

KUDUwave 5000

User Manual



CE 0088

	<p>eMoyo</p>	<p>EC REP</p>	<p>PSF Medical</p>
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I WARNINGS AND SAFETY NOTICES



1) GENERAL WARNINGS AND NOTICES

The Kuduwave 5000 is highly sensitive and technically complex and should be treated with care.

The Kuduwave is NOT suitable for use in the presence of flammable anesthetic.

No modification of this equipment is allowed. Only use the components supplied with the Kuduwave 5000.

2) POWER SUPPLY SAFETY



Before any testing is allowed, unplug the Personal Computer (laptop or notebook) from the mains power and run it on battery only. Should it be required changing the battery can be done between patients.

The Kuduwave 5000 is powered from two standard USB ports on a Laptop or Notebook. These are specified as being part of the Kuduwave 5000 medical equipment system.

The Kuduwave 5000 must not be operated via a USB hub except if approved by the manufacturer.



The Personal Computer used with the Kuduwave must be suitably approved, supply 500mA per USB port and setup as per its instructions. Particular attention must be paid to ensure that the Laptop or Notebook and all peripherals connected to it are properly earthed if required.

3) PRECAUTIONS AGAINST EMC INTERFERENCE

Radiated electromagnetic fields, particularly from high powered medical devices, must be avoided as they may possibly cause the Kuduwave 5000 to become temporarily unresponsive. Likewise high powered portable/mobile RF devices may possibly affect its performance. As such, the Kuduwave 5000 should not be used adjacent to, or stacked with other electrical equipment, or if such placement is absolutely necessary, the device must be observed to verify normal operation before being used to test patients.

It is best to place the Kuduwave 5000 as far away as practical from sources of electromagnetic interference.

The Kuduwave 5000 may emit low levels of radiation; therefore care must be taken not to use sensitive equipment in close proximity.

Do not use ANY non supplied equipment with the Kuduwave 5000 such as USB cables or 3rd party USB hub's as it could affect the amount of electromagnetic interference emitted and thereby affect the operation of nearby sensitive electro medical devices.

See IEC 60601-1-2:2001 Sub-Clause 6.8.201 for requirements that are applicable when putting electro medical devices into service.

Should the Kuduwave 5000 or Laptop or Notebook software become unresponsive this is a typical indication that the unit is experiencing significant electromagnetic interference. Please



ensure that the Kuduwave 5000 is used in an electromagnetic interference free environment.

4) OPERATOR QUALIFICATIONS AND TRAINING

Audiometry must be performed by **skilled, trained operators**. eMoyo is not liable for morbidity caused by any untrained operators. Please see the Operator Training Manuals and the Operator Training section in this User Manual for more details.

5) SAFE USE OF USB CABLES

Please wind the USB cable up in large loops to prevent unnecessary damage to the USB cables. **Always fold the cable double before winding** up the twisted dual cable in large loops.

6) SOFTWARE OPERATION

The Kuduwave system software must be installed before the Kuduwave headset is attached for the first time. This will ensure that the Laptop or Notebook settings do not interfere with the functionality of the Kuduwave.

The application must be launched with **Administrative rights** in order for it to function correctly.

7) ACCESSORIES AND DISPOSABLES

Use only the Kudufoam ear tips supplied by eMoyo. The Kuduwave is calibrated specifically for use with Kudufoam ear tips. Other insert ear tips will cause incorrect test results.

The Kudufoam ear tips are disposable and for single use only to prevent hazardous cross contamination. eMoyo will not be liable for any complications if you re-use the ear tips.



Use only accessories and disposables that are defined as part of the Kuduwave 5000 system.

8) PATIENT POSITIONING AND ENVIRONMENT

Please ensure the patient is at all times positioned at least **1.5 meters** from the Laptop or Notebook facing away from the Laptop or Notebook in order to ensure that the Patient Zone is free from all hazards and distractions.

In order to minimize any risk of sound interference, the "Patient Zone" must be both quiet and free from any distractions that could potentially influence and distract either the operator or the patient.

Please ensure that the Maximum Permissible Ambient Noise Levels complies with the local state or country standards to ensure that ambient noise does not cause incorrect test results.

9) SHIPPING AND STORAGE

The original casing is the preferred method for use when shipping the Kuduwave.

IMPORTANT:
Always seal the shipping case securely and mark as FRAGILE.



II END USER LICENSE AGREEMENT (EULA)

This 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 Laptop or Notebook 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. Whenever it is plugged in, the Kuduwave will check that the Laptop or Notebook 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 Laptop or Notebooks. The hardware can be operated over a network by any number of people from any number of Laptop or Notebooks.

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

Due to continued development and product enhancement, specifications are subject to change without notice.

eMoyo reserves all rights not expressly granted.



III WARRANTY AND DISCLAIMER

1. 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 and will substantially conform to eMoyo's high quality specifications for the period of 3 years as also stipulated on the Terms and Conditions of 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 defects
- 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 have the option to repair or replace the Kuduwave. All shipping costs to repair or replace the device remain the responsibility of the purchaser.

2. Disclaimer

The Purchaser shall have no claim against eMoyo whatsoever, notwithstanding the termination or lapse of any contract. eMoyo will not be 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

USER MANUAL: KUDUWAVE 5000

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.



IV INTRODUCTION

1. Purpose of this manual

The intention of this manual is to give the user a good understanding of how to operate the Kuduwave 5000 and to understand how the different technologies work. It contains not only the technical specifications but also details all potential hazards, usage methodologies and all other information related to the purchasing, maintenance and safe usage of the device.

The intention of this manual is not to train operators to be professionals or to act as professionals.

Note: In Tele-Audiology, a subsection of Tele-Medicine, a facilitator that might not be trained to perform the professional tests and interpret the results might 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 facilitate the process of remote Tele-Audiology tests.



