KUDUwave™

thinking out the booth

User Manual

eMoyo

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Tel: +27 11 782 1154 | Fax: +27 11 86 542 0142 | Email: info@emoyo.net
Address: 179 Beyers Naude Drive, Northcliff, Johannesburg, 2195, South Africa
eMoyoDotNet (Pty) Ltd | Reg No: 2005/032169/07 | www.emoyo.net

Contents

1. Introduction

Purpose of this Manual

The intention of this manual is to provide you with a good understanding of the KUDUwave 5000 (from hereon referred to as KUDUwave™) operations, and to understand how its different technologies work together.

The manual contains technical specifications and also details potential hazards, usage methodologies and other information related to the purchasing, maintenance and safe usage of the device.

Please note that this manual's purpose is not to train KUDUwave™ operators to be healthcare professionals or to act as such.

If you would like to attain a hard copy of this manual, please contact eMoyo and one will be delivered to you free of charge.

Note: In tele-audiology, a subsection of telemedicine, a facilitator that might not be trained to perform the professional tests and interpret the results may fit the KUDUwave™ on the patient for an operator. This facilitator cannot act as an operator or a professional. The role of the facilitator is to assist an operator or professional to complete the process of remote tele-audiology tests.

The following sections providing a broad overview of the KUDUwave™ from a user's perspective.

Medical Purpose

The KUDUwave™ is a mobile audiometer featuring Ambi-Dome™ technology, which provides compliant testing outside a certified sound room using its built-in sound proofing, while including the functions found in a typical audiometer. This is achieved through a combination of sound damping and real time monitoring of ambient noise. The KUDUwave™'s medical purpose is to assist in testing a patient's behavioural auditory responses in order to determine their hearing thresholds, and as such assist in diagnosing any hearing impediments.

Patient Populations

There are no restrictions on a patient's gender, age, weight, general health or race for using the KUDUwave™. However, the KUDUwave™ cannot be used to test very young children, or people with physical or mental disabilities that prevent them from clearly signaling that they have heard a test audio tone presented to them. During testing the patient should be calm and comfortable and should not be distracted.

Device Description

The KUDUwave™ looks like a normal circumaural earphone headset typically used to listen to music. However, the KUDUwave™'s circumaural cups also help to attenuate environmental ambient noise. The KUDUwave™ electronics are all built into the headset, meaning the headset and the control are combined into a single, compact device and not separate physical modules (i.e. there is no separate box to drive the audiometer).

Device Placement

Place the KUDUwave™ headset on the patient's head, above the ears and carefully insert the foam eartips into the each of the patient's ears. Carefully place each Ambi-Dome™ over one ear at a time, and once placement is secure, ensure that the sound tubes are still connected before starting with a test. If needed, the KUDUwave™'s bone vibrator can be attached and positioned on the patient's forehead. When not in use there are no specific requirements, beyond those outlined in this document, for its placement and storage.

Application

The KUDUwave™ is designed to be completely portable and should be operated and maintained by a trained operator. It may be used for testing as often as required (potentially more than 100 times a day), typically indoors in an area free from noise and distractions. The KUDUwave™ should not be used in an excessively wet, hot or dusty environment. The KUDUwave™ can be used in an open air testing that adheres to the above requirements.

Frequently Used Functions

As the KUDUwave™ is designed for continuous, regular usage. An analysis of all its frequently used functions has been performed in order to ensure that none constitute as an unacceptable risk to either the operator or patient. These functions are detailed in the relevant sections of this User Manual, with guidance describing how to minimise any potential risks.

Details of Applied Parts

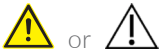
The following parts are defined as “applied parts” in accordance with BS EN 60601-1:

Ear Inserts: The Left and Right Ear Inserts will be positioned in the outer ear by the operator. They do not carry any electrical, chemical or mechanical energy and contain no metallic parts, and facilitate the delivery of sound energy to the patient’s ears.

Bone Vibrator: The bone vibrator is positioned against the patient’s forehead by the operator. From this position it can be used to deliver sound energy to the patient’s cochlea. The KUDUwave™ uses a certified bone vibrator from Radioear.

