

KUDU⁵⁰⁰⁰ wave

User Manual



CE 088



eMOYO

EC REP

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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

The KUDUwave 5000 is powered from two standard USB ports on a PC. These are specified as being part of the KUDUwave 5000 medical equipment system.

The KUDUwave 5000 must not be operated via a USB hub.

The Personal Computer used with the KUDUwave must be suitably approved and setup as per its instructions. Particular attention must be paid to ensure that the PC 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.

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

Should the KUDUwave 5000 or PC software become unresponsive this is a typical indication that the unit is experiencing significant EMC interference. Please ensure that the KUDUwave 5000 is used in an EMC interference free environment.

4) OPERATOR QUALIFICATIONS AND TRAINING

Audiometry must be performed by skilled, trained caregivers and GeoAxon 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, eMOYO, must be installed before the KUDUwave headset is attached for the first time. This will ensure that the PC settings do not interfere with the functionality of the KUDUwave.

The eMOYO 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 GeoAxon. 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. GeoAxon 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

Please ensure the patient is at all times positioned at least **1.5 meters** from the PC 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 all distractions that could potentially influence and distract either the operator or the patient.

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 GeoAxon End-User License Agreement (EULA) is a legal agreement between you (either an individual or a single entity) and GeoAxon for the KUDUwave device and software. Software includes the PC 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 PC 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 PCs. The hardware can be operated over a network by any number of people from any number of PCs.

Even though GeoAxon took care to ensure a safe and compliant device, there is always the slightest possibility for error. GeoAxon 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.

GeoAxon reserves all rights not expressly granted.

III WARRANTY AND DISCLAIMER

1. Limited Warranty

GeoAxon warrants that the KUDUwave, if properly used and installed (as per GeoAxon's instructions), will be free from defects in material and workmanship and will substantially conform to GeoAxon's high quality specifications for the period of 3 years as also stipulated on the Terms and Conditions of your purchase 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, GeoAxon 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 GeoAxon whatsoever, notwithstanding the termination or lapse of any contract. GeoAxon 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 GeoAxon 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 GeoAxon be liable for damage arising from misuse or abuse of the goods. The Customer does hereby indemnify and hold GeoAxon 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: GeoAxon t/a eMoyo 179 Beyers Naude Road Weltevredenpark Randburg South Africa Tel: +27117821154 email: info@geoaxon.com
	Symbol designating Type B Applied Parts
	Safety sign advising operator that accompanying documents must be consulted
	Symbol for the European Union Representative Moulsham Court, 39 Moulsham Street Chelmsford, CM2 0HY United Kingdom Tel: +44791816237 Email: tnmcuk@tnmc.biz
	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)
	Symbol for CE Mark Notified Body number : 088 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.3.1.a. Medical Purpose

The KUDUwave 5000 is an innovative audiometer featuring "Ambidome" which provides compliant testing 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 auditory responses in order to determine his or her hearing thresholds and hence assist in diagnosing any hearing impediments.

IV.3.1.b. 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.3.1.c. 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.3.1.d. Operator Profile

The operator must be a trained healthcare professional (typically an audiologist, general practitioner or occupational therapist) or a practitioner who has been trained in audiometry. They must have received Operator Specific Training in using the KUDUwave 5000 by GeoAxon (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.3.1.e. Application

The KUDUwave 5000 is intended to be highly 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.

IV.3.2. Frequently Used Functions

As the KUDUwave 5000 is designed for continuous, regular use, 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.3.3. Details of Applied Parts

The following parts are defined as “applied parts” in accordance with IEC60601-1:

- **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, general practitioner or occupational therapist) 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 GeoAxon Operator Training Manual.

IV.4.2. Training and Certification Requirements

GeoAxon 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 GeoAxon so that they may dispose of, or recycle it, in the most suitable manner.

V TECHNICAL SPECIFICATION

1. System description & related models

The GeoAxon 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.

A “+” in the model name is indicative that that KUDUwave can also perform High-Frequency audiometry testing up to a frequency of 16kHz.