2. Description of Markings and Labels

The following markings and labels are used on the Kuduwave 5000 and on its accessories:

Symbol	Description and Notes
	Name and Address of Manufacturer: eMoyoDotNet (Pty) Ltd Silhouette Building 179 Beyers Naude Drive Northcliff Randburg South Africa Tel: +27 11 782 1154 Email: info@emoyo.net
	Symbol designating Type B Applied Parts
	Safety sign advising operator that accompanying documents must be consulted
	Contains Phthalates
	Symbol for the European Union Representative PSF Medical 2nd Floor, Boundary House Delftechpark 26 2628 XH Delft The Netherlands Tel: +31 15 260 0412 Fax: +31 84 748 5176 Email: vigilance@psfmedical.com



Symbol	Description and Notes
	Serial Number Symbol and Unique Serial Number for this device
	Symbol for "Single Use Only" application (this symbol appears only on the ear-inserts packaging)
IP20	<ul style="list-style-type: none">- Protected against solid foreign objects of 12,5 mm and greater- No Protection against water, please see cleaning instructions
	Symbol for CE Mark Notified Body number : 0088 Lloyd's Register Quality Assurance Ltd (0088) Hiramford Middlemarch Office Village Siskin Drive Coventry CV3 4FJ United Kingdom Phone : +44 (0)1926 633572

3. Intended Use of the Kuduwave 5000

IV.3.1. Application Specification

The following sections comprise the Application Specification providing a broad overview of the Kuduwave from a user's perspective.

IV.3.2. Medical Purpose

The Kuduwave 5000 is an innovative audiometer featuring "Ambidome" which provides compliant testing outside a certified sound room using its built-in sound proofing, while including the functions found in a typical audiometer. It achieved this through a combination of sound damping and real time monitoring of the ambient noise. Its medical



purpose is to assist in testing a patient's behavioural auditory responses in order to determine his or her hearing thresholds and hence assist in diagnosing any hearing impediments.

IV.3.3. Patient Populations

There are no restrictions on a patient's gender, age, weight, general health or race for using the Kuduwave 5000. However, the Kuduwave 5000 cannot be used to test either 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 using the patient response button. The patient should be calm and comfortable and should not be distracted during testing.

IV.3.4. Device Placement

When in use the Kuduwave 5000 headset will be placed on the patient's head in exactly the same manner as normal headphones would. The Kudufoam ear tips will be positioned in the outer ear. If it is to be used, the optional Bone Vibrator can subsequently 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.

IV.3.5. Operator Profile

The operator must be a trained healthcare professional (typically an audiologist, hearing aid acoustician, general practitioner, ENT practitioner, nurse, audiometrist or a practitioner who has been trained in audiometry. They must have received Operator Specific Training in using the Kuduwave 5000 by eMoyo (Pty) Ltd within the last 5 years. The operator should be able to communicate fluently in English, and if different, in the primary language of the patient.

IV.3.6. Application

The Kuduwave 5000 is intended to be exceptionally portable and should be operated and maintained by a trained operator. It may be used as often as is necessary (potentially more than 100 times a day), typically



indoors in an area free from noise and distractions. The Kuduwave 5000 should not be used in an excessively wet, hot or dusty environment. The Kuduwave can be used in tents if the above recommendations are met.

IV.3.7. Frequently Used Functions

As the Kuduwave 5000 is designed for continuous, regular usage, an analysis of all frequently used functions has been performed in order to ensure that none constitute an unacceptable risk to either the operator or patient. These functions are detailed in the relevant sections of this User Manual along with guidance as to how to minimize any potential risks.

IV.3.8. Details of Applied Parts

The following parts are defined as “applied parts” in accordance with 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 but they do 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 where it can be used to deliver sound energy to the patient. The Kuduwave 5000 uses a certified Bone Vibrator from Radioear, model number “B71”.





4. Operator Training Requirements

IV.4.1. 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 if different, in the primary language of the patient. More details can be found in the eMoyo Operator Training Manual.

IV.4.2. Training and Certification Requirements

eMoyo provides structured training for both facilitators and operators of the Kuduwave 5000.

The operator must have received this training in using the Kuduwave 5000 within the last 5 years. The operator will be awarded a certificate on completion of this training.

5. Expected Service Life

The Kuduwave 5000 has an expected service life of at least 5 years of continuous use. Regular maintenance and general care will prolong the service life considerably. The Kuduwave 5000 can be used any number of times without restriction as long as it is both calibrated, and used and cleaned in accordance with the instructions in this User Manual.

6. Disposal and Recycling

There are no specific disposal requirements for the Kuduwave 5000. However, it is advisable that the unit is returned to eMoyo so that they may dispose of, or recycle it, in the most suitable manner.



V TECHNICAL SPECIFICATION

1. System description & related models

The eMoyo Kuduwave 5000 can test both pure tone air and bone to the amplitude threshold levels of that of a *Type 2 Clinical Diagnostic Audiometer* as described in the European Standard EN60645-1 specification. It conforms to the *Type B* requirements as set out in the European Standard EN60645-2. Additionally, the Kuduwave 5000 headset provides a virtual “booth” allowing for compliant testing without a physical booth.

An “Eclipse” in the model name is indicative that the Kuduwave 5000 can also perform High-Frequency audiometry testing up to a frequency of 16kHz.

A “MOBI” in the model name is indicative that the Kuduwave 5000 cannot perform Bone Conduction testing.

2. Conformity with Standards

The Kuduwave 5000 has been independently examined, tested and certified by a registered Notified Body in order to ensure it conforms in full with each of with the Audiometry, Safety and Design Standards detailed in the General and Audiometry Specifications.