Description of Symbols

The following important symbols are used on the KUDUwave™ and its accessories:

Symbol	Description
	Manufacturer, eMoyoDotNet (Pty) Ltd, 179 Beyers Naude Drive, Johannesburg, South Africa
	EC Authorised Representative, PSF Medical BV, Marten Messweg 8, 3068AV Rotterdam, The Netherlands
	Symbol for CE Mark with Notified Body Number. Conforms to Medical Device Directive 93/42/EEC.
	Symbol designating Type B Applied Parts according BS EN 60601-1.
	Caution. Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Consult instructions for use. Indicates the need for the user to consult the instructions for use.
	Single use only.
	Serial number.
	Batch code. Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Ingress protection.
	Keep Dry. Indicates that the medical device needs to be protected from moisture
	Temperature limit. Indicates the temperature limits to which the medical device can be exposed safely.
	Humidity limit. Indicates the range of humidity to which the medical device can be safely exposed.
	Fragile, handle with care. Indicates a medical device that can be broken or damaged if not handled carefully.

2. Operator Training Requirements

Basic Requirements

The operator must be a trained healthcare professional (typically an audiologist, hearing aid acoustician, general practitioner, ENT, nurse or audiometrist) or a practitioner who has been trained in audiometry. The operator must be able to read and communicate fluently in English, and as needed, in the primary language of the patient.

Training and Certification Requirements

eMoyo provides online training for both facilitators and operators of the KUDUwave™. The operator will receive a certificate of completion after successfully completing his/her training.

3. Getting Started

This section outlines the installation and setup procedures of the KUDUwave™.

⚠ **Warning:** The KUDUwave™ is highly sensitive and technically complex and should be treated with care.

The ear cups of the KUDUwave™ block out the ambient noise as a first attenuation barrier. Tubes which fit eartips can be found at the bottom of each ear cup. Eartips are inserted into the patient's ear, and act as a second sound attenuation barrier. The ear cups are fitted over the insert eartips.

The KUDUwave™ is controlled via standard USB cables that connect each earcup of the The KUDUwave™ to a personal computer. The USB cables also provide the requisite power to the KUDUwave™.

The bone vibrator is mounted on an independent headband and is connected directly to the KUDUwave™ headset. The bone vibrator can be kept in position on the KUDUwave™ using the headband screw.

Unpacking the KUDUwave™ Hardware

The KUDUwave™ is packaged in a robust shock absorbing case designed to protect it during transportation. Inspect the case for signs of any damage and notify your supplier immediately if any signs of mechanical or physical damage are found.

⚠ Warning: eMoyo recommends that you use the robust shock absorbing carry case to ship your KUDUwave™. Please mark the package as FRAGILE.

KUDUwave™ Configurations

KUDUwave™ Prime	KUDUwave™ Plus	KUDUwave™ Pro
Screening	Screening	Screening
-	Diagnostic	Diagnostic
-	-	Monitoring of Ototoxicity
Pure Tone Air Conduction	Pure Tone Air and Bone Conduction	Pure Tone Air and Bone Conduction
Active Noise Monitoring	Active Noise Monitoring	Active Noise Monitoring
Automated and Manual Testing Protocols	Automated and Manual Testing Protocols	Automated and Manual Testing Protocols
Patient Management and Medical Record Suite	Patient Management and Medical Record Suite	Patient Management and Medical Record Suite
Telemedicine Enabled	Telemedicine Enabled	Telemedicine Enabled
-	-	Extended High Frequency (up to 16kHz)
PC Based Software	PC Based Software	PC Based Software

Packaging Checklist

Please check that all items listed below are received in good condition. If any items are missing or damaged, immediately notify your KUDUwave™ distributor.

- The KUDUwave™ headset
- Three meter long twisted KUDUwave™ dual USB cable
- USB patient response button
- Radio Ear Bone vibrator with headband attached to the KUDUwave™ headband with a headband screw (Plus and Pro configurations only)
- Calibration certificate
- Two sound tubes with eartip couplers attached to the KUDUwave™
- Spares (6 sound tubes and 1 brass connector)
- Starter pack of eartips

Serial Number

The unique serial number is clearly marked on the bottom of the KUDUwave™ headset. Serial number information is required when contacting customer support.

Software Installation

If your KUDUwave™ contoller PC was professionally configured by eMoyo, all the necessary software will already be installed, optimised and initialised. Should this not be the case, or should you wish to install the software on more than one computer, please contact eMoyo and on of our friendly technicians will be assigned to assist you.

Device Drivers

Drivers will automatically begin installing as the KUDUwave™'s USB cables have been plugged into a personal computer. The KUDUwave™ is a plug and play device and all drivers will be installed automatically.

If the device is plugged into a new USB port on the same computer for the first time, then some drivers will be installed again. Please wait until Windows notifies you that the drivers have been installed successfully.

