration	Factory calibration
Interval	Daily and weekly (or as required for mobile testing)	Annually	When required i.e. after 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 acceptable standards	To return equipment to calibration after major fault
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 calibration check label be attached to indicate date of next objective check	Only required when equipment cannot be calibrated on site due to major failure

The standard states that audiograms taken after the audiometer has been moved from its calibration site are deemed to be valid if the tester knows that the audiometer has stayed within the specified design limits during the calibration time interval. For example, the climatic conditions should not have been changed dramatically by moving the test site to an extremely tropical and humid climate. The tester must know that the audiometer has stayed within the specified calibration limits during the calibration time interval, by carrying out subjective tests before the audiometer is used, as stated in Table 3. The subjective test can be conducted using an electro-acoustic ear; e.g. with an OSCAR® or on a human subject. The electro-acoustic ear allows for consistency in the process but, if not available, testing one ear known to be normal and not recently exposed to noise can be used. In this case both the left and right earphones are used sequentially to obtain hearing threshold levels within 10 dB of each other[11]. Best practice requires that records of the daily listening checks and biological calibration should be kept for audit purposes.

SANS 10154-1 and SANS 8253-1 specify that the time interval between calibration of mobile equipment is a minimum of every three months[4,5]. These requirements are valid for the Kuduwave.

Table 4 The Kuduwave (KW) evaluated against the calibration requirements

SANS 10154-1:2012	Kuduwave complies		Evidence
	Yes	No	
1. Does the KW calibration process comply with calibration requirements for ISO389-2 and IEC60318-5?	√		Accreditation letter from UK based accreditation company Intertek (affiliated to IEC).
2. Is KW calibration done at an organization that has personnel with the necessary education, training, technical knowledge and experience for their assigned functions (at least one Registered Professional Engineer, Scientist or Technologist)?	√		Kuduwave manufacturers calibrate the equipment. Staff comprises of Technologists.
3. Is KW calibration done at an organization that has the necessary facilities with properly maintained and calibrated instruments?	√		Accredited by LRQ for management system in compliance with ISO 13485:2003.
4. Is KW calibration done at an organization thatimplements and maintains a quality management system?	√		Observation of organizational facilities. ISO 13485:2003 documentation.
5. Does KW recommend that if the instrument is used for mobile purposes that it should be calibrated where the maximum interval between such checks should not exceed 3 months?	√		Recommended on invoices and calibration certificates.
6. Does KW calibration process use an occluded ear simulator or an	√		Laboratory standard operating procedure documents.

acoustic coupler that complies with ISO 389-2 & IEC 70318-5?			
7. Do KW calibration checks include measuring of the sound pressure levels from the insert earphones in an acoustic coupler or ear simulator and comparing results with SANS 8253-1?	√		Laboratory standard operating procedure documents.
8. Is SANS 10154-1 Table 2 entitled — *Reference values for frequencies and sound pressure levels*, *for insert earphones as specified in ISO 389-2, in an acoustic coupler that complies with IEC 60318-5* used as the reference values for frequencies and sound pressure levels calibrating the KW earphones?	√		Laboratory standard operating procedure documents.
9. Do owners get a printout that compares their machine with Table 2 and 3 of SANS 10154-1?	√		Calibration certificate states it is available on request
10. Do KW calibration checks include measuring of the frequencies of test signals and comparing results with SANS 8253-1?	√		Laboratory standard operating procedure documents.
11. Is the recommended maximum interval between calibration checks not exceeding 12 months?	√		Calibration certificates
12. During calibration of the KW is a class 1 sound level meter used that has a pressure-calibrated condenser microphone suitable for the ear simulator and that complies with the IEC 61672-1 standard?	√		Laboratory standard operating procedure documents.
13. During calibration of the KW is a sound level meter used that has a one-third-octave-band filter set	√		Laboratory standard operating procedure documents.