3. Kuduwave 5000

V.3.1. General Specifications

ASPECT	SPECIFICATION
Dimensions	210mm X 260mm X 110mm
Net Weight	250g
Shipping Weight	1,800g
Shipping Dimensions	410mm X 320mm X 190mm
Power supply	2 standard Laptop or Notebook / Laptop USB ports (5V, 500mA max per port) (Unplug the laptop from the mains when testing)
Safety and Design Standards	EN60601-1, EN60601-1-1, EN60601-2, EN60601-1-6, ISO14971
Medical Device Class	Class IIa
Measurement & Labelling Standards	ISO1000/80/181/EEC, ISO1041, EN980
Type of protection (electric shock)	Class II
Degree of protection (electric shock)	Type B
Warm up time	10-20 seconds
Protection against ingress (IP)	IP20
Operational Temperature	0°C to +40°C
Usage environment	Indoor use only
Protection against pollution	Pollution degree 2
Operational Humidity	5% to 90% non-condensing
Operational ambient pressure	500 hPa to 1200 hPa



ASPECT	SPECIFICATION
Operational background sound levels to test to 0 dB HL as per EN26189	< 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
Shipping & Storage Temperature	-5°C to +55°C
Shipping & Storage Humidity	5% to 90% non-condensing
Supplied Equipment and Accessories that make up the ME System	Kuduwave 5000 headset Kudufoam ear tips Twisted 3 meter dual USB cable USB Windows Response Button B71 bone vibrator & headband User Manual

V.3.2. Audiometry and Attenuator Specifications

ASPECT	SPECIFICATION
Audiometry Standards	EN60645-1, EN60645-2; ANSI S3.6
Pure Tone Audiometer Type	Type 2, Clinical Audiometer in accordance with EN60645-1
Monosyllabic Speech Audiometer Type	Type B, in accordance with EN60645-2
Maximum patient response time	3.0 seconds
Bone Conduction Frequency Range	250Hz to 4000Hz
Air Conduction Frequency Range	125Hz to 8000Hz
Frequency Accuracy	<0.05%
Air Conduction Total Harmonic Distortion	<2.5%
Bone Conduction Total Harmonic Distortion	<5.5%
Air conduction transducers	Kuduwave built-in insert ear phone transducer
Air conduction system	Sound is conducted through Ear Inserts.



ASPECT	SPECIFICATION
sound attenuation characteristics	The combined ear-cup and ear-insert attenuation is: 37.7 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
Air conduction calibration	Transducers calibrated using IEC60711 compliant ear simulator. RETSPL as per ISO389.
Pure Tone presentation	Pure Tone or Warble Tone
Warble Tone Waveform	Sine wave
Warble Tone Repetition Rate	4Hz to 20Hz (Default is 5Hz)
Warble Tone Frequency Deviation	5% to 25% (Default is 10%)
Bone conduction transducer	Radioear B71 (10Ω) Headband provides 5N static force.
Bone conduction system	The Bone Vibrator is positioned on the patient forehead. The non-test ear must be masked at least 20dB above the thresholds of the unoccluded non-test ear. Airborne sounds from the bone conductor are blocked because of combined effect of forehead bone conductor placement and the ear cup attenuation.
Masking	Manual or automatic narrow band masking. Levels equivalent to Pure Tones from 125Hz to 8KHz.
Modes of operation	Manual Automatic Shortened Ascending (Hughson & Westlake method - ISO 8253-1)



ASPECT	SPECIFICATION
	Automatic Standard Ascending Shortened and Standard Bracketing Fixed Frequency Békésy sweep
Time window for automatic testing	500ms to 3000ms (Default 1500ms)
Speech signal calibration	All words in word lists calibrated against a 1kHz calibration signal
Talk forward	Adjustable 40dB HL to 100dB HL



V.3.3. Frequency Specifications

V.3.3.a. Air Conduction Frequencies Specifications

Frequency (Hz)	KUDUwave Maximum Air Hearing Levels (dB-HL)
125	85
250	95
500	110
750	110
1000	110
1500	110
2000	110
3000	110
4000	110
6000	100
8000	90



V.3.3.b. Bone Conduction Frequency Specifications

Freq. (Hz)	IEC 64645-1 Type 2 Minimum required Hearing levels (dB) mastoid / forehead	KUDUwave Maximum Mastoid Hearing Levels	KUDUwave Maximum Forehead Hearing Levels	KUDUwave Maximum Mastoid Hearing Levels (Occluded ear)
250	45 / 33	45	35	55
500	60 / 46	65	55	70
750	-	70	60	70
1000	70 / 61	80	75	80
1500	70 / 59	90	80	80
2000	70 / 58	85	75	75
3000	70 / 58	80	70	70
4000	60 / 52	80	75	75

Occluded ear (Bilateral ear tips in situ)



V.3.3.c. Narrow Band Masking

Frequency (Hz)	Lower Cut-Off Frequency (Hz)	Upper Cut-Off Frequency (Hz)
125	105	150
250	210	290
500	435	570
750	650	890
1000	865	1150
1500	1295	1770
2000	1740	2310
3000	2600	3560
4000	3475	4700
6000	5095	7110
8000	6770	9330

V.3.1. Replacement Item Specification

NO.	ITEM	SPECIFICATION	COMMENT/ WARNING
1	Ear Tip	Classic Foam, manufactured to eMoyo Specification	Do not replace with any other than eMoyo supplied items
2	Ear Cup Cushions	Acoustic Foam, manufactured to eMoyo Specification	Do not replace with any other than eMoyo supplied items
3	Detachable Tubes	Manufactured from PVC with Phthalates present	 Do not replace with any other than eMoyo supplied items
			



VI GETTING STARTED

1. Introduction

This section outlines the installation and setup procedures of the Kuduwave software and hardware.

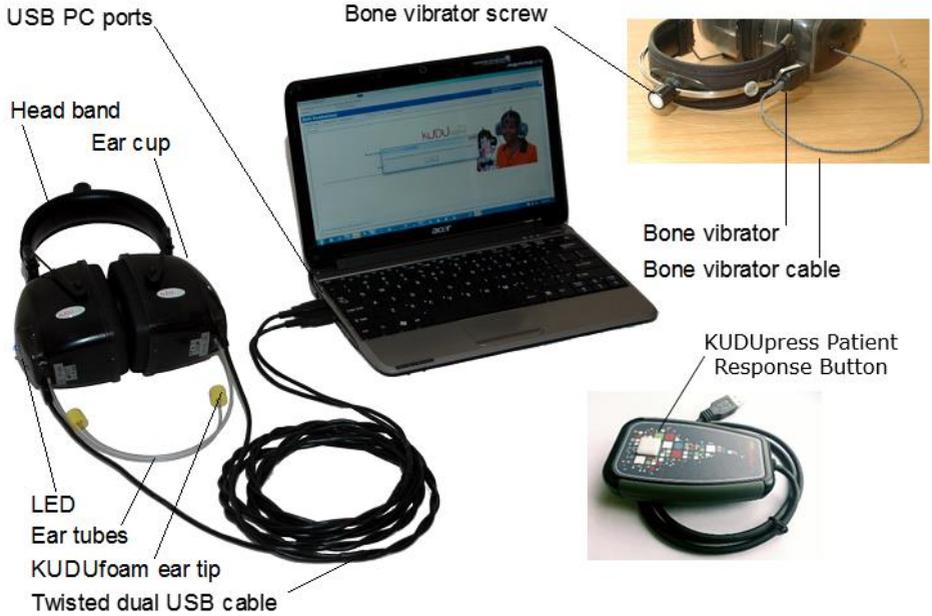
WARNING!