⚠ **Warning:** If you launch the KUDUwave™ software before the drivers were installed, the KUDUwave™ software will prompt you that it could not find the device, even though the device is plugged in.

This can happen if you launch the KUDUwave™ software shortly after plugging the KUDUwave™ into the USB ports for the first time.

Software Launch

You should find the **KUDUwave 5** shortcut on your PCs desktop. Alternatively you can find **KUDUwave 5** under programs in your start menu. Launch the software by clicking the **KUDUwave 5** icon.

⚠ **Warning:** The **KUDUwave 5** software must be launched with Administrator rights in Windows 7, 8 and 10 in order to ensure that it functions correctly. To do this right click on the **KUDUwave 5** icon and select "Run as administrator".

Software Language

The software is currently only available in English.

Preparing the Test Environment

It is essential that the test environment is as quiet as possible in order to ensure test compliance and that the patient is not disturbed.

The KUDUwave™ monitors the ambient noise in real time and will indicate if ambient noise is sufficiently loud to disrupt the test.

The test environment should be free from any distractions that may disturb either

the operator or the patient as these may result in incorrect test results.

Preparing and Positioning the Patient

The patient should be seated in the test environment at least 1.5 meters from the test computer. It is important that the patient cannot see the screen of the test computer. Care should be taken to ensure the patient is as comfortable as is possible to minimise distractions.

Should the patient be unable to sit, care must be taken to ensure they are positioned in as comfortable and relaxed a position as is possible. Patients who are notably anxious should be reassured and made as comfortable as possible.

Checking Device Connectivity

Make sure the KUDUwave™ is plugged into the personal computer before you select any of the KUDUwave™ tests in the **KUDUwave 5** software.

If the KUDUwave™ is plugged into the personal computer both the Red and Blue LED will light up and you will be able to press the “Next >>” button to continue performing the test. If the device is not plugged in it will not be possible to proceed.

4. Preparing the KUDUwave™ Equipment

Twisted KUDUwave™ Dual USB Cable

Plug the larger USB plugs of the twisted KUDUwave™ USB cable into the USB ports of the test personal computer. Plug the smaller plugs of the twisted KUDUwave™ USB cable directly into the bottom of the KUDUwave™ headset. The KUDUwave™ will indicate the right side with a red light, and will indicate the left side with a blue light when powered.

Ensure that both USB cables are securely connected from the left and right KUDUwave™ ear cups to two USB ports on the test personal computer. The USB cables must not be tangled or left in a position where they may cause someone to trip over or become entangled in them.

⚠ **Warning:** Please wind the USB cable up in large loops to prevent unnecessary damage before storing it away in the KUDUwave™ case.

KUDUwave™ Headset

The headset must be placed on a stable surface. It must be cleaned and disinfected after each use with a cleaning wipe in compliance with EN1276 that are intended for use on plastic items.

Ear Inserts

A new set of foam eartips must be firmly attached to the plastic tubes. Used eartips must be disposed of as medical waste after testing.

⚠ **Warning:** The foam eartips are disposable and for single use only to prevent hazardous cross contamination. eMoyo will not be held liable for any complications if eartips are reused.

USB Patient Response Button

The USB cable from the Patient Response Button must be firmly attached to the USB connector on the left ear-cup of the KUDUwave™. Attaching it to the right ear-cup

is not recommended. Alternatively it may also be attached directly to the personal computer.

5. Positioning the KUDUwave™ Headset

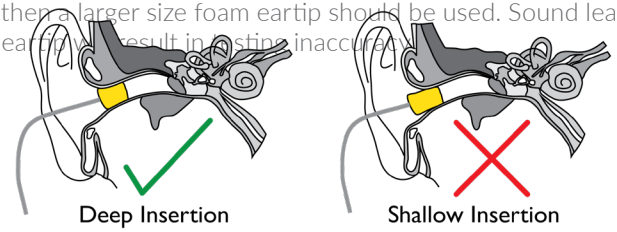
Although there are a number of ways to position the KUDUwave™ correctly on the patient's head, the following technique is recommended:

Step 1: KUDUwave™ – Initial Position

The KUDUwave™ headset should first be gently placed on the patient's head, resting just above their ears. Care must be taken to ensure that the headset is the correct way around (i.e. the left ear cup must be on the patient's left hand side and vice versa).