that complies with the IEC 61260 standard?			
14. During calibration of the KW are ear simulators or acoustic couplers used that comply with IEC 60318-1[4], IEC 60318-3[5], IEC 60318-4[6], and IEC 60318-5[7]?	√		Laboratory standard operating procedure documents.
15. During calibration of the KW a digital frequency counter is used?	√		Laboratory standard operating procedure documents.
16. During calibration of the KW an oscilloscope is used?	√		Laboratory standard operating procedure documents.
17. During calibration of the KW is a contact thermometer for checking the operating temperature (23 °C) of the mechanical coupler is used?	√		Laboratory standard operating procedure documents.
18. After calibration of the KW is a calibration label attached to the equipment, giving the date on which the next objective test is due?	√		The Kuduwave software prompts the user. Calibration certificate example includes date.
19. If after completion of the calibration procedure the audiometer performance is found to be in accordance with the relevant standards, is a certificate issued that is valid for a period of one year from the date of calibration?	√		Calibration certificate example.
20. Does the certificate state that it will immediately become invalid if either the audiometer or its earphones or inserts are subjected to any misuse or rough handling, or to repairs or replacement?	√		Calibration certificate example.
21. Does the certificate state that it	√		Calibration certificate example.

will immediately become invalid if moved from the site of calibration by road, rail or air, unless the audiometer shall be mounted on an anti-vibration platform whenever it is moved?			
22. Does the calibration certificate state that the air conduction calibration of the audiometer has been checked in accordance with SANS 10154 and has been found to be in agreement with the recommended limits?	√		Calibration certificate example.
23. Does the calibration certificate states the date of calibration?	√		Calibration certificate example.
24. Does the calibration certificate state the name and address of the calibrating laboratory/organization?	√		Calibration certificate example.
25. Does the calibration certificate state the make, model number and serial number of the audiometer?	√		Calibration certificate example.
26. Does the calibration certificate state the type and serial number of the earphones or inserts?	√		Calibration certificate example.
27. Does the calibration certificate state the calibration certificate numbers and dates of calibration of all equipment used to check the audiometer?	√		Calibration certificate example
28. Does the calibration certificate contain the name and signature of the person conducting the calibration?	√		Calibration certificate example

4. Suitability of the test environment

The standards set for ambient sound pressure levels in audiometric test rooms are specified to ensure that the noise levels do not mask the test tones and are therefore limited to values specified as maximum permissible ambient sound pressure levels (L_{perm}) for specific frequencies[7].

The limits are calculated to allow testing to a lowest hearing threshold level of 0 dB for both diagnostic audiometry and screening audiometry (Table 5). The limits allow for a maximum amount of uncertainty in the thresholds of up to +5 dB. The ambient noise level measurements must be made when conditions resemble the usual ambient noise levels during audiometric testing; e.g. if an air conditioning system is usually operating during testing, noise measurements must be made with that system operating[7].

In the South African medical surveillance context the requirement to test as low as 0 dB and to have as low as 5 dB inter-test variability is less stringent since the PLH calculations only require testing to 15 dB and the accepted standard for inter-test variability is 10 dB. Therefore, if the maximum permissible ambient noise levels in the testing environment comply with the levels calculated in Table 5 below, the Kuduwave user complies with the required standards.

Table 5 Maximum permissible ambient sound pressure levels, *L*perm, in octave bands for air conduction audiometry for typical supra-aural headsets (Source: SANS 10182 Table 1)

Mid-frequency of octave band Hz	**Maximum permissible ambient sound pressure levels *L*perm** dB	
	Diagnostic audiometry	**Screening audiometry**
125	29,0	52,0
250	21,0	38,5
500	20,5	22,0
1 000	24,0	24,0
2 000	31,0	31,0
4 000	37,0	37,0
8 000	35,5	35,5

SANS 10182, *The measurement and assessment of acoustic environments for audiometric tests*, covers procedures for verifying the suitability of an acoustic environment for audiometric tests. The procedures in this standard cover equipment required and the methods to be used to determine the suitability of rooms, audiometric booths and mobile facilities used for audiometric testing. If a Kuduwave is used in a booth or a mobile facility the standards in Table 5 apply as they would for any other type of audiometer.