The Kuduwave is highly sensitive and technically complex and should be treated with care!



2. Kuduwave 5000 Description

The Kuduwave looks like a normal circumaural earphone headset that is typically used to listen to music however in this case the circumaural cups also help to attenuate the ambient noise in the environment. The Kuduwave electronics are all built into this 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 this Audiometer)





The ear-cups of this Kuduwave block out the ambient noise as a first attenuation barrier. At the bottom of each ear piece there are tubes at the end of which one can fit ear-tips. These tips are inserted into the ear of the patient and act as a second sound attenuation barrier. The ear-cups will then fit over these insert earphones through which sound is delivered to each ear of the patient.



The Kuduwave is connected to a Laptop or Notebook from each ear cup using standard USB cables through which the operator can control the Kuduwave. Power to the device is also supplied through these USB cables.

The Bone Vibrator resides on an independent headband and is connected directly to the Kuduwave headset. The bone vibrator can be kept in position on the headband using the headband screw.

3. Laptop or Notebook Requirements

VI.3.1. Minimum Laptop or Notebook specifications

- Processor speed of Pentium 3 equivalence
- 128 MB RAM
- 2 USB ports
- 200MB free disk space
- Keyboard and Mouse
- Screen resolution of at least 800x600 pixels
- Windows* 98 2nd Edition, Windows 2000, Windows XP, , Windows 7, Windows 8 operating systems, Windows 10

*Windows is a registered trademark of Microsoft Corporation



WARNING!

Other Operating Systems (e.g. Windows 95, Windows 98 1st edition or Windows Vista) are not suitable and the product will not operate reliably on these platforms. It is strongly advised not to install on these operating platforms, as intermittent problems can occur. eMoyo does not support other operating systems.



VI.3.2. How do I confirm my Laptop or Notebook specifications?

- **Processor speed / RAM / Operating platform:** Your Laptop or Notebook System Properties will display the above information (with Windows Explorer, right-click on "My Computer").
- **Screen resolution:** Right-click on Desktop >> click on "Properties" or "Personalize" >> click on "Settings" or "Display". Move the screen-resolution slider to at least 800 by 480 pixels.
- **USB port:** A physical (or visual) check will reveal the presence of the following – if not, kindly approach your local IT consultant for assistance. Some substandard USB ports do not



supply 500mA as per the USB standards. If in doubt a Kuduwave can be plugged into the USB ports and eMoyo can assist the user to determine if the USB ports do supply enough Amperes.



VI.3.3. In Need of Assistance?

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

4. Kuduwave Software Pre-installation check list for Laptop or Notebook

If the Kuduwave software was not installed by eMoyo it must be installed on the target Laptop or Notebook by the operator.

It is important to complete the Pre Installation Checklist, as it will guide you through obtaining all the necessary information to determine if you should schedule an installation, or whether to first contract third party IT assistance.

	YES	NO
The Laptop or Notebook is at least a Pentium 3 (Most Laptop or Notebook's bought since 2003 will be fast enough)		
The Laptop or Notebook Operating System is Windows 98 2 nd Edition, Windows 2000, Windows XP or Windows Vista		
This Laptop or Notebook has 128MB of free RAM		
The Laptop or Notebook has at least 2 free USB ports (Preferably 3)		
The Screen resolution is at least 800x480 pixels		
The Laptop or Notebook has at least 200 Mb free space on the Hard Disk Drive		
The Laptop or Notebook and all peripherals connected to it are properly earthed if connected to the mains power		



If you answered **NO** to any of the above questions, then you may experience problems with the installation. eMoyo cannot support Laptop or Notebook systems which do not meet the above minimum requirements. Please contact a local IT consultant to assist you with upgrading or supplying you with a compliant system.

5. Installation of the Kuduwave 5000

The Kuduwave is packaged in a sealed and tamper proof box. Inspect the case for signs of any damage. Notify the supplier immediately if any signs of mechanical or physical damage are found.

WARNING!

When shipping the Kuduwave preferably use the original packaging and remember to seal the shipping container securely and to mark the container **FRAGILE**.



VI.5.1. Unpacking the Kuduwave hardware

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

Note: A mobile case is also available for your Kuduwave 5000. If you haven't purchased a mobile case, be sure to save the box your unit came in. It has been designed specifically to protect the Kuduwave during transportation



VI.5.2. Packaging Checklist

Open the box containing the Kuduwave and check to see that you have the following items:

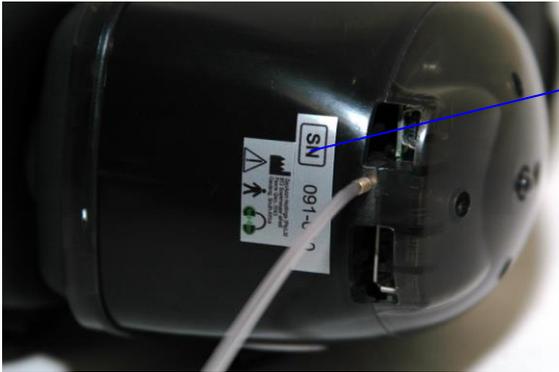
- **Kuduwave 5000 Headset**
- **Two 3 meter long double twisted USB Cables (one for use and one for a backup in case the used cable breaks or get lost)**
- **Patient Response Button**
- **Bone vibrator with headband attached to the head band with a headband screw**
- **Calibration certificate**
- **Kudufoam ear tips**
- **Two detachable sound tubes attached to the Kuduwave**
- **6 additional backup sound tubes (one with a Kudufoam connector)**

VI.5.3. Serial number

The serial number is clearly marked on the Kuduwave headset.