Step 2: Insert Eartips

Insert the foam eartip onto the tubing, and make sure that the eartip is inserted up to the end of the brass ridge. Squeeze the foam tip between thumb and index finger. Pull the ear by the pinna (up and back in adults and down in children) and insert the squeezed foam tip into the canal. Make sure the tip is inserted deep enough into the ear canal. The eartip must be held in the ear canal until the foam has expanded sufficiently so that it is securely in place. If the eartip is fit loosely in the ear canal then a larger size foam eartip should be used. Sound leakage around a loosely fitted ear tip will result in testing inaccuracy.



⚠ **Warning:** Improper insertion of eartips may affect test results.

Step 3: KUDUwave™ – Final Position

The headset can now be lifted up to, and simultaneously placed over, the patient's ears. Ensure the ear cups are supported by the headband and do not hang on the ears. Care must be taken not to dislodge the ear inserts from the patient's ear canal.

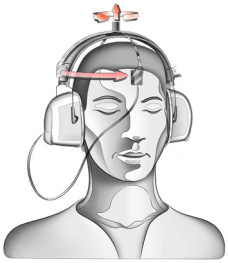
It is important to lift the left and right ear cups slightly in turn to visually confirm the ear inserts are still correctly positioned. Make sure that the tubing is not tangled under the cups. The tubing should loop out under the cups towards the front of the ear to avoid tangling and or bending.

Step 4: Patient Response Button

The Patient Response Button must be placed in the patient's hands. Ensure that the cable does not become tangled or damaged. The patient must keep his finger on the button and be ready to press it when a sound is played. The patient must be told to press the button as quickly as possible and then let go of the button.

Step 5: Bone Vibrator Positioning (Optional)

If the bone vibrator is to be used, the metal headband must be adjusted and placed over the patient's head in such a way as to ensure that it is positioned carefully in line with the middle partition between eyebrows/middle of the eyes of the patient's forehead.



⚠ **Warning:** Bone vibrators are calibrated to a specific KUDUwave™. They are not interchangeable between KUDUwaves™. Swapping of bone vibrators between devices may result in inaccurate testing. If you are unsure about which bone vibrator should be used with your KUDUwave™ please check its calibration certificate or alternatively contact eMoyo support.

6. Performing a Test

Please see the **KUDUwave 5** User Manual for full details on how to perform KUDUwave™ tone threshold test (manual or automatic), bisyllabic speech test (speech reception threshold) and monosyllabic speech test (speech discrimination), using the KUDUwave™.

For a quick reference, please see the **KUDUwave 5** Quick Start Guide included with your device or use the help included in the **KUDUwave 5** software package (this can be accessed by pressing the "?" button in the **KUDUwave 5** application whilst performing a KUDUwave™ test.

Remote Testing

The KUDUwave™ can easily and safely be used for remote testing over local and internet connections.

To test remotely

1. The trained operator starts the **KUDUwave 5** software application on his or her local personal computer.
2. A connection is made to a KUDUwave™ headset connected to a remote personal computer.
3. The remote personal computer is specified using its unique IP address.
4. A trained facilitator can then fit the KUDUwave™ headset on the patient. The operator can proceed with the test.

Both the operator and facilitator need to complete the eMoyo KUDUwave™ training.

7. Cleaning and Maintenance

General Care

The KUDUwave™ is a highly sensitive, state of the art device that must be treated with care. It must be cleaned and disinfected regularly and care should be taken not to damage any of the sensitive microphones or speakers when cleaning or handling the device.

Cleaning Procedure

The KUDUwave™ must be thoroughly cleaned and disinfected after each and every use (i.e. before each new patient is tested) with a cleaning and disinfection wipes complying with EN1276 that are intended for use on plastic items.

When Cleaning the KUDUwave™

1. Disconnect all USB cables and use an antibacterial wipe to clean the KUDUwave™ headset, ear cups, sound tubes, response button and the bone vibrator (if it was used).
2. It is important to ensure that during cleaning no liquid enters any holes in the ear cups.
3. Used foam eartips must be disposed of after each test as medical waste.
4. When cleaning the device, avoid bending or twisting any of the cables or sound tubes.
5. If any permanent sharp bends, cracks or holes in the sound tubes are visible, replace them with spares provided. Calibration can be verified using the standard daily biological calibration check routine.
6. Check that the sound tube or brass eartip coupler has not become blocked or obstructed over time.

⚠ **Warning!** Never use acetone based cleaning products when cleaning the KUDUwave™.

Note: Ear wax and debris can collect in the ear probe. Make sure that there is no debris on the ear probe or inside the disposable eartip before placing an eartip. Once debris or any foreign material has lodged into the little holes of the ear probe, it may be possible to remove the debris from the holes. If debris enters the holes, then the debris must be removed, cleaned and disinfected and the calibration should be verified using the standard biological calibration verification routines.