SANS 8253-1 stipulates that if earphones other than the TDH 39 earphones are used then the sound attenuation values of the alternative earphones must be used to determine what the maximum permissible ambient noise (L_{max}) in the test room may be for hearing thresholds to be reliably measured.

The method of calculation is to subtract the average attenuation levels provided by the standard in Table 5 for the TDH 39, from those of the earphones being used. The Ambidome attenuation levels have been independently determined by the University of Pretoria and are listed in the Table 6. To determine the permissible ambient noise levels in the testing room the difference in dB must be added to the values in SANS 8253-1 Table 2, depending on the frequency range used. In the case of an occupational setting 500 Hz to 8 000 Hz is used; therefore, column 3 of Table 2 will apply. The difference between the average attenuation provided by the typical earphones and the Ambidome is added to the permissible ambient noise levels in the room for screening audiometry for calculating the maximum levels allowed (Table 6).

Table 6 Calculating the maximum permissible ambient noise levels for use of Kuduwave in a room to test accurately to 0 dBHL

Hz	Average attenuation provided by TDH39	Average attenuation provided by Kuduwave (UP study)	Difference between the average attenuation provided by two earphones	Permissible ambient noise levels for screening audiometry	Maximum permissible ambient noise levels when an Ambidome is used
125	3dB	38 dB	34 dB	52 dB	52+34=86dB
250	5 dB	41 dB	35 dB	38 dB	38+35=73dB
500	7 dB	46 dB	38 dB	22 dB	22+38 =60dB
1000	15 dB	47 dB	32 dB	24 dB	24+32=56dB
2000	26 dB	50 dB	24 dB	31 dB	31+24=55dB

4000	31 dB	60 dB	28 dB	37 dB	37+28=65dB
8000	24 dB	53 dB	28 dB	35 dB	35+28=63dB

SANS 8253-1 section 11.2 states that if sound pressure level measurements cannot be carried out, a psycho-acoustic check of the ambient noise may be carried out by conducting an audiometric test on at least two test subjects who are known to have stable audiograms and hearing levels at all frequencies better than the lowest hearing levels to be used during regular testing (in the case of South African PLH calculations 15 dB is the lowest necessary level to test). If hearing threshold levels on the two subjects differ by 5 dB or more from the baseline test used, this indicates that the room is not suitable for the relevant audiometric testing and an alternative test site needs to be found or the noise in the room must be reduced. The audiometric test shall be carried out during the time in which the audiometry would normally be conducted.

The Kuduwave has a built-in monitor of ambient noise levels that are recorded on the test report print-out. If used correctly; i.e. if test is stopped when ambient noise levels are shown by the Kuduwave to be non-compliant and the test redone when noise levels are reduced, the Kuduwave has an advantage for quality control of the test validity and reliability, which is often a concern in occupational and industrial settings.

Conclusion and recommendations

The evaluation of the Kuduwave 5000 against standards and regulations revealed that the Kuduwave complies with all required standards as an audiometer, if the user is mindful that mobile use requires a minimum of three-monthly calibration and the keeping of adequate records of daily and weekly biological checks. Most importantly, for compliance with standards the user must ensure that the room where testing down to 0 dBHL is conducted complies with maximum permissible ambient noise levels as calculated in Table 6. Test room compliance can be determined either by objective measurement or by subjective measurement. Detailed records of all verifications should be kept.

The Kuduwave complies for use in hearing conservation and therefore in medical surveillance since the above-mentioned standards are requirements for SANS 10083:2012, the standard which specifies how the medical surveillance is conducted.

Using the Kuduwave in the occupational setting can provide the opportunity for improved quality control of the audiometric test due to the real-time ambient noise level monitoring provided by the Ambidome. The use of the Kuduwave also provides the opportunity for more mobile testing; e.g. Temporary Threshold Shift (TTS) monitoring as an indicator of Hearing Protection Devices (HPD) effectiveness. Finally, the opportunity for easy remote monitoring of testing by more experienced or qualified staff and for regular evaluation and monitoring through the distance view of the Kuduwave also provides potential for improvement of HCP management.

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