The KUDUwave 5000 can be upgraded to include built-in tympanometry . A “**T**” for “**T**ympanometer” at the end of the model number of the KUDUwave 5000 indicates that this device has a built-in Tympanometer.

A “**D**” at the end of the model number is indicative that the KUDUwave 5000 can also perform DPOAE (**D**istortion Product Otoacoustic Emissions) testing.

An “**I**” at the end of the model number indicates that the KUDUwave can perform in ear testing while fitting a hearing aid.

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

Dimensions	210mm X 260mm X 110mm
Net Weight	250g
Shipping Weight	1,800g
Shipping Dimensions	410mm X 320mm X 190mm
Power supply	2 standard PC / Laptop USB ports (5V, 500mA max per port)
Safety and Design Standards	IEC60601-1, IEC6060-1-2, IEC60601-1-6, ISO14971
Medical Device Class	Class IIa
Measurement & Labeling 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)	No specific protection
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 1 200 hPa
Operational background sound levels	< 70 dB SLP (100 Hz – 8 kHz)
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 2 x 3 meter USB cables Logitech Precision Gamepad B71 bone vibrator & headband User Manual

V.3.2. *Audiometry Specifications*

Audiometry Standards	IEC60645-1, IEC60645-2; ANSI S3.6
Pure Tone Audiometer Type	Type 2, Basic Diagnostic in accordance with IEC60645-1
Monosyllabic Speech Audiometer Type	Type B, in acc. with IEC60645-2 (1993)
Maximum patient response time	1.5 seconds
Bone Conduction Frequency Range	250Hz to 8000Hz
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	"Eartone 3A" transducer copies
Air conduction system	Sound is conducted through Ear Inserts. The combined ear-cup and ear-insert attenuation is always greater than 33dB (typically between 50dB and 60dB).
Air conduction calibration	Transducers calibrated using G.R.A.S IEC711. 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 (50Ω) Headband provides 5N static force.
Bone conduction system	The Bone Vibrator is positioned on the patient forehead. Airborne sound vibration has no effect on testing due to sound insulation and masking.

Audiometry Standards	IEC60645-1, IEC60645-2; ANSI S3.6
Masking	Manual or automatic narrow band masking. Levels equivalent to Pure Tones
Modes of operation	Manual or Automatic (Hughson & Westlake method - ISO 8253-1)
Speech signal calibration	All words in word lists calibrated against a 1kHz calibration signal
Talk forward	Adjustable 50dB SPL to 110dB SPL

V.3.3. *Frequency Specifications*

V.3.3.a. **Air Conduction**

	Maximum Air Hearing Levels without harmonic distortion dB-SPL
125Hz	85
250Hz	95
500Hz	100
1000Hz	110
1500Hz	110
2000Hz	110
3000Hz	105
4000Hz	100
6000Hz	95
8000Hz	90

V.3.3.b. Bone Conduction

	Maximum Bone Hearing Levels without harmonic distortion dB-SPL
125Hz	N/A
250Hz	35
500Hz	50
1000Hz	65
1500Hz	70
2000Hz	65
3000Hz	65
4000Hz	65
6000Hz	N/A
8000Hz	N/A

V.3.3.c. Narrow Band Masking

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

VI GETTING STARTED

1. Introduction

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

WARNING!

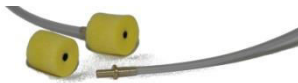
The KUDUwave is highly sensitive and technically complex and should be treated with care!

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 PC 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. PC Requirements

VI.3.1. Minimum PC 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, or Windows Vista operating systems

WARNING!

Other Operating Systems (e.g. Windows 95 or Windows 98 1st edition) 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. GeoAxon does not support other operating systems.