⚠ **Warning!** Make sure that there is no debris on the ear probe or inside the disposable eartip before placing an eartip onto the ear probe.

Note: The recommended daily biological calibration routine is as follows: Put the KUDUwave™ on your head and do an automatic KUDUwave™ tone threshold test of all the octave frequencies. Save the test results. Remove the KUDUwave™, turn it around so that the left side is on the right ear and the right side is on the left ear and redo the automatic KUDUwave™ tone threshold test. Compare the left and right thresholds of the two tests with each other. None of the thresholds of the compared sides may differ with more than 10 dB.

Note: Disposable eartips of different sizes act as barrier between the ear probe and the patient. Never reuse disposable eartips because old ear wax and cleaning solutions can damage the ear probe permanently. Cleaning solutions also damages the foam of the eartips and can lead to incorrect readings. It is an irresponsible risk to clean eartips for re-use, as cleaning solution or wax can end up inside the ear probe and give incorrect results.

⚠ Warning! Never reuse disposable eartips. Eartips are cheap and any perceived cost saving will not outweigh the risks to the device and more importantly, the patient.

Calibration

In order for the KUDUwave™ to operate correctly it is vital that it is calibrated correctly. eMoyo has the equipment and necessary expertise to calibrate your KUDUwave™. Please contact eMoyo to schedule your next calibration.

Daily Calibration

Although there is no need for daily biological testing, it is advisable to perform a biological test at the start of each day that the KUDUwave™ will be used.

Annual Calibration

Annual calibration is required. eMoyo will calibrate and return your KUDUwave™ to you in accordance with your maintenance contract.

Note: The KUDUwave™ software has been designed to automatically warn you when the minimum calibration is due. Your device will be assessed annually to determine its serviceability before it is calibrated. The KUDUwave™ users can expect a minimum service life of 5 years.

Ad Hoc Calibrations

Some states or countries require audiometers to be calibrated more than once a year, especially when audiometers are used for mobile testing. Please make sure of what the legislatory requirements are for your state or country. If you are ever in doubt whether the KUDUwave™ is in calibration it is recommended to verify the calibration biologically. If you are still in doubt it is essential to do an electro-acoustic calibration check.

Calibrations by Other Organisations

Due to the digital, robust and integrated design of the KUDUwave™, chances of it going out of calibration are very slim. If another organisation wants to calibrate a KUDUwave™, they may perform a typical calibration process to verify that the thresholds and frequencies of the unit are correct. After completing the calibration routine the calibration organisation will not need to adjust any thresholds or frequencies. A calibration certificate must be issued to show that the KUDUwave™ is within calibration limits. In the unlikely event where the calibration shows limits outside acceptable limits, please contact eMoyo immediately.

8. Storage and Shipping

⚠ **Warning!** When shipping the KUDUwave™ please use the robust shock absorbing carry case to reduce the risk of damage to the device during transit. Remember to seal the shipping container securely and to mark the container FRAGILE. Always store the KUDUwave™ out of direct sunlight in a clean and dry environment within the temperature and humidity limits detailed in the Technical Specifications.

9. Expected Service Life

The KUDUwave™ has an expected service life of at least five years of continuous use. Regular maintenance and general care will prolong the service life considerably. The KUDUwave™ can be used any number of times without restriction as long as it is both calibrated, and cleaned in accordance with the instructions in this User Manual.

10. Disposal and Recycling

There are no specific disposal requirements for the KUDUwave™. However, it is advisable that the unit is returned to eMoyo for disposal and recycling.

11. Traveling with Your KUDUwave™

When traveling or shipping the KUDUwave™ it is important to use its original case. This casing is specifically designed for traveling and to absorb shock.

Please make sure to perform the following tasks:

- Always unplug all USB cables before placing the KUDUwave™ into the case.
- Also make sure the bone vibrator is attached to the headband to ensure it does not move while being shipped.
- Keep a foam eartip on each sound tube tip to prevent dirt from entering the sound tubes.
- Make sure no cables or sound tubes are caught up between the lid and the case before closing it.
- Always perform a biological test after traveling with your KUDUwave™.

12. Upgrades, Maintenance and Support

Upgrades and New Features

eMoyo provides software and hardware upgrades for existing products. Please contact eMoyo at info@emoyo.net for the latest information on upgrades and new features. You can also visit our website at www.kuduwave.com.