VI.5.3.a. Serial number [SN]



Serial number

Note: Serial number information is required when contacting customer support. Please keep this information handy when contacting customer support.

VI.5.4. Software installation

If you purchased a laptop from eMoyo along with your Kuduwave 5000, all the necessary software will already be installed and initialized. Should this not be the case, or should you wish to install the software on more Laptop or Notebook's, please follow these instructions.

WARNING!

The eMOYO application must be installed BEFORE the Kuduwave headset is attached for the first time.





VI.5.4.a. Installation from USB Stick

This procedure will install the software and generate a shortcut under Start|Programs| eMoyo to launch this application:

- Place the USB Stick into a free USB slot on the Laptop or Notebook
- After a few moments an installation wizard will appear to guide you through an automated installation process.

If the wizard does not automatically start then proceed with the following steps:

- Place the USB Stick into a free USB slot on the Laptop or Notebook
- Go to the USB drive in Windows Explorer
- Double-click on the Install application
- An installation wizard will appear to guide you through an automated installation process.

VI.5.5. Software Removal

To remove the software, use the 'Add/Remove Software' feature.

Note: For Windows 7 and Windows 8 this feature is called 'Programs and Features' in your Windows 'Control Panel'.

VI.5.6. Device Drivers

Once the Kuduwave USB cables have been plugged into a Laptop or Notebook, the Laptop or Notebook will automatically install the drivers. The Kuduwave is a plug-and-play device and all drivers will automatically be installed.

If the device is plugged into a new USB port on the same computer for the first time, then some drivers will again be installed. Please wait



until Windows prompts you that the drivers have been installed successfully.

Note: 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.

VI.5.7. Software Launch

WARNING!

The eMOYO Software must be launched with Administrator rights in Windows 7 and Windows 8 in order to ensure that it functions correctly.



You will find a group of shortcuts under the eMoyo Group of Programs (All Programs) after installation of the software.

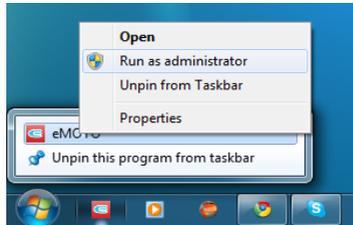
To find these shortcuts, click on

- 1.Start, then
- 2.Programs (All Programs), then
3. eMoyo and lastly on
4. **eMOYO**. Click on the eMOYO icon to launch the software.





Should you need to run eMOYO as “Administrator”, this can be done by right-clicking on the eMOYO application and selecting “Run as Administrator”.



VI.5.8. Software Language

The software is currently only available in English.

VI.5.9. Registration

When the Kuduwave software in eMOYO is started for the first time, and periodically thereafter, you may be prompted to enter an “Unlock Key”. If you do not yet have one please fill the form in under the Support page on the website (www.emoyo.net) and eMoyo will promptly send you a unique “Unlock Key” for you software. Simply enter it into the Kuduwave software when prompted and the Kuduwave software in eMOYO software will launch correctly.

VI.5.10. Checking Device Connectivity

Make sure the Kuduwave is plugged into the Laptop or Notebook before you select any of the Kuduwave tests in the “eMOYO” software.

If the Kuduwave is plugged into the Laptop or Notebook 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.





6. Post-installation check list

Customer Name			
Telephone Work		Telephone Mobile	
Date / Time		Region	
Person that did the installation			
Device Model			
Software version		Serial number	
			Yes
			No
The eMoyo Program Group exists under "Start Programs"			
eMoyo "eMOYO" installation was completed successfully			
The Kuduwave 5000 is plugged into the Laptop or Notebook using both USB cables			
The "eMOYO" application was run with Administrator privileges			
The Game Pad is plugged into either the Kuduwave 5000 headset or a spare USB port on the Laptop or Notebook			
A new patient was created after launching the "eMOYO" software			
A "Kuduwave Tone Threshold audiometry test" on both ears of a normal hearing person gives the impression that the device is calibrated			
The "Kuduwave Tone Threshold audiometry test" showed a report			
The "Kuduwave Tone Threshold audiometry test" test report can be printed			
Close the eMOYO software and then start the eMoyo "eMOYO" software again and see if the last test can be retrieved			
The operator has completed all relevant training by eMoyo			
Comments:			



VII USING AND MAINTAINING THE KUDUWAVE 5000

1. Introduction

The following guidelines are a subset of the instructions provided in the eMoyo Operator Training Manuals. The operator is expected to be intimately familiar with the content of these manuals.

2. Preparing the Test Environment

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

The Kuduwave 5000 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.

3. Preparing and Positioning the Patient

The patient should be seated in the test environment at least **1.5 meters** from the test Laptop or Notebook. Care should be taken to ensure the patient is as comfortable as is possible in order to minimize 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.



4. Preparing the Kuduwave 5000 equipment

VII.4.1. USB Cables

Ensure that both USB cables are securely connected from the left and right Kuduwave ear-cups to two USB ports on the test Laptop or Notebook. The USB cables must not be twisted or 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 to the USB cables. Always fold the cable double before winding up the twisted dual cable in large loops. Always wind the wire in figure 8 loops to prevent twisting of the cables.



VII.4.2. Kuduwave 5000 headset

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

VII.4.3. Ear inserts

A new set of Kudufoam ear inserts must be firmly attached to the plastic pipes. Used ear inserts must be disposed of immediately as medical waste.



Warning

The Kudufoam ear tips are disposable and for single use only to prevent hazardous cross contamination. eMoyo will not be liable for any complications if you re-use the ear tips.



VII.4.4. 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 5000. It may also be attached to the right ear-cup but this is not recommended. It may also be attached directly to the Laptop or Notebook and this is the recommended manner to use the response button.