*Windows is a registered trademark of Microsoft Corporation

VI.3.2. *How do I confirm my PC specifications?*

- **CD-ROM drive / Keyboard / Mouse:** A physical (or visual) check will instantly confirm the presence of these.
- **Processor speed / RAM / Operating platform:** Your PC's 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.**



VI.3.3. *In Need of Assistance?*

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

4. KUDUwave Software Pre-installation check list for PC

If the KUDUwave software was not installed by GeoAxon it must be installed on the target PC 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 PC is at least a Pentium 3 (Most PC's bought since 2003 will be fast enough)		
The PC Operating System is Windows 98 2 nd Edition, Windows 2000, Windows XP or Windows Vista		
This PC has 128MB of free RAM		
The PC has at least 2 free USB ports (Preferably 3)		
The PC has a CD-ROM drive or the PC has access to a Network CD-ROM drive (for installation from CD only)		
The Screen resolution is at least 800x480 pixels		
The PC as at least 100 Mb free space on the Hard Disk Drive		
The PC and all peripherals connected to it are properly earthed if required		

If you answered **NO** to any of the above questions, then you may experience problems with the installation. GeoAxon cannot support PC 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*

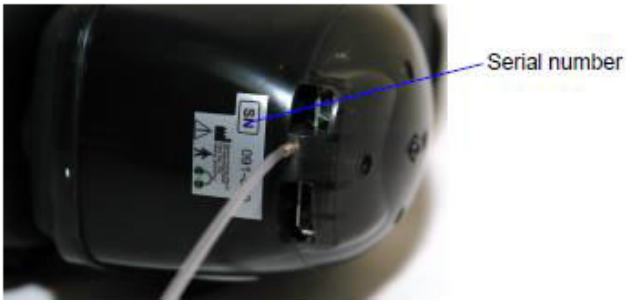
Open the box containing the KUDUwave and check to see that you have the following items:

- **KUDUwave 5000 Headset**
- **Two 3 meter long double twisted USB Cables**
- **Patient Response Button**
- **Bone vibrator with headband**
- **Calibration certificate**
- **KUDUfoam ear tips**
- **Two sound tubes**
- **Installation USB Stick (Contains software)**
- **eMoyo (the operating software for the KUDUwave)**
- **User manual**
- **Quick start cards**

VI.5.3. Model & Serial number

Both the model number and serial number are clearly marked on the KUDUwave headset.

VI.5.3.a. Serial number [SN]



VI.5.3.b. Model number



Note: Model and serial number information are 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 GeoAxon 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 PC'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|GeoAxon to launch this application:

- Place the USB Stick into a free USB slot on the PC
- 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 PC
- 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 Vista and Windows 7 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 PC, the PC 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.

VI.5.7. *Software Launch*

WARNING!

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

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

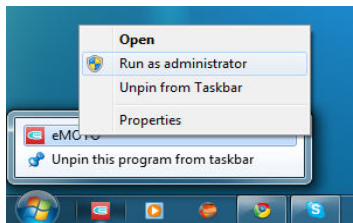
To find these shortcuts, click on

- 1.Start, then
- 2.Programs (All Programs), then
- 3.GeoAxon 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 eMOYO software 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 email or fax the registration form provided to GeoAxon and they will promptly send you a unique "Unlock Key" for you software. Simply enter it when prompted and the eMOYO software will launch correctly.

eMOYO version 2.3.1.29




Welcome to eMOYO, the health operating system for all of GeoAxon's Medical Devices



UNLOCK your eMOYO software for free

Lock code: **6XAGV,J77Q8,X5G60,6CN4N,VZN96**

Enter your unlock key here if you received one from us:

Due to the future requirements of CE certification GeoAxon needs to keep track of all installations of our medical software to ensure compliance to the CE standard. CE requires tracking of software to minimise patient health risks and to ensure prompt software updates if required.

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Enter your unlock key here if you received one from us:

Due to the future requirements of CE certification GeoAxon needs to keep track of all installations of our medical software to ensure compliance to the CE standard. CE requires tracking of software to minimise patient health risks and to ensure prompt software updates if required.