Frequently Asked Questions (FAQs)

Please refer to websites for more information

13. Support Service

At eMoyo we are confident that we can deliver a unique support service specifically designed for clients in remote areas.

Loan Devices

In the unlikely event that one of our devices has a problem, we will express courier a loan device to you at your cost (if available).

Online Virtual Support

You can obtain online training using video conferencing software on your laptop.

To receive online virtual support, you will need to be located in an area with a good broadband internet connection.

Service, Support and Maintenance Contract

The latest service, support and maintenance contract can be obtained from your local sales representative.

14. Troubleshooting

If you experience problems, kindly send an email with as much information as possible (including the specific error message(s) and under which circumstances they occurred) to support@emoyo.net or contact your local sales representative. Additional support information can also be accessed at http:/kuduwave.com

Troubleshooting Checklist

Problem	Possible Solution
KUDUwave 5 software does not recognise that the KUDUwave™ is connected.	Check that the USB cables have been firmly connected from both ear cups to the USB ports on the personal computer. The left and right LED's will indicate if power is being received from the USB port.
	Try the second set of two new USB cables in case the original pair have become damaged.
	Ensure the Patient Response Handset has been connected to a USB port.
	Restart the computer and try to launch the software again.
Responses from the Patient Response button are not being recorded by the KUDUwave 5 software.	Ensure the Patient Response Handset has been firmly connected to the left ear cup.
	If another Patient Response Handset is available try it instead to ascertain if the response button is broken.
	Ensure that the patient environment is not too noisy so non-compliant results are not being recorded.
	Confirm that the operator can hear sounds being presented using the same headset.
The patient cannot hear sounds being presented even at high intensities.	Inspect the ear probes and eartips for debris that may be blocking the sounds.
I have run out of ear foam eartips.	Contact your sales representative to obtain new eartips. Do not continue using the existing ones or attempt to clean and reuse them.
The KUDUwave 5 software keeps telling me I have X days until the device needs calibration.	Ensure that you send your KUDUwave™ to eMoyo to be calibrated whenever prompted. Contact your local sales representative for more details.

In Need of Assistance?

Please contact your local IT consultant if you need assistance with confirming your personal computer's specifications, or need an upgrade to meet the minimum requirements.

15. Technical Specifications

Standards

The KUDUwave™ has been independently examined, tested and certified by a registered Notified Body in order to ensure Safety and Design Standards detailed in the General and Audiometry Specifications.

Audiometry Standards	Pure tone: BS EN 60645-1 (Type 3) Speech: BS EN 60645-2 (Type B)
Other Standards	BS EN 60601-1, BS EN 60601-1-2, BS EN 60601-1-6, BS EN ISO 13485, BS EN ISO 14971, BS EN 62304, BS EN ISO 14155, BS EN ISO 15223-1, EN 1041
Medical CE mark	European Council Directive 93/42/EEC
Medical device class	IIa
Calibration	Laboratory calibrated in accordance with: BS EN 60645-1, EN 60645-2, SANS 10154-1 and SANS 10154-2

Instrument Specifications

Dimensions	210 x 260 x 110 mm
Shipping dimensions	410 x 320 x 190 mm
Net weight	250 g
Shipping weight	1627 g

Power supply	2x standard laptop USB ports (5 V, 500 mA max per port) Unplug laptop from mains while testing	
Data transfer	Twisted KUDUwave™ dual USB cable 2x standard 3 meter A Male to Mini B Male USB cables	
Environmental conditions Indoor use only	Operational temperature	15 - 35 °C
	Operational humidity (non-condensing)	30 - 90 %
	Operational ambient pressure	98 - 104 kPa
	Shipping and storage temperature	10 - 40 °C
	Shipping and storage humidity (non-condensing)	30 - 75 %
	Shipping and storage ambient pressure	70 - 106 kPa
Warm-up time	10 - 20 sec	
Patient response system	Handheld tactile push button (USB)	
Sound tube	Medical grade PVC 80 shore, Clear with white x-ray line, L 180 mm, ID 1.7 mm, OD 2.9 mm	

Audiometry Specifications

Pure tone testing, speech testing, general, air conduction frequency specification, bone vibrator frequency specification and narrow band frequency specification.