5. Positioning the Kuduwave 5000 headset

Although there are a number of ways to position the Kuduwave 5000 correctly on the patient's head, the following proven technique is recommended:

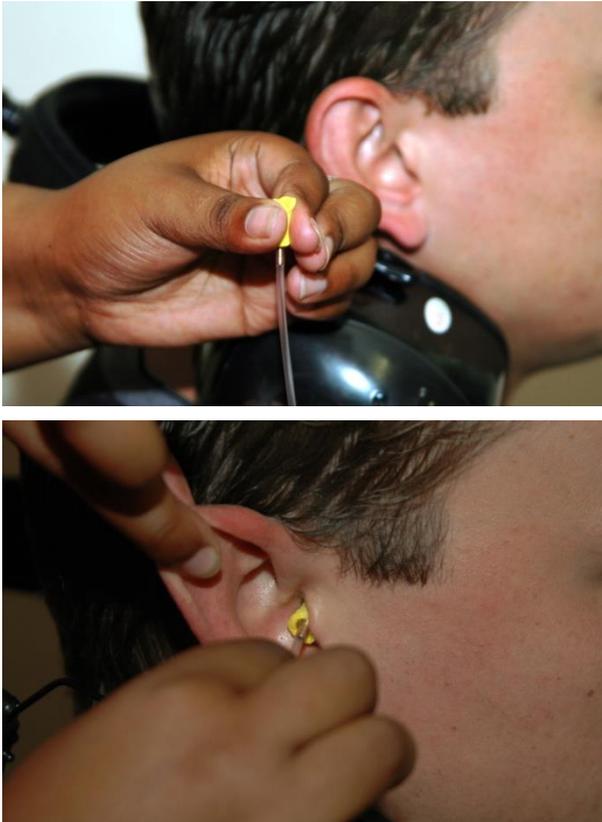
VII.5.1. Step 1: Kuduwave 5000 – Initial Position

The Kuduwave 5000 headset should first be gently placed around the patient's neck resting on his or her shoulders. Make sure the Kuduwave is not too far forward around the neck or else the sound tubes cannot reach the ear for insertion of the Kudufoam ear tips. Care must be taken to ensure the headset is the right way around (i.e. the left ear-cup must be on the patient's left hand side and vice versa).



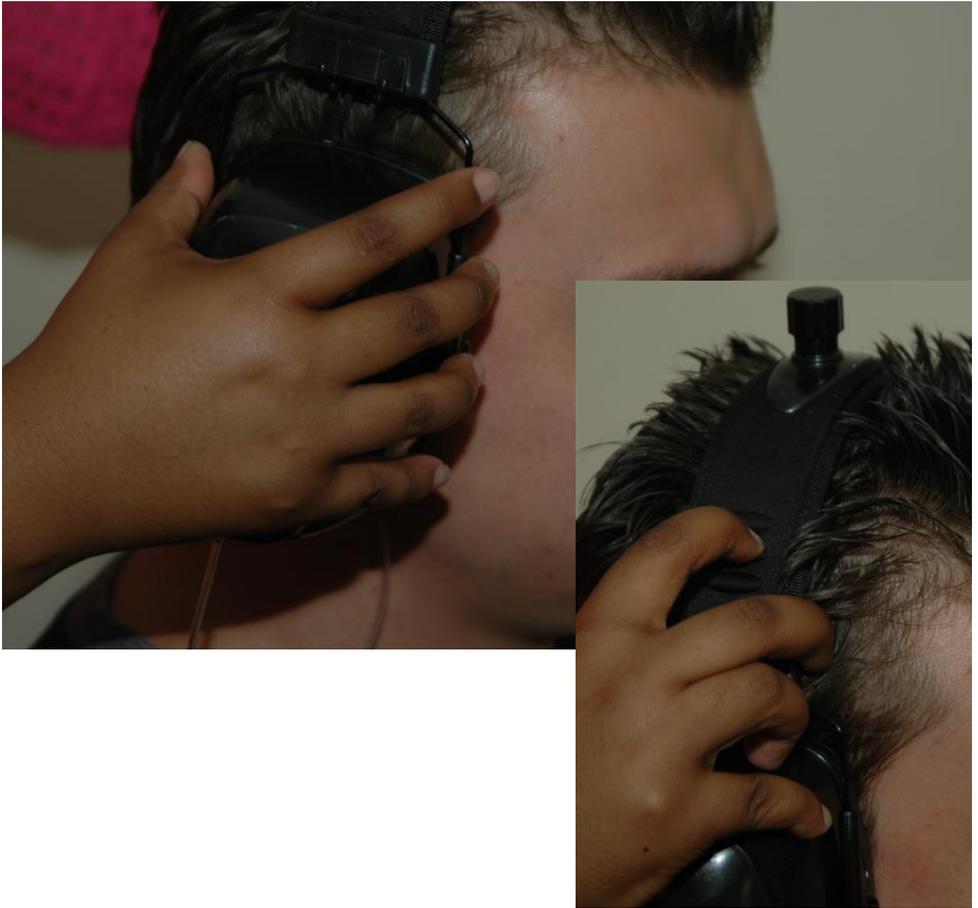
VII.5.2. Step 2: Ear Inserts

The ear inserts may now be slowly rolled into a tight tube and inserted well into the patient's ear canal. When inserting the rolled up ear tip into the ear canal pull the ear Supero-Postero-Lateral in adults and Postero-Lateral in children while aiming the ear tip towards the occiput of the head. The tip must be held in the ear canal until the foam has expanded sufficiently to hold the ear tip securely in place. If the ear tips fit loosely in the ear canal then a larger size Kudufoam ear tip should be used. Sound leakage around a loosely fitted ear tip will cause low frequencies to test inaccurately.



VII.5.3. Step 3: Kuduwave 5000 – Final Position

The headset may now be opened and 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.



Note: Peek test (visually confirm from the front that the ear inserts are still correctly positioned)



VII.5.4. Step 4: KUDUpress Patient Response Button

The Patient Response Button must be placed in the patient's hands. Care must be taken to ensure the cable does not become tangled or damaged. The patient must keep his finger on the button ready to press the button when s/he hears a sound. The patient must be told to press the button as quick as possible and then let go of the button and keep his/her finger on the button ready to react when the next tone is heard.

VII.5.5. (Optional) Step 5: Bone Vibrator Positioning

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 the Bone Vibrator is positioned in the middle of the patient's forehead. Care must be taken to ensure the Bone Vibrator is correctly placed.