If you did not receive an unlock key from GeoAxon, then complete the form below and deliver the form to GeoAxon

Name and surname / Company name*:

Country*:

Physical address and postal code / zip*:

Postal address and postal code / zip*:

Telephone number*:

Name of the person that administrates this PC*:

Email address of the administrator of this PC*:

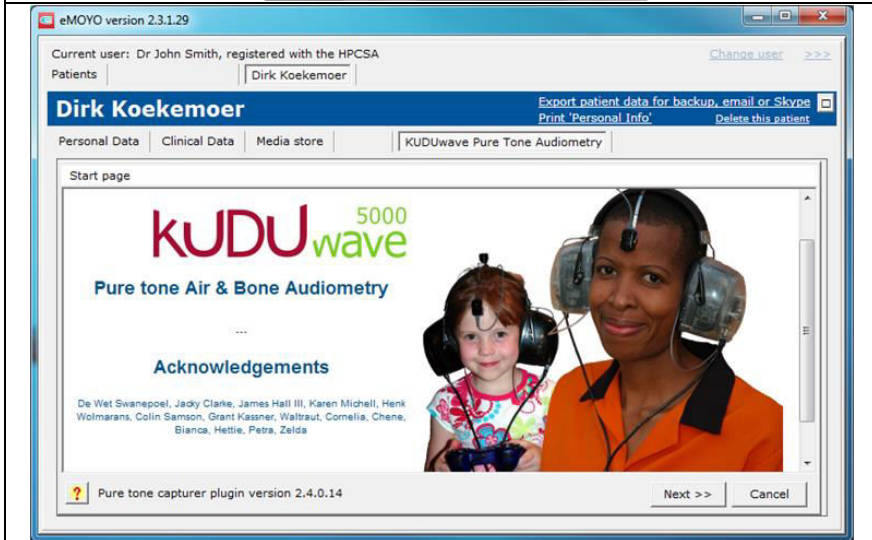
Cellular phone number of the administrator*:

Name of this computer*:

VI.5.10. *Checking Device Connectivity*

Make sure the KUDUwave is plugged into the PC before you select any of the KUDUwave tests in the “eMOYO” software.

If the KUDUwave is plugged into the PC 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 GeoAxon Program Group exists under "Start Programs"				
GeoAxon "eMOYO" installation was completed successfully				
The KUDUwave 5000 is plugged into the PC 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 PC				
A new patient was created after launching the "eMOYO" software				
A quick pure tone air test on both ears of a normal hearing person gives the impression that the device is calibrated				
The "KUDU pure tone audiometry" test showed a report				
The "KUDU pure tone audiometry" test report can be printed (Attach printout to this report)				
Exit all "KUDU" software tests, start the GeoAxon "eMOYO" software and see if the last test can be retrieved				
The operator has completed all relevant training by GeoAxon				
Comments:				

VII USING AND MAINTAINING THE KUDUWAVE 5000

1. Introduction

The following guidelines are a subset of the instructions provided in the GeoAxon 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 not record patient responses when the ambient noise is sufficiently loud to disrupt the test. This will result in a longer test sequence.

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 PC. 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 PC. 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 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 after each use in accordance with the cleaning and disinfection instructions.

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.

Warning

The KUDUfoam ear tips are disposable and for single use only to prevent hazardous cross contamination. GeoAxon 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, or even directly to the PC, but this is not recommended.

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. 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. The tip must be held in the ear canal until the foam has expanded sufficiently to hold the ear tip securely in place.



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 hand 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 the ear inserts are still correctly positioned)



VII.5.4. Step 4: 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.



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 GeoAxon Operator Training Manuals for full details on how to perform Pure Tone, Manual, Automatic and Monosyllabic testing, 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 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 PC and
- 2) a connection is made to a KUDUwave 5000 headset connected to a remote PC.
- 3) This remote PC 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 PC.

Both the operator and facilitator are required to have completed the appropriate GeoAxon 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).

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 **must** be disposed of after each test.

WARNING!

When cleaning the KUDUwave 5000, never use acetone or alcohol 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 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 is 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 calibration can be verified using the standard 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: 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.

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. GeoAxon 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. GeoAxon 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 calibration is due.

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.
- Roll the Patient response button cable up in a figure eight.

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

GeoAxon often provides software and hardware upgrades for existing products. Please contact GeoAxon at info@geoaxo.com 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?