Pure Tone Testing Specifications

Air conduction transducer	KUDUwave™ 5000 built-in insert earphone
Bone vibrator transducer	Radio Ear B71, B71W or B81
Bone vibrator placement	Forehead
Air conduction frequency range	125 Hz - 8 kHz standard 8 kHz - 16 kHz extended
Bone vibrator frequency range	250 Hz - 4 kHz
Frequency accuracy	< 0.05 %
Air conduction total harmonic distortion	< 3 %
Bone vibrator total harmonic distortion	< 6 %
Bone vibrator headband static force	5.4 N ±0.5 N
Air conduction calibration coupler	IEC 60318-4 (IEC 711) Ear Simulator RETSPL as per ISO 389-2, ISO 389-4*
Bone vibrator calibration coupler	IEC 60318-1 Ear Simulator with IEC 60318-6 Artificial Mastoid RETSPL as per ISO 389-3
Tone presentation	Pure tone or warble tone
Warble tone waveform	Sinusoidal
Warble tone repetition rate	4 - 20 Hz Default = 5 Hz
Warble tone frequency deviation	5 - 25 % Default = 10 %
Masking	Narrow band noise automatically centered at the test frequency

Speech Testing Specifications

Transducer	KUDUwave 5000 built-in insert earphone
Masking	Speech weighted random noise Spectrum constant from 125 Hz to 1000 Hz, then -12 dB/oct from 1 kHz to 6 kHz ±5 dB
Calibration	All pre-recorded words in word lists calibrated against 1 kHz calibration signal

* The default extended high frequency (8 kHz - 16 kHz) reference equivalent threshold sound pressure levels (RETSPL) are different to those of ISO 389-5 for insert earphones.

Additional Audiometry Specifications

Talk forward	40 - 100 dBHL adjustable
Modes of operation	Manual Automatic shortened ascending (Hughson and Westlake method - ISO 8253-1) Automatic standard ascending Shortened and standard bracketing Fixed frequency Békésy sweep (optional) Pure tone Stenger (optional)
Air conduction system sound attenuation characteristics using Ambi-dome™ technology Combined ear-cup and ear-insert attenuation	31.0 dB at 125 Hz 37.7 dB at 250 Hz 43.8 dB at 500 Hz 40.8 dB at 1000 Hz 38.1 dB at 2000 Hz 52.3 dB at 4000 Hz 45.8 dB at 8000 Hz
Operational background sound pressure levels to test down to 0dBHL	< 70 dB SPL at 125 Hz < 69 dB SPL at 250 Hz < 58 dB SPL at 500 Hz < 53 dB SPL at 1000 Hz < 50 dB SPL at 2000 Hz < 59 dB SPL at 4000 Hz < 59 dB SPL at 8000 Hz

Air Conduction Frequency Specifications

Freq (Hz)	RETSPLs (dB)	Max Output (dBHL)
125	28.0	80
250	17.5	90
500	9.5	105
750	6.0	110
1000	5.5	110
1500	9.5	110
2000	11.5	110
3000	13.0	105
4000	15.0	100
6000	16.0	90
8000	15.5	85
9000	13.5	85
11200	21.5	75
12500	25.5	80
14000	32.5	65
16000	41	50

Bone Conduction Frequency Specifications

Freq (Hz)	RETFLs (dB)	Maximum Mastoid Hearing Levels (dBHL)	Maximum Forehead Hearing Levels (dBHL)	Maximum Mastoid Hearing Levels (Occluded ear) (dBHL)
250	67.0	35	25	45

500	58.0	60	45	60
750	48.5	65	50	60
1000	42.5	70	60	65
1500	36.5	80	70	70
2000	31.0	80	70	70
3000	30.0	80	70	70
4000	35.5	65	60	60

Occluded ear (bilateral eartips in sito)

Narrowband Masking Specifications

Freq (Hz)	Max Output (dBHL)	Lower Cut-Off Frequency (Hz)	Upper Cut-Off Frequency (Hz)
125	80	110	145
250	90	215	290
500	105	435	575
750	110	650	890
1000	110	865	1150
1500	110	1295	1770
2000	110	1730	2310
3000	105	2600	3560
4000	100	3475	4700
6000	90	5100	7120
8000	85	6770	9380

Replacement Item Specification

Item	Specification	Comment/Warning
Eartip	Foam, manufactured to eMoyo specification	Do not replace with any other than eMoyo supplied items.
Ear Cup Cushions	Acoustic Foam, manufactured to eMoyo specification	Do not replace with any other than eMoyo supplied items.

Detachable Sound Tubes	Medical grade PVC	Do not replace with any other than eMoyo supplied items.

16. Electromagnetic Compatibility (EMC)

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this section. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment. Following the guidelines in this section will help prevent this.