6. Performing a Test

Please see the eMoyo Operator Training Manuals 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 5000.

For a quick reference, please see the Software Quick Start guide included with your device or use the help included in the eMOYO software package (this can be accessed by pressing the "?" button in the eMOYO application whilst running a Kuduwave test).



VII.6.1. Remote testing

The Kuduwave 5000 can easily and safely be used for remote testing over local and Internet connections.

In these conditions,

- 1) the trained operator starts the eMOYO software application on his or her local Laptop or Notebook and
- 2) a connection is made to a Kuduwave 5000 headset connected to a remote Laptop or Notebook.
- 3) This remote Laptop or Notebook is specified using its unique IP address.
- 4) A trained facilitator can then fit the Kuduwave 5000 headset on the patient and the operator can proceed with the test as if they were using the remote Laptop or Notebook.

Both the operator and facilitator are required to have completed the appropriate eMoyo Kuduwave 5000 training.

7. Cleaning and Maintenance

VII.7.1. 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.

VII.7.2. Cleaning Procedure

The Kuduwave 5000 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 the use on plastic items.



1. Firstly, disconnect all USB cables and use an anti-bacterial wipe to clean the Kuduwave headset, ear cups, probe pipes, response handset and the bone vibrator (if it was used).
2. It is important to ensure that during cleaning no liquids run into any holes in the ear cups, especially the external microphone holes or the ear probes.
3. Both of the used Kudufoam ear inserts/tips **must** be disposed of after each test as medical waste.

WARNING!

When cleaning the Kuduwave 5000, never use acetone based cleaning products.



4. When cleaning the device, avoid bending or twisting any of the **cables** or **probe pipes** sharply. If the **probe pipe** has any visible permanent sharp bends or holes then calibration can be verified using the standard daily biological calibration routine.
5. If any cracks or holes in the probe pipe are visible, then the probe should be replaced by a trained technician.

Note: Ear wax and debris can collect in the **ear probe**. Make sure that there are no debris on the ear probe or inside the disposable ear tip before placing an ear tip onto the ear probe. Once debris or any foreign material has lodged into the little holes of the ear probe, then it might be impossible 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 ear tip before placing an ear tip 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. Take the Kuduwave off your head, turn it around so that the Left side is Right and the Right side is Left 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 ear tips of different sizes act as barrier between the ear probe and the patient. Never reuse disposable ear tips because old ear wax and cleaning solutions can damage the expensive ear probe permanently. Cleaning solutions also damages the rubber of the ear tips and can lead to incorrect readings. It is a huge risk to clean ear tips and re-use the ear tips because cleaning solution or wax can land up inside the ear probe and give incorrect results.

WARNING!

Never reuse disposable ear tips. Ear tips are cheap and cost savings will not outweigh the risks to the device and most importantly to the patient.





8. Calibration

In order for the Kuduwave 5000 to operate correctly it is vital that it is correctly calibrated. eMoyo has the equipment and expertise necessary to calibrate your equipment whenever necessary.

VII.8.1. Daily

Although there is no need for daily biological testing, it is advisable to perform a biological test at the start of each day the Kuduwave 5000 is to be used.

VII.8.2. Annual

Annual calibration is required by legislation. eMoyo will calibrate and return your Kuduwave 5000 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. The Kuduwave was designed to perform many thousand test procedures. Your device will be assessed annually to determine its serviceability before it is calibrated. The Kuduwave is indicated for a minimum of 5 years expected service life.

VII.8.3. Ad hoc calibrations

Some states or countries require audiometers to be calibrated more often than annually when audiometers are used in the mobile environment. Please make sure of what the legislative requirements are for your state or country. If ever in doubt whether the Kuduwave is in calibration it is recommended to verify the calibration biologically. If still in doubt it is essential to do an electro-acoustic calibration check.



VII.8.4. Calibrations by other organizations

Due to the digital, robust and integrated design of the Kuduwave the chances for a Kuduwave to go out of calibration is very limited. If another organization wants to calibrate a Kuduwave then the organization can go through a typical calibration process and verify that the thresholds and frequencies of the Kuduwave are all correct. After completing the calibration routine the calibration organization will not need to adjust any thresholds or frequencies. The calibration organization can then issue a calibration certificate since the Kuduwave is within the calibration limits. In the unlikely event where it seems as if calibration is out then the calibration organization must contact eMOYO immediately.

9. Storage and Shipping

WARNING!

When shipping the Kuduwave preferably use the original packaging and 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 Specification.

10. Traveling with your Kuduwave



When traveling or shipping the Kuduwave 5000 it is important to use the original case of the Kuduwave. This casing is specifically designed for traveling to protect the Kuduwave 5000 and to absorb shock.

Please make sure to perform the following tasks:

- Always unplug all USB cables before placing the Kuduwave 5000 into the case.
- Also make sure the Bone vibrator is attached to the headband to ensure it does not fall around in the case while being shipped.
- Keep a Kudufoam ear tip on each Sound tube tip to prevent dirt from entering the sound tubes.
- Make sure no cables are caught up between the lid and the case before closing the case

After you traveled with the Kuduwave 5000, always perform a biological test for comfort of mind.





VIII UPGRADES, MAINTENANCE AND SUPPORT

1. Upgrades and New Features

eMoyo often provides software and hardware upgrades for existing products. Please contact eMoyo at info@emoyo.net for the latest information on upgrades and new features

2. Frequently Asked Questions (FAQ)

Is periodic calibration required and if yes, how often, and how much do you charge for it?

When the Kuduwave is due for calibration please make a booking on the support page of the eMoyo website (www.emoyo.net) for calibration and/or servicing before shipping the Kuduwave to us (the software will automatically tell when the minimum calibration is due), and we calibrate and/or service and ship it back to you.

Regular calibration and servicing will ensure that your Kuduwave functions at its optimum level, decreasing the risk of unexpected problems in the field.

If any regulation or decision requires the Kuduwave to be calibrated more often, then these additional calibrations fall outside the scope of yearly calibrations. Some regulations might require the user to calibrate every 3 months.

Note: Because of the nature of the Kuduwave design, it is basically two audiometers - one on each side. If one side fails, one typically can continue testing by just swapping the two sides around while waiting for a backup Kuduwave at cost from your distributor.