ALL YEARLY CALIBRATIONS are free for the first 3 years. Simply ship your device to us once a year (the software will automatically tell when calibration is due), and we calibrate, 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 your overnight speed services loan device from your distributor.

Where do I obtain spares, ear inserts and consumables?

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

What size ear inserts is available?

Ear inserts are available in three sizes as follows:

- Small (Pediatric)
- Medium (Adult)
- Large (Jumbo)

What happens if my device fails?

GeoAxon's distributors supply the GeoAxon KUDUwave 5000 with a unique 3 year warranty combined with a fast courier service device exchange policy should your device fail. Please see your Service Support and Maintenance promise contract from your distributor.

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

GeoAxon'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 on-site (typically virtual training) on how to use your KUDUwave shortly after it is delivered. You will also be issued a certificate after training and a practical evaluation. Training for a maximum of 2 people on how to use the KUDUwave is at no additional cost for each device purchased.

Is there any after sales and technical support?

Yes there is, simply contact GeoAxon or GeoAxon's distributor for your technical support and after sales service.

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 GeoAxon. There is no need for a technician to visit your premises. You will be required to ship your KUDUwave to GeoAxon.. After we received the device, we will service the device, calibrate it, produce calibration certificates where appropriate and ship the device back to you within a one to two working days (like a motor plan). The price of the KUDUwave 5000 includes 3 years of calibration services.

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 software on as many PC'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 pieces on delivery of the KUDUwave. They are disposable and can easily be purchased in bulk from GeoAxon or GeoAxon's distributors. Please see the following link for more information on the cost saving benefits of the KUDUwave.

(<http://downloads.geoaxon.co.za/KUDUwave/Persistent/KUDUwave%20Cost%20Savings.pdf>)

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 promise from GeoAxon or GeoAxon'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 is included in the quoted price.

Will there be any other additional costs involved in the purchase and life of this equipment?

No, there are no other costs in the first 3 years, except for consumables. An optional service contract can be purchased after 3 years.

3. Support Service

VIII.3.1. Overview

At GeoAxon we are confident that we can deliver a **unique** support service specifically designed for clients in distributed or 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. Customers in South Africa can expect a loan device within one to two days.

Please download our unique Service Support and Maintenance promise contract for full details for our Loan Device policy.

(<http://downloads.geoaxon.co.za/KUDUwave/Persistent/KUDUwave%20Standard%20Service,%20Support%20and%20Maintenance%20Agreement.pdf>)

VIII.3.3. PC Problems

If your PC was purchased with your KUDUwave from a distributor, it will be an approved KUDUwave laptop. Typically these laptops have worldwide warranties. For service please call your local agency for the laptop and they will repair your laptop.

For problems with PCs that were not purchased from a GeoAxon 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 PC into an ADSL line or you will need to dial up 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 either from your local representative or downloaded from the internet at the following location:

(<http://downloads.geoaxon.co.za/KUDUwave/Persistent/KUDUwave%20Standard%20Service,%20Support%20and%20Maintenance%20Agreement.pdf>)

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 disk to restore it. GeoAxon 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 PC. The left and right LED's will indicate if power is being received from the USB port.
eMOYO does not recognize that the KUDUwave 5000 is connected.	Try the second set of two new USB cables in case the original pair has become damaged.



USER MANUAL: KUDUWAVE 5000

eMOYO does not recognize that the KUDUwave 5000 is connected.	Ensure the Patient Response Handset has been connected to an ear cup.
eMOYO does not recognize that the KUDUwave 5000 is connected.	Restart the PC 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.
Responses from the Patient Response Handset are not being recorded by the eMOYO software.	If another Patient Response Handset is available try it instead to ascertain if the response button is broken.
Responses from the Patient Response Handset are not being recorded by the eMOYO software.	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.
The patient cannot hear sounds being presented even at high intensities.	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 GeoAxon to be calibrated whenever prompted. Contact your local representative for more details

VIII.4.2. Troubleshooting Form

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



USER MANUAL: KUDUWAVE 5000