⚠ **Warning!** The KUDUwave™ has been tested to the BS EN 60601-1-2:2007 for both immunity (susceptibility to interference from external sources) and emissions (interference generated by the KUDUwave™). In order to ensure correct operation the following precautions must be adhered to:

- The use of accessories and cables other than those specified or sold by eMoyo may result in increased emission or decreased immunity of the KUDUwave™. The list of cables and accessories below must be adhered to in order to ensure compliance.
- The KUDUwave™ should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary then the KUDUwave™ should be observed to verify normal operation in the configuration in which it will be used.

List of cables and accessories that affect compliance

1. USB Cable, Type A to mini-B, maximum length 3.0 metres.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The KUDUwave™ is intended for use in the electromagnetic environment specified below. The customer or operator of the KUDUwave™ must ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**

RF emissions CISPR 11	Group 1	The KUDUwave™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The KUDUwave™ is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The KUDUwave™ is intended for use in the electromagnetic environment specified below. The customer or operator of the KUDUwave™ must ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Power supply lines: not applicable, see note 2 ±1 kV for input/ output lines	See note 2

Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable, see note 2	See note 2
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not applicable, see note 2	See note 2
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE 1 - U_T is the a.c. mains voltage prior to application of the test level.

NOTE 2 - Power supply line electrical fast transient is not applicable because the KUDUwave™ is powered from the USB port of a laptop running on its battery.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The KUDUwave™ is intended for use in the electromagnetic environment specified below. The customer or operator of the KUDUwave™ must ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

			Portable and mobile RF communications equipment should be no closer to any part of the KUDUwave™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the KUDUwave™ is used exceeds the applicable RF compliance level above, the KUDUwave™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the KUDUwave™.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the KUDUwave™

The KUDUwave™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the operator of the KUDUwave™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KUDUwave™ as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 - At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.

NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

16. End User License Agreement (EULA)

The eMoyoDotNet (Pty) Ltd. End-User License Agreement (EULA) is a legal agreement between you, either an individual or a single entity and eMoyo, for the KUDUwave™ device and software. Software includes the personal computer software and the KUDUwave™ device firmware.

Software may be installed and used by any number of people (either an individual or a single entity). The software may be installed on any number of computers. The software can be operated over a network by any number of people from any number of computers. When it is plugged in, the KUDUwave™ will check that the Personal Computer Software is suitable to control it. Additional software functionality purchased will be associated with a single device and such software will only work for devices that have the license to use the new software.

The hardware may be used by any number of people (either an individual or a single entity). The hardware may be used on any number of Personal Computers and can be operated over a network by any number of people.

eMoyo took all reasonable care to ensure a safe and compliant device, but there is always the slightest possibility for error. eMoyo and its employees and consultants do not take responsibly for any complications that may be the result of errors in the device or software.

Specifications are subject to change without notice due to the continued development and enhancement of the KUDUwave™.

eMoyo reserves all rights not expressly granted.

17. Warranty and Disclaimer

Limited Warranty

eMoyoDotNet (Pty) Ltd. t/a eMoyo warrants that the KUDUwave™, if properly used and installed as per eMoyo's instructions, will be free from defects in material and workmanship. The KUDUwave™ will conform to eMoyo's high quality specifications for the period of three years, as stipulated on the Terms and Conditions found on the invoice.

This warranty

- begins on the date of purchase, (for your convenience, please keep the dated tax invoice as evidence of this date)
- is extended through distributors,
- covers defect(s);
- and does not cover tamper, drop, misuse or modifications.

If the KUDUwave™, which is the subject of this Limited Warranty, fails during the warranty period for reasons covered by this Limited Warranty, eMoyo will retain the option to repair or replace the KUDUwave™. All shipping costs required to repair or replace the device remain the responsibility of the purchaser.

Disclaimer

The Purchaser shall have no claim against eMoyo whatsoever, notwithstanding the termination or lapse of any contract. eMoyo will not be held responsible for loss or damage of any nature whatsoever, whether direct or indirect, consequential or otherwise, sustained as a result of any goods or equipment supplied or any advice given or any installation effected or any maintenance undertaken by eMoyo being in any way defective or absent or not conforming to the description thereof as a result of any other cause whatsoever.

Under no circumstances will eMoyo be liable for damage arising from misuse or abuse of the goods. The Customer does hereby indemnify and hold eMoyo harmless against any claim by any third person arising directly or indirectly out of any defect(s) in the goods or equipment supplied and or advice given to the Customer.