Where do I obtain spares, ear inserts and consumables?



Please contact eMoyo at info@geoaxon.com or eMoyo's distributors for all spare parts and consumables. The Kudufoam ear tips available from eMoyo is the **only** approved calibrated ear tips.

What size ear inserts are available?

Ear inserts are available in three sizes as follows:

- Small (Beige)
- Medium (Yellow)

What happens if my device fails?

eMoyo's distributors supply the Kuduwave 5000 with a unique 3 year warranty. Please see your Service Support and Maintenance contract from your distributor.

Does eMoyo or eMoyo's distributors provide on-site training after I have purchased the equipment? If so, is it at an additional cost?

eMoyo's distributors will support and train you virtually, immediately, via the Internet if you need quick help. A trainer from a distributor will train you virtual via remote desktop sharing software on how to use your Kuduwave shortly after it is delivered. Your distributor might offer on-site training. You will also be issued a Kuduwave competency certificate after training and a practical evaluation..

Is there any after sales and technical support?

Yes there is, simply contact eMoyo or eMoyo's distributor for your technical support and after sales service. As a first step visit our Support page on www.emoyo.net where you will find answers to many support queries.

Is it possible for our Occupational Health Practitioner to conduct the calibration on the equipment by herself, or does



he/she require a technician to come in and conduct the calibration, and at what additional cost? How often will this need to be done?

Kuduwave calibration can only be done by eMoyo. There is no need for a technician to visit your premises. You will be required to ship your Kuduwave to eMoyo.. After we received the device, we will service the device, calibrate it, produce a calibration certificate where appropriate and ship the device back to you within a one or two working days. Other calibration organisations can test whether the Kuduwave is still electro-acoustically calibrated. Such a calibration organisation must communicate with eMoyo to ensure the correct procedures are followed and that the correct equipment is used to verify the calibration. If a Kuduwave is tested to be out of calibration by the third party calibration house then it is important to contact eMoyo immediately before testing continues.

Is any additional software required to effectively operate the equipment?

No additional software is required except Adobe Acrobat Reader to print special reports. You can install the Kuduwave eMOYO software on as many Laptop or Notebook's as you want to without any additional costs.

Are ear plugs included with the equipment on your quotation? Are these disposable? Are we required to replace them, and what is the cost?

You will receive a number of foam ear tips on delivery of the Kuduwave if you purchased ear tips. They are disposable and can easily be purchased in bulk from eMoyo or eMoyo's distributors.

Is any technician support, (equipment care and maintenance) provided, and what exactly is covered by your 3 year warranty on the quotation?



Please see your service, support and maintenance contract from eMoyo or eMoyo’s distributor. The 3 year warranty covers all breakages except, of course, severe damage.

As the equipment is mobile, does it come with a carry bag? Is this included in the quoted price?

Yes, a carry case for shipping is included in the quoted price.

3. Support Service

VIII.3.1. Overview

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

VIII.3.2. Loan Devices

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

VIII.3.3. Laptop or Notebook Problems

If your Laptop or Notebook was purchased with your Kuduwave from a distributor, it will be an approved Kuduwave laptop. For service please call your local agency for the laptop and they will repair your laptop.

For problems with Laptop or Notebooks that were not purchased from a eMoyo distributor, please contact the appropriate dealer or a local IT specialist.



VIII.3.4. Online Virtual Support

You can obtain online training over the Internet using video conferencing software on your laptop. The video conferencing software comes pre-installed on the Distributor supplied laptops.

If you are using a non Distributor supplied laptop, then we will supply you with the video conferencing software for your laptop. To receive on-line training, you will need to be located in an area with a good broadband Internet connection. This means you will need to plug your Laptop or Notebook into an ADSL line or you will need to dial up at least via a 3G modem in an area with good reception. You will be issued a certificate of competency to operate our devices after training and a short practical evaluation.

VIII.3.5. Service, Support and Maintenance Contract

The latest Service, Support and Maintenance contract can be obtained from your local representative



4. Troubleshooting

If you experience problems, kindly send an e-mail with as much information as possible (including the specific error message(s) and under which circumstances they occurred) to support@geoaxon.com or contact your local representative.

It is strongly recommended that you keep the Original Supplied Software USB Installation Memory stick (or a copy of it on your Hard Disk Drive) at the installed location of the Kuduwave at all times. If the software should ever malfunction, the end-user will need that software to restore it. eMoyo may ask for this USB Installation Memory stick during a support call.

VIII.4.1. Troubleshooting Checklist

Problem	Possible Solution
eMOYO does not recognize that the Kuduwave 5000 is connected.	Check that the USB cables have been firmly connected from both ear cups to the USB ports on the Laptop or Notebook. 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 post.
	Restart the Laptop or Notebook and try to launch eMOYO again.
Responses from the Patient Response button are not being recorded by the eMOYO software.	Ensure the Patient Response Handset has been firmly connected to the left ear cup.



Problem	Possible Solution
	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.
The patient cannot hear sounds being presented even at high intensities.	Confirm that the operator can hear sounds being presented using the same headset.
	Inspect the ear probes and ear tips for debris that may be blocking the sounds.
I have run out of ear inserts	Contact your representative to obtain a new bag of ear inserts. Do not continue using the existing ones or attempt to clean and reuse them.
The eMOYO 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 representative for more details.



VIII.4.2. Troubleshooting Form

TROUBLESHOOTING FORM			
Customer Name			
Telephone Work		Telephone Mobile	
Date / Time		Region	
Person that did the installation			
Device Model			
Software version		Serial number	
Other eMoyo devices already installed			
Other USB devices previously used on the Laptop or Notebook			
Operating System		Make / Model of Laptop or Notebook	
Processor use		Processor Speed	MHz
Hard Drive Space Total		Hard Drive Space Free	
Screen resolution	pixels	RAM	
USB Ports		CD-Rom Drive	



TROUBLESHOOTING FORM

Is this computer on a network? If yes, specify role and type of network:

--

Describe the installation in broad steps / sequence as performed so far

--

Any problems encountered with the installation

--

What further action do you required?

--



IX NOTES